XII. IMPLEMENTATIONS

The criteria set forth in the regulations are based on generally recognized scientific principles for testing and evaluating chemical compounds for potential carcinogenesis. Congress comtemplated that FDA would adhere to these principles when it enacted the Food Additives Amendment of 1958 and the Animal Drug Amendments of 1968 (21 U.S.C. 348 (b) and (c) and 360b (b) and (d)).

The 1973 proposal would have applied the regulatory requirements to all new applications (basic or supplemental) filed or approved after the effective date of the regulations. Prior approvals were to be dealt with on a class-by-class basis, and the classes, in order of decreasing priority, were known carcinogens, suspected carcinogens, and continuing through all compounds previously approved on the basis of zero tolerance. These were to be reviewed as part of the agency's general safety review for previously approved new animal drugs.

The February 1977 notice announced that the regulations would apply to all new animal drug applications, feed additive petitions, and appropriate color additive petitions, including appropriate supplemental applications, submitted after the effective date of the regulations. In addition, the regulations would apply to all pending petitions and applications unless the Commissioner determined that compliance with the act could be adequately assured by requiring completion of one or more of the required studies subsequent to approval.

Because some standards are needed for the day to day evaluation of petitions under sections 409 and 512, FDA has applied all the basic aspects of these proposed standards on a case-by-case basis for several years (e.g., diethylstilbestrol published in the FEDERAL REGISTER of November 26, 1976 (41 FR 52105) and the nitrofurans published in the FEDERAL REGISTER of May 13, 1976 (41 FR 19906) and August 17, 1976 (41 FR 34883)). It continues to apply them to compounds currently being evaluated for approval or subject to proposals to withdraw approval.

All previously approved applications for compounds will be reviewed as part of the cyclic review of the safety of marketed animal drugs, which will be described in detail in a separate forthcoming notice in the FEDERAL REGISTER. When the agency finds deficiencies in the data supporting a prior approval, it will issue either a FEDERAL REGISTER notice or a letter in accordance with section 512(e) of the act. The criteria of these regulations will be used to determine whether the data supporting applications are acceptable and adequate.

One comment argued that the final regulations, when promulgated, should apply only to all applications pending approval at that time. For previously approved compounds, the comment stated that the holders of the approvals should be required to submit data for at least a threshold assessment. For any compound found to require submission of additional data as set forth in the proposed regulations, the comment argued that the petitions for those compounds should immediately be suspended. Another comment, however, argued that the Commissioner lacks authority to apply the regulations to any previously approved compound without new evidence.

The Commissioner disagrees with both comments. The act expressly deals with these situations. It defines the new evidence that the Commissioner can consider in determining whether a previously approved compound is safe to include: "Tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available * * * when the application was approved" (section 512(e)(1)(B)). The tests proposed in these regulations are necessary to show that a sponsored compound is safe under the act. For that reason, the absence of data satisfying the above criteria, in conjunction with the evidence already available about a compound, clearly can support the withdrawal of approval of an application. A reasonable implementation program is, of course, necessary to avoid chaos in the marketplace, permit an efficient application of the criteria, and provide the maximum public health protection. Proposed § 500.98 provides for such a plan.

XIII. CONCLUSION

The proposed regulations are designed to provide a comprehensive, systematic data collection procedure for evaluating the carcinogenic potential of chemical compounds intended for use in food-producing animals and to ensure that edible tissues derived from such animals are safe. The system is constructed with severable portions that can be modified or replaced as the capacity of science to resolve, or the need for resolving, the issues improves.

This regulation establishes a multistep procedure for evaluating the carcinogenic risk presented by a sponsored compound and criteria for the conduct of each step. In developing the steps and criteria, FDA applied high standards of scientific acceptability and public health protection. In the agency's view, each decision, reflected in the regulations can be defended on that ground. The agency recognizes, however, that the totality of these decisions may impose a set of requirements that cannot feasibly be met by sponsors of compounds—for economic, technical, or other reasons. The agency, therefore, invites comments on whether the regulation imposes requirements that, as a totality, are unreasonable; and, if so, comments are invited on what specific provisions should be modified so that the requirements imposed by the modified regulation would be reasonable. Proposed modifications should be analyzed with respect to their impact on protection of the public health. No modification or set of modifications would be acceptable if its effect would be that the regulation would fail to provide satisfactory assurance that compounds approved for use pursuant to the regulation will not subject humans to any significant increase in carcinogenic risk.

The Commissioner has carefully considered the environmental effects of the regulations and, because this action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk. (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

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Therefore, under the Federal Food, Drug, and Cosmetic Act (sections 402, 403, 409, 512, 701(a), 706, 52 Stat. 1046-1048 as amended, 1055, 72 Stat. 1785-1788 as amended, 74 Stat. 399-403 as amended, 82 Stat. 343-351 (21 U.S.C. 342, 343, 348, 360b, 371(a), 376)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Chapter I of Title 21 of the Code of Federal Regulations as follows:

PART 70—COLOR ADDITIVES

1. In Part 70, by amending § 70.50 by adding new paragraph (c), to read as follows:

§ 70.50 Application of the cancer clause of section 706 of the act.

* * * * *

(c) *Color additives for use as an ingredient of feed for animals that are raised for food production.* Color additives that are an ingredient of the feed for animals raised for food production must satisfy the requirments of subpart E of Part 500 of this chapter.

PART 500—GENERAL

2. In Part 500, by adding a new Subpart E, consisting of §§ 500.80 through 500.98, to read as follows:

Subpart E—Criteria and Procedures for Evaluating Assays for Carcinogenic Residues in Edible Products of Animals

Sec.

500.80 Chemical compounds used in food-producing animals: Procedures and criteria for determining acceptability of assays for carcinogenic residues in edible products.
500.83 Definitions.
500.84 Metabolic study in target animals to identify residues for chronic testing.
500.85 Criteria for test animal selection; comparative metabolic studies to aid in assessing the carcinogenicity of intractable residues.
500.87 Chronic testing.
500.89 Metabolic study to identify the marker residue and target tissue.
500.90 Evaluation and approval of a regulatory assay.
500.92 Withdrawal periods.
500.94 Publication of the approved regulatory assay.
500.95 Compliance.
500.96 Waiver of requirements.
500.98 Implementation.

AUTHORITY: Secs. 402, 403, 409, 512, 701(a), 706, 52 Stat. 1046-1048 as amended, 1055, 72 Stat. 1785-1788 as amended, 74 Stat. 399-403 as amended, 82 Stat. 343-351 (21 U.S.C. 342, 343, 348, 360b, 371(a), 376).

Subpart E—Criteria and Procedures for Evaluating Assays for Carcinogenic Residues in Edible Products of Animals

§ 500.80 Chemical compounds used in food-producing animals: Procedures and criteria for determining acceptability of assays for carcinogenic residues in edible products.

(a) *Scope of this subpart.* (1) The Food, Drug, and Cosmetic Act requires that compounds intended for use in food-producing animals be shown to be safe and that food produced from animals exposed to these compounds be shown to be safe for human consumption. The statute prohibits the use in food-producing animals of any compound found to induce cancer when ingested by human or animal unless it can be determined by methods of examination prescribed or approved by the Secretary (a function delegated to the Commissioner of Food and Drugs under § 5.1 of this chapter) that no residue of that compound will be found in the food produced from those animals under conditions of use reasonably certain to be followed in practice.

(2) Petitions for the approval of the use of a compound in food-producing animals must include adequate data for establishing the absence of residues of carcinogenic concern in the food produced from those animals.

(3) This subpart establishes the following: (i) The lowest limit of reliable measurement for the regulatory assay required for carcinogenic residues by sections 409(c)(3)(A), 512(d)(1)(H), and 706(b)(5)(B) and sections 409(b)(2)(D), 512(b)(7) and 706(b)(5)(A)(iv) of the act.

(ii) The procedures and criteria for evaluation and approval of such assays.

(iii) The procedures and criteria for establishing the premarketing withdrawal period for use of compounds likely to produce such residues.

(4) This subpart applies specifically to the use in food-producing animals and in their feed of compounds that have the potential to contaminate human food with residues whose consumption could present a human risk of cancer. The determination of this potential will be based on considerations of chemical, biochemical, physiological, and toxicological data derived from the scientific literature and from other sources available to the petitioner or to the Commissioner and on the proposed patterns of compound use. This subpart establishes a sequential process for the collection of other chemical, biochemical, physiological, and toxicological data pertinent to the

safety of the proposed use of the sponsored compound.

(5) This subpart does not apply to essential nutrients.

(b) *General approach.* (1) When the Commissioner determines that a sponsored compound has the potential to contaminate food from food-producing animals with residues (the sponsored compound, metabolites, or any other substances formed in or on food (e.g., endogenous substances) because of the compound's use) whose consumption could present a human risk of cancer, the following procedure for data collection and evaluation will apply:

(i) A metabolic study in the animals in which the sponsored compound is intended for use (target animals) designed to identify metabolites of concern and, when appropriate, to determine if normal levels of carcinogenic or potentially carcinogenic endogenous substances are affected.

(ii) Metabolic studies of the sponsored compound in different species of experimental animals designed to aid in selecting the appropriate species for chronic toxicity testing and in assessing the carcinogenicity of residues that cannot practicably be tested individually (intractable residues).

(iii) Chronic testing in test animal to assess the carcinogenic potential of residues of the sponsored compound, to furnish data suitable for statistical treament by the linear extrapolation procedure of Gross, M. A., O. G. Fitzhugh, and N. Mantel, "Evaluation of Safety of Food Additives," *Biometrics*, 26 (2): 181-194 (1970) and Hoel, D. G., et al., "Estimation of Risks of Irreversible, Delayed Toxicity," *Journal of Toxicology and Environmental Health*, 1:133-151 (1975)[1] (which are incorporated by reference), and to permit the no-residue requirement of the act to be operationally defined for purposes of establishing a lowest limit of reliable measurement for an assay to measure residues of the sponsored compound.

(iv) A detailed metabolic study of the sponsored compound in target animals designed to identify a specific residue and tissue to serve as indicators (marker residue and target tissue) to determine whether the no-residue requirement of act is satisfied.

(v) Development of a regulatory assay to measure the marker residue in the target tissue at and above the level operationally defined as satisfying the no-residue requirement of the act.

(vi) Establishment of the premarketing withdrawal period required for the safe use of the sponsored compound.

(2) If, at any point in the sequential process of data collection set forth in paragraph (b)(1) of this section, the evaluation of the data satisfies the Commissioner that no human risk of carcinogenesis arises from the proposed use of the sponsored compound, the compound will be considered for approval under the general safety provisions of the act for risks other than cancer.

§ 500.83 Definitions.

The following definitions apply to this subpart:

(a) "Sponsored compound" means any drug or additive proposed for use, or used in, food-producing animals.

(b) "Target animals" means the production class of animals in which a sponsored compound is proposed or intended for use.

(c) "Sponsor" means the person proposing or holding an approval by the Food and Drug Administration for the use of a sponsored compound.

(d) "Threshold assessment" means the Food and Drug Administration's review of data and information available about a sponsored compound to determine whether the compound should be subject to regulation under this subpart as well as under the other general safety provisions of the Federal Food, Drug, and Cosmetic Act for risks other than cancer.

(e) "Total residue of the sponsored compound" means all compounds present in edible tissues of the target animal that result from the use of the sponsored compound, including the sponsored compound, its metabolites, and any other substances formed in or on food because of the sponsored compound's use.

(f) "Residue" means any single compound present among the total residue.

(g) "Residue of toxicological concern" means all compounds in the total residue minus any compounds shown to be safe.

(h) "Metabolic studies" means studies designed to identify the residues that occur in edible tissues when the sponsored compound is administered to target animals and to determine the depletion characteristics of the residues.

(i) "Intracable residues" means residues of the sponsored compond that, using the best available technology, cannot be obtained, by isolation, synthesis, etc., in sufficient amounts for carcinogenicity testing.

(j) "Comparative metabolism" means the study of the metabolism of a sponsored compound in different species/strains of test animals that are potential surrogates for man in chronic toxicity testing. Comparative metabolism studies will assist in assessing the toxicity testing. Comparative metabolism studies will assist in assessing the toxicity of intrectable residues and in selecting species/strains of test animals for bioassays of selected tractable residues.

(k) "S_o" means the residue level of a sponsored compound in a total test diet of animals that corresponds to a lifetime risk of cancer of 1 in 1 million in the test animals. For the purpose of this subpart, this S_o level in the test animal corresponds to a level in the total human diet that is assumed to represent a level of risk to humans of no more than 1 in 1 million over a lifetime.

(l) "S_m" means the level of total residues of carcinogenic concern for a specific edible tissue as determined by the formula in § 500.87(d).

(m) "Marker residue" means the selected residue whose level in a particular tissue is in a known relationship to the level of the total residue of carcinogenic concern in all edible tissues and that can be taken as a measure of the total residue of concern in the target animal.

(n) "Target tissue" means the tissue selected to monitor for residues in the target animal. The target tissue is selected so that the absence of marker residue at or above the required level of measurement (R_m) can be taken as confirmation that the safe, or acceptable, residue level (S_m) is not exceeded in any of the edible tissues of the target animal.

(o) "R_m" means the level of the marker residue(s) in the target tissue when the sum of the levels of the residues of toxicological concern is equal to S_m for the edible tissue requiring the longest time to deplete to its S_m.

(p) "Endogenous compound" means any compound that its metabolically produced by and is present in untreated target animals.

(q) "Essential nutrients" means compounds that are found in the tissues of untreated target animals and required for the animals' growth, and that must be supplied from external sources, e.g., essential amino acids.

(r) "Norm" means the normal background levels of an endogenous substance in untreated target animals, plotted as a cumulative frequency distribution of levels.

(s) "R_m for an endogenous marker residue" means the level of the endogenous marker residue that corresponds to the 33d percentile of the norm.

(t) "Spiked tissue samples" means samples of target tissue to which known amounts of marker residue have been added.

(u) "Control tissue samples" means samples of target tissue from untreated target animals.

(v) "Dosed tissue samples" means samples of target tissues from target

[1] Copies may be obtained from: Industry Information (HFV-226), Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

animals administered the sponsored compound.

(w) "L_m" means the level of marker residue in target tissue that gives a response greater than, or equal to, 0.75 times the spread of the 99 percent confidence bounds of a single assay response measured parallel to the observed assay response axis based on the analytical curve of the assay. (See Plate IV in § 500.90(d)(5).)

(x) "Assay" means the aggregate of all experimental procedures for measuring the presence of the marker residue of the sponsored compound in the target tissue of the target animals at or above the L_m. It includes the procedures for sample of instrument preparation. The assay must satisfy criteria set forth in § 500.90, and it will usually consist of multiple measurement procedures that utilize different physiocochemial principles, e.g., gas chromatography-mass spectrometry, to assure compliance with the regulatory requirements.

(y) "Withdrawal period" means the time required, after cessation of target animal exposure to the sponsored compound, for the marker residue to deplete to L_m in the target tissue.

(z) "Analytical curve" means the plot of the observed responses of the regulatory assay when analyzing "spiked" tissues compared to the amount of marker residue added to the "spiked" tissues.

(aa) "Ninety nine percent confidence interval" means an interval, determined by confidence limits, that is expected to contain the population parameter being estimated 99 times out of 100 times.

(bb) "Upper ninety nine percent confidence limit" means a value that is expected to be equal to or larger than the population parameter being estimated 99 times out of 100 times.

(cc) "Statistical tolerance limits" means upper and lower values between which it can be stated with a given level of confidence that a specified portion of the population will be included.

§ 500.84 Metabolic study in target animals to identify residues for chronic testing.

(a) A metabolic study, described in paragraph (b) of this section, shall be conducted in target animals to provide data on the physicochemical characteristics of residues, their relative proportions, their distribution among the various edible tissues (which include milk or eggs when applicable), and their retention and depletion in animal tissues.

(b) The metabolic target animal study shall satisfy the following minimum requirements:

(1) The metabolic study shall be conducted in target animals with the sponsored compound bearing appropriate radiolabels, unless other experimental methods permit measurement of total residues with accuracy and precision equivalent to radiolabel methods. Such labels shall assure that residues containing structural moieties of potenetial carcinogenic concern are detected and measured in edible tissues at levels as low as the best available technology will permit. Hypotheses about the sponsored compound's projected metabolic pathways may be used as a guide to experimentation, but they are not a substitute for actual experimentation.

(2) The dosing regimen shall be the maximum proposed use level and proposed duration of exposure to the sponsored compound. For a compound that is proposed for continuous or repeated use in target animals, administration for the metabolic study need continue only until tissue saturation has been demonstrated. If tissue saturation cannot be attained, residue equilibration or showing a stable metabolite profile will be adequate.

(3) The metabolic study shall be designed to yield the following information:

(i) The concentrations and total number of residues detacted in edible tissues of target animals immediately following cessation of exposure.

(ii) The concentrations and total number of residues detacted in edible tissues of target animals at a sufficient number of different time intervals, following the initial measurement, to determine the depletion trend of individual residues.

(iii) The physicochemical properties of the detected residues to identify compounds of potential carcinogenic concern.

(4) The results of the metabolic study shall be submitted in the form of a detailed report conforming to the standards required of scientific manuscripts submitted for publication in the journals of professional scientific societies, such as the American Chemical Society and the American Society of Biological Chemists. In addition, all raw data shall accompany and be referenced in the report.

(c) If the Commissioner determines that a sponsored compound has potential to contaminate food with residues whose consumption presents a human risk of cancer, the petitioner shall determine the carcinogenic potency of the sponsored compound and those residues that may be of public health concern due to chemical structure or persistence and concentration in edible tissues.

(d) Ordinarily, chronic testing of the sponsored compound and selected residues in experimental animals will be the preferred means of assessing carcinogenic potency.

(e) Reisidues in edible tissues of target animals that are intermediate metabolites in metabolic pathways that are reasonably expected to be similar in humans and the selected test animal species/strain need not be subjected to independent chronic toxicity testing. Testing the leading substrate in each metabolic pathway is sufficient. In the absence of information that the leading substrate is noncarcinogenic, tractable residues that are produced in the target animals but that are not produced in the test animal species/strain shall be subjected to independent chronic toxicity testing.

(f) Section 500.85 describes an alternative means of assessing the carcinogenic potency of residues whose isolation or synthesis in sufficient quantities for chronic testing proves to be beyond the practical limits of current chemical technology (intractable residues) by establishing additional criteria for selecting test animal species/strains used to conduct chronic toxicity testing of the sponsored compound.

§ 500.85 Criteria for test animal selection: Comparative metabolic studies to aid in assessing the carcinogenicity

(a) The primary criterion for selecting species or strains of test animals for chronic testing of both the sponsored compound and any metabolities selected in accordance with § 500.84 shall be the suitability of the species or strain as a model for man.

(b) If one or more intratable residues are also selected for chronic testing based upon the matabolic study in target animals, a secondary criterion shall be employed for selecting species or strains of animals for testing the sponsored compound. Metabolic studies of the sponsored compound in test animal species or strains determined to be suitable for chronic testing by the primary criterion shall be conducted to determine whether the intractabel residues present in the tissues of target animals are also produced in the test animals. Chronic testing of the sponsored compound in a species or strain of test animals in which the complement of residues produced is similar to the complement of residues produced in the tissues of the target animals is considered an appropriate method of assessing the carcinogenic potency of the intractable residues.

§ 500.87 Chronic testing.

(a) Chronic toxicity tests shall be conducted to assess the carcinogenic potential of the residues of the sponsored compound.

(1) The sponsored compound and any residues selected for chronic toxicity testing shall be subjected to oral, lifetime, dose-response studies in the test animal species or strains selected

in accordance with § 500.85. Each of these studies shall be designed to determine whether the test compound is carcinogenic. Protocols for these studies should be submitted to the Food and Drug Administration for review before commencing testing.

(2) On the basis of the results of these chronic toxicity studies and other available information, the Commissioner will determine whether any of the compounds tested is carcinogenic. If this evidence is equivocal, the compound will be regulated as a carcinogen until further testing resolves the remaining questions regarding carcinogenicity.

(b) When the Commissioner determines that a sponsored compound has the potential to increase the normal levels (pools) of carcinogenic and potentially carcinogenic substances endogenous to the target animals, the petitioner shall meet the requirements of § 500.89(c), (d), and (e) or (f).

(c) For each tested compound regulated as a carcinogen, the appropriate data from the chronic dose-response studies shall be analyzed according to procedures described by Gross, et al. and Hoel, et al. subject to the modifications and restrictions set forth in paragraph (c)(1) through (8) of this section. The purpose of this analysis is to interpret the "no residue" requirement of the act as it applies to the total residue of carcinogenic concern of the sponsored compound and thereby to determine the lowest level of reliable measurement required for a regulatory assay to be approved for the monitoring of the total residue.

(1) The administered dose of each test compound shall be expressed as a fraction of the total diet fed the test animal species/strains, e.g., parts per million, parts per billion.

(2) The permissible level, determined by the linear extrapolation model for each test compound in accordance with this section, shall be expressed as a fraction of the total diet fed the test animal species/strains. It shall be calculated using the 99 percent confidence limit of the observations for a maximum lifetime risk that is essentially zero but never expected to exceed 1 in 1 million.

(3) Data obtained from more than one dose level fed to groups of experimental animals of the same strain shall be combined as described by Gross, et al. and Hoel, et al. and are subject to the restrictions specified by these authors.

(4) Pooling data from various chronic tests using different animal sexes, species, or strains is permitted if it can be demonstrated that the protocols are of compatible design. If statistically significant biological differences in tumorigenic responses are observed between sexes or among species or strains of experiental animals, only subsets of data representing statistically and biologically compatible bioassays may be combined for analysis.

(5) All tumors, benign and/or malignant, shall be considered in the analysis.

(6) The number of animals at risk may be adjusted for competing risks unrelated to compound-induced carcinogenesis only when the data clearly support such an adjustment.

(7) When only the sponsored compound is subjected to chronic testing, the calculated "acceptable" level is to be designated as S_o. When more than one compound is subjected to chronic testing, the lowest of all calculated acceptable levels is to be designated S_o. S_o shall be expressed as the fraction of the diet fed the test animals, e.g., parts per million, parts per billion.

(8) The no-residue requirement of the act is considered satisfied when conditions and use of the compound, including any required withdrawal period, can be prescribed to assure that the sum of the levels of all potential residues of carcinogenic concern will not exceed S_o in the total diet of man, and a regulatory assay is available that is capable of reliably measuring such residues at and above that level. All residues of the sponsored compound are regulated as carcinogenic except those that have been shown to be noncarcinogenic.

(d) The S_o value represents the sum of all residues of carcinogenic concern that shall not be exceeded in the total diet of man. For individual edible tissues, the value that shall not be exceeded is to be designated S_m and calculated according to the following formula:

$$S_m = S_o/T$$

NOTE.—T is the fraction of the total daily diet of man represented by an individual edible tissue.

(1) The principal S_m calculations (defining T as noted in the formula above in paragraph (c) of this section) are as follows:

Edible tissue	T	S_m
Muscle	⅛	$3S_o$
Milk	1	S_o
Eggs	⅛	$3S_o$

(2) Calculation of S_m for tissues consumed less frequently than muscle may take into consideration the frequency of consumption of those tissues if it can be clearly shown that S_o will not be exceeded in the total human diet.

§ 500.89 Metabolic study to identify the marker residue and target tissue.

(a) The petitioner shall conduct a study of the metabolic fate of the sponsored compound in target animals adequate to provide the data necessary for selecting a marker residue in target tissue.

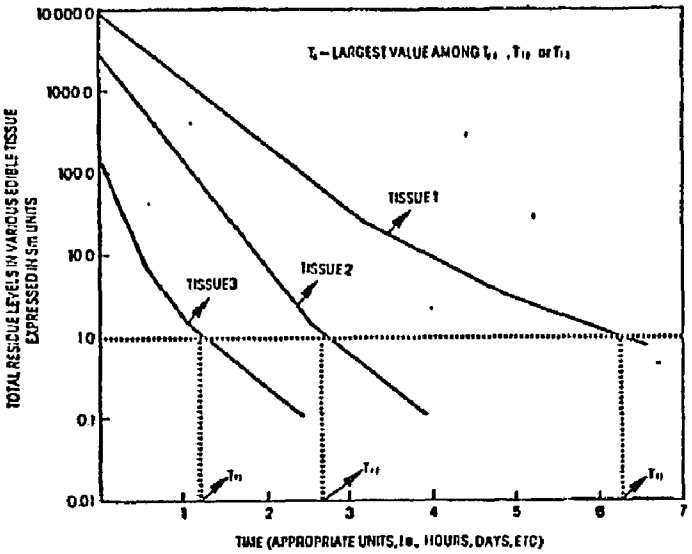
(1) The target tissue is that tissue in which measurement of the total residue burden of carcinogenic concern is a reliable measure of the total residue burden of carcinogenic concern in all edible tissues.

(2) The marker residue for the sponsored compound is that residue (the sponsored compound, any metabolite, or more than one of these) whose level in the target tissue is a reliable measure of the total burden of all residues of carcinogenic concern in all edible tissues.

(b) The metabolic study to establish the marker residue and target tissue shall comply with the requirements set forth in § 500.84(b) (2) and (4), with the following additional specifications:

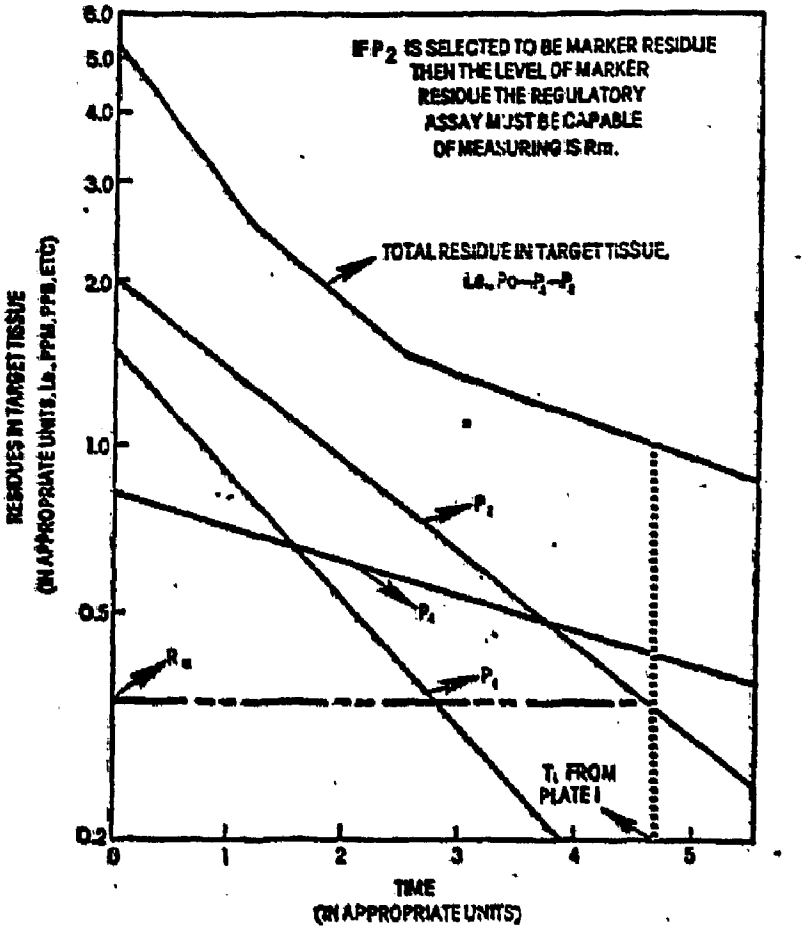
(1) For each edible tissue, the depletion profile of the total residue of carcinogenic concern shall be constructed and shall include measurements of levels at least as low as the S_m appropriate to the tissue under study, as set forth in Plate I as follows:

PLATE I. RESIDUE DEPLETION CURVES TO BE USED IN THE DETERMINATION OF MARKER RESIDUE AND TARGET TISSUE.



(2) Depletion profiles for one or more potential marker residues shall be constructed as set forth in Plate II as follows, and shall include measurements of levels corresponding to the time when the total residue level has reached S_m in the edible tissue requiring the longest time to deplete to S_m (T_L of Plate I in paragraph (b)(1) of this section).

PLATE II. SELECTION OF MARKER RESIDUE AND ITS LEVEL Rm THAT MUST BE MEASURED BY THE REGULATORY ASSAY.



(3) If these specifications have been met by the metabolic study required by § 500.84(b), a second metabolic study need not be performed to satisfy the section.

(4) From these data, the Commissioner will select a marker residue and target tissue and will also designate the required level of marker residue, R_m (set forth in Plate II in paragraph (b)(2) of this section), that regulatory assays shall be capable of measuring in the target tissue. The selection of R_m will be such that the absence of the marker residue in the target tissue above R_m can be taken as confirmation that the total residue burden of carcinogenic concern does not exceed S_m in each of the various edible tissues and therefore that the total burden of carcinogenic concern in the human diet does not exceed S_m. When a compound is to be used in milk- or egg-producing animals, milk or eggs will be the target tissue in addition to one tissue selected to represent the depletion of residues in the edible carcass.

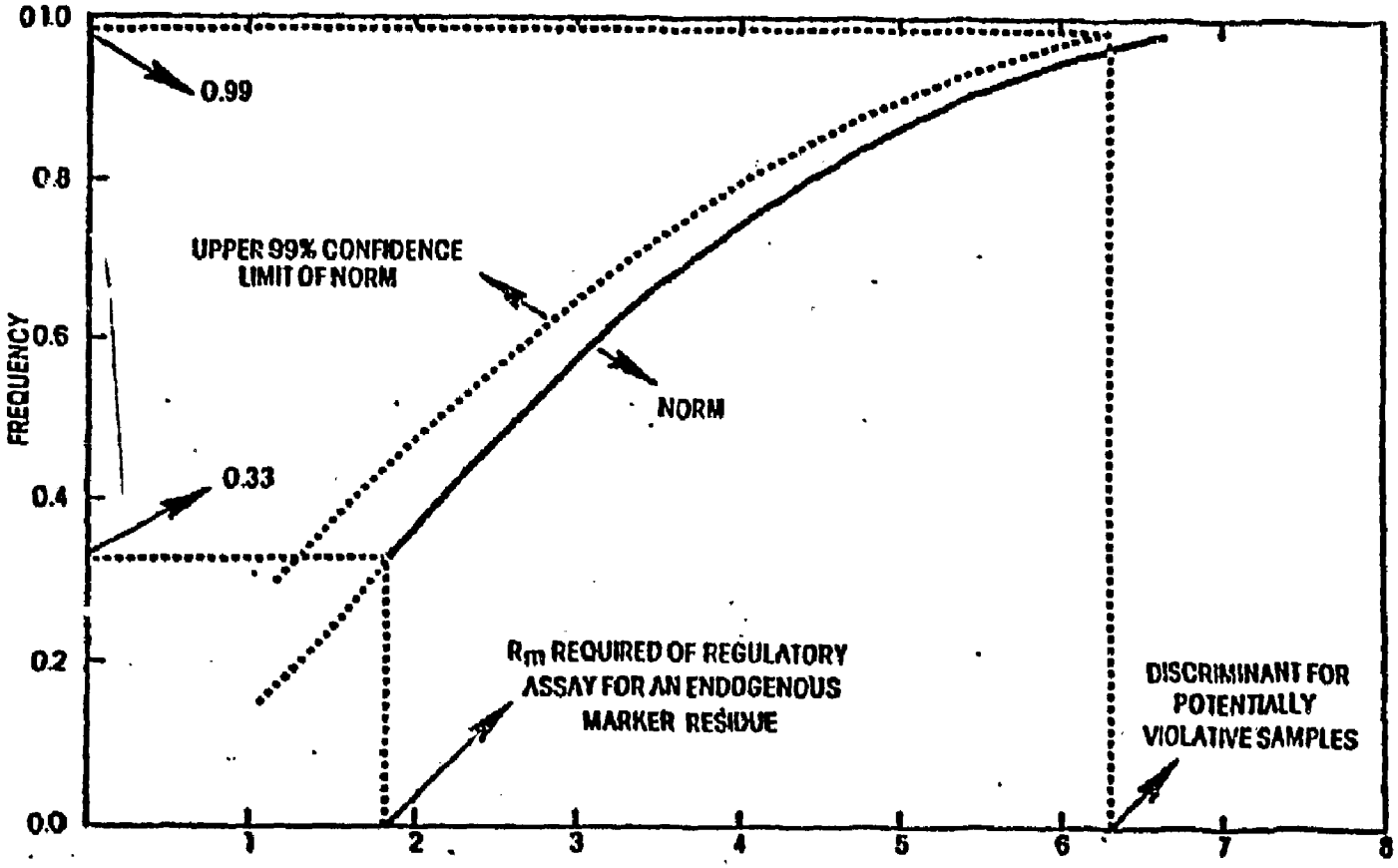
(c) When the Commissioner determines on the basis of available scientific information that a sponsored compound has the potential to increase the normal levels (pools) of potentially carcinogenic substances edogenous to target animals, the petitioner shall provide the following additional data:

(1) An experimental determination of the background levels (norm) of each of the potentially carcinogenic endogenous substances of concern in untreated target animals that are increased by administration of the sponsored compound.

(i) The norm shall be specific for the untreated target animals.

(ii) Each norm shall be submitted in the form of a graph of the cumulative frequency distribution versus the observed naturally occurring levels, including the upper 99 percent confidence limit set forth in Plate III as follows:

PLATE III. SAMPLE OF A NORM



(iii) An assay will be acceptable for the determination of a norm only if it yields values for the endogenous compound of interest greater than zero in at least two-thirds of the untreated target animals.

(2) Studies to measure the effect of the sponsored compound on the norm and the postexposure decay of any increase in the norm caused by administration of the sponsored compound. All data from these studies submitted in accordance with the requirements of § 500.84(b)(4).

(d) For a potentially carcinogenic endogenous compound whose norm is increased by the administration of a sponsored compound, the no-residue requirement of the act is considered satisified when the norm is restored.

(1) The norm is considered restored when, with 99 percent confidence, the cumulative frequency distributions of the observed levels of the endogenous compound in the untreated target animals and in the treated target animals do not differ by more than 0.1 at any specific point.

(2) The market residue is the affected endogenous substance.

(3) When the norm of more than one potentially carcinogenic endogenous compound is increased by administration of the sponsored compound, the market residue for all endogenous compounds of concern is that endogenous compound whose norm requires the longest time for restoration.

(e) For an endogenous compound selected to be a marker residue, the required level of measurement, R_m, for the regulatory assay is the level of that endogenous compound corresponding to the 33d percentile of the norm, set forth in Plate III in paragraph (c)(1)(ii) of this section.

(f) The Commissioner will permit a shift in the norm of a potentially carcinogenic endogenous compound if there are available toxicology data of the type specified by §§ 500.84, 500.85, 500.87, and 500.89 that permit estimation of a permissible level corresponding to a lifetime cancer risk increment no greater than 1 in 1 million. If the endogenous compound is also selected to be the marker residue, the required level of measurement, R_m, for the regulatory assay is the level of that endogenous compound corresponding to the 33d percentile of the norm set forth in Plate III in paragraph (c)(1)(ii) of this section.

§ 500.90 Evaluation and approval of a regulatory assay.

(a) Before an application is considered for approval, the petitioner shall submit for evaluation and validation a regulatory assay developed to monitor compliance with the no-residue requirement of the act. The regulatory assay shall reliably measure the marker residue in the target tissue at levels at least equal to and above R_m, as defined in § 500.89(b), (e), and (f). The criteria and procedures in paragraphs (b) through (g) of this section apply to the evaluation and approval of assays.

(b) The regulatory assay will be evaluated and validated using data collected from three types of samples:

(1) Samples containing various known concentrations of marker residue added to the target tissue, i.e., "spiked" tissue samples.

(2) Samples containing various levels of the marker residue obtained from target tissue at appropriate time intervals after the sponsored compound is administered in accordance with the proposed labeling, i.e., "dosed" tissue samples.

(3) Samples obtained from untreated target animals, i.e., "control" tissue samples.

(c) The petition for approval of the proposed regulatory assay shall contain the following:

(1) A complete description of the assay.

(2) A list of all necessary equipment and reagents.

(3) A standard curve prepared from samples of the marker residue of known purity.

(4) An analytical curve of the observed assay response compared to the tissue concentrations of the marker residue in spiked target tissue. The curve shall include the 99 percent confidence limits for individual predicted assay responses.

(5) All relevant data, including worksheets, calculations, any statistical analyses, spectrograms, chromatograms, etc., from the analyses of spiked, dosed, and control tissue samples, and from the analysis used in preparing the standard curve including data on runs started but not completed.

(6) A discussion of the data collected in the assay development process pertinent to the evaluation criteria set forth in paragraph (d) of this section explaining how the data show that the proposed assay conforms to those criteria.

(d) A regulatory assay shall satisfy the following criteria:

(1) *Dependability.* The assay is considered dependable if it does not result in an unreasonable number of failures due to unknown, uncontrollable, or random factors. Evaluation of the data to determine dependability will be based on the total number of assay runs that are started to provide data points for the analytical curve required by paragraph (c)(4) of this section. An explanation will be required for any assay run started that yields no final determination.

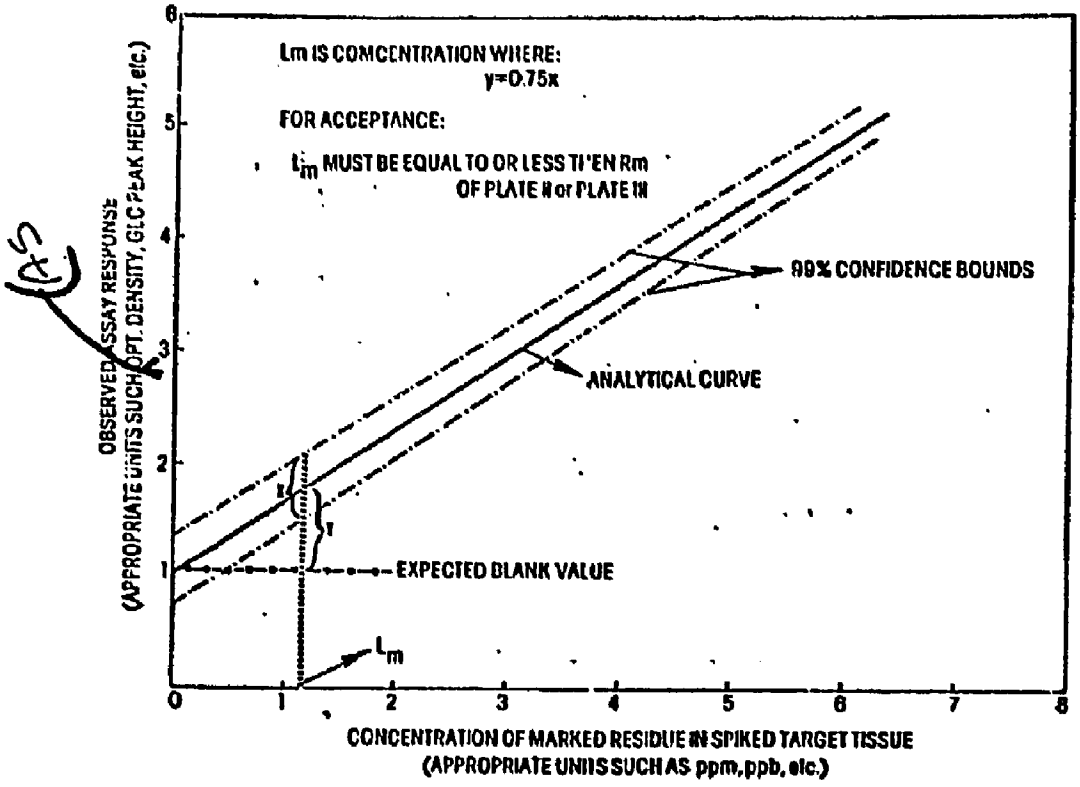
(2) *Practicability.* The assay is considered practicable only if it is suitable for routine use in a government regulatory laboratory. The time required to complete the assay shall be consistent with regulatory objectives, e.g., monitoring, compliance, etc. All supplies, equipment, reagents, standards, and other materials necessary to conduct the assay shall either be commercially available or readily available from the petitioner upon request. The Commissioner will withdraw approval of any assay and initiate regulatory action against the sponsored compound if such a condition of the compound's approval is no longer satisfied.

(3) *Specificity.* The assay is considered specific if the observed response is a smooth and continuously decreasing or increasing function of the concentration of the marker residue and of that compound only. The regulatory assay shall be composed of a sufficient number of independent measurements based on different biological, biochemical, or physicochemical principles to ensure that the identity of the marker residue is confirmed.

(4) *Accuracy.* The assay is considered accurate if the averages of the observed responses fall within 80 to 110 percent of the true value when the lowest level of reliable measurement (L_m) is equal to or greater than 100 parts per billion and within 60 to 110 percent of the true value when L_m is below 100 parts per billion. This requirement need not be met throughout the full range of the analytical curve; it shall be met in the range between L_m and $3L_m$.

(5) *Lowest limit of reliable measurement.* The regulatory assay is considered approvable if it can reliably discriminate with 99 percent confidence the marker residue response from the target tissue background response at or below the required lowest limit of reliable measurement, the R_m, defined in § 500.89(b), (e), or (f). The lowest limit of reliable measurement of the proposed assay is that level, L_m, which gives a response above the expected blank value that is greater than or equal to 0.75 times the spread of the 99 percent confidence limits on a single assay response measured paralle to the observed assay response axis (Plate IV below in this paragraph). If the L_m for the assay is at or below the applicable R_m of § 500.89(b), (e), or (f), the Commissioner will approve the compound for use only under conditions that will not result in residues above that level.

PLATE IV. ANALYTICAL CURVE OF A REGULATORY ASSAY



(e) The Commissioner will review and evaluate the data submitted in accordance with paragraphs (a), (b), and (c) of this section. If the assay satisfies the evaluation criteria of paragraph (d) of this section, it will then be subjected to the interlaboratory validation study described in paragraph (f) of this section.

(f) Two Food and Drug Administration laboratories and one U.S. Department of Agriculture laboratory will independently run a number of assays to ascertain whether the regulatory assay conforms to the criteria set forth in paragraph (d) of this section.

(1) The petitioner shall supply the validating laboratories with the number and amount of dosed and control tissue samples, requested by the Commissioner.

(2) The petitioner shall supply reagents, standards, supplies, and equipment to the validating laboratories, as requested by the Commissioner.

(g) The Commissioner will evaluate the data gathered from the study run by the three validating laboratories described in paragraph (f) of this section. The assay will be approved if it meets the criteria set forth in paragraph (d) of this section in each laboratory.

§ 500.92 Withdrawal periods.

(a) The withdrawal period is the time after cessation of administration of the sponsored compound necessary for the marker residue to deplete to the lowest level of reliable measurement (L_m) in the target tissue. This time is the interval required for the statistical tolerance limit for the 99th percentile of the marker residue concentration for individual animals to deplete to L_m. The time will be extended if necessary to be consistent with conditions of livestock management so that directions for use of the compound with respect to the withdrawal period will be reasonably certain to be followed in practice.

(b) The sponsor shall submit studies of the marker residue's depletion from the target tissue of animals dosed according to the maximum level of use proposed in the petition and maintained under field conditions. The validated regulatory assay shall be used to collect these data.

(1) The petitioner shall submit a plot of the concentration of marker residues in target tissue as a function of time (depletion curve) including the statistical tolerance limits for the 99th percentile of the expected marker residue concentrations for individual animals.

(2) All relevant data, including worksheets, calculations, and statistical analyses, shall be submitted along with a referenced discussion of the results.

(3) Use of the sponsored compound will be approved only if the available evidence demonstrates that the proposed conditions of use, including any withdrawal period, are reasonably certain to be followed in practice.

(c) When the marker residue is an endogenous compound, the withdrawal period will be the time required after cessation of administration of the sponsored compound for the norm to be restored, as described in § 500.89(d)(1). The time will be extended if necessary, but not reduced, to be compatible with conditions of livestock management so that the directions for use of the compound with respect to the withdrawal period will be reasonably certain to be followed in practice. The validated regulatory assay shall be used to collect data on the rate of restoration of the norm.

(1) The petitioner shall submit a series of curves that demonstrate the time required for restoration of the norm.

(2) All relevant data including worksheets, calculations, and statistical analyses shall be submitted along with a referenced discussion of the results.

(3) Approval of the petition for the sponsored compound will be granted only if the available evidence demonstrates that the proposed labeling is reasonably certain to be followed in practice.

§ 500.94 Publication of the approved regulatory assay.

The lowest level of reliable measurement (L_m), the complete regulatory assay for measuring the marker residue in the target tissue, and the analytical curve will be published in the FEDERAL REGISTER, in accordance with the provisions of sections 409(c)(3)(A), 512(d)(1)(H) and (i), and 706(b)(5)(B) of the act. For an endogenous marker residue, the norm will also be published.

§ 500.95 Compliance.

Compliance with the act will be determined as follows:

(a) When a target tissue is found to contain the marker residue at or above the lowest level of reliable measurement (L_m), the Commissioner will conclude (1) that the carcass from which the target tissue was taken is unsafe for human consumption; and (2) that the sponsored compound may have been used in violation of the act.

(b) When animals are found to contain an endogenous marker residue at or above the 99th percentile of the norm (Plate III under § 500.89(c)(1)(ii)), they will be designated as potentially violative. Before regulatory action will be initiated, and investigation will be undertaken. This investigation is to determine whether the potentially violative sample came from target animals adminstered the sponsored compound whose median level of the endogenous marker residue is greater than the median of the norm.

§ 500.96 Waiver of requirements.

In response to a petition or on the Commissioner's own initiative, the Commissioner may waive, in whole or in part, any of the requirements of this subpart for the scientific evaluation of sponsored compounds that have the potential to contaminate food with residues which, when consumed, could engender a human risk of cancer. A petition for this waiver may be filed by any person who would be adversely affected by the application of the requirements to a particular compound. The petition shall explain and document why some or all of the requirements are not reasonably applicable to the compound, and describe the alternative procedures that have been, or could be, followed to assure that use of the compound will not contaminate human food with residues whose consumption could engender a human risk of cancer and that an assay exists that satisfies the requirements of § 500.90(d)(1) through (5) and that is capable of measuring any residues that might occur when the compound was improperly used. Interagency validation of the assay will always be required. The petition shall set forth clearly the reasons why the alternative procedures will provide the basis for concluding that approval of the compound satisfies the requirements of the anticancer provisions of the act. If the Commissioner determines that waiver of any of the requirements of this subpart is appropriate, the Commissioner will state the

basis for the determination in the regulation approving marketing of the sponsored compound.

§ 500.98 Implementation.

(a) This subpart applies to all new animal drug applications, feed additive petitions, and relevant color additive petitions (i.e., applications and petitions concerning any compound intended for use in food-producing animals) submitted to the Food and Drug Administration, including relevant supplemental applications and amendments to petitions, and to all these applications or petitions on file with the agency. If the Commissioner determines that consumer protection can be adequately ensured by imposing the requirements under paragraph (b) of this section, the Commissioner will do so.

(b) This subpart also applies to the following compounds already approved:

(1) Those compounds that the Commissoner determines, on the basis of available information, have been shown to induce cancer when ingested by man or animals.

(2) Those compounds that the Commissioner determines may induce cancer when ingested by man or animals, i.e., suspect carcinogens.

(3) Any compound for which the Commissioner concludes sufficient information has not been provided to determine whether residues of the sponsored compound present a risk of cancer to man.

(c) Any compound already approved, to which the Commissioner determines the anticancer provisions of the act apply, or for which additional data are required for such a determination, will be the subject of a notice published in the FEDERAL REGISTER or a letter issued under section 512(e) of the act establishing the time within which the requirements of this subpart shall be satisfied.

(1) Notices already published in the FEDERAL REGISTER and letters already sent by the Food and Drug Administration requiring additional studies or submission of an improved regulatory assay will remain in effect, and this subpart will be used in determining compliance with the requirements of the act identified in those notices and letters.

(2) The Commissioner will proceed to withdraw approval of any compound on the basis of data or information indicating a health hazard or in response to any failure to undertake studies necessary to comply with this subpart.

PART 514—NEW ANIMAL DRUG APPLICATIONS

3. In Part 514:

a. By amending § 514.1, by revising paragraph (b)(7) to read as follows:

§ 514.1 Applications.

* * * * *

(b) * * *

(7) *Assays for residues.* A description of practicable methods for determining the quantity, if any, of the new animal drug in or on food, and any substance formed in or on food because of its use, and the proposed tolerance or withdrawal period or other use restrictions for this drug if any tolerance or withdrawal period or other use restrictions are required to ensure that the proposed use of this drug will be safe.

(i) The required information may include: Complete experimental protocols for determining drug residue levels in the edible products, and the time required for residues to be eliminated from the edible products following the drug's use; residue studies conducted under appropriate (i. e., consistent with the proposed usage) conditions of dosage, time, and route of administration to show levels, if any, of the drug and/or its metabolites in test animals during and upon ceasing treatment and at intervals thereafter to establish a depletion curve; if the drug is to be used in combination with other drugs, possible effects of interaction demonstrated by the appropriate disappearance curve or depletion patterns after drug withdrawal under appropriate (i. e., consistent with the proposed usage) conditions of dosage, time, and route of administration; if the drug is given in the feed or water, appropriate consumption records of the medicated feed or water and appropriate performance data in the treated animal; if the drug is to be used in more than one species, drug residue studies or appropriate metabolic studies conducted for each food-producing species. Appropriate use of labeled compounds (e.g., radioactive tracers) may be used to establish metabolism and depletion curves. Drug residue levels ordinarily should be determined in muscle, liver, kidney, fat, and where applicable, in skin, milk, and eggs (yolk and white). As a part of the metabolic studies, levels of the drug or metabolite should be determined in blood when feasible. Samples may be combined if necessary. When residues are suspected or known to be present in litter from treated animals, it may be necessary to include data on those residues' becoming components of other agricultural commodities because of the use of litter from treated animals.

(ii) If the new animal drug has the potential to contaminate human food with residues (parent compound, metabolites, conversion products, or other substances found in or on food because of the drug's use) whose consumption could engender a human risk of carcinogenicity, the applicant and the new animal drug are subject to the requirements of Subpart E of Part 500 of this chapter.

* * * * *

b. By amending § 514.111, by adding a new paragraph (a)(10) to read as follows:

§ 514.111 Refusal to approve an application.

(a) * * *

(10) The drug fails to satisfy the requirements of Subpart E of Part 500 of this chapter.

* * * * *

PART 571—FOOD ADDITIVE PETITIONS

4. In Part 571, by adding new § 571.115, to read as follows:

§ 571.115 Application of the anticancer clause of section 409.

Food additives intended for use as an ingredient in food for animals that are raised for food production must satisfy the requirements of Subpart E of Part 500 of this chapter.

Interested persons may, on or before May 21, 1979, submit to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: February 26, 1979.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

NOTE—Incorporations by reference provisions approved by the Director of the Office of the Federal Register on December 21, 1978 and on file in the library of that office.

[FR Doc. 79-8215 Filed 3-19-79; 8:45 am]

47 FR 24278-01

RULES and REGULATIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Parts 74, 81, and 82

[Docket No. 81N-0301]

D&C Green No. 6; Listing as a Color Additive in Externally Applied Drugs and Cosmetics; Confirmation of Effective Date

Friday, June 4, 1982

***24278** AGENCY: Food and Drug Administration.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of May 4, 1982, for a final rule that amended the color additive regulations by "permanently" listing D&C Green No. 6 for use in externally applied drugs and cosmetics. That document also provided for the depletion of existing stocks of D&C Green No. 6 for all uses involving ingestion of the color additive.

DATE: Effective date confirmed: May 4, 1982.

FOR FURTHER INFORMATION CONTACT:

Garnett R. Higginbotham, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: FDA published a final rule in the Federal Register of April 2, 1982 (47 FR 14138) that amended the color additive regulations by "permanently" listing D&C Green No. 6 for use in externally applied drugs and cosmetics. That document also provided for the depletion of existing stocks of D&C Green No. 6 for all uses involving ingestion of the color additive.

Interested persons were given until May 3, 1982, to file objections. FDA received no objections on the final rule. Therefore, the agency concludes that the final rule published on April 2, 1982, for D&C Green No. 6 should be confirmed.

List of Subjects in 21 CFR Parts 74, 81, 82

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), notice is given that no objections or requests for a hearing were filed in response to the final rule of April 2, 1982. Accordingly, the amendments promulgated thereby became effective on May 4, 1982.

Dated: May 27, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-14964 Filed 5-28-82; 11:30 am]

BILLING CODE 4160-01-M

50 FR 45530-01
PROPOSED RULES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Parts 70, 500, 514, and 571
[Docket No. 77N-0026]

Sponsored Compounds in Food-Producing Animals; Criteria and Procedures for Evaluating the Safety of Carcinogenic Residues

Thursday, October 31, 1985

***45530** AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to establish procedures and minimum criteria to ensure the absence of significant concentrations of cancer-causing residues in edible products of food-producing animals to which drugs, food additives, or color additives have been administered. The procedures and criteria implement the DES Proviso, an exception to the Delaney anticancer clause, which permits approval of the use of carcinogenic compounds in food-producing animals, provided that the level of any residue remaining in edible tissues is so minimal that it would not present any significant risk of cancer for human consumption.

DATE: Written comments on or before February 28, 1986.

ADDRESS: Written comments are to be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert Benson, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4500.

SUPPLEMENTARY INFORMATION: The Food Additives Amendment of 1958 (Pub. L. 85-929) added the “Delaney Clause” to the Federal Food, Drug, and Cosmetic Act (the act). The clause proscribes the approval of any food additive found to induce cancer in man or in laboratory animals. FDA interpreted the clause as applying to compounds for use in food-producing animals. This interpretation barred the approval of carcinogenic compounds that were potentially useful in raising food-producing animals. Accordingly, the Drug Amendments of 1962 (Pub. L. 87-781) included an additional provision to the Delaney Clause that permitted the approval of the use of a carcinogenic compound in food-producing animals if “no residue” of the compound would be found in the edible tissues of treated animals by an FDA-approved analytical method capable of verifying the absence of residues. This provision is referred to as the DES Proviso. The DES Proviso also proved to be unworkable because the development of more sensitive analytical methods for detecting residues of a compound resulted in the identification of residues in tissue at concentrations much lower than expected when the DES Proviso was enacted. In fact, beginning in the early 1970's, progress in analytical chemistry was so rapid that even approved methods of analysis soon became dated or obsolete. FDA could never conclude that no trace of a carcinogenic compound or residue would remain in the edible tissues of animals to which the compound had been administered.

As a result FDA attempted to reconcile the purpose and language of the DES Proviso with the basic statutory objective of minimizing public exposure to carcinogenic compounds. FDA attempted to establish procedures and criteria for approving methods for identifying unacceptable concentrations of residues in edible products of food-producing animals to which drugs, food additives, or color additives had been administered. The procedures and criteria were proposed as regulations comprising what are commonly referred to as the “sensitivity of the method” or “SOM” procedures. As discussed in further detail

below, the procedures were proposed in 1973, finalized in 1977, withdrawn in 1978, and reproposed in 1979. FDA is now proposing the procedures again. The procedures are designed to permit the identification of that concentration of residue of a carcinogenic compound that presents an insignificant risk of cancer to the consuming public. Accordingly, the procedures call for a quantitative estimation of the risk of cancer presented by the residues of any carcinogenic compound proposed for use in food-producing animals. The procedures provide that, before a carcinogenic compound can be approved for use in food-producing animals, an analytical method must be available that can accurately and dependably measure the carcinogenic residues of the compound at concentrations greater than that estimated to be insignificant. That concentration is defined under the procedures as “no residue.” The definition renders the DES Proviso operable.

I. Introduction

A. Satutory Background

The act contains three Delaney, or anticancer, clauses: sections 409(c)(3)(A), 512(d)(1)(H), and 706(b)(5)(B) (21 U.S.C. 348(c)(3)(A), 360b(d)(1)(H), and 376 (b)(5)(B)). Each clause contains an exception applicable to compounds administered to food-producing animals. The exception, the DES Proviso, hinges on the finding of “no residue” of carcinogenic concern. The DES Proviso is the statutory basis for these proposed regulations. A discussion of the history, interpretation, and application of the DES Proviso follows.

1. Food Additives Amendment of 1958. Section 409 of the act, the Food Additives Amendment of 1958, establishes a licensing procedure for food additives, substances that are likely to become components of food. Section 409 of the act provides that a food additive must be shown to be safe through adequate scientific testing procedures. A primary function of the amendments was to require that manufacturers of food additives test substances that are added to food even if the substances are only potentially unsafe.

Before the amendment, FDA's authority for ensuring the safety of substances added to food was limited to section 402 (a)(1) and (2)(A) of the act (21 U.S.C. 342 (a)(1) and (2)(A)). The section applies to intentionally added food substances that may be injurious to health. The section places a burden upon the agency to show that an added substance may be injurious. The Food Additives Amendment of 1958 shifted this burden by requiring a sponsor or proponent of a food additive to prove that the additive could be safely used.

When first introduced in Congress, the Food Additives Amendment of 1958 did not contain a specific anticancer clause. The amendment contained a section requiring that food additives be demonstrated by premarketing testing to be safe. That section was enacted and is known as the General Food Safety Clause (section 409(c)(3)(A) of the act). Elliott L. Richardson, then Assistant Secretary of the Department of Health, Education, and Welfare (HEW), noted in commenting on the amendment that the General Food Safety Clause provided adequate grounds to protect the public from cancer-causing agents as well as from other toxins. (Ref. 1):

The scientific tests [required by the General Food Safety Clause] that are adequate to establish the safety of an additive will give information about the tendency of an additive to produce cancer when it is present in food. Any indication that the additive may thus be carcinogenic would, under the terms of the bill, restrain the Secretary [of HEW] from approving the ***45531** proposed use of the additive unless and until further testing shows to the point of reasonable certainty that the additive would not produce cancer and, thus, would be safe under the proposed conditions of use.

After the amendment was reported out of committee, Congressman Delaney from New York suggested the addition of an express anticancer clause. As a result, the following provision was added to the bill on August 13, 1958:

[N]o additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal or if it is found after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal * * *.

The House Committee on Interstate and Foreign Commerce and HEW agreed to the amendment. HEW, however, continued to maintain that the amendment did not change the meaning of the bill and that the power to regulate carcinogenic substances, as Assistant Secretary Richardson explained, was already contained in the General Food Safety Clause.

2. Color Additive Amendments of 1960. Section 706 of the act, the Color Additive Amendments of 1960, applies to all substances used to impart color to food and requires that before a color additive may be marketed it must be demonstrated to be safe by scientific testing. Section 706 of the act also has an anticancer clause for color additives in food. The clause is nearly identical to that promulgated in the Food Additives Amendment of 1958. Before the amendments became law, HEW commented again that an express anticancer clause was unnecessary to prevent approval of carcinogenic or potentially carcinogenic color additives because the clause did not offer any public protection that was not already provided by the general requirement to perform premarketing safety tests (Ref. 2).

3. Drug Amendments of 1962 and Animal Drug Amendments of 1968. Until 1962, the anticancer clauses in sections 409 and 706 did not distinguish between compounds added directly to human food and compounds that might indirectly enter human food by virtue of having been administered to food-producing animals. FDA interpreted the act as prohibiting the approval of a carcinogenic substance for use in animals. Accordingly, FDA did not consider whether a carcinogenic compound administered to animals left any residues in the edible tissue of the animal. A modification of section 706, however, was suggested by the Secretary of HEW during congressional consideration of the Color Additive Amendments of 1960. The Secretary explained (Ref. 2):

There is * * * one respect to which the anticancer proviso has proved to be needlessly stringent as applied to the use of additives in animal feed. For example, in the case of various animals raised for food production, certain drugs are used in animal feed which will leave no residue in the animal after slaughter or in any food product (such as milk or eggs) obtained from the living animal, and which are therefore perfectly safe for man. If this is demonstrated with respect to any particular additive intended for animal feed, and the additive will not adversely affect the animal itself during its expected or intended life cycle, we can see no reason for not permitting such a use of an additive which could be highly useful and beneficial in the raising of animals for food * * *.

We therefore have included in the enclosed draft bill an amendment to permit use of an additive in animal feed under the above-mentioned conditions.* * *

Under the amendment, the assay methods applicable in determining whether there will be a residue shall be those prescribed or approved by us by regulations. This will give reasonable certainty in that regard, although, of course, such regulations may from time to time be changed as new scientific developments demonstrate a need for change. It should be clearly understood that the industry still would have the responsibility of developing adequate analytical methods for detecting residues and furnishing them to the Government with a petition for approval of an additive.

The amendments proposed by the Secretary were not included in the color additive legislation.
In 1962 Congress extensively amended the new drug provisions of the act. At the time “new drugs” included animal drugs as well as human drugs. The amendments were designed, among other things, to rectify the problems identified by the Secretary in 1960 regarding the application of the anticancer clause in section 409 of the act to substances used in food-producing animals. Under section 409 of the act, the drug diethylstilbestrol (DES) could legally be administered to animals for certain longstanding uses. However, no “new” uses of the drug in food-producing animals were permissible under section 409 of the act by operation of the Delaney Clause. Citing this situation, the House Committee on Interstate and Foreign Commerce modified the anticancer clause by adding the DES Proviso. The committee explained the modification as follows (Ref. 3):

The committee amended the anticancer clause of the Food Additives Amendment and the Color Additive Amendments of the Federal Food, Drug, and Cosmetic Act by making this clause inapplicable to chemicals such as veterinary drugs when used in feed for food-producing animals if the Secretary finds: (1) That under the conditions of use and feeding specified in the

proposed labeling and reasonably certain to be followed in practice such additive will not adversely affect the animals for which such feed is intended, and (2) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations) in any edible portion of the animal after slaughter or in any food such as milk or eggs yielded by or derived from the living animals.

The Senate accepted the addition of the DES Proviso and modified the anticancer clauses. In 1968, Congress consolidated the various provisions of the act that govern the premarketing approval of drugs used in animals into section 512 of the act. The DES Proviso in section 512(d)(1)(H) of the act provides that the Secretary shall deny an application for approval of a new animal drug if he finds that the "drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal, except that the foregoing provisions of this subparagraph shall not apply with respect to such drug if the Secretary finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice (i) such drug will not adversely affect the animals for which it is intended, and (ii) no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (c), (d), and (h)), in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals.* * *" (emphasis added). (A nearly identical proviso exists for food additives (section 409(c)(3)(A) of the act) and for color additives (section 706(b)(5)(B) of the act). To avoid repetition, the language quoted above from section 512(d)(1)(H) of the act will be used or referred to throughout this document.)

B. Interpretation of the DES Proviso

Most compounds used in food-producing animals require premarketing approval under the act. Accordingly, the Delaney Clause as modified by the DES Proviso is potentially applicable to many compounds. Because the DES Proviso is an exception to the application of the Delaney Clause, arriving at an appropriate interpretation of the proviso has been controversial. Several interpretations are possible. FDA believes that there are three plausible interpretations.

***45532** Under one interpretation, the term "no residue" in the DES Proviso could be considered satisfied when no residue can be found at the lowest limit of measurement of the available analytical methodology. Under this interpretation, the application of the DES Proviso would be geared to advancements in techniques of measurement. The resulting degree of public health protection would be a function solely of the capability of available technology.

A second interpretation is to construe "no residue" as calling for the definition of some low finite concentration of residues (such as 1 part per billion) as "no residue" for any compound. Under this interpretation, a sponsor of a product would merely have to develop an analytical method that could reliably measure residues of a sponsored compound at the benchmark concentration. This interpretation would not take into account the potency of different carcinogenic residues.

A third interpretation is that which the agency has adopted in these proposed regulations. Under this interpretation, the term "no residue" is defined on the basis of quantitative carcinogenicity testing of residues and the extrapolation of the test data to that estimated concentration of residues that may be considered safe in the total diet of people. Under this approach, the estimated concentration of residues that will be considered safe will vary from compound to compound depending on the carcinogenic potency of the residues. Also, under this approach any future development of a regulatory assay with the capability of measuring even lower concentrations of residues would not result, as under the first interpretation, in precluding the application of the DES Proviso in a given case.

C. History of the SOM Procedures

In addition to the General Food Safety Clause for food additives (section 409(c)(3)(A) of the act), there are virtually identical clauses for new animal drugs (section 512(d)(1)(B) of the act) and color additives (section 706(b)(4) of the act). The essence of these clauses is that a food additive, new animal drug, or color additive for use in food-producing animals cannot be approved for use until it is shown to be safe. "Safe" means a reasonable certainty of no harm from any toxicity, including carcinogenicity. In the case of a drug or food or color additive proposed for use in food-producing animals, FDA must determine not only

whether the sponsored compound has been shown to be safe for the animals to which it will be administered, but also whether food derived from the animals will be safe for consumption by people. The sponsor of a compound is required to furnish to FDA the scientific and technical information necessary to make a determination as to safety. Prior to 1973, FDA did not have a consistently applied system for showing the safety of carcinogenic compounds proposed for use in food-producing animals or for invoking the DES Proviso to the Delaney Clause.

In the Federal Register of July 19, 1973 (38 FR 19226), FDA published a proposal to establish "the minimum standards for determining the acceptability of assay methods used to assure the absence of residues [of carcinogenic concern] in edible products of food-producing animals." The proposal was the agency's first attempt to provide a consistent and predictable approach: (1) To approve methods of measurement that would trigger the application of the DES Proviso and, therefore, (2) to demonstrate the safety of carcinogenic compounds for use in food-producing animals.

In the Federal Register of February 22, 1977 (42 FR 10412), the Commissioner of Food and Drugs promulgated final regulations based on the 1973 proposal. The Commissioner also solicited comments on four specific issues: (1) Acceptable level of risk, (2) comparative metabolism, (3) regulation of endogenous compounds, and (4) methods of determining an assay's lowest limit of reliable measurement.

On May 12, 1977, the Animal Health Institute (AHI) filed a complaint in the United States District Court for the District of Columbia alleging that the regulations were unlawful because they broadened the scope of the Delaney Clause to include substances not determined to be carcinogenic and because they foreclosed the marketing of a compound unless there exits an assay of sufficient sensitivity to detect residues of the compound at "theoretically" safe concentration. Also, AHI alleged that the regulations were impractical and embodied novel and highly suspect technical principles that would impose an environmental burden on the public and enormous financial costs on the animal health industry. AHI also alleged that the regulations violated the Administrative Procedure Act (5 U.S.C. 551 et seq.) because the regulations were not republished for comment.

The court agreed with AHI's letter contention because it found that the final order was significantly different from that proposed. The court remanded the case to FDA for further consideration. The court did not suggest that the agency's basic approach was suspect. The court, however, requested FDA specifically to consider AHI's question regarding the technical feasibility of the regulations. The court recommended that FDA repropose the regulations.

FDA revoked the regulations on May 26, 1978 (43 FR 22675), and on March 20, 1979 (44 FR 17070), reproposed them for public comment. The 1979 proposal contained an evaluation of the response to AHI's criticisms, the court's questions, and the substantative comments filed on the final rule. The reproposal was also supported by a lengthy and detailed administrative record. Furthermore, in an effort to promote the submission of well-directed comments, FDA held a public hearing on the proposal on June 21-22, 1979 (44 FR 23538, April 29, 1979; 44 FR 26899, May 8, 1979). A transcript of the hearing has been made a part of the administrative record of this proceeding.

II. The New Proposal

In reviewing the comments and in listening to participants at the June 1979 public hearing, FDA has concluded that there was a misunderstanding regarding the scope and purpose of the regulations proposed in 1979. In the interest of: (1) Increasing understanding about the SOM procedures and criteria; (2) continuing to draw upon valuable public comment; (3) being open to developments in science, and, most importantly; (4) developing a workable system for ensuring the safety of edible products of food-producing animals, FDA has decided to repropose less detailed regulations and to make available specific guidelines for implementing the regulations. (A notice of availability of the guidelines is published elsewhere in this issue of the Federal Register.)

A. Overview of the Proposed Procedures

The proposed regulations and guidelines identify the procedures and the criteria that if followed will permit the approval of carcinogenic compounds intended for use in food-producing animals, provided that the level of any residue remaining in edible tissues is so minimal that it would not present any significant risk of cancer. FDA emphasizes that the proposed regulations pertain to only one potential adverse effect: carcinogenicity. Every sponsored compound must also be evaluated for other potential adverse effects, which are not the subject of the proposed regulations, but which are included in the guidelines made available with this proposed rule.

***45533** The first step in the evaluation of any compound proposed for use in animals is the "threshold assessment," the agency's pivotal determination whether carcinogenicity testing is necessary for a sponsored compound. The elements FDA considers in making the threshold assessment are contained in a guideline. The elements include the relationship of the chemical structure of the sponsored compound to that of known carcinogens, the biological activity of the sponsored compound, the possible mutagenic activity of the compound, and the potential exposure of people to residues of the compound. See section III below.

If, after conducting the threshold assessment, FDA determines, under the General Food Safety Clause, that carcinogenicity testing (lifetime feeding studies) of the compound in laboratory animals is necessary, FDA will request the sponsor to test the parent compound and the metabolites identified by FDA to be of carcinogenic concern. (A compound that is administered to a food-producing animal can result in residues in the edible products of the animal that differ in structure from the compound. The enzymatic systems and physiological fluids of the animal often act upon a compound administered to the animal and produce these new substances, commonly known as metabolites or degradation products. Thus, the toxic response in animals could result from the administered parent compound or from the metabolites that the test animals produce by their own metabolism. The latter phenomenon is known as autoexposure.) As an alternative to separate toxicological testing of each metabolite, the guideline provides that FDA will compare metabolite profiles from tissues of target and test animals and will determine whether the bioassay has adequately tested the metabolites by autoexposure. FDA may require separate studies on a metabolite if it appears that a metabolite has not been adequately tested and is likely to have carcinogenic potency greater than the parent compound. If the data from the chronic tests do not demonstrate carcinogenicity, the sponsored compound is not subject to the proposed regulations.

If the data collected demonstrate carcinogenicity, the proposed regulations provide that FDA will evaluate the data on the quantitative aspects of the carcinogenicity of the compound and its metabolites and determine the concentration of the residues of carcinogenic concern that may be considered safe in the total diet of people. That concentration, for purposes of approval, will be defined as "no residue" and will be the permitted concentration of residue in edible tissues of treated animals.

The proposed regulations then provide that the sponsor of the compound must develop a reliable and practical regulatory assay to monitor the permitted concentration of residues in the edible tissues of treated animals.

The final step in the procedure is the determination of when the concentration of residues of carcinogenic concern in the edible tissues of the treated animals reaches the permitted concentration. This information allows for the determination of the last time before marketing an animal may be administered the sponsored compound.

B. Summary of Significant Changes in the Proposed Procedures

The proposed procedures differ significantly in several respects from the 1979 proposal. First, the regulations have been extensively revised to emphasize general principles. Much of the detail in the 1977 and 1979 regulations is now contained in guidelines. The guidelines describe an appropriate way of conducting scientific tests and provide FDA's criteria for evaluating data collected from the tests. If a sponsor follows the procedure prescribed in the regulations and guidelines, the sponsor is assured that the data collected will be sufficient to support an approval of the sponsored carcinogenic compound, assuming that the data that are collected are adequate to demonstrate the safety of the compound. The existence of guidelines does not preclude a sponsor from meeting the statutory and regulatory requirements by collecting data of information in a manner different from that described in the guidelines. Alternative means of showing that a given statutory standard is met may exist.

The proposed regulations and implementing guidelines represent FDA's perception of one acceptable way to show that a carcinogenic compound may be safely used in food.

Second, the guidelines explain how to conduct studies to identify residues for chronic testing. SOM procedures proposed in the past, without offering guidance, called for rigorous metabolic studies to identify and then test metabolites of carcinogenic concern in edible tissue. The guidelines now provide that usually only major metabolites will need to be identified. The guidelines define a major metabolite as one that, upon administration to an animal, is either present in an amount greater than 10 percent of the total residue in an edible tissue or has a concentration that exceeds 0.1 part per million in tissue.

Third, the proposed procedures rely upon the linear interpolation model for determining from the results of chronic tests in animals the amount of residue of a sponsored compound permitted in the diet of people. The new model takes into account all the dose response data collected from the chronic tests.

Fourth, the proposed procedures do not focus on what constitutes the lowest limit of reliable measurement of a regulatory assay, but rather on whether the assay reliably identifies the concentration defined as “no residue.” Under the proposed regulations, if a regulatory assay identifies any residue below that defined as “no residue,” FDA will consider the edible tissues containing the detected residue to be safe. FDA will consider actionable only the finding of a concentration of residues above that concentration defined as “no residue.”

III. Threshold Assessment

A. Background

When considering whether a sponsored compound for use in food-producing animals is safe within the meaning of the General Food Safety Clause, the agency determines whether the compound has the potential to contaminate the edible tissues of food-producing animals with residues that, if consumed, would present a risk of cancer to people. As each Federal Register notice concerning these procedures and criteria, has recognized, FDA will not require carcinogenicity testing for every sponsored compound. The mechanism by which FDA makes the determination that carcinogenicity testing is necessary is explained in the threshold assessment guideline.

Since the 1973 proposal, the elements of the threshold assessment have been refined. In the Federal Register of February 2, 1982 (47 FR 4972), FDA made available a threshold assessment guideline that superseded the approach recommended in the 1979 proposal. FDA received many favorable and well-focused comments on the revised guideline. In response to comments, FDA has further modified the 1982 guideline. Elsewhere in this issue of the Federal Register, FDA announces the availability of the new threshold assessment guideline.

B. Overview of the Threshold Assessment

The threshold assessment guidelines offers a decision-tree approach for deciding whether the sponsored ***45534** compound should be tested for carcinogenicity. The guideline is based on the assumption that the potential of a sponsored compound to present the risk of cancer to people includes two primary elements: (1) The potential carcinogenicity of the compound and (2) the exposure of people to residues of the compound. A brief discussion of how FDA applies the threshold assessment guideline follows.

When considering the potential carcinogenicity of the sponsored compound, FDA will evaluate the structure of the parent compound as well as data from short-term genetic toxicity tests and from subchronic toxicity tests performed on the compound. FDA will also evaluate any other available relevant information concerning the potential carcinogenicity of the compound. As a measure of that potential, FDA will assign a “toxicity factor” to the sponsored compound. FDA will assign an “A” toxicity factor to compounds for which the available information reveals there is a low potential for carcinogenicity. FDA will assign a

"B," "C," or "D" toxicity factor to compounds with higher potentials for carcinogenicity, with D representing the compounds with the highest potential to be carcinogenic.

When considering the potential exposure of people to residues of the compound, FDA will evaluate both the frequency of exposure to residues and the amount of residue ingested during a single exposure. As a measure of the frequency of exposure of people to the compound in food from food-producing animals, FDA will assign to the compound either a "high" or "low" use factor. For example, if most of the animals in a given herd or flock would normally be treated with the sponsored compound, then people would frequently ingest residues of the compound. Under these circumstances, FDA will assign that compound to the "high" use factor. If only a few animals would normally be treated with the compound, then people would ingest residues of the compound only intermittently. Under these circumstances, FDA will assign the sponsored compound to the "low" use factor.

As a measure of the amount of residue of a compound ingested by a person during a single exposure, FDA will use the results of a residue depletion study on the compound, which takes into account the duration of treatment, the dose administered, the time of treatment in relation to slaughter, and the contribution of various edible tissues to the total diet of people.

After all available information is evaluated and the toxicity, use, and residue factors have been assigned, FDA will follow the decision elements of the threshold assessment guideline to determine whether it will request carcinogenicity testing. For example, FDA will not request carcinogenicity testing for any compound assigned an A toxicity factor. FDA will request testing for a compound assigned a B toxicity factor only if the compound is assigned the high use factor and a total residue factor that exceeds 0.25 microgram per kilogram body weight per day or if the compound is assigned the low use factor and a total residue factor that exceeds 6.25 micrograms per kilogram body weight per day. FDA will request testing for any compound assigned a C or D toxicity factor. However, in the case of a compound that has a short half-life in edible tissue and is administered a long time before slaughter of the animal, FDA may conclude that any potential risk to people will be too low to justify requesting carcinogenicity testing regardless of its assigned toxicity factor.

If FDA does not request testing for carcinogenicity, the proposed regulations do not apply to the compound. Although not likely, it is possible that subsequent testing performed under the general food safety requirements of the act and necessary for approval of the product may indicate that the compound possesses the potential to be carcinogenic. Under these circumstances, the compound may be reassigned to a toxicity category that may result in a request for carcinogenicity testing.

C. Comments on the 1982 Guideline

As discussed above, many comments were received on the 1982 guideline. As a result of the comments, FDA has revised the guideline. In the following discussion, FDA responds to the substantive comments received.

1. A comment stated that FDA in the threshold assessment should not automatically request carcinogenicity testing even when adverse data are obtained. The comment suggested that FDA should also consider use patterns, pharmacokinetic data, and residue concentration.

FDA agrees with the comment and has modified the threshold assessment accordingly. The guideline now provides that: "After all available information is evaluated, FDA will request carcinogenicity testing for a compound assigned a C or D toxicity factor. If, however, a specific compound imparts residues that have a short half-life in edible tissue and the compound is administered a long time before slaughter (for example, several months), then FDA may not require carcinogenicity testing. Under these circumstances FDA can conclude that any potential risk to people will be too low to justify chronic testing."

2. Another comment interpreted the threshold assessment as classifying a compound as a carcinogen if the short-term tests of the compound yield positive results. The comment stated that positive results in short-term tests do not provide sufficient evidence to classify a compound as a carcinogen.

FDA agrees with the comment's position regarding the limitations of short-term testing. When positive data are obtained from a battery of short-term tests, FDA does not classify the sponsored compound as a carcinogen. Rather, FDA requests the sponsor of the compound to conduct adequate carcinogenicity testing to provide definitive data to determine whether the compound is a carcinogen.

3. Many comments stated that the threshold assessment placed too much weight on structure-activity relationships and insufficient weight on the results of biological testing. The comments contended that under the threshold assessment FDA should assign all compounds an A toxicity factor when no adverse biological data are submitted by the sponsor.

FDA believes that none of the types of information relied upon in the threshold assessment to assign compounds a toxicity factor (that is, structure, results from short-term genetic toxicity tests, and results from subchronic feeding studies) is sufficient to determine whether a compound is carcinogenic. Information from each category may raise or lower concern that a given sponsored compound is carcinogenic. Even negative results from genetic toxicity tests and subchronic feeding studies cannot completely eliminate concern that arises from a compound that possesses a structural relationship with known carcinogens because genetic toxicity tests and subchronic feeding studies may not be sufficiently sensitive and may give false-negative or false-positive results. The comments correctly argued, however, that FDA has in past threshold assessment guidelines placed undue weight on structure-activity relationships. Accordingly, FDA has revised that aspect of the guideline that applies to a compound that gives no adverse data from genetic toxicity and subchronic feeding tests but possesses a structural relationship to a known carcinogen. The compound will be assigned a B toxicity factor but in determining whether carcinogenicity ***45535** testing will be requested the agency will take into account not only the proposed use of the compound but also its residue concentration. The guideline now provides that:

“FDA will request a sponsor to conduct chronic bioassays for carcinogenicity for a compound assigned a B toxicity factor if it is assigned a high-use factor and a total residue factor exceeds 0.25 microgram/kilogram body weight/day (equivalent to a concentration of 10 parts per billion in the total diet of people, assuming a 60-kilogram body weight and a total solid diet of 1,500 grams).

“FDA will request a sponsor to conduct chronic bioassays for carcinogenicity for a compound assigned to a B toxicity factor if it is assigned to a low-use factor and a total residue factor that exceeds 6.25 micrograms/kilogram body weight/day (equivalent to a concentration of 250 parts per billion in the total diet of people).”

FDA suggests the 0.25 microgram/kilogram body weight/day value for a high use compound assigned a B toxicity factor because demonstrated carcinogens recently reviewed by FDA have been determined to present an insignificant risk of cancer using criteria similar to these proposed in these regulations. As FDA gains more experience using the criteria in these proposed regulations, FDA may change this value. FDA suggests the 6.25 micrograms/kilogram body weight/day value for a low use compound assigned a B toxicity factor because FDA uses this value in deciding whether carcinogenicity testing is necessary for direct human food additives.

4. Several comments stated that the structure list, although improved, remained too broad and inclusive.

In response to a similar comment, FDA stated in the 1982 notice (47 FR 4975) that: “The list of structures was intentionally general to ensure that compounds with some carcinogenic potential would not be missed. Because of the uncertainties in selecting potential carcinogens on the basis of molecular structure, the guide will be used as a screening tool by an internal committee of agency scientists.” FDA continues to believe in the propriety of an inclusive structure list. Any relevant information on the potential carcinogenicity of a compound should be considered during the threshold assessment. As noted above, however, FDA has modified the threshold assessment so as not to place undue emphasis on the significance of structure-activity relationships in the absence of other relevant evidence bearing on the question of the carcinogenicity of a sponsored compound.

5. One comment requested that FDA explain how it will interpret equivocal results from a battery of genetic toxicity tests.

Because the burden of demonstrating the safety of a compound is on the sponsor, FDA under the threshold assessment will not assign a compound to a more favorable toxicity factor on the basis of equivocal results from the battery of genetic toxicity tests. Under these circumstances, a sponsor has the option of submitting additional genetic toxicity data or of conducting chronic bioassays to resolve questions concerning the carcinogenicity of the compound.

6. Some comments also argued that the threshold assessment should take into account in the use factor the difference between drugs given to a herd or flock early in an animal's life as opposed to those administered to a herd or flock throughout an animal's life.

The threshold assessment guideline does take these distinctions into account. An anthelmintic and a growth promotant, for example, could be assigned to the same use category if they would both be given to approximately the same number of animals, an entire herd or flock, on a routine basis. However, the respective total residue factors assigned to each use would differ, for that factor accounts for the amount of residue present at the time of slaughter.

7. One comment contended that for compounds available only through a veterinarian by prescription the threshold assessment should provide for the assignment of a compound to the low use factor.

A product available through prescription is usually administered after signs of disease are present and after a diagnosis has been made. Thus, FDA will usually assign a prescription product a low use factor.

8. One comment asked how approved compounds would be classified if the criteria in the threshold assessment were applied to them.

FDA does not have the results of genetic toxicity testing and total residue data on all approved compounds. However, approximately one-third of the approved products would be classified as “suspect structure, high use.”

9. Several comments requested that FDA revise the correction factors to reflect more closely the actual consumption by people of organ tissue.

FDA has obtained new data on the consumption of organ tissues and is presently evaluating this information to ascertain if a revision of the current guideline is warranted. Pending such a change, FDA will continue to use the “Guideline for Establishing a Tolerance” made available for comment elsewhere in this issue of the Federal Register.

IV. Studies to Identify Residues of Toxicological Concern

A. The Need To Identify Residues in Edible Tissues

In determining whether a sponsored compound proposed for use in food-producing animals is safe, section 512(d)(2)(A) of the act provides that FDA should consider the safety of any substance formed in or on food by the sponsored compound. A similar requirement is found in section 512(b)(7) of the act. The compound administered to food-producing animals is not necessarily the substance or substances that will be present in the edible products of the treated animals. The enzymatic systems and physiological fluids of an animal can act upon a compound administered to the animal and produce new substances, which are commonly referred to as metabolites or degradation products. The amount of these substances in edible animal products will be a complex function of the rate and extent of absorption of the parent compound, the rate and extent of the metabolism of the absorbed parent compound, and the rate of excretion of the parent compound and metabolites (Refs. 4 through 7).

Because the structure of metabolites can vary greatly from that of the parent compound, the toxicological properties of these metabolites may also vary. In many instances, a metabolite may be less toxic than the parent compound. However, in other instances, a metabolite may be more toxic than the parent compound (Refs. 8, 9, and 10).

The total residue of the sponsored compound in edible animal products will consist of the parent compound, free metabolites, and metabolites that are covalently bound to endogenous molecules. The relative and absolute amounts of each residue will vary among the tissues according to the time following the last administration of the sponsored compound to the animal. Because different components of the total residue may possess dissimilar toxicological potential, a compound cannot be shown to be safe until the sponsor has collected information on the amount, persistence, and chemical nature of the total residue in the edible products of the treated animals.

Comments on past notices concerning the SOM procedures and criteria have ***45536** complained that FDA has not provided adequate guidance on how to design and conduct appropriate studies for identifying residues of toxicological concern. In the absence of this guidance, comments have mistakenly believed that FDA required that every metabolite be identified and tested for carcinogenicity in separate chronic bioassays. In an effort to provide guidance and clarification in this area, FDA has prepared a detailed " Guideline for Metabolism Studies and for Identification of Residues for Toxicological Testing." The guideline is made available for comment elsewhere in this issue of the Federal Register. The guideline identifies the extent of metabolite identification and testing FDA believes is necessary. For example, the guideline permits reliance upon autoexposure testing to the extent scientifically appropriate in an effort to avoid the need to conduct separate testing on individual metabolites. The autoexposure approach assumes that the toxic response in the treated animals results from the administered parent compound or the substances that test animals produce from the administered compound by their own metabolism.

If FDA requires that a sponsored compound be subjected to carcinogenicity testing, a sponsor will always be required to test the parent compound in chronic bioassays. FDA uses the information on the amount, persistence, and chemical nature of the metabolites in target animals to select those metabolites of the parent compound that should also be subjected to carcinogenicity testing. FDA will compare data submitted by the sponsor on the metabolites of the compound in target and test animals and will use scientific judgment in determining the adequacy of autoexposure to test metabolites of the sponsored compound. FDA may still require separate toxicity studies if a metabolite is not adequately tested through autoexposure and is likely to have carcinogenic potency significantly greater than the parent compound.

B. Comments on the 1979 Proposal

Many comments were received concerning how to perform studies of the metabolism of a sponsored compound in target and test animals. The comments identified many issues that the proposed regulations did not describe in sufficient detail. The guideline and the responses to the comments, below, provide needed clarification in this area.

Metabolite Identification

10. Comments stated that FDA should clearly distinguish a study that provides a qualitative profile of metabolites for comparative purposes from a study that involves exhaustive identification of all drug-related residues. The comments stated that the first type of study is feasible and scientifically supportable. The comments argued, however, that the second type of study is technically infeasible and not very relevant to an assessment of the carcinogenicity of a residue. One of the comments recommended that FDA require the study in the target animal to provide information on excretion rates, total residue depletion rates in tissue, and a qualitative chromatographic pattern of residues in the tissue.

Comments also noted that there are no standardized procedures for the identification of an unknown metabolite in tissue at the parts per billion level and that standard techniques used in the identification of metabolites in excreta are generally not useful in the identification of metabolites in tissues. Additional comments stated that the identification of metabolites should be limited to state-of-the-art procedures, and that sponsors should be required to identify major metabolites but only to estimate the number and properties of minor metabolites. Another comment suggested that complete structural identification of minor metabolites

should not be required because the fact that the metabolite is present in small amounts is sufficient information to conclude that the metabolite is of insignificant carcinogenic risk to people. Another comment expressed the view that references cited in the 1979 proposal are not germane to the proposed rule because they deal with classic drug metabolism and not with drug-related metabolites in tissue.

The comments demonstrate that FDA did not clearly explain its position on the need for identification of metabolites in edible animal tissue. FDA intended to say that techniques used in the identification of metabolites (e.g., ultraviolet-visible spectroscopy, infrared spectroscopy, nuclear magnetic resonance spectrometry, and mass spectrometry) are routine state-of-the-art techniques employed in basic biochemical and pharmacological investigations. FDA recognizes that procedures for the isolation of metabolites from edible tissues may be quite different from procedures used to isolate metabolites from urine and that there are practical limitations on the isolation of metabolites from tissues. The sponsor may isolate metabolites from excreta or from overdosed animals for purposes of chemical characterization and structural identification and should provide information to ensure that metabolites identified in excreta are the metabolites present in tissue.

FDA acknowledges the difficulties in the isolation, purification, and structural characterization of metabolites in tissue and recognizes that complete structural elucidation of minor metabolites is not possible. As discussed in the guideline, FDA will usually require structural identification of major metabolites, but will normally not require structural identification or chemical characterization of minor metabolites. FDA will consider a metabolite to be a major metabolite if either: (1) It is present in an amount greater than 10 percent of the total residue in an edible tissue at zero withdrawal, or (2) its concentration exceeds 0.1 part per million at zero withdrawal. In some cases, chemical characterization rather than unequivocal structural identification will be sufficient for major metabolites.

FDA disagrees with the assertion that the presence of only small amounts of a metabolite in tissue is sufficient information upon which to conclude that the metabolite presents an insignificant risk of cancer to people. The comment ignores the fact that the potency of chemical carcinogens varies over orders of magnitude (Ref. 11).

Radiolabeling

11. Several comments noted that the radiopurity of the parent compound used in the studies is critical because contaminants can greatly affect the interpretation of results. Comments also suggested that obtaining adequate radiopurity would be particularly difficult for high specific activity preparations because a certain degree of radiodecomposition of the parent compound is anticipated.

Many comments stated that the use of compounds with the highest specific activity available would be enormously costly, would be dangerous to personnel, and would create a waste disposal problem. Another comment stated that the investigator conducts these studies to address different questions and should be allowed to choose the specific activity for each study. Another comment stated that the use of compounds with such high specific activity is often unwarranted because individual metabolites in the tissue cannot feasibly be identified when they occur at very low concentrations.

***45537** FDA agrees that radiolabeled contaminants in a preparation of the parent compound can render the interpretation of metabolism studies difficult or impossible. In FDA's experience, radiochemical purity of 98 percent will usually give satisfactory results, but lower percentages may suffice. If the sponsor believes that a residue is present in tissue solely as a result of a contaminant in the radiolabeled preparation of the parent compound, FDA will consider submitted data pertinent to this issue when deciding if that residue is of concern.

All phases of the studies need not be conducted with radiolabeled compounds of the highest specific activity available. The sponsor may choose a specific activity that will be compatible with the objective of the experiment, thus reducing costs. FDA believes that any hazard incurred by personnel in the handling and disposal of radioactive substances may be minimized by usual laboratory safety procedures associated with the use of radioisotopes.

FDA disagrees with the comment's assertion that merely because detected residues may not be identified, the use of a high specific activity radiolabel is unnecessary. Even in the absence of structural identification of individual residues, a sensitive measure of the total residue in edible animal tissue is an essential aspect in a safety evaluation. For a compound that is to be regulated as a carcinogen, FDA will require that the specific activity of the compound be high enough to measure the metabolites at the concentration that will satisfy the operational definition of no residue.

Maximum Proposed Dosage

12. One comment stated that it is not possible to know the maximum proposed dosage of a drug because field trials for efficacy will often still be in progress, and the maximum proposed dosage may change after evaluation of these results.

The sponsor may choose to await completion of field trials before beginning metabolism studies. Alternatively, the sponsor may choose the likely maximum dosage and proceed with the studies. If the maximum proposed dosage changes, FDA will determine if any additional information is necessary.

Reporting Format

13. Some comments stated that the American Chemical Society and American Society of Biological Chemists publication formats were too restrictive in terms of data presentation for FDA to evaluate the information properly.

FDA's purpose in requiring that results of these studies be presented in a format similar to publications of professional societies is to ensure that data are submitted in a clear, concise manner. This will facilitate FDA review. FDA will not require rigid adherence to any specific format. The sponsor should include in the report a statement of the purpose for conducting the experiment, a description of the methods used, and a discussion of the results obtained.

Selecting Metabolites For Chronic Bioassay

14. Several comments dealt with FDA's proposal to use structure-activity relationships to select metabolites for separate chronic bioassays. The consensus of these comments was that structural identification of residues and physicochemical data are of little value in predicting the carcinogenic potential of metabolites. Other comments recommended that FDA use data obtained from genetic toxicity tests, instead of structure-activity relationships, to select metabolites for separate chronic bioassays. One comment stated that, because short-term genetic toxicity tests are of proven accuracy and prediction of carcinogenicity based on structure is not, a compound yielding negative results in genetic toxicity tests (provided that known carcinogens of the same chemical class have been shown to be positive in these tests) should not be of carcinogenic concern even if it possesses a structural moiety of carcinogenic concern. Another comment alleged that FDA's proposal may require separate chronic bioassays for many metabolites, that this testing will not yield meaningful data, and that research and development of drugs and feed additives will be deterred.

Structural information is of value in predicting the pharmacological and toxicological (including carcinogenic) properties of a compound (Ref. 12). FDA also recognizes the merit of using data obtained from genetic toxicity tests in selecting metabolites for separate chronic bioassays. However, FDA believes that there are limitations in the use of these data. For example, certain classes of compounds are carcinogenic, but are not well detected in some genetic toxicity tests. (See appendix 2 of the “Guideline for Threshold Assessment.”) Because of these limitations, the results from genetic toxicity tests cannot always be used to reduce the concern for potential carcinogenicity arising from structure-activity relationships.

FDA may require separate toxicological studies on a metabolite if it is not adequately tested through autoexposure and is likely to have toxicological potency significantly greater than the parent compound. FDA will normally conclude that autoexposure provides an adequate test of the toxicity of the sponsored compound if at least one species of laboratory animal produces the metabolites that collectively comprise over 90 percent of the amount of residue that people will consume from tissues of treated

target animals. Failing that, FDA will use the information obtained from target animals on the concentration, persistence, and chemical structure or characterization of that metabolite to determine whether separate toxicological testing is required.

Relay Toxicity

15. Many comments recommended that results of relay toxicity tests should be used in evaluating the safety of a sponsored compound. Another comment recommended that relay toxicity testing completely replace chronic testing of the parent and any or all metabolites.

FDA disagrees with the proposal that relay toxicity testing of metabolites replace testing of the parent compound or any of its metabolites. Methods for relay toxicity testing provide an excellent means of equating test animal and human exposure. However, no appropriate means of exaggerating this exposure are available. The exaggeration of dose is an essential part of any toxicity test. Should future developments in relay toxicity testing successfully overcome this deficiency, then FDA will reconsider its position on the ability of this type of study to address the lack of carcinogenic potential of metabolites in edible animal tissue. However, a positive response in a relay toxicity test indicates a serious toxicological hazard and cannot be ignored.

Bound Metabolites and Bioavailability

16. Many comments urged FDA to consider that bound metabolites are probably of little or no carcinogenic concern because: (1) The bound metabolites are unlikely to be bioavailable; (2) if they are bioavailable, then they will be rapidly cleared from the body by excretory processes; (3) the reactive portion of a bound metabolite is already involved in a covalent linkage, and it is unlikely that further metabolic activation to a toxic metabolite will occur due to thermodynamic considerations; and (4) FDA's contention that bound metabolites may be of carcinogenic concern is undocumented.

***45538** One comment recommended that separate chronic bioassays should be necessary for bound metabolites only when: (1) The bound metabolite is bioavailable, (2) the bound metabolite gives a positive response in in vitro mutagenicity tests, and (3) the bound metabolite is of greater potency than the parent compound in a mutagenicity test. Another comment contended that because bound metabolites cannot be synthesized for toxicity testing, they should not be considered to be residues.

Under the act, FDA must consider the safety of any substance formed in or on food as the result of use of the sponsored compound, including bound metabolites. Information on the toxicity of covalently bound metabolites is quite sparse because of difficulties in the isolation, identification, and synthesis of these residues for toxicity testing. Some information is available indicating that a covalently bound metabolite of aflatoxin-B1 isolated from rats fed radiolabeled aflatoxin is not reincorporated in liver DNA when the covalently metabolite is fed to a second set of rats (Ref. 23). FDA is unaware of any chronic feeding studies designed to test the carcinogenic potential of bound metabolites, and has no basis for concluding that bound metabolites cannot be carcinogenic.

FDA does not believe that results obtained from bioavailability studies alone can be used in a routine fashion to evaluate the safety of a compound. It would not be scientifically defensible for FDA to conclude that a metabolite is not of carcinogenic concern because only a small portion of that metabolite is absorbed. Additional information, such as the results of genetic toxicity tests, may be required to evaluate properly the potential carcinogenic risk from exposure to these metabolites. Although FDA agrees that genetic toxicity testing and other data may be useful on a case-by-case basis to reduce the concern that a covalently bound metabolite may be carcinogenic, there are not sufficient scientific data to conclude that potency in a genetic toxicity test correlates well with carcinogenci potency.

In situations where the concentration of total residue (free plus covalently bound) is below the concentration of residue that will satisfy FDA's operational definition of no residue, the sponsored compound is shown to be safe. Therefore, further study of the covalently bound residue is unnecessary. In situations where the concentration of covalently bound residue exceeds the concentration of residue that will satisfy FDA's operational definition of no residue, the sponsor may propose a series of studies

to remove the concern for the covalently bound residue. FDA will determine on a case-by-case basis the adequacy of the studies to address the issue.

Alternative Data Collection Schemes

17. Several comments stated that the data collection steps of the 1979 proposal do not follow a logical sequence.

The sponsor of a product may choose to collect the required information in any sequence. For example, a sponsor may believe that it is to its advantage to choose a marker substance and to develop an analytical method early in the data collection process. FDA, however, will not be able to determine whether the choice of marker is appropriate or if the limit of measurement is sufficiently low until results of chronic bioassays and metabolism and total residue studies in target animals have been evaluated and an So is determined.

18. FDA received many comments that recommended alternative data collection schemes for showing the safety of a sponsored compound that may be carcinogenic.

As stated in the proposal, FDA will accept data collected under alternative procedures provided that the data permit an adequate evaluation of the carcinogenic potential of residues. Below are several data collection schemes presented in comments.

Scheme A. 1. Lifetime chronic studies should be performed on those compounds that exceed an accepted threshold score based on the use of the compound, the concentration of metabolites, and the potential hazard of these residues to the consumer. After the lifetime studies have been completed, a second threshold assessment should be conducted. Compounds receiving overall scores below the accepted threshold value should be released from the proposed requirements and be judged by conventional toxicological criteria.

2. Studies of the metabolism of the compound should be conducted in the target animal and in one of the two species employed in the chronic study. The specific radioactivity of the radiotracer should be chosen to provide a measurable response at a concentration at which characterization of the radiocative residue is reasonable, recommended in the comment to be about 10 parts per billion. Positive results in the lifetime study with the sponsored compound would be reason for more rigorous approaches if the sponsor elected to continue with development of the compound.

3. Metabolites comprising 50 parts per billion or more should be identified to the extent possible. All metabolites that have been identified and synthesized should be subjected to the mutagenicity tests in bacteria and/or other short-term mutagenicity tests deemed appropriate by toxicologists. A positive response in these tests should be considered reason for further study.

4. The lifetime bioassay of the sponsored compound should be considered an acceptable evaluation of those metabolites present in both test and target species and all metabolites present at levels below 50 parts per billion, or comprising less than 10 percent of the total residue in the edible tissue.

5. Relay-toxicity and bioavailability testing should be recommended in those cases where the metabolic patterns of commonly used test animals are not similar to the metabolic patterns of the target species.

FDA agrees with many aspects of this alternative data collection process. FDA will require lifetime studies on those products that the threshold assessment indicates require further evaluation to resolve issues of carcinogenicity. When the issue of carcinogenicity is satisfactorily addressed with no finding of carcinogenicity, FDA may regulate the sponsored compound under its general food safety requirements for risks other than cancer. A second threshold assessment is, therefore, unnecessary.

FDA will generally require studies on the metabolism of the compound in target and in laboratory animals (see section IV.B. “Selecting Metabolites for Chronic Bioassay,” above). A limit of detection in the 10 parts per billion range will generally be

sufficient for an initial residue depletion study. However, if the product is a carcinogen, FDA will require that the residue of carcinogenic concern be measurable at the concentration that will satisfy FDA's operational definition of no residue.

The sponsor should identify metabolites that are major metabolites as defined in section IV.B. “Metabolite Identification,” above, if they represent an amount greater than 10 percent of the total residue at zero withdrawal regardless of the possibility that the concentration may be below 0.1 part per million. FDA will generally rely on autoexposure testing of the metabolites (see section IV.B. “Selecting Metabolites for Chronic Bioassay,” above). If a metabolite is not adequately tested by autoexposure, then genetic toxicity testing may be useful in deciding whether chronic bioassays are ***45539** necessary (see section IV.B. “Selecting Metabolites for Chronic Bioassay,” above). FDA's position on relay toxicity testing and bioavailability studies are discussed in sections IV.B. “Relay Toxicity” and “ Bound Metabolites and Bioavailability,” above.

Scheme B. Information on the absorption, distribution, and excretion of a single dose of radiolabeled drug in target and test animals would first be collected. Emphasis would be placed on the isolation and identification of major metabolites, with an estimation of the number and properties of minor metabolites. From this study, an estimate of the required specific activity of radiolabeled drug would be made. Following multiple dosing with labeled material, excreted metabolites would be examined in target and test animals. Urinary metabolites that constitute less than 2 percent of the dose would likely be artifacts. Metabolites extractable from target tissues of the target species would be examined at steady state and at one and two half-lives of depletion. The extent of covalent binding would also be determined at these times. Metabolites in target tissues that constitute 20 percent or less of extractable material would likely be artifacts and would be considered for chronic bioassays only if they are also excreted in large amounts. From these studies, metabolic pathways would be established, metabolites would be selected for in vitro testing, and a marker substance would be selected.

FDA also agrees with aspects of this alternative. Single dose studies with a radiolabeled compound are useful to the sponsor. These studies are useful for delineating basic metabolic pathways for the product, for determining the required specific activity for future studies, for providing information on likely major and minor metabolites, and for providing information on a likely marker substance. However, single dose studies are not sufficient for the safety evaluation of a product given continuously or in repeated doses. FDA discusses appropriate metabolism studies for compounds given continuously in the “Guideline for Metabolism Studies and for Identification of Residues for Toxicological Testing.” FDA agrees that the sponsor first collect information on the major metabolites and obtain an estimate of the number and properties of minor metabolites. If necessary for its evaluation of the compound, FDA will request additional information on the minor metabolites. FDA specifically rejects the proposal to examine metabolites at one and two half-lives because the residues may require more than two half-lives to deplete to the concentration that will satisfy the operational definition of no residue. FDA cannot accept without experimental verification the assertion that metabolites that comprise less than 2 percent of the radioactivity in urine or less than 20 percent of radioactivity in tissue are artifacts. FDA's experience is that actual metabolites of sponsored compounds are frequently less than 20 percent of the total residue in tissue.

Scheme C. 1. The parent compound is administered to the food-producing animal and tissues are analyzed for parent compound and metabolites.

2. The metabolism of the parent compound is investigated in vitro using a series of tissues from potential test species/strains and human autopsy material. Using this information, test animals are selected that have a metabolite profile closest to people.

3. The metabolites are synthesized and chronic bioassays are conducted with the mixture of metabolites at the maximum tolerated dose.

4. Individual metabolites are evaluated in genetic toxicity tests using human autopsy tissue for metabolic activation. If any matabolite shows a potential for genetic toxicity, then a separate chronic bioassay on this metabolite is necessary.

FDA believes agrees that this approach, too, may have merit in evaluating the carcinogenic potential of residues. Sponsors proposing in vitro studies on the metabolism of the compound should also present information demonstrating that the tissue preparations used are representative of in vivo metabolism for the species. Sponsors should also be aware that suitable human autopsy material may not be available.

V. Cronic Toxicity Testing

A. Introduction

The sponsored compound and any metabolites selected for separate carcinogenicity testing must be subjected to oral, lifetime, dose-response studies in two test animal species. The purpose of these studies is to determine whether the compounds under test are carcinogenic and, if so, to establish the concentration that will satisfy FDA's operational definition of no residue.

B. Comments on the 1979 Proposal

The two major issues raised by comments on this feature of the 1979 proposal were: (1) The design of chronic studies and (2) the interpretation of the test data to determine whether the compound is a carcinogen.

Design of Carcinogenicity Studies

19. Comments stated that FDA did not give the criteria or any other guidance for designing carcinogenicity studies.

The purpose of the proposal was to detail the type of information required to evaluate the possible carcinogenicity of the sponsored compounds, not to provide protocols for conducting studies. For guidance in developing an acceptable protocol, FDA recommends the report of the Food and Drug Advisory Committee on Protocols for Safety Evaluation of Food Additives and Pesticides (Toxicology and Applied Pharmacology, 20:419-438, 1971) as well as “Guidelines for Carcinogen Bioassays in Small Rodents” (National Cancer Institute, Carcinogenesis Technical Report Series No. 1. HEW Publication No. (NIH) 76-8601, 1976). FDA has also adopted minimum protocols and required quality standards for chronic bioassays (Ref. 13). FDA recommends that the sponsor submit protocols for review before starting the projects.

20. One comment argued that a time limit must be included for FDA comment on submitted protocols. The comment suggested that FDA should be deemed to have approved the protocol in the absence of a timely response.

FDA does not agree that the use of time limits is desirable or feasible. The availability of detailed protocols (Ref. 13) acceptable to FDA should reduce the need for extensive FDA comment on protocols.

21. Comments suggested that when extrapolating tumor data from animals to people it is not appropriate to use the dietary concentration of the test substance because young animals consume more food than adults in proportion to their body weight and thus receive a higher dose. The comments further suggested that the increased consumption of food by young animals under test might lead to metabolic overload. Accordingly, comments suggested that dose be expressed as miligrams per kilogram body weight and be held constant by varying the dietary concentration to match the food consumption and growth of the animals.

The two common ways of dosing animals on bioassay are: (1) To administer the test ***45540** substance as a constant fraction of the daily diet (parts per million) or (2) to administer the test substance as a constant fraction of the body weight (milligrams per kilogram). Each approach has advantages and disadvantages. FDA previously required that the sponsor administer the test substance as a constant fraction of the daily diet to minimize the potential for dosing errors. FDA is aware of the principal disadvantage of this approach; that is, the change in the relative dose with the change in the body weight of the test animals.

FDA is eliminating the requirement that the test substance be administered as a constant fraction of the daily diet. Also, FDA will accept bioassays in which the test substance has been administered as a constant fraction of the test animal's body weight.

However, a sponsor who chooses this procedure must maintain and submit with the report detailed records of individual animal weights and food consumption and the concentration of the test substance in the diet. Further, the sponsor's choice for dosing the animals will commit the sponsor to accept risk estimates from the bioassay data calculated on the same basis. For example, if the study were conducted with the dose administered as a constant fraction of the test animal's daily diet, then the extrapolated safe dose in parts per million will be used to determine directly the permitted dose in the total diet of people. If the study were conducted with the dose administered as a constant fraction of the test animal's body weight, then the extrapolated safe dose in milligrams per kilogram would be multiplied by the weight in kilograms of the average adult (approximately 60 kilograms) to determine the permitted dose in milligrams in the total diet of people.

The change introduced as a result of this comment was brought about by advances in good laboratory practices, not by the argument based on metabolic overload. It is possible, of course, to overload the metabolic machinery of test animals. However, FDA will not use the potential for metabolic overload to modify its interpretation of data unless the sponsor provides convincing experimental data justifying such a modification.

22. Some comments suggested that the sharply increasing incidence of naturally occurring tumors with age could confuse the determination of the true carcinogenicity of a compound. The comments hypothesized that some compounds, although not carcinogenic themselves, can change the pattern of these naturally occurring tumors, increasing some types while decreasing others. These comments also stated that all potent carcinogens induce tumors in rodents within 1 year and suggest that the bioassays could be terminated at 1 year.

FDA does not agree that the bioassays should be terminated after 1 year. FDA is interested in detecting carcinogens with long time-to-tumor periods, as well as potent carcinogens with short time-to-tumor periods. Therefore, these proposed regulations continue to require lifetime bioassays.

FDA does not agree that naturally occurring late tumors can necessarily obscure carcinogen-induced tumors. Proper consideration of experimental design should assure that a carcinogenic effect of a given magnitude over the control animal tumor background can be determined to a given degree of statistical significance. In some cases, FDA may use a time-to-tumor analysis to evaluate the incidence of early appearing tumors in treated groups versus late appearing tumors in the control group.

It is true, as the comments state, that certain bioassay results show not only a statistically significant increase in a particular tumor type (which may result in a finding that the test substance is a carcinogen), but also on occasion a statistically significant decrease in another tumor type. When FDA evaluates the results, it will emphasize the increase in frequency of a given tumor.

Interpretation of Test Data

23. The 1979 proposal (44 FR 17086) stated that "* * * the absence of a significant increase in tumor incidence in each of two different animal bioassays, conducted in accordance with good laboratory practices and designed according to principles referenced above, is * * * sufficient evidence of noncarcinogenicity." During the public hearing and in written comments, FDA was asked to define the term carcinogen and to specify the criteria FDA would use to decide if there is no significant increase in tumor incidence.

In determining whether a tested substance is a carcinogen, FDA will rely upon the criteria given by the Subcommittee on Environmental Carcinogenesis, National Cancer Advisory Board (Ref. 14):

The carcinogenicity of a substance is established when the administration to groups of animals in adequately designed and conducted experiments results in increases in the incidence of one or more types of maligant neoplasms (or a combination of benign and malignant neoplasms) in the treated groups as compared to control groups maintained under identical conditions but not given the test compound.* * *"

In general, FDA evaluates the results of chronic bioassays by the guidelines contained in the "General Criteria for Assessing the Evidence for Carcinogenicity of chemical Substances," National Cancer Advisory Board, 1976, and the "Guidelines for Carcinogen Bioassay in Small Rodents," National Cancer Institute, 1976. FDA considers both the statistical and biological significance of the data as part of the review.

24. Comments stated that an evaluation procedure is deficient unless it screens out results from inappropriate routes of exposure, results from exposure to above tolerable doses, results affected by the genetic proclivity of the strains, and results from a single species that produces a unique metabolite.

FDA will not disregard positive results (excess tumors) from experiments that use a nonoral route of exposure, excessive doses, or unique test animals because, at the very least, these results raise questions concerning the safety of the compound that must be resolved by more definitive testing. However, because people will ingest residues of compounds that are the subject of these regulations, the regulations specify that the bioassays must be conducted using the oral route of exposure. FDA expects that the sponsor will use commonly available rodent species for this testing.

FDA will consider a positive result (excess tumors) from a study conducted at a dose above the maximum tolerated dose as providing evidence of carcinogenicity unless there is convincing evidence to the contrary. FDA will not, however, always be able to consider a negative result (no excess tumors) from a study conducted at a dose above the maximum tolerated dose as providing convincing evidence of safety because the study may not have placed a sufficient number of animals at risk for a sufficiently long period of time. Accordingly, in some cases, the sponsor will have to provide additional evidence and a persuasive scientific rationale to support the conclusion that a negative study demonstrates the safety of the sponsored compound.

25. Many comments suggested that because benign tumors are not life threatening and do not affect animal mortality, FDA, when evaluating the residues of chronic bioassays, should discount the effects of benign tumors. One comment stated that the majority of benign tumores do not turn malignant and FDA should ignore them.

FDA will continue to consider both benign and malignant tumor incidences when evaluating the results of chronic bioassays. In reaching this conclusion, FDA will rely upon the criteria of the Subcommittee on Environmental Carcinogenesis, National Cancer ***45541** Advisory Board, which has stated (Ref. 14):

The occurrence of benign neoplasms raises the strong possibility that the agent in question is also carcinogenic since compounds that induce benign neoplasms frequently induce malignant neoplasms. In addition, benign neoplasms may be an early stage in a multi-step carcinogenic process and they may progress to malignant neoplasms; also, benign neoplasms may themselves jeopardize the health and life of the host. For these reasons, if a substance is found to induce benign neoplasms in experimental animals, it should be considered a pontential human health hazard which requires further evaluation. In experiments where the increased incidence of malignant neoplasms in the treated group is of questionable significance, a parallel increase in incidence of benign tumors in the same tissue adds weight to the evidence for carcinogenicity of the test substance.

VI. Operational Definition of No Residue

A. The Level of Risk

If FDA has concluded that a sponsored compound is carcinogenic, FDA cannot approve the use of that sponsored compound unless the sponsor can demonstrate with an acceptable regulatory method that no residue of the sponsored compound remains in the edible products of treated animals. As discussed in the 1979 proposal (47 FR 17073), FDA has concluded that Congress did not intend a literal interpretation of the term no residue. Because there will always be some residue, albeit below the limit of measurement of the analytical method, such an interpretation would preclude approval of any carcinogen. Instead, FDA has concluded that Congress intended that any remaining residues should present an insignificant risk of cancer to people. As discussed earlier in this document, FDA has chosen to define operationally "no residue" on the basis of quantitative carcinogenicity testing of residues and the extrapolation of test data to arrive at a concentration of residue that presents an

insignificant risk to test animals and, by extrapolation of the animal bioassay data to people, would also present an insignificant risk to people.

FDA cannot avoid the fact that the actual risk to people presented by carcinogenic compounds in meat, milk, and eggs is not known and cannot be precisely quantified. The 1973 proposal suggested that the insignificant level of risk could be 1 in 100 million over a lifetime using a “liberal” extrapolation procedure (Mantel-Bryan). The 1977 final regulations raised that level to 1 in 1 million over a lifetime using a slightly modified Mantel-Bryan extrapolation procedure. The 1979 reproposal retained the 1 in 1 million level of risk but used a more “conservative” extrapolation procedure (linear). Industry panelists at the June 21-22, 1979, public hearing observed that selecting a level of risk is a “no-man's land.” Others testified that they had no way of knowing whether 1 in 1 million is “right or wrong.” The reasons and factors offered by FDA in the 1979 proposal do not definitively resolve this issue. The selection of an insignificant level of risk is a choice which, although susceptible to being posed as a question of fact, cannot be answered solely by science or currently available information (Ref. 15). It is, instead, a policy question that must be answered by weighing a number of subjective considerations.

No comments on the 1979 proposal were received that disagreed with FDA's decision that the 1 in 1 million level presents an insignificant risk to the public. No comments at all, however, were received from the general public. All comments were from regulated industry. These comments contended that, the 1 in 1 million level represented an insignificant risk but that higher levels might also represent insignificant risks. The comments, however, as discussed below, failed to demonstrate that any higher level satisfied FDA's responsibility under the statute to protect the public health. FDA has carefully studied the submitted comments, the suggested alternatives, and other available information on risk assessment and has concluded that the 1 in 1 million level represents an insignificant level of risks.

FDA emphasize that the 1 in 1 million level of risk adopted for these regulations does not mean that 1 in every 1 million people will contact cancer as a result of this regulation. Rather, as far as can be determined, in all probability no one will contact cancer as a result of this regulation. The 1 in 1 million level represents a (1) 1 in 1 million increase in risk over the normal risk of cancer and (2) a lifetime—not annual—risk. Furthermore, because of a number of assumptions used in the risk assessment procedure (see Section VI.B., below) and the extrapolation model used (See Section VI.C., below), FDA expects that the actual risk to an individual will be between 1 in 1 million and some much lower, but indeterminable, level.

No Specific Level of Risk

26. Some comments on the 1979 proposal suggested, without support, that no specific level of risk should be adopted for general use, but that a level of risk should be chosen for each compound on an individual basis.

FDA disagrees. Under the suggested procedure sponsors would receive no guidance about the likelihood of approval of a compound during the expensive stage of drug development or about the factors consider in determining whether the compound should be approved. This unstructured ad hoc approach would be contrary to the interests of the public health and would result in inequitable treatment of sponsors.

The Use of Public Preference in Selecting a Level of Risk

27. Comments argued that FDA could determine a level of insignificant risk by comparing risk presented from carcinogens in food with risks individuals voluntarily assume from using their occupation, from common forms of transportation, from leisure activities, and the like. Comments also contended that FDA could similarly use involuntary risks. Accordingly, comments argued that because risks of a magnitude of 1 in 15,000 over a lifetime (1 in 1 million yearly) do not concern (that is, are “accepted by”) most people, FDA should adopt that level of risk for these regulations. Other comments used similar reasoning to support a 1 in 100,000 risk level.

The comments overlook the fact that when FDA approves the use of a carcinogenic compound, FDA affirmatively allows a risk to be imposed on the public. The public is not “accepting” that risk because (1) The public has no information on the risk

presented by carcinogenic compounds in its food, and (2) the public has no way of avoiding that risk assuming it wishes to continue to eat meat, milk, or eggs. Furthermore, these comments do not address the growing evidence that group attitudes and group choices do not follow the same patterns as individual choices (Ref. 16). Reliance on group preference, therefore, might cause the imposition of a risk that is unacceptable to many individuals.

In the final analysis, the comments and information regarding public perception of risk at best allow FDA to infer the increment of risk of cancer that certain members of society would consider unavoidable, tolerable, or unnoticeable. Although FDA has considered the comments and information provided, FDA concludes that the sole use of social preferences and the magnitude of involuntary risks to select an insignificant level of risk provides an incomplete basis for determining the level of risk to which the public should be exposed by substances permitted in the food supply. ***45542** FDA also concludes that an increase in the level of risk to 1 in 15,000 might significantly increase the risk of cancer to people, and, until better information is provided, such a level must be viewed as unacceptable in light of current knowledge and legal standards.

The 1 in 100,000 Level of Risk

Adoption of the 1 in 15,000 level in FDA's view might significantly increase the risk of cancer. FDA and those who commented on the point agree that the 1 in 1 million risk level will not significantly increase the risk of cancer. The question that logically follows is whether a level of 1 in 100,000 presents a significant risk to people. If FDA were to propose 1 in 100,000 as the insignificant level of risk, the permitted concentration of residue would increase by a factor of 10. Table III in the 1979 proposal (44 FR 17077) indicated dietary concentrations for carcinogens corresponding to lifetime risk of 1 in 1 million. The concentrations varied from 0.05 to 260 parts per billion. The range with a 1 in 100,000 level of risk would be from 0.5 part per billion to 2.6 parts per million. (FDA was criticized in some comments for not including animal health products in the table. There is no scientific reason to believe that the carcinogenic potency of animal health products will differ greatly from other chemicals.) Whether the 1 in 100,000 level would pose a significant increase in the risk of cancer to people is, however, the critical question. It is not a question which can be unequivocally answered, and it calls for a difficult decision by FDA: for no matter what arguments are made and no matter what numbers are used, the actual risk of cancer to people remains unquantifiable.

The 1 in 100,000 level does not carry with it the degree of concern presented by the 1 in 15,000 level. Similarly, it is not as insignificant as the 1 in 1 million level. The approval of a carcinogenic sponsored compound, at any level of risk, does not include consideration of the potential interaction or synergy between an approved compound and any other substance or substances to which people are exposed. Certainly, the more approved carcinogenic compounds that are marketed the greater is the likelihood of cancer induction in people.

In the presence of these uncertainties, FDA cannot, with assurance, state that the 1 in 100,000 level would pose an insignificant level of risk of cancer to people. FDA can state, and comments agree, that the 1 in 1 million level presents an insignificant level of risk of cancer to people. Furthermore, FDA has developed confidence in the merit of the 1 in 1 million level because in recent years the agency has considered that level as its benchmark in evaluating the safety of carcinogenic compounds administered to food-producing animals. Under these circumstances, the agency believes that the most reasonable level of risk to apply in these regulations is the 1 in 1 million level. In making this decision, FDA recognizes that there may be a higher level of risk that is more appropriate but, that in light of the current uncertainties that accompany making a decision as to the most appropriate level of risk, the agency believes that choosing to rely on the 1 in 1 million level is reasonable and defensible.

B. Uncertainties in Quantitative Risk Assessment

28. Several comments requested that FDA identify the conservative assumptions used in the risk assessment procedures proposed for these regulations, identify the sources of uncertainty in those risk assessment procedures, and determine the actual or most likely estimate of risk rather than the upper bound on the risk.

FDA agrees that a discussion of the uncertainties, assumptions, and conservatisms in the risk assessment procedures is warranted. Pervasive uncertainty is the primary analytical difficulty in making a risk assessment that involves trying to define the

human health effects of exposure to harmful residues. Although the risk assessment procedures proposed for these regulations draw extensively on science, which has developed a basis for linking exposure to residues to potential chronic health effects, there is uncertainty in types, probability, and magnitude of the health effects that will be associated with a given compound and its residues. These problems have no immediate solutions because of the many gaps in FDA's understanding of the causal mechanisms of carcinogenesis and in FDA's ability to ascertain the nature or extent of the effects associated with specific exposures. Where science fails to provide solutions, FDA applies conservative assumptions to ensure that its decisions will not adversely affect the public health.

For example, FDA relies upon the results of animal bioassays on a given substance to make a regulatory decision. FDA recognizes the inherent limitations and uncertainties in such bioassays, but relies on their results because there is scientific consensus that the bioassay is the best way currently available of determining the carcinogenicity of a compound. However, if one were to conduct a superb bioassay in which 1,000 animals were placed at risk and no tumors were detected, one could not conclude that the compound was not a carcinogen, but only that at the 99 percent confidence level the lifetime risk of cancer to the test animal was less than approximately 1 in 200. In such circumstances, FDA would regulate the compound under the general food safety requirements of the act for risks other than cancer and would apply a safety factor of 100 to the dose giving no observed effect in the bioassay. Thus, assuming a superb bioassay and assuming that the highest dose used in the bioassay is also the dose that gives no observed toxicological effect, FDA may be imposing a maximum lifetime risk of cancer of 1 in 20,000 on the public. FDA allows marketing of the compound because there is a scientific consensus that the results of such an assay are sufficient to create a rebuttable presumption that the compound is not carcinogenic.

On the other hand, if FDA concludes that the bioassay shows that the sponsored compound or its residues are carcinogenic, there are uncertainties in the estimate of risk to people from the compound's residues in edible products of target animals. These uncertainties exist because people are exposed to much lower residue levels than are experimental animals and because it has not been determined whether the potency of a carcinogen is proportionately the same at that lower level. The scientific community has not reached a consensus on the procedure for making this extrapolation of risk.

The risk assessment procedure used by FDA requires that the upper 95 percent confidence limit on the tumor incidence data be used to estimate the carcinogenic potency of a substance. Assuming a typical bioassay conducted on a sponsored compound (e.g., 50 animals per sex per dose) and a 20 percent incidence of tumors, this requirement causes an overestimate of the most probable potency by a factor of two. In addition, data from the most sensitive species and the most sensitive sex are used, resulting in an overestimate of the most probable potency by a factor of one to four.

The risk assessment procedure used by FDA assumes that each residue is as potent as the most potent compound detected in the bioassay. This is unlikely to be true, but in the absence of a bioassay on each residue and of knowlege of the quantity of each residue in the tissue, the effect on risk to the consuming public cannot be quantified.

The risk assessment procedure used by FDA assumes that a lower frequency of dosing has no effect on carcinogenic ***45543** potency. This is unlikely to be true. Because the animals used in the bioassay receive a constant and daily dose, but people will most likely be exposed to sporadic doses, the carcinogenic potency to people is most likely overestimated. However, FDA has no data that will allow a reliable prediction of the magnitude of this overestimate.

The risk assessment procedure used by FDA includes a calculation of the upper limit of carcinogenic potency at low dose, a dose representative of what people are exposed to. The statistical procedure used in this calculation is discussed in section VI.C., below.

The risk assessment procedure used by FDA assumes a one to one correspondence between the carcinogenic potency of the compound in the test animals and in people. The available, but extremely limited, data submitted in a comment suggest that carcinogenic potency of a specific chemical in rodents and people may vary by an order of magnitude, but is as likely to be high as low.

The risk assessment procedure used by FDA assumes that the concentration of residue in the edible product is at the permitted concentration, that consumption of that edible product by all people is equal to the consumption by the 90th percentile eater, and that all marketed animals are treated with the carcinogen (market penetration of 100 percent). These assumptions may overestimate risk. The extent of the overestimation cannot be quantified.

For the comments, the assumptions and requirements discussed above are multiple conservatisms; for FDA, each of these assumptions and requirements is a matter of prudence dictated by the lack of scientific consensus and FDA's responsibility under the statute to ensure to a reasonable certainty that the public will not be harmed.

C. Analysis of Animal Carcinogenesis Data Introduction

FDA's interpretation of the DES Proviso where “no residue” is construed to mean “no significant risk” requires an assessment of the risk anticipated from a known carcinogen as a function of the dose. Experiments designed to observe responses in the range of interest (that is, 1 in 1 million) would require impossibly large populations of test animals. Therefore, some method is required to extrapolate data from the standard bioassays, which use much smaller and more manageable numbers of animals, to the range of interest. Because the mechanism of chemical carcinogenesis is not sufficiently understood, none of the available statistical extrapolation procedures has a fully adequate biological rationale. Matters are further complicated by the fact that the dose-response relations assumed by the various procedures diverge substantially in the projections of risks presented in the range below the lowest dose tested.

FDA's objective has been to select an extrapolation procedure that is reasonably well supported by current science and a level of risk that is protective of the public health. FDA still believes that its objectives are best met by a nonthreshold, linear-at-low-dose extrapolation procedure that determines the upper limit of the risk. After considering the comments on the 1979 proposal and other available information on extrapolation procedures, FDA has concluded that the linear interpolation procedure of Gaylor and Kodell should be adopted for these proposed regulations. (Gaylor, D. W. and R. L. Kodell, “Linear Interpolation Algorithm for Low Dose Risk Assessment of Toxic Substances,” Journal of Environmental Pathology and Toxicology, 4:305-312, 1980.) As discussed in this paper, the linear interpolation procedure consists of the following steps:

1. Use any appropriate mathematical model which adequately fits the data to approximate the dose response relationship in the experimental data range.

2. Obtain the upper confidence limits on the excess tumor rate above the spontaneous background rate in the experimental dosage range.

3. Connect a straight line from the origin to the point on the upper confidence limit at the lowest experimental dosage.

4. Obtain upper limits of risk for low dosages or, conversely, dosages corresponding to low upper limits of risk from the interpolation line obtained in Step 3.

FDA will require the use of the upper 95 percent confidence limit and the upper limit of lifetime risk of 1 in 1 million. The principal advantage of the linear interpolation procedure over the extrapolation procedure adopted in the 1979 proposal is that it uses all of the data in the experimental dosage range.

FDA recognizes that alternative procedures may have merit. Accordingly, FDA solicits comments on the propriety of those alternative procedures and what is believed to be their advantages over the proposed linear interpolation procedure. Of particular interest are the Crump modified multi-stage model (Ref. 17) and the one-hit model (Ref. 18).

Comments on the 1979 Proposal

29. The most frequent comment on the 1979 proposal stated or requested that other extrapolation models be used or that a class of acceptable extrapolation models be established and that the best model be selected on a case-by-case basis. The comments stated that an extrapolation model should be based on its scientific merit, how well it agrees with the observed data, and its consistency with other information available about the carcinogen. Many additional comments stated that the linear model was not a valid model for representation of the mechanism of action of a carcinogen. The arguments presented were based on: (1) The lack of close agreement between observed responses and a straight line fit of these observed responses, (2) the concept that most physical and biological systems follow exponential relationships, (3) the existence of biological thresholds, and (4) the knowledge about DNA repair mechanisms.

Neither the linear extrapolation procedure adopted in the 1979 proposal nor the linear interpolation procedure adopted in this reproposal should be construed as a mechanistic model of carcinogenicity. FDA selected the linear interpolation procedure primarily because of the procedures that do not disregard data from a chronic bioassay; the linear interpolation procedure is the least likely to underestimate risk.

The futility of attempting to select an extrapolation procedure based on how closely the procedure can describe the observed data and then predict risk at a low dose was illustrated in one of the comments. Six different models, each with a different biological rationale, were compared. The models were the one-hit, Weibull, logistic, log-probit, multi-hit, and multi-stage. The data used were derived from the ED01 study conducted at FDA's National Center for Toxicological Research. Because this study was specifically designed to investigate the carcinogenic response in the low dose region, many of the deficiencies found in studies designed to give only qualitative answers about carcinogenicity were not present. For liver neoplasms, the Weibull, logistic, and log-probit models could equally describe responses in the observed regions, but the predicted responses at a dose of 10 parts per billion varied by a factor of 1012 . For bladder hyperplasia, none of the models even came close to describing the observed responses.

30. Several comments stated that use of the linear extrapolation procedure would result in stagnating the ***45544** development of new products and better methods of extrapolation. These comments and several additional comments stated that the linear extrapolation procedure was too conservative, needlessly inflexible, restrictive, arbitrary, and unnecessarily rigid.

FDA does not believe that adopting a specific extrapolation procedure will stagnate development of new products or new methods of extrapolation. FDA is always open to new concepts and procedures when they are supported by sound data or cogent scientific rationale and when they provide the required degree of protection to the public health. The waiver provisions of the regulations were included for this reason.

31. Several comments stated that simplicity of use and ease of calculation should not be part of the consideration in selecting an extrapolation procedure.

FDA agrees that simplicity and ease of calculation should not be a major consideration in the selection of an extrapolation procedure. However, the availability, complexity, reliability, and reproducibility of the Mantel et al. extrapolation procedure (Ref. 19) and the associated computer programs were issues raised by AHI in its suit against the 1977 regulations. Therefore, these aspects were discussed in the 1979 proposal and were considered by FDA in the selection of the linear extrapolation procedure.

32. Several comments stated that the proposed regulations did not have clearly defined provisions for combining data from different dose levels, different sexes, different experiments, and different species. These comments concluded that as a result of this deficiency, additional unnecessary conservatism is introduced because the extrapolation is not based on all of the available data. Several comments advocated using the Mantel et al. procedure (Ref. 19) because it has specific methods for pooling data.

As noted previously, the linear interpolation procedure uses data from all the dose levels of the experiment to determine the upper confidence limit and to estimate the risk. In some instances, combining data from different experiments could reduce the

upper confidence limit; however, in other instances data from different experiments may contain different types of information and should not be pooled. The sponsor must provide the scientific rationale that will justify combining data. FDA will use its statistical and biological evaluation of the data to determine which data, if any, will be appropriate for pooling. Where there are significant statistical or biological differences in the observed responses, FDA will not combine the data for analysis.

FDA, as stated in the 1979 proposal, does not believe that the Mantel et al. procedure is appropriate for these regulations because it may underestimate the risk at low doses. This deficiency is not outweighed by the procedure's specific methods for pooling data.

33. Several comments stated that the actual risk, or at least a realistic projection of the potential hazard, should be used for extrapolation rather than the upper bound on the risk.

As a policy matter, FDA has decided to continue to base the extrapolation on the upper confidence limit of the responses from the animal bioassay. This approach provides added assurance that the risk will not be underestimated. However, FDA will now use the upper 95 percent confidence limit, rather than the upper 99 percent confidence limit.

34. Several comments stressed that extrapolation was only one part of the risk estimation procedure and undue emphasis should not be placed on the use of mathematical procedures. These comments suggested that several extrapolation models be used to bracket the acceptable dose and then judgment be used in selecting the final acceptable dose.

FDA does not believe that this approach would be helpful. If the suggested procedure were adopted, FDA would have a set of residue concentrations that would vary by orders of magnitude, but no way of choosing among them. FDA has already used its judgment to select the extrapolation procedure that best meets the objectives of the regulations.

35. One comment posed the question of which lesions should be counted when attempting low dose extrapolations.

When chronic bioassays are conducted in such a way that dependable data are available for determining dose-response curves for various lesions at various ages of test animals, then FDA believes that the appropriate dose-response curve to use is the one that yields the lowest dose at the level of insignificant risk. However, the opportunity to select among various age-dependent dose-response curves will usually not occur with the chronic bioassays recommended under these proposed regulations. FDA does not require that sponsors use the number of animals or the number of doses necessary to yield well-defined dose-response curves from serial sacrifices. Of course, sponsors are free on their own initiative to test a larger number of animals and a larger number of doses than FDA requests.

36. Two comments stated that no extrapolation procedure should be used because the animal bioassays were, at best, qualitative and not quantitative. One of these comments went on to state that carcinogens should be classified as either weak, moderate, or strong. Strong carcinogens would not be approved for use. Weak and moderate carcinogens would be assigned a preselected safe concentration of residue that would satisfy the operational definition of no residue.

FDA disagrees. Accepting this comment would be the equivalent of adopting an alternative interpretation of the DES Proviso that was rejected by FDA because a single permitted concentration of residue is not suitable for weak and moderate carcinogens that have large differences in measured carcinogenic potencies (Ref. 11). (See also Section I.B., “Interpretation of the DES Proviso.”)

37. Several comments urged that FDA use any available epidemiological data to establish an upper limit on the risk.

FDA agrees and will accept risk estimates based on appropriate epidemiological data when the data are relevant to decisions on the approval of sponsored compounds for use in food-producing animals.

38. One comment stated that FDA should establish general standards for an acceptable extrapolation and allow the sponsors to demonstrate that these standards have been satisfied by the specific procedure selated by the sponsor.

In these regulations, FDA has established acceptable procedures for extrapolating data from animal bioassays. In acting upon submitted applications, FDA will consider alternate procedures that provide the equivalent degree of assurance that the sponsored compound can be used in animals without posing an unacceptable risk of cancer to people. For example, if a sponsor has information establishing the mechanism of carcinogenicity for a specific compound, then the sponsor may use that information to develop a more suitable extrapolation procedure. The waiver provisions were included for this purpose.

D. Derivation of the Concentration of the Residue of Carcinogenic Concern That Will Be Defined as No Residue

As used in these regulations, S_0 means the concentration of the test compound in the total diet of test animals that corresponds to a maximum lifetime risk ***45545** of cancer in the test animals of 1 in 1 million. For these regulations, FDA will also assume that if the S_0 concentration of residue were to occur in the total human diet, no significant increase in the risk of cancer to people would result. In some cases a sponsor will have tested for carcinogenicity metabolites in addition to the sponsored compound. In these instances, FDA will assume that the most potent carcinogen of those tested poses the greatest potential carcinogenic threat among the residues. FDA will use that carcinogen to calculate S_0.

Because the total human diet is not derived from food-producing animals, FDA will make corrections for food intake in determining the permitted concentration of residue of carcinogenic concern (see “Guideline for Establishing A Tolerance”). The S_m value represents the concentration of total residue of carcinogenic concern that FDA will permit for specific classes of edible products that constitute finite percentages of the total human diet.

VII. Studies To Select Marker Residue and Target Tissue

A. Introduction

Before the use of a carcinogenic compound can be approved, FDA must determine that a practical and reliable assay is available to measure the residue of carcinogenic concern at the concentration that will satisfy FDA's operational defintion of no residue. One approach to this problem would be to require assays that can be used to measure every residue in each of the various edible tissues. Because the number of residues in edible tissues is likely to be large, such an approach would be impractical. There is another, far more more practical approach which sacrifices no principle of safety. This alternative approach centers on the concept of a marker residue and a target tissue.

A marker residue is a residue whose concentration is in a known relationship to the concentration of the residue of carcinogenic concern in the last tissue to achieve its permitted concentration. The marker residue can be the sponsored compound, any of its metabolites, or a combination of residues for which a common assay can be developed. The marker residue can be a carcinogenic or a noncarcinogenic residue.

The target tissue is the edible tissue selected to monitor for residues in the target animal. The target tissue and marker residue are selected so that the absence of marker residue above the permitted concentration will confirm that each edible tissue has a concentration of residue of carcinogenic concern below its S_m, and, therefore, FDA's operational defintion of no residue has been satisfied for all edible tissues of the animal.

When a compound is to be used in milk- or egg-producing animals, milk or eggs will be a target tissue in addition to one tissue selected for the edible carcass. If a compound is used in both milk- and egg-producing animals, milk and eggs each must be a target tissue in addition to the one selected for the edible carcass. This is necessary because milk or eggs enter the food supply independently. In these cases, it may be necessary to select a marker residue for milk or eggs that is different from the marker residue selected for the target tissue representing the edible carcass.

Application of the concepts of marker residue and target tissue requires an experimental determination of the quantitative relationships among the residues that might serve as marker residues in each of the various edible tissues that might serve as target tissues. Because these relationships change with time, the sponsor must measure the depletion of the potential marker residues in the potential target tissues starting after the last treatment with the compound and continuing until the total residue of carcinogenic concern has reached Sm for that tissue. FDA will use the residue depletion profiles and the regulatory method to determine the Rm for the marker residue. The Rm is the concentration of the marker in the target tissue when the concentration of the total residue of carcinogenic concern is equal to Sm in the last tissue to achieve this value.

B. Comments on the 1979 Proposal

39. One comment argued that it was wrong to require that milk or eggs also be the target tissue when a sponsored compound is to be used in milk- or egg-producing animals.

FDA disagrees and will retain the requirement. As discussed above, milk or eggs and the edible portions of the carcass enter the food supply independently. Therefore, a regulatory method must be available to measure the residue of carcinogenic concern in eggs or milk as well as the edible portion of the carcass.

40. One comment contended that because FDA will select the target tissue, the marker residue, and the Rm, it will be many months before the sponsor can begin developing the regulatory method for the marker residue. The comment requested that once sponsors have submitted adequate data, they should be free to make these selections and begin the necessary testing rather than again having to wait for FDA review and approval.

FDA expects that sponsors will select the target tissue and the marker residue, and designate Rm. Upon submission of these data, FDA will review the information to ensure that the sponsor has reached a valid conclusion. Sponsors generally make excellent choices in selecting a marker residue and target tissue, FDA, therefore, does not believe its particular role in validating the selections is likely to result in delays in data development.

VIII. Sponsored Compounds Affecting Pools of Carcinogenic or Potentially Carcinogenic Substances Endogenous to Target Animals

FDA is withdrawing those sections of the 1979 proposal that were concerned with endogenous substances. The criteria and procedues FDA will employ in evaluating the safety of endogenous substances will be discussed in the “Guideline for Toxicological Testing.”

IX. Regulatory Method

A. Introduction

Under the proposed regulations, FDA will approve a carcinogenic compound for use in food-producing animals if the concentration of residue of carcinogenic concern satisfies the operational definition of no residue, and if a method is available that can reliably measure that concentration of residues in edible animal products. The criteria for determining whether a method is acceptable are described in the “Guideline for Approval of Methods of Analysis for Residues.”

B. Comments on the 1979 Proposal

41. FDA received many comments on the criteria for evaluating regulatory methods. Generally, the comments criticized FDA for referring to the nonstandard analytical attributes dependability and practicability.

FDA believes that in large part the criticisms made in the comments are well taken. FDA's new guideline for analytical methods refers only to standard attributes of an analytical method. In approving a regulatory method, however, FDA believes that it is

important to consider some of the aspects of practicability, a nonstandard attribute. Therefore, FDA will continue to consider the following items, in addition to the standard attributes of analytical methodology, when evaluating a regulatory assay: The commercial availability of equipment and supplies; the degree of training required to complete the assay ***45546** successfully; the length of time required to complete the procedure; and the costs associated with developing and running the assay.

42. Comments stated that it would be hard to envision a method satisfying the proposed regulations that would not involve the modification of existing instrumentation of the use of sophisticated techniques. Comments also stated that the proposed regulations are unreasonable because they either demand that the equipment and materials employed be commercially available or else force the sponsor to advance and market the analytical instrumentation. Furthermore, the comments argued that one of the biggest obstacles to gaining new animal drug application (NADA) approval has been that government regulatory laboratories do not have the equipment or expertise to implement the proposed procedures, a problem that will increase in severity with the greater demands put on analytical capability by these procedures. Another comment noted that some methods are now available for detecting animal drugs in tissue in the 5 to 100 parts per trillion range, but that these methods require the participation of highly skilled and careful scientists. The comment further complained that even these methods do not allow the determination of residues in tissue for a large number of samples in one day's time. The comment concluded that procedures that require new technology and that involve detection limits at ultra low levels will, for the foreseeable future, require great skill and a significant amount of time to carry out sample analysis.

FDA is aware of the problems in developing a method for detecting a carcinogenic compound in edible tissue. When a sponsor develops a method based on new technology and the method passes FDA's desk review, then FDA will gain the expertise needed to perform the method. FDA agrees that one must not label all new and ultrasensitive methodologies impracticable.

43. One comment found the phrases “suitable for routine use in a government regulatory laboratory” and “consistent with regulatory objectives” meaningless as goals for the developmental analytical chemist. The comment asserted that FDA should accept a method on its merits, not on the length of time required to conduct the procedure.

The phrases in question pertain mostly to the time requried to complete the procedure in a government laboratory. For research purposes, the time required to complete the procedure may be of a secondary consideration; for the regulatory purposes of compliance and surveillance, the time required to complete the procedure is of great importance. The U.S. Department of Agriculture (USDA) and FDA would be unable to fulfill their regulatory responsibilities with a method yielding, for example, one analytical result per day. Although FDA agrees that practicability may not be a scientific attribute of a method, FDA must consider collateral factors when evaluating the proposed regulatory method. FDA discusses these factors in the “Guideline for Approval of Methods of Analysis for Residues.”

44. One comment suggested redefining practicability such that a method is practicable if four out of five laboratories can successfully repeat it.

Practicability has been defined mainly in terms of timeliness, though other factors such as safety of reagents and procedures will be assessed. The comment refers to attributes of the method that are considered under the requirements for reproducibility.

45. One comment emphasized that no method can claim to provide a response that is due to “that compound only” and, accordingly, recommended that “should” replace “must” in the first sentence of the definition of specificity which appeared in the preamble to the 1979 proposal. The same comment stated that the preamble implied that mass spectrometry is the only acceptable confirmatory technique, a proposition that would be unreasonable and technology limiting. The comment added that FDA should clarify the distinction between a method for screening of samples and a method for confirming positive results found by the screening method.

FDA agrees that no method can guarantee that an analytical response is unique to that compound. The regulatory method must be able to quantify the marker residue (sometimes referred to as the determinative aspect of the method) and to verify the

identity of the marker residue (confirmatory procedure). FDA did not and does not mean to limit sponsors to the use of mass spectrometry for confirming the identity of the marker residue. In fact, FDA proposed only the regulatory method be composed of a sufficient number of independent measurements to ensure that the identity of the marker residue is confirmed.

46. Another comment declared as meaningless FDA's statement that “the method is considered specific if the observed response is a smooth and continuously decreasing or increasing function of the concentration of the marker residue and of that compound only.” The comment also stated that the regulations should address what other residues must be tested to characterize the method.

The quoted statement was intended simply to remind sponsors of a criterion central to good analytical practice, single-valuedness. FDA agrees that it should give guidance to sponsors about possible interfering substances that could affect the analysis.

47. One comment proposed that a confirmatory procedure be made available only for a method that tends to generate an unusual number of false-positives. A related comment argued that confirmation of marker residue is necessary while developing the method but not during routine operation of the method.

FDA disagrees that a regulatory method should be capable of confirming the marker residue only when special conditions exist. Because compounds regulated for animal use may yield violative residues in edible tissues, FDA must be able to ensure that the compound responsible for a violation can be measured and identified. In a surveillance situation, if initial measurements demonstrate that tissues are nonviolative with respect to a particular drug, further inquiry is not necessary. However, confirmatory procedures must always be available for those instances in which violations occur.

48. Comments argued that a method which produced average recoveries somewhat below the 60 to 110 percent or 80 to 110 percent ranges, but which had high precision, would be disapproved under the proposed regulations even though current technology might consider the method good. Several comments also pointed to the use of internal standards containing stable isotopes. The comments argued that the use of these internal standards provides accurate analyses even with extremely low recoveries.

The average recovery for an acceptable assay will ordinarily be within the stated ranges. However, FDA may consider a different range if a method provides high precision with lower recoveries.

49. One comment noted that the 60 to 110 percent and 80 to 110 percent limits are unrealistic for measurement at or near the detection limit of an analytical method and proposed a limit for the average recoveries of 25 to 175 percent. Another comment proposed that 80 to 110 percent should always be the limits; however, should FDA accept methodolgy with average recoveries ***45547** between 60 to 80 percent, it should require that a correction factor be applied to the analytical result. One comment asked that FDA specify maximum and minimum acceptable values for individual recoveries.

Because it relies substantially on analytical chemistry to carry out its regulatory responsibility to ensure public protection, FDA must establish reasonable and defensible criteria for evaluating a method proposed to monitor edible tissue. It has been FDA's experience that average recoveries of 80 to 110 percent for 100 parts per billion and above are attainable. Although average recoveries of compounds below 100 parts per billion are more variable, FDA's regulatory objective to monitor effectively for carcinogenic residues would be compromised if recoveries of 25 to 175 percent, as suggested, were accepted. In choosing 60 to 110 percent as an acceptable limit for recoveries, FDA sought both to make allowances for the increased variability that could be expected to occur below a concentration of 100 parts per billion and to establish a standard that would not render the method unreliable. Rather than becoming entangled in justifying how to determine and use a correction factor to adjust an observed analytical result, FDA, having rigorously evaluated and validated the method, prefers to rely upon the analytical result itself.

With regard to maximum and minimum acceptable values for individual recoveries, FDA expects that for average recoveries to fall within the designated 60 to 110 percent and 80 to 110 percent limits, the individual recoveries will ordinarily fall near those

same ranges. Average recoveries of 60 to 110 percent or 80 to 110 percent can be obtained by averaging very high and very low values; however, in such cases, the precision will be adversely affected. When a set of data contains a result that appears to deviate excessively from the average or median, FDA will base the decision to retain or disregard that result upon usual statistical considerations such as those recommended by the Association of Official Analytical Chemists (AOAC) in “Statistical Techniques for Collaborative Tests” (Ref. 20).

50. One comment stated that the proposed regulations failed to specify what type of hydrolytic enzymes should be used if exhausitve extraction is used to ascertain accuracy.

FDA is deleting the requirement for treatment of target tissue from dosed animals with hydrolytic enzymes to free bound or conjugated marker residue (unless, of course, it is part of the proposed method) because the method need not measure all the potential marker residue present in tissue. The method must, however, consistently remove an amount of marker residue that has been demonstrated to be in some known relation to the total residue.

51. One comment noted that the proposed regulations would require that a series of spiked samples be run to obtain a response curve each time a set of unknown samples is assayed. The comment noted that this procedure will reduce the number of samples that can be run in a given period of time.

FDA will develop an analytical curve from spiked tissue during the method trial. In actual surveillance situations, an analyst will conduct several trials to determine that the method works in his or her hands, and, assured of that, he or she will then conduct the analyses of the unknown samples and analyze a series of spiked samples if such a procedure is an integral part of the regulatory method.

52. Many comments expressed disagreement with the proposed validation procedure. The comments stated that the use of only three laboratories is not statistically sound; accordingly, the comments suggested that additional laboratories, including commercial and State laboratories, be required to participate in the validation. In addressing the appropriateness of AOAC involvement in method validation, the comments indicated that AOAC applies requirements similar to those listed under section VIII. of the 1979 proposal. In response to FDA's statement that the AOAC process was time-consuming, one comment suggested that the collaborative study be conducted simultaneously with the development of other data, rather than after the NADA was submitted.

FDA agrees that a method trial involving more than three laboratories would improve the characterization of the method. However, FDA believes the sampling procedure to be followed by the three laboratories will provide sufficient data to judge the adequacy of a proposed regulatory method for surveillance purposes.

FDA's decision in the 1979 proposal to decline to accept the AOAC procedure was based on considerations of time and practical implementation. Up until then it had been the experience of FDA analysts and laboratory managers that the mechanics of coordinating a collaborative study, such as that developed by AOAC, required more time than is needed to initiate and complete a three-government laboratory study. However, because the purpose of method trials is to ascertain whether the regulatory method conforms to the criteria for acceptance, FDA would not object to a sponsor's trying its proposed regulatory method in an expanded study in laboratories in addition to the three government laboratories. Sponsors should be aware that such a procedure might increase the time required for completion of the method trial and would require the sponsors to furnish an increased number of samples and other materials that are not available commercially. In any event, however, the three government laboratories participating in the method trial must be able to perform the method satisfactorily because they have the responsibility for surveillance and enforcement.

The suggestion that FDA validate a method while other data are being collected is not an acceptable time-saving idea. Under this scheme, a method trial could begin before collection of the toxicity and metabolism data necessary for establishing the target tissue, marker residue, So, and Rm. Without such information, FDA cannot initiate a method trial.

53. Other comments contended that the requirements on method evaluation were unclear and that FDA should clarify at what stage in the review process validation will occur. The comment also requested that appropriate time for preparation of samples by the applicant be allowed.

The criteria and procedures for evaluating the proposed regulatory method are discussed in FDA's guideline. Provided a desk review of the data submitted in support of the methodology satisfies the criteria in the guideline, FDA will recommend that the method undergo an interlaboratory validation trial. In notifying the sponsor of the acceptance of its method for a validation trial, FDA will outline the number and type of tissue samples to be forwarded to each participating laboratory. FDA will work closely with sponsors in setting up the method trial and will allow ample time for preparation of the samples.

54. In connection with the validation process, one comment suggested that the interlaboratory study should include and provide for a prevalidation desk review and evaluation of the regulatory method by each laboratory that is to participate in the validation study.

FDA agrees with this comment. If FDA finds a proposed regulatory method acceptable for a validation trial, each participating laboratory reviews the method prior to initiation of the trial. ***45548** FDA forwards comments made by each laboratory to the sponsor.

55. Another comment suggested that if one of the three government laboratories failed to validate the method, a fourth laboratory should be asked to repeat the method. At the same time, the laboratory in which the method failed should provide all raw data to the sponsor so that the sponsor can comment knowledgeably on the inability to validate.

As indicated previously, FDA requires that the proposed method be validated in three participating government laboratories. In the course of method validation, should problems arise, FDA will investigate the reason. FDA will discuss with the sponsor problems encountered with the method and, if warranted, repeat the trial.

56. A related comment raised concern that the requirement that the sponsor provide supplies to the laboratories involved in the method trial could represent an open-ended potential for requiring industry to supply the government laboratories with equipment and supplies, and therefore suggested that the phrase “if they are not commercially available” be appended to the regulation. The comment added that the sponsor should be allowed to supply training to the government personnel involved in the validation if FDA considers training necessary.

FDA agrees that the sponsor will have to supply the government laboratories with equipment and supplies that are not commercially available. FDA already allows a sponsor to demonstrate its proposed regulatory method. Demonstrations help government scientists to become acquainted with proposed methods and to identify defects prior to initiating a validation trial.

X. Withdrawal Periods

A. Introduction

The regulations propose to define the preslaughter withdrawal period or the milk discard time for a sponsored compound as the period of time required, after the last administration of the sponsored compound, for the concentration of the marker residue to deplete to Rm in the target tissue. The preslaughter withdrawal period or milk discard time must also be compatible with actual conditions of livestock management and be reasonably certain to be followed in practice. Because of the way in which the regulations define marker residue, target tissue, and Rm, the use of the sponsored compound in accordance with the prescribed preslaughter withdrawal period or milk discard time will assure that unacceptable levels of a carcinogenic residue will not be present in human food derived from treated animals. The data required and the procedure for determining the preslaughter withdrawal period or the milk discard time are described in the “Guideline for Establishing Withdrawal Periods.”

B. Comments on the 1979 Proposal

57. A comment contended that in choosing the Rm as the concentration to which the residues must deplete, FDA is inconsistent with its interpretation of no residue. The comment contended that this procedure is the same as alternative two—rejected by FDA—found on page 17086 of the 1979 proposal.

FDA has revised this aspect of the proposed regulations. FDA now proposes that when the residues have depleted to or below Rm, then FDA's operational definition of no residue has been satisfied. If the residues do not deplete to or below Rm, then FDA cannot approve the use of the sponsored compound.

58. Comments contended that the statement “validated regulatory method” is improperly used, because methods are not validated until the final stages of a petition's review, and the sponsor cannot wait for this method validation before initiating residue depletion studies to establish a withdrawal period.

FDA does not agree with the suggestion that the withdrawal period be established using a method that is not the one submitted for validation. Because different methods may have a different specificity, precision, or systematic error, the data collected with different methods could establish different withdrawal periods. However, the sponsor does not need to wait until after official FDA validation to collect the required data for establishing the withdrawal period. The key requirement is that the method submitted for validation also be the one used to collect the data for establishing the withdrawal period.

59. One comment questioned the use of withdrawal periods based on individual animals because the risk to people is related to the average residue concentration at a given withdrawal period and the fact that compounds may be given to production units containing more than one animal, e.g., flocks, herds, pens, etc. The comment suggested that the variability of these units be used in the calculations of the required withdrawal periods.

FDA agrees that if the mean of the herd or flock is at or below Rm, then the herd or flock is in compliance with FDA's operational definition of no residue. However, because the withdrawal period is established from only a limited number of animals that are maintained under typical field conditions, FDA will use a tolerance limit on these observations to establish the withdrawal period. A tolerance limit provides an internal within which a given percentile of the population lies, with a given confidence that the interval does contain that percentile of the population. When calculating a tolerance limit, FDA will use the 99th percentile of the population and the 95 percent confidence level. This procedure will ensure with a high degree of confidence that the mean residue concentration of any future herd or flock presented for slaughter will be in compliance.

FDA believes that the tolerance limit approach is necessary because a number of variables associated with normal husbandry practices may alter the extent to which residues accumulate or the rate with which residues deplete. Relevant variables may include breed, diet, state of confinement, geographical location, age of animals, state of health, and other herd-to-herd variables.

60. One comment stated that the 1979 proposal indicates that extended withdrawal periods will not be approved for drug products if the withdrawal period is longer than that commonly accepted in livestock management practices. The comment continued that these “commonly accepted livestock management practices” have not been determined empirically by livestock producers and are often a result of producers following the withdrawal periods set by FDA. The comment concluded that it was incongruous for FDA to say that it will not approve any withdrawal periods longer than those it has previously established.

FDA does not agree with this comment. As stated in the 1979 proposal, section 512(d)(2)(D) of the act provides expressly that, in determining whether a compound is approvable, FDA must consider whether the conditions of use of a sponsored compound are reasonably certain to be followed in practice. The withdrawal period is one of the conditions of use. In determining a withdrawal period, FDA does not base its decision on previously established withdrawal periods, but rather on available data and the proposed conditions of use for the sponsored compound.

***45549 XI. Compliance**

The approved regulatory method will be used to monitor the concentration of the marker residue in the target tissue of slaughtered animals. Information and data from monitoring will be used by FDA in conjunction with USDA in a comprehensive effort to assure the safety of food from food-producing animals. If the concentration of the marker residue is found above the Rm in target issue, the remainder of the carcass may contain violative residues and the carcass may be seized under 21 U.S.C. 334 as adulterated under 21 U.S.C. 342(a). If the circumstances are appropriate, the articles may also be detained under the Poultry Producers or Meat Inspection Acts (see 21 U.S.C. 451 et seq. and 601 et seq.).

61. A comment on the 1979 proposal questioned whether an entire animal carcass is required to be condemned under the regulations when it is found that the concentrations of the marker residue in target tissue exceeds Rm.

Based on data submitted to FDA, the agency may be able to make reliable and accurate predictions of the concentration of residue in other tissues when the concentration of residue in target tissue is above Rm. If FDA can determine from these data that muscle does not contian residues of carcinogenic concern in excess of its Sm, then the muscle is nonviolative and will not be subject to regulatory action. Whether regulatory action will be taken in any particular case will depend not only upon the degree of confidence FDA has in extrapolating results from one tissue to another but also upon the applicable legal standard; for example, whether the government has to show that the carcass is unfit for food or merely that it bears or contains unapproved concentrations of an animal drug. FDA will work closely with USDA in providing the necessary evaluations for determining whether regulatory action is advisable.

Regardless of whether a seizure occurs, information gathered from monitoring may assist both FDA and USDA in identifying producers who customarily submit for slaughter animals adulterated within the meaning of the act. This information may be helpful in detaining for prophylactice investigation herds, flocks, etc., from such producers. Lastly, and perhaps most importantly, information regarding the rate and extent of residues above safe concentrations in edible tissue may result in formal FDA action under section 512(e) of the act to withdraw the approval of the sponsored compound.

XII. Waiver of Requirements

In response to a petition or on his own initiative, the Commissioner may waive, in whole or in part, the requirements of the proposed regulations, except the requirement under proposed 21 CFR 500.88 for a regulatory method. (The possibility always exists that the agency may be precluded from enforcing a statutory requirement. In the special circumstances attending estradiol-containing products in cattle, for example, FDA has decided that imposing the requirement for a regulatory method for estradiol would be legally inappropriate because doing so would yield a result so unreasonable that it "could not be thoroughly attributed to Congressional design." United States v. Rutherford, 442 U.S. 544, 545 (1979). This exception is very narrow and rarely capable of being met.)

A petition for a waiver may be filed by any person who would be adversely affected by the application of the requirements to a particular compound. The petition should explain and document why some or all of the requirements are not reasonably applicable to the compound, and describe the alternative procedures that have been, or coud be, followed to assure that use of the compound will not contaminate human food with residues whose consumption could present a risk of cancer to people. The petition shall clearly set forth the reasons and supporting information that demonstrate why the alternative procedures will provide an adequate basis for concluding that approval of the compound satisfies the requirements of the anticancer provisions of the act. If the Commissioner determines that waiver of any of the requirements of proposed Subpart E of 21 CFR Part 500 is appropriate, the Commissioner will state the basis for the determination in the regulation approving marketing of the sponsored compound.

XIII. Implementation

The proposed regulations are based on recognized scientific principles for testing and evaluating compounds for potential carcinogenicity. Until a final rule is published, FDA will use these proposed regulations as a guideline for determining whether a sponsored compound is shown to be safe. FDA will apply the proposed regulations and guidelines to compounds being evaluated for approval or subject to proposals to withdraw approval.

Accordingly, FDA will apply the threshold assessment to all sponsored compounds currently in any stage of review and for all future applications, except when each of the following conditions is satisfied:

1. Substantial and acceptable work on the human food safety data requirements for an application was begun before March 20, 1979.

2. The administrative file reveals an FDA commitment to the sponsor before March 20, 1979, concerning the human food safety data required for approval.

3. The sponsor has continued its efforts to obtain a new animal drug application or a food or color additive petition approval after receiving FDA's commitment.

4. The compound is shown to be safe under standards being applied shortly before March 20, 1979, and no apparent safety concerns exist regarding the product under the conditions prescribed, recommended, or suggested in the proposed labeling as required under section 512(d)(2) of the act.

Recently, FDA published a notice in the Federal Register in which the agency discussed this implementation plan in greater detail (see 48 FR 6361; February 11, 1983). FDA continues to solicit comments on the plan.

XIV. General Comments on the 1979 Proposal

A. Statutory Construction

62. Several comments argued that, because the Delaney Clause applies only to substances found to induce cancer when ingested by man or animals, the clause cannot be applied to compounds for which carcinogenicity is merely suspected.

FDA agrees. The comments went on to reason that FDA could not require chronic testing of compounds that are merely potential carcinogens. In making this analysis, the comments overlooked the fact that the General Food Safety Clause requires that an additive or new animal drug be shown to be safe. If there is good reason to suspect that a compound is a carcinogen, the compound cannot be shown to be safe until evidence is available that adequately answers the questions concerning carcingenicity. In evaluating for approval any additive or new animal drug, FDA applies the threshold assessment criteria to determine whether there is a reasonable basis to suspect the carcinogenicity of a compound. If there is, FDA requires that chronic tests be conducted on the compound and where applicable, on its metabolites of carcinogenic concern. If the tests demonstrate that the compound or its metabolites are carcinogenic, then the compound comes under the ***45550** proscription of the Delaney Clause, in which case these proposed regulations provide a mechanism for implementing the DES Proviso and approving the use of the compound.

63. Several comments contended that the proposed regulations exceeded FDA's statutory authority because the agency stated that it would apply the operational definition, standards, and criteria put forth in the 1979 proposal to withdrawal actions against approved compounds. Comments contended that the agency may not evaluate an approved compound under the SOM procedures and consider the evaluation new evidence under section 512(e)(1) of the act supporting withdrawal of an approved NADA.

FDA agrees that new evidence is necessary before bringing action under section 512(e)(1) of the act. In specific situations the application of these proposed regulations and guidelines to the reevaluation of approved products may constitute new evidence

sufficient to demonstrate that the approved products no longer are shown to be safe. Section 512(e)(1)(B) of the act provides as follows:

(e)(1) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed pursuant to subsection (b) with respect to any new animal drug if the Secretary finds—
* * * * *
(B) that new evidence not contained in such application or not available * * * until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved * * *. [Emphasis added.]

Thus, if new evidence evaluated together with previously existing evidence shows that the drug is no longer shown to be safe, the burden of proof under this provision is met by the agency, and unless the product can be shown to be safe by the manufacturing party, the approval of the product must be withdrawn. Congress was careful to make clear that new evidence includes any evidence not available at the time the application was approved. New evidence includes tests by new methods, tests by methods not originally considered applicable, and new interpretations of previously collected data and information. In withdrawing the approval of a new animal drug, it is not the agency's burden to show that the use of the drug is unsafe. Instead, FDA must provide a reasonable basis for concluding that there are important questions about the safety of the compound and the residues that may result from its use. FDA may appropriately reach this conclusion and satisfy its burden under the new evidence clause of section 512(e)(1)(B) of the act by relying on the standards and criteria provided in the regulations and the guidelines. In fact, this interpretation was followed by the Commissioner in his withdrawal of the NADA's for DES and was upheld by the reviewing court in Rhone Poulenc, Inc. v. FDA, 626 F.2d 750 (D.C. Cir. 1980).
64. A related comment argued that any attempt to withdraw the approval of a compound like DES “where no residues have been detected using approved test methods is inconsistent with the law both as it appears on the face of the statute, and as the statute has been judicially construed.”

The sponsor of an NADA for a carcinogenic drug must submit as part of that NADA an acceptable method of analysis to detect residues of the drug in edible products of the treated animal. The statute requires the submission of “a description of practicable methods for determining the quantity, if any, of such drug in or on food, and any substance formed in or on food, because of its use; * * *” (see section 512(b)(7) of the act, see also section 512(d)(1)(H) of the act). In addition, the legislative history of the DES Proviso shows that that provision contemplates that the sponsor will have the responsibility for developing an analytical method for a carcinogenic drug (Ref. 21). When the sponsor of an NADA for a carcinogen fails to submit an adequate analytical method to detect residues, FDA cannot approve the NADA. In the case of an approved NADA for a carcinogenic compound, if FDA determines based on new information that the approved analytical method for detecting residues is inadequate, FDA has two grounds upon which it may withdraw the approval. First, FDA may withdraw the approval because the compound is no longer shown to be safe (see section 512(e)(1)(B) of the act). This ground was relied upon by the Commissioner in his decision to withdraw the approved NADA's for the use of DES (see 44 FR 54859; September 21, 1979). Second, FDA could withdraw the approval on the basis of the Delaney Clause. Faced with evidence that an approved method was inadequate, FDA could not make a finding that “no residue” of the sponsored compound would be found in the edible products of treated animals. The DES Proviso cannot begin to operate without that finding, and, accordingly, the Delaney Clause would preclude continued approval. A more lengthy discussion of this position may be found in the Commissioner's order withdrawing the approved NADA's for DES (44 FR 54858-54860).

65. Several comments contended that the proposed regulations were arbitrary, capricious, and vague and therefore violated the Administrative Procedure Act. The primary grounds for the contention were: FDA's failure in the proposal to define carcinogen and FDA's failure in general to follow statutory time limits for action upon an application for approval.

As discussed above, when determining whether a tested substance is a carcinogen, FDA will rely upon the criteria given by the Subcommittee on Environmental Carcinogenesis, National Cancer Advisory Board (Ref. 14).

In response to the comments on statutory time limits, FDA would like to clarify that, once an application is complete and accepted for filing, or once an application is filed over protest, the statutory time limits provided in the respective sections of the act begin to run. Much of the delay in the approval process of a sponsored compound is attributable to the time needed to collect the data necessary to complete an application, not to FDA's review of the data.

66. One comment argued that the comment period for the proposed regulations should be extended until FDA has established criteria for evaluating chronic tests for carcinogenicity, until FDA has prepared and published guidelines on critical parts of the proposed regulation, and until criteria for considering exceptions to the proposed criteria are prepared.

Instead of extending the comment period and promulgating a final rule, FDA has decided to repropose the regulations and make available the implementing guidelines.

67. One comment suggested that FDA should consider allowing the conditional marketing of compounds prior to approval and prior to the completion of the data collection process provided in the regulations. The comment contended that the periods required for the review of data were excessively long. Another comment suggested that unapproved compounds should be subjected to veterinary prescription provisions and be marketed under the supervision of a veterinarian on a limited basis once short-term tests had been performed.

FDA recognizes that the data collection process may be time consuming. Nevertheless, the statute requires that the sponsor demonstrate ***45551** safety by adequate tests by all methods reasonably applicable before any compound can be approved. Unit that statutory standard is met, FDA cannot, either conditionally or otherwise, legally approve a sponsored compound. FDA will make every effort to expedite not only its review of collected data but also the review of protocols for desired testing.

68. One comment recommended the creation of an “evaluation and classification panel” to be composed of government and nongovernment experts to identify, classify, and categorize carcinogens. The panel's cancer determinations would be binding upon the various regulatory agencies, including FDA. The determinations would be limited to scientific issues and, according to the comment, would not intrude upon the regulatory responsibilities of the agencies involved. The comment suggested that the panel would make scientific judgments as opposed to regulatory judgments.

FDA recognizes the benefit of consulting qualified experts for opinions concerning difficult scientific questions. Accordingly, FDA often seeks outside advice and, to the extent possible under the act (see 21 U.S.C. 331(j)) and FDA's regulations (see 21 CFR 514.11), FDA will continue to do so. However, FDA does not agree that the creation of an outside panel that would make decisions binding on FDA is either necessary or desirable.

B. Economic Issues

69. Several comments contended that in making a decision as to the safety of the sponsored compound FDA should consider whether the societal and economic benefits which a sponsored compound might produce outweigh the costs of restricting its use. A comment contended that the decision in American Petroleum Institute v. Occupational Safety and Health Administration (OSHA), 581 F.2d 493 (5th Cir. 1978), aff'd on other grounds sub. nom., Industrial Union Department v. American Petroleum Institute, 488 U.S. 607 (1980), supports such a consideration by the agency.

FDA is required to make an assessment of the costs and benefits of every rule it issues and to prepare a regulatory impact analysis and/or regulatory flexibility analysis if the rule meets the criteria of Executive Order 12291 or the Regulatory Flexibility Act. This assessment is intended to assist in making regulatory decisions and/or to inform the public of the consequences of those decisions. In preparing an assessment, FDA considers whether alternative acceptable methods of accomplishing the desired end, in this case the showing of safety, exist. FDA recognizes the obligation to select the alternative that involves the least cost to society. However, FDA is not allowed to factor into the determination of the safety of the compound the costs or benefits to society of that compound (see 44 FR 54881-54883).

The decision in American Petroleum Institute (API) provides little support for the comments' contentions. And, a related, more recent case, American Textile Manufacturers Institute, Inc. v. Donovan, 617 F.2d 636 (D.C. Cir. 1979), aff'd 452 U.S. 490 (1981), is contrary to the comment's position. In API the Supreme Court found that the Occupational Safety and Health Administration (OSHA), prior to setting an exposure limit on the airborne concentration of a toxic substance in the work place, had to make a finding that the toxic substance in question posed a significant health risk and that the proposed standard was necessary and appropriate. The Court declined to decide whether the Occupational Safety and Health Act (OSH Act) required that in making such a decision OSHA had to determine whether the benefits expected from the new standard bore a reasonable relationship to the costs that it imposed. However, in American Textile the Court held that risk benefit balancing under the OSH Act would be inconsistent with the congressional design and that no cost-benefit analysis requirement on the issuance of the standard existed under this act. The statutory language in the General Food Safety Clause is less equivocal concerning cost than the provisions of the OSH Act that were the subject of the Court's attention.

70. Comments contended that the 1979 proposed regulations would be overly burdensome because nearly every compound currently regulated or to be regulated would be included under the regulations.

The comment assumes that every compound for which an approval is sought is carcinogenic. In fact, only a minority of sponsored compounds, probably 20 percent or less, have or will be determined to be carcinogenic in laboratory animals (Ref. 22). Only carcinogenic compounds will be regulated under these proposed regulations.

71. A comment contended that the regulations resulted in an unfair restriction of trade because small companies producing limited numbers of drug products are not financially able to compete with larger, better financed companies, and because the proposed regulation would be effective only in the United States.

The act makes no distinction between large, well-financed manufacturers of sponsored compounds and smaller, less well-financed manufacturers. The legal requirements remain: The sponsored product must be demonstrated to be safe by adequate tests by all methods reasonably applicable. However, FDA recognizes the necessity for being especially attentive to the needs of small business to the extent that its obligation to protect the public health allows. FDA specifically solicits focused comment and alternatives as to how FDA may, within the requirements of the act, minimize the economic impact of the proposed regulations on small—as well as big—business. To date no small firm has sponsored a compound that would be subject to this proposed rule.

The comment is correct that the regulations are only effective for the approval of compounds for use in this country. Compounds administered in foreign countries to animals that may be imported into this country will not be approved under these proposed regulations because FDA has no control over the compounds that are given or administered to food-producing animals in other countries. To the extent that FDA is aware of an adulterated or misbranded product being offered for importation into this country, FDA will take action to preclude that importation under section 801 of the act (21 U.S.C. 381).

C. Technology Forcing Issues

72. Comments argued that the development of a practical and reliable assay to measure residues in animal tissues in the low parts per billion or high parts per trillion will not always be possible with current technology. Although the comments agreed in general that analytical chemistry has shown great progress in recent years, the comments argued with what they perceived to be FDA's position that continued progress will allow the development of the methodologies called for under the SOM procedures and criteria. In support of these arguments, the comments stated that Tables I and II contained in the preamble to the 1979 proposal (44 FR 17076) do not accurately reflect the state of the art in analytical chemistry for two reasons: (1) The compounds cited as examples either possess intense fluorescence or are substituted with halogen atoms permitting easy detection; and (2) the development of acceptable regulatory methods for detecting residues in the edible products ***45552** of food-producing animals is simple not supported by trends in specific methodology in areas of technology.

FDA agrees that for some sponsored compounds the development of an adequate regulatory method may be beyond the capacity of current technology. FDA never intended to give a contrary impression, for it is indisputable that some compounds will be so potent that a sponsor will be unable to develop a regulatory method with a sufficiently low limit of measurement. Other compounds may leave residues too difficult to characterize and identify sufficiently. Not all sponsored compounds, however, will create similar problems. FDA recognizes that the development of an analytical method for monitoring residues is not an easy task. FDA does not minimize the problems that can be associated with extracting and measuring residues contained in animal tissues. Nevertheless, as Tables I and II in the 1979 proposal showed, methodology for trace analysis has been characterized by marked and continuous improvements over the past three decades. Developments and improvements in available technology are the result of efforts by industry and the government to resolve public health protection problems like those presented by carcinogenic residues in edible tissue.

D. Additional Comments

Several comments provided, in addition to narrative comments on the proposal, specific comments on proposed sections of the regulations. Many of these comments duplicated comments received on the 1979 proposal.

21 CFR 500.80

73. One comment contended that the term “sponsored compound” should not be used in the regulations but rather the terms “drug” and “food additive” should be used because, according to the comment, those terms are more generally acceptable.

The term “sponsored compound” means any drug or additive proposed for use or used in food-producing animals. Thus, by definition it includes not only new animal drugs and food additives, but also color additives. For purposes of clarity and convenience, the term “sponsored compound,” FDA believes, is more acceptable than the comment's proposal.

74. One comment questioned why the term “residues of carcinogenic concern” was not defined and also queried whether the term was synonymous with “residues of toxicological concern.”

FDA meant the two terms to be synonymous. To avoid confusion, this reproposal will use the term “residues of carcinogenic concern.”

75. A comment contended that § 500.80 should contain a statement to the effect that the regulations do not apply to new animal drugs or food additives intended solely for investigational use.

These regulations are not meant to supersede the provisions of 21 CFR Part 511. The regulations in no manner hinder or affect the securing under 21 CFR 511.1 of an exemption to ship or deliver an investigational drug. The regulations and guidelines, however, will provide models for data collection under an investigational new animal drug application. These standards may also be used to determine whether an authorization for use of edible products of animals receiving the investigational drug is warranted (see CFR 511.1(b)(5)).

76. A comment requested that for purposes of clarity § 500.80 should be revised to read as follows: “If at any point in the process of data collection set forth in paragraph (b)(1) of this section, the evaluation of the data shows that the compound should not be regulated under these regulations, the sponsored compound will continue to be considered for approval under the general safety provisions of the act for risks other than cancer.”

FDA has amended § 500.80(c) to reflect the substance of this comment.

Definitions

77. One comment suggested that “target tissue” be defined as the edible tissue selected to monitor for residues.

FDA agrees with this comment.

78. Another comment requested that the definition of essential nutrients be expanded to read “is required for the animal's growth, development, function, and reproduction and that must be supplied from external sources, e.g., minerals, trace minerals, essential amino acids, and essential fatty acids.”

FDA has amended the regulations to reflect the substance of this comment.

21 CFR 514.1

79. One comment noted that the proposed revision to § 514.1(b)(7) omitted the last sentence of the introductory paragraph. The sentence provided that “when data or other adequate information establish that it is not reasonable to expect a new animal drug to become a component of food, assay methodology is not required.” The comment contended that the sentence is important and should be reinstated, arguing that certain drugs used in food-producing animals are so poorly absorbed or so rapidly deplete from the tissues that they shoud not be considered as components of food. The comment also contended that it may be impractical to develop a regulatory method with sufficient sensitivity to detect traces of residues that are not unsafe.

FDA agrees that the sentence referred to should be retained, with some modification in § 514.1(b)(7). The following sentence has been added. “When data or other adequate information establish that it is not reasonable to expect the new animal drug to become a component of food at concentrations considered unsafe, a regulatory method is not required.”

XV. Conclusion

The proposed regulations and the implementing guidelines are designed to ensure that edible tissues derived from animals treated with sponsored compounds are safe. In developing these regulations and guidelines, FDA followed well-recognized scientific procedures and applied high standards of public health protection. All sponsored compounds will be evaluated under the general safety provisions of the act. Sponsored compounds shown by adequate testing to be carcinogens will be regulated under proposed Subpart E of 21 CFR Part 500.

Executive Order 12291 and the Regulatory Flexibility Act require economic impact analyses of proposed regulations that are likely to have significant consequences on the overall regulated industry or on particular sections of it. In the economic impact analysis prepared for the 1979 proposal, FDA concluded that the expenses of conducting the biological studies and developing the regulatory method of analysis would be several million dollars for each carcinogenic compound. Without this testing, however, the carcinogenic compound could not be approved. In the economic analysis prepared for this proposal, FDA makes similar conclusions. However, because FDA is unlikely to receive requests to approve a large number of carcinogenic compounds, this regulation will not impose an annual effect on the economy of $100 million or more, the threshold value established by Executive Order 12291. In accordance with the Regulatory Flexibility Act, FDA has considered the effect that this proposal would have on small entities including small businesses and has determined that to date no small firm has sponsored a compound that would be subject to this proposed rule. Therefore, FDA certifies in accordance with section ***45553** 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action. The economic and regulatory flexibility analyses are on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

The agency has determined under 21 CFR 25.24(a)(8) (April 26, 1985 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Sections 500.86, 500.88, 500.90, and 514.1(b)(7) of this proposed rule contain collection of information requirements. As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this proposed rule to the

Office of Management and Budget (OMB) for its review of these collection of information requirements. Other organizations and individuals desiring to submit comments on the collection of information requirements should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, Rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Bruce Artim.

The following information has been placed on display in the Dockets Management Branch (address above), and may be reviewed in that office between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects

21 CFR Part 70
Color additives, Cosmetics, Definitions, Drugs, Labeling, Packaging and containers.

21 CFR Part 500
Animal drugs, Animal feeds, Labeling.

21 CFR Part 514
Administrative practice and procedure, Animal drugs.

21 CFR Part 571
Administrative practice and procedure, Animal feeds, Animal foods, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that Parts 70, 500, 514, and 571 be amended as follows:

PART 70—COLOR ADDITIVES
21 CFR § 70.50

1. The authority citation for 21 CFR Part 70 is revised as set forth below, and the authority citation under 21 CFR 70.50 is removed.

Authority: Secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376); 21 CFR 5.10, 5.11.

21 CFR § 70.50

2. Part 70 is amended in § 70.50 by adding new paragraph (c) to read as follows:

21 CFR § 70.50

§ 70.50 Application of the cancer clause of section 706 of the act.

* * * * *

(c) Color additives for use as an ingredient of feed for animals that are raised for food production. Color additives that are an ingredient of the feed for animals raised for food production that have the potential to contaminate human food with residues whose consumption could present a risk of cancer to people must satisfy the requirements of Subpart E of Part 500 of this chapter.

PART 500—GENERAL

2. Part 500 is amended by adding a new Subpart E to read as follows:

Subpart E—Regulation of Carcinogenic Compounds Used in Food-Producing Animals

Sec.500.80 Scope of this subpart.500.82 Definitions.500.84 Operational definition of no residue.500.86 Marker residue and target tissue.500.88 Regulatory method.500.90 Waiver of requirements.

Authority: Secs. 402, 403, 409, 512, 701(a), 706, 52 Stat. 1046-1048 as amended, 1055, 72 ***45554** Stat. 1785-1788 as amended, 74 Stat. 399-403 as amended, 82 Stat. 343-351 (21 U.S.C. 342, 343, 348, 360b, 371(a), 376).

Subpart E—Regulation of Carcinogenic Compounds Used in Food-Producing Animals

21 CFR § 500.80

§ 500.80 Scope of this subpart.

(a) The Federal Food, Drug, and Cosmetic Act requires that sponsored compounds intended for use in food-producing animals be shown to be safe and that food produced from animals exposed to these compounds be shown to be safe for consumption by people. The statute prohibits the use in food-producing animals of any compound found to induce cancer when ingested by people or animals unless it can be determined by methods of examination prescribed or approved by the Secretary (a function delegated to the Commissioner of Food and Drugs under § 5.10 of this chapter) that no residue of that compound will be found in the food produced from those animals under conditions of use reasonably certain to be followed in practice. This subpart provides an operational definition of no residue and identifies the steps a sponsor of a compound shall follow to secure the approval of the compound. FDA guidelines contain the procedures and protocols FDA recommends for the implementation of this subpart. These guidelines are available from the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Requests for these guidelines should be identified with Docket No. 83D-0288.

(b) If FDA concludes on the basis of the threshold assessment that a sponsor shall conduct carcinogenicity testing on the sponsored compound, FDA will also determine whether and to what extent the sponsor shall conduct carcinogenicity testing on metabolites of the sponsored compound. The bioassays that sponsor conducts must be oral, lifetime, dose-response studies and must be designed to assess carcinogenicity and to determine the quantitative aspects of any carcinogenic response.

(c) If FDA concludes on the basis of the threshold assessment or at a later time during the approval process that the data show that the sponsored compound and its metabolites should not be subject to these regulations, FDA will continue to consider the compound for approval under the general safety provisions of the act for risks other than cancer.

(d) This subpart does not apply to essential nutrients.
21 CFR § 500.82

§ 500.82 Definitions.
(a) The definitions and interpretations contained in section 201 of the act apply to those terms when used in this subpart.

(b) The following definitions apply to this subpart:

“Act” means the Federal Food, Drug, and Cosmetic Act (sections 201-901, 52 Stat. 1040 et seq., as amended (21 U.S.C. 301-392)).

“Essential nutrients” means compounds that are found in the tissues of untreated, healthy target animals and not produced in sufficient quantity to support the animal's growth, development, function, or reproduction, e.g., vitamins, essential minerals, essential amino acids, and essential fatty acids. These compounds must be supplied from external sources.

“FDA” means the Food and Drug Administration.

“Marker residue” means the residue selected for assay whose concentration is in a known relationship to the concentration of the residue of carcinogenic concern in the last tissue to deplete to its permitted concentration.

“Preslaughter withdrawal period” or “milk discard time” means the time after cessation of administration of the sponsored compound for the residue of carcinogenic concern in the edible product to deplete to the concentration that will satisfy the operational definition of no residue.

“Regulatory method” means the aggregate of all experimental procedures for measuring and confirming the presence of the marker residue of the sponsored compound in the target tissue of the target animal.

“Rm” means the concentration of the marker residue in the target tissue when the residue of carcinogenic concern is equal to Sm in the last tissue to deplete to its permitted concentration.

‘'Residue” means any compound present in edible tissues of the target animal that results from the use of the sponsored compound, including the sponsored compound, its metabolites, and any other substances formed in or on food because of the sponsored compound's use.

“Residue of carcinogenic concern” means all compounds in the total residue of a demonstrated carcinogen excluding any compounds judged by FDA not to present a carcinogenic risk.

“Sm” means the permitted concentration of residue of carcinogenic concern for a specific edible tissue.

“So” means the concentration of the test compound in the total diet of test animals that corresponds to a maximum lifetime risk of cancer in the test animals of 1 in 1 million. For the purpose of this subpart, FDA will also assume that this So will correspond to the concentration of residue of carcinogenic concern in the total human diet that represents no significant increase in the risk of cancer to people.

“Sponsor” means the person or organization proposing or holding an approval by FDA for the use of a sponsored compound.

“Sponsored compound” means any drug or food additive or color additive proposed for use, or used, in food-producing animals or in their feed.

“Target animals” means the production class of animals in which a sponsored compound is proposed or intended for use.

“Target tissue” means the edible tissue selected to monitor for residues in the target animals.

“Test animals” means the species selected for use in the toxicity tests.

“Threshold assessment” means FDA's review of data and information available about a sponsored compound to determine whether chronic bioassays in test animals are necessary to resolve questions concerning the carcinogenicity of the compound.
21 CFR § 500.84

§ 500.84 Operational definition of no residue.
(a) On the basis of the results of the chronic bioassays and other available information, FDA will determine whether any of the substances tested are carcinogenic. If the results of the chronic bioassays are equivocal, FDA will regulate the sponsored compound as a carcinogen until further testing resolves the remaining questions regarding carcinogenicity.

(b) If FDA concludes that the results of the bioassays do not establish carcinogenicity, then FDA will not subject the sponsored compound to the remainder of the requirements of this subpart.

(c) For each sponsored compound that FDA decides should be regulated as a carcinogen, FDA will analyze the data from the bioassays according to the linear interpolation procedure described by Gaylor, D.W. and R.L. Kodell, “Linear Interpolation Algorithm for Low Dose Risk Assessment of Toxic Substances,” Journal of Environmental Pathology and Toxicology, 4:305-312, 1980.

(1) For each substance tested in a separate bioassay, FDA will calculate, using the upper 95 percent confidence limit on the observations, the concentration of the residue of carcinogenic concern that corresponds to a maximum lifetime risk to the test animal of 1 in 1 million. FDA will ***45555** designate the lowest value obtained as So.

(2) FDA will consider that “no residue” of the compound remains in the edible tissue when conditions of use of the sponsored compound, including any required preslaughter withdrawal period or milk discard time, assure that the concentration of the residue of carcinogenic concern in the total diet of people will not exceed So. Because the total diet is not derived from food-producing animals, FDA will make corrections for food intake. FDA will designate as Sm the concentration of residue of carcinogenic concern that is permitted in a specific edible product.
21 CFR § 500.86

§ 500.86 Marker residue and target tissue.
(a) For each edible tissue, the sponsor shall measure the depletion of the residue of carcinogenic concern until its concentration is at or below Sm.

(b) For each edible tissue, the sponsor shall also measure the depletion of one or more potential marker residues until the concentration of the residues of carcinogenic concern is at or below Sm.

(c) From these data, FDA will select a target tissue and a marker residue and designate the concentration of marker residue (Rm) that the regulatory method must be capable of measuring in the target tissue. FDA will select Rm such that the absence of the marker residue in the target tissue above Rm can be taken as confirmation that the residue of carcinogenic concern does not exceed Sm in each of the edible tissues and, therefore, that the residue of carcinogenic concern in the diet of people does not exceed So.

(d) When a compound is to be used in milk- or egg-producing animals, milk or eggs must be the target tissue in addition to the tissue selected to monitor for residues in the edible carcass.
21 CFR § 500.88

§ 500.88 Regulatory method.

(a) The sponsor shall submit for evaluation and validation a regulatory method developed to monitor compliance with FDA's operational definition of no residue.

(b) The regulatory method must reliably measure and confirm the identity of the marker residue in the target tissue at concentrations equal to and above Rm.

(c) FDA will publish in the Federal Register the complete regulatory method for measuring the marker residue in the target tissue in accordance with the provisions of sections 409(c)(3)(A), 512(d)(1)(H) and (i), and 706(b)(5)(B) of the act.

21 CFR § 500.90

§ 500.90 Waiver of requirements.

In response to a petition or on the Commissioner's own initiative, the Commissioner may waive, in whole or in part, the requirements of this subpart except those provided under § 500.88. A petition for this waiver may be filed by any person who would be adversely affected by the application of the requirements to a particular compound. The petition shall explain and document why some or all of the requirements are not reasonably applicable to the compound, and set forth clearly the reasons why the alternative procedures will provide the basis for concluding that approval of the compound satisfies the requirements of the anticancer provisions of the act. If the Commissioner determines that waiver of any of the requirements of this subpart is appropriate, the Commissioner will state the basis for that determination in the regulation approving marketing of the sponsored compound.

PART 514—NEW ANIMAL DRUG APPLICATIONS

21 CFR § 514.1

4. The authority citation for 21 CFR Part 514 is revised to read as set forth below, and the authority citations under 21 CFR 514.1, 514.8, 514.11, 514.15, 514.50, 514.51, 514.55, 514.60, 514.110, 514.111, 514.115, 514.150, 514.155, 514.160, and 514.200 are removed.

Authority: Secs. 512 (i) and (n), 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b(i) and (n), 371(a)); 21 CFR 5.10, 5.11; §§ 514.50, 514.55, 514.60, 514.150, 514.155, 514.160 are issued only under secs. 507 and 512(n), 59 Stat. 463 as amended, 82 Stat. 350-351 (21 U.S.C. 357, 360b(n)); 21 CFR 5.10, 5.11.

21 CFR § 514.1

5. Part 514 is amended in § 514.1 by revising the introductory text of paragraph (b)(7) and by revising paragraph (b)(7)(ii), to read as follows.

21 CFR § 514.1

§ 514.1 Applications.

* * * * *

(b) * * *

(7) Analytical methods for residues. Applications shall include a description of practicable methods for determining the quantity, if any, of the new animal drug in or on food, and any substance formed in or on food because of its use, and the proposed tolerance or withdrawal period or other use restrictions to ensure that the proposed use of this drug will be safe. When data or other adequate information establish that it is not reasonable to expect the new animal drug to become a component of food at concentrations considered unsafe, a regulatory method is not required.

* * * * *

(ii) A new animal drug that has the potential to contaminate human food with residues whose consumption could present a risk of cancer to people must satisfy the requirements of Subpart E of Part 500 of this chapter.

* * * * *21 CFR § 514.111

6. In § 514.111 by adding new paragraph (a)(10) to read as follows:
21 CFR § 514.111

§ 514.111 Refusal to approve an application.
(a) * * *

(10) The drug fails to satisfy the requirements of Subpart E of Part 500 of this chapter.
* * * * *

PART 571—FOOD ADDITIVE PETITIONS
21 CFR § 571.1
7. The authority citation for 21 CFR Part 571 is revised to read as set forth below and the authority citations under 21 CFR 571.1 and 571.6 are removed.

Authority: Secs. 409, 701, 52 Stat. 1055-1056 as amended, 72 Stat. 1785-1788 as amended (21 U.S.C. 348, 371); 21 CFR 5.10 5.11.
21 CFR § 571.115
8. Part 571 is amended by adding new § 571.115 to read as follows:
21 CFR § 571.115

§ 571.115 Application of the anticancer clause of section 409 of the act.
Food additives intended for use as an ingredient in food for animals that are raised for food production that have the potential to contaminate human food with residues whose consumption could present a risk of cancer to people must satisfy the requirements of Subpart E of Part 500 of this chapter.

Interested persons may, on or before, February 28, 1986, submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 19, 1985.

Frank E. Young,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

[FR Doc. 85-25808 Filed 10-30-85; 8:45 am]

BILLING CODE 4160-01-M

50 FR 51551-03
PROPOSED RULES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 700
[Docket No. 85N-0536]

Cosmetics; Proposed Ban on the Use of Methylene Chloride as an Ingredient of Aerosol Cosmetic Products

Wednesday, December 18, 1985

***51551** AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to ban the use of methylene chloride as an ingredient of cosmetic products. The agency is proposing this action because recent scientific studies have revealed that inhalation of methylene chlolride causes cancer in laboratory animals. These studies have shown that the continued use of methylene chloride in cosmetic products may pose a significant risk to the public health, especially to specific segments of the population that are continually exposed to cosmetics containing methylene chloride. FDA is not proposing to lower the maximum permitted residue level of methylene chloride in decaffeinated coffee because that level is considered to be safe.

DATES: Comments by February 18, 1986. The agency proposes that any final rule based on this proposal become effective 60 days after its date of publication for products initially introduced and initially delivered for introduction into interstate commerce.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:John M. Taylor, Center for Food Safety and Applied Nutrition (HFF-300), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-485-0160.

SUPPLEMENTARY INFORMATION:

I. Introduction

Methylene chloride (CAS Reg. No. 75-09-2, dichloromethane) is a colorless, volatile liquid that is used in a variety of consumer and industrial products as a solvent and flame suppressant. The cosmetic use of methylene chloride is primarily in hair sprays. In these products, it is used as a solvent and flame suppressant, and because of its volatility, it serves to cause quick drying and setting of the applied resin.

Methylene chloride is also used in foods as an extraction solvent in the processing of coffee beans, spices, and hops. When used to decaffeinate coffee, methylene chloride is a food additive within the meaning of section 201(s) of the Federal Food, and Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)).

II. Carcinogenicity of Methylene Chloride

Several recent chronic studies of methylene chloride have raised questions about the safety of this chemical. The National Toxicology Program (NTP) sponsored inhalation studies in rats and mice; the National Coffee Association (NCA) sponsored drinking water studies in rats and mice; and the Dow Chemical Co. performed three inhalation studies, two in rats and one in hamsters. In addition to these seven studies, NTP sponsored gavage studies in rats and mice. These gavage studies may have no

value for carcinogenicity assessment because of serious problems with the manner in which the studies were conducted. NTP did not draw any conclusions from the gavage studies, and, therefore, FDA is not employing them in this proposal.

In one NTP-sponsored 2-year inhalation study, test groups of B6C3F1 mice were exposed to air containing 0 ppm, 2,000 ppm, and 4,000 ppm of methylene chloride for 6 hours per day, 5 days per week (Ref. 1). Increases in the incidence of mice with benign and malignant neoplasms derived from hepatocytes (liver cells), as well as benign and malignant neoplasms of the lung, were observed in the treatment groups of both sexes. The increases in these neoplasms were distinctly dose related. The agency concludes that methylene chloride is carcinogenic to the liver and lung of male and female mice. This study also demonstrates that methylene chloride induces cancer at a site (the liver) remote from the tissues directly exposed by the inhalation treatment (Ref. 2).

In the other NTP-sponsored 2-year inhalation study, test groups of Fischer 344 rats were exposed to air containing 0 ppm, 1,000 ppm, 2,000 ppm, and 4,000 ppm of methylene chloride for 6 hours per day, 5 days a week (Ref. 1). In the female rat groups, the incidence of animals with benign fibroadenomas of the mammary glands was increased by treatment and provided some evidence of a dose-response effect. The agency considers these results to be suggestive of a tumorigenic effect of methylene chloride on the mammary glands of female rats (Ref. 2).

***51552** The NTP studies were reviewed and validated by NTP's Board of Scientific Counselors, which concluded that methylene chloride is a carcinogen in mice, but that the evidence is equivocal in rats (Ref. 3).

Dow performed a pair of 2-year inhalation studies in Sprague-Dawley rats: a high-dose study and a low-dose study in which groups of animals were exposed to vaporized methylene chloride at 0 ppm, 500 ppm, 1,500 ppm, and 3,500 ppm; and 0 ppm, 50 ppm, 200 ppm, and 500 ppm, respectively, for 6 hours per day, 5 days per week (Refs. 4 and 5). Compound-related neoplastic effects were not observed in the low-dose study. In the high-dose inhalation study, an increase in the incidence of male rats with sarcomas in the region of the salivary gland was reported at the 1,500 ppm and 3,500 ppm exposure levels. The study investigators believed that this effect was associated with a viral infection of the salivary gland. However, similar tumorigenic effects from viral infections of the salivary gland were not observed among the female or male animals in the other test groups in this study.

Moreover, two unusual sarcomas of the salivary gland/integument were observed in treatment groups in the NTP-sponsored inhalation study on Fischer 344 rats. FDA and NTP pathologists found these two sarcomas to be very similar to those observed in the Dow high-dose study. The agency believes that these observations provide suggestive evidence that methylene chloride induces sarcomas of the salivary gland/integument in rats upon inhalation (Ref. 2).

Dow also performed a 2-year inhalation bioassay in Syrian Golden hamsters in which test groups were exposed to vaporized methylene chloride at 0 ppm, 500 ppm, 1,500 ppm, and 3,500 ppm for 6 hours per day, 5 days per week (Ref. 4). There were no treatment-related toxic effects observed in this study.

NCA sponsored 2-year multidose drinking water studies in Fischer 344 rats and B6C3F1 mice. In the rat study, the concentration of methylene chloride in the drinking water provided intakes for test groups ranging from 5 milligrams per kilogram of body weight per day (mg/kg/day) to 250 mg/kg/day (Ref. 6). In the mouse study, the methylene chloride intakes for the test groups ranged from 60 mg/kg/day to 250 mg/kg/day (Ref. 7). In these drinking water studies, there were no significant increases in the incidences of rats or mice with neoplasms at any site examined. However, higher treatment levels could have enhanced the sensitivity of this study. Because the treatment levels were relatively low, the animals that received methylene chloride via drinking water may not have received as much as those receiving methylene chloride by inhalation (Ref. 2).

Two epidemiology studies have been conducted on workers exposed to methylene chloride in manufacturing plants (Refs. 8 and 9). Neither study reported an increase in cancer attributable to methylene chloride. Design limitations such as small numbers

of workers and insufficient duration of exposure make it impossible for FDA to draw any definitive conclusions from these studies about the potential for methylene chloride to cause cancer in humans.

A variety of genotoxicity studies have been performed on methylene chloride. Methylene chloride gave positive results for mutagenicity in bacteria (Salmonella typhimurium strains TA-98, TA-100, and TA-1535) (Refs. 10 through 17) and in yeast (Saccharomyces cerevisiae) (Ref. 18) without metabolic activation.

A more complete assessment of the specific types of tumors found in testing of methylene chloride and of the significance of these findings is presented in the report of the Cancer Assessment Committee of FDA's Center for Food Safety and Applied Nutrition (Ref. 2).

Based on these adverse findings, the agency concludes that methylene chloride is an animal carcinogen by inhalation and may be carcinogenic to humans. It has been the agency's policy that substances that cause cancer in laboratory animals should be considered potential human carcinogens unless there is clear epidemiological evidence to the contrary or unless there is other evidence that the effects observed in animals are not relevant to humans. In the case of methylene chloride, FDA has found that although the epidemiological studies that have been conducted have not reported any increase in cancer attributable to methylene chloride, these results must be considered inconclusive due to design limitations such as small numbers of workers and insufficient duration of exposure. The Environmental Protection Agency reached a similar conclusion about these studies in its Federal Register notice of October 17, 1985 (50 FR 42037). In addition, the agency is unaware of any basis on which to find that the animal studies discussed above are not relevant to humans. Although there is some evidence indicating that at high doses the metabolic pathways of methylene chloride may become saturated, FDA agrees with EPA that currently available data are insufficient to assess the effect of saturation on the carcinogenic potential of methylene chloride (50 FR 42038-42039). FDA will evaluate any additional data from ongoing studies on this point when they become available.

III. Risk Estimate—Cosmetic Uses

The agency has examined the potential level of exposure from the use of methylene chloride as an ingredient of aerosol cosmetic products and has made preliminary estimates of the carcinogenic risks to users of these products.

In calculating the risk from exposure to methylene chloride, the agency considered two population groups. One group, hair care specialists, represents the group with the highest exposure level expected from aerosol hair sprays. The other group is the segment of the population that routinely uses aerosol hair sprays as part of their grooming practices.

The exposure estimates used in the agency's risk assessment are based on data obtained from studies published in 1976 that measures methylene chloride concentration in the breathing zone after use (Refs. 19 and 20). The agency needed to make various assumptions in order to calculate exposure levels for consumers. For example, FDA's exposure estimates assumes that a consumer will use the hair spray once a day, that the spray period is 5 seconds, that the consumer will remain in the spraying zone for 5 to 10 minutes, and that the average concentrations of methylene chloride in the breathing zone is 50 ppm. The agency believes that these assumptions reasonably reflect the actual consumer use conditions and are not drawn to represent worst-case conditions (Ref. 21).

To make comparisons between mice exposed to 2,000 ppm methylene chloride by inhalation in the NTP study and potential human exposure at different exposure levels and for different time intervals, the agency has chosen to use a time-weighted average. The time-weighted average air concentration represents the concentration of methylene chloride to which individuals are exposed on a continuous daily basis, calculated by averaging over time the intermittent air concentrations for fractions of the day or fractions of the week. Use of this averaging concept permits a direct comparison between average human exposure and test animal exposure.

Accordingly, a consumer exposed to 50 ppm methlyene chloride in air for 5 ***51553** minutes per day, 7 days a week, would have a time-weighted average exposure of 0.174 ppm

(50 ppm x 5 min x 1 hr x 7 days =0.174 ppm),
--------- -------- ---------
60 min 24 hr 7days

and a mouse exposed to 2,000 ppm for 6 hours per day, 5 days a week, would have a time-weighted average exposure of 357 ppm
(2,000 ppm x 6 hr x 5 days =357)ppm.
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24 hr 7 days

time-weighted average human exposure to methlyene chloride from consumer use of hair spray is thus 0.174 ppm of air inhaled. Assuming that all of the inhaled methylene chloride is absorbed from the lungs into the blood stream, the time-weighted average human exposure is 0.15 milligrams per kilogram of body weight per day.
FDA's time-weighted exposure estimates for hair care specialists are about one order of magnitude higher (1.74 ppm or 1.5 milligrams per kilogram of body weight per day).

Extrapolating, using a linear model, from the incidence of benign and malignant neoplasms in female mice exposed to 2,000 ppm (357 ppm time-weighted exposure) in the NTP study to average human exposure from use of aerosol cosmetics containing methylene chloride, the upper bound estimated lifetime cancer risk for consumers is in the range of 1x10-3 (1 in 1,000) to 1x10-4 (1 in 10,000), depending on whether the animal-to-human dose comparison is based on the concentration in air or on milligrams per kilogram of body weight per day. For hair care specialist, the upper bound of lifetime risk is in the range of 1x10-2 (1 in 100) to 1x10-3 (1 in 1,000). These risks are relatively high primarily because the anticipated exposures from aerosol uses are high. Methylene chloride is not a particularly potent carcinogen. Additional discussion of how FDA has calculated the potency of methylene chloride is provided in the discussion of its use in decaffeinated coffee.

The agency assumed a linear dose-response model from zero dose to the experimental level of 2,000 ppm. Extrapolation models incorporating low dose linearity have been recommended by the Office of Science and Technology Policy when uncertainty exists regarding the mechanism of carcinogenicity, as is the case with methlyene chloride (50 FR 10371-10442; March 14, 1985).

Full details of the specific assumptions and methods used to project these upper bound risk assessments are described in Ref. 21.

IV. Risk Estimate—Food Additive Use for Decaffeination

Methylene chloride has been listed in FDA's food and color additive regulations for more than 20 years. It is currently listed in the following regulations: § 73.1 Diluents in color additive mixtures for food use exempt from certification (21 CFR 73.1), § 172.560 Modified hop extract (21 CFR 172.560), § 173.255 Methylene chloride (21 CFR 173.255), § 175.105 Adhesives (21 CFR 175.105), and § 177.1580 Polycarbonate resins (21 CFR 177.1580).

The agency has sufficient information to determine that the existing methylene chloride residue level for decaffeinated coffee is safe. Because the U.S. population consumes a large volume of decaffeinated coffee, the majority of which is manufactured using methylene chloride in the extraction procedure, it is important to make an assessment of safety. FDA is deferring consideration of the other uses of methylene chloride in food (as well as its presence as an impurity in food additives) because the agency is not aware of any information indicating that the other uses of methylene chloride present a public health hazard.

Methylene chloride is regulated as a food additive in § 173.255. Paragraph (c) of that section authorizes the use of this additive to extract caffeine from green coffee beans and limits residual methylene chloride to a level not to exceed 10 parts per million (ppm) in decaffeinated roasted coffee and in decaffeinated soluble coffee extract (instant coffee).

FDA issued § 173.255(c) in the Federal Register of August 31, 1967 (32 FR 12605), in response to a food additive petition (FAP 7A2061). The petitioner submitted data showing that use of both decaffeinated roasted coffee and decaffeinated instant coffee

containing 10 ppm methylene chloride would result in approximately 0.1 ppm methylene chloride in a 5 ounce (148 gram) cup of coffee. The petitioner also showed that the average level of methylene chloride in dried decaffeinated instant coffee was approximately 2 ppm, based on an analysis of 33 batches.

As discussed in section II above, methylene chloride has been shown to be carcinogenic to both sexes of B6C3F1 mice upon inhalation. The NTP inhalation mouse bioassay demonstrates that methylene chloride can induce cancer at sites remote from the site of administration. The evidence is also suggestive that methylene chloride may induce tumors in two strains of rats upon inhalation. Based on this evidence, the agency concludes that methylene chloride is an animal carcinogen, and that the NTP inhalation study provides a suitable basis for evaluating the safety of its food additive uses because methylene chloride displayed the greatest potency in this study.

General Foods Corp., the manufacturer that produces the largest amount of decaffeinated coffee, has surveyed its decaffeinated coffee products from 10 nationwide grocery locations (Ref. 22). For 69 samples of decaffeinated roasted and ground coffee products that it has analyzed since 1982, General Foods found methylene chloride levels of 0.01 ppm or less in 82.6 percent of the samples, 0.05 ppm or less in 91.3 percent of the samples, and 0.10 ppm or less in 100 percent of the samples. For 54 samples of decaffeinated instant coffee products that it has analyzed over the same period, General Foods found methylene chloride levels of 0.01 ppm or less in 96.3 percent of the samples, 0.05 ppm or less in 98.2 percent of the samples, and 0.10 ppm or less in 100 percent of the samples.

The agency is aware of four other manufacturers of decaffeinated coffee (Ref. 23). Although FDA does not know whether any methylene chloride residues in the products of these manufacturers are as low as those in the products of General Foods, the agency is aware that these products comply with the current regulation.

Quantitative risk assessment of methylene chloride consists of two parts: (1) Assessment of probable exposure to methylene chloride from its use to decaffeinate coffee under a specific residue limitation, and (2) extrapolation of the risk from methylene chloride observed in the NTP bioassay to the conditions of probable exposure to humans.

1. Exposure to methylene chloride. The exposure to methylene chloride from its use in decaffeinating coffee is a product of three factors: (a) The methylene chloride concentration in ***51554** coffee products, (b) the amount of coffee product used to make the coffee beverage, and (c) the amount of beverage consumed.

(a) Methylene chloride concentration in coffee products. FDA decided to assess the risk from the existing limitation on the concentration of methylene chloride of 10 ppm. The agency recognizes that the average level of methylene chloride likely to be present in decaffeinated coffee would be much lower than that limitation. The available data, however, did not allow the agency to estimate what the average residue level would be under the 10 ppm limitation. Therefore, in conducting the risk assessment, FDA assumed that all products would contain methylene chloride at a concentration equal to the limitation of 10 ppm.

(b) Amount of coffee product used to make the coffee beverage. The General Foods' submission of August 7, 1985, reported that 1 pound of roasted and ground coffee makes 70 to 90 cups of coffee (each cup containing 5 fluid ounces or 148 grams) based on current brewing practices (Ref. 22). Therefore, approximately 5.7 grams of roasted and ground product is used for each cup. General Foods also reported that instant coffee drinkers use about 2.2 grams soluble solids per cup. The agency used these numbers as elements of its exposure estimate (Ref. 23).

In estimating methylene chloride exposure, the agency also assumed that all of the methylene chloride in the roasted and ground product is extracted during brewing and becomes a part of the coffee beverage. Although this assumption may result in an overestimate of exposure, the agency does not now have sufficient reliable data to refine this estimate (Ref. 24).

(c) Beverage consumption. The agency considered three surveys in estimating decaffeinated coffee beverage consumption. Based on 1977-1978 surveys, the Market Research Corp. of America (MRCA) estimated a 90th percentile consumption of

decaffeinated coffee (among persons who consumed decaffeinated coffee) of 389 grams per day for roasted and ground coffee and 435 grams per day for instant coffee. MRCA estimated average consumption for decaffeinated coffee drinkers of 136 grams per day for roasted and ground coffee and 192 grams per day for instant coffee. MRCA's survey involved a 14-day menu census of 10,819 individuals in the 2 years and older age group. The values for decaffeinated coffee are based on 458 “eaters” of brewed decaffeinated coffee and 1,362 “eaters” of instant decaffeinated coffee (Ref. 25).

The International Coffee Organizataion (ICO) performs a survey each winter. Its winter 1985 coffee drinking survey indicates that 17.3 percent of the U.S. population was drinking decaffeinated coffee at the time of the survey. Decaffeinated coffee drinkers consume the beverage at a rate of 2.42 cups per day (358 grams per day). The ICO data are bsed on wintertime telephone inverviews of 7,500 individuals who were questioned about their coffee consumption on the previous day (Ref. 26).

In 1977-1978, the U.S. Department of Agriculture (USDA) also performed a food consumption survey. This survey included 37,874 individuals of whom 7.3 percent consumed decaffeinated coffee at least once in 3 days. For those individuals consuming decaffeinated coffee at least once in 3 days, USDA computed average consumption and 90th percentile consumption of 347 grams per day and 720 grams per day, respectively (Ref. 27).

Based on these surveys, the agency believes that the estimated consumption of 740 grams per day (five cups) is adequate to represent consumers of large amounts of decaffeinated coffee for a time span of several years (Ref. 28). It is unlikely, however, that individuals will average this consumption rate over a lifetime because decaffeinated coffee drinking varies from essentially no consumption by children to the highest consumption among the oldest age group. In the ICO survey, for example, the percentages of the individuals who drank decaffeinated coffee were 1.7 percent for the 10 to 19 year old age group, 7.3 percent for the 20 to 29 year old age group, 21.0 percent for the 30 to 59 year old age group, and age group, 21.0 percent for the 30 to 59 year old age group, and 33.8 percent for the 60 year old and older age group (Ref. 26). Because of this variation in consumption across age groups, the agency believes that individuals are unlikely to average more than 370 grams per day consumption of decaffeinated coffee over their lifetime (which is equivalent to one-half a lifetime at 740 grams per day) (Ref. 28). The agency used this 370 gram consumption level in computing its exposure estimate.

Dietary exposure can be calculated by multiplying together the three factors (10 ppm methylene chloride in the product, 5.7 grams roasted and ground or 2.2 grams instant product per 148 gram cup, and 370 grams per person per day consumption). By this approach the agency estimated that the lifetime-averaged exposure to methylene chloride under a 10 ppm regulatory limitation would not be likely to exceed 140 micrograms per day for consumers of brewed (roasted and ground) decaffeinated coffee and 55 micrograms per day for consumers of instant decaffeinated coffee (Ref. 28).

2. Risk extrapolation. The second part of the evaluation of risk presented by the dietary exposure to methylene chloride is an extrapolation from the actual compound-related incidence of animals with tumors (risk) found in animal bioassays under conditions of exaggerated exposure to the conditions of probable exposure for humans. Among the available studies, the agency considers the NTP inhalation study in mice and the NCA drinking water study in mice to be suitable studies for risk assessment. The NTP study is used because methylene chloride displayed the greatest potency in it.

The agency recognizes, however, that there are problems with using an inhalation study for assessing the risk from ingestion of methylene chloride. The problems stem from a lack of knowledge about the differences in the pharmacokinetics of the absorptioh, distribution, metabolism, and excretion of methylene chloride (and the ultimate carcinogenic entity, which also is not known) when it is inhaled as opposed to when it is ingested.

The NCA drinking water study in mice provides a way of confirming that using the inhalation study for upper bound risk estimation is not likely to underestimate any potential risk. Although the NCA study, which was performed in the same strain of mice as the NTP study, negative, it is useful for determining a maximum possible potency for methylene chloride by ingestion.

In the NTP inhalation study in mice, methylene chloride induced liver cell neoplasms and lung neoplasms. The agency used the female mice data for risk assessment because the female mice give a somewhat stronger response than the male mice. To estimate the risk, the agency considered the lung and liver neoplasia to be independent and added them together. The agency then computed the carcinogenic potency based on the incidence of animals with tumors at the low dose (2,000 ppm).

The computed carcinogenic potency is the risk (the probability that an animal will develop a tumor) divided by the dose that produced that risk. An inhalation exposure of 2,000 ppm for mice is equivalent to an exposure of 2,250 mg/kg/day if it is assumed that all the inhaled methylene chloride vapor is absorbed systemically. Thus, for methylene chloride, the calculated ***51555** carcinogenic potency is 4.x10-4 per kilogram of body weight per day (Refes. 21 and 28).

The NCA drinking water study in mice did not demonstrate any distinct neoplastic effects to liver or lung. However, the dosage levels were considerably lower than those in the inhalation study. Making the assumption that methylene chloride would induce neoplasia at a dose just above the highest level tested in the drinking water study, a maximum potency can be estimated. This estimate is approximately the same as the potency estimated from the inhalation study and provides more confidence that the inhalation study is not likely to underestimate the potency of methylene chloride by ingestion (Ref. 28).

The agency therefore finds that the available bioassays are consistent with a methylene chloride carcinogenic potency of no greater than 4.4X10-4 per milligram per kilogram of body weight per day when ingested. For a 60 kilogram human, this corresponds to a potency of 7.3X10-6 per milligram per day.

The potency for methylene chloride derived by the Environmental Protection Agency (EPA) is about 26 times higher than FDA's value. Most of the difference (a factor of 13) between the two estimates is attributable to the fact that EPA uses body surface area for interspecies comparison of exposure, whereas FDA uses body weight for such comparison. An additional factor of two is attributable to a combination of other small differences in risk assessment procedures employed by the two agencies.

FDA has traditionally used body weight scaling to compare doses among laboratory test species and for estimating comparable levels of exposure in humans. Under contract with FDA, the Life Sciences Research Office of the Federation of American Societies for Experimental Biology in initiating a study to examine the biological basis extrapolating doese among laboratory test species and humans (50 FR 45669; November 1, 1985). In the meantime, FDA will continue to use body weight scaling for interspecies comparison of doses.

In FDA's view, the overall risk assessment procedures used by both FDA and EPA are conservative. Neither FDA's nor EPA's procedures are likely to underestimate the actual risk from very low doses. In fact, both are likely to exaggerate the risk because the overall procedures of both agencies are designed to estimate an upper bound risk consistent with the data.

FDA has estimated the upper bound risk from exposure to methylene chloride from consumption of decaffeinated coffee produced in compliance with the 10 ppm limitation. Using 7.3X10-6 per milligram per day as the potency for methylene chloride when ingested at very low levels and the estimated lifetime-averaged methylene chloride exposure of 140 micrograms per day for consumers of large amounts of decaffeinated brewed coffee and 55 micrograms per day for consumers of large amounts of decaffeinated instant coffee, the agency estimates upper bound of lifetime risks to be 1X10-6 (i.e., 1 in million) and 4X10-7 (i.e., 1 in 2.5 million), respectively (Ref. 28).

It should be emphasized that the actual levels of residual methylene chloride in the decaffeinated coffee produced by the major manufacturer are much less than 10 ppm and, therefore, pose an even smaller risk. Most decaffeinated coffee contains mehtylene chloride residue of less than 0.1 ppm. The risks posed by this level of residue are two orders of magnitude lower than the already small risk posed by the 10 ppm level, i.e., 1X-8 (1 in 100 million) and 4X-9 (1 in 250 million), respectively.

V. Determination That Existing Limit for Decaffeination is Consistent with Safe Use of Methylene chloride

Because decaffeinated coffee that meets a 10 ppm regulatory limitation presents such extremely low levels of risk, FDA is not proposing to amend § 173.255(c).

Under section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, FDA cannot approve a food additive for a particular use unless the data presented to FDA establish that the food additive is safe for that use. The concept of safety embodied in this requirement was explained in the House Report on the Food Additives Amendment of 1958:

The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not —and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance.

This was emphasized particularly by the scientific panel which testified before the subcommittee. The scientists pointed out that it is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of any chemical substance.

H. Rept. 2284, 85th Cong., 2d Sess. 1, 4-5 (1958).
This determination of safety has been incorporated into FDA's food additive regulations in 21 CFR 170.3(i).

The Delaney anticancer clause of the Food Additives Amendment of 1958 (section 409(c)(3)(A) of the act) provides further:

That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal * * * .

Because methylene chloride has been shown at a statistically significant level to be a carcinogen by inhalation in the NTP mouse bioassay, if the Delaney anticancer clause (21 U.S.C. 348(c)(3)(A)) is to be interpreted as applying even it a de minimis risk is involved, FDA could not find that use of methylene chloride for decaffeinating coffee is safe. Yet, if the associated risk is essentially negligible, there is no gain to the public, and the statutory purpose is not implemented, if the words of the statute are interpreted not to leave the agency any discretion to apply it reasonably. The calculated risk for this use of methylene chloride is extremely low. The risk (no greater than 1 in 1 million and probably closer to 1 in 100 million) is so low as to be essentially nonexistent. Given such a low level of risk, FDA has concluded that there would be no safety gain to the public if it interpreted the Delaney Clause to require a ban on this use of methylene chloride. Therefore, FDA, exercising its inherent authority under the de minimis doctrine, concludes that the Delaney Clause does not require a ban in this situation. Because there are no other known safety problems with this use of methylene chloride, FDA finds that the use of methylene chloride to decaffeinate coffee is safe.

A. The de Minimis Doctrine

The de minimis doctrine holds that the law does not concern itself with trifling matters, and that courts consequently should be reluctant to apply the literal terms of a statute to mandate pointless results. Alabama Power Co. v. Costle, 636 F.2d 323, 360 (D.C. Cir. 1979). In District of Columbia v. Orleans, 406 F.2d 957, 959 (D.C. Cir. 1968), the United States Court of Appeals for the District of Columbia Circuit stated that this doctrine was properly applied to the administration by the government of its regulatory programs. Thus, an administrative agancy has the inherent power under most statutory schemes to overlook circumstances that are contrary to the literal terms of a statute when those ***51556** circumstances can fairly be considered de minimis. As the court in Alabama Power Co. v. Costle, supra, explained:

Unless Congress has been extraordinarily rigid, there is likely a basis for an implication of de minimis authority to provide exemption when the burdens of regulation yield a gain of trivial or no value.

636 F.2d at 360-361. Accord, Environmental Defense Fund, Inc. v. Environmental Protection Agency, 636 F.2d 1267, 1284 n. 46 (D.C. Cir. 1980).

B. The de Minimis Doctrine and the Federal Food, Drug, and Cosmetic Act

Section 201(s) of the act states that a "food additive" is "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food * * *." Yet, in Monsanto v. Kennedy, 613 F.2d 947 (D.C. Cir. 1979), the court held that not all chemicals that become components of food need be considered food additives. The court stated that FDA has the authority to ignore a chemical that migrates from plastic packaging material into beverages if the amount of the chemical that migrates is de minimis.

The Monsanto decision is important to the agency's present action even though that case involved the definition of "food additive" and not the application of the Delaney Clause, and even though the carcinogenicity of the chemical at issue in that case, acrylonitrile monomer, had not been established at the time of the decision. The court held that the de minimis concept is appropriately used to allow marketing of a product that would otherwise be banned by a Delaney Clause. In that case, the agency had interpreted the statute as defining a carcinogenic substance that migrated into food in low amounts as technically a "food additive" whose approval is banned by the food additive provision's Delaney Clause, see 21 U.S.C. 321(s), 331(a), 342(a)(2)(C), 348 (a) and (c)(3)(A). Although the reviewing court accepted that interpretation, it nevertheless held that the "de minimis" concept, applied to the threshold "food additive" definition, could be utilized to allow such a substance into the market when it presents no real public health risk, see 613 F.2d at 955-956. Thus, the court's decision in Monsanto has the practical effect of shielding substances that present effectively no carcinogenic risk from the Delaney Clause. Although the court did not explicitly interpret the Delaney Clause as inapplicable to such substances, the court presumably knew that if a carcinogenic chemical was disregarded as de minimis in relation to the food additive definition, the chemical would not be subject to the Delaney Clause, which applies only when that definition is met. Necessarily, therefore, the court regarded this consequence as legally warranted.[FN1]

Moreover, in Scott v. FDA, 728 F.2d 322, 325 (6th Cir. 1984), the Sixth Circuit upheld the so-called constituents policy, whereby FDA may approve known carcinogens present in color additives as intermediaries or impurities present at levels too low to cause a response using conventional tests. Noting that FDA had determined the public health risk presented by D and C Green 5 was negligible, the Court reasoned:

. . . We find this determination by the Monsanto court persuasive and relevant to the particular facts of the instant case. We agree with the FDA's conclusion that since it 'has discretion to find that low level migration into food of substances in indirect additives is so insignificant as to present no public health or safety concern . . . . it can make a similar finding regarding a carcinogenic constituent or impurity that is present in a color additive' 47 FR 24280 (1982).

C. Application of the de Minimis Doctrine

Two conditions must apply to justify an agency's exercise of its authority to interpret a legal requirement as not requiring action in de minimis situations. First, it must be consistent with the legislative design for the agency to find that a situation is trivial and, therefore, one that need not be regulated. Alabama Power Co. v. Costle, supra, 636 F.2d at 630. Second, it must be clear that the situation is in fact trivial, and that no real benefit will flow from regulating the particular situation. Environmental Defense Fund v. Environmental Protection Agency, 636 F.2d 1267, 1283-1284 (D.C. Cir. 1980). Both conditions apply here.

1. The establishment of a de minimis exception to the Delaney Clause is consistent with the legislative design.

In Alabama Power Co. v. Costle, supra, the court stated that the implication of de minimis authority is consistent with most statutes. The court stated that unless Congress has been extraordinarily rigid, there is likely a basis for an implication of such authority. Id. at 360-361. That Congress was not so rigid as to preclude the implication of de minimis authority under the Delaney Clause is evidenced both by the stated congressional intent in enacting the Clause and by the stated purpose of this provision.

Although the Delaney Clause in section 409(c)(3)(A) of the act was passed as part of the Food Additives Amendment of 1958, the clearest statement of the congressional intent for that provision is in the legislative history of the Color Additive Amendments of 1960. The Color Additive Amendments contain a provision that is very similar to section 409(c)(3)(A) of the act. See section 706(b)(5)(B) of the act (21 U.S.C. 376(b)(5)(B)).

The Senate considered that the calculation of risk would permit interpretation of the Delaney Clause to allow approval of color additives producing a negligible risk. This is clear from a colloquy on the Senate floor initiated by Senator Jacob Javits in debate on his motion to reconsider the vote to approve the Color Additive Amendments. Senator Javits, focusing on the Delaney Clause, made the record clear in discussion with Republican leader Senator Dirksen and committee chairman Senator Hill that the Senate had agreed to pass the Color Additive Amendments with the Delaney Clause based upon its understanding that the authority conferred by that clause "should be used and applied within the 'rule of reason.' " 106 Congressional Record 15381 (July 1, 1960).[FN2] Both Senator Dirksen and Senator Hill agreed that the "rule of reason" was to be applied in interpreting the Delaney Clause. Id. On that basis, Senator Javits did not pursue his motion to reconsider.

The term "rule of reason" was taken from a report to the President from the President's Science Advisory Committee and from the Departments of Agriculture and of Health, Education, and Welfare (the predecessor to the Department of Health and Human Services) that analyzed the effect of the Delaney Clause that is applicable to food additives. That report defines the "rule of reason" as meaning that: "Every ***51557** statute must be interpreted in the light of reason and common understanding to reach the results intended by the legislature." 106 Congressional Record 15380. The report stated its conclusion that "an area of administrative discretion based on the rule of reason is unavoidable if the clause is to be workable." 106 Congressional Record 15381.

This report on implementation of the food additive provision, relied upon by the Senators as illustrating their understanding of the types of circumstances in which the "rule of reason" would appropriately be applied, in fact accurately predicted the advent of the science of risk assessment, the science that the agency is now applying in making its determination about the use of methylene chloride in decaffeinating coffee. The report stated that: "From the experience obtained in animal experiments and study of humans who have been exposed to carcinogens in the course of their work the panel believes that the probability of cancer induction from a particular carcinogen in minute doses may be eventually assessed by weighing scientific evidence as it becomes available." 106 Congressional Record 15380-15381.

Thus, the Senate agreed to adopt the color additive Delaney Clause only with the understanding that the clause would, like the food additive Delaney Clause, be administered with a "rule of reason," premised on the expectation that scientists would be able to determine the "probability of cancer induction." Thus, far from having been "extraordinarily rigid," Congress clearly contemplated that those administering the Delaney Clause would have discretion to implement that provision in a reasonable way.

The purpose of the Delaney Clause in section 409 of the act is, after all, to protect the public from the possibility of increasing cancer risks through the use of food additives. It does not advance this purpose to prohibit uses that present a risk that is, for all practical purposes, zero. Congress recognized this fact in warning FDA not to "go overboard" in applying the Delaney Clause. 106 Congressional Record 15381. Thus, it is not inconsistent with the Delaney Clause to permit some uses of a carcinogenic food additive when those uses are shown to present a potential carcinogenic risk that is so trivial, based on conservative statistical analyses, as to be the functional equivalent of no risk at all.

2. FDA finds that the risk from the use of methylene chloride in decaffeinating coffee (no greater than 1 in 1 million) is so small as to be effectively no risk. The agency makes this finding for the following reasons:

a. This computed level of risk is an upper bound level. It is not an actuarial risk. An actuarial risk is the risk determined by the actual incidence of an event. In contrast, the computed risk is a projection based on certain assumptions that enable the

agency to estimate a risk that is too small to actually be measured. The agency uses conservative assumptions to ensure that the computation does not understate the risk. Among the assumptions that the agency relied upon in this computation are that:

(i) FDA assumes that methylene chloride is as effective in inducing cancer on a proportional basis at extremely low doses as it is at the exaggerated doses used in the animal studies.

(ii) FDA assumes that methylene chloride is present in all decaffeinated coffee at the highest level permitted by the regulation.

(iii) FDA assumes that lifetime-average consumption for the high consumer is used, rather than the average consumer.

Based on its computations, the agency is confident that the risk from the use of methylene chloride to decaffeinate coffee will not exceed 1 in 1 million and is likely to be somewhere between that level and zero. FDA emphasizes that the 1 in 1 million level of risk does not mean that 1 in every 1 million people will contract cancer as a result. Rather, in all likelihood, no one will contract cancer as a result of this exposure. The 1 in 1 million level represents a 1 in 1 million increase in risk over the normal risk of cancer in a lifetime—not annual—risk.

Because of the conservative assumptions in the foregoing risk assessement computation, it is probable that the incidence of tumors that would result the use of methylene chloride is likely to be even lower. In fact, the level of risk from most decaffeinated coffee is an incidence of less than one tumor after a lifetime of consumption in the entire population of coffee drinkers. As previously noted, it is likely that in fact there will be no increase incidence.

b. FDA has previously considered the risk level of 1 in 1 million in serveral contexts. In the ongoing rulemaking proceeding to establish procedures and standards for applying the so-called DES-proviso to the Delaney Clause for carcinogenic drug and food additive residues in edible animal tissues (21 U.S.C. 360b(d)(1)(H)), FDA has proposed than an assay method sufficient to detect a residue posing a calculated upper bound risk of 1 in 1 million be required posing a calculated upper bound risk of 1 in 1 million be required becasue “a risk level of 1 in 1 million over a lifetime imposes no additional risk of cancer to the public” (44 FR 17070, 17093; March 20, 1979). The agency noted that by using that level of risk, “as far as can be determined, in all probability no one will contract cancer” (50 FR 45530, 45541; October 31, 1985).

In several proceedings involving the agency's policy for carcinogenic impurities in food and color additives, FDA has used the risk of 1 in 1 million as a standard for determining whether the calculated upper bound risk of cancer posed by an impurity is low enough to be considered “safe” within the meaning of the general safety clause. See, e.g., the administrative record compiled in the rulemaking on D&C Green No. 6, 47 FR 14138; April 2, 1985.

FDA believes that these uses of the 1 in 1 million risk level are indistinguishable from the use 1 in 1 million as a de minimis level of risk with respect to the Delaney Clause. A finding that a substance with a 1 in 1 million risk is “safe,” or that it “imposes no additional risk of cancer to the public,” is the same as a finding that the risk is of no public health consequence or that it is insignificant. It is in just those circrumstances, where there is no meaningful increase in public health protection from applying the strict terms of a legal standard, that the courts have found the de minimis doctrine to be applicable. For example, the court in Monsanto equated “de minimis” with a finding that migration of an indirect food additive is “insignificant” (613 F.2d at 947) in a context where the court clearly recognized that the real question was the toxicity of a particular level of migration.

For these reasons, FDA concludes that a risk level on the order of 1 in 1 million for cancer constitutes a de minimis level of risk, and that its use of that level of risk in other regulatory contexts is consistent with that conclusion, although the agency until now has not had occasion to consider what levels of risk might be considered de minimis under the Delaney Clause with respect to be considered de minimis under the Delaney Clause with respect to a food or color additive.

Based on the foregoing, FDA concludes that the risk of cancer from the use of methylene chloride to decaffeinate coffee is so low as to be effectively no risk, and that there would be no benefit to the public from prohibiting its use in this case. Further,

consistent with section 409 of the act, FDA concludes, for the same reasons ***51558** and because there are no other safety problems with this use of methylene chloride, that methylene chloride is safe for use to decaffeinate coffee. Therefore, FDA will permit the continued use of methylene chloride to decaffeinate coffee so long as the residue levels are kept within the limits established in § 173.25.

VI. Regulatory Action

Under section 601(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 361(a)), a cosmetic is deemed to be adulterated "[i]f it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling therof, or, under such conditions of use as use are customary or usual * * *." FDA believes that the evidence discussed above establishes that methylene chloride is a poisonous or deleterious substance, and that its use in cosmetic products may render those products injurious to users. Therefore, FDA has tentatively concluded that cosmetics that contain methylene chloride are adulterated under section 601(a) of the act, and the agency is consequently proposing to prohibit the use of methylene chloride in all cosmetic products.

FDA has been informed by several cosmetic manufacturers that they have either ceased using methylene chloride in their hair spray products or are in the process or will soon be in the process to so reformulate. The agency acknowledges these substantial voluntary efforts and the availability of safe substitutes. Consequently, given the severity of the public health risk presented, a regulation is necessary to ensure that all hair spray manufacturers cease using methylene chloride and that no new hair spray manufacturers being using it.

FDA, however, is not taking any action with regard to the use of methylene chloride is decaffeinated coffee.

VII. Economic Impact

FDA, in accordance with the Reguatory Flexibilitiy Act, has considered the effect that this proposed rule would have on small entities including small businesses. The agency has determined that the economic impact arising from this proposed rule will result from one-time reformulation and relabeling costs for those cosmetic products currently containing methylene chloride. Information available to the agency has indicated that the only products potentially affected by this proposal are aerosol hair spray products, and that the use of methylene chloride in these products has declined sharply in recent years. The agency estimates the aggregate costs of this proposed rule to be approximately $1 million. Therefore, FDA certifies, in accordance with section 605(b) of the Regulatory Flexibiltiy Act, that no significant ecomonic impact on a substantial number of small entities will derive from this action.

Further, in accordance with Executive Order 12291, FDA has analyzed the economic effects of this proposal and has determined that it is not major rule as defined by that Order. A copy of the threshold assessment is on file the Dockets Managment Branch.

VII. Environmental Impact

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that findings, contained in an environmental assessment, may be seen in the Dockets Managment Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25) that was published in the Federal Register of April 26, 1985 (50 FR 16636, effective July 25, 1985).

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. “Technical Report on the Toxicology and Carcinogenesis Studies of Dichloromethane (Methylene Chloride) in F344/N Rats and B6C3F1 Mice,” NTP Draft Report, NTP-TR-306, National Institutes of Health Publication No. 85-2562, 1985.

2. Cancer Assessment Committee, Memorandum of Conferences, “Methylene Chloride,” January 20, 1983, August 8, 1984, and June 13, 1985.

3. Summary Minutes for Peer Review of Draft Technical Reports of Long-Term Toxicological Studies by the Technical Review Subcommittee of the Board of Scientific Counselors and Panel of Experts, March 29, 1985.

4. Burek, J.E., et al., “Methylene Chloride: A Two-Year Inhalation Toxicity and Oncogenicity Study in Rats and Hamsters,” Toxicological Research Laboratories, Dow Chemical U.S.A., December 31, 1980.

5. Nitschke, K.D., “Methylene Chloride: A Two-Year Inhalation Toxicity and Oncogenicity Study,” Toxicological Research Laboratories, Dow Chemical U.S.A., October 1982.

6. National Coffee Association, “24-Month Chronic Toxicity and Oncogenicity Study of Methylene Chloride in Rats—Final Report,” August 11, 1982, and “Addition to Final Report,” November 5, 1982, Hazelton Laboratories America, Inc. Vienna, VA.

7. National Coffee Association, “24-Month Oncogenicity Study of Methylene Chloride in Mice—Final Report,” Hazelton Laboratories America, Inc., Vienna, VA, November 30, 1983.

8. Friedlander, B. R., et al., “Epidemiologic Investigation of Employees Chronically Exposed to Methylene Chloride: Mortality Analysis,” Journal of Occupational Medicine, 20:675-666, 1978.

9. Ott, M.G., et al., “Health Evaluation of Employees Occupationally Exposed to Methylene Chloride,” Scandinavian Journal of Work, Environment & Health, 9:Suppl 1:1-38, 1983.

10. Jongen, W.M.F., et al., “Mutagenic Effect of Dichloromethane on Salmonella typhimurium,” Mutation Research, 56:245-248, 1978.

11. Kanada, T., and M. Uyeta, “Mutagenicity Screening of Organic Solvents in Microbial Systems,” Mutation Research, 54:215, 1978.

12. Jongen, W.M.F., et al., “The Effect of Glutathione Conjugation and Microsomal Oxidation on the Mutagenicity of Dichloromethane is S. typhimurium,” Mutation Research, 95:183-189, 1982.

13. Snow, L., et al., “Mutagenesis Testing of Methylene Chloride and 1,1,1-Trichloroethane in Salmonella Strains TA100 and TA98,” Northrop Services, Inc., Research Triangle Park, NC, September 19, 1979.

14. Brusick, D.J., “Mutagenicity Evaluation of Methylene Chloride—Final Report,” Litton Bionetics, Kensington, MD, July 30, 1976.

15. Green, T., “The Metabolic Activation of Dichloromethane and Chlorofluoromethane in a Bacterial Mutation Assay Using S. typhimurium,” Mutation Research, 118:277-288, 1983.

16. Simmon, V.F., et al., “Mutagenic Activity of Chemicals Identified in Drinking Water,” in “Progress in Genetic Toxicology,” Scott, I.D., et al., editors, Elsevier, Amsterdam, pp. 249-258, 1977.

17. Nestmann, E.R., et al., "Mutagenicity of Paint Removers Containing Dichloromethane," Cancer Letters, 11:295-302, 1981.

18. Callen, D.F., et al., "Cytochrome P-450 Medicated Genetic Activity and Cytotoxicity of Seven Halogenated Aliphatic Hydrocarbons in Saccharomyces cerevisiae," Mutation Research, 77:55-63, 1980.

19. Sayad, R.S., et al., "Methylene Chloride in Hair Sprays," Soap/Cosmetic/Chemical Specialties, March 1976.

20. Skory, L.K., T. Anthony, and M.P. Stevenson, "Carboxyhemoglobin Studies Show Methylene Chloride Safe in Aerosol Use," Aerosol Age, 20(5), May 1975.

21. Quantitative Risk Assessment Committee, Memorandum, "Preliminary Assessment of Upper-Bound Cancer Risk from Exposure to Methylene Chloride Used in Cosmetic Aerosol Sprays," April 23, 1985.

***51559** 22. Letter dated August 7, 1985, J. Kirschman, General Foods Corp., to R. Scheuplein, FDA, with attachment.

23. Memorandum dated November 12, 1985, G. Cramer, Food Additive Chemistry Evaluation Branch, FDA.

24. Memorandum dated November 14, 1985, G. Cramer, Food Additive Chemistry Evaluation Branch, FDA.

25. Letter dated November 18, 1985, I. Abrams, MRCA Information Service, to A. Beloian, FDA.

26. International Coffee Organization, "United States of America Coffee Drinking Study, Winter 1985," London, England.

27. Pao, E., et al., "Foods Commonly Eaten by Individuals: Amounts Per Day and Per Eating Occasion," U.S. Department of Agriculture, Home Economics Research Report No. 44, pp. 24-25, 1982.

28. Quantitative Risk Assessment Committee, Memorandum, "Upper Bound Estimate of Cancer Risk from Methylene Chloride (MC) in MC-based Decaffeinated Coffee Products," November 15, 1985.

X. Comments

Interested persons may, on or before February 18, 1986, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 700

Cosmetics, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that Part 700 be amended as follows:

PART 700—GENERAL

1. The authority citation for 21 CFR Part 700 is revised to read as follows:

Authority: Secs. 601, 602, 701(a), 704, 52 Stat. 1054 as amended, 1055, 67 Stat. 477 as amended (21 U.S.C. 361, 362, 371(a), 374); 21 CFR 5.10 and 5.11.

21 CFR § 700.19

2. By adding new § 700.19, to read as follows:

21 CFR § 700.19

§ 700.19 Use of methylene chloride as an ingredient of cosmetic products.

(a) Methylene chloride has been used as an ingredient of aerosol cosmetic products, principally hair sprays, at concentrations generally ranging from 10 to 25 percent. In a 2-year animal inhalation study sponsored by the National Toxicology Program, methylene chloride produced a significant increase in benign and malignant tumors of the lung and liver of male and female mice. Based on these findings and on estimates of human exposure from the customary use of hair sprays, the Food and Drug Administration concludes that the use of methylene chloride in cosmetic products poses a significant cancer risk to consumers, and that the use of this ingredient in cosmetic products may render these products injurious to health.

(b) Any cosmetic product that contains methylene chloride as an ingredient is deemed adulterated and is subject to regulatory action under sections 301 and 601(a) of the Federal Food, Drug, and Cosmetic Act.

Dated: December 12, 1985.

Frank E. Young,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

[FR Doc. 85-29851 Filed 12-17-85; 8:45 am]

BILLING CODE 4160-01-M

Footnotes

1 FDA has not always been clear about its position on the Monsanto decision. For example, in questioning by Senator Orrin G. Hatch that took place in 1983 during hearings on food safety by the Senate Committee on Labor and Human Resources, then-Commissioner Arthur Hull Hayes, Jr. expressed some uncertainty about whether the Monsanto decision should be interpreted beyond its specific factual context (S. Hearing 98-309, 98th Cong., 1st Sess. 248 (1983)). FDA has concluded that the Monsanto decision is correctly interpreted as extending to the Delaney Clause.

2 Senator Javits, now retired, recently reviewed this discussion. On July 10, 1985, he sent Margaret Heckler, Secretary of the Department of Health and Human Services, a letter stating that his views had not changed since 1960. He stated that it was his continuing understanding that the rule of reason “would dictate that where the danger to the public is negligible in using products with such color additives, then use should not be prohibited.” A copy of Senator Javits' letter to Secretary Heckler is included in the record of this rulemaking.

(9:00 a.m. to 5:00 p.m.) and June 16, 1976 (9:00 a.m. to 12 Noon) at the Consumer Product Safety Commission, 1750 K Street, N.W., 6th Floor Conference Room.

The purpose of the Technical Advisory Committee is to provide advice and recommendations on the types and kinds of packaging that will protect children from injury or illness resulting from handling or ingestion of household substances.

The agenda for the June 15 meeting will include a discussion of outstanding petitions and the regulations covering ammonia. The afternoon session of the meeting will be devoted to further discussion of adult protocol.

On Wednesday, June 16, there will be a discussion of consumer oriented programs of the Consumer Product Safety Commission and presentation of certificates to the outgoing members of the Committee.

Persons wishing to make oral or written presentations to the Committee should notify the Secretary of the Consumer Product Safety Commission at least five days in advance of the meeting. The meeting is open to the public, however, space is limited. Further information concerning this meeting may be obtained from the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207, phone (202) 634-7700.

Dated: May 19, 1976.

SADYE E. DUNN,
Secretary, Consumer Product Safety Commission.

[FR Doc.76-15168 Filed 5-24-76;8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 547-7; OPP-42011A]

COMMONWEALTH OF PENNSYLVANIA

Approval of State Plan for Certification of Commercial and Private Applicators of Restricted Use Pesticides

Section 4(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 7 U.S.C. 136), and the implementing regulations of 40 CFR Part 171 require each State desiring to certify applicators to submit a plan for its certification programs. Any State certification program under this section shall be maintained in accordance with the State Plan approved under this section.

On March 4, 1976, notice was published in the FEDERAL REGISTER (41 FR 9418) of the intent of the Regional Administrator, EPA Region III, to approve, on a contingency basis, the Commonwealth of Pennsylvania State Plan for Certification of Commercial and Private Applicators of Restricted Use Pesticides (Pennsylvania State Plan). Contingency approval was requested by the Commonwealth of Pennsylvania pending promulgation of regulations pursuant to the "Pennsylvania Pesticide Control Act of 1973". Complete copies of the Pennsylvania State Plan were made available for public inspection at the Agency's Region III office in Philadelphia, Pennsylvania, at the Bureau of Plant Industry, Pennsylvania Department of Agriculture, Harrisburg, Pennsylvania, and at the Agency's Technical Services Division, Federal Register Section, Office of Pesticide Programs, EPA Headquarters, Washington, D.C.

There were no comments received concerning the State Plan during the 30 day comment period.

The Pennsylvania State Plan will remain available for public inspection at Room 102, Agriculture Office Building, 2301 N. Cameron Street, Harrisburg, Pennsylvania.

It has been determined that the Pennsylvania State Plan will satisfy the requirements of Section 4(a)(2) of the amended FIFRA and of 40 CFR Part 171 if proposed regulations implementing the Pennsylvania Pesticide Control Act of 1973 are promulgated by the Pennsylvania Department of Agriculture. Accordingly, the Pennsylvania State Plan is approved contingent upon promulgation of implementing regulations in accordance with and as prescribed in the Pennsylvania State Plan.

This contingency approval shall expire one (1) year from its effective date, if these terms and conditions are not satisfied by that time. On or before the expiration of the period of contingency approval, a notice shall be published in the FEDERAL REGISTER concerning the extent to which these terms and conditions have been satisfied, and the approval status of the Pennsylvania State Plan as a result thereof.

Effective date: Pursuant to Section 4(d) of the Administrative Procedures Act, 5 U.S.C. 553(d), the Agency finds that there is good cause for providing that the one year contingency approval granted herein to the Pennsylvania State Plan shall be effective immediately. Neither the Pennsylvania State Plan itself nor this Agency's contingency approval of the Plan create any direct or immediate obligations on pesticide applicators or other persons in the Commonwealth of Pennsylvania. Delays in starting the work necessary to implement the Plan, such as may be occasioned by providing some later effective date for this contingency approval, are inconsistent with the public interest. Accordingly, this contingent approval shall become effective immediately.

Dated: April 15, 1976.

A. R. MORRIS,
Acting Regional Administrator.

[FR Doc.76-15138 Filed 5-24-76;8:45 am]

[FRL 548-2]

HEALTH RISK AND ECONOMIC IMPACT ASSESSMENTS OF SUSPECTED CARCINOGENS

Interim Procedures & Guidelines

In issuing the Interim Procedures and Guidelines for Health Risk and Economic Impact Assessments of Suspected Carcinogens, I think it appropriate to state once again EPA's approach to regulatory action for suspect carcinogens.

Cancer is the second ranking cause of death in this country; it has a particularly severe impact on the affected individuals and their families in terms of physical and mental suffering and economic costs. There is evidence that a substantial amount of human cancer is caused by chemical and physical agents in the environment. Bioassay programs, currently testing hundreds of substances, are beginning to show that some important industrial and agricultural chemicals are carcinogenic for animals and are, therefore, candidates for regulatory action.

The EPA, by law, has responsibility to regulate many agents which may either cause or promote the development of cancer. At present, EPA is charged with the responsibility to prohibit or restrict the use of carcinogenic pesticides. EPA also has authority to regulate those carcinogens which are emitted directly to the outside air by stationary sources (such as factories) and motor vehicles, or discharged into water from point sources, or found in drinking water. Other agencies such as the Occupational Safety and Health Administration and the Food and Drug Administration also have responsibilities to regulate carcinogens. It is important to emphasize that there are serious regulatory gaps which permit understandable exposure of the public to carcinogens. I have strongly advocated the passage of a toxic substances bill to help close those gaps.

Regulatory action against chemical carcinogens is relatively new. Until the late 1950's, no agents, either chemical or physical, had been regulated in this country on the basis of their carcinogenic action with the sole exception of ionizing radiation, which had been known to cause cancer since the turn of the century. Standards of permissible exposure to ionizing radiation were set by the arbitrary use of safety factors applied to exposure levels that were known to have produced damaging health effects. It was not assumed that these permissible exposure standards were safe but rather that they represented upper limits of exposure with the understanding that actual exposures were to be kept as low as possible. In the debate over the health effects of radioactive fallout from atomic weapons in the 1950's, the evidence for a no-threshold concept for cancer induction emerged, which supported the idea that there is no such thing as a completely safe dose; in other words any exposure, however small, will confer some risk of cancer on the exposed population.

Evidence has accumulated that indicates that the no-threshold concept can also be applicable to chemical carcinogens. On the basis of this concept, the first significant regulatory legislation relating to chemical carcinogens, the Delaney Clause of the Pure Food and Drug Act, imposed a complete ban on any food additive that showed evidence of tumorigenic activity for humans or animals. This statutory requirement represents the approach of eliminating all risk. However, it has become increasingly clear that in many areas risks cannot

be eliminated completely without unacceptable social and economic consequences.

Consonant with this view, the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), which is the enabling legislation for the control of health hazards for pesticides, requires a balancing of risks and benefits as the basis for final regulatory action. We, thus, have a comparable conceptual basis for the regulation of chemicals as for ionizing radiation where the philosophy has been to eliminate or reduce exposure to the greatest extent possible consistent with the acceptability of the costs involved.

I believe that it is important to emphasize the two-step nature of the decision-making process with regard to the regulation of a potential carcinogen. Although different EPA statutory authorities have different requirements, in general two decisions must be made with regard to each potential carcinogen. The first decision is whether a particular substance constitutes a cancer risk. The second decision is what regulatory action, if any, should be taken to reduce that risk.

With respect to the first decision—whether a particular substance constitutes a cancer risk—in very few cases is it possible to "prove" that a substance will cause cancer in man, because in most instances the evidence is limited to animal studies. In this regard, a substance will be considered a presumptive cancer risk when it causes a statistically significant excess incidence of benign or malignant tumors in humans or animals. However, the decision that a cancer risk may exist does not mean that the EPA will automatically take regulatory action. In the case of pesticides, the decision that a presumptive cancer risk exists will trigger the detailed and independent risk and economic assessments that form the basis for the second decision, namely, what, if any, regulatory action to take to eliminate or restrict the use of the pesticide. In other regulatory areas, for example those under the Clean Air Act, the Federal Water Pollution Control Act, or the Safe Drinking Water Act where a large number of suspect carcinogens may exist in the atmosphere or public water supplies, the detailed risk benefit assessment will, because of limited Agency resources, necessarily have to be carried out on a priority basis in terms of which agents appear to be the most important.

Once the detailed risk and benefit analyses are available, I must consider the extent of the risk, the benefits conferred by the substance, the availability of substitutes and the costs of control of the substance. On the basis of careful review, I may determine that the risks are so small or the benefits so great that no action or only limited action is warranted. Conversely, I may decide that the risks of some or all uses exceed the benefits and that stronger action is essential.

In considering the risks, it will be necessary to view the evidence for carcinogenicity in terms of a warning signal, the strength of which is a function of many factors including those relating to the quality and scope of the data, the character of the toxicological response, and the possible impact on public health. It is understood that qualifications relating to the strength of the evidence for carcinogenicity may be relevant to this consideration because of the uncertainties in our knowledge of the qualitative and quantitative similarities of human and animal responses. In all events, it is essential in making decisions about suspect carcinogens that all relevant information be taken into consideration.

In my opinion, the current guidelines represent a significant improvement in the Agency's approach to the processes of decision-making for carcinogens by providing improved procedures for making risks and benefit assessments while providing the maximum opportunity for public review of the Agency's deliberations. However, while these guidelines should improve Agency procedures, I do not view them as representing a change in the Agency's cancer policy. Earlier regulatory decisions involving various pesticides were also based in each case on a comprehensive evaluation of the scientific evidence and a careful weighing of risks and benefits. These decisions in every instance resulted in selective control measures rather than a complete prohibition of use.

I want to emphasize that I will not permit these new procedural guidelines to unduly delay regulatory decision-making. I will be closely reviewing them to assure that they do not do so. If they do cause undue delay, they will be revised. I would like to point out that these guidelines provide a means of organizing available information rather than requirements for the acquisition of new information.

I believe that the approach presented here is a significant step toward the objective of achieving real benefits in improved public health while avoiding the burden of undesirable regulatory action. I recognize that the aspect of cancer research dealing specifically with the issues involved in decision-making is relatively undeveloped, but hopefully the commitment of this Agency and other Federal agencies to the development of new knowledge in this area will improve the scientific basis for regulatory decisions and that the Interim Procedures and Guidelines will thereby benefit from periodic revision.

I consider it extremely important that the leading government agencies work closely with each other and with experts outside the government in the field of carcinogenicity in the development of government procedures and policies concerning cancer. I am publishing these interim procedures and the guidelines in the FEDERAL REGISTER not only to provide public notice of the approach which EPA will be following in our current activities but also to stimulate commentary from all sources upon that approach. I am also furnishing copies of these Interim Procedures and Guidelines to and requesting the views of the Secretaries of Health, Education, and Welfare, Interior, Labor, Commerce and Agriculture and also the Council on Environmental Quality, the National Academy of Sciences, the National Science Foundation, EPA's Pesticide Policy Advisory Committee and EPA's Science Advisory Board, among others. I also plan to meet personally with leading authorities in this area as part of a continuing process to discuss these cancer policies and exchange information and views.

RUSSELL TRAIN,
Administrator.

MAY 19, 1976.

INTERIM ADMINISTRATIVE PROCEDURES FOR REGULATORY DECISIONS INVOLVING SUSPECTED CARCINOGENS

Procedures described in this paper provide a more uniform Agency approach to regulatory decisions involving cancer risk. Procedure A applies to pesticide decisions involving the cancellation, suspension and registration of potentially carcinogenic pesticides. Procedure B applies to other selected Agency decisions where the pivot factor in the decision is cancer risk.

The purpose of these procedures is to assure that appropriate analyses of the risks and benefits of suspected carcinogenic chemicals are performed as part of the regulatory process. Appendices I and II establish guidelines for risk assessment and economic impact analyses. These guidelines are procedural guidelines and are not intended to affect the substantive regulatory standards of any statute. Therefore, the assessment of the risk posed by potentially carcinogenic substances will be made pursuant to the individual standards of the applicable statute and regulations. Furthermore, these analyses will be carried out within the constraints of Agency resources and will not delay actions by the Agency to address urgent environmental problems.

The Cancer Assessment Group (CAG) is an advisory body comprised of senior scientists from within the Agency with a liaison member from the Department of Health, Education and Welfare. It will also utilize, as appropriate, expert consultants and advisors from various Federal Agencies and the private sector. The CAG will conduct analyses of data related to risk and make recommendations to the lead program office and the appropriate Working Group concerning the risk associated with each suspect carcinogen. These analyses will be directed towards risk assessment and will be conducted independently of economic impact analyses. The CAG will also review the final risk assessment portion of the regulatory package.

APPLICABILITY

For all decisions involving the cancellation, suspension, reregistration and registration of potentially carcinogenic pesticides, Procedure A will be followed inclusive of the preparation of (1) a risk assessment pursuant to the interim guidelines contained in Appendix I and (2) an economic impact analysis pursuant to the interim guideline contained in Appendix II.

For the following rulemaking, where the pivotal factor in the decision is cancer risk, the procedures outlined in EPA Order 1000.6 will be followed, and in addition, a risk assessment pursuant to Appendix I will be prepared and will be reviewed in accordance with Procedure B:

1. Proposed regulations to augment the current list of toxic substances published

pursuant to Section 307(a) of the FWPCA and any standard proposed under this augmented list.

2. Primary drinking water regulations or revisions thereof under Section 1412 of SDWA.

3. Additions to or revisions of the water quality criteria (pursuant to Section 304(a) of FWPCA) currently pending publication, except that detailed exposure patterns and estimates of cancer risk need not be prepared.

4. Proposed technology-based regulations or revisions pursuant to Sections 301, 304, 306, 307(b) and 307(c) of the FWPCA (proposed after April 1, 1977), and Section 111 of the CAA, except that detailed exposure patterns and estimates of cancer risk need not be prepared.

For all other rulemaking under existing legislation which involves the regulation of a potential carcinogen(s), and which is not currently under development, the determination of whether and to what extent to use Appendix I and Procedure B will be made at the time the Administrator approves the plan for such rulemaking.

Where the development of a surrogate parameter is being proposed to regulate one or more potential carcinogens and perhaps other pollutants (e.g., a total organic carbon standard for drinking water), the risk assessment, as required above, will address at least one of the potential carcinogens and should address, to the extent feasible, as many of the others as possible.

All risk assessments need only be based on currently available information. These procedures do not require the undertaking of research or monitoring to expand the available data base.

A. Procedure for pesticide decisions involving potential carcinogens. This procedure is similar to the current procedure for informal rulemaking set forth by EPA Order 1000.6.

1. Formation of the working group. The Deputy Assistant Administrator for Pesticides, in cooperation with the Office of Planning and Management, establishes a working group.

2. OPP/working group responsibility. The Office of Pesticide Programs (OPP), in consultation with the Working Group, is responsible for developing a Data Summary Report, a Position Document (including health risk assessment and the economic impact analysis) and a proposed FEDERAL REGISTER notice at the appropriate points in the regulatory process. Guidelines for health risk assessment and economic analysis are included as Appendices I and II.

3. Review of a suspect chemical prior to reregistration or the issuance of a rebuttable presumption against registration (RPAR).

a. Data relevant to the carcinogenicity of a pesticide is submitted to the CAG for review and comment. Following review by the CAG, a Data Summary Report is prepared by OPP and the Working Group. This report includes a summary of all available data relevant to carcinogenicity.

b. A draft Position Document including the Data Summary Report, a summary of the issues surrounding potential regulatory actions, and a proposed FEDERAL REGISTER notice are presented to the Pesticide Chemical Review Committee (PCRC) which includes a representative from the CAG.

c. On the basis of PCRC comments, the OPP and the Working Group revise the draft Position Document and the FEDERAL REGISTER notice. The PCRC reviews the revised package.

d. The package recommending a reregistration or the issuance of a RPAR goes to the Deputy Assistant Administrator for Pesticide Programs for a final decision.

4. Post-RPAR: Issuance of a notice of intent to cancel, suspend or reregister.

a. After a RPAR is issued, and rebuttal information if any is submitted, the OPP and the Working Group develop a final Position Document. This document includes a summary of all information available in rebuttal of the RPAR, a recommended finding on whether or not the presumption against registration has been rebutted (including the risk assessment), economic impact analysis as necessary, a summary of the issues surrounding potential regulatory actions, and a draft FEDERAL REGISTER notice.

b. The final Position Document is reviewed by PCRC and the risk assessment is reviewed by CAG.

c. If the decision is to reregister the product, a notice to this effect is published in the FEDERAL REGISTER.

d. If the decision is to cancel or suspend the product, the proposed notice of intent to cancel or suspend is forwarded to USDA and the Scientific Advisory Panel for comment, pursuant to the 1975 amendments to Section 6(b) of FIFRA. However, if it is determined that suspension of the pesticide is necessary to prevent an imminent hazard to humans, the 1975 amendments provide for waiver of the requirement for consultation with USDA and the Scientific Advisory Panel.

The notice of intent to register, cancel or suspend, including the risk assessment and economic impact analyses, is circulated for General Counsel and Assistant Administrator concurrence and forwarded to the Administrator for a final decision.

B. Other rulemaking to regulate carcinogens. All other Agency decisions involving carcinogenesis as the pivotal factor will follow EPA Order 1000.6 with the following additions:

1. The CAG will review the relevant data during the development of the rulemaking and make recommendations to the lead office and the working group regarding the interpretation of the data and provide other advice, as appropriate, concerning the risk assessment.

2. The CAG will review that portion of the rulemaking package containing the risk assessment. CAG comments will be presented to the Steering Committee.

C. External scientific review. In addition to the external reviews required by statute and the 1000.6 process, other external scientific review will be obtained in appropriate cases as determined by the lead program office. This review may take place at any time in the development of the regulatory package.

While risk and economic impact analyses may be reviewed externally, regulatory recommendations will not normally be submitted for external review. Reviewers for risk analyses may be from the Science Advisory Board, National Cancer Institute, or other appropriate Institutions.

APPENDIX I

INTERIM GUIDELINE FOR CARCINOGEN RISK ASSESSMENT

1.0 Introduction. This preliminary guideline describes the general framework to be followed in developing an analysis of carcinogen risks and some salient principles to be used in evaluating the quality of data and formulating judgments concerning the nature and magnitude of the cancer hazard from suspect carcinogens.

This guideline is to be used within the policy framework already provided by applicable statutes and does not alter such policies. The guideline provides a general format for analyzing and organizing available data. It does not imply that one kind of data or another is prerequisite for regulatory action to control, prohibit, or allow the use of a carcinogen. Also, the guideline does not change any statutory-prescribed standards as to which party has the responsibility of remonstrating the safety, or alternatively the risk, of an agent.

The analysis of health risks will be carried out independently from considerations of the socio-economic consequences of regulatory action.

The risk assessment document will contain or identify by reference the background material essential to substantiate the evaluations contained therein.

2.0 General Principles Concerning the Assessment of Carcinogenesis Data. The central purpose of the health risk assessment[1] is to provide a judgment concerning the weight of evidence that an agent is a potential human carcinogen and, if so, how great an impact it is likely to have on public health.

Judgments about the weight of evidence involve considerations of the quality and adequacy of the data and the kinds of responses induced by the suspect carcinogen. The best evidence that an agent is a human carcinogen comes from epidemiological studies in conjunction with confirmatory animal tests. Substantial evidence is provided by animal tests that demonstrate the induction of malignant tumors in one or more species including benign tumors that are generally recognized as early stages of malignancies. Suggestive evidence includes the induction of only those nonlife shortening benign tumors which are generally accepted as not progressing to malignancy, and indirect tests of tumorigenic activity, such as mutagenicity, in-vitro cell transformation, and initiation-promotion skin tests in mice. Ancillary reasons that bear on judgments about carcinogenic potential, e.g., evidence from systematic studies that relate chemical structure to carcinogenicity should be included in the assessment.

When an agent is judged to be a potential human carcinogen, estimates should be made of its possible impact on public health at current and anticipated levels of exposure. The available techniques for assessing the magnitude of cancer risk to human populations on the basis of animal data only are very crude due to uncertainties in the extrapolation of dose-response data to very low dose levels and also because of differences in levels of susceptibility of animals and humans. Hence, the risk estimates should be regarded only as rough indications of effect. Where appropriate, a range of estimates should be given on the basis of several modes of extrapolation.

Expert scientific judgments in the areas of toxicology, pathology, biometry, and epidemiology are required to resolve uncertainties about the quality, adequacy, and interpretation of experimental and epidemiology data to be used for the risk assessment.

3.0 Format of the Risk Analysis.

3.1 Exposure Patterns. This section should summarize the known and possible modes of exposure attendant to the various uses of the

[1] This health risk assessment is part of the risk-benefit analyses. In actions taken to regulate pesticides, this assessment is made after a determination that a health risk exists

agent. It should include or identify by reference available data on factors relevant to effective dosage, physical and chemical parameters, e.g., solubility, particle size for aerosols, skin penetration, absorption rates, etc. Interaction of agents which may produce a synergistic or antagonistic effect should also be indicated, if available.

3.2 Metabolic Characteristics. This section should summarize known metabolic characteristics including transport, fate and excretion, and biochemical similarities to other known classes of carcinogens at high and low dose levels and should provide comparisons between relevant species as well as variations in different strains of certain species.

3.3 Experimental Carcinogenesis Studies. Available experimental reports should be summarized. If some experiments are to be rejected for the risk assessment, give reasons for doing so. Reprints of key papers and reports should be included as appendices to the analysis.

Judgements should be provided on the quality of the experimental data and their interpretations for each study on the basis of (a) experimental protocols, (b) survival rates in controls particularly in relation to acceptance of negative results, (c) incidence of spontaneous tumors in the control compared to general laboratory experience for the same species or strain, (d) diagnostic criteria and nomenclature used for tumor characterization (additional evaluation of histological material should be obtained when appropriate), and (e) observed results of positive controls (i.e., a test group given a standardized exposure to a known carcinogen) in light of expected results.

3.4 Epidemiological Studies. Summarize epidemiological studies, together with critiques of the work with respect to its limitations and significance. Summarize other published critiques whether supportive or at variance with the judgement made here.

3.5 Cancer Risk Estimates.

3.5.1 Exposure Patterns. Describe likely exposure levels with respect to long-term temporal trends, short-term temporal patterns, and weighted averages for both the total exposed populations and for subgroups whose exposure patterns may be distinctly different from the average. Characterize, to the extent possible, the size of the exposed population for each of the above categories with an indication of whether the exposures are likely to involve children and pregnant women. Discuss the adequacy of the methods used to estimate exposures and indicate the range of uncertainty in the estimates.

3.5.2 Dose-Response Relationships. Both human and animal data should be used as available. Include available human data, even if inadequate for a characterization of the actual magnitude of risk, where such data could be helpful in interpreting animal responses in relation to human sensitivity.

3.5.3 Estimates of Cancer Risk. The procedure will involve a variety of risk extrapolation models, e.g., the linear non-threshold model and the log-probit model. Analyses will be done separately for all suitable experimental data and human epidemiological data. The results should be presented in terms of excess lifetime incidence, or average excess cancer rates; life-shortening estimates should also be made when the data permit. The uncertainty in the data and extrapolation techniques should be clearly indicated. The results predicted for humans should be presented in relationship to the current cancer experience in the assumed target organ(s).

Some judgements should be included regarding the relevance of the mode of exposure used in animal studies to that associated with human exposure.

4.0 Summary. The summary section of the risk assessment should provide a statement which encompasses answers to the following questions: (1) How likely is the agent to be a human carcinogen? (2) If the agent is a human carcinogen, what is the estimated impact on human health?

Appendix II

Interim Guideline for Economic Impact Analysis of Proposed Regulatory Actions to Control Carcinogenic Pesticides

The purpose of this guideline is to define the factors to be considered and the procedures to be utilized in assessing the economic impact resulting from future regulatory actions, (as described below) affecting carcinogenic pesticides. Economic impact assessment for other regulatory actions to control environmental carcinogens will follow established agency procedures.

The principal concern in the economic analysis will be the assessment of economic impacts on pesticides users and on the consumers of the products of the users. The impacts on pesticide manufacturers are not germane to this type of regulatory decision, in which the risk of the use of a pesticide is compared to the benefit of those uses.

As used in this guideline the economic impact of the regulation is equated to the anticipated loss in benefit from use of the pesticide. For agricultural pesticides the analysis will focus on the impacts on farmers, farm productivity, and consumer costs associated with farm productivity. Similarly, analyses of other pesticides will focus on the impacts on other user groups and related effects on the economy.

Regulatory procedures. The purpose of this section of the guidelines is to define how the economic impact analysis fits into the regulatory framework for pesticide-related actions.

If a pesticide meets or exceeds criteria defined in 40 CFR 162.11, a Rebuttable Presumption Against Registration (RPAR) will be issued. The Agency will analyze any rebuttal information that is submitted; it may also take into account other available information to determine whether the RPAR has been rebutted. At the conclusion of this risk assessment, the Administrator will be presented with sufficient evidence to determine if the use of a pesticide poses the risk of a significant adverse effect. If such is the case, then the Administrator must determine what type of regulatory response is warranted.

In making that decision, 40 CFR 162.11 provides that the Administrator will be provided with a preliminary assessment of the benefits of the use of the pesticide. Furthermore, § 162.11 essentially provides: (1) That if the risks appear to outweigh the benefits, the Administrator will issue a notice of intent to cancel, which may lead to a full adjudicatory hearing on the question of whether the pesticide causes or will cause unreasonable adverse effects on the environment, or (2) if the benefits appear to outweigh the risks, the Administrator will either issue a notice of intent to hold a hearing (adjudicatory or non-adjudicatory) or a notice of intent to register. Such notice of intent to register provides an opportunity for a hearing upon request (accompanied by submission of a statement of factual reasons) of an interested party that a hearing is warranted. The decision to cancel reached at this time will not result in the removal of a product from the market if the decision is contested. Instead, any such regulatory action will be preceded by a hearing to weigh fully the risks and benefits of the uses of a product.

The benefit evidence provided to the Administrator at this stage is by definition a preliminary staff analysis. A specific effort will be made by the Agency to contact parties that have an interest in the use of the pesticide and to attempt to solicit their comments on the benefits of the pesticide under review. In particular, EPA intends that the U.S. Department of Agriculture will be heavily relied upon from the earliest stages of review to provide its special expertise and data resources on uses.

Because of the many variables surrounding the multiple uses of different pesticides, the benefit or economic impact analysis must of necessity be done on a case-by-case basis. All relevant economic considerations raised in criticisms of the preliminary benefit analysis will be addressed prior to final action.

Content of the economic impact analyses

Based upon all the available information, a preliminary analysis will be developed. Such analysis will be organized in the following manner:

1. Identification of the major uses of the pesticide, including estimated quantities used by crop or other application.
2. Preliminary identification of the minor uses of the pesticide, including estimated quantities used by category such as lawn and garden uses and household uses.
3. Identification of registered alternative products for the uses set forth in (1) and (2) above, including an estimate of their availability.
4. Determination of the change in costs to the use of providing equivalent pesticide treatment with any available substitute products.
5. Assessment of regulation impact upon user productivity (e.g., yield per acre and/or total output) from using available substitute pesticides or from using no other pesticide.
6. If the impacts upon either user costs or productivity are significant, a qualitative assessment of the regulation's impact on production of major agricultural commodities and retail food prices of such commodities.

[FR Doc.76-15254 Filed 5-24-76;8:45 am]

[FRL 547-8; PP4G1495/T59]

RENEWAL OF A TEMPORARY TOLERANCE

2-Ethoxy-2,3-Dihydro-3,3-Dimethyl-5-Benzofuranyl Methanesulfonate

On March 11, 1976, the Environmental Protection Agency (EPA) announced (41 FR 10476) that in response to a request from the Fisons Corp., Agricultural Chemicals Div., Two Preston Court, Bedford MA 01730, the temporary tolerances which were established in response to pesticide petition (PP 4G1495) (40 FR 6389) for combined residues of the herbicide 2-ethoxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl methanesulfonate and its metabolites 2 - hydroxy-2,3-dihydro-3,3-dimethyl - 5-benzofuranyl methanesulfonate and 2,3-dihydro-3,3-dimethyl-2-oxo - 5-benzofuranyl methanesulfonate (both calculated as the parent compound) in or on the raw agricultural commodities sugarbeet tops at 1 part per million (ppm), sugarbeet roots at 0.1 ppm, and in the meat, fat, and meat byproducts cattle, goats, hogs, horses, and sheep at 0.03 ppm, were extended until April 4, 1976.

ENVIRONMENTAL PROTECTION AGENCY

[FRL 1623-3]

Water Quality Criteria Documents; Availability

AGENCY: Environmental Protection Agency.

ACTION: Notice of Water Quality Criteria Documents.

SUMMARY: EPA announces the availability and provides summaries of water quality criteria documents for 64 toxic pollutants or pollutant categories. These criteria are published pursuant to section 304(a)(1) of the Clean Water Act.

AVAILABILITY OF DOCUMENTS: Summaries of both aquatic-based and health-based criteria from the documents are published below. Copies of the complete documents for individual pollutants may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, (703-487-4650). A list of the NTIS publication order numbers for all 64 criteria documents is published below. These documents are also available for public inspection and copying during normal business hours at: Public Information Reference Unit, U.S. Environmental Protection Agency, Room 2404 (rear), 401 M St., S.W., Washington, D.C. 20460. As provided in 40 CFR Part 2, a reasonable fee may be charged for copying services. Copies of these documents are also available for review in the EPA Regional Office libraries.

Copies of the documents are not available from the EPA office listed below. Requests sent to that office will be forwarded to NTIS or returned to the sender.

1. Acenaphthene, PB81-117269.
2. Acrolein, PB81-117277.
3. Acrylonitrile, PB81-117285.
4. Aldrin/Dieldrin, PB81-117301.
5. Antimony, PB81-117319.
6. Arsenic, PB81-117327.
7. Asbestos, PB81-117335.
8. Benzene, PB81-117293.
9. Benzidine, PB81-117343.
10. Beryllium, PB81-117350.
11. Cadmium, PB81-117368.
12. Carbon Tetrachloride, PB81-117376.
13. Chlordane, PB81-117384.
14. Chlorinated benzenes, PB81-117392.
15. Chlorinated ethanes, PB81-117400.
16. Chloroalkyl ethers, PB81-117418.
17. Chlorinated naphthalene, PB81-117426.
18. Chlorinated phenols, PB81-117434.
19. Chloroform, PB81-117442.
20. 2-chlorophenol, PB81-117459.
21. Chromium, PB81-117467.
22. Copper, PB81-117475.
23. Cyanides, PB81-117483.
24. DDT, PB81-117491.
25. Dichlorobenzenes, PB81-117509.
26. Dichlorobenzidine, PB81-117517.
27. Dichloroethylenes, PB81-117525.
28. 2,4-dichlorophenol, PB81-117533.
29. Dichloropropanes/propenes, PB81-117541.
30. 2,4-dimethylphenol, PB81-117558.
31. Dinitrotoluene, PB81-117566.
32. Diphenylhydrazine, PB81-117731.
33. Endosulfan, PB81-117574.
34. Endrin, PB81-117582.
35. Ethylbenzene, PB81-117590.
36. Fluoranthene, PB81-117608.
37. Haloethers, PB81-117616.
38. Halomethanes, PB81-117624.
39. Heptachlor, PB81-117632.
40. Hexachlorobutadiene, PB81-117640.
41. Hexachlorocyclohexane, PB81-117657.
42. Hexachlorocyclopentadiene, PB81-117665.
43. Isophorone, PB81-117673.
44. Lead, PB81-117681.
45. Mercury, PB81-117699.
46. Naphthalene, PB81-117707.
47. Nickel, PB81-117715.
48. Nitrobenzene, PB81-117723.
49. Nitrophenols, PB81-117749.
50. Nitrosamines, PB81-117756.
51. Pentachlorophenol, PB81-117764.
52. Phenol, PB81-117772.
53. Phthalate esters, PB81-117780.
54. Polychlorinated biphenyls (PCBs), PB81-117798.
55. Polynuclear aromatic hydrocarbons, PB81-117806.
56. Selenium, PB81-117814.
57. Silver, PB81-117822.
58. Tetrachloroethylene, PB81-117830.
59. Thallium, PB81-117848.
60. Toluene, PB81-117855.
61. Toxaphene, PB81-117863.
62. Trichloroethylene, PB81-117871.
63. Vinyl chloride, PB81-117889.
64. Zinc, PB81-117897.

FOR FURTHER INFORMATION CONTACT: Dr. Frank Gostomski, Criteria and Standards Division (WH-585), United States Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, (202) 245-3042.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to section 304(a)(1) of the Clean Water Act, 33 U.S.C. 1314(a)(1), EPA is required to periodically review and publish criteria for water quality accurately reflecting the latest scientific knowledge:

(A) on the kind and extent of all identifiable effects on health and welfare including, but not limited to, plankton, fish, shellfish, wildlife, plant life, shorelines, beaches, esthetics, and recreation which may be expected from the presence of pollutants in any body of water, including groundwater, (B) on the concentration and dispersal of pollutants, or their byproducts, through biological, physical, and chemical processes, and (C) on the effects of pollutants on biological community diversity, productivity, and stability, including information on the factors affecting rates of eutrophication and rates of organic and inorganic sedimentation for varying types of receiving waters.

EPA is today announcing the availability of criteria documents for 64 of the 65 pollutants designated as toxic under section 307(a)(1) of the Act. The document on TCDD (Dioxin) will be published within the next month after review of recent studies. Criteria for the section 307(a)(1) toxic pollutants being published today will replace the criteria for those same pollutants found in the EPA publication, *Quality Criteria for Water*, (the "Red Book.") Criteria for all other pollutants and water constituents found in the "Red Book" remain valid. The criteria published today have been derived using revised methodologies for determining pollutant concentrations that will, when not exceeded, reasonably protect human health and aquatic life. Draft criteria documents were made available for public comment (44 FR 15926, March 15, 1979, 44 FR 43660, July 25, 1979, 44 FR 56628, October 1, 1979). These final criteria have been derived after consideration of all comments received.

These criteria documents are also issued in satisfaction of the Settlement Agreement in *Natural Resources Defense Council, et al.* v. *Train*, 8 E.R.C. 2120 (1976), modified, 12 E.R.C. 1833 (D.D.C. 1979). Pursuant to paragraph 11 of that agreement, EPA is required to publish criteria documents for the 65 pollutants which Congress, in the 1977 amendments to the Act, designated as toxic under section 307(a)(1). These documents contain recommended maximum permissible pollutant concentrations consistent with the protection of aquatic organisms, human health, and some recreational activities. Although paragraph 11 imposes certain obligations on the Agency, it does not create additional authority.

The Development of Water Quality Criteria

Section 304(a)(1) criteria contain two essential types of information: (1) discussions of available scientific data on the effects of pollutants on public health and welfare, aquatic life and recreation, and (2) quantitative concentrations or qualitative assessments of the pollutants in water which will generally ensure water

quality adequate to support a specified water use. Under section 304(a)(1), these criteria are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Criteria values do not reflect considerations of economic or technological feasibility.

Publication of water quality criteria of this type has been an ongoing process which EPA, and its predecessor Agency, the Federal Water Pollution Control Administration, have been engaged in since 1968. At that time the first Federal compilation of water quality criteria, the so-called "Green Book" *(Water Quality Criteria)*, was published. As now, these criteria contained both narrative discussions of the environmental effects of pollutants on a range of possible uses and concentrations of pollutants necessary to support these uses. Since that time, water quality criteria have been revised and expanded with publication of the "Blue Book" *(Water Quality Criteria 1972)* in 1973 and the "Red Book" *(Quality Criteria for Water)* in 1976.

Since publication of the Red Book there have been substantial changes in EPA's approach to assessing scientific data and deriving section 304(a)(1) criteria. Previous criteria were derived from a limited data base. For many pollutants, an aquatic life criterion was derived by multiplying the lowest concentration known to have acute lethal effect on half of a test group of an aquatic species (the LC50 value) by an application factor in order to protect against chronic effects. If data showed a substance to be bioaccumulative or to have other significant long-term effects, a factor was used to reduce the indicated concentrations to a level presumed to be protective. Criteria for the protection of human health were similarly derived by considering the pollutants' acute, chronic, and bioaccumulative effects on non-human mammals and humans.

Although a continuation of the process of criteria development, the criteria published today were derived using revised methodologies (Guidelines) for calculating the impact of pollutants on human health and aquatic organisms. These Guidelines consist of systematic methods for assessing valid and appropriate data concerning acute and chronic adverse effects of pollutants on aquatic organisms, non-human mammals, and humans. By use of these data in prescribed ways, criteria are formulated to protect aquatic life and human health from exposure to the pollutants. For some pollutants, bioconcentration properties are used to formulate criteria protective of aquatic life uses. For almost all of the pollutants, bioconcentration properties are used to assess the relative extent of human exposure to the pollutant either directly through ingestion of water or indirectly through consumption of aquatic organisms. Human health criteria for carcinogens are presented as incremental risks to man associated with specific concentrations of the pollutant in ambient water. The Guidelines used to derive criteria protective of aquatic life and human health are fully described in appendices B and C, respectively, of this Notice.

The Agency believes that these Guidelines provide criteria which more accurately reflect the effects of these pollutants on human health and on aquatic organisms and their uses. They are based on a more rational and consistent approach for using scientific data. These Guidelines were developed by EPA scientists in consultation with scientists from outside the Agency and they have been subjected to intensive public comment.

Neither the Guidelines nor the criteria are considered inflexible doctrine. Even at this time, EPA is taking action to employ the resources of peer review groups, including the Science Advisory Board, to evaluate recently published data, and EPA is conducting its own evaluation of new data to determine whether revisions to the criteria documents would be warranted.

The criteria published today are based solely on the effect of a single pollutant. However, pollutants in combination may have different effects because of synergistic, additive, or antagonistic properties. It is impossible in these documents to quantify the combined effects of these pollutants, and persons using criteria should be aware that site-specific analysis of actual combinations of pollutants may be necessary to give more precise indications of the actual environmental impacts of a discharge.

Relationship of the Section 304(a)(1) Criteria to Regulatory Programs

Section 304(a)(1) criteria are not rules and they have no regulatory inpact. Rather, these criteria present scientific data and guidance on the enviromental effect of pollutants which can be useful to derive regulatory requirements based on considerations of water quality impacts. Under the Clean Water Act, these regulatory requirements may include the promulgation of water quality-based effluent limitations under section 302, water quality standards under section 303, or toxic pollutant effluent standards under section 307. States are encouraged to begin to modify or, if necessary, develop new programs necessary to support the implementation of regulatory controls for toxic pollutants. As appropriate, States may incorporate criteria for toxic pollutants, based on this guidance, into their water quality standards.

Section 304(a)(1) criteria have been most closely associated with the development of State water quality standards, and the "Red Book" values have, in the past, been the basis for EPA's assessments of the adequacy of State requirements. However, EPA is now completing a major review of its water quality standards policies and regulations. After consideration of comments received on an Advance Notice of Proposed Rulemaking (43 FR 29588, July 10, 1978) and the draft criteria documents, the Agency intends to propose, by the end of this year, a revised water quality standards regulation which will clarify the Agency's position on a number of significant standards issues.

With the publication of these criteria, however, it is appropriate to discuss EPA's current thinking on standards issues relating to their use. This discussion does not establish new regulatory requirements and is intended as guidance on the possible uses of these criteria and an indication of future rulemaking the Agency may undertake. No substantive requirements will be established without further opportunity for public comment.

Water Quality Standards

Section 303 of the Clean Water Act provides that water quality standards be developed for all surface waters. A water quality standard consists basically of two parts: (1) A "designated use" for which the water body is to be protected (such as "agricultural," "recreation" or "fish and wildlife"), and (2) "criteria" which are numerical pollutant concentration limits or narrative statements necessary to preserve or achieve the designated use. A water quality standard is developed through State or Federal rulemaking proceedings and must be translated into enforceable effluent limitations in a point source (NPDES) permit or may form the basis of best management practices applicable to nonpoint sources under section 208 of the Act.

Relationship of Section 304(a)(1) Criteria to the Criteria Component of State Water Quality Standards:

In the ANPRM, EPA announced a policy of "presumptive applicability" for

section 304(a)(1) criteria codified in the "Red Book." Presumptive applicability meant that a State had to adopt a criterion for a particular water quality parameter at least as stringent as the recommendation in the Red Book unless the State was able to justify a less stringent criterion based on: natural background conditions, more recent scientific evidence, or local, site-specific information. EPA is rescinding the policy of presumptive applicability because it has proven to be too inflexible in actual practice.

Although the section 304(a)(1) criteria represent a reasonable estimate of pollutant concentrations consistent with the maintenance of designated water uses, States may appropriately modify these values to reflect local conditions. In certain circumstances, the criteria may not accurately reflect the toxicity of a pollutant because of the effect of local water quality characteristics or varying sensitivities of local populations. For example, in some cases, ecosystem adaptation may enable a viable, balanced aquatic population to exist in waters with high natural background levels of certain pollutants. Similarly, certain compounds may be more or less toxic in some waters because of differences in alkalinity, temperature, hardness, and other factors.

Methods for adjusting the section 304(a)(1) criteria to reflect these local differences are discussed below.

Relationship of Section 304(a)(1) Criteria to Designated Water Uses:

The criteria published today can be used to support the designated uses which are generally found in State standards. The following section discusses the relationship between the criteria and individual use classifications. Where a water body is designated for more than one use, criteria necessary to protect the most sensitive use should be applied.

1. *Recreation:* Recreational uses of water include such activities as swimming, wading, boating and fishing. Although insufficient data exist on the effects of toxic pollutants resulting from exposure through such primary contact as swimming, section 304(a)(1) criteria based on human health effects may be used to support this designated use where fishing is included in the State definition of "recreation." In this situation only the portion of the criterion based on fish consumption should be used.

2. *Protection and Propagation of Fish and Other Aquatic Life:* The section 304(a)(1) criteria based on toxicity to aquatic life may be used directly to support this designated use.

3. *Agricultural and Industrial Uses:* The section 304(a)(1) criteria were not specifically developed to reflect the impact of pollutants on agricultural and industrial uses. However, the criteria developed for human health and aquatic life are sufficiently stringent to protect these other uses. States may establish criteria specifically designed to protect these uses.

4. *Public Water Supply:* The drinking water exposure component of the human health effects criteria can apply directly to this use classification or may be appropriately modified depending upon whether the specific water supply system falls within the auspices of the Safe Drinking Water Act's (SDWA) regulatory control, and the type and level of treatment imposed upon the supply before delivery to the consumer. The SDWA controls the presence of toxic pollutants in finished ("end-of-tap") drinking water. A brief description of relevant sections of this Act is necessary to explain how the SDWA will work in conjunction with section 304(a)(1) criteria in protecting human health from the effects of toxics due to consumption of water.

Pursuant to section 1412 of the SDWA, EPA has promulgated "National Interim Primary Drinking Water Standards" for certain organic and inorganic substances. These standards establish "maximum contaminant levels" ("MCLs") which specify the maximum permissible level of a contaminant in water which may be delivered to a user of a public water system now defined as serving a minimum of 25 people. MCLs are established based on consideration of a range of factors including not only the health effects of the contaminants but also technological and economic feasibility of the contaminants' removal from the supply. EPA is required to establish revised primary drinking water regulations based on the effects of a contaminant on human health, and include treatment capability, monitoring availability, and costs. Under Section 1401(1)(D)(i) of the SDWA, EPA is also allowed to establish the minimum quality criteria for water which may be taken into a public water supply system.

Section 304(a)(1) criteria provide estimates of pollutant concentrations protective of human health, but do not consider treatment technology, costs and other feasibility factors. The section 304(a)(1) criteria also include fish bioaccumulation and consumption factors in addition to direct human drinking water intake. These numbers were not developed to serve as "end of tap" drinking water standards, and they have no regulatory significance under the SDWA. Drinking water standards are established based on considerations, including technological and economic feasibility, not relevant to section 304(a)(1) criteria. Section 304(a)(1) criteria may be analogous to the recommended maximum contaminant levels (RMCLs) under section 1412(b)(1)(B) of the SDWA in which, based upon a report from the National Academy of Sciences, the Administrator should set target levels for contaminants in drinking water at which "no known or anticipated adverse effects occur and which allows an adequate margin of safety". RMCLs do not take treatment, cost, and other feasibility factors into consideration. Section 304(a)(1) criteria are, in concept, related to the health-based goals specified in the RMCLs. Specific mandates of the SDWA such as the consideration of multi-media exposure, as well as different methods for setting maximum contaminant levels under the two Acts, may result in differences between the two numbers.

MCLs of the SDWA, where they exist, control toxic chemicals in finished drinking water. However, because of variations in treatment and the fact that only a relatively small number of MCLs have been developed, ambient water criteria may be used by the States as a supplement to SDWA regulations. States will have the option of applying MCLs, section 304(a)(1) human health effects criteria, modified section 304(a)(1) criteria or controls more stringent than these three to protect against the effects of toxic pollutants by ingestion from drinking water.

For untreated drinking water supplies, States may control toxics in the ambient water through either use of MCLs (if they exist for the pollutants of concern), section 304(a)(1) human health effects criteria, or a more strigent contaminant level than the former two options.

For treated drinking water supplies serving less than 25 people, States may choose toxics control through application of MCLs (if they exist for the pollutants of concern and are attainable by the type of treatment) in the finished drinking water. States also have the options to control toxics in the ambient water by choosing section 304(a)(1,) criteria, adjusted section 304(a)(1) criteria resulting from the reduction of the direct drinking water exposure component in the criteria calculation to the extent that the treatment procedure reduces the level of pollutants, or a more stringent contaminant level than the former three options.

For treated drinking water supplies serving 25 people or greater, States *must* control toxics down to levels at least as stringent as MCLs (where they exist for

the pollutants of concern) in the finished drinking water. However, States also have the options to control toxics in the ambient water by choosing section 304(a)(1) criteria, adjusted section 304(a)(1) criteria resulting from the reduction of the direct drinking water exposure component in the criteria calculation to the extent that the treatment process reduces the level of pollutants, or a more stringent contaminant level than the former three options.

Inclusion of Specific Pollutants in State Standards:

To date, EPA has not required that a State address any specific pollutant in its standards. Although all States have established standards for most conventional pollutants, the treatment of toxic pollutants has been much less extensive. In the ANPRM, EPA suggested a policy under which States would be required to address a set of pollutants and incorporate specific toxic pollutant criteria into water quality standards. If the State failed to incorporate these criteria, EPA would promulgate the standards based upon these criteria pursuant to section 303(c)(4)(B).

In the forthcoming proposed revision to the water quality standard regulations, a significant change in policy will be proposed relating to the incorporation of certain pollutants in State water quality standards. This proposal will differ from the proposal made in the ANPRM. The ANPRM proposed an EPA-published list of pollutants for which States would have had to develop water quality standards. This list might have contained some (or all) of the 65 toxic pollutants. However, the revised water quality standards regulation will propose a process by which EPA will assist States in identifying specific toxic pollutants required for assessment for possible inclusion in State water quality standards. For these pollutants, States will have the option of adopting the published criteria or of adjusting those criteria based on site-specific analysis.

These pollutants would generally represent the greatest threat to sustaining a healthy, balanced ecosystem in water bodies or to human health due to exposure directly or indirectly from water. EPA is currently developing a process to determine which pollutants a State must assess for possible inclusion in its water quality standards. Relevant factors might include the toxicity of the pollutant, the frequency and concentration of its discharge, its geographical distribution, the breadth of data underlying the scientific assessment of its aquatic life and human health effects, and the technological and economic capacity to control the discharge of the pollutant. For some of the pollutants, all States may be required to assess them for possible inclusion in their standards. For others, assessment would be restricted to States or limited to specific water bodies where the pollutants pose a particular site-specific problem.

Criteria Modification Process

Flexibility is available in the application of these and any other valid water quality criteria to regulatory programs. Although in some cases they may be used by the States as developed, the criteria may be modified to refect local environmental conditions and human exposure patterns before incorporation into programs such as water quality standards. If significant impacts of site-specific water quality conditions in the toxicities of pollutants can be demonstrated or significantly different exposure patterns of these pollutants to humans can be shown, section 304(a)(1) criteria may be modified to reflect these local conditions. The term "local" may refer to any appropriate geographic area where common aquatic environmental conditions or exposure patterns exist. Thus, "local" may signify a Statewide, regional, river reach, or entire river basin area. On the other hand, the criteria of some pollutants might be applicable nationwide without the need for adaptation to reflect local conditions. The degree of toxicity toward aquatic organisms and humans characteristic of these pollutants would not change significantly due to local water quality conditions.

EPA is examining a series of environmental factors or water quality parameters which might realistically be expected to affect the laboratory-derived water quality criterion recommendation for a specific pollutant. Factors such as hardness, pH, suspended solids, types of aquatic organisms present, etc. could impact on the chemical's effect in the aquatic environment. Therefore, local information can be assembled and analyzed to adjust the criterion recommendation if necessary.

The Guidelines for deriving criteria for the protection of aquatic life suggest several approaches for modifying the criteria. First, toxicity data, both acute and chronic, for local species could be substituted for some or all of the species used in deriving criteria for the water quality standard. The minimum data requirements should still be fulfilled in calculating a revised criterion. Second, criteria may be specifically tailored to a local water body by use of data from toxicity tests performed with that ambient water. A procedure such as this would account for local environmental conditions in formulating a criterion relevant to the local water body. Third, site-specific water quality characteristics resulting in either enhancement or mitigation of aquatic life toxicity for the pollutant could be factored into final formulation of the criterion. Finally, the criteria may be made more stringent to ensure protection of an individual species not otherwise adequately protected by any of the three modification procedures previously mentioned.

EPA does not intend to have States assess every local stream segment and lake in the country on an individual basis before determining if an adjustment is necessary. Rather, it is envisioned that water bodies having similar hydrological, chemical, physical, and biological properties will be grouped for the purpose of criteria adjustment. The purpose of this effort is to assist States in adapting the section 304(a) criteria to local conditions where needed, thereby precluding the setting of arbitrary and perhaps unnecessarily stringent or underprotective criteria in a water body. In all cases, EPA will still be required, pursuant to section 303(c), to determine whether the State water quality standards are consistent with the goals of the Act, including a determination of whether State-established criteria are adequate to support a designated use.

Criteria for the Protection of Aquatic Life

Interpretation of the Criteria

The aquatic life criteria issued today are summarized in Appendix A of this Federal Register notice. Criteria have been formulated by applying a set of Guidelines to a data base for each pollutant. The criteria for the protection of aquatic life specify pollutant concentrations which, if not exceeded, should protect most, but not necessarily all, aquatic life and its uses. The Guidelines specify that criteria should be based on an array of data from organisms, both plant and animal, occupying various trophic levels. Based on these data, criteria can be derived which should be adequate to protect the types of organisms necessary to support an aquatic community.

The Guidelines are not designed to derive criteria which will protect all life stages of all species under all conditions. Generally some life stage of one or more tested species, and

probably some untested species, will have sensitivities below the maximum value or the 24-hour average under some conditions and would be adversely affected if the highest allowable pollutant concentrations and the worst conditions existed for a long time. In actual practice, such a situation is not likely to occur and thus the aquatic community as a whole will normally be protected if the criteria are not exceeded. In any aquatic community there is a wide range of individual species sensitivities to the effects of toxic pollutants. A criterion adequate to protect the most susceptible life stage of the most sensitive species would in many cases be more stringent than necessary to protect the overall aquatic community.

The aquatic life criteria specify both maximum and 24-hour average values. The combination of the two values is designed to provide adequate protection of aquatic life and its uses from acute and chronic toxicity and bioconcentration without being as restrictive as a one-number criterion would have to be to provide the same amount of protection. A time period of 24 hours was chosen in order to ensure that concentrations not reach harmful levels for unacceptably long periods. Averaging for longer periods, such as a week or a month for example, could permit high concentrations to persist long enough to produce significant adverse effects. A 24-hour period was chosen instead of a slightly longer or shorter period in recognition of daily fluctuations in waste discharges and of the influence of daily cycles of sunlight and darkness and temperature on both pollutants and aquatic organisms.

The maximum value, which is derived from acute toxicity data, prevents significant risk of adverse impact to organisms exposed to concentrations above the 24-hour average. Merely specifying the average value over a specified time period is insufficient because concentrations of chemicals higher than the average value can kill or cause irreparable damage in short periods. Furthermore, for some chemicals the effect of intermittent high exposures is cumulative. It is therefore necessary to place an upper limit on pollutant concentrations to which aquatic organisms might be exposed. The two-number criterion is intended to describe the highest average ambient water concentration which will produce a water quality generally suited to the maintenance of aquatic life while restricting the extent and duration of the excursions over that average to levels which will not cause harm. The only way to assure the same degree of protection with a one-number criterion would be to use the 24-hour average as a concentration that is not to be exceeded at any time in any place.

Since some substances may be more toxic in freshwater than in saltwater, or vice versa, provision is made for deriving separate water quality criteria for freshwater and for saltwater for each substance. However, for some substances sufficient data may not be available to derive one or both of these criteria using the Guidelines.

Specific aquatic life criteria have not been developed for all of the 65 toxic pollutants. In those cases where there were insufficient data to allow the derivation of a criterion, narrative descriptions of apparent threshold levels for acute and/or chronic effects based on the available data are presented. These descriptions are intended to convey a sense of the degree of toxicity of the pollutant in the absence of a criterion recommendation.

Summary of the Aquatic Life Guidelines

The Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and its Uses were developed to describe an objective, internally consistent, and appropriate way of ensuring that water quality criteria for aquatic life would provide, on the average, a reasonable amount of protection without an unreasonable amount of overprotection or underprotection. The resulting criteria are not intended to provide 100 percent protection of all species and all uses of aquatic life all of the time, but they are intended to protect most species in a balanced, healthy aquatic community. The Guidelines are published as Appendix B of this Notice. Responses to public comments on these Guidelines are attached as Appendix D.

Minimum data requirements are identified in four areas: acute toxicity to animals (eight data points), chronic toxicity to animals (three data points), toxicity to plants, and residues. Guidance is also given for discarding poor quality data.

Data on acute toxicity are needed for a variety of fish and invertebrate species and are used to derive a Final Acute Value. By taking into account the number and relative sensitivities of the tested species, the Final Acute Value is designed to protect most, but not necessarily all, of the tested and untested species.

Data on chronic toxicity to animals can be used to derive a Final Chronic Value by two different means. If chronic values are available for a specified number and array of species, a final chronic value can be calculated directly. If not, an acute-chronic ratio is derived and then used with the Final Acute Value to obtain the Final Chronic Value.

The Final Plant Value is obtained by selecting the lowest plant toxicity value based on measured concentrations.

The Final Residue Value is intended to protect wildlife which consume aquatic organisms and the marketability of aquatic organisms. Protection of the marketability of aquatic organisms is, in actuality, protection of a use of that water body ("commercial fishery"). Two kinds of data are necessary to calculate the Final Residue Value: a bioconcentration factor (BCF) and a maximum permissible tissue concentration, which can be an FDA action level or can be the result of a chronic wildlife feeding study. For lipid soluble pollutants, the BCF is normalized for percent lipids and then the Final Residue Value is calculated by dividing the maximum permissible tissue concentration by the normalized BCF and by an appropriate percent lipid value. BCFs are normalized for percent lipids since the BCF measured for any individual aquatic species is generally proportional to the percent lipids in that species.

If sufficient data are available to demonstrate that one or more of the final values should be related to a water quality characteristic, such as salinity, hardness, or suspended solids, the final value(s) are expressed as a function of that characteristic.

After the four final values (Final Acute Value, Final Chronic Value, Final Plant Value, and Final Residue Value) have been obtained, the criterion is established with the Final Acute Value becoming the maximum value and the lowest of the other three values becoming the 24-hour average value. All of the data used to calculate the four final values and any additional pertinent information are then reviewed to determine if the criterion is reasonable. If sound scientific evidence indicates that the criterion should be raised or lowered, appropriate changes are made as necessary.

The present Guidelines have been revised from the earlier published versions (43 FR 21506, May 18, 1978; 43 FR 29028, July 5, 1978; 44 FR 15926, March 15, 1979). Details have been added in many places and the concept of a minimum data base has been incorporated. In addition, three adjustment factors and the species sensitivity factor have been deleted. These modifications were the result of the Agency's analysis of public comments and comments received from the Science Advisory Board on earlier

versions of the Guidelines. These comments and the Resultant modifications are addressed fully in Appendix D to this notice.

Criteria for the Protection of Human Health

Interpretation of the Human Health Criteria

The human health criteria issued today are summarized in Appendix A of this Federal Register notice. Criteria for the protection of human health are presented for 62 of the 65 pollutants based on their carcinogenic, toxic, or organoleptic (taste and odor) properties. The meanings and practical uses of the criteria values are distinctly different depending on the properties on which they are based.

The objective of the health assessment portions of the criteria documents is to estimate ambient water concentrations which, in the case of non-carcinogens, prevent adverse health effects in humans, and in the case of suspect or proven carcinogens, represent various levels of incremental cancer risk.

Health assessments typically contain discussions of four elements: Exposure, pharmacokinetics, toxic effects, and criterion formulation.

The exposure section summarizes information on exposure routes: ingestion directly from water, indirectly from consumption of aquatic organisms found in ambient water, other dietary sources, inhalation, and dermal contact. Exposure assumptions are used to derive human health criteria. Most criteria are based solely on exposure from consumption of water containing a specified concentration of a toxic pollutant and through consumption of aquatic organisms which are assumed to have bioconcentrated pollutants from the water in which they live. Other multimedia routes of exposure such as air, non-aquatic diet, or dermal are not factored into the criterion formulation for the vast majority of pollutants due to lack of data. The criteria are calculated using the combined aquatic exposure pathway and also using the aquatic organism ingestion exposure route alone. In criteria reflecting both the water consumption and aquatic organism ingestion routes of exposure, the relative exposure contribution varies with the propensity of a pollutant to bioconcentrate, with the consumption of aquatic organisms becoming more important as the bioconcentration factor (BCF) increases. As additional information on total exposure is assembled for pollutants for which criteria reflect only the two specified aquatic exposure routes, adjustments in water concentration values may be made. The Agency intends to publish guidance which will permit the States to identify significantly different exposure patterns for their populations. If warranted by the demonstration of significantly different exposure patterns, this will become an element of a process to adapt/modify human health-based criteria to local conditions, somewhat analogous to the aquatic life criteria modification process discussed previously. It is anticipated that States at their discretion will be able to set appropriate human health criteria based on this process.

The pharmacokinetics section reviews data on absorption, distribution, metabolism, and excretion to assess the biochemical fate of the compounds in the human and animal system. The toxic effects section reviews data on acute, subacute, and chronic toxicity, synergistic and antagonistic effects, and specific information on mutagenicity, teratogenicity, and carcinogenicity. From this review, the toxic effect to be protected against is identified taking into account the quality, quantity, and weight of evidence characteristic of the data. The criterion formulation section reviews the highlights of the text and specifies a rationale for criterion development and the mathematical derivation of the criterion number.

Within the limitations of time and resources, current published information of significance was incorporated into the human health assessments. Review articles and reports were used for data evaluation and synthesis. Scientific judgment was exercised in reviewing and evaluating the data in each criteria document and in identifying the adverse effects for which protective criteria were published.

Specific health-based criteria are developed only if a weight of evidence supports the occurrence of the toxic effect and if dose/response data exist from which criteria can be estimated.

Criteria for suspect or proven carcinogens are presented as concentrations in water associated with a range of incremental cancer risks to man. Criteria for non-carcinogens represent levels at which exposure to a single chemical is not anticipated to produce adverse effects in man. In a few cases, organoleptic (taste and odor) data form the basis for the criterion. While this type of criterion does not represent a value which directly affects human health, it is presented as an estimate of the level of a pollutant that will not produce unpleasant taste or odor either directly from water consumption or indirectly by consumption of aquatic organisms found in ambient waters. A criterion developed in this manner is judged to be as useful as other types of criteria in protecting designated water uses. In addition, where data are available, toxicity-based criteria are also presented for pollutants with derived organoleptic criteria. The choice of criteria used in water quality standards for these pollutants will depend upon the designated use to be protected. In the case of a multiple use water body, the criterion protecting the most sensitive use will be applied. Finally, for several pollutants no criteria are recommended due to a lack of information sufficient for quantitative criterion formulation.

Risk Extrapolation

Because methods do not now exist to establish the presence of a threshold for carcinogenic effects, EPA's policy is that there is no scientific basis for estimating "safe" levels for carcinogens. The criteria for carcinogens, therefore, state that the recommended concentration for maximum protection of human health is zero. In addition, the Agency has presented a range of concentrations corresponding to incremental cancer risks of 10^{-7} to 10^{-5} (one additional case of cancer in populations ranging from ten million to 100,000, respectively). Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Summary of the Human Health Guidelines

The health assessments and corresponding criteria published today were derived based on *Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Criteria Documents* (the Guidelines) developed by EPA's Office of Reserch and Development. The estimation of health risks associated with human exposure to environmental pollutants requires predicting the effect of low doses for up to a lifetime in duration. A combination of epidemiological and animal dose/response data is considered the preferred basis for quantitative criterion derivation. The complete Guidelines are presented as Appendix C. Major issues associated with these Guidelines and responses to public comments are presented as Appendix E.

No-effect (non-carcinogen) or specified risk (carcinogen) concentrations were estimated by extrapolation from animal toxicity or

human epidemiology studies using the following basic exposure assumptions: a 70-kilogram male person (*Report of the Task Group on Reference Man*, International Commission for Radiation Protection, November 23, 1957) as the exposed individual; the average daily consumption of freshwater and estuarine fish and shellfish products equal to 6.5 grams/day; and the average ingestion of two liters/day of water (*Drinking Water and Health*, National Academy of Sciences, National Research Council, 1977). Criteria based on these assumptions are estimated to be protective of an adult male who experiences average exposure conditions.

Two basic methods were used to formulate health criteria, depending on whether the prominent adverse effect was cancer or other toxic manifestations. The following sections detail these methods.

Carcinogens

Extrapolation of cancer responses from high to low doses and subsequent risk estimation from animal data is performed using a linearized multi-stage model. This procedure is flexible enough to fit all monotonically-increasing dose response data, since it incorporates several adjustable parameters. The multi-stage model is a linear non-threshold model as was the "one-hit" model originally used in the proposed criteria documents. The linearized multi-stage model and its characteristics are described fully in Appendix C. The linear non-threshold concept has been endorsed by the four agencies in the Interagency Regulatory Liaison Group and is less likely to underestimate risk at the low doses typical of environmental exposure than other models that could be used. Because of the uncertainties associated with dose response, animal-to-human extrapolation and other unknown factors, because of the use of average exposure assumptions, and because of the serious public health consequences that could result if risk were underestimated, EPA believes that it is prudent to use conservative methods to estimate risk in the water quality criteria program. The linearized multistage model is more systematic and invokes fewer arbitrary assumptions than the "one-hit" procedure previously used.

It should be noted that extrapolation models provide estimates of risk since a varitey of assumptions are built into any model. Models using widely different assumptions may produce estimates ranging over several orders of magnitude. Since there is at present no way to demonstrate the scientific validity of any model, the use of risk extrapolation models is a subject of debate in the scientific community. However, risk extrapolation is generally recognized as the only tool available at this time for estimating the magnitude of health hazards associated with non-threshold toxicants and has been endorsed by numerous Federal agencies and scientific organizations, including EPA's Carcinogen Assessment Group, the National Academy of Sciences, and the Interagency Regulatory Liaison Group as a useful means of assessing the risks of exposure to various carcinogenic pollutants.

Non-Carcinogens

Health criteria based on toxic effects of pollutants other than carcinogenicity are estimates of concentrations which are not expected to produce adverse effects in humans. They are based upon Acceptable Daily Intake (ADI) levels and are generally derived using no-observed-adverse-effect-level (NOAEL) data from animal studies although human data are used wherever available. The ADI is calculated using safety factors to account for uncertainties inherent in extrapolation from animal to man. In accordance with the National Research Council recommendations (*Drinking Water and Health*, National Academy of Sciences, National Research Council, 1977), safety factors of 10, 100, or 1,000 are used depending on the quality and quantity of data. In some instances extrapolations are made from inhalation studies or limits to approximate a human response from ingestion using the Stokinger-Woodward model (Journal of American Water Works Association, 1958). Calculations of criteria from ADIs are made using the standard exposure assumptions (2 liters of water, 6.5 grams of edible aquatic products, and an average body weight of 70 kg).

Dated: October 24, 1980.

Douglas M. Costle,

Administrator.

Appendix A—Summary of Water Quality Criteria

Acenaphthene

Freshwater Aquatic Life

The available data for acenaphthene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 1,700 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of acenaphthene to sensitive freshwater aquatic animals but toxicity to freshwater algae occur at concentrations as low as 520 μg/l.

Saltwater Aquatic Life

The available data for acenaphthene indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 970 and 710 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. Toxicity to algae occurs at concentrations as low as 500 μg/l.

Human Health

Sufficient data is not available for acenaphthene to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 20 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Acrolein

Freshwater Aquatic Life

The available data for acrolein indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 68 and 21 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for acrolein indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 55 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of acrolein to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of acrolein ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 320 μg/l.

For the protection of human health from the toxic properties of acrolein ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 780 μg/l.

Acrylonitrile

Freshwater Aquatic Life

The available data for acrylonitrile indicate that acute toxicity to freshwater aquatic life occurs at concentrations as

low as 7,550 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of acrylonitrile to sensitive freshwater aquatic life but mortality occurs at concentrations as low as 2,600 μg/l with a fish species exposed for 30 days.

Saltwater Aquatic Life

Only one saltwater species has been tested with acrylonitrile and no statement can be made concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of acrylonitrile through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .58 μg/l, .058 μg/l and .006 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 6.5 μg/l, .65 μg/l, and .065 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Aldrin-Dieldrin

Dieldrin

Freshwater Aquatic Life

For dieldrin the criterion to protect fresh water aquatic life as derived using the Guidelines is 0.0019 μg/l as a 24-hour average and the concentration should not exceed 2.5 μg/l at any time.

Saltwater Aquatic Life

For dieldrin the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.0019 μg/l as a 24-hour average and the concentration should not exceed 0.71 μg/l at any time.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of dieldrin through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .71 ng/l, .071 ng/l, and .0071 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are .76 ng/l, .076 ng/l, and .0076 ng/l respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Aldrin

Freshwater Aquatic Life

For freshwater aquatic life the concentration of aldrin should not exceed 3.0 μg/l at any time. No data are available concerning the chronic toxicity of aldrin to sensitive freshwater aquatic life.

Saltwater Aquatic Life

For saltwater aquatic life the concentration of aldrin should not exceed 1.3 μg/l at any time. No data are available concerning the chronic toxicity of aldrin to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of aldrin through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .74 ng/1, .074 ng/1, and .0074 ng/1, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are .79 ng/1, .079 ng/1, and .0079 ng/1, respectively. Other concentrations respresenting different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Antimony

Freshwater Aquatic Life

The available data for antimony indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 9,000 and 1,600 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. Toxicity to algae occurs at concentrations as low as 610 μg/l.

Saltwater Aquatic Life

No saltwater organisms have been adequately tested with antimony, and no statement can be made concerning acute or chronic toxicity.

Human Health

For the protection of human health from the toxic properties of antimony ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 146 μg/l.

For the protection of human health from the toxic properties of antimony ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 45,000 μg/l.

Arsenic

Freshwater Aquatic Life

For freshwater aquatic life the concentration of total recoverable trivalent inorganic arsenic should not exceed 440 μg/l at any time. Short-term effects on embryos and larvae of aquatic vertebrate species have been shown to occur at concentrations as low as 40 μg/l.

Saltwater Aquatic Life

The available data for total recoverable trivalent inorganic arsenic indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 508 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of trivalent inorganic arsenic to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of arsenic through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are

estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 22 ng/l, 2.2 ng/l, and .22 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 175 ng/l, 17.5 ng/l, and 1.75 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Asbestos

Freshwater Aquatic Life

No freshwater organisms have been tested with any asbestiform mineral and no statement can be made concerning acute or chronic toxicity.

Saltwater Aquatic Life

No saltwater organisms have been tested with any asbestiform mineral and no statement can be made concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of asbestos through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 300,000 fibers/1,30,000 fibers/1, and 3,000 fibers/1, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Benzene

Freshwater Aquatic Life

The available data for benzene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 5,300 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of benzene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for benzene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 5,100 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of benzene to sensitive saltwater aquatic life, but adverse effects occur at concentrations as low as 700 μg/l with a fish species exposed for 168 days.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of benzene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 6.6 μg/l, .66 μg/l, and .066 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 400 μg/l, 40.0 μg/l, and 4.0 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Benzidine

Freshwater Aquatic Life

The available data for benzidine indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 2,500 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of benzidine to sensitive freshwater aquatic life.

Saltwater Aquatic Life

No saltwater organisms have been tested with benzidine and no statement can be made concerning acute and chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of benzidine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 1.2 ng/1, .12 ng/1, and .01 ng/1, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 5.3 ng/1, .53 ng/1, and .05 ng/1, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Beryllium

Freshwater Aquatic Life

The available data for beryllium indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 130 and 5.3 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. Hardness has a substantial effect on acute toxicity.

Salt water Aquatic Life

The limited saltwater data base available for beryllium does not permit any statement concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of beryllium through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 37 ng/l, 3.7 ng/l, and .37 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 641 ng/l, 64.1 ng/l, and 6.41 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Cadmium

Freshwater Aquatic Life

For total recoverable cadmium the criterion (in μg/l) to protect freshwater aquatic life as derived using the Guidelines is the numerical value given

by $e^{(1.05\ [\ln(\text{hardness})]-8.63)}$ as a 24-hour average and the concentration (in μg/l) should not exceed the numerical value given by $e^{(1.05\ [\ln(\text{hardness})]-3.73)}$ at any time. For example, a hardnesses of 50, 100, and 200 mg/l as $CaCO_3$ the criteria are 0.012, 0.025, and 0.051 μg/l, respectively, and the concentration of total recoverable cadmium should not exceed 1.5, 3.0 and 6.3 μg/l, respectively, at any time.

Saltwater Aquatic Life

For total recoverable cadmium the criterion to protect saltwater aquatic life as derived using the Guidelines is 4.5 μg/l as a 24-hour average and the concentration should not exceed 59 μg/l at any time.

Human Health

The ambient water quality criterion for cadmium is recommended to be identical to the existing drinking water standard which is 10 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Carbon Tetrachloride

Freshwater Aquatic Life

The available date for carbon tetrachloride indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 35,200 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of carbon tetrachloride to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for carbon tetrachloride indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 50,000 μg/l and would occur at lower concentrations among species that are more sensitive that those tested. No data are available concerning the chronic toxicity of carbon tetrachloride to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of carbon tetrachloride through ingestion of contaminated water and contaminated aquatic organisms the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 4.0μg/l, .40 μg/l, and .04 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 69.4 μg/l, 6.94 μg/l, and .69 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Chlordane

Freshwater Aquatic Life

For chlordane the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.0043 μg/l as a 24-hour average and the concentration should not exceed 2.4 μg/l at any time.

Saltwater Aquatic Life

For chlordane the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.0040 μg/l as a 24-hour average and the concentration should not exceed 0.09 μg/l at any time.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of chlordane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 4.6 ng/l, .46 ng/l, and .046 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 4.8 ng/l, .48 ng/l, and .048 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Chlorinated Benzenes

Freshwater Aquatic Life

The available data for chlorinated benzenes indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 250 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of the more toxic of the chlorinated benzenes to sensitive freshwater aquatic life but toxicity occurs at concentrations as low as 50 μg/l for a fish species exposed for 7.5 days.

Saltwater Aquatic Life

The available data for chlorinated benzenes indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 160 and 129 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of hexachlorobenzene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding recommended criteria are 7.2 ng/l, .72 ng/l, and .072 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 7.4 ng/l, .74 ng/l, and .074 ng/l, respectively.

For the protection of human health from the toxic properties of 1,2,4,5-tetrachlorobenzene ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 38 μg/l.

For the protection of human health from the toxic properties of 1,2,4,5-tetrachlorobenzene ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 48 μg/l.

For the protection of human health from the toxic properties of pentachlorobenzene ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 74 μg/l.

For the protection of human health from the toxic properties of pentachlorobenzene ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 85 μg/l.

Using the present guidelines, a satisfactory criterion cannot be derived

at this time due to the insufficiency in the available data for trichlorobenzene.

For comparison purposes, two approaches were used to derive criterion levels for monochlorobenzene. Based on available toxicity data, for the protection of public health, the derived level is 488 μg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 20 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Chlorinated Ethanes

Freshwater Aquatic Life

The available freshwater data for chlorinated ethanes indicate that toxicity increases greatly with increasing chlorination, and that acute toxicity occurs at concentrations as low as 118,000 μg/l for 1,2-dichloroethane, 18,000 μg/l for two trichloroethanes, 9,320 μg/l for two tetrachloroethanes, 7,240 μg/l for pentachloroethane, and 980 μg/l for hexachloroethane. Chronic toxicity occurs at concentrations as low as 20,000 μg/l for 1,2-dichloroethane, 9,400 μg/l for 1,1,2-trichloroethane, 2,400 μg/l for 1,1,2,2,-tetrachloroethane, 1,100 μg/l for pentachloroethane, and 540 μg/l for hexachloroethane. Acute and chronic toxicity would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available saltwater data for chlorinated ethanes indicate that toxicity increases greatly with increasing chlorination and that acute toxicity to fish and invertebrate species occurs at concentrations as low as 113,000 μg/l for 1,2-dichloroethane, 31,200 μg/l for 1,1,1-trichloroethane, 9,020 μg/l for 1,1,2,2-tetrachloroethane, 390 μg/l for pentachloroethane, and 940 μg/l for hexachloroethane. Chronic toxicity occurs at concentrations as low as 281 μg/l for pentachloroethane. Acute and chronic toxicity would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,2-dichloroethane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 9.4 μg/l, .94 μg/l, and .094 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 2,430 μg/l, 243 μg/l, and 24.3 μg/l respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the protection of human health from the toxic properties of 1,1,1-trichloroethane ingested through water and contaminated aquatic organism, the ambient water criterion is determined to be 18.4 mg/l.

For the protection of human health from the toxic properties of 1,1,1,-trichloroethane ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 1.03 g/l.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,1,2-trichloroethane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 6.0 μg/l, .6 μg/l, and .06 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 418 μg/l, 41.8 μg/l, and 4.18 μg/l respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,1,2,2-tetrachloroethane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 1.7 μg/l, .17 μg/l, and .017 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 107 μg/l, 10.7 μg/l, and 1.07 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of hexachloroethane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 19 μg/l, 1.9 μg/l, and .19 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 87.4 μg/l, 8.74 μg/l, and .87 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for monochloroethane.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for 1,1,-dichloroethane.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for 1,1,1,2-tetrachloroethane.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for pentachloroethane.

Chlorinated Naphthalenes

Freshwater Aquatic Life

The available data for chlorinated naphthalenes indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 1,600 μg/l and would occur at lower concentrations among species that are

more sensitive than those tested. No data are available concerning the chronic toxicity of chlorinated naphthalenes to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for chlorinated napthalenes indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 7.5 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of chlorinated naphthalenes to sensitive saltwater aquatic life.

Human Health

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for chlorinated napthalenes.

Chlorinated Phenols

Freshwater Aquatic Life

The available freshwater data for chlorinated phenols indicate that toxicity generally increases with increasing chlorination, and that acute toxicity occurs at concentrations as low as 30 μg/l for 4-chloro-3-methylphenol to greater than 500,000 μg/l for other compounds. Chronic toxicity occurs at concentrations as low as 970 μg/l for 2,4,6-trichlorophenol. Acute and chronic toxicity would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available saltwater data for chlorinated phenols indicate that toxicity generally increases with increasing chlorination and that acute toxicity occurs at concentrations as low as 440 μg/l for 2,3,5,6-tetrachlorophenol and 29,700 μg/l for 4-chlorophenol. Acute toxicity would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of chlorinated phenols to sensitive saltwater aquatic life.

Human Health

Sufficient data is not available for 3-monoclilorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 0.1 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 4-monochlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 0.1 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 2,3-dichlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is .04 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 2,5-dichlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is .5 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 2,6-dichlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is .2 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 3,4-dichlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is .3 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 2,3,4,6-tetrachlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 1 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

For comparison purposes, two approaches were used to derive criterion levels for 2,4,5-trichlorophenol. Based on available toxicity data, for the protection of public health, the derived level is 2.6 mg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 1.0 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 2,4,6-trichlorophenol through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 12 μg/l, 1.2 μg/l, and .12 μg/l respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 36 μg/l, 3.6 μg/l, and .36 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 2 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 2-methyl-4-chlorophenol to derive a level which would protect against any potential toxicity of this compound. Using available organoleptic data for controlling undesirable taste and odor quality of ambient water, the estimated level is 1800 μg/l. It should be

recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 3-methyl-4-chlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 3000 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 3-methyl-6-chlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 20 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Chloroalkyl Ethers

Freshwater Aquatic Life

The available data for chloroalkyl ethers indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 238,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of chloroalkyl ethers to sensitive freshwater aquatic life.

Saltwater Aquatic Life

No saltwater organisms have been tested with any chloroalkyl ether and no statement can be made concerning acute and chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of bis-(chloromethyl)-ether through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .038 ng/l, .0038 ng/l, and .00038 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 18.4 ng/l, 1.84 ng/l, and .184 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of bis (2-chloroethyl) ether through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .3 μg/l, .03 μg/l, and .003 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 13.6 μg/l, 1.36 μg/l, and .136 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the protection of human health from the toxic properties of bis (2-chloroisopropyl) ether ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 34.7 μg/l.

For the protection of human health from the toxic properties of bis (2-chloroisopropyl) ether ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 4.36 mg/l.

Chloroform

Freshwater Aquatic Life

The available data for choloroform indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 28,900 μg/l, and would occur at lower concentrations among species that are more sensitive than the three tested species. Twenty-seven-day LC50 values indicate that chronic toxicity occurs at concentrations as low as 1,240 μg/l, and could occur at lower concentrations among species or other life stages that are more sensitive than the earliest life cycle stage of the rainbow trout.

Saltwater Aquatic Life

The data base for saltwater species is limited to one test and no statement can be made concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of chloroform through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 1.90 μg/l, .19 μg/l, and .019 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 157 μg/l, 15.7 μg/l, and 1.57 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

2-Chlorophenol

Freshwater Aquatic Life

The availabe data for 2-chlorophenol indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 4,380 μg/l and would occur at lower concentrations among species that are more sensitive that those tested. No definitive data are available concerning the chronic toxicity of 2-chlorophenol to sensitive freshwater aquatic life but flavor impairment occurs in one species of fish at concentrations as low as 2,000 μg/l.

Saltwater Aquatic Life

No saltwater organisms have been tested with 2-chlorophenol and no statement can be made concerning acute and chronic toxicity.

Human Health

Sufficient data is not available for 2-chlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 0.1 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no

demonstrated relationship to potential adverse human health effects.

Chromium

Freshwater Aquatic Life

For total recoverable hexavalent chromium the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.29 μg/l as a 24-hour average and the concentration should not exceed 21 μg/l at any time.

For freshwater aquatic life the concentration (in μg/l) of total recoverable trivalent chromium should not exceed the numerical value given by "e{1.08[ln(hardness)]+3.48)" at any time. For example, at hardnesses of 50, 100 and 200 mg/l as $CaCO_3$ the concentration of total recoverable trivalent chromium should not exceed 2,200, 4,700, and 9,900 μg/l, respectively, at any time. The available data indicate that chronic toxicity to freshwater aquatic life occurs at concentrations as low a 44 μg/l and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

For total recoverable hexavalent chromium the criterion to protect saltwater aquatic life as derived using the Guidelines is 18 μg/l as a 24-hour average and the concentration should not exceed 1,260 μg/l at any time.

For total recoverable trivalent chromium, the availabe data indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 10,300 μg/l, and would occur at lower concentrations amoung species that are more sensitive than those tested. No data are available concerning the chronic toxicity of trivalent chromium to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of Chromium III ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 170 mg/l.

For the protection of human health from the toxic properties of Chromium III ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 3433 mg/l.

The ambient water quality criterion for total Chromium VI is recommended to be identical to the existing drinking water standard which is 50 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Copper

Freshwater Aquatic Life

For total recoverable copper the criterion to protect freshwater aquatic life as derived using the Guidelines is 5.6 μg/l as a 24-hour average and the concentration (in μg/l) should not exceed the numerical value given by e{0.94[ln(hardness)]-1.23} at any time. For example, at hardnesses of 50, 100, and 200 mg/l $CaCO_3$ the concentration of total recoverable copper should not exceed 12, 22, and 43 μg/l at any time.

Saltwater Aquatic Life

For total recoverable copper the criterion to protect saltwater aquatic life as derived using the Guidelines is 4.0 μg/l as a 24-hour average and the concentration should not exceed 23 μg/l at any time.

Human Health

Sufficient data is not available for copper to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 1 mg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Cyanide

Freshwater Aquatic Life

For free cyanide (sum of cyanide present as HCN and CN^-, expressed as CN) the criterion to protect freshwater aquatic life as derived using the Guidelines is 3.5 μg/l as a 24-hour average and the concentration should not exceed 52 μg/l at any time.

Saltwater Aquatic Life

The available data for free cyanide (sum of cyanide present as HCN and CN^-, expressed as CN) indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 30 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. If the acute-chronic ratio for saltwater organisms is similar to that for freshwater organisms, chronic toxicity would occur at concentrations as low as 2.0 μg/l for the tested species and at lower concentrations among species that are more sensitive than those tested.

Human Health

The ambient water quality criterion for cyanide is recommended to be identical to the existing drinking water standard which is 200 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

DDT and Metabolites

Freshwater Aquatic Life

DDT

For DDT and its metabolites the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.0010 μg/l as a 24-hour average and the concentration should not exceed 1.1 μg/l at any time.

TDE

The available data for TDE indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 0.6 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of TDE to sensitive freshwater aquatic life.

DDE

The available data for DDE indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 1,050 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of DDE to sensitive freshwater aquatic life.

Saltwater Aquatic Life

DDT

For DDT and its metabolites the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.0010 μg/l as a 24-hour average and the concentration should not exceed 0.13 μg/l at any time.

TDE

The available data for TDE indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 3.6 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the

chronic toxicity of TDE to sensitive saltwater aquatic life.

DDE

The available data for DDE indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 14 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of DDE to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of DDT through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .24 ng/l, .024 ng/l, and .0024 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are .24 ng/l, .024 ng/l, and .0024 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment of an "acceptable" risk level.

Dichlorobenzenes

Freshwater Aquatic Life

The available data for dichlorobenzenes indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 1,120 and 763 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for dichlorobenzenes indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 1,970 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of dichlorobenzenes to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of dichlorobenzenes (all isomers) ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 400 μg/l.

For the protection of human health from the toxic properties of dichlorobenzenes (all isomers) ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 2.6 mg/l.

Dichlorobenzidines

Freshwater Aquatic Life

The data base available for dichlorobenzidines and freshwater organisms is limited to one test on bioconcentration of 3,3'-dichlorobenzidine and no statement can be made concerning acute or chronic toxicity.

Saltwater Aquatic Life

No saltwater organisms have been tested with any dichlorobenzidine and no statement can be made concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of dichlorobenzidine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero base on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .103 μg/l, .0103 μg/l, and .00103 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are .204 μg/l, .0204 μg/l, and .00204 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Dichloroethylenes

Freshwater Aquatic Life

The available data for dichloroethylenes indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 11,600 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of dichlorethylenes to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for dichlorethylenes indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 224,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity dichloroethylenes to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,1-dichloroethylene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .33 μg/l, .033 μg/l, and .0033 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 18.5 μg/l, 1.85 μg/l, and .185 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficency in the available data for 1,2-dichloroethylene.

2,4-Dichlorophenol

Freshwater Aquatic Life

The available data for 2,4-dichlorophenol indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 2,020 and 365 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive that those tested. Mortality to early life stages of one species of fish occurs at concentrations as low as 70 μg/l.

Saltwater Aquatic Life

Only one test has been conducted with saltwater organisms on 2,4-dichlorophenol and no statement can be made concerning acute or chronic toxicity.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for 2,4-dichlorophenol.

Based on available toxicity data, for the protection of public health, the derived level is 3.09 mg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 0.3 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Dichloropropanes/Dichloropropenes

Freshwater Aquatic Life

The available data for dichloropropanes indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 23,000 and 5,700 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

The available data for dichloropropenes indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 6,060 and 244 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for dichloropropanes indicate that acute and chronic toxicity to saltwater aquatic life occurs at concentrations as low as 10,300 and 3,040 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

The available data for dichloropropenes indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low a as 790 μg/l, and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of dichloropropenes to sensitive saltwater aquatic life.

Human Health

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for dichloropropanes.

For the protection of human health from the toxic properties of dichloropropenes ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 87 μg/l.

For the protection of human health from the toxic properties of dichloropropenes ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 14.1 mg/l.

2,4-Dimethylphenol

Freshwater Aquatic Life

The available data for 2,4-dimethylphenol indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 2,120 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of dimethylphenol to sensitive freshwater aquatic life.

Saltwater Aquatic Life

No saltwater organisms have been tested with 2,4-dimethylphenol and no statement can be made concerning acute and chronic toxicity.

Human Health

Sufficient data are not available for 2,4-dimethylphenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undersirable taste and odor quality of ambient water, the estimated level is 400 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

2,4-Dinitrotoluene

Freshwater Aquatic Life

The available data for 2,4-dinitrotoluene indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 330 and 230 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for 2,4-diritrotoluenes indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 590 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of 2,4-dinitrotoluenes to sensitive saltwater aquatic life but a decrease in algal cell numbers occurs at concentrations as low as 370 μg/l.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 2,4-dinitrotoluene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 1.1 μg/l, 0.11 μg/l, and 0.011 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 91 μg/l, 9.1 μg/l, and 0.91 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

1,2-Diphenylhydrazine

Freshwater Aquatic Life

The available data for 1,2-diphenylhydrazine indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 270 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of 1,2-diphenylhydrazine to sensitive freshwater aquatic life.

Saltwater Aquatic Life

No saltwater organisms have been tested with 1,2-diphenylhydrazine and no statement can be made concerning acute and chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,2-diphenylhydrazine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 422 ng/l, 42 ng/l, and 4 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 5.6 μg/l, 0.56 μg/l, and 0.056 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not

represent an Agency judgment on an "acceptable" risk level.

Endosulfan

Freshwater Aquatic Life

For endosulfan the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.056 μg/l as a 24-hour average and the concentration should not exceed 0.22 μg/l at any time.

Saltwater Aquatic Life

For endosulfan the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.0087 μg/l as a 24-hour average and the concentration should not exceed 0.034 μg/l at any time.

Human Health

For the protection of human health from the toxic properties of endosulfan ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 74 μg/l.

For the protection of human health from the toxic properties of endosulfan ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 159 μg/l.

Endrin

Freshwater Aquatic Life

For endrin the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.0023 μg/l as a 24-hour average and the concentration should not exceed 0.18 μg/l at any time.

Saltwater Aquatic Life

For endrin the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.0023 μg/l as a 24-hour average and the concentration should not exceed 0.037 μg/l at any time.

Human Health

The ambient water quality criterion for endrin is recommended to be identical to the existing drinking water standard which is 1 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Ethylbenzene

Freshwater Aquatic Life

The available data for ethylbenzene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 32,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of ethylbenzene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for ethylbenzene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 430 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of ethylbenzene to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of ethylbenzene ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 1.4 mg/l.

For the protection of human health from the toxic properties of ethylbenzene ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 3.28 mg/l.

Fluoranthene

Freshwater Aquatic Life

The available data for fluoranthene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 3980 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of fluoranthene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for fluoranthene indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 40 and 16 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the protection of human health from the toxic properties of fluoranthene ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 42 μg/l.

For the protection of human health from the toxic properties of fluoranthene ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 54 μg/l.

Haloethers

Freshwater Aquatic Life

The available data for haloethers indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 360 and 122 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

No saltwater organisms have been tested with any haloether and no statement can be made concerning acute or chronic toxicity.

Human Health

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for haloethers.

Halomethanes

Freshwater Aquatic Life

The available data for halomethanes indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 11,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of halomethanes to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for halomethanes indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 12,000 and 6,400 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. A decrease in algal cell numbers occurs at concentrations as low as 11,500 μg/l.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of chloromethane, bromomethane, dichloromethane, bromodichloromethane, tribromomethane, dichlorodifluoromethane, trichlorofluoromethane, or combinations of these chemicals through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are

1.9 μg/l, 0.19 μg/l, and 0.019 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 157 μg/l, 15.7 μg/l, and 1.57 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Heptachlor

Freshwater Aquatic Life

For heptachlor the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.0038 μg/l as a 24-hour average and the concentration should not exceed 0.52 μg/l at any time.

Saltwater Aquatic Life

For heptachlor the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.0036 μg/l as a 24-hour average and the concentration should not exceed 0.053 μg/l at any time.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of heptachlor through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 2.78 ng/l, .28 ng/l, and .028 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 2.85 ng/l, .29 ng/l, and .029 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Hexachlorobutadiene

Freshwater Aquatic Life

The available data for hexachlorobutadiene indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 90 and 9.3 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for hexachlorobutadiene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 32 μg/l and would occur at lower concentrations among species that are more sensitive that those tested. No data are available concerning the chronic toxicity of hexachlorobutadiene to sensitive saltwater aquatic life

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of hexachlorobutadiene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 4.47 μg/l, 0.45 μg/l, and 0.045 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 500 μg/l, 50 μg/l, and 5 μg/l respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Hexachlorocyclohexane

Lindane

Freshwater Aquatic Life

For Lindane the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.080 μg/l as a 24-hour average and the concentration should not exceed 2.0 μg/l at any time.

Saltwater Aquatic Life

For saltwater aquatic life the concentration of lindane should not exceed 0.16 μg/l at any time. No data are available concerning the chronic toxicity of lindane to sensitive saltwater aquatic life.

BHC

Freshwater Aquatic Life

The available date for a mixture of isomers of BHC indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 100 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of a mixture of isomers of BHC to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available date for a mixture of isomers of BHC indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 0.34 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of a mixture of isomers of BHC to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of alpha-HCH through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 92 ng/l, 9.2 ng/l, and .92 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 310 ng/l, 31.0 ng/l, and 3.1 ng/l respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of beta-HCH through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 163 ng/l, 16.3 ng/l, and 1.63 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 547 ng/l, 54.7 ng/l, and 5.47 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not

represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of tech-HCH through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 123 ng/l, 12.3 ng/l, and 1.23 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 414 ng/l, 41.4 ng/l, and 4.14 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of gamma-HCH through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentrations should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 186 ng/l, 18.6 ng/l, and 1.86 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 625 ng/l, 62.5 ng/l, 6.25 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for delta-HCH.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for epsilon-HCH.

Hexachlorocyclopentadiene

Freshwater Aquatic Life

The available data for hexachlorocyclopentadiene indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 7.0 and 5.2 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data to hexachlorocyclopentadiene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 7.0 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of hexachlorocyclopentadiene to sensitive saltwater aquatic life.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for hexachlorocyclopentadiene. Based on available toxicity data, for the protection of public health, the derived level is 206 μg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 1.0 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Isophorone

Freshwater Aquatic Life

The available data for isophorone indicate that acute toxicity to freshwater aquatic life ocurs at concentrations as low as 117,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of isophorone to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for isophorone indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 12,900 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of isophorone to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of isophorone ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 5.2 mg/l.

For the protection of human health from the toxic properties of isophorone ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 520 mg/l.

Lead

Freshwater Aquatic Life

For total recoverable lead the criterion (in μg/l) to protect freshwater aquatic life as derived using the Guidelines is the numerical value given by e(2.35[ln(hardness)]-9.48) as a 24-hour average and the concentration (in μg/l) should not exceed the numerical value given by e(1.22[ln(hardness)]-0.47) at any time. For example, at hardnesses of 50, 100, and 200 mg/l as $CaCO_3$ the criteria are 0.75, 3.8, and 20 μg/l, respectively, as 24-hour averages, and the concentrations should not exceed 74, 170, and 400 μg/l, respectively, at any time.

Saltwater Aquatic Life

The available data for total recoverable lead indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 668 and 25 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

The ambient water quality criterion for lead is recommended to be identical to the existing drinking water standard which is 50 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective to human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Mercury

Freshwater Aquatic Life

For total recoverable mercury the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.00057 μg/l as a 24-hour average and the concentration should not exceed 0.0017 μg/l at any time.

Saltwater Aquatic Life

For total recoverable mercury the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.025 μg/l as a 24-hour average and the concentration should not exceed 3.7 μg/l at any time.

Human Health

For the protection of human health from the toxic properties of mercury

ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 144 ng/l.

For the protection of human health from the toxic properties of mercury ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 146 ng/l.

Note.—These values include the consumption of freshwater, estuarine, and marine species.

Naphthalene

Freshwater Aquatic Life

The available data to naphthalene indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 2,300 and 620 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for naphthalene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 2,350 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of naphthalene to sensitive saltwater aquatic life.

Human Health

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for naphthalene.

Nickel

Freshwater Aquatic Life

For total recoverable nickel the criterion (in μg/l) to protect freshwater aquatic life as derived using the Guidelines is the numerical value given by e(0.76 [ln (hardness)] + 1.06) as a 24-hour average and the concentration (in μg/l) should not exceed the numerical value given by e(0.76[ln (hardness)] + 4.02) at any time. For example, at hardnesses of 50, 100, and 200 mg/l as $CaCO_3$ the criteria are 56, 96, and 160 μg/l, respectively, as 24-hour averages, and the concentrations should not exceed 1,100, 1,800, and 3,100 μg/l, respectively, at any time.

Saltwater Aquatic Life

For total recoverable nickel the criterion to protect saltwater aquatic life as derived using the Guidelines is 7.1 μg/l as a 24-hour average and the concentration should not exceed 140 μg/l at any time.

Human Health

For the protection of human health from the toxic properties of nickel ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 13.4 μg/l.

For the protection of human health from the toxic properties of nickel ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 100 μg/l.

Nitrobenzene

Freshwater Aquatic Life

The available data for nitrobenzene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 27,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of nitrobenzene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for nitrobenzene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 6,680 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of nitrobenzene to sensitive saltwater aquatic life.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for nitrobenzene. Based on available toxicity data, for the protection of public health, the derived level is 19.8 mg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 30 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Nitrophenols

Freshwater Aquatic Life

The available data for nitrophenols indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 230 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of nitrophenols to sensitive freshwater aquatic life but toxicity to one species of algae occurs at concentrations as low as 150 μg/l.

Saltwater Aquatic Life

The available data for nitrophenols indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 4,850 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of nitrophenols to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of 2,4-dinitro-o-cresol ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 13.4 μg/l.

For the protection of human health from the toxic properties of 2,4-dinitro-o-cresol ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 765 μg/l.

For the protection of human health from the toxic properties of dinitrophenol ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 70 μg/l.

For the protection of human health from the toxic properties of dinitrophenol ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 14.3 mg/l.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for mononitrophenol.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for tri-nitrophenol.

Nitrosamines

Freshwater Aquatic Life

The available data for nitrosamines indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 5,850 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of nitrosamines to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for nitrosamines indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 3,300,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of nitrosamines to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of n-nitrosodimethylamine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 14 ng/l, 1.4 ng/l, and .14 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 160,000 ng/l, 16,000 ng/l, and 1,600 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of n-nitrosodiethylamine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 8 ng/l, 0.8 ng/l, and 0.08 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 12,400 ng/l, 1,240 ng/l, and 124 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure in n-nitrosodi-n-butylamine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 64 ng/l 6.4 ng/l and .064 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 5,868 ng/l, 587 ng/l, and 58.7 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure in n-nitrosodiphenylamine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 49,000 ng/l 4,900 ng/l and 490 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 161,000 ng/l, 16,100 ng/l, and 1,610 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure in n-nitrosopyrrolidine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 160 ng/l 16.0 ng/l and 1.60 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 919,000 ng/l, 91,900 ng/l, and 9,190 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Pentachlorophenol

Freshwater Aquatic Life

The available data for pentachlorophenol indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 55 and 3.2 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for pentachlorophenol indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 53 and 34 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for pentachlorophenol. Based on available toxicity data, for the protection of public health, the derived level is 1.01 mg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 30 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Phenol

Freshwater Aquatic Life

The available data for phenol indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 10,200 and 2,560 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for phenol indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 5,800 ug/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of phenol to sensitive saltwater aquatic life.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for phenol. Based on available toxicity data, for the protection of public health, the derived level is 3.5 mg/l. Using available organoleptic data, for controlling

undesirable taste and odor quality of ambient water, the estimated level is 0.3 mg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Phthalate Esters

Freshwater Aquatic Life

The available data for phthalate esters indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 940 and 3 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for phthalate esters indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 2944 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of phthalate esters to sensitive saltwater aquatic life but toxicity to one species of algae occurs at concentrations as low as 3.4 μg/l.

Human Health

For the protection of human health from the toxic properties of dimethyl-phthalate ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 313 mg/l.

For the protection of human health from the toxic properties of dimethyl-phthalate ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 2.9 g/l.

For the protection of human health from the toxic properties of diethyl-phthalate ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 350 mg/l.

For the protection of human health from the toxic properties of diethyl-phthalate ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 1.8 g/l.

For the protection of human health from the toxic properties of dibutyl-phthalate ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 34 mg/l.

For the protection of human health from the toxic properties of dibutyl-phthalate ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 154 mg/l.

For the protection of human health from the toxic properties of di-2-ethylhexyl-phthalate ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 15 mg/l.

For the protection of human health from the toxic properties of di-2-ethylhexyl-phthalate ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 50 mg/l.

Polychlorinated Biphenyls

Freshwater Aquatic Life

For polychlorinated biphenyls the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.014 μg/l as a 24-hour average. The available data indicate that acute toxicity to freshwater aquatic life probably will only occur at concentrations above 2.0 μg/l and that the 24-hour average should provide adequate protection against acute toxicity.

Saltwater Aquatic Live

For polychlorinated biphenyls the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.030 μg/l as a 24-hour average. The available data indicate that acute toxicity to saltwater aquatic life probably will only occur at concentrations above 10 μg/l and that the 24-hour average should provide adequate protection against acute toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of PCBs through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .79 ng/l, 0.79 ng/l, and .0079 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are .79 ng/l, .079 ng/l, and .0079 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Polynuclear Aromatic Hydrocarbons (PAHs)

Freshwater Aquatic Life

The limited freshwater data base available for polynuclear aromatic hydrocarbons, mostly from short-term bioconcentration studies with two compounds, does not permit a statement concerning acute or chronic toxicity.

Saltwater Aquatic Life

The available data for polynuclear aromatic hydrocarbons indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 300 ug/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of polynuclear aromatic hydrocarbons to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of PAHs through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 28 ng/l, 2.8 ng/l, and .28 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 311 ng/l, 31.1 ng/l, and 3.11 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Selenium

Freshwater Aquatic Life

For total recoverable inorganic selenite the criterion to protect freshwater aquatic life as derived using the Guidelines is 35 μg/l as a 24-hour average and the concentration should not exceed 260 μg/l at any time.

The available data for inorganic selenate indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 760 μg/l and would occur at lower concentrations among species that are more sensitive

than those tested. No data are available concerning the chronic toxicity of inorganic selenate to sensitive freshwater aquatic life.

Saltwater Aquatic Life

For total recoverable inorganic selenite the criterion to protect saltwater aquatic life as derived using the Guidelines is 54 μg/l as a 24-hour average and the concentration should not exceed 410 μg/l at any time.

No data are available concerning the toxicity of inorganic selenate to saltwater aquatic life.

Human Health

The ambient water quality criterion for selenium is recommended to be identical to the existing drinking water standard which is 10 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Silver

Freshwater Aquatic Life

For freshwater aquatic life the concentration (in μg/l) of total recoverable silver should not exceed the numerical value given by "e[1.72(ln (hardness)-6.52)]" at any time. For example, at hardnesses of 50, 100, 200 mg/l as $CaCO_3$ the concentration of total recoverable silver should not exceed 1.2, 4.1, and 13 μg/l, respectively, at any time. The available data indicate that chronic toxicity to freshwater aquatic life may occur at concentrations as low as 0.12 μg/l.

Saltwater Aquatic Life

For saltwater aquatic life the concentration of total recoverable silver should not exceed 2.3 μg/l at any time. No data are available concerning the chronic toxicity of silver to sensitive saltwater aquatic life.

Human Health

The ambient water quality criterion for silver is recommended to be identical to the existing drinking water standard which is 50 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Tetrachloroethylene

Freshwater Aquatic Life

The available data for tetrachloroethylene indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 5,280 and 840 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for tetrachloroethylene indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations low as 10,200 and 450 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of tetrachloroethylene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 8 μg/l, .8 μg/l, and .08 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 88.5 μg/l, 8.85 μg/l, and .88 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Thallium

Freshwater Aquatic Life

The available data for thallium indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 1,400 and 40 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. Toxicity to one species of fish occurs at concentrations as low as 20 μg/l after 2,600 hours of exposure.

Saltwater Aquatic Life

The available data for thallium indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 2,130 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of thallium to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of thallium ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 13 μg/l.

For the protection of human health from the toxic properties of thallium ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 48 μg/l.

Toluene

Freshwater Aquatic Life

The available data for toluene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 17,500 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of toluene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for toluene indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 6,300 and 5,000 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the protection of human health from the toxic properties of toluene ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 14.3 mg/l.

For the protection of human health from the toxic properties of toluene ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 424 mg/l.

Toxaphene

Freshwater Aquatic Life

For toxaphene the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.013 μg/l as a 24-hour average and the concentration should not exceed 1.6 μg/l at any time.

Saltwater Aquatic Life

For saltwater aquatic life the concentration of toxaphene should not exceed 0.070 μg/l at any time. No data

are available concerning the chronic toxicity of toxaphene to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of toxaphene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 7.1 ng/l, .71 ng/l, and .07 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 7.3 ng/l, .73 ng/l, and .07 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Trichloroethylene

Freshwater Aquatic Life

The available data for trichloroethylene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 45,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of trichloroethylene to sensitive freshwater aquatic life but adverse behavioral effects occurs to one species at concentrations as low as 21,900 μg/l.

Saltwater Aquatic Life

The available data for trichloroethylene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 2,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of trichloroethylene to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of trichloroethylene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 27 μg/l, 2.7 μg/l, and .27 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 807 μg/l, 80.7 μg/l, and 8.07 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Vinyl Chloride

Freshwater Aquatic Life

No freshwater organisms have been tested with vinyl chloride and no statement can be made concerning acute or chronic toxicity.

Saltwater Aquatic Life

No saltwater organisms have been tested with vinyl chloride and no statement can be made concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of vinyl chloride through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 20 μg/l, 2.0 μg/l, and .2 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 5,246 μg/l, 525 μg/l, and 52.5 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Zinc

Freshwater Aquatic Life

For total recoverable zinc the criterion to protect freshwater aquatic life as derived using the Guidelines is 47 μg/l as a 24-hour average and the concentration (in μg/l) should not exceed the numerical value given by $e^{(0.83[\ln(\text{hardness})]+1.95)}$ at any time. For example, at hardnesses of 50, 100, and 200 mg/l as $CaCO_3$ the concentration of total recoverable zinc should not exceed 180, 320, and 570 μg/l at any time.

Saltwater Aquatic Life

For total recoverable zinc the criterion to protect saltwater aquatic life as derived using the Guidelines is 58 μg/l as a 24-hour average and the concentration should not exceed 170 μg/l at any time.

Human Health

Sufficient data is not available for zinc to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 5 mg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have not demonstrated relationship to potential adverse human health effects.

Appendix B—Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and Its Uses

Introduction

This version of the Guidelines provides clarifications, additional details, and technical and editorial changes in the last version published in the **Federal Register** [44 FR 15970 (March 15, 1979)]. This version incorporates changes resulting from comments on previous versions and from experience gained during U.S. EPA's use of the previous versions. Future versions of the Guidelines will incorporate new ideas and data as their usefulness is demonstrated.

Criteria may be expressed in several forms. The numerical form is commonly used, but descriptive and procedural forms can be used if numerical criteria are not possible or desirable. The purpose of these Guidelines is to describe an objective, internally consistent and appropriate way of deriving numerical water quality criteria for the protection of the uses of, as well as the presence of, aquatic organisms.

A numerical criterion might be thought of as an estimate of the highest concentration of a substance in water which does not present a significant risk to the aquatic organisms in the water and their uses. Thus the Guidelines are intended to derive criteria which will protect aquatic communities by protecting most of the species and their uses most of the time, but not

necessarily all of the species all of the time. Aquatic communities can tolerate some stress and occasional adverse effects on a few species, and so total protection of all of the species all of the time is not necessary. Rather, the Guidelines attempt to provide a reasonable and adequate amount of protection with only a small possibility of considerable overprotection or underprotection. Within these constraints, it seems appropriate to err on the side of overprotection.

The numerical aquatic life criteria derived using the Guidelines are expressed as two numbers, rather than the traditional one number, so that the criteria can more accurately reflect toxicological and practical realities. The combination of both a maximum value and a 24-hour average value is designed to provide adequate protection of aquatic life and its uses from acute and chronic toxicity to animals, toxicity to plants and bioconcentration by aquatic organisms without being as restrictive as a one-number criterion would have to be to provide the same amout of protection. The only way to assure the same degree of protection with a one-number criterion would be to use the 24-hour average as a concentration that is not to be exceeded at any time in any place.

The two-number criterion is intended to identify an average pollutant concentration which will produce a water qualtiy generally suited to the maintenance of aquatic life and its uses while restricting the extent and duration of excursions over the average so that the total exposure will not cause unacceptable adverse effects. Merely specifying an average value over a time period is insufficient, unless the period of time is rather short, because of concentration higher than the average value can kill or cause substantial damage in short periods. Furthermore, for some substances the effect of intermittent high exposures is cumulative. It is therefore necessary to place an upper limit on pollutant concentrations to which aquatic organisms might be exposed, especially when the maximum value is not much higher than the average value. For some substances the maximum may be so much higher than the 24-hour average that in any real-world situation the maximum will never be reached if the 24-hour average is achieved. In such cases the 24-hour average will be limiting and the maximum will have no practical significance, except to indicate that elevated concentrations are acceptable as long as the 24-hour average is achieved.

These Guidelines have been developed on the assumption that the results of laboratory tests are generally useful for predicting what will happen in field situations. The resulting criteria are meant to apply to most bodies of water in the United States, except for the Great Salt Lake. All aquatic organisms and their common uses are meant to be considered, but not necessarily protected, if relevant data are available, with at least one specific exception. This exception is the accumulation of residues of organic compounds in the siscowet subspecies of lake trout which occurs in Lake Superior and contains up to 67% fat in the fillets (Thurston, C.E., 1962, Physical Characteristics and Chemical Composition of Two Subspecies of Lake Trout, J. Fish. Res. Bd. Canada 19:39–44). Neither siscowet nor organisms in the Great Salt Lake are intentionally protected by these Guidelines because both may be too atypical.

With appropriate modifications these Guidelines can be used to derive criteria for any specified geographical area, body of water (such as the Great Salt Lake), or group of similar bodies of water. Thus with appropriate modifications the Guidelines can be used to derive national, state, or local criteria if adequate information is available concerning the effects of the substance of concern on appropriate species and their uses. However, the basic concepts described in the Guidelines should be modified only when sound scientific evidence indicates that a criterion produced using the Guidelines would probably significantly overprotect or underprotect the presence or uses of aquatic life.

Criteria produced by these Guidelines are not enforceable numbers. They may be used in developing enforceable numbers, such as water quality standards and effluent standards. However, the development of standards may take into account additional factors such as social, legal, economic, and hydrological considerations, the environmental and analytical chemistry of the substance, the extrapolation from laboratory data to field situations, and the relationship between the species for which data are available and the species which are to be protected.

Because fresh water and salt water (including both estuarine and marine waters) have basically different chemical compositions and because freshwater and saltwater species rarely inhabit the same water simultaneously, separate criteria should be derived for these two kinds of waters. However, for some substances sufficient data may not be available to allow derivation of one or both of these criteria using the Guidelines.

These Guidelines are meant to be used after a decision is made that a criterion is needed for a substance. The Guidelines do not address the rationale for making that decision. If the potential for adverse effects on aquatic life and its uses are part of the basis for deciding whether or not a criterion is needed for a substance, these Guidelines may be helpful in the collection and interpretation of relevant data.

I. Define the Substance for Which the Criterion Is To Be Derived

A. Each separate chemical which would not ionize significantly in most natural bodies of water should usually be considered a separate substance, except possibly for structurally similar organic compounds that only differ in the number and location of atoms of a specific halogen, and only exist in large quantities as commercial mixtures of the various compounds, and apparently have similar chemical, biological, and toxicological properties.

B. For chemicals, which would ionize significantly in most natural bodies of water, such as inorganic salts, organic acids and phenols, all forms that would be in chemical equilibrium should usually be considered one substance. For metals, each different valence and each different covalently bonded organometallic compound should usually be considered a separate substance.

C. The definition of the substance may also need to take into account the analytical chemistry and fate of the substance.

II. Collect and Review Available Data

A. Collect all available data on the substance concerning (1) toxicity to, and bioaccumulation by, aquatic animals and plants, (2) FDA action levels, and (3) chronic feeding studies with wildlife.

B. Discard all data that are not available in hard copy (publication, manuscript, letter, memorandum, etc.) with enough supporting information to indicate that acceptable test procedures were used and that the results are reliable. Do not assume that all published data are acceptable.

C. Discard questionable data. For example, discard data from tests for which no control treatment existed, in which too many organisms in the control treatment died or showed signs of stress or disease, or in which distilled or deionized water was used as the dilution water for aquatic organisms. Discard data on formulated mixtures and emulsifiable concentrates of the

substance of concern, but not necessarily data on technical grade material.

D. Do not use data obtained using:

1. Brine shrimp, because they usually only occur naturally in water with salinity greater than 35 g/kg.

2. Species that do not have reproducing wild populations resident in—but not necessarily native to—North America. Resident North American species of fishes are defined as those listed in "A List of Common and Scientific Names of Fishes from the United States and Canada", 3rd ed., Special Publication No. 6, American Fisheries Society, Washington, D.C., 1970. Data obtained with non-resident species can be used to indicate relationships and possible problem areas, but cannot be used in the derivation of criteria.

3. Organisms that were previously exposed to significant concentrations of the test material or other pollutants.

III. Minimum Data Base

A. A minimum amount of data should be available to help ensure that each of the four major kinds of possible adverse effects receives some consideration. Results of acute and chronic toxicity tests with a reasonable number and variety of aquatic animals are necessary so that data available for tested species can be considered a useful indication of the sensitivities of the numerous untested species. The requirements concerning toxicity to aquatic plants are less stringent because procedures for conducting tests with plants are not as well developed and the interpretation of the results is more questionable. Data concerning bioconcentration by aquatic organisms can only be used if other relevant data are available.

B. To derive a criterion for freshwater aquatic life, the following should be available:

1. Acute tests (see Section IV) with freshwater animals in at least eight different families provided that of the eight species:
—at least one is a salmonid fish
—at least one is a non-salmonid fish
—at least one is a planktonic crustacean
—at least one is a benthic crustacean
—at least one is a benthic insect
—at least one of the benthic species is a detritivore

2. Acute-chronic ratios (see Section VI) for at least three species of aquatic animals provided that of the three species:
—at least one is a fish
—at least one is an invertebrate
—at least one is a freshwater species (the other two may be saltwater species)

3. At least one test with a freshwater alga or a chronic test with a freshwater vascular plant (see Section VIII). If plants are among the aquatic organisms that are most sensitive to the substance, tests with more than one species should be available.

4. At least one acceptable bioconcentration factor determined with an aquatic animal species, if a maximum permissible tissue concentration is available (see Section IX).

C. To derive a criterion for saltwater aquatic life, the following should be available:

1. Acute tests (see Section IV) with saltwater animals in at least eight different families provided that of the eight species:
—at least two different fish families are included
—at least five different invertebrate families are included
—either the Mysidae or Penaeidae family or both are included
—at least one of the invertebrate families is in a phylum other than Arthropoda

2. Acute-chronic ratios (see Section VI) for at least three species of aquatic animals provided that of the three species:
—at least one is a fish
—at least one is an invertebrate
—at least one is a saltwater species (the other two may be freshwater species)

3. At least one test with a saltwater alga or a chronic test with a saltwater vascular plant (see Section VIII). If plants are among the aquatic organisms most sensitive to the substance, tests with more than one species should be available.

4. At least one acceptable bioconcentration factor determined with an aquatic animal species, if a maximum permissible tissue concentration is available (see Section IX).

D. If all the requirements of the minimum data base are met, a criterion can usually be derived, except in special cases. For example, a criterion might not be possible if the acute-chronic ratios vary greatly with no apparent pattern. Also, if a criterion is to be related to a water quality characteristic, (see Sections V and VII), more data will be necessary.

Similarly, if the minimum data requirements are not satisfied, generally a criterion should not be derived, except in special cases. One such special case would be when less than the minimum amount of acute and chronic data are available, but the available data clearly indicate that the Final Residue Value would be substantially lower then either the Final Chronic Value or the Final Plant Value.

IV. Final Acute Value

A. Appropriate measures of the acute (short-term) toxicity of the substance to various species of aquatic animals are used to calculate the Final Acute Value. If acute values are available for fewer than twenty species, the Final Acute Value probably should be lower than the lowest value. On the other hand, if acute values are available for more than twenty species, the Final Acute Value probably should be higher than the lowest value, unless the most sensitive species is an important one. Although the procedure used to calculate the Final Acute Value has some limitations, it apparently is the best of the procedures currently available.

B. Acute toxicity tests should be conducted using procedures such as those described in:

ASTM Standard E 729–80, Practice for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians. American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

ASTM Standard E 724–80, Practice for Conducting Static Acute Toxicity Tests with Larvae of Four Species of Bivalve Molluscs. American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

C. Results of acute tests in which food was added to the test solutions should not be used, because this may unnecessarily affect the results of the test.

D. Results of acute tests conducted with embryos should not be used (but see Section IV.E.2), because this is often an insensitive life stage.

E. Acute values should be based on endpoints and lengths of exposure appropriate to the life stage of the species tested. Therefore, only the following kinds of data on acute toxicity to aquatic animals should be used:

1. 48-hr EC50 values based on immobilization and 48-hr LC50 values for first-instar (less than 24 hours old) daphnids and other cladocerans, and second- or third-instar midge larvae.

2. 48- to 96-hr EC50 values based on incomplete shell development and 48- to 96-hr LC50 values for embryos and larvae of barnacles, bivalve molluscs (clams, mussels, oysters, and scallops), sea urchins, lobsters, crabs, shrimps, and abalones.

3. 96-hr EC50 values based on decreased shell deposition for oysters.

4. 96-hr EC50 values on immobilization or loss of equilibrium or both and 96-hr LC50 values for aquatic animals, except for cladocerans, midges, and animals whose behavior or physiology allows them to avoid

exposure to toxicant or for whom the acute adverse effect of the exposure cannot be adequately measured. Such freshwater and saltwater animals include air-breathing molluscs, unionid clams, operculate snails, and bivalve molluscs, except for some species that cannot "close up" and thus prevent exposure to toxicant, such as the bay scallop (*Argopecten irradians*).

F. For the use of LC50 or EC50 values for durations shorter and longer than those listed above, see Section X.

G. If the acute toxicity of the substance to aquatic animals has been shown to be related to a water quality characteristic such as hardness for freshwater organisms or salinity for saltwater organisms, a Final Acute Equation should be derived based on that water quality characteristic. Go to Section V.

H. If the acute toxicity of the substance has not been adequately shown to be related to a water quality characteristic, for each species for which at least one acute value is available, calculate the geometric mean of the results of all flow-through tests in which the toxicant concentrations were measured. For a species for which no such result is available, calculate the geometric mean of all available acute values, i.e., results of flow-through tests in which the toxicant concentrations were not measured and results of static and renewal tests based on initial total toxicant concentrations.

Note.—The geometric mean of N numbers is obtained by taking the N^{th} root of the product of N numbers. Alternatively, the geometric mean can be calculated by adding the logarithms of the N numbers, dividing the sum by N, and taking the antilog of the quotient. The geometric mean of two numbers can also be calculated as the square root of the product of the two numbers. The geometric mean of one number is that number. Either natural (base e) or common (base 10) logarithms can be used to calculate geometric means as long as they are used consistently within each set of data, i.e., the antilog used must match the logarithm used.

I. Count the number=N of species for which a species mean acute value is available.

J. Order the species mean acute values from low to high. Take the common logarithms of the N values (log mean values).

K. The intervals (cell widths) for the lower cumulative proportion calculations are 0.11 common log units apart, starting from the lowest log value. The value of 0.11 is an estimate of average precision and was calculated from replicate species acute values.

L. Starting with the lowest log mean value, separate the N values into intervals (or cells) calculated in Step IV. K.

M. Calculate cumulative proportions for each non-empty interval by summing the number of values in the present and all lower intervals and dividing by N. These calculations only need to be done for the first three non-empty intervals (or cells).

N. Calculate the arithmetic mean of the log mean values for each of the three intervals.

O. Using the two interval mean acute values and cumulative proportions closest to 0.05, linearly extrapolate or interpolate to the 0.05 log concentration. The Final Acute Value is the antilog of the 0.05 concentration.

In other words, where

Prop(1) and conc(1) are the cumulative proportion and mean log value for the lowest non-empty interval.

Prop(2) and conc(2) are the cumulative proportion and mean log value for the second lowest non-empty interval.

A=Slope of the cumulative proportions

B=The 0.05 log value

Then:

$A=[0.05-Prop(1)]/[Prop(2)-Prop(1)]$

$B=conc(1)+A\,[conc(2)-conc(1)]$

Final Acute Value=10^B

P. If for an important species, such as a recreationally or commercially important species, the geometric mean of the acute values from flow-through tests in which the toxicant concentrations were measured is lower than the Final Acute Value, then that geometric mean should be used as the Final Acute Value.

Q. Go to Section VI.

V. Final Acute Equation

A. When enough data are available to show that acute toxicity to two or more species is similarly affected by a water quality characteristic, this effect can be taken into account as described below. Pooled regression analysis should produce similar results, although data available for individual species would be weighted differently.

B. For each species for which comparable acute toxicity values are available at two or more different values of a water quality characteristic which apparently affects toxicity, perform a least squares regression of the natural logarithms of the acute toxicity values on the natural logarithms of the values of the water quality characteristic. [Natural logarithms [logarithms to the base e, denoted as ln] are used herein merely because they are easier to use on some hand calculators and computers than common logarithms [logarithms to the base 10]. Consistent use of either will produce the same result.] No transformation or a different transformation may be used if it fits the data better, but appropriate changes will be necessary throughout this section.

C. Determine whether or not each acute slope is meaningful, taking into account the range and number of values of the water quality characteristic tested. For example, a slope based on four data points may be of limited value if it is based only on data for a narrow range of values of the water quality characteristic. On the other hand, a slope based on only two data points may be meaningful if it is consistent with other information and if the two points cover a broad enough range of the water quality characteristic. If meaningful slopes are not available for at least two species or if the available slopes are not similar, return to Section IV. H., using the results of tests conducted under conditions and in water similar to those commonly used for toxicity tests with the species.

D. Calculate the mean acute slope (V) as the arithmetic average of all the meaningful acute slopes for individual species.

E. For each species calculate the geometric mean (W) of the acute toxicity values and the geometric mean (X) of the related values of the water quality characteristic.

F. For each species calculate the logarithmic intercept (Y) using the equation: $Y=\ln W-V(\ln X)$.

G. For each species calculate the species mean acute intercept as the antilog of Y.

H. Obtain the Final Acute Intercept by using the procedure described in Section IV. I–O, except insert "Intercept" for "Value".

I. If for an important species, such as a recreationally or commercially important species, the intercept calculated only from results of flow-through tests in which the toxicant concentrations were measured is lower than the Final Acute Intercept, then that intercept should be used as the Final Acute Intercept.

J. The Final Acute Equation is written as $e^{(V[\ln(\text{water quality characteristic})]+\ln Z)}$, where V=mean acute slope and Z=Final Acute Intercept.

VI. Final Chronic Value

A. The Final Chronic Value can be calculated in the same manner as the Final Acute Value or by dividing the Final Acute Value by the Final Acute-Chronic Ratio, depending on the data available. In some cases it will not be possible to calculate a Final Chronic Value.

B. Use only the results of flow-through (except renewal is acceptable for

daphnids) chronic tests in which the concentrations of toxicant in the test solutions were measured.

C. Do not use the results of any chronic test in which survival, growth, or reproduction among the controls was unacceptably low.

D. Chronic values should be based on endpoints and lengths of exposure appropriate to the species. Therefore, only the results of the following kinds of chronic toxicity tests should be used:

1. Life-cycle toxicity tests consisting of exposures of each of several groups of individuals of a species to a different concentration of the toxicant throughout a life cycle. To ensure that all life stages and life processes are exposed, the test should begin with embryos or newly hatched young less than 48 hours old (less than 24 hours old for daphnids), continue through maturation and reproduction, and with fish should end not less than 24 days (90 days for salmonids) after the hatching of the next generation. For fish, data should be obtained and analyzed on survival and growth of adults and young, maturation of males and females, embryos spawned per female, embryo viability (salmonids only) and hatchability. For daphnids, data should be obtained and analyzed on survival and young per female.

2. Partial life-cycle toxicity tests consisting of exposures of each of several groups of individuals of a species of fish to a different concentration of the toxicant through most portions of a life cycle. Partial life-cycle tests are conducted with fish species that require more than a year to reach sexual maturity, so that the test can be completed in less than 15 months, but still expose all major life stages to the toxicant. Exposure to the toxicant begins with immature juveniles at least 2 months prior to active gonad development, continues through maturation and reproduction, and ends not less than 24 days (90 days for salmonids) after the hatching of the next generation. Data should be obtained and analyzed on survival and growth of adults and young, maturation of males and females, embryos spawned per female, embryo viability (salmonids only) and hatchability.

3. Early-life-stage toxicity tests consisting of 28- to 32-days (60 days post-hatch for salmonids) exposures of the early life stages of a species of fish from shortly after fertilization through embryonic, larval, and early juvenile development. Data should be obtained and analyzed on survival and growth.

E. Do not use the results of an early-life-stage test if results of a life-cycle or partial life-cycle test with the same species are available.

F. A chronic value is obtained by calculating the geometric mean of the lower and upper chronic limits from a chronic test. A lower chronic limit is the highest tested concentration (1) in an acceptable chronic test, (2) which did not cause the occurrence (which was statistically significantly different from the control at $p=0.05$) of a specified adverse effect, and (3) below which no tested concentration caused such an occurrence. An upper chronic limit is the lowest tested concentration (1) in an acceptable chronic test, (2) which did cause the occurrence (which was statistically significantly different from the control at $p=0.05$) of a specified adverse effect and (3) above which all tested concentrations caused such an occurrence.

Note.—Various authors have used a variety of terms and definitions to interpret the results of chronic tests, so reported results should be reviewed carefully.

G. If the chronic toxicity of the substance to aquatic animals has been adequately shown to be related to a water quality characteristic such as hardness for freshwater organisms or salinity for saltwater organisms, a Final Chronic Equation should be derived based on that water quality characteristic. Go to Section VII.

H. If chronic values are available for eight species as described in Section III. B.1 or III. C.1, a species mean chronic value should be calculated for each species for which at least one chronic value is available by calculating the geometric mean of all the chronic values for the species. The Final Chronic Value should then be obtained using the procedures described in Section IV. I–O. Then go to Section VI. M.

I. For each chronic value for which at least one appropriate acute value is available, calculate an acute-chronic ratio, using for the numerator the arithmetic average of the results of all standard flow-through acute tests in which the concentrations were measured and which are from the same study as the chronic test. If such an acute test is not available, use for the numerator the results of a standard acute test performed at the same laboratory with the same species, toxicant and dilution water. If no such acute test is available, use the species mean acute value for the numerator.

Note.—If the acute toxicity or chronic toxicity or both of the substance have been adequately shown to be related to a water quality characteristic, the numerator and the denominator must be based on tests performed in the same water.

J. For each species, calcuate the species mean acute-chronic ratio as the geometric mean of all the acute-chronic ratios available for that species.

K. For some substances the species mean acute-chronic ratio seems to be the same for all species, but for other substances the ratio seems to increase as the species mean acute value increases. Thus the Final Acute-Chronic Ratio can be obtained in two ways, depending on the data available.

1. If no major trend is apparent and the acute-chronic ratios for a number of species are within a factor of ten, the final Acute-Chronic Ratio should be calculated as the geometric mean of all the species mean acute-chronic ratios available for both freshwater and saltwater species.

2. If the species mean acute-chronic ratio seems to increase as the species mean acute value increases, the value of the acute-chronic ratio for species whose acute values are close to the Final Acute Value should be chosen as the Final Acute-Chronic Ratio.

L. Calculate the Final Chronic Value by dividing the Final Acute Value by the Final Acute-Chronic Ratio.

M. If the species mean chronic value of an important species, such as a commercially or recreationally important species, is lower than the Final Chronic Value, then that species mean chronic value should be used as the Final Chronic Value.

N. Go to Section VIII.

VII. Final Chronic Equation

A. For each species for which comparable chronic toxicity values are available at two or more different values of a water quality characteristic which apparently affects chronic toxicity, perform a least squares regression of the natural logarithms of the chronic toxicity values on the natural logarithms of the water quality characteristic values. No transformation or a different transformation may be used if it fits the data better, but appropriate changes will be necessary throughout this section. It is probably preferable, but not necessary, to use the same transformation that was used with the acute values in Section V.

B. Determine whether or not each chronic slope is meaningful, taking into account the range and number of values of the water quality characteristic tested. For example, a slope based on four data points may be of limited value if it is based only on data for a narrow range of values of the water quality characteristic. On the other hand, a slope based on only two data points may be meaningful if it is consistent with other information and if the two points cover a broad enough range of the water quality characteristic. If a

meaningful chronic slope is not available for at least one species, return to Section VI. H.

C. Calculate the mean chronic slope (L) as the arithmetic average of all the meaningful chronic slopes for individual species.

D. For each species calculate the geometric mean (M) of the toxicity values and the geometric mean (P) of the related values of the water quality characteristic.

E. For each species calculate the logarithmic intercept (Q) using the equation: $Q = \ln M - L(\ln P)$.

F. For each species calculate a species mean chronic intercept as the antilog of Q.

G. Obtain the Final Chronic Intercept by using the procedure described in Section IV. I–O, except insert "Intercept" for "Value".

H. If the species mean chronic intercept of an important species, such as a commercially or recreationally important species, is lower than the Final Chronic Intercept, then that species mean chronic intercept should be used as the Final Chronic Intercept.

I. The Final Chronic Equation is written as $e^{(L[\ln(\text{Water quality characteristic})]+\ln R)}$, where L = mean chronic slope and R = Final Chronic Intercept.

VIII. Final Plant Value

A. Appropriate measures of the toxicity of the substance to aquatic plants are used to compare the relative sensitivities of aquatic plants and animals.

B. A value is a concentration which decreased growth (as measured by dry weight, chlorophyll, etc.) in a 96-hr or longer test with an alga or in a chronic test with an aquatic vascular plant.

C. Obtain the Final Plant Value by selecting the lowest plant value from a test in which the toxicant concentrations were measured.

IX. Final Residue Value

A. The Final Residue Value is derived in order to (1) prevent commercially or recreationally important aquatic organisms from exceeding relevant FDA action levels and (2) protect wildlife, including fishes and birds, that eat aquatic organisms from demonstrated adverse effects. A residue value is calculated by dividing a maximum permissible tissue concentration by an appropriate bioconcentration factor (BCF), where the BCF is the quotient of the concentration of a substance in all or part of an aquatic organism divided by the concentration in water to which the organism has been exposed. A maximum permissible tissue concentration is either (1) an action level from the FDA Administrative Guidelines Manual for fish oil or for the edible portion of fish or shellfish, or (2) a maximum acceptable dietary intake based on observations on survival, growth or reproduction in a chronic wildlife feeding study. If no maximum permissible tissue concentration is available, go to Section X because no Final Residue Value can be derived.

B. 1. A BCF determined in a laboratory test should be used only if it was calculated based on measured concentrations of the substance in the test solution and was based on an exposure that continued until either steady-state or 28-days was reached. Steady-state is reached when the BCF does not change significantly over a period of time, such as two days or 16 percent of the length of the exposure, whichever is longer. If a steady-state BCF is not available for a species, the available BCF for the longest exposure over 28 days should be used for that species.

2. A BCF from a field exposure should be used only when it is known that the concentration of the substance was reasonably constant for a long enough period of time over the range of territory inhabited by the organisms.

3. If BCF values from field exposures are consistently lower or higher than those from laboratory exposures, then only those values from field exposures should be used if possible.

4. A BCF should be calculated based on the concentration of the substance and its metabolites, which are structurally similar and are not much more soluble in water than the parent compound, in appropriate tissue and should be corrected for the concentration in the organisms at the beginning of the test.

5. A BCF value obtained from a laboratory or field exposure that caused an observable adverse effect on the test organism may be used only if it is similar to that obtained with unaffected organisms at lower concentrations in the same test.

6. Whenever a BCF is determined for a lipid-soluble substance, the percent lipids should also be determined in the tissue for which the BCF was calculated.

C. A BCF calculated using dry tissue weights must be converted to a wet tissue weight basis by multiplying the dry weight BCF value by 0.1 for plankton and by 0.2 for individual species of fishes and invertebrates.

Note.—The values of 0.2 and 0.1 were derived from data published in:

McDiffett, W. F., 1970. Ecology 51:975–988.
Brocksen, R. W., et al. 1968. J. Wildlife Management 32:52–75.
Cummins, K. W., et al. 1973. Ecology 54: 336–345.
Pesticide Analytical Manual, Volume I. Food and Drug Administration, 1969.
Love, R. M., 1957. In The Physiology of Fishes, Vol. I, M. E. Brown, ed. Academic Press, New York. p. 411.
Ruttner, F., 1963. Fundamentals of Limnology. 3rd ed. Trans. by D. G. Frey and F. E. J. Fry. Univ. of Toronto Press, Toronto.

Some additional values can be found in:

Sculthorpe, C. D., 1967. The Biology of Aquatic Vascular Plants. Arnold Publishing Ltd., London.

D. If enough pertinent data exist, several residue values can be calculated by dividing maximum permissible tissue concentrations by appropriate BCF values.

1. For each available maximum acceptable dietary intake derived from a chronic feeding study with wildlife, including birds and aquatic organisms, the appropriate BCF is based on the whole body of aquatic species which constitute or represent a major portion of the diet of the tested wildlife species.

2. For an FDA action level, the appropriate BCF is the highest geometric mean species BCF for the edible portion (muscle for decapods, muscle with or without skin for fishes, adductor muscle for scallops and total living tissue for other bivalve molluscs) of a consumed species. The highest species BCF is used because FDA action levels are applied on a species-by-species basis.

E. For lipid-soluble substances, it may be possible to calculate additional residue values. Because steady-state BCF values for a lipid-soluble chemical seem to be proportional to percent lipids from one tissue to another and from one species to another, extrapolations can be made from tested tissues or species to untested tissues or species on the basis of percent lipids.

1. For each BCF for which the percent lipids is known for the same tissue for which the BCF was measured, the BCF should be normalized to a one percent lipid basis by dividing the BCF by the percent lipids. This adjustment to a one percent lipid basis makes all the measured BCF values comparable regardless of the species or tissue for which the BCF was measured.

2. Calculate the geometric mean normalized BCF. Data for both saltwater and freshwater species can be used to determine the mean normalized BCF, because the normalized BCF seems to be about the same for both kinds of organisms.

3. Residue values can then be calculated by dividing the maximum permissible tissue concentrations by the mean normalized BCF and by a percent lipids value appropriate to the maximum permissible tissue concentration, *i.e.*,

$$\text{Residue Value} = \frac{\text{(maximum permissible tissue concentration)}}{\text{(mean normalized BCF)(appropriate percent lipids)}}$$

a. For an FDA action level for fish oil, the appropriate percent lipids value is 100.

b. For an FDA action level for fish, the appropriate percent lipids value is 15 for freshwater criteria and 16 for saltwater criteria because FDA action levels are applied on a species-by-species basis to commonly consumed species. The edible portion of the freshwater lake trout averages about 15 percent lipids, and the edible portion of the saltwater Atlantic herring averages about 16 percent lipids (Sidwell, V. D., et al. 1974 Composition of the Edible Portion of Raw (Fresh or Frozen) Crustaceans, Finfish, and Mollusks. I. Protein, Fat, Moisture, Ash, Carbohydrate, Energy Value, and Cholesterol. Marine Fisheries Review 36:21–35).

c. For a maximum acceptable dietary intake derived from a chronic feeding study with wildlife, the appropriate percent lipids is the percent lipids of an aquatic species or group of aquatic species which constitute a major portion of the diet of the wildlife species.

F. The Final Residue Value is obtained by selecting the lowest of the available residue values. It should be noted that in many cases the Final Residue Value will not be low enough. For example, a residue value calculated from an FDA action level would result in an average concentration in the edible portion of a fatty species that is at the action level. On the average half of the individuals of the species would have concentrations above the FDA action level. Also, the results of many chronic feeding studies are concentrations that cause adverse effects.

X. Other Data

Pertinent information that could not be used in earlier sections may be available concerning adverse effects on aquatic organisms and their uses. The most important of these are data on flavor impairment, reduction in survival, growth, or reproduction, or any other adverse effect that has been shown to be biologically significant. Especially important are data for species for which no other data are available. Data from behavioral, micorcosm, field, and physiological studies may also be available.

XI. Criterion

A. The criterion consists of two concentrations, one that should not be exceeded on the average in a 24-hour period and one that should not be exceeded at any time during the 24-hour period. This two-number criterion is intended to identify water quality conditions that should protect aquatic life and its uses from acute and chronic adverse effects of both cumulative and noncumulative substances without being as restrictive as a one-number criterion would have to be to provide the same degree of protection.

B. The maximum concentration is the Final Acute Value or is obtained from the Final Acute Equation.

C. The 24-hour average concentration is obtained from the Final Chronic Value, the Final Plant Value, and the Final Residue Value by selecting the lowest available value, unless other data (see Section X) from tests in which the toxicant concentrations were measured show that a lower value should be used. If toxicity is related to a water quality characteristic, the 24-hour average concentration is obtained from the Final Chronic Equation, the Final Plant Value, and the Final Residue Value by selecting the one that results in the lowest concentrations in the normal range of the water quality characteristic, unless other data (see Section X) from tests in which the toxicant concentrations were measured show that a lower value should be used.

D. The criterion is (the 24-hour average concentration) as a 24-hour average and the concentration should not exceed (the maximum concentration) at any time.

XII. Review

A. On the basis of all available pertinent laboratory and field information, determine if the criterion is consistent with sound scientific evidence. If it is not, another criterion, either higher or lower, should be derived using appropriate modifications of the Guidelines.

These Guidelines were written by Charles E. Stephan, Donald I. Mount, David J. Hansen, John H. Gentile, Gary A. Chapman and William A. Brungs of the U.S.E.P.A. Environmental Research Laboratories in Corvallis, Oregon, Duluth, Minnesota, Gulf Breeze, Florida, and Narragansett, Rhode Island. Numerous other people, many of whom do not work for U.S.E.P.A., provided assistance and suggestions.

Appendix C–Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Criteria Documents

I. Objective

The objective of the health effect assessment chapters of the ambient water criteria documents is to estimate ambient water concentrations which do not represent a significant risk to the public. These assessments should constitute a review of all relevant information on individual chemicals or chemical classes in order to derive criteria that represent, in the case of suspect or proven carcinogens, various levels of incremental cancer risk, or, in the case of other pollutants, estimates of no-effect levels.

Ideally, ambient water quality criteria should represent levels for compounds in ambient water that do not pose a hazard to the human population. However, in any realistic assessment of human health hazard, a fundamental distinction must be made between absolute safety and the recognition of some risk. Criteria for absolute safety would have to be based on detailed knowledge of dose-response relationships in humans, including all sources of chemical exposure, the types of toxic effects elicited, the existence of thresholds for the toxic effects, the significance of toxicant interactions, and the variances of sensitivities and exposure levels within the human population. In practice, such absolute criteria cannot be established because of deficiencies in both the available data and the means of interpreting this information. Consequently, the individual human health effects chapters propose criteria which minimize or specify the potential risk of adverse human effects due to substances in ambient water. Potential social or economic costs and benefits are not considered in the formulation of the criteria.

II. Types of Criteria

Ambient water quality criteria are based on three types of biological endpoints: carcinogenicity, toxicity (i.e., all adverse effects other than cancer), and organoleptic effects.

For the purpose of deriving ambient water quality criteria, carcinogenicity is regarded as a non-threshold phenomenon. Using this assumption, "safe" or "no effect" levels for carcinogens cannot be established because even extremely small doses must be assumed to elicit a finite increase in the incidence of the response. Consequently, water quality

criteria for carcinogens are presented as a range of pollutant concentrations associated with corresponding incremental risks.

For compounds which do not manifest any apparent carcinogenic effect, the threshold assumption is used in deriving a criterion. This assumption is based on the premise that a physiological reserve capacity exists within the organism which is thought to be depleted before clinical disease ensues. Alternatively, it may be assumed that the rate of damage will be insignificant over the life span of the organism. Thus, ambient water quality criteria are derived for non-carcinogenic chemicals, and presumably result in no observable-adverse-effect levels (NOAELs) in the exposed human population.

In some instances, criteria are based on organoleptic characteristics, i.e., thresholds for taste or odor. Such criteria are established when insufficient information is available on toxicologic effects or when the estimate of the level of the pollutant in ambient water based on organoleptic effects is lower than the level calculated from toxicologic data. It should be recognized that criteria based solely on organoleptic effects do not necessarily represent approximations of acceptable risk levels for human health.

Several ambient water quality criteria documents deal with classes of compounds which include chemicals exhibiting varying degrees of structural similarity. Because prediction of biological effects based solely on structural parameters is difficult, the derivation of compound-specific criteria is preferable to a class criterion. A compound-specific criterion is defined as a level derived from data on each individual subject compound that does not represent a significant risk to the public. For some chemical classes, however, a compound-specific criterion cannot be derived for each member of a class. In such instances, it is sometimes justifiable to derive a class criterion in which available data on one member of a class may be used to estimate criteria for other chemicals of the class because a sufficient data base is not available for those compounds.

For some chemicals and chemical classes, the data base was judged to be insufficient for the derivation of a criterion. In those cases, deficiencies in the available information are detailed.

III. Approach

The human health effects chapters attempt to summarize all information on the individual chemicals or classes of chemicals which might be useful in the risk assessment process to develop water quality criteria. Although primary emphasis is placed on identifying epidemiologic and toxicologic data, these assessments typically contain discussions on four topics: existing levels of human exposure, pharmacokinetics, toxic effects, and criterion formulation.

For all documents, an attempt is made to include the known relevant information. Review articles and reports are often used in the process of data evaluation and synthesis. Scientific judgment is exercised in the review and evaluation of the data in each document and in the identification of the adverse effects against which protective criteria are sought. In addition, each of these documents is reviewed by a peer committee of scientists familiar with the specific compound(s). These work groups evaluate the quality of the available data, the completeness of the data summary, and the validity of the derived criterion.

In the analysis and organization of the data, an attempt is made to be consistent with respect to the format and the application of acceptable scientific principles. Evaluation procedures used in the hazard assessment process follow the principles outlined by the National Academy of Sciences in *Drinking Water and Health* (1977) and the guidelines of the Carcinogen Assessment Group of the U.S. EPA.

A. Exposure

The exposure section of the health effects chapters reviews known information on current levels of human exposure to the individual pollutant from all sources. Much of the data was obtained from monitoring studies of air, water, food, soil, and human or animal tissue residues. The major purpose of this section is to provide background information on the contribution of water exposure relative to all other sources. Consequently, the exposure section includes subsections reviewing different routes of exposure including water and food ingestion, inhalation, and dermal contact.

Information on exposure can be valuable in developing and assessing a water quality criterion. In these documents exposure from consumption of contaminated water and contaminated fish and shellfish products is used in criterion formulation. Data for all modes of exposure are useful in relating total intake to the expected contribution from contaminated water, fish, and shellfish. In addition, information for all routes of exposure, not limited to drinking water and fish and shellfish ingestion, can be used to justify or assess the feasibility of the formulation of criteria for ambient water.

The use of fish consumption as an exposure factor requires the quantitation of pollutant residues in the edible portions of the ingested species. Accordingly, bioconcentration factors (BCFs) are used to relate pollutant residues in aquatic organisms to the pollutant concentration in the ambient waters in which they reside.

To estimate the average per capita intake of a pollutant due to consumption of contaminated fish and shellfish the results of a diet survey were analyzed to calculate the average consumption of freshwater and estuarine fish and shellfish (U.S. EPA, 1980). A species is considered to be a consumed freshwater or estuarine fish and shellfish species if at some stage in its life cycle, it is harvested from fresh or estuarine water for human consumption in significant quantities (Stephan, 1980).

Three different procedures are used to estimate the weighted average BCF depending upon the lipid solubility of the chemical and the availability of bioconcentration data.

For lipid-soluble compounds, the average BCF is calculated from the weighted average percent lipids in the edible portions of consumed freshwater and estuarine fish and shellfish which was calculated from data on consumption of each species and its corresponding percent lipids to be 3.0 percent (Stephan, 1980). Because the steady-state BCFs for lipid-soluble compounds are proportional to percent lipids, bioconcentration factors for fish and shellfish can be adjusted to the average percent lipids for aquatic organisms consumed by Americans. For many lipid-soluble pollutants, there exists at least one BCF for which the percent lipid value was measured for the tissues for which the BCF is determined.

With 3.0 percent as the weighted average percent lipids for freshwater and estuarine fish and shellfish in the average diet, a BCF, and a corresponding percent lipid value, the weighted average bioconcentration factor can be calculated.

Example:

Weighted average percent lipids for average diet = 3.0 percent

Measured BCF of 17 for trichloroethylene with bluegills at 4.8 percent lipids

Weighted average BCF for average diet equals

$$17 \times \frac{3.0\%}{4.8\%} = 10.6$$

As an estimate, 10.6 is used for the BCF.

In those cases where an appropriate bioconcentration factor is not available, the equation "Log BCF=(0.85 Log P)-0.70" can be used (Veith, et al. 1979) to estimate the BCF for aquatic organisms containing about 7.6 percent lipids (Veith, 1980) from the octanol/water partition coefficient P. An adjustment for percent lipids in the average diet versus 7.6 percent is made in order to derive the weighted average bioconcentration factor.

For non-lipid-soluble compounds, the available BCFs for the edible portion of consumed freshwater and estuarine fish and shellfish are weighted according to consumption factors to determine a weighted BCF representative of the average diet.

B. Pharmacokinetics

This section summarizes the available information on the absorption, distribution, metabolism, and elimination of the compound(s) in humans and experimental mammals. Conceptually, such information is useful in validation of inter- and intraspecies extrapolations, and in characterizing the modes of toxic action. Sufficient information on absorption and excretion in animals, together with a knowledge of ambient concentrations in water, food, and air, could be useful in estimating body burdens of chemicals in the human population. Distribution data which suggest target organs or tissues are desirable for interspecies comparison techniques. In terms of the derivation of criteria, pharmacokinetic data are essential to estimate equivalent oral doses based on data from inhalation or other routes of exposure.

C. Effects

This section summarizes information on biological effects in both humans and experimental mammals resulting in: acute, subacute, and chronic toxicity, synergism and/or antagonism, teratogenicity, mutagenicity, or carcinogenicity.

The major goal of this section is to survey the suitability of the data for use in assessment of hazard and to determine which biological end-point, i.e., non-threshold, threshold, or organoleptic, should be selected for use in criterion formulation.

Because this section attempts to assess potential human health effects, data on documented human effects are thoroughly evaluated. However, several factors inherent in human epidemiological studies usually preclude the use of such data in generating water quality criteria. These problems, as summarized by the National Academy of Sciences (NAS, 1977) are as follows:

1. Epidemiology cannot tell what effects a material will have until after humans have been exposed. One must not conduct what might be hazardous experiments on man.

2. If exposure has been ubiquitous, it may be impossible to assess the effects of a material, because there is no unexposed control group. Statistics of morbidity obtained before use of a new material can sometimes be useful, but when latent periods are variable and times of introduction and removal of materials overlap, historical data on chronic effects are usually unsatisfactory.

3. It is usually difficult to determine doses in human exposures.

4. Usually, it is hard to identify small changes in common effects, which may nonetheless be important if the population is large.

5. Interactions in a "nature-designed" experiment usually cannot be controlled.

Although these problems often prevent the use of epidemiological data in quantitative risk assessments, qualitative similarities or differences between documented effects in humans and observed effects in experimental mammals are extremely useful in testing the validity of animal-to-man extrapolations. Consequently, in each case, an attempt is made to identify and utilize both epidemiologic and animal dose-response data. Criteria derived from such a confirmed data base are considered to be reliable.

The decision to establish a criterion based on a non-threshold model is made after evaluating all available information on carcinogenicity and supportive information on mutagenicity. The approach and conditions for the qualitative decision of carcinogenicity are outlined in the U.S. EPA Interim Cancer Guidelines (41 FR 21402), in a report by Albert, et al. (1977), and in the Interagency Regulatory Liaison Group (IRLG) guidelines on carcinogenic risks (IRLG, 1979). It is assumed that a substance which induces a statistically significant carcinogenic response in animals has the capacity to cause cancer in humans. A chemical which has not induced a significant cancer response in humans or experimental animals is not identified as a carcinogen, even though its metabolites or close structural analogues might induce a carcinogenic response or it was shown to be mutagenic in an *in vitro* system.

It is recognized that some potential human carcinogens may not be identified by the guidelines given above. For example, compounds for which there is plausible but weak qualitative evidence of carcinogenicity in experimental animal systems (such as data from mouse skin painting or strain A mouse pulmonary adenoma) would be included in this category. The derivation of a criterion for human consumption from these studies in not valid, regardless of the qualitative outcome. In addition, there are certain compounds (e.g., nickel and beryllium) which were shown to be carcinogenic in humans after inhalation exposure by chemical form, but have induced thus far no response in animals or humans via ingesting their soluble salts. Nevertheless, a non-threshold criterion is developed for beryllium because tumors have been produced in animals at a site removed from the site of administration; in contrast, a threshold criterion is recommended for nickel because there is no evidence of tumors at sites distant resulting from administration of nickel solutions by either ingestion or injection.

For those compounds which were not reported to induce carcinogenic effects or for those compounds for which carcinogenic data are lacking or insufficient, an attempt is made to estimate a no-effect level. In many respects, the hazard evaluation from these studies is similar to that of bioassays for carcinogenicity. In order to more closely approximate conditions of human exposure, preference is given to chronic studies involving oral exposures in water or diet over a significant portion of the animal life span. Greatest confidence is placed in those studies which demonstrate dose-related adverse effects as well as no-effect levels.

There is considerable variability in the biological endpoints used to define a no-effect level. They may range from gross effects, such as mortality, to more subtle biochemical, physiological, or pathological changes. Teratogenicity, reproductive impairment, and behavioral effects are significant toxic consequences of environmental contamination. In instances where carcinogenic or other chronic effects occur at exposure levels below those causing teratogenicity, reproductive impairment, or behavioral effects, the former are used in deriving the criterion. For most of the compounds evaluated thus far, teratogenicity and reproductive impairment occur at doses near maximum tolerated levels with dose administration schedules well above estimated environmental exposure levels. Moreover, information on behavioral effects, which could be of

significance, is not available for most of the compounds under study. Consequently, most NOAELs derived from chronic studies are based either on gross toxic effects or on effects directly related to functional impairment or defined pathological lesions.

For compounds on which adequate chronic toxicity studies are not available, studies on acute and subacute toxicity assume greater significance. Acute toxicity studies usually involve single exposures at lethal or near lethal doses. Subacute studies often involve exposures exceeding 10 percent of the life span of the test organism, e.g., 90 days for the rat with an average life span of 30 months. Such studies are useful in establishing the nature of the compound's toxic effects and other parameters of compound toxicity, such as target organ effects, metabolic behavior, physiological/biochemical effects, and patterns of retention and tissue distribution. The utility of acute and subacute studies in deriving environmentally meaningful NOELs is uncertain, although McNamara (1976) has developed application factors for such derivations.

In some cases where adequate data are not available from studies utilizing oral routes of administration, no-effect levels for oral exposures may be estimated from dermal or inhalation studies. Such estimates involve approximations of the total dose administered based on assumptions about breathing rates and/or magnitude of absorption.

D. Criterion Rationale

This section reviews existing standards for the chemical(s), summarizes data on current levels of human exposure, attempts to identify special groups at risk, and defines the basis for the recommended criterion.

Information on existing standards is included primarily for comparison with the proposed water quality criteria. Some of the present standards, such as those recommended by the Occupational Safety and Health Administration (OSHA) or the American Conference of Governmental Industrial Hygienists (ACGIH), are based on toxicologic data but are intended as acceptable levels for occupational rather than environmental exposure. Other levels, such as those recommended by the National Academy of Sciences in *Drinking Water and Health* (1977) or in the U.S. EPA Interim Primary Drinking Water Standards, are more closely related to proposed water quality criteria. Emphasis is placed on detailing the basis for the existing standards wherever possible.

Summaries of current levels of human exposure, presented in this section, specifically address the suitability of the data to derive water quality criteria. The identification of special groups at risk, either because of geographical or occupational differences in exposure or biological differences in susceptibility to the compound(s), focuses on the impact that these groups should have on the development of water quality criteria.

The basis for the recommended criteria section summarizes and qualifies all of the data used in developing the criteria.

IV. Guidelines for Criteria Derivation

The derivation of water quality criteria from laboratory animal toxicity data is essentially a two-step procedure. First, a total daily intake for humans must be estimated which establishes either a defined level of risk for non-threshold effects or a no-effect level for threshold effects. Secondly, assumptions must be made about the contribution of contaminated water and the consumption of fish/shellfish to the total daily intake of the chemical. These estimates are then used to establish the tolerable daily intake and consequently the water quality criterion.

A. Non-Threshold Effects

After the decision has been made that a compound has the potential for causing cancers in humans and that data exist which permit the derivation of a criterion, the water concentration which is estimated to cause a lifetime carcinogenic risk of 10^{-5} is determined. The lifetime carcinogenicity risk is the probability that a person would get cancer sometime in his or her life assuming continuous exposure to the compound. The water concentration is calculated by using the low-dose extrapolation procedure proposed by Crump (1980). This procedure is an improvement on the multistage low dose extrapolation procedure by Crump, et al. (1977).

The data used for quantitative estimates are of two types: (1) lifetime animal studies, and (2) human studies where excess cancer risk has been associated with exposure to the agent. In animal studies it is assumed, unless evidence exists to the contrary, that if a carcinogenic response occurs at the dose levels used in the study, then proportionately lower responses will also occur at all lower doses, with an incidence determined by the extrapolation model discussed below.

1. Choice of Model.

There is no really solid scientific basis for any mathematical extrapolation model which relates carcinogen exposure to cancer risks at the extremely low levels of concentration that must be dealt with in evaluating the environmental hazards. For practical reasons, such low levels of risk cannot be measured directly either using animal experiments or epidemiologic studies. We must, therefore, depend on our current understanding of the mechanisms of carcinogenesis for guidance as to which risk model to use. At the present time, the dominant view of the carcinogenic process involves the concept that most agents which cause cancer also cause irreversible damage to DNA. This position is reflected by the fact that a very large proportion of agents which cause cancer are also mutagenic. There is reason to expect that the quantal type of biological response that is characteristic of mutagenesis is associated with a linear non-threshold dose-response relationship. Indeed, there is substantial evidence from mutagenesis studies with both ionizing radiation and with a wide variety of chemicals that this type of dose-response model is the appropriate one to use. This is particularly true at the lower end of the dose-response curve; at higher doses, there can be an upward curvature, probably reflecting the effects of multistage processes on the mutagenic response. The linear non-threshold dose-response relationship is also consistent with the relatively few epidemiological studies of cancer responses to specific agents that contain enough information to make the evaluation possible (e.g., radiation-induced leukemia, breast and thyroid cancer, skin cancer induced by arsenic in drinking water, and liver cancer induced by aflatoxin in the diet). There is also some evidence from animal experiments that is consistent with the linear non-threshold hypothesis (e.g., liver tumors induced in mice by 2-acetylaminofluorene in the large scale ED_{01} study at the National Center of Toxicological Research, and the initiation stage of the two-stage carcinogenesis model in the rat liver and the mouse skin).

Because it has the best, albeit limited, scientific basis of any of the current mathematical extrapolation models, the linear non-threshold model has been adopted as the primary basis for risk extrapolation to low levels of the dose-response relationship. The risk assessments made with this model should be regarded as conservative, representing the most plausible upper limit for the risk; i.e., the true risk is not likely to be higher than the estimate, but it could be smaller.

The mathematical formulation chosen to describe the linear, non-threshold dose-response relationship at low doses is the improved multistage model developed by Crump (1980). This model employs enough arbitrary constants to be able to fit almost any monotonically increasing dose-response data and it incorporates a procedure for estimating the largest possible linear slope (in the 95 percent confidence limit sense) at low extrapolated doses that is consistent with the data at all dose levels of the experiment. For this reason, it may be called a "linearized" multistage model.

2. Procedure of Low-Dose Extrapolation Based on Animal Carcinogenicity Data.

A. Description of the Extrapolation Model

Let P(d) represent the lifetime risk (probability) of cancer at dose d. The multistage model has the form

$$P(d)=1-\exp[-(q_0+q_1d+q_2d^2+\ldots+q_kd^k)]$$

where:

$q_i \geq 0$, and $i=0, 1, 2, \ldots, k$

Equivalently,

$$A(d)=1-\exp[-(q_1d+q_2d^2+\ldots+q_kd^k)]$$

where:

$$A(d)=\frac{P(d)-P(o)}{1-P(o)},$$

is the extra risk over background rate at dose d.

The point estimate of the coefficients q_i, $i=0, 1, 2, \ldots, k$, and consequently the extra risk function A(d) at any given dose d, is calculated by maximizing the likelihood function of the data.

The point estimate and the 95 percent upper confidence limit of the extra risk A(d) are calculated by using the computer program GLOBAL 79 developed by Crump and Watson (1979). Upper 95 percent confidence limits on the extra risk and lower 95 percent confidence limits on the dose producing a given risk are determined from a 95 percent upper confidence limit, q_1^*, on parameter q_1. Whenever $q_1 \neq 0$, at low doses extra risk A(d) has approximately the form $A(d)=q_1 \times d$. Therefore, $q_1 \times d$ is a 95 percent upper confidence limit on the extra risk and R/q_1^* is a 95 percent lower confidence limit on the dose producing an extra risk of R. Let L_0 be the maximum value of the log-likelihood function. The upper limit q_1^* is calculated buy increasing q_1 to a value q_1^* such that when the log-likelihood is again maximized subject to this fixed value q_1^* for the linear coefficient, the resulting maximum value of the log-likelihood L_1 satisfies the equation $2(L_0-L_1)=2.70554$ where 2.70554 is the cumulative 90 percent point of the chi-square distribution with one degree of freedom, which corresponds to a 95 percent upper limit (one-sided). This approach of computing the upper confidence limit for the extra risk A(d) is an improvement on the Crump, et al. (1977) model. The upper confidence limit for the extra risk calculated at low doses is always linear. This is conceptually consistent with the linear nonthreshold concept discussed earlier. The slope q_1^* is taken as an upper bound of the potency of the chemical in inducing cancer at low doses.

In fitting the dose-response model, the number of terms in the polynomial g is chosen equal to (h-1), where h is the number of dose groups in the experiment, including the control group.

Whenever the multistage model does not fit the data sufficiently, data at the highest dose is deleted and the model is refitted to the rest of the data. This is continued until an acceptable fit to the data is obtained. To determine whether or not a fit is acceptable, the chi-square statistic:

$$X^2=\sum_{i=1}^{h}\frac{(X_i-N_iP_i)^2}{N_iP_i(1-P_i)}$$

is calculated, where N_i is the number of animals in the i^{th} dose group, X_i is the number of animals in the i^{th} dose group with a tumor response, P_i is the probability of a response in the i^{th} dose group estimated by fitting the multistage model to the data, and h is the number of remaining groups.

The fit is determined to be unacceptable whenever chi-square (X^2) is larger than the cumulative 99 percent point of the chi-square distribution with f degrees of freedom, where f equals the number of dose groups minus the number of non-zero multistage coefficients.

3. Selection and Form of Data used to Estimate Parameters in the Extrapolation Model.

For some chemicals, several studies in different animal species, strains, and sexes each conducted at several doses and different routes of exposure are available. A choice must be made as to which of the data sets from several studies are to be used in the model. It is also necessary to correct for metabolism differences between species and for differences in absorption via different routes of administration. The procedures, listed below, used in evaluating these data are consistent with the estimate of a maximum-likely-risk.

a. The tumor incidence data are separated according to organ sites or tumor types. The set data (i.e., dose and tumor incidence) used in the model is set where the incidence is statistically significantly higher than the control for at least one test dose level and/or where the tumor incidence rate shows a statistically significant trend with respect to dose level. The data set which gives the highest estimate of lifetime carcinogenic risk q_1^* is selected in most cases. However, efforts are made to exclude data sets which produce spuriously high risk estimates because of a small number of animals. That is, if two sets of data show a similar dose-response relationship and one has a very small sample size, the set of data which has the larger sample size is selected for calculating the carcinogenic potency.

b. If there are two or more data sets of comparable size which are identical with respect to species, strain, sex, and tumor sites, the geometric mean of q_1^*, estimated from each of these data sets is used for risk assessment. The geometric mean of numbers $A_1, A_2, \ldots, A_m$ is defined as $(A_1 \times A_2 \times \ldots \times A_m)^{1/m}$

c. If sufficient data exist for two or more significant tumor sites in the same study, the number of animals with at least one of the specific tumor sites under consideration is used as incidence data in the model.

d. Following the suggestion of Mantel and Schneiderman (1975), we assume that mg/surface area/day is an equivalent dose between species. Since to a close approximation the surface area is proportional to the ⅔rds power of the weight as would be the case for a perfect sphere, the exposure in mg/⅔rds power of the body weight/day is similarly considered to be an equivalent exposure. In an animal experiment, this equivalent dose is computed in the following manner:

Let:

L_e = duration of experiment
l_e = duration of exposure
m = average dose per day in mg during administration of the agent (i.e., during l_e)
W = average weight of the experimental animal.

Then, the lifetime average exposure is

$$d=\frac{l_e \times m}{L_e \times W^{2/3}}$$

Often exposures are not given in units of mg/day, and it becomes necessary to convert the given exposures into mg/day. For example, in most feeding studies, exposure is expressed as ppm in the diet. In this case the exposure (mg/day) is derived by: $m=ppm \times F \times r$

where ppm is parts per million of the carcinogenic agent in the diet, F is the weight of the food consumed per day in kgms, and r is the absorption fraction.

In the absence of any data to the contrary, r is assumed to be one. For a uniform diet the weight of the food consumed is proportional to the calories required, which, in turn, is proportional to the surface area or the ⅔rds power of the weight, so that: $m \alpha ppm \times W^{2/3} \times r$ or

$$\frac{m}{rW^{2/3}} \alpha ppm$$

As a result, ppm in the diet is often assumed to be an equivalent exposure between species. However, we feel that this is not justified since the calories/kg of food is significantly different in the diet of man vs. laboratory animals, primarily due to moisture content differences. Instead, we use an empirically derived food factor, f=F/W, which is the fraction of a species body weight that is consumed per day as food. We use the rates given below.

Species	W	f
Man	70	0.028
Rat	0.35	0.05
Mice	0.03	0.13

Thus, when the exposure is given as a certain dietary concentration in ppm, the exposure in $mg/W^{2/3}$ is

$$\frac{m}{r \times W^{2/3}} = \frac{ppm \times F}{W^{2/3}} =$$

$$\frac{ppm \times f \times W}{W^{2/3}} = ppm \times f \times W^{1/3}$$

When exposure is given in terms of mg/kg/day=m/Wr=s the conversion is simply:

$$\frac{m}{rW^{2/3}} = s \times W^{1/3}$$

When exposure is via inhalation, the calculation of dose can be considered for two cases where (1) the carcinogenic agent is either a completely water-soluble gas or an aerosol and is absorbed proportionally to the amount of air breathed in, and (2) where the carcinogen is a poorly water-soluble gas which reaches an equilibrium between the air breathed and the body compartments. After equilibrium is reached, the rate of absorption of these agents is expected to be proportional to metabolic rate, which in turn is proportional to the rate of oxygen consumption, which in turn is a function of surface area.

Case 1

Agents that are in the form of particulate matter or virtually completely absorbed gases such as SO_2 can reasonably be expected to be absorbed proportional to the breathing rate. In this case the exposure in mg/day may be expressed as: $m=I \times v \times r$ where I is inhalation rate per day in m^3, v is mg/m^3 of the agent in air, and r is the absorption fraction.

The inhalation rates, I, for various species can be calculated from the observation (FASEB, 1974) that 25 gm mice breathe 34.5 liters/day and 113 gm rats breathe 105 liters/day. For mice and rats of other weights, W, (expressed in kg), the surface area proportionality can be used to determine breathing rates (in m^3/day) as follows:

For mice, $I=0.0345\ (W/0.025)^{2/3} m^3$/day

For rats, $I=0.105\ (W/0.113)^{2/3} m^3$/day

For humans, the values of 20 m^3/day [a] is adopted as a standard breathing rate (ICRP, 1977).

The equivalent exposure in $mg/W^{2/3}$ for these agents can be derived from the air intake data in a way analogous to the food intake data. The empirical factors for the air intake per kg per day, i=I/W based upon the previously stated relationships, are as tabulated below:

Species	W	i=I/W
Man	70	0.29
Rat	0.35	0.64
Mice	0.03	1.3

Therefore, for particulates or completely absorbed gases, the equivalent exposure in $mg/W^{2/3}$ is:

$$\frac{m}{W^{2/3}} = \frac{Ivr}{W^{2/3}} = \frac{iWvr}{W^{2/3}} = iW^{1/3}\,vr$$

In the absence of empirical data or a sound theoretical argument to the contrary, the fraction absorbed, r, is assumed to be the same for all species.

Case 2

The dose in mg/day of partially soluble vapors is proportional to the O_2 consumption which in turn is proportional to $W^{2/3}$ and to the solubility of gas in body fluids, which can be expressed as an absorption coefficient r for the gas. Therefore, when expressing the O_2 consumption as $O_2=k\,W^{2/3}$, where k is a constant independent of species, it follows that $m=k\,W^{2/3} \times v \times r$ or

$$d = \frac{m}{W^{2/3}} = kvr$$

As with Case 1, in the absence of experimental information or a sound theoretical argument to the contrary, the absorption fraction, r, is assumed to be the same for all species. Therefore, for these substances a certain concentration in ppm or μ/m^3 in experimental animals is equivalent to the same concentration in humans. This is supported by the observation that the minimum alveolar concentration, necessary to produce a given "stage" of anesthesia, is similar in man and animals (Dripps, et al. 1977). When the animals were exposed via the oral route and human exposure is via inhalation or vice-versa, the assumption is made, unless there is pharmacokinetic evidence to the contrary, that absorption is equal by either exposure route.

e. If the duration of experiment (L_e) is less than the natural life span of the test animal (L), the slope q_1^*, or more generally the exponent g(d), is increased by multiplying a factor $(L/L_e)^3$. We assume that if the average dose, d, is continued, the age specific rate of cancer will continue to increase as a constant function of the background rate. The age specific rates for humans increase at least by the 2nd power of the age and often by a considerably higher power, as demonstrated by Doll (1971). Thus, we would expect the cumulative tumor rate to increase by at least the 3rd power of age. Using this fact, we assume that the slope q_1^*, or more generally, the exponent g(d), would also increase by at least the 3rd power of age. As a result, if the slope q_1^* [or g(d)] is calculated at age L_e, we would expect that if the experiment had been continued for the full life span, L, at the given average exposure, the slope q_1^* [or g(d)] would have been increased by at least $(L/L_e)^3$.

This adjustment is conceptually consistent to the proportional hazard model proposed by Cox (1972) and the time-to-tumor model considered by Crump, et al. (1977) where the probability of cancer at age t and dose d is given by $P(d,t)=1-\exp[-f(t) \times g(d)]$

4. Calculation of Carcinogenic Potency Based on Human Data. If human epidemiology studies and sufficiently valid exposure information are available for the compound, they are always used in some way. If they show a carcinogenic effect, the data are analyzed to give an estimate of the linear dependence of cancer rates on lifetime average dose, which is equivalent to the factor q_1^*. If they show

[a] From "Recommendation of the International Commission on Radiological Protection," page 9, the average breathing rate is 10^7 cm^3 per 8-hour work day and 2×10^7 cm^3 in 24 hours.

no carcinogenic effect when positive animal evidence is available, then it is assumed that a risk does exist but it is smaller than could have been observed in the epidemiologic study, and an upper limit of the cancer incidence is calculated assuming hypothetically that the true incidence is just below the level of detection in the cohort studied, which is determined largely by the cohort size. Whenever possible, human data are used in perference to animal bioassay data.

In human studies, the response is measured in terms of the relative risk of the exposed cohort of individuals compared to the control group. In the analysis of this data, it is assumed that the excess risk, or relative risk minus one, $R(X)-1$, is proportional to the lifetime average exposure, X, and that it is the same for all ages. It follows that the carcinogenic potency is equal to $[R(X)-1]/X$ multiplied by the lifetime risk at that site in the general population. Except for an unusually well-documented human study, the confidence limit for the excess risk is not calculated, due to the difficulty in accounting for the uncertainty inherent in the data (exposure and cancer response).

5. Calculation of Water Quality Criteria. After the value of q_1^* in $(mg/kg/day)^{-1}$ has been determined, the lifetime risk, P, from an average daily exposure of x mg/kg/day is found from the equation $P=q_1^*x$. Therefore, if the lifetime risk is set at $P=10^{-5}$ for calculation purposes, the intake, I, in mg/day for a 70 kg person can be found by the equation: $I=70\times10^{-5}/q_1^*$ The intake of the agent from ambient water is assumed to come from two sources: (1) drinking an average of 2 liters of water per day, and (2) ingesting an average of 6.5 grams of fish per day. Because of accumulation of residues in fish, the amount of the pollutant in fish (mg/kg of edible fish) is equal to a factor R times the water concentration (mg/kg of water). Therefore, the total intake I can be written as sum of two terms: $I(mg/day)=C(mg/l)\times R(l/kg\ fish)\times 0.0065\ kg\ fish/day+C(mg/l\times 2l/day=C(2+0.0065R)$ where C is the water concentration in mg/l. Therefore, the water concentration in mg/l corresponding to a lifetime risk of 10^{-5} for a 70 kg person is calculated by the formula:

$$C = \frac{70 \times 10^{-5}}{q_1^*(2 + 0.0065\ R)}$$

B. Threshold Effects

1. Use of Animal Toxicity Data (Oral). In developing guidelines for deriving criteria based on noncarcinogenic responses, five types of response levels are considered:

NOEL—No-Observed-Effect-Level
NOAEL—No-Observed-Adverse-Effect-Level
LOEL—Lowest-Observed-Effect-Level
LOAEL—Lowest-Observed-Adverse-Effect-Level
FEL—Frank-Effect-Level

Adverse effects are defined as any effects which result in functional impairment and/or pathological lesions which may affect the performance of the whole organism, or which reduce an organism's ability to respond to an additional challenge.

One of the major problems encountered in consideration of these concepts regards the reporting of "observed effect levels" as contrasted to "observed adverse effect levels". The terms "adverse" vs. "not adverse" are at times satisfactorily defined, but due to increasingly sophisticated testing protocols, more subtle responses are being identified, resulting in a need for judgment regarding the exact definition of adversity.

The concepts listed above (NOEL, NOAEL, LOEL, LOAEL) have received much attention because they represent landmarks which help to define the threshold region in specific experiments. Thus, if a single experiment yields a NOEL, a NOAEL, a LOAEL, and a clearly defined FEL in relatively closely spaced doses, the threshold region has been relatively well defined; such data are very useful for the purpose of deriving a criterion. On the other hand, a clearly defined FEL has little utility in establishing criteria when it stands alone, because such a level gives no indication how far removed the data point is from the threshold region. Similarly, a free-standing NOEL has little utility, because there is no indication of its proximity to the LOEL, since a free-standing NOEL may be many orders of magnitude below the threshold region.

Based on the above dose-response classification system, the following guidelines for deriving criteria have been adopted:

a. A free-standing FEL is unsuitable for the derivation of criteria.

b. A free-standing NOEL is unsuitable for the derivation of criteria. If multiple NOELs are available without additional data on LOELs, NOAELs, or LOAELs, the highest NOEL should be used to derive a criterion.

c. A NOAEL, LOEL, or LOAEL can be suitable for criteria derivation. A well-defined NOAEL from a chronic (at least 90-day) study may be used directly, applying the appropriate uncertainty factor. For a LOEL, a judgment needs to be made whether it actually corresponds to a NOAEL or a LOAEL. In the case of a LOAEL, an additional uncertainty factor is applied; the magnitude of the additional uncertainty factor is judgmental and should lie in the range of 1 to 10. Caution must be exercised not to substitute "Frank-Effect-Levels" for "Lowest-Observable-Adverse-Effect-Levels".

d. If for reasonably closely spaced doses only a NOEL and a LOAEL of equal quality are available, then the appropriate uncertainty factor is applied to the NOEL.

In using this approach, the selection and justification of uncertainty factors are critical. The basic definition and guidelines for using uncertainty factors has been given by the National Academy of Sciences (1977). "Safety Factor" or "Uncertainty Factor" is defined as a number that reflects the degree or amount of uncertainty that must be considered when experimental data in animals are extrapolated to man. When the quality and quantity of experimental data are satisfactory, a low uncertainty factor is used; when data is judged to be inadequate or equivocal, a larger uncertainty factor is used. The following general guidelines have been adopted in establishing the uncertainty factors:

a. Valid experimental results from studies on prolonged ingestion by man, with no indication of carcinogenicity. Uncertainty Factor=10

b. Experimental results of studies of human ingestion not available or scanty (e.g., acute exposure only) with valid results of long-term feeding studies on experimental animals, or in the absence of human studies, valid animal studies on one or more species. No indication of carcinogenicity. Uncertainty Factor=100

c. No long-term or acute human data. Scanty results on experimental animals with no indication of carcinogenicity. Uncertainty Factor=1,000

Considerable judgment must be used in selecting the appropriate safety factors for deriving a criterion. In those cases where the data do not completely fulfill the conditions for one category and appear to be intermediate between two categories an intermediate uncertainty factor is used. Such an intermediate uncertainty factor may be developed based on a logarithmic scale (e.g., 33, being halfway between 10 and 100 on a logarithmic scale).

In determining the appropriate use of the uncertainty factors, the phrase "no

indication of carcinogenicity" is interpreted as the absence of carcinogenicity data from animal experimental studies or human epidemiology. Available short-term carcinogenicity screening tests are reported in the criteria documents, but they are not used either for derivation of numerical criteria nor to rule out the uncertainty factor approach.

Because of the high degree of judgment involved in the selection of a safety factor, the criterion derivation section of each document should provide a detailed discussion and justification for both the selection of the safety factor and the data to which it is applied. This discussion should reflect a critical review of the available data base. Factors to be considered include number of animals, species, and parameters tested; quality of controls; dose levels; route; and dosing schedules. An effort should be made to differentiate between results which constitute a toxicologically sufficient data base and data which may be spurious in nature.

2. Use of Acceptable Daily Intake (ADI). For carcinogens, the assumption of low dose linearity precludes the necessity for defining total exposure in the estimation of increased incremental risk. For non-carcinogens, ADIs and criteria derived therefrom are calculated from total exposure data that include contributions from the diet and air. The equation used to derive the criterion (C) is: $C=ADI-(DT+IN)/[2\ l+(0.0065\ kg \times R)]$ where 2 l is assumed daily water consumption, 0.0065 kg is assumed daily fish consumption, R is bioconcentration factor in units of l/kg, DT is estimated non-fish dietary intake, and IN is estimated daily intake by inhalation.

If estimates of IN and DT cannot be provided from experimental data, an assumption must be made concerning total exposure. It is recognized that either the inability to estimate DT and IN due to lack of data or the wide variability in DT and IN in different states may add an additional element of uncertainty to the criterion formulation process. In terms of scientific validity, the accurate estimate of the Acceptable Daily Intake is the major factor in satisfactory derivation of water quality criteria.

3. Use of Threshold Limit Values or Animal Inhalation Studies. Threshold Limit Values (TLVs) are established by the American Conference of Governmental and Industrial Hygienists (ACGIH) and represent 8-hour time-weighted average concentrations in air that are intended to protect workers from various adverse health effects over a normal working lifetime. Similar values are set by NIOSH (criteria) and OSHA (standards) for 10- and 8-hour exposures, respectively. To the extent that these values are based on sound toxicologic assessments and have been protective in the work environment, they provide useful information for deriving or evaluating water quality criteria. However, each TLV must be carefully examined to determine if the basis of the TLV contains data which can be used directly to derive a water quality criterion using the uncertainty factor approach. In addition, the history of each TLV must be examined to assess the extent to which it has assured worker safety. In each case, the types of effects against which TLVs are designed to protect are examined in terms of their relevance to exposure from water. It must be demonstrated that the chemical is not a localized irritant and that there is no significant effect at the site of entry irrespective of the routes of exposure (i.e., oral or inhalation).

If the TLV or similar value is recommended as the basis of the criterion, consideration of the above points is explicitly stated in the criterion derivation section of the document. Particular emphasis is placed on the quality of the TLV relative to the available toxicity data that normally is given priority over TLVs or similar established values. If the TLV can be justified as the basis for the cirterion, then the problems associated with the estimation of acceptable oral doses from inhalation data must be addressed.

Estimating equivalencies of dose-response relationships from one route of exposure to another introduces an additional element of uncertainty in the derivation of criteria. Consequently, whenever possible, ambient water quality criteria should be based on data involving oral exposures. if oral data are insufficient, data from other routes of exposure may be useful in the criterion derivation process.

Inhalation data, including TLVs or similar values, are the most common alternatives to oral data. Estimates of equivalent doses can be based upon: (1) available pharmacokinetic data for oral and inhalation routes, (2) measurements of absorption efficiency from ingested or inhaled chemicals, or (3) comparative excretion data when the associated metabolic pathways are equivalent to those following oral ingestion or inhalation. Given that sufficient pharmacokinetic data are available, the use of accepted pharmacokinetic models provides the most satisfactory approach for dose conversions. However, if available pharmacokinetic data are marginal or of questionable quality, pharmacokinetic modeling is inappropriate.

The Stokinger and Woodward (1958) approach, or similar models based on assumptions of breathing rate and absorption efficiency, represents possible alternatives when data are not sufficient to justify pharmacokinetic modeling. Such alternative approaches, however, provide less satisfactory approximations because they are not based on pharmacokinetic data. Consequently, in using the Stokinger and Woodward or related models, the uncertainties inherent in each of the assumptions and the basis of each assumption must be clearly stated in the derivation of the criterion.

The use of data pertaining to other routes of exposure to derive water quality criteria may also be considered. As with inhalation data, an attempt is made to use accepted toxicologic and pharmacokinetic principles to estimate equivalent oral doses. If simplifying assumptions are used, their bases and limitations must be clearly specified.

Because of the uncertainties involved in extrapolating from one route of exposure to another and the consequent limitations that this may place on the derived criterion, the decision to disallow such extrapolation and recommend no criterion is highly judgmental and must be made on a case-by-case basis. A decision for or against criteria derivation must balance the quantity and quality of the available data against a perceived risk to the human population.

If the Stokinger and Woodward (1958) approach is used to calculate an ADI from a TLV, the general equation is:
$ADI=TLV\times BR\times DE\times d\times A_A/(A_O\times SF)$
where:

ADI = Acceptable daily intake in mg
TLV = Concentration in air in mg/m^3
DE = Duration of exposure in hours per day
d = 5 days/7 days
A_A = Efficiency of absorption from air
A_O = Efficiency of absorption from oral exposure
SF = Safety factor following guidelines given above
BR = Amount of air breathed per day; assume 10 m^3

For deriving an ADI from animal toxicity data, the equation is:
$ADI=C_A\times D_E\times d\times A_A\times BR\times 70\ kg/(BW_A\times A_O\times SF)$
where:

ADI = Acceptable daily intake in mg
C_A = Concentration in air in mg/m^3
D_E = Duration of exposure in hours per day
d = Number of days exposed/number of days observed
A_A = Efficiency of absorption from air
BR = Volume of air breathed per day in m^3
70 kg = Assumed human body weight
BW_A = Body weight of experimental animals in kg

A_o = Efficiency of absorption from oral exposure
SF = Safety factor following guidelines given above.

More formal pharmacokinetic models must be developed on a compound-by-compound basis.

It should be noted that the safety factors used in the above formulae are intended to account for species variability. Consequently, the mg/surface area/day conversion factor is not used in the derivation of toxicity based criterion.

C. Organoleptic Criteria

Organoleptic criteria define concentrations of materials which impart undesirable taste and/or odor to water. In developing and utilizing such criteria two factors must be appreciated: the limitations of most organoleptic data and the human health significance of organoleptic properties.

The publications which report taste and odor thresholds are, with very few exceptions, cryptic in their descriptions of test methodologies, number of subjects tested, concentration: response relationships, and sensory characteristics at specific concentrations above threshold. Thus, the quality of organoleptic data is often significantly less than that of toxicologic data used in establishing other criteria. Consequently, a critical evaluation of the available organoleptic data must be made and the selection of the most appropriate data base for the criterion must be based on sound scientific judgment.

Organoleptic criteria are not based on toxicologic information and have no direct relationship to potential adverse human health effects. Although sufficiently intense organoleptic characteristics could result in depressed fluid intake which, in turn, might aggravate a variety of functional disease states (i.e., kidney and circulatory diseases), such effects are not used in the derivation process of organoleptic criteria unless available data would indicate an indirect human health effect via decreased fluid consumption, criteria derived solely from organoleptic data are based upon aesthetic qualities only.

Since organoleptic and human health effects criteria are based on different endpoints, a distinction must be made between these two sets of information. In criteria summaries involving both types of data, the following format is used:

For comparison purposes, two approaches were used to derive criterion levels for ———. Based on available toxicity data, for the protection of public health the derived level is ——. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water the estimated level is ——. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have no demonstrated relationship to potential adverse human health effects.

In those instances where a level to limit toxicity cannot be derived, the following statement is to be appropriately inserted:

Sufficient data are not available for ——— to derive a level which would protect against the potential toxicity of this compound.

D. Criteria for Chemical Classes

A chemical class is broadly defined as any group of chemical compounds which are reviewed in a single risk assessment document. In criterion derivation, isomers should be regarded as a part of a chemical class rather than as a single compound. A class criterion is an estimate of risk/safety which applies to more than one member of a class. It involves the use of available data on one or more chemicals of a class to derive criteria for other compounds of the same class in the event that there are insufficient data available to derive compound-specific criteria.

A class criterion usually applies to each member of a class rather than to the sum of the compounds within the class. While the potential hazards of multiple toxicant exposure are not to be minimized, a criterion, by definition, most often applies to an individual compound. Exceptions may be made for complex mixtures which are produced, released, and toxicologically tested as mixtures (e.g., toxaphene and PCBs). For such exceptions, some attempt is made to assess the effects of environmental partitioning (i.e., different patterns of environmental transport and degradation) on the validity of the criterion. If these effects cannot be assessed, an appropriate statement of uncertainty should accompany the criterion.

Since relatively minor structural changes within a class of compounds can have pronounced effects on their biological activities, reliance on class criteria should be minimized. Whenever sufficient toxicologic data are available on a chemical within a class, a compound-specific criterion should be derived. Nonetheless, for some chemical classes, scientific judgment may suggest a sufficient degree of similarity among chemicals within a class to justify a class criterion applicable to some of all members of a class.

The development of a class criterion takes into consideration the following:

1. A detailed review of the chemical and physical properties of chemicals within the group should be made. A close relationship within the class with respect to chemical acitivity would suggest a similar potential to reach common biological sites within tissue. Likewise, similar lipid solubilities would suggest the possibility of comparable absorption and tissue distribution.

2. Qualitative and quantitative data for chemicals within the group are examined. Adequate toxicologic data on a number of compounds within a group provides a more reasonable basis for extrapolation to other chemicals of the same class than minimal data on one chemical or a few chemicals within the group.

3. Similarities in the nature of the toxicologic response to chemicals in the class provides additional support for the prediction that the response to other members of the class may be similar. In contrast, where the biological response has been shown to differ markedly on a qualitative and quantitative basis for chemicals within a class, the extrapolation of a criterion to other members of that class is not appropriate.

4. Additional support for the validity of extrapolation of a criterion to other members of a class could be provided by evidence of similar metabolic and pharmacokinetic data for some members of the class.

Based on the above considerations, it may be reasonable in some cases to divide a chemical class into various subclasses. Such divisions could be based on biological endpoints (e.g., carcinogens/non-carcinogens), potency, and/or sufficiency of data (e.g., a criterion for some members of a class but no criterion for others). While no *a priori* limits can be placed on the extent of subclassification, each subclassification must be explicitly justified by the available data.

Class criteria, if properly derived and supported, can constitute valid scientific assessments of potential risk/safety. Conversely, the development of a class criterion from an insufficient data base can lead to serious errors in underestimating or overestimating risk/safety and should be rigorously avoided. Although scientific judgment has a proper role in the development of class criteria, such criteria are useful and defensible only if they are based on adequate data and scientific reasoning. The definition of sufficient data on similarities in physical, chemical, pharmacokinetic, or toxicologic properties to justify a class criterion may vary markedly depending on the degree of structural similarity and the gravity of the perceived risk. Consequently, it is imperative that the criterion derivation section of each document in which a class criterion is recommended explicity address each of the key issues discussed above, and define, as clearly as possible, the

limitations of the proposed criterion as well as the type of data needed to generate a compound-specific criterion.

A class criterion should be abandoned when there is sufficient data availabe to derive a compound-specific criterion which protects against the biological effect of primary concern; e.g., the availability of a good subchronic study would not necessarily result in the abandonment of a class criterion based on potential carcinogenicity.

The inability to derive a valid class criterion does not, and should not, preclude regulation of a compound or group of compounds based on concern for potential human health effects. The failure to recommend a criterion is simply a statement that the degree of concern cannot be quantified based on the available data and risk assessment methodology.

E. Essential Elements

Some chemicals, particularly certain metals, are essential to biological organisms at low levels but may be toxic and/ or carcinogenic at high levels. Because of potential toxic effects, it is legitimate to establish criteria for such essential elements. However, criteria must consider essentiality and cannot be established at levels which would result in deficiency of the element in the human population.

Elements are accepted as essential if listed by NAS Food and Nutrition Board or a comparably qualified panel. Elements not yet determined to be essential but for which supportive data on essentiality exists need to be further reviewed by such a panel.

To modify the toxicity and carcinogenicity based criteria, essentiality must be quantified either as a "recommended daily allowance" (RDA) or "minimum daily requirement" (MDR). These levels are then compared to estimated daily doses associated with the adverse effect of primary concern. The difference between the RDA or MDR and the daily doses causing a specified risk level for carcinogens or ADIs for non-carcinogens defines the spread of daily doses from which the criterion may be derived. Because errors are inherent in defining both essential and maximum tolerable levels, the criterion is derived from dose levels near the center of such a dose range. The decision to use either the MDR or RDA is guided by the spread of the doses and the quality of the essentiality and toxicity estimates.

The modification of criteria by consideration of essentiality must take into account all routes of exposure. If water is a significant source of the MDR or RDA, the criterion must allow for attainment of essential intake. Conversely, even when essentiality may be attained from nonwater sources, standard criteria derivation methods may be adjusted if the derived criterion represents a small fraction of the ADI or MDR. On a case-by-case basis, the modification in the use of the guidelines may include the use of different safety factors for non-carcinogens or other modifications which can be explicitly justified.

F. Use of Existing Standards

For some chemicals for which criteria are to be established, drinking water standards already exist. These standards represent not only a critical assessment of literature, but also a body of human experience since their promulgation. Therefore, it is valid to accept the existing standard unless there is compelling evidence to the contrary. This decision should be made after considering the existing standards vs. new scientific evidence which has accumulated since the standards have been established. There are several instances where the peer review process recommended usage of the present drinking water standards.

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Appendix D—Response to Comments on Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and Its Uses

Introduction

Two versions of the Guidelines were published in the Federal Register for comment. The first version (43 FR 21506, May 18, 1978 and 43 FR 29028, July 5, 1979) was simply published for comment. The second (44 FR 15926, March 15, 1979) was published as part of the request for comments on the water quality criteria for 27 of the 65 pollutants. The second version was meant to be clearer and more detailed than the first, but very similar technically. Since the two versions were so similar, comments on both will be dealt with simultaneously.

Many comments were received that no draft water quality criteria for any of the 65 pollutants should have been issued for public comment until the comments on the first version of the Guidelines had been dealt with adequately and the Guidelines changed appropriately. The comments on the first version were read and the Guidelines were revised in an attempt to make the second version clearer and more detailed than the first. However, an extensive revision of the technical content of the Guidelines was not attempted between the first and second versions because the Agency was preparing water quality criteria based on the Guidelines. The Agency could have avoided this criticism simply by not publishing any version of the Guidelines for comment until March 15, 1979, but this would have greatly reduced the length of time available for people to consider the Guidelines and comment on them. As it was, some people commented that the comment period announced on March 15, 1979, was too short.

1. Comment—The procedures used to derive criteria in the "Red Book" were upheld in court and probably should still be used.

Response—The procedures used in the Guidelines are similar to some of the procedures used to develop criteria in the "Green Book", "Blue Book", and "Red Book". The Guidelines are designed to be more objective and systematic, to deal more adequately with residues, and to incorporate the concept of a minimum data base.

2. Comment—Criteria should be compilations of critically reviewed data with no synthesis or interpretation.

Response—Neither P.L. 92-500 nor the Consent Decree specify the form which a criterion must take. The Consent Decree (para. 11, p. 14) specifies that such criteria "shall state, *inter alia*, recommended maximum permissible concentrations". Adequate precedents have been set in the "Green Book", "Blue Book", and "Red Book" for the form of criteria used in the Guidelines.

3. Comment—The Guidelines and criteria should be developed by a consensus of aquatic toxicologists rather than by EPA personnel only.

Response—EPA certainly wants the Guidelines and the criteria to be as good as possible and as acceptable to as many interested people as possible. To this end, EPA has widely distributed draft versions of the Guidelines and the criteria documents, discussed them with many people, considered the comments received, and made many significant technical changes and editorial revisions. It is questionable whether or not a true consensus could have been reached by any means within the time available. In addition, EPA has a legislative responsibility which it should not delegate to someone else.

4. Comment—The Guidelines should be updated regularly.

Response—The Guidelines are not being promulgated as a regulation or directive. The purpose of presenting these Guidelines is to show how the water quality criteria for aquatic life were derived for the 65 pollutants. If EPA uses these Guidelines again, they will be revised to take into account new data, concepts, and ideas.

5. Comment—The objectives, purpose, and limitations of the Guidelines should be stated.

Response—The introductory portion of the Guidelines has been expanded to address these subjects more fully.

6. Comment—The Guidelines are too ambiguous.

Response—The Guidelines have been revised and rewritten, partly to improve clarity and provide additional details. It is not possible to provide explicit details on all items; in some areas only general guidance can be provided at this time.

EPA attempted to clearly and concisely deal with all issues which might significantly affect the resulting criteria without going into extreme detail on every potential problem. Because numerous judgments must be made, a reasonable amount of experience in aquatic toxicology will be necessary for a person to utilize the Guidelines effectively.

7. Comment—The Guidelines are too complex.

Response—Deriving a water quality criterion is a complex exercise because several different kinds of data and a wide variety of organisms need to be considered. In addition, because data have been generated using various procedures, numerous individual decisions need to be made and the Guidelines attempt to provide guidance concerning decisions that seem to need to be made frequently. The Guidelines are more complex than initially envisioned to help insure that criteria for different pollutants are derived in a reasonably comparable manner. Although the process of deriving a water quality criterion for aquatic life is complex, the Guidelines help organize the process into logical components and steps.

8. Comment—The Guidelines should be more flexible.

Response—The Guidelines are meant to provide guidance and at the same time allow reasonable flexibility. They have been used with quite a variety of pollutants for which the requirements of the minimum data base are satisfied, and they seem to be reasonably appropriate in all cases because the experiences with these substances were a major part of the basis for the Guidelines. If sound scientific evidence indicates that a particular aspect of the Guidelines is not appropriate for a specific substance, then some other more appropriate procedure should be used. However, the Guidelines should not be changed based on individual whim or personal preference.

9. Comment—The Guidelines should take into account synergism and antagonism by a wide variety of factors and the effect of the pollutant on important ecological relationships.

Response—Very little practically useful information is available on these factors in connection with the effects of pollutants on aquatic organisms. Synergism and antagonism are possible between numerous combination of two or more pollutants, and some data indicate that such interactions are not only species specific, but also vary with the ratios and absolute concentrations of the pollutants and the life stage of the species. Pollutants may affect the structure and function of aquatic ecosystems separate from their effects on individual species, but practical applications of such ideas seem very tenuous at this time. Little information is available concerning such effects, and the significance of the available data is questionable. An obviously important ecological relationship is the dependence of higher organisms on lower organisns for food. Even here, the existence of numerous lower species and their adaptability reduces the importance of any individual food species.

10. Comment—The Guidelines should take into account all identifiable effects—beneficial as well as harmful.

Response—Few tests have been conducted to identify beneficial effects of individual pollutants on aquatic organisms. However, beneficial effects are sometimes observed in chronic toxicity tests at concentrations below those that cause adverse effects. Usually in such cases the organisms in low concentrations of the pollutant are longer or heavier or reproduce more that do the controls. Even if such effects are statistically significant, they are not judged as adverse or harmful. On the other hand, a beneficial effect on one species may ultimately be to the detriment of a community if a balance between species is disturbed. Also, a concentration that benefits one species may harm a more sensitive species.

11. Comment—The Guidelines should take into account analytical methodology.

Response—The Guidelines do take into account analytical methodology in the definition of the substance, when necessary, but not in deriving the numerical value of the criterion. Concentrations which cannot be routinely measured accurately can often be measured accurately by nonroutine methods and, more importantly, do sometimes adversely affect aquatic organisms. When aquatic organisms are more sensitive than routine analytical methods, the proper solution is to develop better analytical methods, not to underprotect aquatic life. One use of criteria should be to identify needs in analytical chemistry.

12. Comment—The Guidelines should take into account (a) production and usage patterns, (b) chemical, physical and biological factors pertaining to degradation and fate of pollutants, including properties such as solubility in water, decay rate, persistence, and transformation pathways, and (c) whether or not a criterion is needed for the substance.

Response—Items included in (a) and (b) may be important in deciding whether a criterion is needed for a substance, but the Guidelines are intended to be used after the decision has been made that a criterion is needed. EPA is presently developing principles that can be used to decide whether or not a criterion is needed for a substance and items such as those listed above are probably some of the factors that should be considered when deciding whether or not a criterion is needed. If the toxicity of the chemical is used to evaluate the need for a criterion, the Guidelines may be useful in the collection and interpretation of the available toxicity data.

13. Comment—The Guidelines should take into account costs to states and industries, technological feasibility, and such characteristics of bodies of water as assimilative capacity, dispersal, dissipative factors, dilution, hydrology, mixing zones, and sediment.

Response—Factors such as these should be considered in developing standards, but not in deriving criteria. EPA is presently developing an implementation policy which will describe which of the above factors and which characteristics of the pollutant should be used, and how they should be used, in developing standards.

14. Comment—The Guidelines are not appropriate for establishing a concentration which may be present in an effluent.

Response—The Guidelines are for deriving water quality criteria, not effluent standards nor mixing zone standards nor water quality standards. Water quality criteria will probably be one factor taken into account in the development of water quality standards and toxicity-based effluent standards, but not technology-based effluent standards. EPA is presently developing policies concerning proper use of water quality criteria in various regulatory activities.

15. Comment—The derivation of criteria should be fundamentally a scientific exercise and should not employ subjective judgments.

Response—No exercise which involves the use and interpretation of data can avoid subjective judgment. Indeed, even the generation of scientific data requires subjective judgment, such as how many test organisms to use, what temperature to use, etc. One may decide to accept the recommendations of experts, but this is usually still a subjective decision. In statistics the subjective decisions are made on the basis of probability statements but the final decisions are still subjective judgments. Although the development of the Guidelines and the derivation of criteria cannot avoid subjective

decisions, gross extrapolations, wild assumptions, and novel judgments can be avoided. One can also avoid using large safety factors to "make up" for insufficient data. When some agreement exists between experts, such as on test temperature and duration of tests, the collective opinion can usually be used. EPA feels that the Guidelines do not go too far beyond the state-of-the-art and do not produce criteria by extrapolating far beyond the usefulness of the data.

16. Comment—The Guidelines should not use unproven extrapolations.

Response—EPA feels that the extrapolations used in the Guidelines are reasonable for most pollutants. Probably the most questionable extrapolation is the acute-chronic ratio, but even here an arbitrary ratio is not used. Indeed, the ratio used is usually a mean of experimentally determined acute-chronic ratios for at least three, not just one, species. In addition, the species must include at least one fish and one invertebrate. Even this amount of data does not "prove" the validity of the extrapolation, but it should provide reasonable evidence for or against the use of the ratio with any particular substance. To achieve reasonable criteria without using any extrapolations would require acute and chronic tests with many more species. This would be a high price to pay for disallowing any use of scientific inference in deriving criteria.

The early versions of the Guidelines used adjustment factors and sensitivity factors which were averages derived from data for a wide variety of substances and thus were attempts to make some extrapolations across all substances. The present version of the Guidelines is based on a minimum data base for each individual pollutant and the calculations are essentially pollutant-specific. Thus no extrapolations are made from one pollutant to another.

17. Comment—Laboratory tests overestimate the toxicity of materials because the test organisms are stressed by the artifical conditions.

Response—Laboratory conditions certainly are artificial, but they do not necessarily stress the test organisms. Organisms which survive, grow, and reproduce well in the laboratory cannot be stressed too much. Organisms in a laboratory might be considered pampered because they do not have to compete for food and are not subject to stress due to predators and changing and extreme conditions of turbidity, temperature, flow, and water quality. Also, laboratory organisms are rarely subject to stress from pollutants. Some species probably have longer average life spans in laboratories than they do in field situations.

18. Comment—Laboratory tests underestimate the toxicity of materials because the tests are usually conducted with species which are hardy, adaptable, and insensitive.

Response—Species which are readily adaptable to laboratory conditions are not necessarily insensitive as evidenced by the great range of sensitivities obtained in laboratory tests for some individual pollutants with different species. In fact, once the the proper techniques are developed, a wide variety of species can survive, grow, and reproduce well in laboratories. When the proper techniques are discovered and a species changes form "difficult" to "easy", its sensitivity does not change. Also, some species and life stages which are fragile and must be handled with great care are not particularly sensitive. On the other hand, because so few species have actually been tested in laboratories, species which are more sensitive than any of those tested in laboratories, species which are more sensitive than any of those tested probably exist for most substances.

19. Comment—Laboratory tests are artificial and contrived and do not represent the real world.

Response—Laboratory tests are indeed artificial but they are not contrived to give results that are unnecessarily high or low. Organisms in a laboratory are generally acclimated to water and conditions of constant and desirable quality, whereas in the field they are often subjected to fluctuations and extremes. Organisms in a laboratory do not have to compete for food and are not subject to predators or pollution. Organisms in the field are often exposed to more than one pollutant at a time, with the combinations and concentrations changing often.

It is true that aquatic organisms are usually exposed to instantaneous high concentrations in laboratory tests, but in field situations organisms are often not given much chance to acclimate to spills or short-term discharges. Also, some ameliorating effects occur in field, but not laboratory, situations, but such effects are not always dependable over long periods of time. The concentrations of mitigating anions, suspended solids, and complexing agents are relatively constant in some bodies of water, but not in others. Suspended solids probably do sorb and detoxify significant amounts of some pollutants, but high concentrations of suspended solids also stress some aquatic organisms. In addition, organisms are usually fed in chronic tests, so the test solution contains suspended solids and dissolved organic carbon from the food and fecal matter. Degradation and other transformations are more likely in field situations than in laboratory situations, but degradation products are not always less toxic than the undegraded material. On the other hand, many of these kinds of considerations will probably be taken into account when site-specific criteria and standards are developed under the implementation policy which is being developed by EPA.

20. Comment—Laboratory tests are poor predictors of what will happen in field situations.

Response—If conditions are comparable, laboratory toxicity tests are useful predictors of what will happen in field situations. The usefulness of such predictions will depend on how carefully one accounts for differences between species, water quality, and the form of the pollutant. Extrapolations are much more difficult for some pollutants than for others. Water quality affects the toxicity of some pollutants much more than others, and species differences, even within families, are much greater for some pollutants than for others. If such factors are taken into account, useful predictions are possible. In what is probably the most extensive comparison available of laboratory and field data (Geckler, J. R., et al. 1976. Validity of Laboratory Tests for Predicting Copper Toxicity in Streams. EPA–600/3–76–116. U.S. EPA. Duluth, MN 208 pp.), it was found that effects observed in laboratory exposures were also observed in field exposures. However, avoidance, which was not studied in laboratory exposures, was observed in the field exposures. Laboratory to field comparisons are not simple because several factors must be taken into account, the laboratory test must be conducted well and the field observations and measurements must be extensive. Although adverse effects observed in laboratory tests will usually occur in similar field situations, a problem exists with the bioaccumulation of some persistent substances. For example, PCB's seem to bioaccumulate to much higher levels in some bodies of water than they do in laboratory tests.

21. Comment—The Guidelines should place more emphasis on field information than on laboratory information.

Response—Field information on effects of pollutants on natural populations is acceptable, but the collection of definitive information of this type is high risk and costly. Few studies on the effects of pollution on natural populations provide definitive information because of the multitude of

variables that need to be taken into account. The major advantage of field studies is that conditions are natural (i.e., conditions are not controlled), but this is also the major problem with field studies. With uncontrolled conditions, numerous variables must be taken into account, because any individual variable or combination of variables may affect the results or indeed may be the cause of the results. Therefore, field studies on natural populations usually must last over several seasons and possibly over more than one year to be reasonably sure that proposed cause-and-effect relationships are real.

Another problem with field studies that are based on statistically significant differences is the power of the test. Because natural biological, spacial, and temporal variability is often rather great, a large number of samples is usually required to detect even a moderate change. A field study which purports to show that no change occurred is of no value if the power of the test calculated from the experimental design and observed variability was not high enough.

Because field studies are high cost-high risk ventures, well-designed laboratory tests are usually much more cost-effective for obtaining data on (1) the toxicity of substances to a variety of species and (2) the effect of various water quality characteristics on toxicity. Laboratory tests have been shown to generally be useful predictors of what happens in a field situation, and so it makes little sense to conduct high risk, high cost field studies rather than laboratory tests. Even definitive field studies rarely provide enough information to allow extrapolation of results to other situations, so field studies are more useful in reviewing criteria than in deriving criteria.

22. Comment—Field verification of laboratory tests and of the Guidelines are needed.

Response—Field verification of laboratory tests and of the Guidelines are certainly desirable and provide information that cannot be obtained in a laboratory. Field verification studies do not need to be as risky or as costly as studies on the effects of a pollutant on natural populations because verification studies can be designed (1) as a side-by-side comparison of the results of laboratory tests and field tests or (2) based on existing results of laboratory tests.

23. Comment—EPA should allow criteria to be derived using on-site acute toxicity tests and an application factor.

Response—This approach is usually suggested for developing effluent standards but may be just as applicable to deriving water quality criteria under certain conditions. This approach cannot be used with pollutants whose most sensitive adverse effect is due to residues. Also, it can only be used when the application factor has already been acceptably determined. Finally, acute tests must be determined with either an appropriate range of species or with an appropriate sensitive species. The implementation policy presently being developed by EPA will probably allow the use of appropriate on-site toxicity tests in the development of site-specific criteria and standards.

24. Comment—It is not clear what level of protection is intended.

Response—EPA feels that it is not possible to specify a minimum level of protection that is necessary to "protect aquatic life" or even to protect a particular species for such reasons as:

a. There are so many untested species.

b. Little practically useful information is available concerning synergism, antagonism, ecological relationships, and avoidance.

c. The effect of factors such as temperature on toxicity seems to be species-specific for at least some substances.

d. Information is not available concerning what amount of any effect would be ecologically significant and whether the amount is species-specific.

One possible conclusion is that to protect aquatic life, all species must be adequately protected. A possible extension of this would be that all criteria should be zero because any amount of any pollutant may affect some aquatic organism. Indeed, the assimilative capacity of body of water largely depends on the ability of aquatic life to "process" pollutants and to some extent, any organism which "processes" a pollutant is in some way affected by it.

The apparent level of protection is different for each kind of effect (acute toxicity to animals, chronic toxicity to animals, toxicity to plants, and bioaccumulation) because of the quality and quantity of the available information. An attempt was made to take into account such things as the importance of the effect, the quality of the available data, and the probable ecological relevance of the test methods. Thus it was felt that with regards to toxicity to animals it was probably not necessary to protect all of the species all of the time, but it certainly seems appropriate to protect most of the species most of the time and to protect important species.

On the other hand, the data base on toxicity to aquatic plants is usually very small and a variety of tests and endpoints have been used, especially with algae. Also, little information is available concerning the ecological relevance of the results of any toxicity test with algae in a concentrated test medium, especially because so many species of algae exist in each body of water.

The results of bioconcentration tests with organic chemicals, but not with inorganic chemicals, can apparently be extrapolated reasonably well based on percent lipids from one aquatic animal species to another, at least within commercially and recreationally important species. In addition, the limits on acceptable concentrations in tissue are reasonably well defined in some cases.

These kinds of considerations merely illustrate the complexity of the problem and the necessity for making decisions about each kind of effect individually. In addition, it is important to distinguish between the apparent level of protection provided by the Guidelines and the actual level of protection which will result in a field situation from the use of the implementation policy.

No attempt was made to develop Guidelines which would achieve a predetermined numerical level of protection. For each effect much desirable information is not available, and so it would be misleading to imply a level of sophistication that is not currently possible. EPA believes that the present state-of-the-art in aquatic toxicology does allow some useful conclusions about the ability of a substance to adversely affect aquatic organisms and their uses whenever the requirements of the minimum data base are satisfied, with the full realization that the resulting criterion may be somewhat overprotective or underprotective.

In almost all cases more data would be desirable and so an attempt to reach the "golden mean" will sometimes result incriteria being to high and sometimes too low. One alternative is to derive no criteria until all desirable data are available; this is unacceptable because it will almost always result in no criteria and no protection. The other alternative is to apply safety or uncertainty factors that are inversely proportional to the adequacy of the data base. In the long run this approach would encourage the generation of useful data where it was most needed, but in the short run would require many significant subjective decisions beyond the current state-of-the-art.

25. Comment—The Guidelines should not base criteria on "worst case" assumptions.

Response—The phrase "worst case assumptions" usually refers to the assumption that both the worst water quality and the most sensitive life stage occur at all times. These two assumptions are a natural result of the two concepts that criteria should be constant throughout the year and that aquatic life is not adequatley protected if it is not adequately protected throughout the year. The implementation policy being developed by EPA will determine whether site-specific criteria must be constant throughout the year. If not, then the "worst case assumptions" will not apply. Although the Guidelines might be viewed as making the "worst case assumptions", the implementation policy will determine whether the site-specific water quality criteria and standards will be based on these assumptions.

26. Comment—Safety factors should be used to protect against such things as potential subtle, but important, long term effects.

Response—Pollutants may cause many direct and indirect adverse effects which have not been studied adequately. For instance, some substances may make aquatic organisms more susceptible to disease or other stresses. In spite of such possibilities, the available information indicates that the major possible adverse effects are covered in the Guidelines and that adequate protection will usually be achieved without the use of safety factors. Safety factors would certainly offer additional protection, but the available information does not show that significant additional protection is needed.

Safety factors of from 10 to 1000 are often used to protect people mainly because people feel that people are more important than aquatic organisms and because humans are usually protected on the basis of tests with other species of animals, thus resulting in a greater uncertainty in the applicability of the results. Complete protection can only be achieved by setting all criteria at zero. Unfortunately, even "Mother Nature" sometimes seriously harms large groups of aquatic organisms, such as during droughts or severe winter freezes. EPA feels that complete protection is neither feasible, desirable, nor possible. In addition, aquatic ecosystems can recover from some adverse effects.

27. Comment—The Guidelines do not provide for an adequate margin of safety.

Response—If "margin of safety" is interpreted to mean "safety factor", then the Guidelines do not provide a margin of safety. If the Guidelines are viewed as deriving criteria for a constant quality water, then they provide a margin of safety during those portions of the year during which the most sensitive life stage does not occur. Although some species may occasionally be adversely affected, EPA feels that the Guidelines provide adequate safety because aquatic communities and their uses should not incur any substantial or permanent damage. Whether or not site-specific criteria will have a margin of safety will depend on how they are derived.

28. Comment—Criteria should be set at the least restrictive concentration and states can then apply more restrictive concentrations when necessary.

Response—It is unclear what is meant by the "least restrictive concentration" but presumably it would be a concentration which would not protect very many aquatic communities and their uses. This is contradictory to the concept that criteria are to protect aquatic life and its uses. The implementation policy being developed by EPA will allow site-specific criteria to be higher or lower than the criteria derived using the Guidelines, when adequate information is available.

29. Comment—The Guidelines should produce criteria in the form of a concentration-risk curve with appropriate confidence limits for each kind of effect.

Response—EPA feels that a risk analysis approach is certainly desirable, but far beyond the state-of-the-art at this time. When dealing with safety to humans, only one species is being protected and extrapolations are made far outside the limits of the actual test results, such as to 1 death in 100,000 people. With aquatic life, numerous species need to be protected and extrapolation far beyond the actual data is not readily accepted. In addition, safety or uncertainty factors are more readily accepted when protecting people than when protecting aquatic organisms.

Most aquatic toxicologists are not willing to let criteria for the protection of aquatic life be as dependent on mathematical models, assumptions, and manipulations as on the actual test results. Most people with experience in aquatic toxicology have an intuitive "feel" about how data should be interpreted and the Guidelines are merely an attempt to formalize a resaonable approach. The Guidelines could be written as mathematical algorithms and some approach such as error models could be developed in order to derive confidence limits. However, the algorithms and models would contain many unproven assumptions and, to be worthwhile, would undoubtedly require more data than are usually available. Although such models and algorithms would be acceptable to many statisticians and may be an appropriate future goal, the current Guidelines need to be useable by and comprehensible to current aquatic toxicologists. Most experienced aquatic toxicologists will judge the reasonableness of any set of Guidelines by comparing the resulting criteria for various pollutants with the data available for those pollutants using a "common sense" interpretation of data.

30. Comment—The Guidelines should not use unsound statistical procedures or misuse sound statistical procedures.

Response—EPA has tried to make sure that no statistical procedures are misused in the Guidelines, that no unsound statistical procedures are used, and that the purposes of the calculations are explained adequately.

31. Comment—It appears that geometric means were used instead of arithmetic means in the Guidelines to obtain lower values.

Response—Decisions such as this were made throughout the Guidelines on a case-by-case basis, and none were based on whether the resulting criteria would be higher or lower. The selection of the procedure used to calculate the mean could be based on the distribution of the values in the individual data set. Unfortunately, with small data sets rarely is it possible to reject many possible distributions and with large data sets all possible distributions are often rejected. Because many of the data sets of interest in the Guidelines are small, a reasonable approach is to base the selection of a procedure for calculating the mean on some general principles such as:

a. Sets of ratios and quotients are likely to be closer to lognormal than normal distributions. Thus geometric means, rather than arithmetic means, are used for acute-chronic ratios and for bioconcentration factors.

b. When there are numerous independent possible sources of error for each datum in a set, the error tends to be multiplicative rather than additive. Thus when the acute or chronic toxicity of a substance to a particular species is determined in different laboratories using different batches of organisms, different waters, etc, the geometric means should be used to calculate the species mean value rather than the arithmetic mean.

c. If a set of numbers approximates a lognormal distribution, the logarithms of the numbers will approximate a normal distribution.

d. The distribution of the sensitivities of individual organisms in a toxicity test

is likely to be closer to a lognormal distribution than a normal distribution. Thus the geometric mean, rather than the arithemetic mean, of the upper and lower chronic limits is used.

32. Comment—There should not be any criteria which apply to all bodies of water. Criteria should be specific for individual states, regions, other geographic areas, or bodies of water.

Response—The Guidelines are designed to provide guidance in the collection and interpretation of data concerning the effects of pollutants on aquatic life and its uses. The uses of the resulting criteria will be described by EPA in various regulations. If desired, the Guidelines can be appropriately modified and used to derive a criterion specific to one or more bodies of water or geographic areas if an appropriate data base is available. The critical literature reviews on which the criteria are based will be available for use in the derivation of local, state, or regional criteria. The latitude allowed for deriving local, state, or regional criteria and standards will be determined by the implementation policy presently being developed by EPA.

33. Comment—The Guidelines should result in criteria that are specific for individual species or groups of species (e.g., warmwater and coldwater).

Response—If the necessary data were available, criteria could be derived for any particular species or group of species. It was impractical for EPA to derive criteria for many such groups, but a relatively simple division is freshwater and saltwater organisms because these two groups rarely coexist. Most other possible general divisions of species are faced with the problem that species coexist in various combinations unless the groups are very narrow. In addition, toxicity data are rarely available for very many individual species and so data for representative species must be used, unless appropriate new data are generated. Also, the available data sometimes show wide differences within families so extrapolations from one species to another are often tenuous. Because of these problems, deriving criteria for individual species or groups of species was deemed impractical.

34. Comment—A criterion should be one number, not two.

Response—The two-number criterion is an acknowledgement that aquatic organisms can tolerate short exposures to concentrations that are higher than those they can tolerate continuously. In a two-number criterion, the higher number can assure that short-term fluctuations above the average are not too high, whereas the lower number can assure that the long-term average is not too high. A one-number criterion could be derived by using the existing 24-hour average as an instantaneous maximum. This would certainly provide additional protection, but would provide unnecessary overprotection in most cases. Because a one-number criterion would be more of an approximation than a two-number criterion, one-number criteria would be too high or too low more often and to a greater degree than two-number criteria.

35. Comment—The criteria should not specify sampling schemes.

Response—Criteria should state numerical concentration limits in terms of exposure durations because, everything else being constant, the amount of adverse effect depends on both the concentration of the pollutant and the duration of exposure. Criteria in the Green Book, Blue Book, and Red Book were usually stated as single numbers with no duration expressly stated. The implication was that the criteria were never to be exceeded at any time. Each criterion was apparently and instantaneous maximum. In practice, however, standards derived from these criteria were usually enforced on the basis of 24-hour composite samples. To avoid any ambiguity, the Guidelines specify that a criterion should be explicitly stated in terms of two time frames: an instantaneous maximum and a 24-hour average. However, this is not a specification for a sampling scheme. Standards developed from such a criterion should probably specify a sampling scheme for compliance monitoring, but it would not necessarily be in terms of point measurements and 24-hour averages.

Any sampling scheme used to determine whether or not an ambient concentration exceeds a water quality criterion or a comparable water quality standard should take into account such things as the ratio of the instantaneous maximum and the 24-hour average and the retention time of the body of water because these will primarily determine which portion of the criterion is most limiting in any specific situation. The sampling scheme should probably also take into account the cost of the analyses and results of any past analyses.

36. Comment—The criteria should be stated in terms of time frames longer that an instantaneous maximum and a 24-hour average.

Response—These two time frames were chosen because they would allow the derivation of a criterion which would be less restrictive than, but just as protective as, the previous one-number criterion. These two specific time frames were chosen because they match two kinds of samples that are commonly collected: grab samples and 24-hour composite samples. These specific time frames could probably be changed somewhat without much practical effect, but EPA saw no particular advantage to anyone to introducing novel time periods. For example, for all practical purposes in most situations a 10-minutes average is probably about the same as an instantaneous maximum.

Large increases in the time frames, however, would not provide the same amount of protection. If the instantaneous maximum were changed to a 24- or 96-hour average, and the 24-hour average were changed to a 7- or 30-day average with no change in the numerical limits, the amount of protection afforded aquatic life would fall to an unacceptable level. The longer the time span for the average, the higher the instantaneous concentration could be for short periods of time within that span. Although most chronic tests last for 28-days or longer, some chronic effects may be caused by short exposures of sensitive life stages. If the acute-chronic ratio is small, fluctuations in the instantaneous concentration may even cause acute toxicity, especially for cumulative pollutants, because for some substances the 24-, 48-, and 96-hour acute values do not differ too much.

37. Comment—A two-number criterion will be difficult to enforce.

Response—Criteria are not enforceable. Standards are enforceable. When standards to protect aquatic life are developed, they may or may not be in the same format as the criteria for aquatic life. Few standards are adequately enforced because of the high cost of continuous monitoring. The real value of many criteria and standards is in the design of waste treatment facilities; a two-number criterion should be a better basis for design than a one-number criterion.

38. Comment—The criteria should be expressed to one significant figure, not two.

Response—EPA acknowledges that there is much variability in some of the data and that the range of sensitivites is often great. When the requirements of the minimum data base are satisfied and the data agree reasonably well, two significant figures are not unreasonable. Rounding off to one significant figure could arbitrarily raise or lower the criterion by up to forty percent with no apparent consistent benefits to dischargers, regulators, or aquatic life.

39. Comment—The Guidelines should only use data for species that ought to be protected.

Response—In order to protect commercially and recreationally important species, a wide variety of "unimportant" species must also be protected. Such so-called "unimportant" species include the food organisms all the way to the bottom of the food chain. The "important" species in an aquatic community cannot maintain themselves without the help of primary producers, primary consumers, nitrifiers, dentrifiers, detritivores and saprophytes.

40. Comment—Criteria should not be based on sensitive, short-lived invertebrates.

Response—Many species of invertebrates are short-lived and are not widely distributed. However, these numerous short-lived, local species do serve important functions and should be represented in the data base. This group of organisms needs to be protected even if no one species can be considered important.

41. Comment—Criteria should protect endangered species.

Response—EPA agrees that criteria should protect endangered aquatic species. However, very few toxicity tests have been conducted with endangered species, and it does not appear feasible to require tests with such species. Endangered species are some of the many untested species which should be protected by criteria derived from available data using the Guidelines.

42. Comment—Migratory species are a special problem.

Response—Migratory species should usually be protected by criteria derived using the Guidelines unless such species are unusually sensitive. Migratory species may be especially susceptible to avoidance, but few data are available to compare species on this basis. Avoidance may be a serious latent problem because it might apply to all motile species, rather than just migratory species, and it has not been studied very much.

43. Comment—Estuarine species were ignored.

Response—The term "saltwater organisms" is meant to include estuarine species as well as true marine species.

44. Comment—The classification "invertebrates" includes species that are too dissimilar to be grouped together. These species should be separated into phyla or classes.

Response—The never-ending arguments between the "lumpers" and the "splitters" can only be resolved by considering the advantages and disadvantages of each approach in each situation. The "splitters" can usually argue that obvious differences should be taken into account and it is certainly true that shrimp are different from insects and both are different from worms. It can also be argued that there are significant differences within phyla, classes, and families. Each species could be considered a separate group, if differences between stains are arbitrarily ignored. After the species are split into separate groups, the problem then would be whether to recombine the data to derive one criterion for all species or to derive one criterion for each group. If numerous criteria are derived for a pollutant, how are these to be used to develop standards? Another problem is that unless more data are generated, the greater the number of groups, the less information there is available per group.

The basic question is "What are the important differences that need to be taken into account and how should this be done?" Because there are differences between taxonomic groups, the Guidelines require data on a number of species from a varitety of taxonomic groups. The information of each separate species is treated individually. This approach preserves the differences between species and allows all species to be considered in the development of the criterion. The number of data points is increased and the range of the data is readily apparent. Because "invertebrates" is already a large diverse group and because the range of sensitivities of fish usually overlaps that of invertebrates, little justification exists for not combining all aquatic animals.

45. Comment—Do not extrapolate from freshwater organisms to saltwater organisms or vice versa.

Response—Criteria and absolute toxicity values were not extrapolated from fresh water to salt water, but some relative data were, when it did not appear that factors such as salinity affected the data. The toxicity of some substances apparently is significantly affected by salinity, but most substances seem to have overlapping ranges of toxicity to freshwater and saltwater organisms. However, because these two kinds of organisms rarely inhabit the same body of water simultaneously, separate criteria were derived for each. Even though these two kinds of organisms are physiologically different, they do not seem to be too different toxicologically. Bioconcentration factors and acute-chronic ratios seem to be fairly similar for many freshwater and saltwater species for many pollutants, particularly organic chemicals.

46. Comment—The Guidelines base the criteria only on sensitive species and do not take into account insensitive species.

Response—The Guidelines do not necessarily base the criteria on the data for the most sensitive species. However, an aquatic ecosystem cannot be protected by protecting only the species which are insensitive. Protecting half the species will probably not protect the community. To offer reasonable protection to aquatic life and its uses, each major kind of organism and each major use must be given reasonable protection. In some cases it may in fact be necessary to protect the most sensitive species if it is a highly desirable species.

47. Comment—Species should be tested at their environmental extremes.

Response—Toxicity tests with each pollutant could indeeed be conducted with some or all species under a variety of extreme conditions and the lowest result obtained with a species could be used instead of a mean result. On the other hand, differences between results with different species seem to be much greater, and therefore more important, than the differences between results obtained with one species under different conditions. Furthermore, criteria need not necessarily protect species from all stress under the most extreme conditions, because aquatic communities and populations of individual species can recover from some perturbations.

48. Comment—Only data for species that are widely distributed, representative, critical, indigenous, important, ecologically relevant and sensitive should be used.

Response—Few species would satisfy all of the requirements that have been suggested. As more and more data are obtained with a wider variety of species for any one pollutant, it becomes more obvious that few if any species are atypically sensitive, although that may not be true for aquatic communities which contain very few species. No data exist to show that species in any one key role are toxicologically more sensitive than other kinds of species. Ecologically relevant species and species that have key roles or are relevant to the overall functioning of viable ecosystems are not necessarily toxicologically different from other species. EPA feels that if the available data cover an adequate number and variety of species, it is not necessary to try to identify and conduct tests with all important, sensitive species. In addition, the derivation of a criterion should not be based only on sensitive species, because a knowledge of the range of sensitivities may be useful. For instance, elevated concentrations of a pollutant that produces a narow range of species sensitivities are likely to cause more

damage than elevated concentrations of a pollutant that produces a wide range of species sensitivities.

49. Comment—The distinction between ionizable and unionizable compounds is not very good because some chemicals ionize and reach chemical equilibrium very slowly and others very rapidly.

Response—Most chemicals can readily be classified into one of three groups:

A. Chemicals that ionize, including hydrolyze, at least 90% and reach 90% of equilibrium in less than 8 hours in most surface waters.

B. Chemicals that ionize, including hydrolyze, less than 10% in 30 days in most surface waters.

C. Chemicals that do not fit into either one of the above categories.

For the purpose of the Guidelines, chemicals in the A group should be considered ionizable, chemicals in the B group should be considered non-ionizable, and chemicals in the C group should be classified on a case-by-case basis. Although the distinction between ionizable and unionizable may not be perfect, it is very useful for most chemicals.

50. Comment—Each individual organic compound should be considered separately.

Response—The vast majority of organic chemicals will be considered separately according to the Guidelines except for structurally similar organic compounds that meet all three specifications given in the Guidelines, such as polychlorinated biphenyls and toxaphene.

51. Comment—In-stream water quality criteria are meaningless for substances that are highly insoluble.

Response—The concentration of some substances in sediment may be important separate from the concentration of the substance in the ambient water and for these compounds a sediment quality criterion may be necessary. Generally such compounds can also cause adverse effects if the concentration in the ambient water is too high even if the concentration in the sediment is low. Thus for such compounds both kinds of criteria may be necessary rather than just one or the other.

52. Comment—If a substance is not dissolved, it is not biologically or toxicologically available.

Response—Although this may usually be true, it certainly does not apply to elemental mercury which can be oxidized and methylated to form a very toxic compound. Some organic acids and phenols and hydroxide and carbonate salts of metals have solubilities which differ substantially from one body of water to another.

53. Comment—Criteria for metals should not be for total metal.

Response—Criteria for metals will generally not be based on total metal. Most will be based on total recoverable metal because forms of metals that are not measured in the total recoverable procedure probably are not, and will not become, toxic. A major problem is that some people use a procedure for total recorverable, but report the results as total, metal. In many situations the two results are about the same, but in some cases the results are quite different.

54. Comment—The Guidelines should give more guidance for distinguishing between acceptable and unacceptable data.

Response—The Guidelines contain as much detail on this subject as EPA believes is currently feasible. Items such as the maximum acceptable control mortality and minimum number of test organisms are based on what many aquatic toxicologists generally feel are acceptable, as expressed in published methods. No data should be used in the derivation of a criteria until their quality and acceptability had been reviewed by a competent person. Competent people will occasionally disagree, but that is a fundamental property of subjective decisions.

55. Comment—Only published data should be used.

Response—Peer review is one of many concepts that is better in theory than in practice. Some poor quality data are published and some high quality data are rejected. In addition, publication is not a particularly rapid process. Whether or not data are used should depend on the applicability and quality of the data, not on whether they have been published. Data that are not published should be made readily available if they are used to derive water quality criteria.

56. Comment—All static test are unacceptable

Response—In general, high quality flow-through acute tests are preferable to high quality static acute tests, but static tests are by no means unacceptable. Few data are available to show whether static tests consistently produce acute values lower or higher or different than flow-through tests. Whereas degradation, violatilization, and buildup of metabolic products are more likely to be a problem in static tests, operator and mechanical errors are more likely in flow-through tests. Static acute tests are certainly not unacceptable for most pollutants, but static chronic tests generally are unacceptable because of changes in the toxicant concentrations and the quality of the dilution water during the test.

57. Comment—Data obtained using test organisms that were previously exposed to the pollutant should be used.

Response—Comparisons of results obtained with unexposed and previously exposed organisms should indicate whether or not acclimation has occurred. Generally, data obtained with acclimated organisms should not be used in deriving criteria because acclimated organisms are the exception rather than the norm. Rarely, if ever, can acclimation be depended on to protect organisms in a field situation because concentrations often fluctuate and motile organisms do not stay in one location very long. Data obtained with acclimated organisms may be acceptable for use in deriving some site-specific criteria.

58. Comment—Foreign species should be used to expand the data base.

Response—Foreign species may be representative of indigenous species, but some of them are quite unusual. Data obtained with foreign species may give good indications of indigenous speceis that should be used in tests on some pollutants and may identify some potential problems that should be investigated.

59. Comment—If data for brine shrimp are not used, the criteria should not apply to saline waters.

Response—Data obtained using brine shrimp are not used because these organisms are atypical. Although they may not be usually sensitive or insensitive to various pollutants, the species found in North America and used for testing only survive in the Great Salt Lake and in salt ponds near San Francisco Bay. These two habitats are unlike any others in the United States. If criteria were to be derived specifically for the Great Salt Lake or for salt ponds, then data for brine shrimp should be used.

60. Comment—Structure-activity relationships should not be used unless proven.

Response—No provision is made in the Guidelines for the use of structure-activity relationships. Such relationships may soon be well enough understood that they can be used in deriving water quality criteria.

61. Comment—A criterion should not be derived for a pollutant until data are available for a broad range of commercially, recreationally, and ecologically important species. Each species should be acutely and chronically tested under a variety of conditions in a number of different waters.

Response—Except for those people who merely want to stop EPA from deriving any water quality criteria, most people will admit that there must be some reasonable limit as to how much information is necessary concerning any regulatory action. This is as true for deriving water quality criteria, as it is for issuing NPDES permits, submitting PMNs, registering pesticides, etc. All of these regulatory activities deal with potentially significant adverse effects on aquatic organisms and should take into account many of the same possible kinds of adverse effects. Therefore, the data needs for these various activities should probably be somewhat similar, but for each regulatory activity the minimum data requirements also need to take into account the special aspects of the program and practical considerations. Unrealistic data requirements will benefit no one. It is not necessary that all questions be answered before any action is taken. It is only necessary that enough data be available to allow reasonable confidence that the water quality criteria will generally not be too high or too low.

EPA has developed minimum data requirements that describe the amounts and kinds of information that should usually be available if a criterion is to be derived using the Guidelines. When the minimum data requirements are satisfied, it should usually be possible to derive a useful criterion. The requirements take into account many things such as:

a. The existence of some species which are commerically or recreationally important and generally sensitive to some broad classes of pollutants;

b. The range of species for which data are available;

c. The cost of obtaining additional data and the usefulness of the data; and

d. The reasonableness of extrapolations from one species to another within and between groups.

The requirements set forth in the minimum data base are indeed minimal, considering the great varitey of species which exist in most aquatic ecosystems. However, EPA feels that based on the availavble information the routine requirement of more data would probably not improve criteria enough to justify the additional cost.

62. Comment—The mimimum data requirements should depend on the nature of the pollutant.

Response—EPA feels that such an approach may be feasible some time in the future, but would be an unwarrented level of sophistication at this time. For a few pollutants, it may be possible to relax some of the data requirements, but in general this can only be determined after enough data are available to indicate that a special case exists. In other cases the minimum data may indicate that additional data are highly desirable.

63. Comment—Criteria should not be derived if enough data are not available. The alternative procedures which were proposed should not be used.

Response—EPA agrees that a numerical criterion should not be derived if enough appropriate data are not available, except in some special cases. EPA also agrees that the alternative procedures which were proposed should not be used to develop numerical criteria at the present time. However, EPA feels that when a numerical criterion is not derived, a descriptive criterion can be used to accurately reflect the latest scientific knowledge.

64. Comment—The guidelines should give more guidance on relating a criterion to a water quality characteristic.

Response—More detail on this subject has been written into the Guidelines.

65. Comment—If data on the relation of toxicity and water quality are not available, no criterion should be derived.

Response—The purpose of a criterion is to present the best available information, not to ensure that all desirable information is available. Any water quality characteristic may affect the toxicity of each pollutant to some degree and it is never going to be possible to investigate all such interactions for even a few species and pollutants. EPA has adopted a minimum data base requirement for deriving a criterion, but there must be practical limits or no criterion will ever be possible. When the minimum data base requirements are satisfied, a criterion should be derived regardless of speculation that some unstudied relationship exist. When enough good data demonstrate a relation between toxicity and a water quality characteristic, an attempt should be made to use this information in the derivation of a criterion. A major purpose of site-specific criteria is to take into account the effect of local water quality conditions on toxicity.

66. Comment—Do not specify the form that a relationship between toxicity and water quality must take.

Response—The Guidelines allow the use of any set of transformations that fit the data well. The log-log model is given as an example because it seems to fit most of the available data concerning the relationship between hardness and toxicity of metals (the only such relationship for which much quantitative data are available) reasonably well.

67. Comment—The toxicity of metals should not be related to "hardness".

Response—EPA has tried to derive criteria in a form that will (a) adequately protect aquatic organisms and (b) be practically useful. Hardness is used as an easily measured surrogate for a number of interrelated water quality characteristics, such as pH, alkalinity, calcium, and magnesium. Various combinations of these probably affect individual metals differently, but these are all reasonably well correlated with hardness in a wide variety of natural waters. Some waters, such as those impacted by acid mine drainage, obviously are special cases, but they have special problems of their own.

68. Comment—Do not extrapolate slopes for toxicity vs. water quality from fish to invertebrates or from acute values to chronic values.

Response—The Guidelines do not now assume that the acute slope and the chronic slope are similar for a pollutant. On the other hand, there is no reason to believe that invertebrates are more similar than are fish and invertebrates. As explained earlier, the group "invertebrates" does not consist of a collection of species that are similar taxonomically or toxicologically. Some water quality characteristics apparently affect the toxicity of the pollutant, rather than the sensitivity of the organisms. For these kinds of factors, slopes should be the same for different species. Even factors that affect such things as the permeability of membranes may produce similar slopes for a wide variety of species. If each species must be treated separately, no criteria will ever be possible.

69. Comment—Relationships based on only two points should not be used.

Response—Two points certainly do not provide very much information about the shape, slope and position of a line. However, if other information or a reasonable assumption is available concerning the shape of the line, two good data points, spaced at a reasonable interval, can provide very useful information concerning the slope and position of the line. Three appropriately spaced points would certainly be better, and four points would be an ideal minimum.

70. Comment—Do not combine relationships that are and are not statistically significant.

Response—The Guidelines do now specify that relationships should be tested for statistical signficance. A test for statistical significance may be one indication of whether or not a slope is

useful, but such a test cannot be used with just two points and does not take into account such things as the comparability of the data, the quality of the test, and the range of the independent variable. A relationship based on six points may not be as significant as it seems if five of the points are tightly grouped.

71. Comment—The Guidelines should not combine 96-hr LC50 values and 48-hr EC50 values.

Response—Both LC50 values and EC50 values are used to measure acute toxicity of a substance to aquatic organisms. In general, an EC50 can be based on a wide variety of effects, but the Guidelines specify that the only effects to be used for deriving criteria are incomplete shell development, immobilization, and loss of equilibrium. All of these are certainly drastic effects. In a field situation these effects probably often lead to death. Just as the endpoint may be specific for the species, so may be the length of the test. The generally accepted length of an acute test with daphnids is 48 hours, whereas for most species of fish, it is 96 hours. Thus the Guidelines use both 48-hr EC50 values and 96-hr LC50 values because they are the widely accepted durations and endpoints used to measure acute toxicity to specific species.

72. Comment—Shell deposition tests are chronic tests and should not be equated with lethality tests.

Response—"Acute" implies "short" not "death". Many acute toxicity tests do use death for the effect, but many also use non-lethal effects. The shell deposition test is one of many non-lethal acute tests and is generally accepted as a short test compared to the average life span of oysters.

73. Comment—Adjustment factors should not be used to adjust for the length of the test, the technique, and unmeasured concentrations.

Response—All three kinds of adjustment factors have been deleted from the Guidelines. The factor for the length of the test was found to be unnecessary because most tests had been conducted for the standard times usually specified for the individual species. Thus the Guidelines now specify that only data from tests conducted for the time specified for the species should be used to calculate the Final Acute Value.

EPA has found that on the average flow-through acute tests give results slightly lower than do static tests, but the relationship does not seem to be too consistent and may vary from species to species for some pollutants. In addition, on the average results based on measured concerntrations do not seem to be much different from those based on unmeasured concentrations.

However, the results of flow-through tests based on measured concentrations are generally accepted as being better measures of acute toxicity than the results of flow-through tests based on unmeasured concentrations or the results of any static or renewal tests.Therefore, whenever the results of flow-through acute tests in which the concentrations were measured are available, the results of all other kinds of acute tests with that species and pollutant are not used in the calculation of the species mean acute value.

74. Comment—Species sensitivity factors should be pollutant-specific; and average factor should not be calculated for a variety of substances.

Response—EPA agrees. The requirement for acute values for at least eight different species was developed in part to allow for a reasonably good calculation of a mean acute value and a species sensitivity factor for each individual pollutant. A better way of using the acute values for the individual species has been developed, but no extrapolations are made from one pollutant to another.

75. Comment—The distribution of species mean acute values for a pollutant will be truncated if the species cannot be killed or affected by concentrations above solubility.

Response—Some species are so resistant to some pollutants that they cannot be killed or affected in acute tests even by concentrations which are much above solubility. Such "greater than" values cannot be used in the calculation of means and variances for pollutants. When the "greater than" values are for insensitive species and are at or above solubility, the values can be used in the calculation of the Final Acute Value by adjusting the cumulative proportions for all the speices with quantitative values. The shape of the curve at the high end cannot be determined, but the Final Acute Value is more dependent on the species mean acute values and the cumulative probabilities at the low end.

76. Comment—Early life-stage tests with fish should be used interchangeably with life-cycle and partial life-cycle tests with fish.

Response—EPA agrees that early life-stage tests with fish generally give about the same results as comparable life-cycle and partial life-cycle tests. However, because the shorter test is merely a predictor of the longer tests, whenever both kinds of results are available, the results of life-cycle and partial life-cycle tests should be used instead of the results of early life-stage tests.

77. Comment—Appropriate measures of chronic toxicity and appropriate lengths of exposure should be defined.

Response—The descriptions of appropriate chronic tests have been clarified.

78. Comment—The factor of 0.44 should not be used.

Response—It is not now used.

79. Comment—The Final Chronic Value should not be lower than the lowest measured species chronic value, even if chronic data are not available for sensitive species.

Response—Aquatic ecosystems cannot be protected from chronic toxicity by protecting only the insensitive species from chronic toxicity. In the past both arbitrary and experimentally determined application factors have been used to relate acute and chronic toxicity. For a variety of reasons the Guidelines do not use an application factor, but instead use the acute-chronic ratio, which is similar to the inverse of an application factor. Thus the acute-chronic ratio should normally be greater than one. The acute-chronic ratio is to be used with invertebrates as well as fish and is to be an experimentally determined value for each individual pollutant. The acute-chronic ratio should also avoid the confusion as to whether a large application factor is one that is close to unity or one that has a denominator that is much larger than the numerator. The acute-chronic ratio is calculated by dividing the appropriate measure of acute toxicity for the species (as specified in the Guidelines) by the appropriate measure of chronic toxicity for the same species (as specified in the Guidelines).

Some people have confused application factors and safety factors and use of the term "acute-chronic ratio" should help avoid this problem. Acute-chronic ratios are a way of estimating the chronic sensitivity of a species for which no chronic toxicity data are available. Safety factors would provide an extra margin of safety beyond the sensitivity of the species. Safety or uncertainty factors are intended to reduce the possibility of underprotection, whereas acute-chronic ratios are intended to estimate the actual chronic sensitivity of the species to the pollutant. This estimate is just as likely to be too high as it is to be too low. A mean acute-chronic ratio will in fact be too high for half the species and too low for the other half.

When three or more acute-chronic ratios have been determined for a pollutant with both fish and

invertebrates, three patterns have been observed when the individual species are listed in order of their species mean acute values:

a. The ratios randomly differ by a factor of ten or more.

b. The ratio appears to be about the same (within a factor of ten) for all species.

c. Species with higher acute values also have higher acute-chronic ratios.

The available data indicate that fish and invertebrates do not consistently have different acute-chronic ratios and that for some pollutants freshwater and saltwater species have similar acute-chronic ratios.

80. Comment—No application factor should be used unless it is specific for the pollutant, species, and water.

Response—There is no point in using an application factor or acute-chronic ratio or any concept if it does not allow some generalization or extrapolation from one species to another or from one water to another. Not allowing any generalizations or extrapolations would require that much data be generated for each species and each pollutant in each water in which a criterion is necessary. When enough supporting data are available, extrapolations using such things as acute-chronic ratios are cost-effective and scientifically sound.

81. Comment—Additional development of methodology for toxicity tests with aquatic plants is needed.

Response—This is most certainly true. Much other research also is needed, and generally is considered higher priority. EPA hopes that someday all of the additional research that needs to be done will be done. Few pollutants seem to affect aquatic plants at concentrations which do not chronically affect aquatic animals, and it is hoped that this is not an artifact of the test methods currently used.

82. Comment—Data on toxicity to plants should not be used for deriving criteria because plants are more site-specific than animals.

Response—Numerous species of plants, especially algae, exist in most bodies of water. On the other hand, EPA knows of no data to support the contention that the sensitivities of aquatic plants are any more site-specific than those of aquatic animals, or that the range of sensitivities between plants is as great as that for animals. One species may or may not be representative of other species. After the methodology for toxicity tests with aquatic plants is better developed, tests with a wider variety of species would certainly be desirable.

83. Comment—The Final Plant Value should not be the lowest available plant value based on measured concentrations.

Response—EPA adopted the procedure described in the Guidelines for obtaining the Final Plant Value for several reasons including:

a. The methodology for toxicity tests with aquatic plants is not well developed.

b. For only a few pollutants have toxicity tests been conducted with more than a very few species of plants.

c. Little is known about the range of sensitivities of various species of aquatic plants.

d. Based on available data, almost no pollutants are toxic to aquatic plants at the lowest concentrations which are chronically toxic to aquatic animals or cause unacceptable residues.

84. Comment—Residue accumulation in any part of an aquatic ecosystem should be prevented as much as possible.

Response—Accumulation of residues in aquatic organisms only becomes a problem if the concentration of residue is high enough to adversely affect either (a) the organism itself, (b) a consumer of the organism, or (c) the marketability of the organism. Adverse effects on the aquatic organism itself will be detected in acute and chronic toxicity tests. The use of FDA action levels and chronic feeding studies with wildlife are designed to protect the uses and consumers of aquatic organisms.

85. Comment—Bioconcentration factors (BCFs) derived from field data should not be used.

Response—EPA feels that BCFs derived from adequate data, whether they be laboratory data or field data, should be used. More data are necessary to document a BCF from a field exposure than a laboratory exposure, as specified in the Guidelines, but if enough data are available, field BCFs should be used.

86. Comment—Kinetically derived bioconcentration factors (BCFs) should be used.

Response—Kinetically derived BCFs should be used if the bioconcentration test lasted long enough, *i.e.*, to apparent steady-state, to verify that the model (assumptions) used in the calculations actually fits the data for the individual pollutant.

87. Comment—Bioconcentration factors (BCFs) should not be estimated from octanol-water partition coefficients.

Response—The available data seem to indicate a reasonably good relationship for lipid-soluble substances between steady-state BCFs and octanol-water partition coefficients. BCFs estimated from partition coefficients are not used in the Guidelines because measured BCFs are available for all pollutants for which a maximum permissible tissue concentration is available.

88. Comment—Bioconcentration factors (BCFs) are dependent on temperature, food, salinity, stress, and other things.

Response—Many things such as these probably do affect BCFs. Until data are available to show that such effects are important and are not species-specific, little needs to be, or can be, done to take such factors into account when deriving water quality criteria.

89. Comment—Bioconcentration factors (BCFs) should be based only on tissues that are actually eaten.

Response—Although people usually only eat muscle tissue of fish, wildlife usually eat the whole body of fish. The tissues used in the determination of BCFs must be appropriate to the kind of consumer organism or regulatory action. On the other hand, since the BCF for a lipid-soluble substance seems to be proportional to percent lipids, extrapolations can be made on the basis of percent lipids regardless of the tissue.

90. Comment—Chronic toxicity tests with rats and mice should not be used as representative of tests on mammalian wildlife.

Response—Because results of tests on a variety of species are extrapolated to man, it should be just as reasonable to extrapolate from one mammalian species to another mammalian species within certain limits. However, such extrapolations are not now used in the Guidelines; only the results of chronic toxicity tests with wildlife are used to protect wildlife consumers of aquatic life.

91. Comment—Information concerning bioconcentration should only be used if such information is used to protect aquatic organisms, not to protect the marketability of aquatic organisms.

Response—Protection of aquatic organisms must include not only the protection of the existence of aquatic organisms, but also protection of the common uses of aquatic organisms. Commercially important aquatic organisms cannot be considered adequately protected if they cannot be sold. The Guidelines do not use any data pertaining to safety to humans in an attempt to protect human consumers of aquatic organisms. Instead, the Guidelines merely attempt to ensure that residues in aquatic organisms do not exceed FDA action levels so that the uses of commercially and recreationally important species are not restricted by the Food and Drug Administration.

49 FR 43906-01
PROPOSED RULES
ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 61
[AD-FRL 2694-2]

National Emission Standards for Hazardous Air Pollutants; Regulation of Radionuclides

Wednesday, October 31, 1984

***43906** AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of proposed standards.

SUMMARY: On April 6, 1983, the Environmental Protection Agency, pursuant to section 112 of the Clean Air Act, proposed standards for sources of emissions of radionuclides in four categories: (1) Elemental phosphorus plants; (2) Department of Energy (DOE) facilities; (3) Nuclear Regulatory Commission (NRC)-licensed facilities and non-DOE Federal facilities; and (4) underground uranium mines. In addition, the Agency decided not to propose standards for the following source categories of radionuclide emissions: (1) Coal-fired boilers; (2) the phosphate industry; (3) other extraction industries; (4) uranium fuel cycle facilities, uranium mill tailings, and management of high-level radioactive waste; and (5) low energy accelerators. The Agency is announcing the withdrawal of its four proposed standards for radionuclide emissions under Section 112 of the Clear Air Act and affirms its original decision not to regulate emissions from the other five source categories considered. The U.S. District Court for the Northern District of California has ordered EPA to take final action on its proposed standards by October 23, 1984.
DATE: This withdrawal is effective October 31, 1984.

ADDRESS: The rulemaking record is contained in Docket No. A-79-11. This docket is available for public inspection between 8:00 a.m. and 4:00 p.m., Monday through Friday, at EPA's Central Docket Section, West Tower Lobby, Gallery One, Waterside Mall, 401 M Street, SW., Washington, D.C. 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: James M. Hardin, Environmental Standards Branch (ANR-460), Criteria and Standards Division, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, D.C. 20460, (703) 557-8977.

SUPPLEMENTARY INFORMATION:

I. Supporting Documents

A final Background Information Document has been prepared and single copies may be obtained by writing the Program Management Office, Office of Radiation Programs (ANR-458), U.S. Environmental Protection Agency, Washington, D.C. 20460, or by calling (703) 557-9351. Please refer to “NESHAPS-Radionuclides: Background Information Document for Final Rules, Volumes 1 and 2 [EPA 520/1-84-022-1, EPA 520/1-84-022-2], October 1984. These documents comprise the integrated risk assessment performed to provide the scientific basis for this rulemaking. Volume 1 of the Background Information Document contains a complete description of the Agency's methodology used in its risk assessment of the hazards associated with airborne emissions of radionuclides. Volume 2 is devoted to a detailed description of how the Agency applied this methodology to each source category considered in this rulemaking. For each source category, this document describes the radionuclide emissions, estimated doses and risks to nearby individuals and to populations, description of current emission control technology, and descriptions and cost estimates of additional emission control technology.

The Agency's written responses to oral and written comments on the proposed standards have been placed in Docket No. A-79-11. Single copies of the Agency's responses may be obtained by writing the Program Management Office, Office

of Radiation Programs (ANR-458), U.S. Environmental Protection Agency, Washington, D.C. 20460, or by calling (703) 557-9351. Please refer to "NESHAPS-Radionuclides: Response to Comments for Final Rules, Volumes 1 and 2" [EPA 520/1-84-023-1, EPA 520/1-84-023-2], October 1984.

II. History of Standards Development

In 1977, Congress amended the Clean Air Act (the Act) to adddress airborne emissions of radioactive materials. Before 1977, these emissions were either unregulated or were regulated under the Atomic Energy Act. Section 122 of the Act required the Administrator of EPA, after providing public notice and opportunity for public hearings (44 FR 21704, April 11, 1979), to determine whether emissions of radioactive pollutants "cause, or contribute to, air pollution which may reasonably be anticipated to endanger public health." On December 27, 1979, EPA published a notice in the Federal Register listing radionuclides as a hazardous air pollutant under section 112 of the Act (44 FR 76738). This action was based on the Agency's finding that studies of the biological effects of ionizing radiation indicated that exposure to radionuclides increases the risk of human cancer and genetic damage. In addition, the Agency found that emissions data indicated that radionuclides are released into air from many different sources with the result that millions of people are exposed. To support these findings, EPA issued a report entitled "Radiological Impact Caused By Emissions oof Radionuclides into Air in the United States, Preliminary Report," [EPA 520/7-79-006], Office of Radiation Programs, U.S. EPA, Washington, D.C., August 1979.

Section 122(c)(2) of the Act directed that, after having listed radionuclides as a hazardous air pollutant, EPA enter into an interagency agreement with the Nuclear Regulatory Commission with respect to those facilities under NRC jurisdiction. Such a memorandum of understanding was effected on October 24, 1980, and was subsequently published in the Federal Register (45 FR 72980, November 3, 1980). When EPA began developing standards for Department of Energy facilities, a similar memorandum of understanding was negotiated with DOE and signed in October 1982. Copies of both these memoranda have been placed in the Docket for public review.

On April 6, 1983, EPA announced its proposed standards for sources of emissions of radionuclides from four categories: (1) Elemental phosphorus plants; (2) DOE facilities; (3) NRC-licensed facilities and non-DOE Federal facilities; and (4) underground uranium mines. Several additional source categories emitting radionuclides were identified in the notice. However, the Agency concluded that good reasons existed to propose not to regulate these categories, which included: (1) Coal-fired boilers; (2) the phosphate industry; (3) other extraction industries; (4) uranium fuel cycle facilities, uranium mill tailings, and management of high-level radioactive waste; and (5) low energy accelerators (48 FR 15076, April 6, 1983). At the time of proposal, it was thought that these nine source categories were all that potentially released radionuclides to air at levels that could warrant regulatory attention. In support of these proposed standards and determinations, EPA published a draft report entitled "Background Information Document, Proposed Standards for Radionuclides," [EPA 520/1-83-001], Office of Radiation Programs, U.S. EPA, Washington, D.C., March 1983.

Following publication of the proposed standards, EPA conducted an informal public hearing in Washington, D.C., on April 28 and 29, 1983. The comment period was held open an additional 30 days to receive written comments. Subsequently, EPA received a number of ***43907** requests to extend the time for submission of public comments and to conduct a public hearing outside of Washington, D.C., on the proposed standards to accommodate those were unable to attend the first hearing. In response to these requests, EPA extended the comment period by an additional 45 days and held another informal public hearing in Denver, Colorado, on June 14, 1983 (48 FR 23665, May 26, 1983).

EPA has considered and responded to all written and oral comments; a copy of the Agency's responses is in the Docket. The Background Information Document has been revised and published in final form. In addition, a final economic analysis of the impact of the proposed standards for elemental phosphorus plants has been completed and placed in the Docket (Refer to "Regulatory Impact Analysis of Emission Standards for Elemental Phosphorus Plants," October 1984). The final report on control technology for radionuclide emissions to air at Department of Energy facilities has been published and a copy is available int he Docket. (Refer to "Control Technology for Radioactive Emissions to the Atmosphere at U.S. Department of Energy Facilities," [PNL-4621], October 1984).

In response to requests for wider scientific review of the Agency's risk assessment, the Administrator in December 1983, formed a Subcommittee on Risk Assessment for Radionuclides within the Agency's Science Advisory Board (SAB) to review the scientific basis for the proposed standards. This review is discussed in more detail in Section IV of this notice. On the basis of the Subcommittee's review, the final Background Information Document has been rewritten to incorporate recommendations made by the Subcommittee. The revised Background Information Document presents an integrated risk assessment following the format and methodology suggested by the Subcommittee, to the extent possible.

On February 17, 1984, the Sierra Club filed suit to compel final action in the U.S District Court for the Northern District of California, pursuant to the citizens' suit provision of the Act (Sierra Club v. Ruckelshaus, No. 84-0656 WHO). In August 1984, the Court granted the Sierra Club's summary judgment motion and ordered EPA to take final action on its proposed standards by October 23, 1984. On September 14, 1984, the Administrator requested that the Court delay its deadline until January 1985 to him enable him to personally evaluate the merits of the criticisms and suggestions presented by the Subcommittee. This request was denied.

On August 24, 1984, EPA announced in the Federal Register the availability of new technical information (49 FR 33695). The public was encouraged to comment on this new information which included the Final Report of the SAB Subcommittee, transcripts of all public meetings of the Subcommittee, information presented to the Subcommittee, and technical information relevant to elemental phosphorus plants and underground uranium mines. This new information was available in the Docket on September 7, 1984. The Agency's responses to these comments are included in Volume 2 of “NESHAPS-Radionuclides: Response to Comments for Final Rules.”

III. Summary of the Final Actions.

On April 6, 1983, the Agency proposed standards for sources of emissions of radionuclides in four categories: (1) Elemental phosphorus plants; (2) DOE facilities; (3) NRC-licensed facilities and non-DOE Federal facilities; and (4) underground uranium mines. For DOE facilities, the Agency proposed an emission limit not to exceed an amount that causes a dose equivalent rate of 10 mrem/y to the whole body and 30 mrem/y to any organ of any individual living nearby. For NRC-licensees and non-DOE Federal facilities, the Agency proposed an emission limit not to exceed an amount that causes a dose equivalent rate of 10 mrem/y to any organ of any member of the public. The emission limit proposed for elemental phosphorus plants was 1 Ci/y of polonium-210.

For all three of these source categories, the Administrator has determined that current practice provides an ample margin of safety in protecting the public health from the hazards associated with exposure to airborne radionuclides, and has therefore decided to withdraw the proposed standards.

In the case of underground uranium mines, the Agency proposed a standard to limit the annual average radon-222 concentration in air due to emissions from an underground mine to 0.2 pCi/1 above background in any unrestricted area. The Agency is also withdrawing this proposed standard beacause it has concluded, for the reasons discussed below, that it did not meet the legal requirements of Section 112. The Agency has received additional technical information that suggests the possibility of using bulkheading and other techniques to control radon emissions. However, pursuing this course of action was not advocated or even suggested in the proposal. Indeed, the information available to EPA at the time of proposal indicated that these techniques were costly and “not very effective” and the Agency dismissed these techniques as the basis for an emission standard (48 FR 15083, col. 3). Since that time, new information suggests that conclusion may be erroneous. Technical information on which the base of final regulation or a proposal is not yet available; further work is needed to demonstrate how to set such a regulation at some future time. Therefore, the Agency is publishing, simultaneously with this notice, an Advance Notice of Proposed Rulemaking for Radon-222 Emissions from Underground Uranium Mines to solicit additional information on control methods, such as bulkheading and other forms of operational controls for radon-222 emissions from these mines. Such an approach could avoid many of the technical and legal difficulties pose by EPA's proposed standards.

In addition to the four source categories for which EPA did propose standards, the Agency has made a final determination not to regulate the following five source categories: (1) Coal-fired boilers; (2) the phosphate industry; (3) other extraction facilities; (4) uranium fuel cycle facilities, uranium mill tailings, and management of high-level radioactive waste; and (5) low energy accelerators. The Agency did not receive any new information during the public comment period that convinced it of a need for regulation of any of these five categories. Therefore, the Administrator affirms the original decision not to regulate these sources, believing that adequate public health protection exists to satisfy the requirements of the Clean Air Act.

When the Agency promulgated its standards for active uranium mill tailings (40 CFR 192, Subparts D and E), it decided that the control of the radon-222 emissions from the active uranium mill tailings piles could more appropriately be considered under the Clean Air Act, rather than the Uranium Mill Tailings Radiation Control Act. The preamble to the final uranium mill tailings standards noted that work practice standards were probably the most practical way to control radon emissions at active uranium mills. Consequently, EPA is issuing, simultaneously with this notice, an Advance Notice of Proposed Rulemaking for Radon-222 Emissions from Licensed Uranium Mills.

***43908** The withdrawal of the proposed standards for elemental phosphorus plants, Department of Energy facilities, Nuclear Regulatory Commission-licensed facilities and non-DOE Federal facilities, and underground uranium mines are final actions. Also, the decision not to establish radionuclide emission standards for coal-fired boilers; the phosphate industry, other extraction industries; uranium fuel cycle facilities, uranium mill tailings, and management of high-level radioactive waste; and low energy accelerators are final actions. Judicial review is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit within 60 days of today's publication date.

III. Major Issues Raised in Public Comments

Many commenters expressed considerable dissatisfaction with the proposed standards. Operators of facilities for which standards were proposed objected vigorously to the stringency of the proposed standards; other groups objected on the grounds that the proposed actions were not sufficiently protective of public health. Both groups criticized the proposed standards for not meeting the intent of the Clean Air Act.

A number of comments were made which apply to all of the source categories considered and which address the bases of the standards-setting process. The following is a summary of the most significant comments and the Agency's responses:

Comment: Radionuclides should not be considered a hazardous air pollutant under section 112 of the Clean Air Act because ambient levels do not pose a significant risk to human health. One commenter petitioned for reconsideration of EPA's listing of radionuclides as a section 112 pollutant, on the basis that the Agency had not justified its conclusion that radionuclides are hazardous air pollutants within the meaning of section 112.

Responses: EPA has concluded that existing radionuclide emissions from some stationary sources can represent a significant risk of fatal and nonfatal cancers to exposed populations. There is no scientific doubt that radionuclides are carcinogens. This conclusion is based on extensive scientific evidence derived from studies of populations of humans and animals exposed to radiation at various levels ranging from very high doses to doses only slightly greater than environmental levels.

Both this conclusion and EPA's specific risk esitmates are based on the widely used assumption that there is no threshold below which exposure to radiation does not pose some risk to human health. Based on this premise, EPA concludes that exposure to radionuclides at low levels in the ambient air presents a risk of fatal and nonfatal cancers, as well as genetic damage.

In addition, section 112 requires not only a finding that the pollutant at issue is hazardous in the abstract, but also that it poses a public health risk in its form as an air pollutant. EPA has evaluated the air pollution risk of radionuclide emissions based on the magnitude of such emissions from stationary sources to the ambient air, on observed and estimated ambient concentrations of radionuclides, on the proximity of large populations to emitting sources, on estimates of health risks to exposed populations, and on considerations of uncertainties associated with risk estimates.

Based on this analysis, EPA has concluded that the present record does not support regulation of any of the source categories for which regulation was proposed. This conclusion, however, does not support delisting of radionuclides, because, in the case of uranium mines, the risks appear sufficient to warrant future regulatory action under section 112. It is only because regulation of the appropriate type is impossible at this time, due to the need for further work on the technical issues and the need to provide an opportunity for notice and comment on any proposed action, that no rules for uranium mines are being included in this decision.[FN1]

Therefore, with respect to the petition for reconsideration of the listing of radionuclides as a hazardous air pollutant, EPA has considered this option and has rejected it, believing that the original decision to list under section 112 is still appropriate.

Comment: The EPA standards are unnecesary because current administrative or regulatory standards of 500 mrem/y to the whole body and 1500 mrem/y to any organ (Federal Radiation Council guidance and NRC regulatory values), coupled with directives to keep emissions as low as practicable, are adequately protective of the public health. Other commenters felt that the proposed standards were too lax and that the Agency should set an emission limit of zero, with exceptions allowed only after a case-by-case examination.

Response: EPA does not believe that current Federal Radiation Council guidance and NRC policy of limiting exposure to individuals to 500 mrem/y to the whole body and 1500 mrem/y to any organ protects public health with an ample margin of safety, as required by the Clean Air Act. EPA estimates that a person receiving 500 mrem/y to the whole body over a lifetime would have an added potential risk of developing a fatal cancer of about one in one hundred due to the radiation exposure. In addition, that same person would face an approximately equal level of risk of nonfatal cancer and of passing on nonfatal genetic effects to succeeding generations.

However, EPA recognizes that the “as low as reasonably achievable” (ALARA) emissions policy had led to generally low emissions of radionuclides from most facilities. The Agency expects that this current policy will continue in the future and does not anticipate an increase in the emission level or the associated risks. Therefore, the Agency believes that in cases in which a vigorous and well-implemented ALARA program has achieved low emissions, such practice can provide an ample margin of safety for public health protection.

The Agency does not agree with the approach of establishing an emission limit of zero. The implementation of such a standard for the source categories considered would be extremely burdensome, and would result in little improvement in public health. More important, however, is the Administrator's determination that public health is currently protected to a degree which satisfies the requirement of Section 112 of the Act.

Comment: EPA is required to promulgate standards under all of its applicable authorities in order to fulfill the intent of its Congressional mandates. For example, the Agency must regulate air emissions from uranium fuel cycle facilities under the Clean Air Act, as well as under the Atomic Energy Act.

Response: The Agency believes that its primary objective is to provide reasonable public health protection, but that it was not the intent of Congress that the Agency issue duplicative regulations to achieve this goal. In light of the limited resources in both the ***43909** public and private sector, it would be inefficient and unnecessarily complicated to require sources to comply with a standard they already meet, or alternatively, to meet several comparable standards set by one Agency under different statutory authorities.

Comment: Some commenters stated that the standards should be based on cost analyses, and if not cost-effective, they should not be promulated. Others felt that costs should not be considered at all.

Response: The Agency believes that giving equal weight to costs and benefits is inappropriate in developing standards under Section 112 of the Clean Air Act. Congress clearly intended that public health protection considerations be primary and that cost be secondary.

The Agency did consider, in developing these rules, the availability and practicality of control equipment. While this was not a primary consideration, knowledge of the availability of control technology is necessary when making judgments on the need for and level of emission standards. EPA believes these considerations are within the Administrator's discretion in determining what level of protection is adequate. The Agency considered costs to a limited degree consistent with this overall perspective in reaching its decisions on coal-fired boilers and elemental phosphorus plants, but otherwise today's action does not rest on cost considerations.

Comment: Some commenters stated that the Clean Air Act requires standards for all source categories releasing significant amounts of radionuclides into the air. Determinations that standards are not needed are not allowed for any reason. Others supported EPA's determinations that standards for some categories are unnecessary.

Response: The comment that every stack emitting radionuclides to air must be subject to an emission limit established under the Clean Air Act must be considered in light of the fact that every stack in the United States discharges at least minute quantities of radionuclides. These radionuclides include certain kinds of carbon and potassium atoms and other naturally-occurring radionuclides. Because these emissions are so small, the risk to nearby individuals and the total population group is minimal. To regulate these sources would not significantly improve the public health.

Section 112 of the Act requires the Administrator to assure public health protection with an ample margin of safety. A negative determination of the need for standards is permissible within the context of the Act, so long as this criterion is met. With respect to eight of the source categories considered in this rulemaking, the Agency has concluded that the public health is adequately protected under current practice, and therefore has met the requirements of the Act. For the uranium mines category, the Agency concludes that risks are significant; however, there is presently no feasible way to establish an emission standard. The Agency will consider such a standard, together with alternative design, equipment, work practice and operational standards, for future proposal.

Comment: There has not been sufficient review outside the Agency of EPA's methods and procedures for risk assessment. Specifically, EPA's Science Advisory Board should review the scientific basis of the proposed standards for radionuclides.

Response: The Agency agrees with this comment (see section V below).

Comment: The proposed standards should not be promulgated because they cannot be implemented with reasonable procedures. Compliance with indirect emission standards (dose or concentration limits at site boundary) must be determined by environmental measurements at the site boundary. Because the proposed standards are so restrictive, this is either very expensive or altogether impractical.

Response: Questions concerning the implementations of standards for airborne radionuclide emissions are moot in light of the Administrator's decision to withdraw the proposed rules.

Comment: Standards should be consistent with established international and national policies and regulations governing radiation protection, as well as among each source category.

Response: The Agency agrees with this comment and has based its decision to withdraw the proposed standards, in part, on the fact that current practices in radiation protection do provide adequate public health protection.

Comment: Standards should allow for greater operational flexibility in selecting control technology.

Response: Questions concerning the amount of operational flexibility necessary to comply with standards for airborne radionuclide emissions are moot in light of the Administrator's decision to withdraw the proposed rules.

V. Technical Review by the Science Advisory Board

In response to criticism that the Agency did not have sufficient outside review of its methods used to assess risk due to radionuclides, the Administrator formed a subcommittee of the Agency's Science Advisory Board to review the scientific basis of the proposed standards for radionuclides. The Subcommittee held three public meetings: the first on January 16, 1984, the second on February 21-22, 1984, and the third on March 22, 1984. At these meetings, the Subcommittee was briefed by Agency staff on the methods used in estimating risks caused by airborne radionuclides. The panel heard from members of the public on the Agency's risk assessments, as well. The Subcommittee also held executive sessions to consider the information presented by the Agency and the public.

Transcripts of the public meetings are available in the Docket. The Subcommittee's final report, entitled “Report on the Scientific Basis of EPA's Proposed National Emission Standards for Hazardous Air Pollutants for Radionuclides,” was transmitted to the Administrator on August 17, 1984. A copy of this report and the Agency's response are available in the Docket.

In the Executive Summary of its report, the Subcommittee noted that its activities could be viewed as addressing two interrelated questions. First, did the Agency's staff collect the scientifically relevant data and use scientifically defensible approaches in modeling the transport of radionuclides through the environment from airborne releases, in calculating the doses received by persons inhaling or ingesting this radioactivity and in estimating the potential cancer and genetic risks of the calculated doses? Second, are the individual facts, calculational operations, scientific judgments, and estimates of uncertainty documented and integrated in a clear and logical manner to provide a risk assessment that can be used as a scientific basis for risk management purposes, i.e., standard-setting? With regard to the first question, the Subcommittee concluded that EPA had gathered the appropriate scientific information needed for a risk assessment in a technically proficient manner.

The Subcommittee made several technical suggestions on how EPA could improve its assumptions, models, and methods for estimating risks. Most of these technical suggestions have been incorporated into EPA's risk assessment procedures. The risk assessment for the final rule reflects these modifications. Some of these technical suggestions involve additonal research to improve future risk assessment methods. Those ***43910** suggestions will be used as EPA conducts new studies.

The Subcommittee's greatest criticism in its report was related to the second question. They concluded that EPA had not assembled and integrated the available scientific data in the format of a risk assessment that provides an adequate basis for regulatory decisions. The panel suggested the need for an intermediate step between the collection of the relevant technical information and the selection of regulatory options. Specifically, they encouraged the Agency to assemble an intergrated risk assessment document that would lead a decisionmaker step-by-step from the identification of emission sources, through the calculation of radiation doses and the associated degree of uncertainty, to a variety of regulatory options from which to choose. Only in this way did the Subcommittee feel that a policymaker could be presented with all the facts necessary to make a responsible regulatory decision. Further, this analysis would enable the scientific community and the public to understand the rationale and basis for the Agency's actions.

The Agency recognizes and is concerned about the adverse criticism of its processes by its own Science Advisory Board. EPA does believe that, on balance, its risk estimates for specific sources of radionuclide emissions are accurate within the limitations inherent in making such estimates. It acknowledges, however, that the criticism of the Board does cloud the rulemaking record, and that the Subcommittee's concerns, by their very nature, cannot be fully addressed within the time available for this decision. Nevertheless, the final Background Information Document has been greatly modified to encompass the format and suggestions of the Subcommittee to the extent possible. However, the Subcommittee has not reviewed this revised document.

The Science Advisory Board also made several procedural suggestions for improving the Agency's risk assessment methods. These recommedations will be incorporated into the Agency's procedures and processes. Detailed responses to the Science Advisory Board's recommendations can be found in Volume 2 of “NESHAPS-Radionuclides: Response to Comments for Fiscal Rule.”

VI. **Perspectives on Risk Assessment**

Today's decision is based on a developing body of science and policy concerning the treatment of one particular class of hazardous substances, namely materials that cause, or are thought to cause, cancer. In some cases, scientific evidence indicates that a given substance is hazardous at high levels or exposure, but has no effect below a certain level. For most carcinogenic substances, however, scientists are unable to identify such a threshold below which no effects occur; moreover, to the extent scientists understand the process of carcinogenesis, there is some reason to believe such thresholds may not exist. For these kinds of substances, EPA and other Federal agencies have taken the position that any level of exposure may pose some risks of adverse effects, with the risks increasing as the exposure increases.

EPA's approach to risk assessment for suspected carcinogens may be divided into several steps. The first is qualitative evaluation of the evidence to determine whether a substance should be considered a human carcinogen for regulatory purposes. This was done for radionuclides before they were listed as a hazardous air pollutant in 1979. The second step is quantitative: how large is the risk of cancer at various levels of exposure? The result of this examination is a dose-response function which gives the lifetime risk per unit of exposure (or “potency”). The third step is to estimate how many people are exposed to the sources of radiation, and at what levels. These exposure estimates then are combined with the dose-response function to obtain estimates of the risk caused by emissions of the pollutant, in this case radionuclides, into the environment.

Exposure levels for each specific source category are derived using emissions estimates, dispersion modeling, and population data. For any given level of emissions, dispersion models predict concentrations at different distances from the emission source. By combining those estimated concentrations with census data on population densities, the number of people exposed at different levels can be estimated. Several factors suggest that actual exposure levels will be lower than those estimated. In estimating exposure, the most exposed individuals are hypothetically subjected to the maximum annual average concentration of the emissions for 24 hours every day for 70 years (roughly a lifetime). This does not take into account indoor vs. outdoor air, for instance, or the fact that most people in their daily routines move in and out of the specific areas where the emission concentration are the highest.

The final risk estimates are the product of the exposure levels and the estimated unit-risk factor. Two summary measures are of particular interest: “nearby individual risk” and “total population impact.” The former refers to the estimated increased lifetime risk from a source that is faced by individuals who spent their entire life at the point where predicted concentrations of the pollutant are highest. Nearby individual risk is expressed as a probability; a risk of one in one thousand, for example, means that a person spending a lifetime at the point of maximum exposure faces an estimated increased risk of cancer of one in one thousand. (For comparison, the average lifetime risk of dying of cancer in the United States is about 165 in 1,000, so eliminating a risk of one in one thousand reduces the overall lifetime risk of contracting cancer by less than 0.6 percent.) Estimates of nearby individual risk must be interpreted cautiously, however, since generally few people reside at the points of maximum concentrations and spend their whole lives at such locations.

The second measure, “total population impact,” considers people exposed at all concentrations, low as well as high. It is expressed in terms of annual number of cancer cases, and provides a measure of the overall impact on public health. A total population impact of 0.05 fatal cancer per year, for example, means that emissions of the specific pollutant from the source category are expected to cause one case of cancer every 20 years. Such figures should not be viewed as precise estimates of the likely effects. Together with the estimates of maximum individual risk, they are intended to give an indication of a reasonable upper-limit situation.

The two estimates together provide a better description of the magnitude and distribution of risk in a community than either number alone. “Nearby individual risk” tells us the highest risk, but not how many people bear that risk. “Total population impact” describes the overall health impact on the entire exposed population, but not how much risk the most exposed persons bear. Two sources of radionuclide or chemical emissions could have similar population impacts, but very different maximum individual risks, or vice versa. Any sensible “risk management” system cannot rely on either measure alone; both are important.

Much more is known about the risks from exposure to radiation than exposure to most chemicals. While there is uncertainty in risk estimates from assessments of chemical emissions and radionuclide emissions, there is likely to be much less uncertainty in estimates of ***43911** risk from radionuclide emissions because of the extensive data base on human exposure to radiation. Therefore, a risk estimate of one in one thousand resulting from radionuclide emissions is likely to be more accurate than the same estimate for chemical releases. The situation for estimating risk from radionuclides is much less likely to reflect hypothetical maximum potential estimates than are estimates made for chemical emissions.

To provide general perspective regarding radiation exposure, everyone is exposed to background radiation due to cosmic radiation, and radioactivity in minerals, soils, and even our own bodies. Background radiation levels vary across the U.S., but average about 100 mrem/y for each person. There is very little that people can do to control exposure to background radiation. Over a lifetime this exposure is estimated to contribute to a fatal cancer risk of about one or two cases for every one thousand people.

VII. Withdrawal of Proposed Standards

A. Alternatives

In determining the appropriate course of action for the proposed standards, EPA considered the following alternatives.

1. Withdraw the Proposed Standards

This alternative is based on the finding that current and future emissions at the facilities under consideration are anticipated to be at levels that would protect the public with an ample margin of safety, as required by section 112 of the Act. This alternative is also appropriate if implementation of the proposed standards is infeasible.

2. Promulgate the Proposed Standards

This alternative is based on the conclusion that the findings made in the proposed rule were correct and that the proposed standards are necessary to adequately protect the public health.

3. Promulgate a Standard for Each Category at a Level That Would Limit Dose to 25 mrem/y to the Whole Body and 75 mrem/y to Any Organ

This alternative is based on the conclusion that the need for standards for each category for which the Agency proposed rules was correct, but that EPA could establish the standards at these recommended levels and still provide an ample margin of safety. Establishing the standards at these levels would also respond to several comments regarding consistency among the categories and with the recommendations of recognized national and international radiation protection groups, and regarding the need for greater operator flexibility in selecting control technology and methods of demonstrating compliance.

B. Elemental Phosphorus Plants

One of the decisions presented by this rulemaking concerns emission for elemental phosphorus plants. Risks from these plants are higher than for any other source category in this rulemaking except uranium mines. Moreover, technology to reduce these risks is available. Nevertheless, after consideration of the proposed rule, the public comments, the Science Advisory Board report, the risk assessment, and other pertinent information, it is the Administrator's judgment that the present record does

not support a conclusion that regulation of elemental phosphorus plants is necessary to protect the public health, within the meaning of the Clean Air Act. Therefore, the proposed rule is withdrawn. This decision presents difficult questions and the Agency is undertaking a number of nonregulatory actions, explained below, that may lead to reexamination of this decision at some future date.

EPA estimates the total risk to human populations posed by radionuclide emissions from elemental phosphorus plants to be 0.06 fatal cancer per year, or approximately one case every seventeen years. This risk is similar to other risks that EPA has considered insufficient to warrant Federal regulation in comparable Section 112 proceedings. About 80% of the total risk presented by the industry is accounted for by two plants, the FMC plant in Pocatello, Idaho, and the Monsanto plant in Soda Springs, Idaho.

In the case of one of the plants, EPA estimates the dose rate to individuals at the location of highest air concentrations to be about 600 mrem/y to the lung. The chance of getting cancer from a lifetime of exposure at this location is calculated to be about one in one thousand. If risk to the “most exposed individuals” were the only criterion for judgment, this relatively high risk might well have led to a decision to regulate.

However, this risk must be weighed against both the low aggregate risk described earlier and against other factors. Our studies indicate that present emission controls on these plants are not efficient in removing radionuclides and could be improved. However, adding such additional controls will be expensive measured against the limited public health benefits provided.

Finally, the SAB Subcommittee's report harshly criticized EPA's analysis in support of its proposed standards. That alone would not justify a decision not to regulate, but in the context of the limited aggregate risk and other factors described earlier it contributes to such a decision, particularly given the Science Advisory Board's statutory role as the Agency's science advisor.

Over the next several years, EPA will work with the Science Advisory Board to satisfy its concerns regarding the scientific basis of regulations such as this. Undertaking this effort will also allow the development of answers to the following two questions that may have a bearing on any future EPA action.

1. EPA is curently reconsidering its ambient air quality standard for particulates, and may shift its emphasis toward regulating the smaller-sized particles. Since the two elemental phosphorus plants being considered here emit large amounts of these smallar particles, they may require additional controls based on these new standards. Limiting emissions of these smaller particulates would also control some of the radionuclide emissions from the plants.

2. The area surrounding these two plants is characterized by high total levels of radiation from a variety of sources. The storage and widespread use of slag and possibly other waste products from these plants have significantly increased the natural background radiation levels in parts of the communities. In particular, phosphate slag from these plants has been widely used as aggregate in road and house construction in these areas. EPA and the State of Idaho intend to perform a total assessement of the various sources and will investigate ways to reduce or prevent risks from growing. This assessment may find more effective ways to control the overall risks than by controlling the emissions at issue here.

C. Department of Energy (DOE) Facilities

It is also the Administrator's judgment that the present record does not support a conclusion that regulation of DOE facilities for radio-nuclide emissions to air is necessary to protect the public health with an ample margin of safety, within the meaning of the Clean Air Act. Therefore, the proposed rule is withdrawn and the rulemaking is terminated.

EPA estimates the total risk to exposed human populations by all DOE facilities for which regulation was proposed as 0.08 potential fatal cancer ***43912** per year, or one case every 13 years. This risk is comparable to risks that EPA has considered insufficient to warrant regulation in similar Section 112 proceedings.

Dose rates from the four DOE facilities with the greatest radionuclide emissions range from 50 mrem/y to 88 mrem/y to the lung; one of these facilities delivers a dose rate of 34 mrem/y to the whole body. EPA estimates the chances of fatal cancer from a lifetime of exposure to these plants' most concentrated emissions are about one to eight in ten thousand, somewhat lower than the maximum risks elemental phosphorus plants. Once again, this risk to nearby individuals must be weighed both against the low aggregate risks and the Science Advisory Board report described earlier.

The DOE currently has a program to keep exposure to the public to levels that are as low as reasonably achievable. This program is operated by the Department in keeping with the longstanding recommendations of the National Council on Radiation Protection and Measurements, the International Commission on Radiological Protection, and the Federal Radiation Council to avoid radiation exposure where practical. While the Agency recognizes that DOE facilities maintain very large quantities of radionuclides in their inventories at many of their facilities, there has been a general trend at most facilities for radionuclide emissions to be reduced over the years. Emissions should not significantly increase in the future. EPA intends to continue its oversight of emissions from DOE facilities and should this change, the Agency will reexamine its decision not to regulate.

As previously noted, EPA currently has a Memorandum of Understanding (MOU) with DOE regarding the development and implementation of standards under section 112. EPA intends to coordinate with DOE to seek to modify the Memorandum of Understanding as appropriate.

D. Nuclear Regulatory Commission (NRC)-Licensed Facilities and Non-DOE Federal Facilities

It is also the Administrator's judgment that the present record does not support a conclusion that regulation of NRC-licensed facilities and Federal facilities other than DOE facilities is necessary to protect the public health with an ample margin of safety, within the meaning of section 112. Therefore, the proposed rule is withdrawn and the rulemaking is terminated.

EPA estimates the total risk to human populations posed by NRC-licensed facilities and non-DOE Federal facilities for which regulations were proposed to be no more than 0.02 fatal cancer per year, or less than one case every fifty years. This risk is comparable to other risks that EPA has considered insufficient to warrant regulation in similar Section 112 proceedings.

EPA calculates the changes of developing fatal cancer from a lifetime of exposure to the most concentrated emissions from the NCR facilitiy with the greatest dose rate at no more than two in ten thousands. EPA believes that the Nuclear Regulatory Commission and other Federal facilities will continue to implement programs to keep exposure of the public to levels that are as low as reasonably achievable, and adequate to protect the public against significant adverse effects from radiation. Emissions should not significantly increase in the future. EPA will continue its oversight of emissions from these facilities, and should this change, the Agency will reexamine its decision not to regulate.

As previously noted EPA currently has a Memorandum of Understanding (MOU) with NRC regarding the development and implementation of standards under section 112. EPA intends to coordinate with NRC to seek to modify the Memorandum of Understanding as appropriate.

E. Underground Uranimum Mines

The Agency proposed a standard for underground uranimum mines that would limit the annual average radon-222 concentration in air due to emissions from an underground mine to 0.2 pCi/1 above background in any unrestricted area. The standard was expected to be met by one of the following procedures: (1) Reducing the precentage of time the mine operates, (2) increasing the effective height of the release, and (3) controlling additional land. EPA expected that mine operators would most likely try to control land within about 2 kilometers of the mine vents in order to comply with the standard. EPA did not issue a direct emission standard for radon from underground uranium mines because, as the proposal explained, available information suggested that radon could not be collected by available pollution control equipment before being released from the vents, reductions afforded by better bulkheading or sealants were highly uncertain, and reducing the volume of air flow was not feasible due to the effect

on occupational exposure. Comments on the proposed rule indicated that controlling a sufficient amount of land might not be feasible because private owners of land surrounding the mine might be unwilling to make their land available to the mine owners.

Several comments were received starting that EPA had overestimated the risks from radon-222 emissions from underground uranium mines. It was suggested that the Agency had used overly conservative assumptions in the dispersion and risk calculations and that it used greater risk coefficients than recommended by other recognized radiation experts. EPA has considered these comments in establishing its parameters for emission rates, plume rise, and equilibrium ratios in the revised risk assessment. The most recent estimates of the lifetime risks to individuals living near these mine range from one in one thousand to one in one hundred. The potential exists for even higher risks in some situations, e.g., a person living very close to several horizontal mines vents or in areas influenced by multiple mine emissions. Lifetime risks in these situations could be as high as one in ten. EPA estimates the fatal cancer risk to the total population to be about five fatal cancers per year. The Agency considers these risks to be significant and believes action is needed to protect populations and individuals living near underground uranium mines.

Analysis of the likely reduction in health risks afforded by the proposed standards showed that while risks to nearly individuals were reduced by a factor of about ten, the risks to the total population were only negligibly reduced. The lack of population risk reduction is due to the fact that radon releases would not be reduced by the proposed rule, they would only be more widely dispersed.

EPA has concluded that its proposed standard was legally flawed in two ways. First, because it would not have limited radionuclide emissions on a continuous basis, but was primarily based on the use of dispersion technology to reduce risks to nearby people, it did not qualify an “emission standard” within the meaning of section 112 (See Clean Air Act, section 302(k)). EPA also believes such dispersion techniques cannot qualify in this context as a “design, equipment, work practice or operational standard” within the meaning of section 112(e). EPA believes that for such standards to be valid, they must also have an emission limiting effect. (See Clear Air Act, sections 112(e)(3) and (e)(4).) Second, because this standard would not reduce the aggregate population risk appreciably, when such risk was high, if failed to ***43913** meet the public health protection purposes of the Act.

Because radon-222 is a noble gas and the volume of air discharged through mine vents is very large, there is no practical method to remove radon-222 from the mine exhaust air. Adsorption onto activated charcoal is the most widely used method for removing noble gases from a low volume air stream. However, application of this method to the removal of radon-222 from mine ventilation air at the volumes of air which must be treated would require large, complex, unproven systems which would be extremely costly (i.e., at least $18-44/lb of U3 08 produced).

Since proposal, EPA has received additional technical information in a report prepared for the U.S. Bureau of Mines, indicating that work practices, such as bulkheading abandoned sections of mines to trap the radon before it is vented, may be more feasible and cost-effective than previously thought. This information, which is of a preliminary nature, suggests that bulkheading, even without the use of charcoal filters, could reduce emissions of radon-222 by 10-60% from typical mines at a cost ranging from $4-$60 per curie reduced or about $0.01-0.05/lb of U3 08 produced.

Uranium mines are widely diverse in their characteristics. They differ in configuration; for example, some mines have very few side tunnels and cross cuts whereas others may have many side areas. Consequently, they have a wide variety of surface areas where radon can be generated. In addition, mines differ in the geologic strata, mining techniques, and uranium and radium concentrations. All of these factors tend to decrease the number of common characteristics among mines that can be used to make general predictions of the effectiveness of specific control measures. Therefore, considerable additional work is needed to establish whether these results can be realized consistently for an appreciable segment of the industry, and to determine methods of bulkheading that might potentially produce any such consistently acceptable results. Only after these facts have been established would EPA be able to propose a standard based on these techniques. In any event, no such rule can be promulgated

on the present record because the original proposal considered the use of this form of control and explicitly dismised it as a basis for the standard.

Because the Agency is convinced that the health risks posed by underground uranium mines are significant, EPA has decided to begin developing an emission, design, equipment, work practice, or operational standard to control radon releases from underground uranium mines. An Advance Notice of Proposed Rulemaking announcing this decision is being published simultaneously with this notice.

VIII. Final Determination for Sources EPA Proposed Not To Regulate

EPA previously identified several source categories that emit radionuclides to air but proposed not to regulate them. Final decisions on the need for emission standards for these categories, and the reasons for these decisions, are discussed in the following paragraphs.

A. Coal-Fired Boilers

Large coal-fired boilers are used by utilities and industry to generate electricity and to make process steam and hot water for space heaters and industrial processes. When operating, these boilers emit trace amounts of uranium, radium, thorium, and their decay products found in the feed coal. These radionuclides become incorporated into fly ash and are carried into the air along with the particulate matter these boilers emit. Technology that removes particulates will also limit radionuclide emissions.

Particulate emissions from new utility and new large industrial boilers are controlled by new source performance standards issued under Section 111 of the Clean Air Act reflecting best demonstrated technology. EPA has also proposed new source performance standards for smaller industrial boilers. Existing utility and industrial boilers are regulated for particulate emissions by State implementation plans as required by the Clean Air Act.

EPA proposed not to regulate coal-fired boilers because these existing particulate emission standards also limit radionuclide releases, and result in relatively insignificant risks to nearby individuals and to populations due to radionuclides. The highest dose resulting from this source category is 1 mrem/y to the lung. This is equivalent to an individual lifetime risk of fatal cancer of one in one million. Population risk is estimated to be about two fatal cancers per year, spread over the entire U.S. population. The cost to further reduce radionuclide emissions is greater in comparison to the additional public health protection achieved. In addition, radionuclide emissions will decrease as old plants are replaced with new ones having improved particulate emission controls as required by the Clean Air Act.

Many commenters, mostly industrial groups, strongly supported the determination not to propose regulations for this source category. Several commenters stated that the risks from coal-fired boilers were so low that this fact alone indicated that standards are not needed. The Agency's decision not to regulate is based on both a consideration of the level of risk and on a consideration of total cost and practicality of additional control equipment. Some commenters stated costs should not be considered under section 112 of the Clean Air Act. EPA believes it is not reasonable to avoid considering cost and practicality of control technology; however, the protection of public health was the primary consideration in reaching this decision.

Some commenters raised the question of whether there are some boilers that might burn coal with high uranium content, leading to emission levels far greater than those considered in making this determination. EPA asked for comment on this point and contracted with Los Alamos National Laboratory to investigate the existence of such boilers. The Agency was unable to find boilers with radionuclide emission rates significantly greater than the model facility we studied in detail. In fact, the majority of boilers can be demonstrated to have emissions much lower.

Some commenters stated that the requirements of the Clean Air Act dictate that EPA must propose an emission standard specifically for radionuclides, regardless of other Clean Air Act regulations limiting particulate emissions. EPA believes that to issue a standard that duplicates current regulations is unreasonable. As a practical matter, Clean Air Act regulations limiting

particulate emissions from these boilers also limit radionuclide emissions. Hence, these existing regulations protect the public health with an ample margin of safety as far as radionuclide emissions are concerned.

After carefully considering all comments, EPA has decided not to regulate radionuclide emissions from coal-fired boilers at this time. This decision will be periodically reviewed as additional information on the total impact of all hazardous air pollutants from coal-fired boilers becomes available.

B. Phosphate Industry

The phosphate industry processes phosphate rock to produce fertilizers, detergents, animal feeds, and other products. The production of fertilizer ***43914** uses approximately 80 percent of the phosphate rock mined in the United States. Phosphate deposits contain elevated quantities of natural radioactivity, principally uranium-238 and members of its decay series. Uranium concentrations in phosphate deposits range from ten to one hundred times the concentration of uranium in other natural rocks and soils.

Phosphate Rock Processing Plants

The processing of phosphate rock in dryers, grinders, and fertilizer plants results in the release of radionuclides into the air in the form of dust particles. Control techniques that remove particulates will also control radionuclide emissions.

Particulate emissions from new or modified phosphate rock drying, grinding, and fertilizer plants are controlled by new source performance standards issued under Section 111 of the Clean Air Act. In the case of fertilizer plants, the new source performance standard for fluoride also provides for effective control of particulates. Existing drying, grinding, and fertilizer plants are regulated for particulate emissions by State implementation plans as required by the Clean Air Act. EPA proposed not to regulate phosphate rock processing facilities because the existing particulate and fluoride emission standards also limit radionuclide releases. The risks to nearby individuals and the total population risks due to radionuclide emissions from these three types of facilities are insignificant. The highest doses resulting from emissions from these facilities are 15 mrem/y to the bone and 7 mrem/y to the lung. This is equivalent to a lifetime individual risk of fatal cancer of one in one hundred thousand. Population risk is from all of these facilities about to 0.02 fatal cancer per year. In addition, there is no potential for emissions to increase; rather, they should decrease as older plants are replaced with new ones subject to new source performance standards.

Comments from the phosphate industry strongly supported EPA's proposal not to regulate phosphate rock processing facilities and further stated that EPA had overestimated the radionuclide emissions from these facilities. EPA agrees that its estimates of radionuclide emissions from these facilities were based on some conservative assumptions and has concluded that this serves to reinforce its decision not to regulate these facilities.

Several commenters stated that standards were needed for phosphate rock processing facilities and that cost should not be considered in reaching a decision on the need for these standards. Even without considering costs, EPA does not agree that standards are needed for these facilities for the reasons just stated.

EPA did not previously make any determination regarding radionuclide standards for phosphate rock calciners at wet process fertilizer plants because information on emissions from these facilities was not available. EPA requested comments on these emissions and asked whether standards were needed. In addition, the Agency conducted emission tests at two of these facilities. EPA has not yet completed its analysis of these emission tests or carried out a risk assessment for these calciners. Therefore, no determination of the need for standards for phosphate rock calciners at wet process fertilizer plants is made at this time.

After considering all comments, EPA has decided to affirm and make final its decision not to regulate radionuclide emissions from phosphate rock processing plants, other than phosphate rock calciners at wet process fertilizer plants. A decision regarding the need for standards for this latter source will be made after completion of the Agency's analyses of emissions and risks from these facilities.

Phosphogypsum Piles

Several comments were received requesting EPA to issue standards under the Clean Air Act for radionuclide emissions from phosphogypsum piles (fertilizer plant waste material). EPA did not propose radionuclide standards for this source because it believed that such wastes would be more appropriately regulated under the Resource Conservation and Recovery Act (Pub. L. 94-580).

After considering all comments, EPA is reevaluating the need for radionuclide standards for this source. Preliminary risk estimates indicate that individual lifetime risks from exposure to air emissions from these piles may be as high as eight in ten thousand. Population risks may be on the order of one fatal cancer per year. The Agency will continue its examination of the need for a standard for this source category.

C. Other Extraction Industries

Almost all industrial operations involving removal and processing of soils and rocks to recover mineral resources release some radionuclides into the air. EPA has conducted studies of airborne radioactive emissions from the mining, milling, and smelting of iron, copper, zinc, clay, limestone, fluorspar, and bauxite. These are relatively large industries and are considered to have the greatest potential for air emissions of radionuclides.

EPA proposed not to regulate these extraction industries because the available data showed that the risks to individuals and populations from radionuclide emissions from these facilities are insignificant. Individual lifetime risks range from one in one hundred million to one in ten thousand. Population risks range from 0.000001 to 0.01 fatal cancer per year.

Most of the comments received were from industry representatives who concurred with EPA's proposal not to regulate these facilities. In their opinion, emissions, doses, and risks were so small that a regulation was unnecessary. No new information was provided to the Agency during the public comment period which indicated a need for standards. Additional Agency studies have confirmed that radionuclide emissions from these sources are low.

After considering all comments, EPA has decided to affirm and make final its decision not to regulate radionuclide emissions from extraction industry facilities.

D. Uranium Fuel Cycle Facilities, Uranium Mill Tailings, and Management of High-Level Radioactive Waste

The uranium fuel cycle consists of operations associated with production of commercial electric power by light water reactors using uranium fuel. It includes nuclear power plants and facilities that mill uranium ore, process uranium, and fabricate and reprocess uranium fuel. EPA has promulgated emission standards for normal operations of the uranium fuel cycle under the Atomic Energy Act (40 CFR Part 190). These standards limit the annual dose equivalent from radionuclide emissions to 25 mrem/y to the whole body and to any organ, with the exception of the thyroid, which may receive 75 mrem/y. EPA standards and their implementation by the NRC require the use of available technology which results in low doses to individuals and populations.

Many commenters, both government and industry, supported EPA's decision not to issue emission standards for this source category. Other commenters felt that the Clean Air Act requires EPA to set emission standards for uranium fuel cycle facilities, regardless of any other standards in force.

The Agency believes that current EPA standards for the uranium fuel cycle provide a level of protection which ***43915** satisfies the requirements of the Clean Air Act. An emission standard promulgated under the Clean Air Act would be duplicative with the uranium fuel cycle standard and would not offer any additional public health protection. During the Agency's upcoming review of 40 CFR Part 190, this issue will be reexamined.

Uranium mill tailings remain after uranium is removed from the ore. Many thousands of acres of these tailings exist at both inactive and active uranium mill sites, located mostly in the West. The high concentration of radium-226 in the tailings can result in significant emission or radon-222, a radioactive gas. Under current EPA disposal standards which require long term stabilization of the tailings piles, 95% or more of the random emissions will be controlled. These standards, issued under the authority of the Uranium Mill Tailings Radiation Control Act of 1978 (Pub. L. 95-604), provide a level of public health protection comparable to an air emission standard.

However, commenters noted that randon emissions from the tailings piles at licensed uranium mills are exempted from the requirements of 40 CFR Part 190. They are controlled, instead, by NRC regulations which allow a concentration of 3pCi/1 of radon-222 in unrestricted areas. This value represents a level of risk that may be significant. EPA is publishing, simultaneously with this notice, and Advance Notice of Proposed Rulemaking to consider the need for an emission standard for radon emission from licensed uranium mills.

Highly radioactive liquid or solid wastes from reprocessing spent nuclear fuel, or the spent fuel elements themselves if they are disposed of without reprocessing, are considered high-level radioactive waste. EPA has proposed standards under the Atomic Energy Act to limit public exposure to the radionuclides in this waste prior to disposal and has proposed that operations be conducted to reduce exposures below the standard to the extent reasonably achievable. The Agency expects its standards for the management of high-level radioactive waste to be promulgated in the near future. These standards will control emissions during the operational phase of the disposal site to a level which results in a dose equivalent no greater than 25 mrem/y to the whole body or to any organ, except the thyroid, which may receive a dose as high as 75 mrem/y. These standards will provide a level of public health protection comparable to an emission standard issued under the Clean Air Act.

After consideration of all comments, EPA affirms and makes final its decision not to issue separate standards under the Clean Air Act for radionuclide emissions from the uranium fuel cycle, uranium mill tailings, and management of high-level radioactive waste.

E. Low Energy Accelerators

Accelerators impart energy to charged particles, such as electrons, alpha particles, protons, and neutrons. They are used for a wide variety of applications, including radiography, activation analysis, food sterilization and preservation, and radiation therapy and research. Accelerators, other than those owned by the DOE, operate at comparatively low energy levels and therefore emit very small quantities of radionuclides. The doses and health risks associated with these emissions are extremely low. Lifetime individual risks range from one in ten trillion to one in one billion. Further, there is no potential for the emissions from these facilities to increase significantly.

The Agency proposed not to regulate this category. No comments were received on this proposal, and the Agency is not aware of any new information indicating a need for a standard. Therefore, the Agency affirms and makes final its decision not to regulate radionuclide emissions from low energy accelerators.

IX. Miscellaneous

Docket

The docket is an organized and complete file of all information considered by EPA in this rulemaking. It is a dynamic file, since material is added throughout the rulemaking process. The docket allows interested persons to identify and locate documents so they can effectively participate in the rulemaking process, and it also serves as the record for judicial review.

Transcripts of the hearings, all written statements, the Agency's responses to comments, and other relevant documents have been placed in the docket and are available for inspection and copying during normal working hours.

Dated: October 23, 1984.

William D. Ruckelshaus,

Administrator.

[FR Doc. 84-28438 Filed 10-26-84; 2:12 pm]

BILLING CODE 6560-50-M

Footnotes

1 The Administrator believes, based on an analysis by EPA's Office of General Counsel, that today's actions are consistent with the statute and the court order governing today's decision. EPA acknowledges, however, that an argument exists that the only proper way to procedurally express the substantive conclusions set forth in today's rulemaking is by delisting the particular pollutant involved. Though EPA does not presently accept that position, it stands ready to amend this package promptly along these lines if the Court should so direct.

53 FR 41104-01
NOTICES
ENVIRONMENTAL PROTECTION AGENCY
[OPP-260052; -FRL-3388-3]

Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement

Wednesday, October 19, 1988

***41104** AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This Notice announces a change in the position EPA will take in rulemaking proceedings under section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) concerning certain pesticides intended for use in food production. EPA's position will be that the section 409's so-called Delaney Clause—which, read literally, purports to bar absolutely the issuance of a food additive regulation for a food additive that has been found to induce cancer in test animals—is subject to a de minimis exception where the human dietary risk from residues of the pesticide is at most negligible. This change in position is intended to foster greater consistency in actions EPA will take with respect to the registrations of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and tolerances for pesticide residues on food under sections 408 and 409 of the FFDCA. Elsewhere in this issue of the Federal Register, the Agency is proposing new procedural rules for establishing, modifying, and revoking section 409 food additive regulations, as well as procedural rules governing the filing of objections, requests for hearings, and the holding of hearings under sections 408 and 409. This Notice also discusses how EPA plans to approach the issue of what risks might be considered “negligible.” This Notice provides the Agency's response to the recommendations of the recent National Academy of Sciences report entitled “Regulating Pesticides in Food: The Delaney Paradox”. Public comment is invited on this Notice.

ADDRESS: Comments should bear the document control number “OPP-260052”, and be submitted in triplicate to: Public Docket and Freedom of Information Section, Field Operations Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT:By mail: William L. Jordan, Policy and Special Projects Office, Office of Pesticide Programs (TS-766C), Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. Office location and telephone number: Room 1115, CM 2, 1921 Jefferson Davis Highway, Arlington, VA, (703-557-7102).

SUPPLEMENTARY INFORMATION:

I. Introduction

The Environmental Protection Agency is responsible for regulating the sale and use of pesticide products under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), (7 U.S.C. 136 et seq). FIFRA contains a standard for registration that allows EPA to take both the risks and the benefits of a pesticide's use into account.

The Agency also regulates pesticide residues on food under sections 408 and 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 346a, and 348). Food is “adulterated” and subject to seizure under the FFDCA if it is found to bear pesticide residues that are not permitted by appropriate section 408 and 409 tolerances. Section 408 of the FFDCA, like the FIFRA, gives the Agency authority to balance risks and benefits in reaching regulatory decisions with respect to pesticide residues on raw agricultural commodities section 409 of the FFDCA governs the establishment of food additive regulations (often called 409 tolerances) in processed food and feed. EPA interprets section 409 to also allow EPA to consider benefits to food consumers in reaching its decisions unless the Delaney Clause applies. However, the Delaney Clause of section 409, if

read literally, is a risk-only standard that bars the establishment of any food additive regulation that would authorize residues in or on processed food or feed of any pesticide that has been found to induce cancer when ingested by man or test animals, with certain limited exceptions.

The difference in the standards of these two statutes presents EPA with a major problem in regulating certain pesticide chemicals which have been found to induce cancer in test animals. Such pesticides may be ineligible for food additive regulations under the FFDCA even if they have been found to pose no unreasonable risk to humans and qualify for registration under FIFRA. This problem may arise in three situations: (1) When a food additive regulation is sought for a new pesticide chemical (or a new use of a currently registered chemical) that induces cancer in animals; (2) when new residue data indicate a need for a food additive regulation for a registered pesticide known to induce cancer in animals; or (3) when new toxicity data show that a registered pesticide for which food additive regulations have been established induces cancer in animals.

In the first situation, the issue is whether to allow the pesticide to enter the market or to be marketed initially for a particular food use. EPA's current regulations prohibit FIFRA registration until the issuance of any needed tolerances and food additive regulations associated with the pesticide's use. The second and third situations require EPA to decide whether to make unlawful the marketing of a pesticide for those previously-approved food uses subject to section 409. The number of uses in these latter two categories is increasing as EPA receives more and more toxicity and residue data. Of significant concern are the differences in the standards now applied to old and new pesticides. Under current Agency practice, as described more fully later in this Notice, a new pesticide that poses a relatively low risk of cancer may be barred from registration because of Delaney Clause constraints, while an old pesticide that poses a higher risk and that is used for the same purposes might remain on the market.

To address these issues, in February 1985 the Agency commissioned the Board on Agriculture of the National Research Council/ National Academy of Sciences (“NAS”) to examine the impact of the Delaney Clause on the tolerance-setting process and on EPA decision-making. The NAS committee formed to conduct this study included experts in agricultural pest control, pesticide development, agricultural economics, cancer risk assessment, public health, food science, regulatory decision making, and law.

The detailed report prepared by the NAS, entitled “Regulating Pesticides in Food: The Delaney Paradox,” was issued on May 20, 1987. The report set forth four main recommendations:

1. Pesticide residues in food, whether marketed in raw or processed form or governed by old or new tolerances, should be regulated on the basis of consistent standards. Current law and regulations governing residues in raw and processed foods are inconsistent with this goal.

2. A negligible risk standard for carcinogens in food, applied consistently to all pesticides and to all forms of food, could dramatically reduce total dietary exposure to oncogenic pesticides with modest reduction of benefits.

3. EPA should focus its energies on reducing risk from the most worrisome pesticides on the most-consumed crops.

4. The EPA should develop improved tools and methods to more systematically estimate the overall ***41105** impact of prospective regulatory actions on health, the environment, and food production.

The Agency has evaluated the recommendations of the NAS, and as discussed later in this document, has reached conclusions about what would be an ideal policy, one that would be based on the NAS recommendations. In summary under this ideal policy, the Agency would apply a uniform set of criteria to all FIFRA registration decisions and all FFDCA section 408 tolerance and section 409 food additive regulation decisions. If a pesticide's use would pose no risk or only a negligible risk, the pesticide's use would be approved under both Acts without any particular scrutiny of benefits. This has for some time been EPA's practice with respect to decisions on pesticides that pose only non-cancer risks, and with respect to decisions under FIFRA and under FFDCA section 408 on pesticides that may pose cancer risks. (EPA has assumed that an applicant's willingness to expend the sums required to obtain registration of a pesticide, in the expectation of recovering those sums by sales of the pesticide,

indicates that the pesticide's use will yield benefits that are greater than negligible.) Under the ideal policy, registrations and the associated tolerances and food additive regulations similarly would be granted for pesticides that pose at most a negligible risk of cancer to humans (and meet the other requirements of FIFRA and the FFDCA). For those pesticides deemed to pose a greater-than-negligible risk, a risk/benefit evaluation would determine the appropriateness of FIFRA registration and FFDCA clearances under sections 408 and 409. The greater the degree of risk, the greater the benefits that would have to be shown to justify approval, and the more intensive would be the benefits evaluation required to reach a regulatory decision.

Implementation of this ideal policy, however, is subject to the constraints imposed by the Delaney Clause. In the case of a use of a pesticide that requires a section 409 clearance and that poses a cancer risk that is greater than negligible, the Delaney Clause ordinarily bars approval of the use; the Agency is unaware of any legal theory that would justify a change in its current practice of refusing to issue new food additive regulations in such situations (with certain exceptions discussed in detail later in this Notice). However, for pesticides that pose at most a negligible risk of cancer and whose use requires section 409 clearances, EPA will change its current practice to the extent that, in the future, EPA will propose to issue food additive regulations on the basis of the de minimis doctrine, described in Unit II of this Notice.

The Agency wishes to make it clear that the interpretations and policy changes it is announcing today have no final effect with respect to any individual pesticide. This Notice relates primarily to the regulatory treatment of some pesticides under FFDCA section 409. Any food additive regulation that EPA may issue in reliance on the de minimis doctrine discussed in this Notice will be preceded by issuance of a proposed rule, and also will be referred to the FIFRA Scientific Advisory Panel. Section 409(b) and 409(h) allow “any person” to petition EPA to issue, modify, or revoke a section 409 food additive regulation, and section 409(c) says that EPA must act on such a petition. Under section 409(f), any “adversely affected person” (a term that has been given a very inclusive reading by the courts) may object to an EPA action taken either in response to a section 409(b) petition or at EPA's own initiative under section 409(d). EPA must rule on the objection; if factual matters are at issue, EPA first must hold a formal evidentiary hearing to produce a record upon which the ruling must be based. Although this Notice sets forth positions that the Agency expects to take initially in relevant proceedings arising under FFDCA section 409, EPA decisional officials will be open to all arguments presented in those proceedings and will base their final decisions on the merits of the arguments presented. See McLouth Steel Products Corp. v. Thomas, 838 F. 2d 1317 (D.C. Cir. 1988). Judicial review of rulings on individual objections under FFDCA section 409 is available only in the manner described by section 409(g). EPA will take the position that this Notice is not itself properly the subject of judicial review because it lacks the requisite finality.

A detailed discussion of the policy changes involved is set forth in Unit III. of this Notice.

II. Legal and Regulatory Background

EPA often must apply four different and sometimes conflicting statutory standards in deciding whether a particular pesticide may be used in food production: one under the FIFRA and three under the FFDCA.

A. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

The sale, distribution, and use of pesticides in the United States are governed directly by the FIFRA and are also influenced heavily by the FFDCA. FIFRA requires that all pesticides which are sold or distributed in the United States be registered in accordance with the statutory standard for registration set forth in FIFRA. That standard requires, among other thing, that the pesticide perform its intended function without causing “unreasonable adverse effects on the environment.” (FIFRA section 3(c)(5)). The term “unreasonable adverse effects on the environment” is defined as “any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide,” (FIFRA section 2(bb)). Under FIFRA section 6, EPA may cancel the registration of a use of a pesticide [FN1] (or require modifications in the terms and conditions of registration in lieu of cancellation) if the Agency determines that the risks of use of the pesticide outweigh the benefits of the use.

EPA regulations (40 CFR 162.7(d)(2)(iii)(E)) and 162.167(a)(4), redesignated as 40 CFR 152.112, 152.113, and 152.114, see 53 FR 15952, May 4, 1988) provide that a registration may not be granted if "the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in residues of the pesticide becoming a component of food or feed," unless the necessary sections 408 and 409 clearances have been issued.

This requirement assures that a pesticide use will not be registered for a food crop unless the Agency has determined that the resulting pesticide residues in or on the crop will not exceed a safe level. Moreover, by examining the pesticide use under the statutory scheme as a whole and assuring that the criteria of both FIFRA and FFDCA are met, the Agency avoids the potential for residues that are illegal under the FFDCA appearing in or on foods as a result of pesticide use that is legal under FIFRA. It has been EPA's belief that pesticide users and food processors should be able to safely assume that a pesticide registered under FIFRA has the appropriate clearances under the FFDCA for the food uses listed on the FIFRA label.

B. Sections 408 and 409 of the Federal Food, Drug and Cosmetic Act (FFDCA)

Under FFDCA section 402, a raw agricultural commodity is adulterated if ***41106** it contains a pesticide residue not authorized by a FFDCA section 408 tolerance (maximum permissible level) or an exemption from the requirement of a tolerance. An adulterated commodity sold or distributed in interstate commerce is subject to seizure by the Food and Drug Administration (FDA).[FN2]

To establish a tolerance or exemption regulation under section 408, the Agency must find that the regulation would "protect the public health." (FFDCA section 408(b)). In reaching this determination, the Agency is directed to consider, among "other relevant factors," the necessity for the production of an adequate, wholesome, and economical food supply, and the other ways in which the consumer may be affected by the pesticide. Thus, in the Agency's view, section 408 of the FFDCA expressly gives the Agency the authority to balance risks against benefits in determining appropriate tolerance levels.

Under FFDCA section 402, food is adulterated (and hence subject to seizure) if it contains any food additive (including any pesticide residue) not authorized by a section 409 food additive regulation. An important exception to this provision is that a processed food containing pesticide residues resulting from the "carryover" from treatment at the raw agricultural commodity stage is not regarded as adulterated if the residue level in such a food is no greater than that allowed by the section 408 tolerance established for the raw agricultural commodity.

The establishement of a food additive regulation under section 409 requires a finding under the "general safety clause" in section 409(c)(3) that the use of the pesticide "will be safe." The only direct guidance given by the Act as to the meaning of the term "safe" is that the term "has reference to the health of man or animal," (FFDCA section 201(u)). Factors to be considered in making this "general safety clause" determination are (1) the probable consumption of the pesticide or its metabolites; (2) the cumulative effect of the pesticide in the diet of man or animals, taking into account any related substances in the diet; (3) appropriate safety factors to relate the animal data to the human risk evaluation; and (4) "other relevant factors." FFDCA Section 409(c)(5)).

Appendix A contains a discussion of the procedures followed by the Agency in evaluating safe residue levels for tolerances and food additive regulations.

The general safety clause in section 409(c)(3) has been construed by the Agency to allow the weighing of benefits and risks when issuing food additive regulations. The legislative history indicates that section 409 was intended to permit the use of food additives "which may benefit our people and our economy when the proposed usages of such additives are in amounts accepted * * * as safe," and that "the test which should determine whether or not a particular additive may be used in a specific percentage of relationship of the volume of the product to which it might be added should be that of reasonable certainty in the minds of competent scientists that the additive is not harmful to man or animal." (S. Rep. No. 2422, 85th Cong. 2d Sess., August 18, 1958, at 2-3). In EPA's view, the determination of whether use of a pesticidal food additive is "not harmful" or is "safe" should take into account the net effects of use of the additive on the food supply, including the benefit (or to put it another way the

avoidance of harm) to an adequate, wholesome, and economical supply of food that may result from a pesticide's use as well as any harm to the food supply that may result from the pesticide's use. At least for residues of pesticide chemicals, EPA believes that this kind of benefit should be regarded as one of the "relevant factors" EPA may consider under FFDCA section 409(c)(5), even though it is not listed specifically there as it is in section 408(b). A risk/benefit reading of the general safety clause also was adopted by the one court that has addressed the issue.[FN3] FDA, however, has tended to interpret the section 409 general safety clause as a criterion that focuses solely on the risks to the food supply caused by the food additive, as opposed to the risks avoided, and this view has considerable support in the legislative history of section 409 and in scholarly journals.

C. The Delaney Clause

The one clear exception to the Agency's latitude to balance risks and benefits for food additives under section 409 is the "Delaney Clause" in section 409(c)(3). The Delaney Clause states that a food additive shall not be deemed safe "if it is found to induce cancer when ingested by man or animal or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal." Because FFDCA section 408 contains no counterpart to the Delaney Clause, the Agency has the authority to evaluate the risk posed by the presence of residues of a carcinogenic pesticide in a raw agricultural commodity, and to establish a section 408 tolerance at a level which will protect the public health, taking benefits to the food supply into account. As long as the processed food does not contain residues above the level allowed in the raw agricultural commodity, residues of that carcinogenic pesticide may legally be present in such processed food. However, where residues of the chemical concentrate above the section 408 tolerance level during processing, or result from use of a pesticide during or after processing, a food additive regulation might not be appropriate because of the Delaney Clause bar. The Delaney Clause contains an express exception (the "DES provisio") that allows a carcinogenic ingredient of animal feed to be found "safe" if such ingredient will not adversely affect the animal and if "no residue" of the substance will be found, by an Agency-approved method, in any edible food yielded or derived from the treated animal. FDA has concluded that the provision should be implemented by a "sensitivity-of-method" approach that allows a carcinogenic ingredient to be added to animal feed if "no residues" of that ingredient are detectable by an FDA-approved analytical method that is sensitive enough to detect any level of residue representing a lifetime excess human cancer risk of more than one in a million (44 FR 17070).[FN4] The FDA ***41107** approach incorporates a series of conservative assumptions for calculating the allowable residue levels in individual food items and in the total diet.

EPA has used the sensitivity-of-method approach in two actions establishing food additive regulations, one concerning thiodicarb and its possibly oncogenic metabolite acetamide on the animal feeds cottonseed hulls and soybean hulls (50 FR 27452, July 3, 1985; 50 FR 41341, October 10, 1985), and another concerning cyromazine and its possibly oncogenic metabolite melamine in or on poultry feed (49 FR 18120, April 27, 1984; 50 FR 20370, May 15, 1985).

If the chemcial induced cancer in animal studies in which the route of exposure was other than ingestion, the Delaney Clause by its own terms applies only if the tests in question "are appropriate for the evaluation of the safety of food additives." The Agency thus has discretion to decide whether a test showing cancer induction as a result of, e.g., dermal exposure to a chemical is "appropriate" for Delaney Clause purposes.

Two administratives doctrines, the "constituents policy" and the de minimis approach, also in EPA's view allow the establishment of food additive regulations in appropriate situations. The "consituents policy," developed by FDA, relies on the fact that the prohibitory language of the Delaney Clause pertains to any food additive, that has been shown to induce cancer in animals, but does not bar approval where an unwanted impurity (a "constituent") of the additive, tested by itself, is found to induce cancer. Thus, under the constituents policy, a food additive regulation may be established if the food additive as a whole does not cause cancer, even though the additive contains an undesired, nonfunctional constituent which is itself a carcinogen. In this situation, the impurity is judged under the general safety provisions of the applicable section of the FFDCA, using risk assessment as one of the decision-making tools. The Sixth Circuit Court of Appeals has upheld FDA's use of the constituents policy to interpret the color additives Delaney Clause provision in section 706(b)(5)(B) of the statute. (Scott v. FDA, 728 F. 2d 322 (6th Cir. 1984)). This provision contains a prohibition closely similar to that found in the section 409 Delaney Clause.

EPA has used the constituents policy in a rulemaking establishing a food additive regulation for dicamba in sugarcane molasses. Dicamba itself is not thought to be oncogenic; however, the pesticide formulation contains small amounts of a carcinogenic nitrosamine contaminant. EPA found the potential risk attributable to the presence of this contaminant to be very small, i.e., with an upper limit in the 10-9 range. Accordingly, the agency concluded that the requirements of section 409 were satisfied. (48 FR 11119, March 16, 1983; 48 FR 34024, July 27, 1983; 48 FR 50528, November 2, 1983).

In discussing its use of the "constituents policy" approach for dicamba, EPA noted that it does not regard deliberately added active or inert ingredients, or metabolites thereof, as potential candidates for clearance under the constituents policy. Rather, the Agency said it would only consider applying the rationale to unwanted impurities resulting from the manufacture of the pesticide (intermediates, residual reactants, products of side reactions, and chemical degradates). Furthermore, the Agency said that it would consider using this rationale in issuing a food additive regulation only where the potential risk from the impurity is extremely low, and that in estimating this risk, the Agency would rely on very conservative risk estimation methodology. (48 FR 34024, July 27, 1983).

Finally, the de minimis approach derives from case law holding that an administrative agency ordinarily has the inherent authority to avoid applying the terms of a statute literally when to do so would yield pointless results.[FN5] Two conditions are necessary to allow an agency to invoke the de minimis doctrine. First, the problem that would be addressed by regulation must be trivial in fact, such that no real benefit would result from regulation. Second, the legislative design must allow the Agency not to apply the statute literally in such a case.

In a recent case addressing the Delaney Clause contained in the color additive provisions of the FFDCA enacted in 1960 (Public Citizen v. Young, 831 F.2nd 1108 (D.C. Cir. 1987), cert. denied, 108 S.Ct. 1470), FDA argued that the establishment of a de minimis exception to the Delaney Clause is consistent with the legislative design, and that conservatively-assessed risks of one in a million (10 -6) or less should be regarded as trivial and thus subject to the exception. FDA relied on legislative history indicating that the Delaney Clause should be applied in a reasonable way. But the court rejected FDA's argument that the legislative history of the FFDCA color additive provisions does not preclude the use of the de minimis exception. The court held that "the Delaney Clause of the Color Additive Amendments does not contain an implicit de minimis exception for carcinogenic dyes with trivial risks to humans" because "Congress adopted an 'extraordinarily rigid' position, denying the FDA authority to list a dye once it found it to 'induce cancer in * * * animals'." (831 F.2nd at 1122). In the court's view, the proper mechanism for obtaining relief from the Delaney Clause with respect to color additives whose risk is trivial is to request that Congress make appropriate modifications to the statute. The food additive Delaney Clause in section 409, adopted in 1958, was not at issue in the case. Indeed, the court noted that the context of the section 409 provision was entirely different from that of the color additive Delaney Clause, and that "the operation of the food additive Delaney Clause raises complex issues distinct from those of this appeal" (id. at 1120, 1118 n. 13). The court suggested, moreover, that the legislative history of the section 409 Delaney Clause might lead to a different result (id. at 1120).

The Delaney Clause has long been regarded as allowing the administering agency to exercise scientific judgment and discretion in deciding whether a food additive "induces cancer" in animals.[FN6] EPA has generally assumed that, for purposes of the Delaney Clause, a substance "induces cancer" in animals if, in a well-conducted animal feeding study, a statistically significant increase in the incidence of histologically related tumors (benign, malignant, or combined) ***41108** is observed in treated animals compared to concurrent control animals, unless there is a reason to conclude that the observed increase is unrelated to the ingestion of the test substance. Under this approach, a pesticide may be found to "induce cancer" in animals despite the fact that increased tumor incidence occurs only at high doses, or that only benign tumors occur, and despite negative results in other animal feeding studies. FDA has taken a similar approach in assessing data for the purposes of the Delaney Clause.[FN7]

There is at least "limited evidence" of carcinogenicity (virtually all from animal studies) for 66 or more of the approximately 350 food-use pesticides already approved for use, under the classification scheme set forth in EPA's "Guidelines for Carcinogen Risk Assessment," (51 FR 33992, September 24, 1986), described in Appendix A. EPA expects this number to become somewhat larger as it receives and evaluates more studies on the food-use pesticides.[FN8] A substantial portion of these pesticides require

section 409 food additive regulations for one or more of their uses. Appendix B lists those pesticides which currently have been identified by the Agency as potential carcinogens and indicates which ones have, or have recently been determined to need, section 409 food additive regulations.

D. Current Policy Has Been Constrained by the Delaney Clause

From the foregoing discussion, it is apparent that if EPA determines that a pesticide poses a cancer risk that is greater than negligible and that outweighs the pesticide's benefits, the pesticide's FIFRA registration should be cancelled and its FFDCA sections 408 and 409 clearances should be revoked. There is no conflict between the various standards in such a case, and EPA's current practice reflects this lack of conflict.

Difficulties arise in the two remaining situations. A pesticide may pose only a negligible cancer risk, or it may pose a cancer risk that is greater than negligible but nonetheless is not so great as to outweigh the pesticide's benefits to the food supply. In both of the latter situations, EPA views FIFRA, FFDCA section 408, and FFDCA section 409's general safety clause as allowing the registration or continued registration of the pesticide and the issuance or continuation of needed FFDCA clearances. But the Delaney Clause of FFDCA section 409 arguably bars the issuance of new section 409 clearances for pesticides in either of the latter two situations, and thus concomitantly calls into question the status of such pesticides under FFDCA section 408 and FIFRA. Due to the constraints dictated by the literal approach to the Delaney Clause, the Agency has not been willing to register a carcinogenic pesticide for a new food use which requires a section 409 food additive regulation, even though that pesticide meets the risk/benefit standards in the other statutory provisions. And since there is often no practical way to assure that the raw agricultural commodity at issue will not be processed, the Agency generally does not grant a section 408 tolerance for residues of the pesticide on a raw agricultural commodity in a situation where an associated section 409 food additive regulation is needed but cannot be issued. As noted earlier, EPA's regulations currently provide that before a pesticide may be registered under FIFRA for a food or feed use, there must exist appropriate clearances under FFDCA sections 408 and 409 for the pesticide residues.

However, if the pesticide is to be used on a type of raw agricultural commodity which is not processed or if concentration of the raw-commodity residues does not occur during processing, and if the pesticides is not added during or after processing, no food additive regulation is needed. If the pesticide use passes the risk/benefit test under FIFRA and FFDCA section 408, a registration can be granted. This is true even if the estimated dietary cancer risk to the public is the same as or higher than the risk posed by an analogous pesticide use for which a food additive regulation is required. Thus, very similar risk situations have been treated quite differently because of the inconsistent statutory provisions. This approach has not necessarily resulted in lower health risks for the public. In fact, there is a strong argument that in some cases the constraints of the Delaney Clause paradoxically may have led to greater risks to the public. New pesticides that pose lower cancer risks than pesticides currently on the market have been denied registration while older, more hazardous pesticides remained in use.

The Agency's treatment of established food additive regulations for registered pesticide chemicals shown by new data to induce cancer in test animals has been quite different than the just-described treatment of requests for new food additive regulations. To date, the Agency has not taken action based on the Delaney Clause to revoke established food additive regulations. In many instances, taking such action would require EPA either to revoke the associated 408 tolerances and cancel the FIFRA registration (despite the risk/benefit criteria that would govern such actions), or to abandon its long-standing policy that the lawful application of a pesticide should not result in illegal pesticide residues. Many of these pesticides appear to pose low or negligible risks and to have substantial benefits for the production of food in this country.

The Agency has deferred action in such cases, while studying the dilemma posed by the statutory scheme. Section 409(h), which authorizes EPA to issue regulations establishing procedures for amending or repealing food additive regulations, does not expressly require repeal of food additive regulations when new data indicate that the pesticide induces cancer.[FN9] The Agency arguably has the latitude to assess the safety of established food additive regulations under any standard it chooses to adopt that is not arbitrary and capricious within the meaning of the Administrative Procedure Act; it arguably could adopt a standard based on the general safety clause of section 409(c)(3), or on a non-FFDCA standard, such as the FIFRA risk/

benefit standard. ***41109** Thus, the Agency could conclude that a previously-approved use of a pesticide is "safe" or not "unreasonable," even though the potential risk is greater than "negligible," if the benefits of the use to the food supply outweigh its risks. On the other hand, if the Agency concluded that the presence of residues in the processed food or feed posed a risk that is "unreasonable" within the meaning of FIFRA or not "safe" within the meaning of the general safety clause of FFDCA section 409, considering the balance of risks and benefits, the Agency would be under an obligation to take action to repeal the regulation (or, in appropriate situations, to amend the regulation to allow a lower residue level determined to be "safe" or "reasonable") and to cancel or modify the terms and conditions of the related FIFRA registration as necessary to assure that the use of the pesticide did not cause unreasonable adverse effects on the environment. This approach would allow EPA to reconcile the FIFRA and FFDCA standards.

The contrary argument would rest on the assumption that Congress must have intended any reevaluation of an existing food additive regulation to be based on the section 409(c) criteria for establishing new regulations, and that the Delaney Clause is an integral part of section 409(c). This view of section 409 thus would incorporate section 409(c)—including the Delaney Clause—into section 409(h) of the statute. Under this reading, a food additive regulation would have to be revoked if new information should indicate that the Delaney Clause would have barred issuance of the regulation had that information been available originally.[FN10]

Such an approach might result in the cancellation of pesticide registrations for uses that meet the risk/benefit standard of FIFRA, FFDCA section 408, and FFDCA section 409's general safety clause, but that cannot conform to the risk-only, zero-risk standard of the Delaney Clause. Once the food additive regulation had been repealed, the presence of residues of that pesticide in the processed food in question would be illegal under the FFDCA, and the wisdom of allowing the pesticide to be sold under the FIFRA registration for use in producing that food would be questionable. To be consistent, many related section 408 tolerances also would have to be repealed under this approach, because such tolerances arguably would be inappropriate where residues could concentrate during processing to an unapproved level higher than the tolerance for the raw agricultural commodity. This approach, carried to its logical conclusion, might end many valuable uses of pesticide chemicals and might result in significant adverse consequences to food production, while resulting in little or no risk reduction. It should be noted that a registrant of a pesticide faced with a proposed FIFRA cancellation based entirely or primarily on the fact that the pesticide's residues are not thought to be "safe" within the meaning of FFDCA section 409 might assert that a FIFRA cancellation cannot be based on criteria imported from the FFDCA, and might succeed (see Continental Chemists Corp.v. Ruckelshaus, 461 F. 2d 331 (1972)). If the approach described in this paragraph were successful, however, there again would be no dichotomy in the treatment of old and new pesticides.

The system that has been used by EPA so far has the added undesirable feature of placing new pesticides that are barred from registration because of the strict reading of the Delaney Clause at a disadvantage relative to old products that are shown by new data to pose comparable or higher risks. Given the high costs of data development, there is little incentive to develop a new food use pesticide that shows carcinogenic potential—even if the risk it would pose would be minimal, and even if it could replace an old product that poses a higher risk—if initial registration is likely to be barred by Delaney Clause considerations. Thus, the development of new, lower-risk chemicals to replace old, higher-risk pesticides may have been retarded by the Agency's past implementation of the Delaney Clause.

A reassessment of the data in support of the tolerances for a particular pesticide chemical may present another serious concern. The data review by the Agency may reveal, with respect to a chemical that induces cancer in animal studies, that not all the necessary section 409 tolerances are in place. New residue data or a new review of old data may lead the Agency to determine that residues concentrate during processing and that section 409 food additive regulations have not been promulgated to cover this situation. If the Agency cannot promulgate such regulations because of the Delaney Clause ban, these processed commodities would contain illegal residues and would be subject to seizure by FDA. To prevent the presence of these residues in the processed commodities, the Agency would have to attempt to revoke the corresponding FIFRA registrations and FFDCA section 408 tolerances (unless appropriate use restrictions on the pesticide labeling could be developed to prevent the use of the pesticide on commodities destined for processing). Such action could profoundly limit the use of many beneficial pesticide chemicals.

The Agency is facing the issues discussed here with an ever-increasing number of old pesticide chemicals. (Appendix D discusses certain examples of pesticide chemicals currently or recently under review which give an overview of the practical dimensions of the problem.) EPA's decision on whether to attempt to apply the section 409(c) criteria retrospectively under section 409(h) may depend on whether its approach to negligible-risk situations, set forth in unit III of this document, is upheld.

E. Potential for Legislative Solution

The administrative approaches discussed so far in this document would solve only some of the problems the Agency faces in this area. Moreover, implementing those approaches will be controversial and might involve the Agency in protracted litigation that could cause uncertainty and make it difficult for businesses to make plans about pesticide development and pesticide use. A legislative solution, stating clearly that the Agency has the authority to grant food additive regulations for pesticide residues posing at most a negligible risk, clearly would be desirable. Additional legislative changes would be required to allow the Agency to fully reconcile FFDCA and FIFRA. Such legislation ideally would give the EPA the latitude to establish tolerances and food additive regulations for pesticides under a risk/benefit standard compatible with FIFRA, with a definitive statement that clearances for both raw and processed foods are to be established under a risk/benefit approach.

Hearings have been held recently in the House of Representatives on two bills that would address these issues. H.R. 4739, introduced by Congressman Waxman, would provide for the regulation of pesticide residues exclusively under comprehensively rewritten FFDCA section 408; H.R. 4937, introduced by Congressmen Brown and Roberts, would also provide for regulating pesticide residues under section 408, but would make only minor changes in the substance of that section.

*41110 III. Response to First and Second NAS Recommendations

A. Introduction

The Agency agrees completely with the NAS Report's most important conclusion—that a consistent approach ideally should be followed in the regulation of pesticides for food uses, regardless of whether the pesticides are new or old or whether the foods are raw or processed. As the NAS Report points out, there is no scientific reason to regulate pesticide residues in raw commodities differently from those in processed commodities. For risk assessment purposes, what is critical is not the type of food or feed commodity on which residues are present, but rather the identity and magnitude of the residues in the food and the associated consumption pattern. Likewise, EPA agrees with NAS that pesticides should be regulated consistently whether they are newly developed or have been on the market for many years.

Use of regulatory criteria that reflected those two NAS recommendations would allow the Agency to regulate high-risk pesticides more stringently than those that pose low risks, and permit the registration of new pesticides that offer substantial benefits and pose relatively insignificant risks. Riskier pesticides could then be replaced, and the total dietary risk reduced, with only minor adverse impacts on food production. This approach would be eminently sensible and desirable.

B. Policy for Achieving Greater Consistency in Evaluating Pesticides Under FIFRA and the FFDCA

The Agency believes that the most desirable way to achieve consistency in regulating potentially carcinogenic food-use pesticides would be to evaluate them under the same risk/benefit standard for both registration and tolerance purposes. However, if a section 409 regulation is required for a chemical to which the Delaney Clause applies, EPA believes that current law allows this approach to be used only to the extent that the de minimis doctrine allows Delaney Clause considerations to be dismissed. The following Table I outlines the regulatory outcomes that EPA would propose in response to various types of findings with respect to the cancer risk posed by new chemicals (or new uses of old chemicals). For clarity, Table I ignores non-cancer risks, and also ignores non-dietary cancer risks; in practice EPA would of course consider all risks.[FN11]]

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***41112** The following sections discuss how the new approach will affect pesticides in various regulatory categories.

1. Pesticides That Have no Carcinogenic Effect or That Pose Only a Negligible Risk of Carcinogenicity

For pesticides that are the subjects of applications for intitial registration or for registration for new uses, and that either do not induce cancer in test animals or pose only a negligible human cancer risk (generally a quantitative risk of 10 -6 or less), EPA will propose to establish section 408 tolerances and section 409 food additive regulations, where necessary, and thereafter to approve the applications for registration. Very little scrutiny will be given to the benefits of such non-carcinogenic or negligible-risk pesticides. As it has in the past, the Agency will assume the presence of benefits that outweigh the negligible risk. A list of pesticides that are potential candidates for consideration under the negligible-risk approach is provided in Appendix E.

2. Pesticides That Pose a Caracinogenic Risk That Is Greater Than Negligible

Some pesticides may pose a risk of carcinogenicity that is greater than negligible. Generally, such pesticides will be those with quantified upper-bound risks greater than 10-6 . (Some pesticides with quantified upper-bound risks greater than 10-6 may, however, fall into the negligible risk category for qualitative reasons, as discussed in Unit III.B.3.) For pesticide uses not requiring FFDCA section 409 clearances, EPA will continue its current practice of granting FIFRA registrations and the associated FFDCA section 408 tolerances for pesticides whose carcinogenic risk is greater than negligible only if the benefits are determined to outweigh the risks based on a careful scrutiny of the projected benefits compared to other available means of pest control. Benefits evaluations will be performed for such pesticides; the higher the risk, the more thorough the benefits evaluation that will be necessary. The risks of the available alternative pesticides will also be taken into account to determine if the total risk picture could be reduced by allowing the pesticide on the market. This approach accords with past practice.

But for the Delaney Clause, the Agency would propose to apply the same approach to pesticides in this category that require section 409 regulations. However, the Agency is not aware of any legal theory that would allow use of this approach under section 409 as it is currently written.

3. Treatment of Group C Chemicals

As explained in the EPA Guidelines for Carcinogen Risk Assessment, (51 FR 33992, September 24, 1986), there is great variability from one chemical to another in the amount and persuasiveness of evidence tending to show whether or not a chemical may cause cancer in humans. The EPA Guidelines represent the Agency's scheme for categorizing chemicals in terms of the weight of the evidence relating to their potential for human carcinogenicity. In general, the approach of the Guidelines is (1) to place a chemical in one of the groups (A through E) on the basis of the strength of the qualitative evidence of carcinogenicity from human epidemiology studies and animal tests and (2) for those chemicals showing some evidence of carcinogenicity, to set forth separately a quantitative upper bound on the risk that would be posed to humans if the substance in fact were a human carcinogen (see Appendix A). This information is useful to Agency officials and the public, since it provides a way to compare the risks of chemicals and to determine how consistently chemicals are regulated under the several statutory programs administered by the Agency.

The chemicals that pose the greatest difficulty in determining the proper regulatory response generally are those that fall into Group C (“possible human carcinogens”) under the Guidelines. A chemical is placed in Group C if there is some evidence of potential carcinogenicity from animal studies, but that evidence is so limited that the chemical cannot be assigned to a higher category.

The Guidelines state that is some cases the Agency will not calculate a quantitative risk ceiling for a Group C chemical. Although it is always possible to calculate a quantitative risk number, the Agency believes that in some cases such quantitative estimates may suggest that the chemical definitely poses a risk to humans, even though in fact the Agency is quite unsure whether the chemical poses human risk. Appendix F lists a number of Group C pesticides and states whether quantitation of risk was deemed appropriate for each.

The Delaney Clause, of course, makes no provision for the weighing of animal-test evidence in terms of its pertience to human risk. If a chemical is found to induce cancer when ingested by animals or in other appropriate tests, the chemical is deemed "unsafe" under section 409 (unless the de minimis doctrine or one of the other previously-discussed exceptions applies). This absolute criterion presents special difficulties with respect to Group C pesticides.

The Agency's treatment for Delaney Clause purposes of a pesticide that falls in Group C will very. For example, many chemicals fall into Group C merely because the evidence of carcinogenicity comes from only one study. When the evidence from that study clearly indicates a carcinogenic effect in the animal tested, the Agency ordinarily treats the chemical as falling within the "high" end of the C category range and quantifies the risk. A tolerance decision for such a chemical will be based on the quantitative risk number, and the Delaney Clause will be deemed to apply unless the quantitative upper bound risk level is so low that the chemical's risk may be ignored under the de minimis doctrine. Conversely, a pesticide may be classified in Group C because the data on whether the chemical is an animal carcinogen are limited or uncertain, e.g., if the data are equivocal, unreliable, or subject to significant doubt, or if only benign tumors occurred. If the Agency determines that the weight of the evidence does not support treating the chemical as an animal carcinogen, the Agency will not treat the chemical as falling within the Delaney Clause bar. The Agency will, of course, in any such determination, set forth the reasons for its judgment. For example, a pesticide may be classified as belonging in Group C because the pesticide is associated with an increase in tumors in only one sex of one species with a lack of a clear dose/reponse relationship. Assuming that mutagenic data are negative and that structure/activity analysis shows no association with known carcinogens, the Agency generally would consider such a pesticide to be at the "low" end of the Group C range. It is doubtful that the Agency would require a quantification of the carcinogenic risk, and in such a case, the Delaney Clause would not be deemed applicable.

A pesticide may also fall into Group C, not because of any doubt about whether the chemical induces cancer in certain animal tests, but because of uncertainties as to the relevance of the finding to human risk. Reasons for questioning the relevance of the animal data to human risk could include, among other things, know variations in response between the test species and humans, or mechanistic considerations, e.g., a showing that cancer was induced in animals only as a secondly effect of an organic change in the animals induced by very high doses of the chemical and a showing that this effect would not occur at the low levels of human exposure. If a convincing ***41113** explanation exists for why the chemical poses no risk of cancer for humans, despite the fact that it has been shown to be an animal carcinogen in a feeding study or other appropriate study and has a theoretical upper bound risk greater than 10-6 calculated using a no-threshold model, EPA would propose to treat the chemical as falling into the negligible risk or de minimis category for Delaney Clause purposes because of the qualitative reasons for discounting the animal test results as a predictor of human risk. Given the limited knowledge about interspecies response differences and mechanisms of action for cancer, EPA anticipates that very few pesticides would qualify for de minimis treatment on this qualitative basis in the near future.

A Group C carcinogen would be regarded as subject to the Delaney Clause if it did not fall into the quantitative or qualitative de minimis exception described in this Notice.

The following Table II summarizes the Agency's proposed treatment of Group C carcinogens:

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***41115** If the Agency determines that the Delaney Clause does not apply to a pesticide despite limited evidence of the pesticide's oncogenicity, the Agency will examine all toxicological effects of possible concern in determining the limit of acceptable dietary exposure. The Agency will then determine the no-observed-effect level (NOEL) for the most sensitive effect, which in turn will be used in setting the allowable daily intake (ADI) used in calculating the maximum permissible level of residues. (See Appendix A of this document.)

4. Currently Registered Pesticides

EPA's position with respect to currently registered pesticides that pose at most a negligible dietary risk of cancer will parallel that described earlier for proposed new food uses of pesticides, and the regulatory status of registered pesticides that pose such risks will not be changed as a result of this Notice. At the other end of the spectrum, EPA is not changing its policy of attempting to cancel FIFRA registrations and revoke FFDCA clearances for pesticides that pose risks of cancer (or other adverse effects) that outweigh their benefits. Finally, EPA has not determined how to proceed with respect to a pesticide that poses an upper-bound cancer risk that is greater than negligible but that is outweighed by the benefits of the pesticide.

5. Section 18 Exemptions

Section 18 of FIFRA allows EPA to exempt State and Federal agencies from the provisions of the Act if the Agency finds that emergency conditions exist that warrant the exemption. The changes in the Agency's approach to the issuance of food additive regulations already described in this document would result in conforming changes in the implementation of the emergency exemption program. The Agency will apply the negligible risk standard in evaluating emergency exemption requests in a manner similar to other regulatory decisions concerning pesticides which are carcinogens. If associated dietary risks are greater than negligible, the Agency would consider granting the exemption only if the benefits are so great that they outweigh the risks. In this connection, EPA considers, among other things, whether use of the unregistered pesticide would present a lower dietary risk than currently registered alternatives.

Generally, an emergency exemption will not be granted if adequate progress is not being made toward full registration of the pesticide use. In the recent past, the Agency has treated the need for a section 409 tolerance as an automatic bar to a request for an exemption to allow emergency use of a substance that has been found to induce cancer in appropriate animal studies, on the assumption that no section 409 clearance could be issued and accordingly there would be no possibility of registration. In the future, however, the Agency will not consider the need for a 409 tolerance, per se, as blocking progress toward registration of such a pesticide. Rather it would consider whether it is likely the pesticide may subsequently be registered according to the policies outlined in this document.

6. Minor Uses

FIFRA directs the Agency to make the registration process more flexible for minor use pesticides. Use of the approaches set forth in this Notice should favor minor uses because they ordinarily involve lower exposures than uses of chemicals on major crops such as wheat or corn.

As with section 18 requests, the need for a section 409 tolerance will no longer be treated as an absolute bar to further consideration of a potentially carcinogenic minor use pesticide. In fact, a number of the pesticides listed in Table V of this document as eligible for reconsideration under the negligible risk standard are intended for minor uses.

IV. Response to the Third Recommendation of the NAS

The NAS has recommended that EPA focus on one major crop at a time and evaluate the risks posed by all the major pesticides registered for that crop rather than evaluating individual pesticides according to current procedures. The Agency's historical

approach to reregistration has been to divide pesticides into “clusters” according to their predominant uses. A cluster is a group of chemicals and a group of sites that are closely correlated.

This approach was described in a Federal Register notice (45 FR 75488, November 14, 1980). The clusters were then ranked so that higher priority for review was given to those clusters that have significant use on food crops or were already known to pose special problems. Each individual pesticide chemical within the cluster is then evaluated, one at a time, for all of its uses. Thus, most of the major pesticides used on the 15 “high-consumption” crops identified by the NAS Report have had a recent comprehensive review or are scheduled for one in the near future. Appendix D of this document provides a status report on the Agency's review of 10 chemicals which have been identified as posing certain theoretical risks.

The NAS committee's recommended modification of EPA's approach is designed to ensure that final Agency decisions actually reduce dietary risk, help to preserve benefits of pesticide uses that pose low risks, and help to conserve limited Agency resources. The Agency agrees that this approach has merit in certain cases where the apparent risks are high and sufficient information is available to make comparative risk/benefit assessments. It also allows greater certainty that the final result will improve public health by comparing the risks and the benefits of the major alternatives at the same time.

Given the progress already made in the reregistration process, it is likey that the Agency will have the needed data on the major pesticides at approximately the same time so that comparative assessments can be done, at least for some crop/chemical combinations. During 1988, in fact, the Agency will be able to complete risk assessments for all but one of the six major fungicides (the exception is folpet, whose food use is relatively minor) and to compare the risks and benefits for these chemicals as recommended by the NAS.

There are, however, some problems associated with this approach. Timeliness will certainly be sacrificed in many cases. There will be more data to evaluate, and decisions will be more complex. Comparison of benefits may be difficult: available efficacy data are not designed to permit sophisticated benefits comparisons, and knowledge of all practical alternatives to a given pesticide may be limited and hard for the Agency to identify. For example, a pesticide might be effective for certain uses and yet might never have been registered for those uses because of a registrant's marketing strategy. Finally, it would not be advisable or protective of the public health to delay consideration of significant risks associated with a pesticide just because other pesticides used on the same crops cannot be evaluated at the same time due to the lack of key data. Consequently, the Agency expects to continue with its basic reregistration scheme for scheduling initial Registration Standards. However, adjustments will be made to allow consideration of alternatives whenever sufficient information is available and it appears to improve our ability to focus on high risk chemical/crop combinations.

Because of the Agency's basic priority scheme for Registration Standards, complete data bases for pesticides used on similar crops should be available at ***41116** roughly the same time, as in the case with the fungicides discussed in Appendix D. The sophistication of the comparative analyses may vary significantly, however, depending on the level of risk associated with the pesticide under review. In the case of cyanazine, for example, the final decision document discusses the known effects and the regulatory status of major alternatives briefly, but does not provide an extensive analysis because the Agency had concluded that the continued use of cyanazine did not pose unreasonable risks. It is likely, nevertheless, that the Agency will find it increasingly possible to make critical comparisons of pesticides which may substitute for each other.

V. Response to the Fourth Recommendation of the NAS

EPA is taking steps to implement the NAS recommendation to develop improved tools and methods to estimate more systematically the overall impact of prospective regulatory actions on health, the environment, and food production. A major new analytical tool that allows the Agency greater sophistication in the assessment of dietary risk is the computerized Tolerance Assessment System (TAS). TAS contains information on toxicology and residue date for particular pesticides, as well as food consumption information. Consumption information for various foods is based on a 1977-1978 nationwide survey of food consumption for different subgroups conducted by the U.S. Department of Agriculture (USDA). The TAS can be used to estimate dietary levels of pesticide residues for the average individual, as well as for 22 population subgroups, including various

age and ethnic groups, infants, pregnant women, and nursing mothers. The system can also be used to differentiate overall consumption patterns by season and by region.

One option offered by the TAS is the calculation of separate TMRCs (Theoretical Maximum Residue Contribution, see Appendix A) for each of the 22 subgroups, based on the assumption that residues will be present at tolerance level and that 100 percent of the crop is treated. Alternatively, the TAS may be used to calculate an "Anticipated Residue Contribution" (ARC) where verifiable data are available on the actual distribution of residues on treated crops, the dissipation or concentration of residues during the storage, transport, and processing of food commodities, and/or the percentage of the total crop actually treated with a pesticide.

Since 1986, the TAS has been used to determine if there are particular dietary concerns for pesticides undergoing reevaluation in the Registration Standard Process, for new chemicals and new uses of old chemicals, and for any other pesticide for which the Agency has a special dietary concern.

To solicit guidance on the scientific criteria that EPA should consider in developing its policy regarding the use of the TAS, the Agency presented a paper entitled "Briefing Paper on the Tolerance Assessment System (TAS) for Presentation to the FIFRA Science Advisory Panel" to that Panel in March 1987 to address a number of specific issues. A copy of that paper and the Report of SAP Recommendations is available on request from the Office of Pesticide Programs. In particular, the Agency requested advice on the scientific criteria the Agency should consider for the use of population subgroups in a dietary exposure analysis, and for the use of percentiles of exposure within a particular population in estimations of dietary risk. The Agency also asked the Panel to address the appropriate margins of safety which the Agency should use for determining acceptable exposures for subgroups or percentiles of exposure within a subgroup. Finally, the Agency requested guidance on the scientific criteria that should be used in identifying appropriate residue levels for use in dietary exposure estimations, and on data presentation.

In response, the SAP noted that the TAS will enable the Agency to predict exposure levels for population subgroups with far greater precision than the current system and thus represents an improved approach. On the issue of the appropriate use of population subgroups, the Panel, noting that the focus of the TAS is on exposure rather than on toxicity, commented that calculations based on body weight, will tend to overstate the risk to infants where there is no toxicological basis for increased susceptibility. To correct for this factor, the Panel recommended that the Agency explore the use of body surface rather than body weight as a basis for comparison. On the safety factor issue, the Panel did not recommend any changes to the traditionally-used one-hundred fold safety factor. The Panel also suggested that the use of a controlled field study would be more likely to provide useful data for the TAS than monitoring data. Finally, the Panel recommended that data should be presented in such a way as to indicate the reliance of the approach on exposure, rather than on toxicity, and the Agency should indicate how relevance, biological significance, and other issues could be introduced into the process. The Agency will work to refine the TAS, as recommended by the Panel, and will seek to develop additional tools and methods to improve its risk/benefit assessment capabilities.

VI. Related Agency Activities

The Agency is working on a number of other initiatives and program improvements which are related to the issues discussed here.

A. FFDCA Section 408/409 Procedural Rules

The Agency has made considerable progress in developing consistent procedural rules pertaining to section 408 and 409 tolerances. Elsewhere in this issue of the Federal Register, the Agency is proposing new procedural rules for establishing, modifying, and revoking section 409 food additive regulations, as well as procedural rules governing the filing of objections, requests for hearings, and the holding of hearings under sections 408 and 409. These proposed rules not only will modernize out-of-date hearing rules, but also will restate and update practices that have not necessarily been codified. The next step in the regulatory process will be to expand the regulations to include (1) substantive interpretations and criteria for determining

when tolerances and food additive regulations are required and what data are required in support of them and (2) the criteria and assumptions to be used by EPA in determining whether a tolerance or food additive regulation should be established, modified or revoked.

B. Encouraging Safer Pesticides

The Agency plans to take steps to encourage the development of safer pesticides. The Agency expects to publish a Federal Register notice detailing this plan in the near future.

C. Promoting Innovation in Pest Control

Despite gaps in current data bases, there are indications that human health and/or environmental risks exist for many currently registered nematicides and fungicides. In the case of nonfumigant nematicides, product efficacy depends largely on solubility. Solubility, however, increases soil mobility, giving rise to concern regarding ground and surface water contamination. Certain of the fumigant nematicides also are currently under Agency scrutiny because of potential chronic risks which may be incurred by workers. Of the registered fungicides, 12 ***41117** are currently undergoing Special Review, and additional classes of fungicides may be placed in Special Review in the near future.

The Agency is working with the Agricultural Research Service and the Cooperative State Research Service to focus USDA research efforts on development of alternative controls for nematodes and plant disease. The Agency has identified a particular need for alternative controls for nematodes on citrus and potatoes and for plant diseases on tomatoes, grapes, leafy vegetables, and pome fruits. The Agency is also considering what incentives can be introduced into the registration process to encourage development of alternative controls. These may include waivers of tolerance fees and registration fees for new pesticides that fall into specified categories for which alternative controls are desirable.

The agency has also joined with USDA, FDA, and private industry to establish a National Pest Management Task Force. The Task Force will identify those pests of economic significance for which effective chemical controls are no longer available or for which little or no research or registration effort is underway. The Task Force will develop, in conjunction with member agencies and private associations, mechanisms fostering the development of acceptable control technologies.

D. Revision of Product Performance Guidelines

To improve the efficacy data base, the Agency is in the process of revising its Product Performance Guidelines to require the development of “comparative product performance data.” In the past, product performance data requirements have concentrated on efficacy data that demonstrate how well a pesticide controls the pests listed on the label. The proposed revisions will require that registrants develop and maintain data which will provide information on performance of a pesticide compared to alternative pesticides, non-chemical techniques, and untreated controls.

E. Updating Food Consumption Data and Other TAS Improvements

Resources permitting, EPA hopes to update the food consumption data as part of our overall effort to implement TAS fully. Results of the latest USDA dietary survey should start coming in later this year, and the Agency plans to begin updating the TAS data in 1989. Subsequently, EPA hopes to update TAS every 10 years as results of a new USDA survey become available. The Agency also hopes to be able to enhance the analytical capabilities of TAS and to develop statistical guidelines and computer support for the incorporation of more accurate anticipated residue data based on actual residue studies.

F. Updating Animal Feed Data

Like human food consumption estimates, animal food consumption estimates also need updating. The Agency is currently working on a project to determine whether by-products from food processing plants are significant components of animal feeds. Once these significant feed items are identified, percent of diet figures for these new feed items will be determined.

G. Guidelines and Protocol Improvements

To provide for improved data for use in risk assessments, the Agency is developing guidelines and standard evaluation procedures for the use of registrants and food producers in the generation and submission of data to show actual pesticide residues in food. The Agency will also be working with the food industry to develop protocols for processing studies designed to show what happens to pesticide residues during processing.

H. Reclassification of Raw Versus Processed Commodities

The Agency intends to develop new criteria for classification of commodities as raw or processed in order to update and eliminate inconsistent 408/409 commodity classifications.

I. Factoring in Drinking Water Exposure to Pesticides

The Agency is concerned about human intake of pesticides via routes other than food, particularly drinking water. Historically, the Agency has based its decisions on tolerances only on dietary exposure from foods treated with pesticides. More recently the Office of Pesticides Programs (OPP) and the Office of Drinking Water (ODW) have begun focusing on drinking water as a potential source of pesticide residues in the diet. The Agency has recently made significant progress in its efforts to integrate activities or OPP and ODW with respect to pesticides in groundwater. All Health Advisories for pesticides in drinking water are now developed jointly by ODW and OPP, using the same data base and the same reference dose.

As a part of EPA's implementation of its Agricultural Chemicals in Groundwater Strategy, the Agency will be considering the extent to which pesticide residues in drinking water are a significant factor in dietary exposure to pesticide residues. This may be difficult in some cases, but is necessary in order to get a more complete picture of exposure. In cases where pesticides do reach drinking water supplies, it is necessary to factor this exposure into tolerance decisions.

For example, exposure to aldicarb through drinking water as a result of its presence in groundwater is being considered in the tolerance assessment in the special review of aldicarb. This is a case in which the data are available, and it is clear that drinking water is a potential route of exposure.

VII. Conclusion

In conclusion, the Agency believes that he recommendations of the NAS offer the Agency very useful guidance in improving and refining the process of evaluating pesticides for registration and tolerance purposes. Consistency between the criteria EPA uses in registering pesticides under FIFRA and in setting tolerances for pesticide residues on food under sections 408 and 409 of the FFDCA is a clearly desirable goal. A negligible risk approach to the pesticide regulatory process would allow the Agency to move in the direction of greater consistency, and allow the registration of new pesticides that pose lower risks than certain currently registered products.

The Agency also believes it would be desirable to have the authority to review all food additive regulations, as well as tolerances and registration actions, under a risk/benefit standard. Only by using a risk/benefit standard for all pesticide decisions will the Agency be able to achieve real consistency, and have the latitude to properly exercise its judgment based on a consideration of all relevant factors. Such an approach, over the long run, will be most likely to reduce the total risk attributable to pesticide use. As discussed in this document, the Agency cannot fully implement this goal without legislative change.

Nevertheless, the Agency will propose to follow the negligible-risk approach to the extent possible in future rulemakings on individual pesticides.

With regard to the other recommendations of the NAS, the Agency is focusing its energies on reviewing chemicals under a prioritization scheme in order to reduce risks attributable to pesticide use. Finally, the Agency is engaged in developing tools such as the Tolerance Assessment System to refine its ability to make regulatory decisions.

***41118** Dated: October 11, 1988.

Victor J. Kimm,

Acting Assistant Administrator, Office of Pesticides and Toxic Substances.

Appendix A—Procedures Followed by the Agency in Determining Allowable Residue Levels for Tolerances and Food Additive Regulations

In setting tolerances, EPA reviews residue chemistry data and toxicology data. The required data are essentially the same as those necessary to support the registration of a pesticide product used on food. To be acceptable, a tolerance level must be both high enough to cover residues likely to be left when the pesticide is used in accordance with its labeling, and low enough to be safe.

The Agency estimates the level of daily exposure which is not expected to cause appreciable risks during the human lifetime. With regard to risks other than cancer, this level is called the Accpetable Daily Intake (ADI) or Reference Dose (RfD). The ADI is calculated by dividing the no-observed effect level (NOEL) (the dosage level at which any adverse effects observed at higher dose levels are absent) from the most senstivie test showing adverse effects by an appropriate safety factor. This calculation is based on the concept that the risks of concern other than cancer are threshold effects—i.e., below the ADI there will be no adverse effect.

EPA also calculates the theoretical maximum residue contribution (TMRC), which represents the maximum amount of residue of a pesticide which a typical human could ingest by consuming food that bears the maximum level of the residue allowable under all existing and proposed tolerances. The TMRC is calculated by multiplying the tolerance level for each food by the amount of that in the typical American diet (according to available statistics on food consumption patterns) and totalling the values for all foods which may bear residues of that pesticide.

The TMRC is then compared with the ADI, and the tolerance is established (assuming no other concerns) if the TMRC is less than the ADI. A tolerance may be established in certain situations where the TMRC is higher than the ADI if residue data establish that the actual human exposure is not likely to exceed the ADI. For pesticides which may induce cancer, in addition to performing the ADI calculations discussed above for the effects of concern other than cancer, the Agency usually performs a quantitative risk assessment for the cancer risk. Cancer ordinarily is treated as a non threshold effect, because of a lack of evidence to refute the assumption that the carcinogenic response in humans to low doses is approximately proportional to the response in animals to high dose. Thus, some risk presumptively could result even at very low levels of exposure.

EPA's current carcinogencity testing scheme requires the use of several test doses (up to a level at or near the maximum tolerated dose) in at least two animal species, in order to magnify the likelihood of detection of a carcinogenic response in an economical, practically-sized animal test population (50 animals per sex per dose level) animal test population. At the present time, there is not better way to assess practically the potential carcinogenicity of a pesticide to which the entire U.S. population may be exposed. The animal data, and any available human epidemiology data, are assessed in accordance with EPA's “Cancer Assessment Guildelines, designed for use by all Agency programs in implementing a number of statutes designed to protect the public health, provide a qualititative classification scheme regarding human carcinogenicity based on a weight-of-the-eveidence analysis of the available data. Chemicals are classified into five groups, as follows:

1. Group A
Human Carcinogen: (Sufficient evidence of cancer causality from human epidemiologic studies).

2. Group B
Probable Human Carcinogen B1 limited evidence of carcinogenicity from human epidemiologic studies B2 sufficient evidence of carcinogenicity from animal studies.

3. Group C
Possible Human Carcinogen: Limited evidence of carcinogenicity in animals in the absence of human data, including malignant tumor response in a single well-conducted experiment not meeting conditions for sufficient evidence, tumor responses of marginal statistical significance in studies having inadequate design or reporting, benign tumors where short-term mutagenicity tests are negative, and responses of marginal statistical significance in a tissue with high background rate.

4. Group D
Not classifiable as to Human Carcinogenicity: Either inadequate evidence of carcinogenicity or absence of data.

5. Group E
Evidence of Non-Carcinogenicity for Humans: No evidence of carcinogenicity in at least two adequate animal tests in different species or in both adequate epidemiologic and animal studies.

A weight-of-the-evidence determination may involve consideration of, among other things, (1) the particular bioassay test system(s) used, (2) the evaluation of the histopathological and other results of the test(s), (3) the weight to be given to benign tumors, (4) mechanistic considerations, e.g., a situation where the chemical itself does not cause the tumor, but rather the effect the chemical causes at high doses of administration is the tumor-causing agent, and this effect would not occur at the lower doses of human exposure, and (5) the extent to which the overall quality and conduct of the tests accords with good laboratory practices.

Quantitative risk assessments are routinely performed for Category A and B carcinogens. In the case of pesticides classified as Category C, the Agency decides on a case-by-case basis whether the qualitative evidence is sufficient to warrrant a quantitative risk assessment, bearing in mind the possibility that publishing a risk number may create in the public mind an assumption of the reality of a risk to humans that is not supported by the qualitative data from animal studies.

To estimate the cancer risk posed by a pesticide from animal data, the Agency typically uses the linearized multistage model to extrapolate from the results seen at the high doses of the animal study to predict worst case risks at the much lower levels of estimated or actual human exposure. Using this model, a potency factor (Q1 *, called the “Q-star”) is calculated from the 95 percent confidence limit of the slope of the linearized portion of the dose response curve. This potency factor represents a plausible, statistically-derived upper limit to the carcinogenic potency of the potential carcinogen at doses relevant to human exposure, and when multiplied by human exposure, yields an upper bound estimate of the risk. Such an estimate does not represent the actual risk, which may, in fact, be considerably lower or even as low as zero. Estimates of the upper limit on lifetime dietary risk from consumption of residues of a carcinogenic pesticide are calculated by multiplying the Q1 * by the average human dietary exposure, using food factors derived from USDA data on food consumption patterns. Unless data are available on the actual level of ***41119** residues in particular food commodities, a worst-case risk will be calculated based on the assumption that all treated food bears residues at the tolerance level and that 100 percent of the crops are treated.

EPA's current method of deriving these worst-case risk estimates for a carcinogenic chemical from animal data is based on somewhat more conservative premises than the approach of FDA. FDA assumes that humans and animals are equally sensitive

to the test chemical on an equivalent body weight basis. EPA, on the other hand, bases its assessment on the premise that different sized animals are not equally sensitive to equal concentrations of a chemical, and makes a surface area adjustment to account for this difference.[FN1] The effect of this adjustment is to increase the estimate of human risk by about thirteen fold where data are derived from mice, and about 6[FN12] fold when the data source is the rat as the test animal. Accordingly, EPA's risk numbers represent about an order of magnitude of risk greater than would be calculated using FDA methodology.

Appendix B—Food Use Pesticides With Evidence of Carcinogenicity

Active Ingredient Group [FN1]	409	409 Needs [FN2]		
Tolerances	Tolerances	409		
food	feed	tolerances		
1,3-dichloropropene [FN3,6]	B2			
2,4-D	D	x	x	
Acephate	C	x	x	
Acifluorfen	B2			x
Alachlor 6	B2			x
Aliette (fosetyl al)	C			
Amdro	B2			
Amitraz	C			x
Arsenic acid (orthoarsenic acid)	A			
Asulam	C			
Atrazine	C			
Azinphos-methyl	D			x
Benomyl [FN4]	C	x		
Bifenthrin 5	C			
Bromacil				
Calcium arsenate				
Captafol	B2			
Captan 6	B2	x	x	
Chlordimeform & hydrochloride	B2			
Chlorobenzilate				
Chlorothalonil	B2			
Copper arsenate				
Cypermethrin				
Cyromazine 4			x	
Daminozide 6	B2	x	x	
Diallate				
Dicamba 7		x	x	
Dichlorvos (DDVP)	B2	x		
Diclofop methyl				
Dicofol	B2	x		
Dimethipin (Harvade)	C			x
Dinoseb	C			
EDB	B2			
Ethalfluralin			x	
Ethylene oxide 6		x		
Folpet	B2			
Gardona	C	x	x	
Glyphosate	D	x	x	
Lactofen 5	B2			
Lead arsenate				x
Lindane	D			x
Linuron 6	C			

Mancozeb 4, 6	B2	x		
Magnesium arsenate				
Maneb 4,6	B2			x
Methanearsenic acid			x	
Methidathion	C			x
Methomyl 4				x
Metiram 4 6	B2			
Metolachlor	C			
Oryzalin	C	x		
Oxadiazon	C			
O-phenylphenol				
Paraquat	E	x	x	
Parathion	C			
PCNB (pentachloronitrobenzene)	D			
Permethrin				x
Phosmet	C	x		
Pronamide	C			
Propazine	C			
Propiconazole 5	C			
P-dichlorobenzene 3	C			
Sodium arsenate				
Sodium arsenite				
Terbutryn	C			
Tetrachlorvinphos		x		
Thiodicarb 4				x
Thiophanate methyl 4				x
Toxaphene			x	
Triadimenol (Baytan)	C			
Tridiphane	C			
Trifluralin	C	x		
Zineb 4 6	B2			

Notes:
1 Classification in accordance with EPA's Cancer Assessment Guidelines (see Appendix A) for those chemicals for which a weight-of-the-evidence determination has been made.
2 Chemical has recently been determined to require a 409 tolerance.
3 Registered uses (formerly not considered to be food uses) which have recently been defined as food uses.
4 Included due to potentially oncogenic metabolite.
5 Recently added to list because of newly registered food uses.
6 Currently in Special Review for dietary concerns.
7 Included because a contaminant is an oncogen.

Appendix C—Active Ingredients for Which Registration Standards Have Been Issued or are Scheduled for Next Year

Active ingredient	Calendar year of issue
4-aminophyridine	1980
Acephate	1987
ADBAC	1985
Alachlor	1984
Aldicarb	1984
Aldrin	1986
Aliette (fosetyl al)	1983
[FN1]	1986
Amitraz	1987

Amitrole 1984
Ammonium sulfamate 1981
[FN1] 1987
Anilazine 1983
Arsenic acid (orthoarsenic acid) 1986
Aspon 1980
Asulam 1988
Atrazine 1983
[FN1] 1989
Azinphos-methyl 1986
Bacillus thuringiensis 1988
Barium metaborate 1983
Bendiocarb 1987
Benefin 1989
Benomyl 1987
Bentazon/sodium bentazon 1985
Bifenox 1981
Bifenox (SRR) 1989
Bioallethrin 1988
BKLFI-2 1981
Boron (incl. borax & boric acid) 1983
Bromacil 1982
[FN1] 1989
Bromoxynil 1989
Butoxicarboxime 1981
Butylate 1983
[FN1] 1989
Captafol 1984
Captan 1986
Carbaryl 1984
[FN1] 1988
Carbofuran 1984
Carbophenothion 1984
Carboxin 1981
Chloramben 1981
[FN1] 1989
Chlordane 1986
Chlordimeform hydrochloride 1985
Chlorobenzilate 1983
[FN1] 1989
Chloroneb 1980
[FN1] 1989
Chlorophacinone 1989
Chloropicrin 1982
Chlorpropham 1987
Chlorothalonil 1984
[FN1] 1988
Chlorpyrifos 1984
[FN1] 1989
Chlorsulfuron 1982
Chromated arsenicals 1986
Coal tar/creosote 1986
Copper chloride/nitrates 1987
Copper sulfate 1986
Coumaphos 1981
[FN1] 1989
Cryolite 1983
[FN1] 1988

Cyanazine 1984
Cycloate 1989
Cycloheximide 1982
Cyhexatin 1985
2,4-D 1988
2,4-DB 1988
2,4-DP 1988
Dacthal 1988
Dalapon 1987
Daminozide 1984
DCNA 1983
Deet 1980
Demeton 1985
Dialifor 1981
Diallate 1983
Diazinon 1988
3,5-dibromosalicylanilide 1985
Dicamba 1983
[FN1] 1989
Dichlobenil 1987
Dichlone 1981
1,3-dichloropropene 1986
Dichlorvos (DDVP) 1987
Dicrotophos 1982
Difenzoquat 1988
Diflubenzuron 1985
Dimethoate 1983
[FN1] 1989
Dioxathion 1983
Diphacinone 1989
Diphenamid 1987
Dipropetryn 1985
Diquat dibromide 1986
Disulfoton 1985
Diuron 1983
Dodine 1987
Endosulfan 1982
EPN 1987
EPTC 1983
[FN1] 1989
Ethephon 1988
Ethion 1982
[FN1] 1989
Ethoprop 1983
[FN1] 1988
Ethoxyquin 1981
Ethyl parathion 1986
2-ethyl-1,3-hexanediol 1981
Fenamiphos 1987
Fenaminosulf 1983
Fenitrothion 1987
Fensulfothion 1983
Fenthion 1988
Fluchloralin 1985
Fluometuron 1985
Folpet 1987
Fonofos 1984
Formaldehyde 1986

Formetanate hydrochloride 1983
[FN1] 1989
Fumarin 1980
Glyphosate 1986
Heliothis NPV 1984
Heptachlor 1986
Hexazinone 1982
[FN1] 1988
Isocyanurates 1987
Isopropalin 1981
Lindane 1985
Linuron 1984
MCPA 1982
[FN1] 1988
MCPB 1989
Magnesium & aluminum phosphide 1986
Malathion 1988
Maleic hydrazide 1988
Mancozeb 1987
Maneb 1988
Mecoprop 1989
Methiocarb 1987
Metalaxyl 1981
[FN1] 1988
Metaldehyde 1989
Methamidophos 1982
Methidathion 1981
[FN1] 1988
Methomyl 1982
[FN1] 1988
Methoprene 1982
Methoxychlor 1989
Methyl bromide 1986
Methyl parathion 1986
Methylene bis thiocyanate 1989
Metiram 1988
Metolachlor 1980
[FN1] 1987
Metribuzin 1985
Mevinphos 1988
Monocrotophos 1985
Monuron 1983
Monuron TCA 1983
Nabam 1987
Naled 1983
Napropamide 1989
Napthalene 1981
Naphthalene acetic acid & salts 1981
Naptalam 1985
Nitrapyrin 1985
Norflurazon 1984
[FN1] 1989
OBPA 1981
O-phenylphenol 1989
Oryzalin 1987
Oxamyl 1987
Oxydemeton methyl 1987
Oxytetracycline 1988

Paraquat 1987
PCNB (pentachloronitrobenzene) 1987
Pendimethalin 1985
Perfluidone 1985
Phenmedipham 1987
Phorate 1984
Phorate (SRR) 1988
Phosalone 1981
[FN1] 1987
Phosmet 1986
Phosphamidon 1987
Picloram 1985
[FN1] 1988
Piperonyl butoxide 1989
Potassium bromide 1984
Potassium permanganate 1985
Prometryn 1987
Pronamide 1986
Propachlor 1985
Propanil 1987
Propargite 1986
Propazine 1989
Propham 1987
Resmethrin 1988
Rotenone 1988
Simazine 1984
[FN1] 1989
Sodium & calcium hypochloride 1986
Sodium omadine 1985
Streptomycin 1988
Sulfur 1982
Sulfuryl fluoride 1985
Sulfotepp 1988
Sulprofos 1981
Sumithrin 1987
Tebuthiuron 1987
Temephos 1981
Terbacil 1982
[FN1] 1989
Terbufos 1983
Terbutryn 1986
Terrazole 1980
[FN1] 1989
Tetrachlorvinphos 1988
Thiophanate ethyl 1985
Thiophanate methyl 1988
Thiram 1984
TPTH 1984
Trichlorfon 1984
Trifluralin 1987
Trimethacarb 1985
Vendex 1987
Warfarin 1981
[FN1] 1989
Zinc phosphide 1982

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1 Second round of review of the earlier registration standards.

***41120 Appendix D—Examples of Pesticide Chemicals With Tolerance Issues Currently or Recently Under Review**

1. Benomyl

Benomyl is a broad spectrum systemic fungicide that controls a wide variety of plant diseases in field and vegetable crops, rice, tree fruit and nut crops, greenhouse, ornamentals, and turf sites. It is also used as a postharvest dip for fruits. In the Registration Standard issued for benomyl on March 31, 1986, the Agency concluded that benomyl and its major metabolite, 4-methyl benzimidazole carbamate (MBC), were possible human carcinogens (Group C), based on a significant increase in hepatocellular carcinomas in closely related strains of mice. Based on the established tolerances and the percent of crop treated, the Agency estimated any potential oncogenic risk from dietary exposure to be in the range of 10-5. The Agency noted, however, that this quantitative assessment should not be accorded much weight since the evidence for oncogenicity is limited, but could be taken to represent a worst-case upper limit for risk. The Registration Standard also reassessed the residue data base supporting the established tolerance and food additive regulations for benomyl and concluded that additional data were required to fill the identified data gaps. A conclusion was also reached that additional food ***41121** additive regulations under section 409 may be required to cover residues in the processed fractions of citrus, tomatoes, grapes, and soybeans.

The additional residue data required by the Standard were received in the summer of 1987 and are under review. When general metabolism data (due July 1989) are received, EPA will be able to complete the tolerance reassessment for benomyl.

If the new data indicate that additional section 409 regulations are necessary, the Agency could establish such regulations under a de minimis approach if weight-of-the-evidence considerations lead to a conclusion that the risk to humans is negligible.

2. Captafol

Captafol, which was originally registered in 1962, is used as a fungicide on various vegetable and fruit crops. The Registration Standard for captafol, completed in September 1984, estimated a dietary risk of 10-4 based on tolerance levels, and required registrants to produce data on actual residues in food crops and additional oncogenicity data. A Special Review was also initiated. In early 1987, EPA classified captafol as a B2 (probable human) oncogen. The major registrant, Chevron Chemical Company, voluntarily cancelled its captafol registrations in March 1987. Formulators followed suit the next month. On August 22, 1988, the Agency terminated the Special Review because all registrations of captafol products had been cancelled. Also, the Agency plans to initiate action during 1989 to revoke the remaining tolerances for captafol.

3. Captan

Captan (N-trichloromethylthio-4-cyclohexane-1,2-dicarboximide) is a widely used agricultural fungicide, currently registered for use on a number of fruits and vegetables, small grains, cotton, grasses, flowers, and numerous household uses. The chemical has been the subject of a recent Registration Standard (issued in March 1986) and a Special Review. The Agency has found that the dietary intake of captan resulted in an increased incidence of uncommon adenomas and adenocarcinomas of the upper gastrointestinal tract in the Charles River CD-1 mouse, an increased incidence of these GI tumors in B6C3F1 mice, and a small dose-related increased incidence of kidney tumors in Charles River CD-1 rats. The Agency also noted positive mutagenic activity in gene mutation and chromosomal aberration assays, and a structural relationship to other compounds that demonstrated oncogenic effects.

In the Standard, the Agency requested residue data, including field trials to generate data for raw agricultural commodities treated at the maximum permitted rate, and studies to show the effect of washing, peeling, cooking, and processing on residue levels. Section 408 tolerances are currently established for a number of commodities which are subjected to processing, namely potatoes, soybeans, tomatoes, oranges, grapes, sweet corn, cottonseed, and pineapples. Section 409 tolerances for captan exist for washed raisins at 50 ppm (21 CFR 193.40; 21 CFR 193.40 redesignated as 40 CFR 185.500 at 53 FR 24666, June 29, 1988) and detreated corn seed at 100 ppm (21 CFR 561.65; 21 CFR 561.65 redesignated as 40 CFR 186.500 at 53 FR 24668, June 29,

1988). However, the 409 tolerance for detreated corn seed is in the process of being revoked for failure to submit supporting data. Section 409 tolerances must be set for some commodities, such as dried prunes and dry apple pomace.

In the Preliminary Determination of the Special Review, issued on June 2, 1985, the Agency determined that the dietary risk could be as high as 10-4 based on the assumption that residues are present at tolerance levels. The new data will allow the Agency to refine its risk assessment, and determine whether the currently established tolerances and food additive regulations should be revoked.

4. Chlordimeform

Chlordimeform was previously registered for a number of fruit and vegetable insecticide uses; however, most food uses were withdrawn by the registrants in 1976 because preliminary results of a mouse study suggested that chlordimeform caused malignant blood vessel tumors. In 1978, chlordimeform was registered for use on cotton with new restrictions to reduce applicator exposure. A Registration Standard was published for chlordimeform in January 1986, and the chemical has been referred to Special Review because of worker exposure concerns. In conducting the Registration Standard review, the Agency assessed dietary risks from the cotton use, using data on the percent of cotton crops actually treated (between 10 percent and 12 percent), and actual residue data showing chlordimeform residues ranging from 1 to 2 orders of magnitude lower than tolerance levels. Dietary risk from actual residues of chlordimeform occurring in commodities derived from treated cotton was estimated at 10-7. Under the de minimis approach, the food additive regulations on commodities processed from cotton would be retained.

Very recently, the two registrants of the technical product have offered to voluntarily cancel the remaining cotton use, effective within the next year.

5. Chlorothalonil

Chlorothalonil is a fungicide used on numerous crops such as fruits, vegetables, and peanuts, as well as on ornamental turf. The chlorothalonil Registration Standard, issued in September 1984, identified significant data gaps; data have been submitted in response to the requirements set forth in the Standard. Based on such data, EPA has classified chlorothalonil as a B2 (probable human) oncogen. There are no existing 409 food additive regulations for this chemical; residue data required in the Standard will allow the Agency to determine if such regulations are necessary. A Revised Registration Standard and Tolerance Reassessment is scheduled for completion in September 1988. The Agency will assess during the Standard review whether the chemical should be referred to Special Review.

6. EBDCs

The EBDCs (ethylene bisdithiocarbamates) are a group of six fungicides (maneb, mancozeb, amobam, nabam, metiram, and zineb) with a common contaminant, metabolite, and degradation product called ethylene-thiourea (ETU). In 1984, a data call-in imposed extensive data requirements on the registrants of the EBDCs to enable the Agency to perform a comprehensive risk assessment. In response, registrants of amobam cancelled their products, and registrants of nabam deleted all food uses from their labels. Based on data received in response to the data call-in, the Agency has classified ETU and the EBDCs as B2 (probable human) oncogens. As set forth in the Registration Standard issued in April 1987, the dietary risk for mancozeb is estimated to be 10-4 based on actual residue data. The total dietary risks resulting from the use of all the EBDCs is likely to be higher. Residue data on maneb and metiram were received in March 1988. For zineb, which represents only 5 percent of total EBDC usage, residue data will not be available until 1991.

All the EBDCs have been placed in Special Review; the Preliminary Determination is scheduled for early 1989. The Agency expects to conduct a risk assessment of the dietary risk posed by these chemicals in the summer and fall of 1988, and then to conduct a comparative risk/benefit assessment of the major fungicides (EBDCs, captan, ***41122** chlorothalonil and benomyl) before making a regulatory decision on any one of them. As part of that review, the Agency will also determine what action

to take with respect to the existing tolerances and food additive regulations. There are several food additive regulations for mancozeb, and data may indicate the need for such regulations for maneb, metiram, and zineb.

7. Folpet

Folpet is a broad spectrum fungicide which, in the past, has been used on both food and nonfood crops and as an industrial fungicide in the manufacture of coatings and plastics. Non-agricultural uses and home and garden uses have accounted for approximately 86 percent of its total usage. A Registration Standard was issued for folpet in June 1987, and additional residue data (due in 1991) were requested. Currently, all food uses have been suspended for failure to provide data. Current indications are that the only food use which is likely to be supported by data is the use on avocadoes.

The chemical has been classified as a B2 (probable human) oncogen. Prior to the recent suspensions, theoretical dietary risks, based on the assumption that residues would be present at tolerance levels, were in the 10-4 range, but the Agency believes that, if actual residue data and percent of crop treated were factored into the risk calculation, risks would be likely to be in the 10-6 range. There are no existing section 409 food additive regulations for folpet. If any food uses are reinstituted, and if residue data show that there is a concentration effect during processing, such regulations would be necessary. If the data indicate that the risk is in fact in the 10-6 range, the de minimis approach could be followed in establishing such regulations.

8. Linuron

Linuron, a herbicide used for pre- and post-emergent control of annual grasses and broadleaf weeds, was initially registered in 1966, and a number of tolerances have been established since then for its use on soybeans, corn, cotton, sorghum, wheat, asparagus, carrots, celery, parsnips. and potatoes. There are no section 409 food or feed additive regulations for linuron. However, the Agency has requested processing data to demonstrate whether the chemical does concentrate in processed commodities.

In 1984, a Registration Standard was issued for linuron and additional residue and chronic effects data required. At the time of the Standard, the Agency estimated dietary oncogenic risk in the range of 10-4 (based on residues at tolerance levels with some adjustment for percent of crop treated). However, since the time the Special Review was initiated, the Agency has issued its oncogenicity classification guidelines and has concluded that linuron is a group C (possible human) oncogen. Because only benign tumors are formed, these tumors occur only late in life, and there is no evidence of mutagenic activity, the Agency has concluded that linuron's human carcinogenic potential is low. Therefore the Agency has recently terminated the Special Review based on oncogenicity.

9. Permethrin

Permethrin is an insecticide first registered in 1979 for use on cotton, with a wide variety of other uses, including vegetables and pears (registered in 1982). The toxicology data base for permethrin is complete. The Agency has classified permethrin as a Group C oncogen, based on the induction of lung and liver tumors in female mice. Based on the very weak evidence of oncogenicity observed, the Agency determined that a quantitative risk assessment for this chemical is inappropriate because the likelihood of oncogenic effects in humans from low levels of permethrin is non-existent or extremely low. The Agency has, however, regulated this chemical as a possible oncogen for Delaney Clause purposes, and has declined to set 409 food additive regulations.

A tolerance for tomatoes, a commodity which is usually subject to processing, was established for Florida tomatoes, subject to a restriction that the tomatoes only be used for the fresh market. This approach was believed to be feasible for permethrin because of the unique circumstances of tomato production in Florida, i.e., 98 percent of the tomatoes were for the fresh market, and the limited number of canneries in the area agreed not to process tomatoes into a form which would result in concentrated residues (such as paste, puree, or ketchup). However, the Agency subsequently was informed that a cannery in Florida was

processing permethrin-treated tomatoes into puree and paste. This incident demonstrates the impracticality of expecting growers and processors to distinguish between permethrin-treated tomatoes and untreated tomatoes.

In addition, the Agency is still seeking processing data to clarify whether residues will concentrate in any of the other processed commodities produced by Florida canneries. If the Agency were to follow the de minimis approach, permethrin would be a potential candidate for section 409 food additive regulations for additional uses in which concentration of the residues occurs during processing.

10. Trifluralin

Trifluralin is a selective preemergent herbicide registered for use on a variety of crops for the control of annual grasses and certain broad leaf weeds. This pesticide has been classified as a Group C carcinogen based on a significant increase in the incidence of malignant tumors of the renal pelvis, of the kidney and thyroid gland of male rats, and in the incidence of combined malignant and benign urinary bladder tumors in female rats at the highest dietary concentration tested. The Agency indicated in its August 1986 Registration Standard that processing data is being required for potatoes, sugar beets, soybeans, citrus fruits, sorghum, barley, corn and wheat grain, alfalfa hay, flax seed, cottonseed, peanuts, spent peppermint and spearmint hay, sugarcane, and sunflower seed. These data could indicate that additional food additive regulations are necessary to support current use patterns. Such regulations could be established under a de minimis approach if risks are found to be sufficiently low. Otherwise, if the Agency takes the approach that such regulations would be barred by the Delaney Clause, the corresponding section 408 tolerances might be subject to revocation, thereby eliminating many of the beneficial uses of this pesticide.

Appendix E—Candidates for Negligible Risk Consideration

Chemical	Type	Status	Proposed Use	Group
Aliette	Fungicide	New Use	Hops	C
Amitraz	Insecticide	New Use	Apples	C
Apollo	Insecticide	New Chemical	Apples	C
Cypermethrin corn	Insecticide	New Uses	Soybeans	C
Dicamba [FN1]	Herbicide	New Use	Cotton	Not classified.
Glyphosate	Herbicide	New Use	Wheat	C/D
Harvade	Herbicide	New Use	Sunflowers	C
Methomyl [FN2]	Insecticide	New Use	Hops	Not classified.
Metolachlor	Herbicide	New Uses	Apples, flax, sunflowers	C
Permethrin corn	Insecticide	New Uses	Soybeans, apples, tomatoes	Treated as C
Savey	Insecticide	New Chemical	Apples	C
Verdict	Herbicide	New Chemical	Soybeans	In review

1 A nitrosoamine contaminant of dicamba is an oncogen.
2 Acetamide is an oncogen and an animal metabolite of methomyl.

***41123 Appendix F Group C Carcinogens' Status Re Risk Quantification**

The decision as to whether or not quantification of risk for Group C chemicals is appropriate is subject to change as the Agency analyzes new data or reevaluate existing data. The following lists indicate those chemicals for which, as of August 1988, the Agency has determined a quantified risk number should or should not be used. There are a few other Group C chemicals for which this decision is still pending.

Risk Quantification Deemed Inappropriate

acephate

Aliette (fosetyl al)

amitraz

asulam

benomyl

bifenthrin

cypermethrin

dimethipin (Harvade)

fomesafan

gardona

linuron

methidathion

metolachlor

oryzalin

oxadiazon

parathion

permethion

phosmet

pronamide

propiconazole

triadimenol (Baytan)

tridiphane

trifluralin

[FR Doc. 88-24126 Filed 10-18-88; 8:45 am]

BILLING CODE 3388-03-M

Footnotes

1 The decision to cancel a pesticide can result from a Special Review, an intensive review of the risks and benefits of a pesticide which meets or exceeds risk criteria set forth in 40 CFR Part 154. The Agency also can take action to cancel (and, if necessary, to suspend during the cancellation proceedings) the registration of a pesticide whose risks appear to exceed its benefits, without first going through the Special Review process.

2 Under Reorganization Plan No. 3 of 1970, which established EPA, the authority to set tolerances for pesticide chemicals in raw agricultural commodities and processed food under FFDCA sections 408 and 409 respectively, was transferred from FDA to EPA. FDA enforces most of the pesticide tolerances and food additive regulations that EPA issues, along with the many non-pesticide food additive regulations that FDA issues. The U.S. Department of Agriculture enforces the tolerances and food additive regulations with respect to meat, poultry, and egg products.

3 In Continental Chemiste Corp. v. Ruckelshaus, 461 F.2d 331, 340-341 (7th Cir. 1972), a case dealing with the relationship of FIFRA and FFDCA, the court stated that "[t]he test of safety [contained in the general safety clause of section 409] was intended to take into account the broader concepts of safety under the intended conditions of use; the benefits of the additive were to be evaluated rather than merely its potential for harm. In short, in making its ultimate determination whether new additives, or food containing them, may be marketed, [the FFDCA] employs the kind of substantive standard of product safety embodied in [the pre-1972] FIFRA's injury to man' concept, rather than a narrow consideration of the character of the additive itself." In discussing this "injury to man" concept, the court noted that "the substantive standards, phrased in terms of protection of the public and impact on living man, require consideration of the aggregate effect of a product's use upon the environment, including not only its potential for harm, but also the benefits which would be lost by removing it from the market." Id. at 336.

4 FDA has analyzed the meaning of the DES proviso in proposed regulations published in the Federal Register of March 20, 1979 (44 FR 17070), and February 11, 1983 (48 FR 6361). FDA's final rule establishing procedures implementing this sensitivity-of-method approach was published on December 31, 1987 (52 FR 49572).

5 See Alabama Power Co. v. Costle, 636 F.2d 323, 360 (D.C. Cir. 1979); District of Columbia v. Orleans, 406 F.2d 957, 959 (D.C. Cir. 1968); Environmental Defense Fund, Inc. v. EPA, 636 F.2d 1267, 1284 n. 46 (D.C. Cir. 1980).

6 See, e.g., the 1960 statement by Arthur S. Fleming, Secretary of Health, Education and Welfare, that the Delaney Clause "allows the Department and its scientific people full discretion and judgment in deciding whether a substance has been shown to produce cancer when added to the diet of test animals," cited with approval in the Report of the House Committee on Interstate and Foreign Commerce on the Color Additive Amendments of 1960 (H.R. Rep. No. 1761, 85th Cong. 2d Sess., June 7, 1960) at 14. See also the May 1960 report of the President's Science Advisory Committee, noting that "[t]he definition of a carcinogen implicit in the language of section 409(c) requires discretion in its interpretation because so may variables enter into a judgment as to whether a particular substance is or is not carcinogenic," cited with approval in the Senate floor debate on reconsideration of the Delaney Clause in the Color Additive Amendments of 1960. Congressional Record 15380 (July 1, 1960).

FN7 See 52 FR 49572, 49577 (December 31, 1987) for a statement of FDA's current policy. See also 51 FR 28331, 28340 (August 7, 1986), where FDA specifically noted that "any chemical shown to induce cancer even in only one strain, gender, and species, at one dose in one experiment, is an animal carcinogen." The evidence as a whole may lead FDA to conclude that a substance that only causes benign tumors should be regulated as a carcinogen under the Delaney Clause. (52 FR 49577, December 31, 1987). However, a finding of only benign tumors does not of necessity lead FDA to conclude that the chemical "induces cancer" under the Delaney Clause.

8 In recent years, the Agency has been conducting a systematic review of currently registered pesticides under the Registration Standards process. This review determines the sufficiency of the data base for these chemicals in light of current data requirements, and evaluates the current terms of registration to see if modifications are appropriate. During the development of a Standard, data gaps are identified and data call-in notices sent to registrants pursuant to FIFRA section 3(c)(2)(B), which gives the Agency authority to require the submission of data necessary to support existing registrations. The Agency evaluates the adequacy of existing tolerances and food additive regulations for chemicals registered for food uses during the Registration Standard review. Appendix C lists those food use pesticides for which Registration Standards have been developed or are scheduled for FY 1988.

9 Section 409(h) states: "[The Administrator] shall by regulation prescribe the procedure by which regulations under (section 409) shall be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulation." The interpretation that revocation is not expressly required is based on giving the term "procedure" its normal meaning, rather than reading into the term the substantive criteria of section 409.

10 FDA appears to interpret the Delaney Clause as applying to food additives established prior to any indication of carcinogenic effect for such chemicals. See, for example, the discussion in the proposed FDA determination not to ban the use of methylene chloride in decaffeinated coffee (50 FR 51551, 51555 December 18, 1985).

11 Discussions in this document of risks resulting from pesticide use are limited to cancer risks due to dietary exposure. It is important for the reader to keep in mind that the Agency's reviews and decisions encompass many other risks as well. Table I proceeds from the assumption that all other risk criteria have been satisfied.

1 Theoretically, this assumption is based on the premise that smaller animals, which eliminate heat from the body (an indication of metabolism) more efficiently than larger animals, are more efficient metabolically at detoxifying a chemical than larger animals. This difference in heat elimination has been related to the ratio of the surface area to the volume of the organism. Mathematically, the correction for surface area differences is made by dividing the dose in the animal study by the ratio of human body weight to test animal body weight to the two-thirds power.

End of Document

55 FR 11798-01
RULES and REGULATIONS
ENVIRONMENTAL PROTECTION AGENCY
40 CFR Parts 261, 264, 265, 268, 271, and 302
[SWH-FRL-3601-1; EPA/OSW-FR-89-026]
RIN 2050-AA78

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Toxicity Characteristics Revisions

Thursday, March 29, 1990

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: On June 13, 1986, the Environmental Protection Agency (EPA) proposed to revise the existing toxicity characteristics, which are used to identify those wastes defined as hazardous and which are subject to regulation under subtitle C of the Resource Conservation and Recovery Act (RCRA) due to their potential to leach significant concentrations of specific toxic constituents. The proposed rule was designed to refine and broaden the scope of the hazardous waste regulatory program and to fulfill specific statutory mandates under the Hazardous and Solid Waste Amendments of 1984 (HSWA).

EPA is today promulgating the Toxicity Characteristics (TC). Today's rule retains many of the features of the original proposal: It replaces the Extraction Procedure (EP) leach test with the Toxicity Characteristic Leaching Procedure (TCLP); it adds 25 organic chemicals to the list of toxic constituents of concern; and it establishes regulatory levels for these organic chemicals based on health-based concentration thresholds and a dilution/attenuation factor that was developed using a subsurface fate and transport model. In response to comments received on the proposed rule and related notices, the final rule incorporates a number of modifications in the leaching procedure, the list of toxicants, the chronic toxicity reference levels, and the fate and transport model.

The overall effect of today's action will be to subject additional wastes to regulatory control under subtitle C of RCRA, thereby providing for further protection of human health and the environment.

DATES: Effective Date: September 25, 1990.
Compliance Dates: Large quantity generators: September 25, 1990. Small quantity generators (SQGs): March 29, 1991. Any person that would like to use the Toxicity Characteristic Leaching Procedure (TCLP) before the effective date may do so in order to determine whether the eight heavy metals and six pesticides that are currently regulated under the Extraction Procedure (EP) Toxicity Characteristic leach at levels of regulatory concern.

ADDRESSES: The official record for this rulemaking (Docket Number F-90-TCF-FFFFF) is located in the EPA RCRA Docket (Second Floor, Rm 2427), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. The docket is open from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding federal holidays. The public must make an appointment to review docket materials by calling (202) 475-9327. The public may copy material at a cost of $0.15 per page.

FOR FURTHER INFORMATION CONTACT: For general information about this rulemaking, contact the RCRA/Superfund Hotline at (800) 424-9346 (toll free) or (202) 382-3000 in the Washington, DC metropolitan area. For information on specific

aspects of this rule, contact Steve Cochran, Office of Solid Waste (OS-332), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, (202) 475-8551.

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I. Authority

The amendments to the hazardous waste regulations in 40 CFR parts 261 and 271 are being promulgated under the authority of sections 1006, 2002(a), 3001, 3002, and 3006 of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6905, 6912(a), 6921, 6922, and 6926). The amendments to the list of hazardous substances and reportable quantities in 40 CFR part 302 are being promulgated under the authority of section 102 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9602), as amended, and sections 311 and 501(a) of the Federal Water Pollution Control Act (33 U.S.C. 1321 and 1361).

II. Background

A. Definition of Hazardous Waste

Subtitle C of the Resource Conservation and Recovery Act (RCRA), as amended, establishes a federal program for the comprehensive regulation of hazardous waste. Section 1004(5) of RCRA defines hazardous waste, among other things, as solid waste that may ". . . pose a substantial present or potential hazard to human health and the environment when improperly treated, stored, transported, disposed, or otherwise managed." Under RCRA Section 3001, EPA is charged with defining which

solid wastes are hazardous by either identifying the characteristics of hazardous waste or listing particular hazardous wastes. Identifying characteristics of hazardous waste and listing hazardous wastes are distinct and fundamentally different mechanisms for defining hazardous wastes.

The hazardous waste characteristics promulgated by EPA designate broad classes of wastes which are clearly hazardous by virtue of an inherent property. In the May 19, 1980 final rule (45 FR 33084) that instituted EPA's general framework for identifying hazardous waste, the Agency established two basic criteria for identifying hazardous waste characteristics: (1) The characteristic should be capable of being defined in terms of physical, chemical, or other properties which cause the waste to meet the statutory definition of hazardous waste; and (2) the properties defining the characteristic must be measurable by standardized and available testing protocols or reasonably detected by generators through their knowledge of the waste (40 CFR 261.10). In the May 19, 1980 final rule, EPA stated that it adopted the second criterion in recognition that the primary responsibility for determining whether wastes exhibit hazardous characteristics rests with generators, for whom standardization and availability of testing protocols are essential.

The approach EPA uses to establish hazardous waste characteristics is to determine which properties of a waste would result in harm to human health or the environment if a waste is mismanaged. The Agency then establishes test methods and regulatory levels for each characteristic property; solid waste that exceeds the regulatory level for any characteristic property is a hazardous waste.

The regulatory levels for characteristics that have been established provide a high degree of certainty that wastes exceeding those regulatory levels would pose hazards to human health and the environment if improperly managed and therefore require regulation under subtitle C. Wastes that do not exhibit hazardous waste characteristics are not necessarily nonhazardous. The Agency may ***11800** evaluate wastes from either specific or nonspecific sources and decide to list them as hazardous wastes based on criteria defined in 40 CFR 261.11.

To list a waste as hazardous, EPA conducts a detailed industry or process study involving literature reviews, engineering analyses, surveys and questionnaires, site visits, and waste sampling. For listing, the Agency places particular emphasis on hazardous constituents contained in specific wastes generated by the industry or process being studied (See 40 CFR 261.11(a)(3)). However, EPA uses a comparatively flexible approach when deciding to list wastes as hazardous; the approach includes consideration of factors such as type of threat posed, plausible ways that the waste might be mismanaged, migration potential and persistence in the environment, waste quantity, and actions of other regulatory programs. The Agency also promulgated two other rules for identifying solid wastes as hazardous wastes—the mixture and derived-from rules. The mixture rule says that any mixture of a listed hazardous waste and a solid waste is the listed hazardous waste (40 CFR 261.3(a)(2)(iii)-(iv)); the derived-from rule says that any solid waste derived from the treatment, storage, or disposal of a listed hazardous waste is considered the listed hazardous waste (40 CFR 261.3(c)-(d)).

B. Existing Extraction Procedure Toxicity Characteristic

The Extraction Procedure (EP) toxicity characteristic is one of four existing hazardous waste characteristics (along with ignitability, corrosivity, and reactivity) that EPA has identified and promulgated (40 CFR 261.24). The Extraction Procedure Toxicity Characteristic (EPTC) defines the toxicity of a waste by measuring the potential for the toxic constituents in the waste not subject to subtitle C controls to leach out and contaminate ground water at levels of health or environmental concern. To determine if a waste exhibits the EPTC, constituents are extracted in a procedure that simulates the leaching action that occurs in municipal landfills. Because a “hazardous waste” is defined as a waste that may pose a substantial hazard “when mismanaged,” the EP was designed based on the assumption that wastes not subject to subtitle C controls would be co-disposed with municipal waste in an actively decomposing landfill that overlies an aquifer. Thus, the EP identifies wastes that are likely to leach hazardous concentrations of particular toxic constituents to ground water under conditions of improper management.

The Agency recognized that not all wastes are managed according to the mismanagement scenario postulated for the EP. However, it is necessary to make assumptions about management practices for unregulated wastes in order to determine whether

a waste poses a threat to human health and the environment and thus meets the statutory definition of hazardous waste. In addition, the Agency believed that a reasonably conservative mismanagement scenario was warranted in light of the statutory mandate to protect human health and the environment.

Under the existing EPTC, the liquid waste extract obtained from the EP is analyzed to determine whether it possesses any of 14 toxic contaminants that were identified in the National Interim Primary Drinking Water Standards (NIPDWS): eight metals (arsenic, barium, cadmium, chromium, lead, mercury, selenium, and silver), four insecticides (endrin, lindane, methoxychlor, and toxaphene), and two herbicides (2,4-D and 2,4,5-TP). NIPDWS levels are used as health-based concentration limits. At the time of promulgation of the EPTC, the NIPDWS were the only available benchmarks for toxicity that were scientifically recognized and that also addressed chronic exposure.

The regulatory levels established for the EPTC were 100 times the NIPDWS. The 100-fold factor is a dilution and attenuation factor (DAF) that estimates the dilution and attenuation of the toxic constituents in a waste as they travel through the subsurface from the point of leachate generation (i.e., the landfill) to the point of human or environmental exposure (i.e., at a drinking-water well). The Agency had originally proposed a DAF of 10 for use in the EP. In light of the fact that there were few empirical data on which to base the DAF and other considerations, the Agency adopted a DAF of 100 in the final rule (45 FR 33084, May 19, 1980). EPA was confident that any waste which exhibited the EPTC using the 100-fold factor would have the potential to present a substantial hazard regardless of the actual site-specific attenuation mechanisms. The Agency also noted that it would adjust the DAF if future studies indicated that another DAF was more appropriate.

C. The Hazardous and Solid Waste Amendments of 1984

On November 8, 1984, the Hazardous and Solid Waste Amendments of 1984 (HSWA) were enacted: these amendments have had far-reaching ramifications for EPA's hazardous waste regulatory program. RCRA sections 3001 (g) and (h), which were among the many provisions added by HSWA, direct EPA to examine and revise the EP Toxicity Characteristic and to identify additional hazardous waste characteristics, including measures of toxicity. Today's rule fulfills these mandates by promulgating an improved leaching procedure that better predicts leaching and an expansion of the Toxicity Characteristics (TC) list to include additional toxicants.

RCRA section 3001(g) specifically directs EPA to examine the EP leach procedure as a predictor of the leaching potential of waste and to make changes necessary to ensure that it accurately predicts the leaching potential of wastes that may pose a threat to human health and the environment when mismanaged. The legislative history for this provision indicates that Congress was specifically concerned about the EP's ability to accurately represent the mobility of toxicants under a wide variety of conditions. The legislative history also suggests that Congress intended for EPA to develop a more aggressive leaching medium for the test and noted that the EP only evaluated the mobility of elemental toxicants and not the mobility of organic toxicants.

Concerned that some wastes posing a threat to human health and the environment were not being brought into the hazardous waste system, Congress adopted RCRA section 3001(h), which directs EPA to promulgate additional characteristics. Of specific concern to Congress was the fact that the existing characteristics did not identify wastes that were hazardous due to toxic levels of organic constituents. Although Congress recognized that the development of such a characteristic would entail technical problems, Congress urged the Agency to make reasonable assumptions for purposes of regulation, rather than await definitive technical answers. In response to the 3001(g) and 3001(h) mandates, EPA issued a proposed rule to revise and expand the TC (51 FR 21648, June 13, 1986) which is discussed below in Section II.D.

D. Previous Federal Register Notices

As indicated above, EPA published a Federal Register notice (June 13, 1986) proposing to expand the existing TC. The proposal specifically identified 52 compounds that could cause a waste to be hazardous via toxicity, including the existing 14 EPTC compounds and 38 additional organic compounds. In ***11801** addition, it described the Toxicity Characteristic

Leaching Procedure (TCLP), a new version of the EP. The TCLP is designed to more accurately address the leaching of organic compounds and to improve upon technical aspects of the testing protocol.

The June 13 proposal used a subsurface fate and transport model to determine compound-specific dilution and attenuation factors (DAFs) as a basis for establishing the regulatory levels. (As mentioned above, the existing TC used a generic DAF of 100 which was not derived from modeling, but rather was an estimated factor indicating the potential for substantial hazard.) The extract from the second-generation extraction procedure, the TCLP, was analyzed for the presence of the 52 constituents at the proposed regulatory levels. In choosing the 38 new toxicants, the Agency identified those Appendix VIII constituents for which appropriate chronic toxicity reference levels were available and for which there existed adequate fate and transport data to establish a compound-specific DAF. (Appendix VIII of 40 CFR part 261 is the list of hazardous constituents that the Agency considers in evaluating the potential hazard posed by wastes; these constituents have been shown to have toxic, carcinogenic, mutagenic, or teratogenic effects.)

Chronic toxicity reference levels are those levels below which chronic exposure for individual toxicants in drinking water is considered safe or considered to pose minimal risk (in the case of carcinogens). The Agency decided to use, when possible, human health criteria and standards that have been proposed or promulgated for substances in particular media, because these have already received Agency and public review and evaluation. EPA proposed the continued use of the Drinking Water Standards (DWS) for the 14 existing EP toxicants and use of Recommended Maximum Contaminant Levels (RMCLs) for eight of the constituents being added to the TC list. For the remaining newly added constituents, EPA proposed to establish chronic toxicity reference levels using Reference Doses (RfDs) for non-carcinogens and Risk-Specific Doses (RSDs) for carcinogens.

The RfD is an estimate of the daily dose of a substance that will result in no adverse effect even after a lifetime of exposure to the substance at that dose. In order to account for toxicant exposure from sources other than water (i.e., air and food), the Agency proposed to apportion the RfD based on proportionate compound-specific exposure routes, as is done in developing drinking water standards.

The RSD is the daily dose of a carcinogen over a lifetime that will result in an incidence of cancer equal to a specific risk level. EPA proposed a weight-of-evidence approach, which involves categorizing carcinogens according to the quality and adequacy of the supporting toxicological studies, to establish the risk levels most appropriate for setting chronic toxicity reference levels for carcinogens.

The Agency proposed using a subsurface fate and transport model to calculate constituent-specific DAFs. This model incorporated compound-specific hydrolysis and soil adsorption data, coupled with parameters describing an underground environment (e.g., ground water flow rate, soil porosity, ground water pH). Values for parameters were selected based on review of geological conditions at existing landfills. Since the model was specifically developed to simulate transport of organics and a model for inorganics could not be completed in time for the June 13 proposal, EPA proposed to retain the existing EP levels for the eight inorganic toxicants.

The proposed rule introduced the TCLP as a second-generation leaching procedure to replace the existing EP. The main impetus behind the development of the TCLP was the need to address the leaching of organic compounds. However, the Agency also recognized that the EP protocol could be improved in certain ways. The TCLP was described in detail as a proposed revision to Appendix II of part 261. Further supporting information on the TCLP was provided through notices of availability of reports on July 9, 1986 (51 FR 24856) and September 19, 1986 (51 FR 33297). After the TC proposal, the Land Disposal Restrictions final rule (51 FR 40572, November 7, 1986) promulgated the TCLP for monitoring compliance with treatment standards for certain spent solvent wastes and dioxin-contaminated wastes. See Section II.E below for further discussion of these notices.

E. Other Notices Relating to the Proposal

Today's rule is based on three fundamental analytic components that were set forth in the original June 13 proposal: a set of chronic toxicity reference levels, a subsurface fate and transport model, and the TCLP. In addition to the June 13, 1986 proposed

rule described in the preceding section of this preamble, EPA has published several other notices in the Federal Register dealing with these three components. These notices are listed in Table II.1 and are summarized in this section. A more detailed discussion is presented on several of these notices in other sections of this preamble, as identified in Table II.1.

Table II.1--Related Federal Register Notices Discussing One or More of the Analytical Components of the Revised TC

Federal Register Notice	Analytic Component			Relevant preamble section of today's rule
	CTRLs [FN1]	Model [FN2]	TCLP [FN3]	
Jan. 14, 1986, 51 FR 1602 (Proposed LDR framework)	...	----------	X	III.E, III.I
Nov. 7, 1986, 51 FR 40572 (Final LDR approach)	.....	----------	----------	III.F
May 18, 1987, 52 FR 18583 (Consideration of separate wastewater TC)	.....	----------	X	III.A, III.H
May 19, 1988, 53 FR 18024 (CTRLs updated, two-tiered DAF alternative proposed)	..	X	X	III.C, III.D
May 24, 1988, 53 FR 18792 (Proposal to replace particle reduction)	.....	----------	----------	III.F
Aug. 1, 1988, 53 FR 28892 (Proposed modifications to ground water model)	.....	----------	X	III.E

1 Chronic Toxicity Reference Levels.
2 Ground water fate and transport model.
3 Toxicity Characteristic Leaching Procedure.

***11802** EPA's first discussion of the development of regulatory levels through the use of chronic toxicity reference levels in combination with a subsurface fate and transport model was in the proposed rule governing land disposal restrictions for solvents and dioxins (51 FR 1602, January 14, 1986). This proposal introduced the concept involved in “back-calculating” regulatory levels (i.e., multiplying chronic toxicity reference levels by dilution/ attenuation factors) and also discussed the Agency's plan for revising the EP. In the final rule on land disposal restrictions for solvents and dioxins (51 FR 40572, November 7, 1986), EPA decided not to use the “back-calculation approach” for the LDR program in favor of an engineering determination based on the best demonstrated available technology (BDAT). However, the Agency did promulgate the revised TCLP as the leaching procedure to be used in the land disposal restrictions program. Specifically, the TCLP is used to demonstrate that certain wastes meet the best demonstrated available technology standards.

On May 18, 1987, EPA published a Supplemental Notice of Proposed Rulemaking (52 FR 18583) in response to numerous comments on the June 1986 proposal concerning the application of the revised TC to wastewaters. The commenters' main concern was that it may be inappropriate to apply the TC mismanagement scenario (co-disposal of wastes with municipal wastes in an unlined landfill) to wastewaters managed in surface impoundments. The commenters believe that such an approach would result in inappropriately low regulatory levels. The Supplemental Notice outlined several alternatives for the application of the TC to wastewaters that would result in a separate set of regulatory levels for these wastes. The alternative scenario for wastewaters assumed that subject wastes are managed in an unlined impoundment instead of being co-disposed in a municipal

landfill. Sections III.A.2, III.E., and III.H provide further discussion of the Supplemental Notice for wastewaters and related issues.

The Agency then published a Notice of Data Availability and Request for Comments on May 19, 1988 (53 FR 18024), as a result of its concern about uncertainties and technical difficulties involved with developing sufficiently representative dilution/attenuation factors (DAFs) for specific constituents. In that notice, the Agency proposed an alternative to the constituent-specific DAFs in the proposed TC. The Agency presented a two-phased approach to implementing DAFs for the TC. In the first phase, the Agency would use generic DAFs for all 38 new TC organic constituents while the development of constituent-specific DAFs proceeded; once the development of the constituent-specific DAFs was completed, these DAFs would be implemented in the second phase. The Agency specifically requested comment on the use of a generic DAF that would initially bring into the hazardous waste regulatory system the most toxic of the wastes subject to the June 1986 proposal. The Agency also updated the chronic toxicity reference levels for a number of constituents based on newly available information. Section III.C discusses the incorporation of the new information into the chronic toxicity reference levels for specific constituents and Section III.D describes in more detail the two-tiered DAF approach.

In response to numerous comments expressing concern as to whether the particle reduction requirement in the TCLP was appropriate, EPA published a proposal (53 FR 18792, May 24, 1988) requesting comment on modifications to the TCLP as promulgated on November 7, 1986. Based on further experimental evaluation of the original testing methodology, the Agency proposed to modify the TCLP to include a cage insert requirement in place of the particle reduction step for certain materials. The specific revisions discussed in the proposal are presented in detail in section III.F of this preamble, and the TCLP protocol is presented in Section VIII of today's final rule. Today's rule does not include a cage requirement, but rather retains the particle reduction step for monolithic or fixated wastes.

In addition to the above-mentioned modifications, on August 1, 1988, the Agency published a Supplemental Notice (53 FR 28892) introducing potential modifications to the subsurface fate and transport model used to calculate constituent-specific DAFs in the proposed TC. In addition, the Agency presented currently available hydrogeological data on municipal waste landfills and proposed to modify the subsurface fate and transport model to more accurately reflect conditions in the universe of municipal waste landfills. Section III.E presents a more detailed description of the subsurface fate and transport model and the modifications made during its development.

F. Pollution Prevention

In section 1003(b) of RCRA, Congress declared waste minimization to be a national policy. Similarly, EPA has made pollution prevention an Agency objective, in both regulatory and nonregulatory programs. (See EPA's policy statement emphasizing the importance of pollution prevention (54 FR 3845, January 26, 1989).) This policy places highest priority on source reduction (i.e., reducing the volume or toxicity of wastes generated) and use of all pollutants for all sectors of society. A reduction in the amount of waste which must be managed (i.e., by source reduction and recycling) provides direct benefits related to protecting human health and the environment from the mismanagement of hazardous wastes. Pollution prevention measures can also reduce waste treatment and disposal costs, decrease costs for raw materials, minimize liability and regulatory burdens for waste generators, and may enhance efficiency, product quality, and public image. The Agency encourages industries affected by this rule to consider achieving compliance through pollution prevention.

The Agency has taken several steps to create pollution prevention incentives. First, EPA is developing institutional structures within each of its offices to ensure that the pollution prevention philosophy is incorporated into every feasible aspect of internal EPA planning and decision-making. Second, EPA is making technical information available to help firms reduce waste generation. EPA is developing the Pollution Prevention Information Clearinghouse (PPIC), a network of people and resources throughout the United States that have direct experience in many industries. PPIC includes the Electronic Information Exchange System (EIES), and a database of bulletins, programs, contacts, and reports related to pollution prevention. Third, the Agency is supporting the development of state programs to assist generators in their waste reduction efforts. Many states are already providing such help. For example, the Alaska Health Project has published technical assistance packets for specific

industries; North Carolina has a pollution prevention bibliography; and Oregon conducts a hazardous waste reduction program. Finally, EPA has initiated specific regulatory requirements addressing waste minimization. Under the Resource Conservation and Recovery Act (RCRA) regulations, hazardous waste generators are required to certify on their hazardous waste manifests and annual permit reports that they have a program in place to reduce the volume or quantity and toxicity of their hazardous wastes as much as economically practical. RCRA regulations also require ***11803** generators to describe on their RCRA biennial reports the efforts they have undertaken during the year to reduce the volume and toxicity of their hazardous waste and to compare these efforts to previous years.

As important as the efforts just described is the Agency's commitment to ensuring that regulations under development encourage pollution prevention, whenever possible. The TC (TC), we believe, provides significant incentives for pollution prevention. Currently, there is little incentive for industries to implement pollution prevention efforts for unregulated solid wastes. In particular, there are few controls on units handling solid wastes that have the potential for releases of hazardous constituents to groundwater. Large quantities of solid wastes containing TC constituents currently are managed in unregulated land-based units, such as surface impoundments and landfills. Many of these units are in states that are either highly dependent on groundwater for public water supply or where groundwater is hydraulically connected to surface water, or both. By subjecting management of TC wastes to subtitle C regulation, EPA is in effect requiring that waste managers rethink their practices for solid wastes that contain hazardous constituents. EPA's experience has been that hazardous waste regulations provide significant incentives for pollution prevention. For example, some listed wastestreams (e.g., bottoms from tetrachloroethylene production) are now completely recycled.

The characteristic mechanism used by EPA to identify hazardous waste is especially effective in encouraging pollution prevention because it sets a concentration level or criteria (e.g. test) that determines the point at which the waste is no longer regulated as characteristically hazardous. Because of the high cost of compliance with RCRA subtitle C requirements, members of the regulated community will have significant new incentives to reduce TC waste generation as a result of today's rule. Industries will consider substitutes for the specific chemicals on the TC list of toxicants of concern. Where substitutes are not used, there will be incentive to reduce the use of hazardous substances or otherwise limit their concentrations in wastes, in order to keep concentrations of hazardous chemicals below regulatory levels.

Pollution prevention options range from simple good housekeeping practices, e.g., keeping solvents and oils separate to facilitate recycling of each, to more extensive process reconfigurations and/or raw material substitutions. Even in cases where pollution prevention can not eliminate the need for treatment or disposal of hazardous wastes, it may reduce the generation of waste. For example, tank capacity is constrained by land area, engineering considerations, and cost. Managers of TC wastewaters that switch from surface impoundments to exempt tanks will almost certainly have to reduce volumes of hazardous waste generated, or segregate hazardous portions of their wastestreams.

In order to enhance the pollution preventions effects of this rule, EPA is incorporating pollution prevention into the communication strategy for the TC regulation. EPA will provide information targeted to small businesses specifically and industry in general through pamphlets, industry publications and conferences, on the mechanisms described above. We have found that many small businesses are turning to pollution prevention as a result of implementation of the small quantity generator regulations (see 51 FR 10146, March 24, 1986). For example, PPIC documents relate how one drycleaning operation reduced its solvent wastes to a level well below national industry standards by regularly checking for and sealing any system leaks, and installing a conditioning system and a carbon adsorption unit to recover additional solvent. With the new setup, the plant can clean four times as many clothes per drum of solvent. The Agency believes that other industries may have the potential to substitute less toxic source materials in their processes. EPA will consider whether any technical assistance could aid industry in these efforts. EPA would also be interested in suggestions from industries affected by the TC in ways that the Agency might facilitate these efforts. Inquiries should be directed to the Pollution Prevention Office, U.S. EPA, Washington, DC 20460.

In summary, the TC will alter the management of wastes that contain toxicant at hazardous levels by ending management in unregulated land-based units. As industries reassess their waste generation and management practices, many are likely to seriously consider pollution prevention options, and EPA will take steps to facilitate such efforts.

G. Summary of Final Rule

Today's rule retains many of the features of the June 1986 proposal: it replaces the EP with the TCLP; it adds 25 new organic constituents to the list of toxic constituents of concern; and it establishes regulatory levels for the organic constituents based on health-based concentration limits and a DAF developed using the subsurface fate and transport model. In response to comments received on the proposed rule and related notices, the final rule incorporates a number of modifications to the list of constituents, the leaching procedure, the chronic toxicity reference levels, the subsurface fate and transport model, and the schedule for compliance with the TC rule.

With respect to the list of constituents, the final rule includes 25 of the 38 constituents proposed in 1986. One group that has been excluded in the final rule are constituents that appreciably hydrolyze. EPA has been able to develop scientifically valid DAFs for nondegrading constituents but is still improving its approach for developing DAFs for constituents that are expected to hydrolyze appreciably during transport. In particular, the Agency does not yet have a procedure to address toxic hydrolysis byproducts that may be formed.

Second, in response to comments, the Agency has also evaluated the applicability of the steady-state condition assumed in the subsurface fate and transport model, and has determined that the assumption is valid for most of the originally proposed constituents. However, several of the original proposed constituents have been deferred from the final rule while the Agency continues to evaluate the extent to which the steady-state solution is appropriate in determining their fate and transport.

As a result, all the constituents newly regulated under today's rule are nonhydrolyzing or minimally hydrolyzing constituents, and all are constituents for which the steady-state solution is appropriate. For all these constituents, EPA has determined, based on the results of its subsurface fate and transport model, that use of a DAF of 100 is appropriate for setting regulatory levels. This DAF is sufficient to capture only those wastes that are clearly hazardous. As a result of the Agency's decision to regulate only nonhydrolyzing or minimally hydrolyzing constituents and those for which the steady-state solution is appropriate, 25 additional constituents are being regulated rather than the originally proposed 38. Regulatory levels for hydrolyzing constituents, as well as those constituents for which there remain questions as to whether the steady-state solution is appropriate, will be discussed in future notices.

The list of constituents regulated in today's rule and their respective regulatory levels are presented in Table II.2. As in the proposed rule, where the ***11804** calculated regulatory level (i.e., the chronic toxicity reference level multiplied by the DAF) is below the analytical quantitation limit, the quantitation limit is the final regulatory level. Note that the list of constituents in Table II.2 contains the 14 constituents currently regulated under the existing EPTC. As specified in today's rule, these constituents will continue to be regulated at their current levels.

Table II.2.--Toxicity Characteristic Constituents and Regulatory Levels

EPA HW No. [FN1]	Constituent [FN2]	CAS No.	Chronic toxicity reference level (mg/L)	Regulatory level (mg/L)
D004	Arsenic	7440-38-2	0.05	5.0
D005	Barium	7440-39-3	1.0	100.0
D018	Benzene	71-43-2	0.005	0.5
D006	Cadmium	7440-43-9	0.01	1.0

D019 ..... Carbon tetrachloride 56-23-5 0.005 0.5
D020 ..... Chlordane 57-74-9 0.0003 0.03
D021 ..... Chlorobenzene 108-90-7 1 100.0
D022 ..... Chloroform 67-66-3 0.06 6.0
D007 ..... Chromium 7440-47-3 0.05 5.0
D023 ..... o-Cresol ..... 95-48-7 2 [FN4] 200.0
D024 ..... m-Cresol ..... 108-39-4 2 [FN4] 200.0
D025 ..... p-Cresol ..... 106-44-5 2 [FN4] 200.0
D026 ..... Cresol ..... ---------- 2 [FN4] 200.0
D016 ..... 2,4-D 94-75-7 0.1 10.0
D027 ..... 1,4-Dichlorobenzene 106-46-7 0.075 7.5
D028 ..... 1,2-Dichloroethane 107-06-2 0.005 0.5
D029 ..... 1,1-Dichloroethylene 75-35-4 0.007 0.7
D030 ..... 2,4-Dinitrotoluene ..... 121-14-2 0.0005 [FN3] 0.13
D012 ..... Endrin 72-20-8 0.0002 0.02
D031 ..... Heptachlor (and its
hydroxide) 76-44-8 0.00008 0.008
D032 ..... Hexachlorobenzene ..... 118-74-1 0.0002 [FN3] 0.13
D033 ..... Hexachloro-1,3-butadiene 87-68-3 0.005 0.5
D034 ..... Hexachloroethane 67-72-1 0.03 3.0
D008 ..... Lead 7439-92-1 0.05 5.0
D013 ..... Lindane 58-89-9 0.004 0.4
D009 ..... Mercury 7439-97-6 0.002 0.2
D014 ..... Methoxychlor 72-43-5 0.1 10.0
D035 ..... Methyl ethyl ketone 78-93-3 2 200.0
D036 ..... Nitrobenzene 98-95-3 0.02 2.0
D037 ..... Pentachlorophenol 87-86-5 1 100.0
D038 ..... Pyridine ..... 110-86-1 0.04 [FN3] 5.0
D010 ..... Selenium 7782-49 2 0.01 1.0
D011 ..... Silver 7440-22-4 0.05 5.0
D039 ..... Tetrachloroethylene 127-18-4 0.007 0.7
D015 ..... Toxaphene 8001-35-2 0.005 0.5
D040 ..... Trichloroethylene 79-01-6 0.005 0.5
D041 ..... 2,4,5-Trichlorophenol 95-95-4 4 400.0
D042 ..... 2,4,6-Trichlorophenol 88-06-2 0.02 2.0
D017 ..... 2,4,5-TP (Silvex) 93-72-1 0.01 1.0
D043 ..... Vinyl chloride 75-01-4 0.002 0.2

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1 Hazardous waste number.
2 Chemical abstracts service number.
3 Quantitation limit is greater than the calculated regulatory level. The quantitation limit therefore becomes the regulatory level.
4 If o-, m-, and p-cresol concentrations cannot be differentiated, the total cresol (D026) concentration is used. The regulatory level for total cresol is 200 mg/l.

The regulatory levels reflect modifications to some chronic toxicity reference levels since the original proposal. EPA has revised some of the Maximum Contaminant Levels, Risk-Specific Doses, and Reference Doses to reflect new data and better methods. In response to comments received, EPA has decided not to apportion reference doses of noncarcinogens to account for multiple routes of exposure, as was originally proposed (51 FR 21648). See section III.C for further discussion of comments on apportionment and the Agency's reasons for not including apportionment of reference doses in the final rule. Today's rule also promulgates the TCLP to replace the EP. The TCLP represents an improvement over the EP in that it more accurately addresses leaching potential for use in evaluating wastes containing organic constituents, and also corrects several minor technical deficiencies in the original EP. The version of the TCLP promulgated today reflects additional improvements and modifications made to the TCLP since the original proposal. The TCLP promulgated today will also replace the earlier version of the TCLP promulgated as part of the land disposal restrictions program.

Today's rule incorporates a schedule for compliance that classifies the universe of potentially affected TC waste handlers into two groups: (1) All generators of greater than 100 kg/month and less than 1,000 kg/month of hazardous waste (small-quantity generators) must come into compliance with the subtitle C requirements for management of their TC waste within 1 year; and (2) all generators of 1,000 kg/month or more of hazardous waste are required to comply with all subtitle C requirements for TC wastes within 6 months. The phased schedule for compliance is further discussed in section V.

Wastes identified as hazardous under the Toxicity Characteristic will also become hazardous substances under section 101(14) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. Today's rule amends the list of reportable quantities (RQs) in 40 CFR part 302 by adding appropriate values for each of the new 25 TC toxicants. All of the newly- ***11805** designated TC toxicants are already listed as CERCLA hazardous substances. The RQs being promulgated are the same as those that already apply to all materials containing these hazardous substances.

Today's rule defers applicability of the TC to one type of waste and exempts another. First, the Agency is deferring the applicability of the TC to petroleum-contaminated media and debris at sites subject to the RCRA Underground Storage Tank (UST) cleanup regulations under part 280. (See section III.I.6.) Second, EPA has decided to exempt from today's rule certain polychlorinated biphenyl (PCB) wastes that are fully regulated under the Toxic Substances and Control Act (TSCA) and would be identified as hazardous because of today's rule (See section III.J.7.).

In portions of the existing codified waste regulation of title 40, chapter I, parts 261 through 265, the EPTC is named. Today's action of promulgating the TC necessitates amendment of these references to the EPTC. This amendment which replaces references to the EPTC with the words “Toxicity Characteristic” applies to the following sections of 40 CFR: 261.4(b)(6)(i) not (A)(B)(C); 261.4(b)(9), 264.301(e)(1), 265.221(d)(1) and 265.273(a).

In §§ 264.301(e)(1) and 265.221(d)(1), in addition to amending reference to the EPTC, the universe of constituents remains the same as the EPTC. To accomplish this, the constituents D004-D017, the EPTC constituents, are specifically named as those constituents which would not render the waste hazardous by the TC.

As discussed below, the Agency will continue to refine the TC in order to provide greater accuracy and comprehensiveness in identifying hazardous waste based on the waste's toxic constituents. However, the Agency believes that today's rule fulfills the statutory mandates under sections 3001(g) and 3001(h).

III. Response to Major Comments and Analysis of Issues

The Agency received many comments on the June 13, 1986 proposed rule and in response to subsequent notices. The Agency has carefully considered all comments in the preparation of this final rule. To facilitate the evaluation and response to comments, the Agency grouped the comments into ten categories. The categories are as follows:

A. General Approach

B. Constituents of Concern

C. Chronic Toxicity Reference Levels

D. Use of Generic DAFs

E. Application of a Subsurface Fate and Transport Model

F. The TCLP

G. Testing and Recordkeeping Requirements

H. Applicability to Wastes Managed in Surface Impoundments

I. Relationship to Other RCRA Regulations

J. Relationship to Other Regulatory Authorities

In this preamble, the Agency provides summaries of and responses to major comments. Readers are invited to refer to background documents (Refs. 1, 2, 3, and 4) for complete summaries and responses to all comments.

A. General Approach

1. Expanded Use of Hazardous Waste Characteristics.

The TC revisions specified in today's rule refine and expand the EPTC. Most commenters stated that increased reliance on hazardous waste characteristics is a reasonable approach to defining hazardous waste. Some commenters stated a preference for the hazardous waste characteristic mechanism over the alternative listing mechanism for identifying hazardous wastes. They noted that the characteristics are designed to measure directly the risks that subtitle C regulations are meant to control. Another advantage mentioned by commenters is that hazardous waste characteristics apply uniformly to all wastes, regardless of source.

A few commenters, however, objected to the expanded use of hazardous waste characteristics. Some of these commenters questioned the Agency's authority to develop the TC. One commenter asserted that RCRA section 3001(h) does not authorize EPA to take the action of adding the proposed organic constituents to the list of TC constituents. Another argued that the legislative history of HSWA indicates that changes in the leaching procedure should address the leaching of toxic metals only. This commenter claimed that the Agency had exceeded its statutory mandate by modifying the TC to include organics.

EPA strongly disagrees with those commenters who argued that the Agency lacks authority to expand the TC. The Agency's approach to identifying hazardous wastes through a self-implementing characteristics procedure was well established in 1984, when Congress passed HSWA. HSWA not only confirmed the validity of EPA's approach to identifying hazardous wastes by characteristics, but also directed the Agency to expand the scope of the TC. RCRA section 3001(h) states "* * * the Administrator shall promulgate regulations under this section identifying additional characteristics of hazardous waste, including measures or indicators of toxicity." Thus, the plain language of the statute authorizes EPA to broaden the TC.

Other commenters acknowledged EPA's authority to expand the TC, but offered policy arguments against the use of this mechanism for identifying hazardous wastes. Most commenters who argued against expanded use of characteristics favored use of the listing mechanism instead of an expanded TC. Some of these commenters noted that listings do not present the same technical problems of precision and accuracy as the characteristics. Others stated that listings are more easily enforced since they are not dependent upon use of a leaching procedure. Finally, some commenters claimed that by expanding the toxicity characteristic instead of listing additional wastes, EPA is unfairly shifting the burden for identifying hazardous wastes onto the shoulders of the regulated community.

The Agency maintains that the expanded use of characteristics, in addition to being consistent with the statutory mandate, offers advantages over listing for identifying broad categories of clearly hazardous waste. Establishing a characteristic allows the Agency to identify through one rule those wastes which are reasonably certain to pose a threat to human health and the environment by virtue of an inherent characteristic without expending vast Federal resources to study, characterize, and list numerous individual wastestreams. Since the Agency sets regulatory levels high enough to assure that wastes exhibiting the characteristic are hazardous, the characteristic approach does not bring wastes into the subtitle C system which do not present a substantial present or potential hazard to human health and the environment. By contrast, a listing, since it applies to all wastes that meet a listing description, may capture some individual wastestreams that do not actually pose a threat to human health and the environment. Generators may petition for delisting if this occurs; however, the delisting process can be burdensome to the petitioner and to EPA.

The Agency believes that the characteristic approach has the following advantages. First, it is less burdensome for the regulated community because the characteristic approach limits over-inclusiveness. ***11806** Second, reducing the potential of including wastes that do not, in fact, present a threat conserves hazardous waste management capacity and Agency administrative and enforcement resources for waste management activities that warrant priority attention. Finally, if necessary, a characteristic can be adapted quickly to possible future changes in science or technology, such as lower quantitation limits.

EPA acknowledges that there are also some advantages in using the listing mechanism for identifying hazardous wastes, particularly with respect to ease of implementation; the Agency thus will retain the listing approach as an alternative mechanism for identifying hazardous wastes. The Agency continues to believe that both the characteristic and listing approaches are valid and useful tools in identifying hazardous wastes that are subject to subtitle C regulation.

Finally, the Agency disagrees with commenters who contend that characteristics impose an unfair burden on the regulated community. Since the establishment of the hazardous waste identification framework in 1980, EPA has recognized that the primary responsibility for determining whether wastes exhibit hazardous waste characteristics rests with generators. In accordance with this, one of two criteria for establishing new characteristics is that they must be measurable by standardized and available testing protocols or reasonably detected by generators through their knowledge of the waste (see 40 CFR 261.10). Further, the regulations do not require testing; a generator may apply knowledge of the waste to determine if it is hazardous (40 CFR 262.11).

2. Mismanagement Scenario

Hazardous waste characteristics are designed to identify solid wastes that pose a threat to human health and the environment when improperly managed (RCRA section 1004(5)). Therefore, in developing the TC, EPA's first task was to determine how wastes might plausibly be mismanaged. The mismanagement scenario that both was reasonably realistic and presented the greatest environmental risks could then be chosen as the reasonable worst-case scenario and used as the basis for the revised characteristic. Specifically, the characteristic would be designed to identify any wastes from which toxic constituents would be likely to pose a threat to human health and the environment when managed in accordance with the selected scenario. In this way, EPA ensured that wastes would be adequately controlled, regardless of the manner in which they are actually managed.

In the June 13, 1986 proposal, EPA considered several alternative mismanagement scenarios for use in the development of the TC rule, including segregated management, co-disposal with municipal solid waste (the mismanagement scenario evaluated in the existing Toxicity Characteristic), co-disposal with industrial waste in a landfill subject to subtitle D requirements, and co-disposal with industrial waste in a landfill subject to subtitle C requirements that suffers some form of containment-system failure. The Agency rejected the subtitle C scenario as unrealistic because it is unlikely that waste generators would dispose of their wastes in the more expensive subtitle C landfills unless required to do so. Thus, it would not be a realistic scenario.

EPA determined that each of the remaining options was a plausible mismanagement scenario since most wastes are or may be managed in these types of land disposal facilities. The Agency rejected the segregated management or “monofill” scenario on the grounds that it did not represent a realistic worst-case practice. Facilities dedicated to the management of only one waste or the wastes of only one generator (i.e., a “monofill”) are likely to pose less of a hazard than general municipal or industrial landfills because the design and operation problems for a monofill are simpler and the operators generally have considerably more information on the properties of the wastes that are managed. Also, industrial monofills generally do not generate organic acids that result in an aggressive leaching medium, as is the case for municipal landfills. Thus, industrial monofills pose less of a potential hazard than municipal solid waste (MSW) landfills. EPA also rejected the general (as opposed to “monofill”) industrial landfill scenario on similar grounds (i.e., the generated leaching medium may not, in some cases, be as aggressive as in a municipal landfill). The Agency therefore retained the municipal landfill scenario as the reasonable worst-case mismanagement scenario for the revised TC.

a. Extent to Which Scenario is Reasonable. Several commenters challenged the municipal landfill scenario, claiming that it is based on an unreasonable assumption about the way in which industrial solid wastes are managed. These commenters claimed

that industrial wastes are rarely disposed in MSW landfills. If landfilled at all, these wastes are more likely to be disposed in industrial landfills. In addition, industrial wastes are frequently managed in ways other than landfill disposal (e.g., incineration, recycling, treatment on the land, or treatment in surface impoundments). Thus, commenters argued, it is inappropriate to base the TC on the municipal landfill scenario.

EPA fully recognizes that not all industrial wastes are managed in MSW landfills. Nevertheless, the Agency continues to believe that the MSW landfill scenario is reasonable because such landfills have traditionally accepted unregulated industrial wastes. It is for this reason that the MSW landfill scenario was originally established as the basis for the EPTC (see 45 FR 33112, May 19, 1980). Although fewer types of industrial wastes are being disposed in municipal landfills now as compared to a few years ago, EPA's information confirms the continued appropriateness of this scenario. The “State Subtitle D Regulations on Solid Waste Landfills” (Ref. 5), and the “National Survey of Solid Waste (Municipal) Landfill Facilities” (Ref. 6) indicate that most states impose few restrictions, if any, on the types of nonhazardous wastes accepted at these facilities; moreover, a substantial quantity of the wastes received (typically five to eight percent) are industrial wastes. Thus, EPA continues to believe that the municipal solid waste landfill scenario represents the most appropriate reasonable worst-case mismanagement scenario.

Many commenters suggested that EPA grant exceptions or variances for wastes that are not co-disposed with MSW. In this way, the TC would apply only to those wastes that are actually managed in accordance with the underlying mismanagement scenario. The commenters noted that EPA could separately develop alternative characteristics for wastes managed in other ways to ensure adequate protection of human health and the environment.

After careful consideration, EPA has decided not to adopt this suggestion for various reasons. Applying the TC only to wastes actually managed as suggested in the mismanagement scenario would involve the creation of a management-based approach to identifying hazardous wastes. EPA's current approach to establishing characteristics which identify certain wastes as hazardous is not contingent upon the way individual wastes are actually managed. Rather, consistent with the RCRA Section 1004(5) definition of hazardous waste, EPA is ***11807** identifying waste “* * * that may pose a substantial present or potential hazard to human health and the environment when improperly * * * managed” (emphasis added).

EPA has considered the possibility of developing management-based characteristics, i.e., different characteristics for categories of waste depending on how they are typically managed. However, the Agency believes that such an approach would present a number of difficulties. For instance, a management-based approach to hazardous waste identification could substantially complicate effective implementation of the RCRA regulations. In particular, it is not always possible to determine—at the point of generation, during transport, or even as a waste enters a treatment, storage, or disposal facility—how a solid waste will ultimately be managed. EPA believes that the most effective and appropriate approach is to identify hazardous waste characteristics, not according to the ways in which individual wastes are managed, but by identifying properties of wastes that would pose a threat to human health and the environment if improperly managed. The Agency maintains that co-disposal with MSW is a mismanagement scenario that is reasonably realistic for most industrial solid wastes.

Another group of commenters suggested that EPA exempt broad classes of wastes that, because of their volume or physical properties, cannot reasonably be placed in a municipal landfill. Commenters specifically mentioned wastewaters, mining wastes, and municipal waste combustion ash. They noted that separate characteristics could be developed for each class of wastes that is excluded from the TC, based on the most appropriate mismanagement scenario for each individual category of waste.

After careful consideration of these comments, the Agency agreed that one category of wastes, wastewaters, might warrant special consideration based on the fact that the mismanagement scenario may not be reasonably applicable. Thus, EPA published a Supplemental Notice of Proposed Rulemaking on May 18, 1987 (52 FR 18583), which asked for comment on the development of separate regulatory levels for wastewaters. EPA received considerable information in response to this notice, and reviewed additional information on management of wastewaters in surface impoundments. After analysis of the waste management techniques, attenuative mechanisms, and hydrogeologic processes that govern constituent transport from surface impoundments, the Agency concluded that the DAFs for nondegrading constituents managed in surface impoundments were

similar to those for the same constituents managed in landfills. Thus, for today's rule, the Agency determined that there is no technical basis for setting separate regulatory levels for wastewaters. This issue is discussed in more detail in subsection C, and further in sections III.E (Application of a Subsurface Fate and Transport Model) and III.H (Applicability to Wastes Managed in Surface Impoundments).

The Agency also does not agree that the mismanagement scenario is unreasonable for either non-exempt mineral processing wastes or municipal combustion ash. Although large volume wastes from the extraction, beneficiation and processing of ores and minerals are currently exempt from subtitle C regulation and will not be affected by the TC rule, small volume mineral processing wastes which may be subject to subtitle C regulation (see 54 FR 36592) can plausibly be disposed in municipal landfills. Municipal waste combustion ash can also be disposed in municipal landfills; in fact, the Agency estimates that only about 30 percent of municipal waste combustion facilities utilize ash monofills, and rely principally on municipal landfills for ash disposal. Issues related to the regulation of municipal waste combustion ash are discussed further in section III.I.5.

b. Worst-Case Scenario Selection. A few commenters agreed with EPA that the municipal landfill scenario is reasonable, but they claimed that the scenario does not represent a reasonable worst case. Most of these commenters asserted that co-disposal in a subtitle D industrial landfill poses more of a threat to human health and the environment than disposal in an MSW landfill. They pointed out, for example, that the regulatory standards for subtitle D industrial waste landfills are generally no more stringent than those for municipal landfills. The commenters further claimed that the leaching media in industrial landfills are frequently more aggressive than those in municipal landfills, especially when acids, bases, and solvents are present. Finally, the commenters noted that wastes placed in industrial landfills are not diluted with domestic wastes, as they are in a municipal landfill. The commenters concluded that because the TC proposal was based on a scenario that was less than worst-case, it would not adequately protect human health and the environment.

The Agency believes that the leaching media in a subtitle D municipal landfill is typically more aggressive than leaching media generated in industrial landfills due to the formation of acids during decomposition of putrescible wastes. “State Subtitle D Regulations on Solid Waste Landfills” (Ref. 5) shows that putrescible wastes are accepted at most subtitle D municipal landfills, while “Summary of Data on Industrial Non-Hazardous Waste Disposal Practices” (Ref. 7) shows solvents, acids, and bases (which can also increase the aggressiveness of leachate) are generally not disposed of in subtitle D industrial landfills. The potential for the formation of acids from decomposition of putrescibles in a subtitle D municipal landfill is greater than the potential of acids, bases, or solvents being present in a subtitle D industrial landfill, therefore supporting the municipal landfill scenario as a reasonable worst-case.

EPA acknowledges that, in certain circumstances, industrial wastes may pose more of a threat when placed in a subtitle D industrial landfill than when placed in a subtitle D municipal landfill. However, EPA believes that this situation will only occur in certain circumstances and thus represents a worst case rather than a reasonable worst case. Should the occurrence of this situation increase in frequency, the Agency will reconsider its approach for regulating these wastes in the future.

c. Extent to Which the Mismanagement Scenario for Wastes Managed in Surface Impoundments is Appropriate. In the May 18, 1987 notice, the Agency stated that it is considering developing a separate mismanagement scenario applicable to wastes that are managed in unlined surface impoundments. Developing a surface impoundment scenario, in addition to the landfill scenario, would mean that the TC would have two different sets of regulatory levels. Waste generators would first have to determine which scenario is appropriate and then would be responsible for evaluating whether their waste exceeded the applicable regulatory levels.

In the notice, the Agency requested comments on the appropriate criteria to be used in determining whether the characteristic should apply to a particular waste. The Notice suggested three possible approaches:

1. The “management-based” approach, which would apply only to those wastes actually managed in impoundments;

***11808** 2. The “physical property-based” approach, which would apply to those wastes having a certain physical property indicating that they are likely to be managed in surface impoundments (e.g., percent solids less than 5 percent); and

3. The “definition-based” approach, which would apply to those discharged wastewaters that are subject to regulation under either section 402 or section 307(b) of the Clean Water Act.

Commenters from various industries generally supported a separate mismanagement scenario because they do not believe that the landfill mismanagement scenario is appropriate for aqueous wastes managed in surface impoundments. Most of these commenters requested that EPA adopt either the management-based approach or the definition-based approach.

Other commenters, however, opposed a separate mismanagement scenario for wastes managed in surface impoundments. These commenters contended that the surface impoundment mismanagement scenario would not be a reasonable worst-case scenario, particularly if the scenario modeled biodegradation, because significant biodegradation does not occur in all impoundments. In addition, the commenters stated that if the development of a surface impoundment mismanagement scenario results in two sets of regulatory levels, requirements for storage, handling, and transportation of a waste would be based on the management practice that the generator assumes or expects will actually occur. These commenters were opposed to this result and noted that wastes may not always be ultimately disposed in the manner originally intended by the generator.

After receiving these comments, the Agency decided to revisit the issue of whether or not a separate mismanagement scenario is necessary for surface impoundments due to inappropriately low regulatory levels. As described in section III.E.2, the Agency believes that evaluation of the physical phenomena that affect dilution/attenuation factors (DAFs) indicates that the DAFs generated for landfills are similar, if not greater than, DAFs for surface impoundments (i.e., the regulatory levels for surface impoundments would be equal to or more stringent than those for landfills). To confirm this conclusion, EPA then investigated whether results from modeling a surface impoundment scenario would in fact be significantly different from modeling a landfill scenario. As described later in this preamble, for nondegrading constituents, EPA calculated the 85th and 90th percentile DAFs for landfills (which ranged from 134 to 47) and the 85th and 90th percentile DAFs for surface impoundments (which ranged from 111 to 51). The surface impoundment results were obtained by using the updated model (EPACML) for the landfill scenario with leachate generation and environmental parameters (e.g., well distances, facility areas) derived from surface impoundment data.

As a result of this analysis, EPA is confident that the results from modeling of the landfill mismanagement scenario are also appropriate for wastes managed in surface impoundments (i.e., the DAFs are of the same order of magnitude). The Agency therefore does not plan to develop a separate surface impoundment mismanagement scenario at this time. Since the modeling results indicate that the dilution/attenuation factors for non- and minimally degrading constituents are all on the order of 100, the Agency has concluded that a single value of 100 is an appropriate choice for use in establishing the regulatory levels for all of the constituents addressed in today's rule. (See section III.E. of this preamble for an additional explanation of EPA's modeling efforts and choice of DAFs.)

3. Targeted Risks

Several commenters argued that, even if the co-disposal mismanagement scenario was appropriate, EPA improperly focused on a few selected risks from this scenario. Specifically, they claimed that the Agency restricted its consideration to human health risks resulting from ground water contamination. A number of commenters stated that the Agency should consider additional routes of human exposure, such as air volatilization, surface runoff, and direct contact. One commenter questioned why EPA was not employing the same multimedia risk and exposure models that were originally proposed for use in the land disposal restrictions program (see 51 FR 1602, January 14, 1986).

A few commenters further suggested that EPA take environmental risks (e.g., aquatic toxicity) into account, rather than concentrating exclusively on human health risks. They noted that RCRA section 3001(g), on which the TC rule is based, directs EPA to make changes in the EPTC so that it “accurately predicts the leaching potential of wastes which pose a threat to human health and the environment when mismanaged” (emphasis added).

EPA acknowledges that the characteristic being promulgated today focuses on human health risks from ground water contamination. However, the Agency does not believe that a single characteristic is capable of identifying all wastes that present a threat to human health and the environment. The present TC revisions are only the first step in a long-term strategy to refine and expand the hazardous waste identification program. Future characteristics may address hazards other than human health risks resulting from ground water contamination. EPA continues to believe, however, that ground water contamination, as a route of human exposure, is a priority concern.

4. Accuracy

Several commenters asserted that the proposed TC revisions failed to fulfill the statutory mandate to improve the “accuracy” of the characteristic as a predictor of the leaching potential of solid wastes. Specifically, these commenters argued that, even if EPA selected the proper mismanagement scenario, the Agency failed to model the targeted risks in a reasonable or appropriate manner. (Many of the commenters addressing this issue also focused on the accuracy of individual elements of the characteristic, such as the TCLP, the subsurface fate and transport model, or the chronic toxicity reference levels. These specific concerns are considered in sections III.B through III.F of today's preamble.)

A number of the commenters on the issue of accuracy concentrated on the interrelationship between the various elements of the TC. These commenters pointed out that EPA had employed conservative assumptions at each step in the development of the revised characteristic. They argued that even if these assumptions were reasonable in isolation, they would not be reasonable in combination. According to these commenters, the effect of compounding multiple conservative assumptions would be a characteristic that is unreasonably conservative, thereby resulting in costly overregulation.

Other commenters maintained the opposite position and stated that EPA had employed non-conservative assumptions for many elements of the characteristic. These commenters believe that these assumptions result in a characteristic that is not conservative enough and, thus, not sufficiently protective of human health and the environment.

The Agency disagrees with commenters' assertions that the elements of the TC are either too conservative or not conservative enough. The TC, in particular the fate ***11809** and transport model used to establish the dilution/attenuation factors (DAFs), requires the selection of numerical values for many parameters. Rather than selecting values for each parameter based upon isolated judgments as to what constitutes a “reasonable worst case” value, the Agency used the full range and distribution of values for all parameters for which such data was available. By implementing these data sets through a monte carlo simulation, the model output (i.e., the frequency distribution of DAFs) is as realistic as possible and spans the range of all possible outcomes rather than representing only the “best case,” “reasonable worst-case,” etc. That is, the model output represents all cases, arrayed according to their frequency of occurrence, and does not reflect any qualitative judgement as to what constitutes a “reasonable worst case” or any other “case.” Accordingly, the determination as to which DAF value represents any particular “case” is solely dependent upon the selection of the cumulative frequency level. The Agency's selection of the cumulative frequency level is discussed in section III.E.4.d.

EPA does agree with commenters who recommended that the originally proposed subsurface fate and transport model could be revised to more realistically represent land disposal settings. Accordingly, EPA has modified the original model (EPASMOD) and has collected and incorporated new data into the model. These modifications and data are described in greater detail below (section III.E). The reader is referred to the Response-to-Comments Background Document for the Subsurface Fate and Transport Module (Ref. 1), which presents in detail each of the technical issues raised by public comments on the model and the Agency's responses to these issues. EPA believes that with these changes, the final TC rule represents a reasonable approach to the identification of hazardous wastes.

5. Solvent Override

In the June 13, 1986 TC proposal, the Agency discussed the possibility of incorporating a solvent “override” criterion into the TC because the presence of large amounts of solvents in a waste may result in leachate from the waste mobilizing hazardous constituents from co-disposed nonhazardous waste. The Agency considered setting regulatory levels for solvents based on the total concentration of solvent found in the TCLP extract.

Many commenters claimed that mobilization of toxicants in municipal landfills by industrial solvents is improbable. Commenters argued that there are no data to support the hypothesis that industrial solvents would alter the solubility of hazardous constituents in municipal waste. These commenters asserted that, at levels below their solubility in water, organic solvents exert very little influence on the solubility of other organics. Given the low concentrations of solvent wastes permitted for land disposal, the commenters contended that there is little probability that mobilization will occur. Commenters emphasized that, in general, subtitle D landfills do not accept organic solvents or liquids. Most industrial solvents already are listed hazardous wastes under 40 CFR 261.32 and 261.33 and will be managed in subtitle C hazardous waste facilities. Also, commenters contended that the contribution that industrial solvents will have on the solvent power of a solid-waste-landfill leachate is small compared to the contribution from solvents in household and small quantity generator waste.

Other commenters, however, expressed their support for EPA's proposal to characterize a waste by its ability to leach hazardous constituents from co-disposed wastes. They urged that a method be devised to monitor the influence that solvents have on the solubility of other waste constituents. One commenter suggested that the TCLP leachate could be tested for its ability to dissolve hazardous waste.

After careful consideration of the comments on this issue, EPA has decided not to include a solvent override in today's revision of the TC. EPA is not convinced by commenters who stated conclusively that mobilization of toxicants in municipal landfills by industrial solvents is improbable. EPA also is not convinced that the solvent contribution of industrial wastes at municipal landfills is small compared to that of household waste and small quantity generator waste. Moreover, the comparison to household waste and small quantity generator waste is not relevant to the issue of whether industrial wastes should be regulated based on solvent properties. However, the Agency does agree that there is insufficient data concerning the degree to which industrial solvents would mobilize other hazardous constituents and the amount of solvent wastes that are actually land disposed. Given this lack of data, a solvent override has not been included in today's rule. However, an override may be considered in future rulemakings if information becomes available that indicates a characteristic based on solvent properties is warranted.

One commenter claimed that RCRA does not authorize the imposition of restrictions based on toxicity simply because a substance can mobilize other constituents. The commenter asserted that the authority may reside elsewhere in RCRA, but in that case, a separate rulemaking, not involving the TC, should take place.

EPA does not agree; RCRA clearly authorizes EPA to regulate a waste as hazardous on the basis of its ability to mobilize other constituents. Further, regulating a waste as hazardous based on its ability to mobilize other constituents could be appropriately achieved through the characteristic mechanism. A solid waste is defined as hazardous if its “physical” or “chemical” characteristics “may pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed” (RCRA section 1004(5)). The capacity to mobilize toxic constituents falls within the definition of a physical or chemical characteristic of a waste which may pose a substantial environmental or health hazard. Thus, EPA may incorporate this approach into its characteristic waste identification scheme in the future.

Related to the issue of solubilization, another commenter asserted that if a chemical's capacity for mobilization is considered, treatment implemented to prevent mobilization (e.g., stabilization, containment, and chemical conversion) should be given equal consideration.

The TCLP does consider immobilization in the context of the co-disposal mismanagement scenario. The TCLP was developed to simulate leaching in a municipal landfill, addressing the degree of mobility (or, conversely, immobility) of both organic and

inorganic compounds. Wastes that have been treated to prevent mobilization are less likely to leach toxic constituents. Such wastes may cease to exhibit the TC and would therefore no longer be considered hazardous wastes. Thus, the TCLP already accounts for immobilization of toxic constituents in a waste. However, if wastes that have been treated to prevent mobilization fail the TC, EPA believes that the wastes in question should be managed as hazardous wastes.

B. Constituents of Concern

As noted above, the proposed TC rule identified 52 constituents that, if present at specified levels in a waste extract, ***11810** would render the waste "hazardous" under RCRA subtitle C. Fourteen of the constituents were already encompassed by the existing EPTC. The selection of the remaining 38 constituents was based on the availability of adequate and verified data necessary for establishing (1) a chronic toxicity reference level and (2) a constituent-specific DAF. Thus, the Agency focused on those constituents for which there existed a promulgated or proposed Maximum Contaminant Level (MCL), a Reference Dose (RfD), or a Risk-Specific Dose (RSD), and for which there were sufficient data on environmental fate and transport processes to support modeling of a constituent-specific DAF. The June 13, 1986 proposal also announced EPA's intention to expand the list of TC constituents as additional data became available.

1. Final List of Constituents

The Agency is finalizing the regulatory levels for 25 of the proposed organic constituents (see Table B-1) that do not readily hydrolyze and for which a steady-state subsurface fate and transport model is appropriate. EPA may promulgate or repropose (as warranted) regulatory levels for the other organic constituents at a future date.

Table B-1.--List of Organic Constituents Included in the Expanded TC Rule

Benzene	Hexachloro-1,3-butadiene
Carbon tetrachloride	Hexachlorobenzene
Chlordane	Hexachloroethane
Chlorobenzene	Methyl ethyl ketone
Chloroform	Nitrobenzene
m-Cresol	Pentachlorophenol
o-Cresol	Pyridine
p-Cresol	Tetrachloroethylene
1,4-Dichlorobenzene	Trichloroethylene
1,2-Dichloroethane	2,4,5-Trichlorophenol
1,1-Dichloroethylene	2,4,6-Trichlorophenol
2,4-Dinitrotoluene	Vinyl chloride
Heptachlor (and its hydroxide)	----------

Constituents with regulatory levels established under the EPTC will continue to be regulated at previously established levels, but will require application of the new TCLP instead of the EP.

2. Toxicants Versus Indicator Parameters

A few commenters recommended that EPA abandon its current focus on individual toxicants and rely instead on such indicator parameters as total organic carbon or total organic halogens. The commenters argued that such an approach would broaden the effective scope of the rule and reduce the burdens associated with making hazardous waste determinations.

The Agency does not believe it would be appropriate to use indicators as part of the TC. Indicators generally are used as screening levels or to set priorities for further investigations. They do not achieve sufficient specificity for the regulatory purposes of the TC. For instance, the two indicators suggested by the commenters do not in any way reflect differences in toxicities among organic constituents. Consequently, use of these indicators could lead to both nonhazardous wastes registering as hazardous and wastes that are clearly hazardous registering as nonhazardous.

3. Method for Selecting Constituents

Several commenters questioned the manner in which EPA selected toxicants for inclusion in the TC proposal. Some of these commenters charged that the Agency's choice of toxicants was entirely arbitrary. Others claimed that EPA had based its selections solely on the availability of toxicologic and hydrogeologic data, without considering the magnitude of the hazards presented by the constituents.

The commenters, in general, encouraged EPA to develop specific procedures and criteria for deciding which constituents should be included in the TC. A few commenters offered particular suggestions for the types of factors that might be considered in evaluating toxicants. The recommended factors included (1) the mobility and persistence of the constituents, (2) the frequency with which particular constituents have been found in industrial wastes or leachates from such wastes, and (3) the extent to which various constituents have been detected in ground water supplies in concentrations capable of posing a threat to human health and the environment.

EPA believes that its method for selecting TC constituents is both rational and consistent with the statutory mandate. While selection of constituents in today's rule is in part based on available toxicological data, it should be noted that both the fate and transport of constituents and the magnitude of hazards posed were also given consideration. The toxicants for which regulatory levels are being promulgated today are persistent and can represent a substantial threat to human health and the environment. Because of the lack of reliable data on the frequency with which certain toxic pollutants are found in leachates or ground water, an approach relying on such information would not provide an accurate and valid basis for selecting constituents. Further, where data do exist concerning the frequency at which certain constituents are found in the environment, accompanying information about risk posed in the environment is often absent.

Although the Agency proposed levels only for toxicants for which it has adequate and verified data, generally these data are available because these toxicants do represent a substantial threat to human health and the environment. The Agency will consider adding constituents as additional toxicological data and other supporting data become available; in making such decisions, the Agency will consider the factors identified by the commenters. Until such data are available, there is no technical basis to determine at what level a waste is hazardous under the TC.

A number of commenters argued that EPA was needlessly “cluttering” the characteristic with low-priority constituents that are either not being produced in the United States or are primarily found in wastes that are already subject to regulation.

The Agency does not agree that a substance no longer manufactured in the U.S. will not pose a threat from waste disposal. Some such substances may be contained in products imported into the U.S. Also, wastes generated during cleanup at Superfund sites or RCRA corrective action sites may exhibit the TC due to the presence of these constituents in wastes disposed at some time in the past. Further, the constituents could be manufactured again in the future.

Several of the toxicants listed in today's rule also appear among the list of discarded commercial chemical products, off-specification products, and container and spill residues, as listed in 40 CFR 261.33. A group of commenters argued that it would be redundant to establish regulatory levels for these toxicants because they are already regulated as listed hazardous wastes. Similarly, several commenters argued that some other listed wastes are regulated as hazardous wastes primarily because they contain constituents that will be regulated under the new TC.

EPA does not agree that setting levels for the selected toxicants would be redundant. While it is true that many of the newly designated TC constituents are constituents in wastes that are specifically listed as RCRA hazardous wastes, the current listings do not cover all of the wastestreams that may contain the TC constituents. For example, the commercial chemical product listings in 40 CFR 261.33 primarily encompass ***11811** unused products and off-specification variants of products that are generically identified using the name of a single toxic constituent; however, the listings would not cover other wastestreams containing the same constituent. The listings in 40 CFR 261.32 specify only a limited number of wastestreams that contain TC constituents. As another example, the spent solvent listings in 40 CFR 261.31 cover only those solvents that are used for their

"solvent" properties (i.e., to solubilize or mobilize other constituents). The current listings do not encompass process wastes where solvent constituents are used as reactants or ingredients in the formulation of commercial chemical products. The Agency has previously stated that it is expanding the TC to bring these wastestreams into the hazardous waste management system (see 50 FR 53317, December 31, 1985). Thus, the Agency is appropriately promulgating TC regulatory levels for some constituents that have been used as the basis for listings.

One commenter argued that EPA's approach in selecting TC constituents was too restrictive, ensuring that many toxic constituents may never be regulated. The commenter emphasized that reliance on MCLs, RfDs, and RSDs does not provide a comprehensive list of constituents for which reliable toxicological data exist. In addition, the commenter noted that reliance on human health data does not necessarily address hazards to the environment.

EPA disagrees with the commenter's first point. Reliance on MCLs, RfDs, and RSDs uses the most sound toxicologic data base available to the Agency. At present, there are more than 365 constituents with verified toxicity levels available for EPA use. In regard to the second point, the Agency recognizes that factors other than human health effects are also important to the overall protection of the environment, but points out that the purpose of this characteristic is to identify wastes that pose hazards to human health via a ground water contamination route. In regard to the other factors, the Agency is supporting a research effort focusing on the determination of action levels for ecological effects and evaluating appropriate exposure assessment tools. When sufficient information concerning these ecological risks is available, the Agency will compare the ecological-risk-based levels to the TC regulatory levels to determine whether further revisions to these levels, based on ecological risk, are necessary.

4. Specific Organic Constituents

Many commenters expressed concern over several of the specific organic constituents that EPA proposed to include in the TC. The comments focusing on specific toxicants are discussed below.

a. Vinyl Chloride. A few commenters objected to the inclusion of vinyl chloride in the TC. They suggested that the constituent is already adequately regulated under the Clean Air Act, the Safe Drinking Water Act, the Toxic Substances Control Act, and the Food, Drug, and Cosmetic Act (for food contact applications).

The commenters are correct in stating that vinyl chloride and polyvinyl chloride are already regulated under other environmental health and safety statutes. However, none of these other regulatory authorities address the specific problem of ensuring against releases of vinyl chloride caused by the improper management of solid wastes containing this constituent. Most importantly, none of the authorities directly protect ground water supplies from vinyl chloride contamination. Because vinyl chloride is known to be toxic to humans and has been detected in ground water supplies, EPA believes that regulating the constituent under RCRA will add significantly to the protection of human health and the environment. An analysis completed as part of the Regulatory Impact Analysis (Ref. 8) of this regulation indicates that large quantities of wastes currently not regulated as hazardous contain concentrations of vinyl chloride above the regulatory levels. Therefore, the Agency believes that RCRA regulation under the TC is an important expansion of the overall regulatory coverage of this constituent which poses a threat to human health and the environment.

b. Bis(2-chloroethyl) Ether. One commenter questioned whether incorporating bis(2-chloroethyl) ether into the TC is appropriate, since only an extremely limited quantity of the constituent could potentially be released into the environment. The commenter noted that the constituent is used almost exclusively as an intermediate in the production of ionene polymers. Moreover, it is handled primarily by a single facility, which either recycles the material or destroys it by biodegradation prior to discharge under a National Pollutant Discharge Elimination System (NPDES) permit.

The Agency is not promulgating standards for bis(2-chloroethyl) ether today. As discussed in section III.E.2.a.7, bis(2-chloroethyl ether) is expected to hydrolyze significantly during transport. EPA does not have sufficient data to address the formation and toxicity of hydrolysis products. Thus, the Agency expects to address appropriate regulatory action for this constituent, along with the other hydrolyzing constituents, in a future Federal Register notice.

c. Toxaphene. One commenter questioned the need to include toxaphene in the list of TC analytes. The commenter argued that toxaphene has not been produced in the United States for several years and that generators should not be required to test their wastes for “phantom” constituents that are unlikely to be present.

EPA recognizes that toxaphene is no longer produced domestically. However, because previously generated toxaphene wastes are still being managed in treatment, storage, and disposal facilities there is still a potential threat to human health and the environment from improper management of wastes containing this constituent. Thus, wastes containing toxaphene above the regulatory level should be managed as hazardous wastes.

Moreover, toxaphene has been regulated as an EP constituent since 1980 and today's rule retains the existing regulatory level. Thus, today's rule does not alter any regulatory requirements with respect to toxaphene. The Agency does not believe that maintaining toxaphene as a TC constituent is unnecessarily burdensome to the regulated community. The final TC rule does not require solid waste generators to test their wastes. Instead, generators may continue to determine whether their wastes exhibit the hazardous waste characteristics by relying on their knowledge of the materials and processes that they employ (see 40 CFR 262.11(c)(2)). Accordingly, generators who have reason to believe that their wastes contain no toxaphene are not specifically required to test for that constituent.

d. Phenol. One commenter urged EPA to delete phenol from the list of TC constituents of concern because phenol biodegrades under both aerobic and anaerobic conditions.

The Agency is not including phenol in today's rule because the steady-state assumption used in the model to calculate DAFs in this final rule may not be appropriate for phenol. The Agency will promulgate a TC regulatory level for phenol at a later date.

The issue of biodegradation is discussed in section III.E.2.a.9 as it pertains to phenol and other constituents.

***11812** e. Pentachlorophenol. The Agency is considering revisions to the regulatory level for pentachlorophenol (PCP) because new health data indicate that PCP is more toxic than originally assumed. Two studies of different grades of PCP material were conducted by the National Toxicology Program, and the new data indicate that PCP is carcinogenic in male and female mice under the conditions of the bioassay. These studies were used to support the proposal to list additional wastes from the wood preserving industry (53 FR 53282, December 30, 1988).

The Agency is today finalizing the higher regulatory level for PCP although the Agency expects that the regulatory level will decrease in the future. EPA has determined that it is more prudent to effect control at a higher level during the period necessary to take comment on the appropriateness of modifying the TC level.

5. Specific Inorganic Constituents

As noted earlier, EPA did not propose to add any new inorganic TC constituents in the June 13, 1986 proposal. Nevertheless, the Agency received a large number of comments addressing the eight metallic species that were already covered by the EPTC. The Agency also received many comments on the possibility of proposing TC regulatory levels for nickel and thallium (mentioned in the June 13 proposal). The principal comments are discussed below.

a. Silver. A number of commenters urged EPA to delete silver from the list of TC constituents of concern. They pointed out that a variety of studies have demonstrated that the chief effect of silver on humans is argyria, a blue-gray discoloration of the skin and internal organs. The commenters also stated that argyria is generally considered a cosmetic effect, rather than a health effect, because it does not impair the functioning of the body. While the commenters acknowledged that free silver ions may be toxic to aquatic life, they claimed that such ions are rarely discharged into the environment. Moreover, they argued that even if such ions were discharged, they would quickly be converted into insoluble salts, such as chlorides, sulfides, and phosphates. Finally, the commenters asserted that deleting silver from the TC list would be consistent with current EPA policy. They pointed

out that the Agency has not proposed a Recommended Maximum Contaminant Level (RMCL) for silver in drinking water, on the grounds that silver does not cause adverse health effects.

EPA acknowledges that an RMCL (now referred to as a Maximum Contaminant Level Goal, or MCLG) has not been proposed for silver because the only known adverse effect from exposure to silver is argyria. However, the Agency has specifically requested comments on whether it is appropriate to consider argyria a cosmetic effect as opposed to a health effect (see 50 FR 40979, November 13, l985). EPA believes it would be inappropriate to remove silver from the list of TC constituents until this issue is resolved. If EPA determines, within the scope of the Safe Drinking Water Act rulemaking, that silver does not pose a threat to human health and the environment, the Agency will consider proposing the deletion of silver from the list of TC constituents.

b. Chromium. Several commenters objected to the inclusion of total chromium as a TC constituent of concern. They argued that only hexavalent chromium (Cr(VI)) has been demonstrated to pose a threat to human health and the environment. Although they acknowledged that trivalent chromium (Cr(III)) can be oxidized to hexavalent chromium under certain conditions, they contend that such conversion is unlikely to occur in ground water environments. The commenters, in fact, claimed that iron-bearing soils are likely to effect the opposite transformation, from Cr(VI) to Cr(III). Finally, they stated that even if the oxidation reaction did occur, the resulting Cr(VI) concentrations would be so low as not to present a significant danger to human health and the environment.

EPA continues to believe that total chromium concentrations should be considered in determining whether solid wastes qualify as characteristic hazardous wastes. The Agency has long been aware of the fact that trivalent chromium is less toxic than hexavalent chromium. Nevertheless, the Agency also has been concerned that trivalent chromium could be converted to the hexavalent form under certain plausible mismanagement conditions. It is for this reason as well as the fact that the NIPDWS was developed for total chromium that the regulatory level for chromium in the EPTC was originally established on the basis of total chromium concentrations (see 45 FR 33084, May 19, 1980).

The Agency later proposed to amend the EPTC so that it would apply to hexavalent chromium rather than total chromium (45 FR 72029, October 30, 1980; see also 48 FR 22170, May 17, 1983). This proposal was based on the fact that trivalent chromium has significantly lower migratory potential than hexavalent chromium and is less mobile if it does migrate from a waste matrix. At that time, the Agency also believed that there was little likelihood that Cr(III) could oxidize to Cr(VI) under most plausible types of improper waste management.

More recent evidence, however, suggests that the conversion from trivalent to hexavalent chromium may occur in a number of environmental situations (see 51 FR 26420, July 23, 1986, fn. 6). For example, Cr(III) has been found to oxidize readily to Cr(VI) under conditions found in many field soils. This reaction is catalyzed by manganese dioxide, which is commonly present in both soils and sediments. Moreover, it has been shown that water treatment involving chlorination will effectively transform Cr(III) to Cr(VI). The normal presence of residual oxidizing capacity in treated water is capable of maintaining dissolved chromium in the higher valence state (50 FR 46966, November 13, 1985). Thus, if trivalent chromium is present in high concentrations in well water, chlorination can result in correspondingly high concentrations of hexavalent chromium at the point of exposure (i.e., at the tap).

For these reasons, EPA's original concerns regarding the potential for trivalent chromium to be converted to hexavalent chromium remain. Thus, the Agency believes that the prudent course is to regulate total chromium concentrations under the TC. It should be noted that because of this, the Agency is considering proposing the deletion of the exclusion for specific chromium wastes that contain virtually no hexavalent chromium [see 40 CFR 261.4(b)(6)(i)]. Such a change would affect certain wastes from the leather tanning and finishing industry (as well as certain sludges from the production of TiO2 pigment using chromium-bearing ores by the chloride process).

c. Nickel and Thallium. Several commenters expressed support for incorporating nickel and thallium into the list of TC analytes. One commenter emphasized that unless such a step is taken, a major inequity will continue to exist in the regulation of listed and unlisted wastes that contain comparable levels of nickel. Many other commenters, however, objected to the inclusion of nickel and thallium in the TC. Most of these commenters doubted whether either element poses a threat to human health and the environment, noting that neither one is on the Primary or Secondary Drinking Water Standards list.

***11813** EPA has decided not to add more metals to the TC constituent list at this time because technical issues remain as to their subsurface fate and transport. The regulatory levels for the toxicity characteristic metals are not changed in this rule (i.e., EPA is retaining the regulatory levels set under the previous EP) pending further Agency validation and study of the fate and transport of metals. These validation and study efforts are focusing on the development of the metal speciation model (MINTEQ).

The Agency is developing MINTEQ for the evaluation of the mobility of arsenic, barium, cadmium, chromium, lead, mercury, nickel, selenium, silver, and thallium in ground water. A modified version of MINTEQ will be used in combination with a set of generic ground water specifications and subsurface conditions to determine metal solubility limitations. EPA will then use these results, in conjunction with the subsurface fate and transport model, to estimate dilution during transport to the down-gradient exposure point. (See discussion of the development of the subsurface fate and transport of metals at 51 FR 1653, January 14, 1986.) The Agency is not specifically proposing an approach for evaluating the fate and transport of metals in today's rule, but does expect to propose, at a later time, DAFs specific to metals, including nickel and thallium, and will address comments relating to the toxicity of nickel and thallium at that time.

C. Chronic Toxicity Reference Levels. The Agency proposed to use chronic toxicity reference levels (combined with DAFs) to calculate leachate concentration limits for individual constituents; a waste containing constituents equal to or above those levels would be a hazardous waste under the TC. Specifically, EPA proposed to use the MCLs promulgated as part of the National Interim Primary Drinking Water Standard (NIPDWS), where available, as the starting point for establishing the regulatory levels for each of the constituents. For those constituents for which no MCLs had been promulgated, the Agency proposed to use oral Reference Doses (RfDs) and Risk-Specific Doses (RSDs) to develop chronic toxicity reference levels for the noncarcinogens and carcinogens, respectively. Because exposure to toxic constituents can occur by multiple pathways, the Agency also proposed to apportion the acceptable health risk level of each noncarcinogenic constituent among the various possible routes of exposure. The Agency solicited public comment on: (1) Whether RfDs and RSDs are appropriate to use when MCLs are available; (2) the health levels proposed for RfDs and RSDs; (3) the associated risk levels; and (4) the assumptions used to apportion exposure to the different possible routes. The Agency's decisions regarding the health-related issues for which it solicited comments are presented below.

1. Maximum Contaminant Levels

The original toxicity characteristic—the EPTC (40 CFR 261.24)—used the NIPDWS developed under the Safe Drinking Water Act as the toxicity levels to derive the regulatory levels for the eight metals, four insecticides, and two herbicides then regulated. (For ease of discussion, the acronym “MCLs” will be used in subsequent sections to refer collectively to both MCLs and the existing NIPDWS.) EPA plans to continue this approach in the expanded TC for those constituents for which MCLs are available.

A number of commenters expressed support for the use of MCLs, when they exist, as the starting point for calculating regulatory levels for the TC. Most of these commenters argued that the MCLs provide adequate protection of human health. These commenters stated that MCLs are reliable, scientifically defensible, and recognized and understood by the general public.

Several commenters supported the use of MCLs because factors relating to cost and available treatment technology may be considered along with health effects in the development of the standards. These commenters asserted that MCLs represent a reasonable balance among the factors EPA must consider, while RfDs and RSDs are more limited. A number of commenters also felt that the use of MCLs provides a level of protection consistent with other regulatory programs.

In contrast, other commenters supported the use of RfDs and RSDs as the basis for the chronic toxicity reference levels even when MCLs are available for those constituents. These commenters stated that health-based levels are an appropriate starting point for the regulation. Because the MCLs consider other factors relating to technical and economic feasibility in addition to toxicity, they contend that the RfDs and RSDs are preferable. Many of these commenters also supported a consistent approach for all constituents regulated by the TC, rather than using MCLs for some and RfDs and RSDs for others.

Several commenters asserted that because the MCLs were developed for the purpose of regulating the concentrations of constituents in treated water “at the tap,” it is not appropriate to use the same standards for defining hazardous wastes. Several commenters also expressed concern that the MCLs developed under the Safe Drinking Water Act are potentially more stringent than RfDs and RSDs. This concern was most strongly expressed regarding carcinogens, for which Maximum Contaminant Level Goals (MCLGs), previously referred to as Recommended Maximum Contaminant Levels (RMCLs), are set at zero, and MCLs are set at technically achievable levels that most closely approach this zero goal.

EPA maintains that the MCLs, when they exist, are the most appropriate health criterion to use as the starting point for developing the regulatory levels. The exposure scenario developed for the TC is based on ingesting contaminated drinking water, and because MCLs are developed for regulation of drinking water, they clearly are relevant. In addition, the development of the MCLs follows a rigorous methodology in which all available health information is evaluated in establishing the MCLGs. The MCLs are set as close to the MCLGs as is feasible, and the Agency believes that MCLs are protective of human health.

It should be noted that EPA evaluates the health risks that are associated with various contaminant levels in order to insure that the MCL adequately protects the public health. For drinking water contaminants, EPA sets a reference risk range for carcinogens at 10-4 to 10-6 excess individual risk from lifetime exposure. Most regulatory actions in a variety of EPA programs have generally targeted this range using conservative models which are not likely to underestimate the risk. Since the underlying goal of the Safe Drinking Water Act is to protect the public from adverse effects due to drinking water contaminants, EPA seeks to insure that the health risks associated with MCLs for carcinogenic contaminants are in the general range of 10-4 to 10-6 .

EPA acknowledges that use of MCLs will, in some cases, result in chronic toxicity reference levels that are lower than those that would be calculated using the RfD methodology. For example, many of the non-carcinogenic compounds have MCLs which are approximately 10 to 20 percent of their respective RfDs because exposure sources other than contaminated drinking water are considered in setting the MCLs. On the other hand, the MCLs for some of the constituents addressed in the proposal are higher than the ***11814** levels that would be calculated using the RSD methodology. An example of this situation arises when the health criteria are at such low levels that analytical methods are not available to measure these levels. In cases where the MCL is higher than a purely health-based level, the Agency notes that use of the MCL is not inconsistent with today's rule since the purpose of the rule is to identify wastes that clearly pose hazards, not to identify the lowest level of hazard. However, regardless of whether they are higher or lower than the levels calculated using the RfD or RSD methodologies, EPA believes that MCLs are the appropriate starting point for developing regulatory levels for the TC.

For the constituents lacking MCLs, EPA must rely on the available methodologies to provide chronic toxicity reference levels that are scientifically defensible and protective of human health. EPA believes that the RfD and RSD methodologies meet these two criteria. EPA also realizes that inconsistencies will exist when different methodologies are employed for developing regulatory levels. The Agency intends to evaluate newly promulgated MCLs to determine on a case-by-case basis whether the TC regulatory level will change significantly if the new MCL is used, and to revise the regulatory levels, as appropriate. In the long run, this should provide internal consistency for the TC, as well as consistency with other regulatory programs.

Some commenters supported the use of MCLGs as the basis for chronic toxicity reference levels under the TC because the MCLGs are based on health effects alone, whereas the MCLs consider other factors as well, such as economic and technical feasibility.

EPA disagrees with the commenters who stated that MCLGs are more appropriate than MCLs for use in the TC. MCLGs are nonenforceable health goals for drinking water, which are to be set at levels that would result in no known or anticipated adverse health effects with an adequate margin of safety. The Agency has adopted the policy of setting the MCLGs for probable human carcinogens (Group A and B carcinogens) at zero. If the Agency were to use MCLGs rather than MCLs in the TC, the regulatory levels for defining a waste as hazardous would be based on health criteria that, at least for carcinogens, are more stringent than the criteria used to set concentrations acceptable for direct human ingestion of drinking water. In addition, the regulatory levels would be virtually impossible to detect analytically. This would mean that any waste that contains detectable levels of carcinogens would be hazardous regardless of the potency of the carcinogen or the risk presented by that waste. EPA believes that this is an inappropriate approach for the TC because it would result in the regulation of wastes which are not necessarily hazardous.

2. Risk-Specific Doses for Carcinogenic Constituents

For constituents for which no MCLs have been established, EPA uses oral RSDs to develop chronic toxicity reference levels for carcinogens. The RSD is an upper-bound estimate of the average daily dose of a carcinogenic substance that corresponds to a specified excess cancer risk for lifetime exposure. A predetermined risk level and the oral carcinogenic slope factor estimated by EPA's Carcinogen Risk Assessment Verification Endeavor (CRAVE) Workgroup or Carcinogen Assessment Group (CAG) are used to calculate the RSD.

The Agency proposed a risk level of concern based on the weight of evidence regarding carcinogenicity of each constituent. Constituents classified as known or probable human carcinogens (Group A or B) were assigned a risk level of 1 in 100,000 (i.e., 10-5), while constituents classified as possible human carcinogens (Group C) were assigned a risk level of 1 in 10,000 (i.e., 10-4).

The Agency received comments regarding both the weight-of-evidence approach for establishing risk levels and the risk levels selected. In particular, one commenter supported the Agency's proposal, stating that a single risk level is not appropriate for all constituents, and that use of the weight-of-evidence approach avoids making regulatory decisions based on insufficient data. Another commenter also supported the use of weight-of-evidence to assign risk levels, but stated that it is inappropriate to regulate both known and probable human carcinogens at the same level of risk. Alternatively, a third commenter asserted that the weight-of-evidence approach is inappropriate because (1) new information is constantly being developed on the health effects of toxic constituents, so the weight of evidence is constantly changing, and (2) the classification scheme does not take into account the potency of the carcinogenic risk.

The Agency also received specific comments regarding both the weight-of-evidence approach and the selection of specific risk levels. Several commenters addressed the risk level at which the Agency proposed to regulate carcinogens. Some commenters specifically expressed support for EPA's proposal to regulate Class A and B constituents at a 10-5 risk level and Class C constituents at a 10-4 risk level. One commenter stated that because the procedure for developing risk estimates is extremely conservative, the proposed risk levels would not adversely affect human health and the environment. Another commenter noted that the stated risk levels are estimates of the upper confidence bound of risk and not the maximum likelihood estimate; thus, the actual risk to the public would be less than the stated level.

Other commenters supported the use of a 10-6 risk level for all carcinogens. These commenters argued that the use of the proposed risk levels represents a serious weakening in EPA's regulation of carcinogens and is inconsistent with other policies in effect in other EPA programs.

With respect to the weight-of-evidence approach, the Agency has decided to establish a single risk level of concern for all potential carcinogens (i.e., the Agency will not assign a specific risk level to a specific weight-of-evidence carcinogenicity classification for this rulemaking). The weight-of-evidence approach for classifying a constituent as carcinogenic is based primarily on the amount and quality of data that are available rather than the strength of the toxic response in animals or humans. In effect, it is a qualitative assessment that takes into account the uncertainty in the data for determining whether an agent

is carcinogenic to humans. This means that the actual quantitative difference in risk between an “A” and “B” carcinogen as classified by the weight of evidence may either be zero or may be orders of magnitude. Thus, EPA believes that both the weight-of-evidence and the strength of the toxic response (i.e., potency) should be considered in making regulatory decisions within the context of the TC.

With regard to the specific risk level chosen, the Agency has decided to set the level for carcinogens (Groups A, B, and C) at 1 in 100,000 (i.e., 10-5) for the final rulemaking. Characteristics are established at levels at which the Agency has a very high level of certainty that a waste which exhibits these properties needs to be managed in a controlled manner (i.e., as a hazardous waste). The Agency realizes that not all wastes which exhibit properties at concentrations below the regulatory levels are necessarily safe for disposal as nonhazardous wastes. Rather, those wastes having properties lower than the ***11815** regulatory levels and which are demonstrated to pose a hazard to human health or the environment still remain subject to waste-specific evaluations under the hazardous waste listing program. Wastes which are determined to require controlled management after consideration of the factors identified in 40 CFR 261.11(a)(3) (e.g., the nature of the toxic constituents, toxicant mobility under various environmental management scenarios, volume of waste generated and potential method of management) are then specifically listed as hazardous wastes and subjected to the appropriate RCRA management controls. This reflects EPA's philosophy, first articulated in May of 1980, that the characteristic defines broad classes of wastes that are clearly hazardous, while the listing process defines some wastes that may not exhibit the characteristics but are nonetheless hazardous wastes (45 FR 33111, May 19, 1980).

The chosen risk level of 10-5 is at the midpoint of the reference risk range for carcinogens (10-4 to 10-6) targeted in setting MCLs. This risk level also lies within the reference risk range (10-4 to 10-6) generally used to evaluate CERCLA actions. Furthermore, by setting the risk level at 10-5 for TC carcinogens, EPA believes that this is the highest risk level that is likely to be experienced, and most if not all risk will be below this level due to the generally conservative nature of the exposure scenario and the underlying health criteria. For these reasons, the Agency regards a 10-5 risk level for Group A, B, and C carcinogens as adequate to delineate, under the TC, wastes that clearly pose a hazard when mismanaged.

3. Apportionment of Health Limits

EPA proposed to account for potential exposure from sources other than the TC scenario by apportioning the RfD-based chronic toxicity reference levels. The apportionment scheme effectively reduced each such chronic toxicity reference level to 50 percent of its original value, (i.e., 50 percent of the RfD). The Agency also proposed to estimate environmental partitioning of the apportioned health limits in air and water according to a simplified fractionation scheme using Henry's Law Constants (Hc) and octanol-water coefficients (Kow) for individual constituents. The Agency did not propose to apportion the chronic toxicity reference levels based on RSDs or MCLs.

Several commenters addressed the Agency's proposal to apportion the RfDs. Commenters that criticized the Agency's proposed apportionment scheme argued that it was arbitrary, overly conservative, and unnecessary. Several commenters recommended that EPA either use more realistic estimates of exposure based on the available constituent-specific data or not apportion at all.

After a review of comments on the proposed regulation and consideration of the available data, the Agency has decided not to apportion in this rulemaking. Although the concept of apportionment has some scientific basis in that individuals are exposed to many of the chemicals of concern through more than one route of exposure and from more than one source, the implementation of the concept is very difficult when adequate data on the amount of exposure and/or health effects from all routes of exposure do not exist. Thus, due to the lack of sufficient data to determine an appropriate apportionment factor for the various constituents, the Agency now concludes that its proposed apportionment scheme cannot be supported at the present time. Of course, the proposed apportionment would deal with uncertainty by erring on the side of safety; nevertheless the Agency believes that the conservative approach used to deal with uncertainty in the development of the RfD is sufficiently stringent to define those wastes that clearly pose hazards. This approach is in accordance with the Agency's treatment of noncarcinogens. The Agency therefore will not apportion the RfDs for this rulemaking.

A few commenters criticized the Agency's proposed method for fractionating the apportioned RfD between air and water. These commenters questioned the technical basis of the Agency's approach and/or recommended alternative schemes. The Agency agrees with commenters that the technical basis for supporting fractionation as proposed is inadequate to predict media-specific concentrations. The Agency is exploring the development of an appropriate model. Thus, EPA has decided not to apportion the RfD and not to fractionate the RfD between air and water in this rulemaking.

Other commenters addressed the apportionment of RSDs for carcinogenic constituents. Several of these commenters agreed with EPA's decision not to apportion RSDs, stating that doing so would result in very low regulatory thresholds for some constituents. The commenters also pointed out that many conservative assumptions are already incorporated into the development of the RSDs for carcinogens. Others commented that RSDs should be apportioned because humans are exposed to these constituents by multiple routes.

The Agency continues to believe that it is not appropriate to apportion the RSDs for carcinogenic constituents. RSDs are estimated by a procedure that must deal with unavoidable uncertainties and is therefore intentionally conservative. The Agency stated in the preamble to the proposed rule that a difference in dose of a factor of 2 is still well within the margin of uncertainty of the estimated RSD (51 FR 21667, June 13, 1986).

Table C-1 presents chronic toxicity reference levels for the constituents in today's rule. The Agency received a number of comments on specific chronic toxicity reference levels. In some cases, EPA responded to these comments in the notice of proposed changes to the health levels on May 19, 1988 (53 FR 18024). Other chemical specific comments are addressed in the background document (Ref. 3).

Table C-1.--Chronic Toxicity Reference Levels

Constituent	Chronic toxicity reference level (mg/L)	Basis
Arsenic	0.05	MCL
Barium	1.0	MCL
Benzene	0.005	MCL
Cadmium	0.01	MCL
Carbon tetrachloride	0.005	MCL
Chlordane	0.0003	RSD
Chlorobenzene	1	RfD
Chloroform	0.06	RSD
Chromium	0.05	MCL
o-Cresol	2	RfD
m-Cresol	2	RfD
p-Cresol	2	RfD
2,4-D	0.1	MCL
1,4-Dichlorobenzene	0.075	MCL
1,2-Dichloroethane	0.005	MCL
1,1-Dichloroethylene	0.007	MCL
2,4-Dinitrotoluene	0.0005	RSD
Endrin	0.0002	MCL
Heptachlor (and its hydroxide)	0.00008	RSD
Hexachlorobenzene	0.0002	RSD
Hexachloro-1,3-butadiene	0.005	RSD
Hexachloroethane	0.03	RSD
Lead	0.05	MCL
Lindane	0.004	MCL
Mercury	0.002	MCL
Methoxychlor	0.1	MCL
Methyl ethyl ketone	2	RfD

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Nitrobenzene ..................................................... 0.02 RfD
Pentachlorophenol ................................................ 1 RfD
Pyridine ......................................................... 0.04 RfD
Selenium ......................................................... 0.01 MCL
Silver ........................................................... 0.05 MCL
Tetrachloroethylene ............................................... 0.007 RSD
Toxaphene ........................................................ 0.005 MCL
Trichloroethylene ................................................ 0.005 MCL
2,4,5-Trichlorophenol ............................................ 4 RfD
2,4,6-Trichlorophenol ............................................ 0.02 RSD
2,4,5-TP acid (Silvex) ............................................ 0.01 MCL
Vinyl chloride ................................................... 0.002 MCL
-------------------------------------------------------------------------------
All RSDs are calculated at the 10-5 risk level.
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11816** ***D. Use of Generic Dilution/Attenuation Factors (DAFs)

In the May 19, 1988 supplemental proposal, EPA requested comment on an alternative strategy for setting DAFs in the TC. The alternative involved setting DAFs for these constituents in two phases. The first phase would use a generic DAF in a manner similar to the existing EPTC, which uses a DAF of 100 for all EP constituents. In the second phase, the Agency would further address the manner in which the DAFs are calculated and would either: (1) Continue to use generic DAFs, (2) employ a subsurface fate and transport model to develop constituent-specific DAFs, or (3) use some combination of the two approaches. The Agency also specifically solicited comment on the use of a generic DAF of 100 or 500 in the first phase.

Many commenters recognized the need to expeditiously promulgate the TC; however, most opposed the two-phased approach, arguing that it would cause undue economic burden by: (1) Forcing industries to design new treatment programs for one group of wastes at certain regulatory levels, and a few years later to redesign in order to accommodate new levels and wastes, and (2) over-regulating certain chemical substances under the first generic-DAF phase that may then not be regulated under the second phase. Some commenters were concerned, on the other hand, that EPA would set the generic DAFs so high (to avoid overregulation) that some substances would be under-regulated.

Most commenters opposed the use of generic DAFs and urged EPA to retain the constituent-specific modeling approach. These commenters argued that a generic DAF would be arbitrary and not scientifically defensible; that use of the generic DAFs would violate the statutory requirements to develop a process that accurately assesses leaching ability and differentiates between hazardous and nonhazardous wastes; and that the diversity in dilution and attenuation attributes across the constituents would cause any generic DAF to either severely under-regulate or severely overregulate a large number of the constituents. Even those few commenters who supported the two-phased approach recommended that the Agency move rapidly to the second phase and employ the modeling approach to set DAFs.

EPA acknowledges that the problems noted by the commenters are important ones. The Agency requested comment on the generic DAF approach because of the likelihood that the issues surrounding the proposed fate and transport model for establishing constituent-specific DAFs would not be resolved in a timely manner. Since the Agency has been able to address the concerns regarding the subsurface fate and transport model for the constituents identified in today's regulation, the Agency has decided to use the model to develop DAFs. Consequently, the DAFs set in today's rule for nonhydrolyzing constituents for which the steady-state solution is appropriate are not viewed by EPA as interim and are supported by the subsurface fate and transport model. The Agency intends to establish DAFs for constituents not addressed in today's rule on a constituent-specific basis, and regulatory levels for those constituents will be proposed or promulgated (as warranted) at a later date.

E. Application of a Subsurface Fate and Transport Model

1. Introduction

On June 13, 1986, EPA proposed an approach (see 51 FR 21648) for estimating regulatory concentration levels in a waste leachate using chronic toxicity reference levels, combined with constituent-specific dilution/attenuation factors (DAFs) derived from the application of a subsurface fate and transport model. The model (EPASMOD) was first described for public comment on January 14, 1986 (51 FR 1602).

A DAF represents a reduction in the concentration of a constituent expected to occur during transport through ground water from the bottom of a disposal unit to a drinking-water source. In response to the proposal and supplemental notices (see Section II, Table II.1), the Agency received numerous comments on the subsurface fate and transport model used for the calculation of DAFs. This section describes the different proposals related to the use of the subsurface fate and transport model, the modifications to the model in response to public comments, and the results obtained with the use of the modified model.

a. June 13, 1986 Proposed Rule (51 FR 21648). The Agency's June 13, 1986 proposal used a subsurface fate and transport model (EPASMOD) to calculate specific DAFs for each of the 44 organic hazardous constituents (see Table E-1). The DAFs for each constituent were calculated using the model, incorporating compound-specific hydrolysis and soil adsorption data coupled with parameters describing the subsurface environment (e.g., ground water flow rate, hydraulic conductivity of the aquifer, ground water pH, etc.). The Agency proposed modeling a scenario of waste mismanagement at a subtitle D municipal landfill. Data were incorporated in the model using a monte carlo simulation.

[Note: The following TABLE/FORM is too wide to be displayed on one screen. You must print it for a meaningful review of its contents. The table has been divided into multiple pieces with each piece containing information to help you assemble a printout of the table. The information for each piece includes: (1) a three line message preceding the tabular data showing by line # and character # the position of the upper left-hand corner of the piece and the position of the piece within the entire table; and (2) a numeric scale following the tabular data displaying the character positions.]

****

******** This is piece 1. -- It begins at character 1 of table line 1. ********

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Table E-1.--Dilution

Constituent
Acrylonitrile .....
Benzene .....
Bis(2-chloroethyl)ether .
Carbon disulfide .....
Carbon tetrachloride ....
Chlordane .....
Chlorobenzene .....
Chloroform .....
o-Cresol .....
m-Cresol .....
p-Cresol .....
2,4-D .....
1,2-Dichlorobenzene .....
1,4-Dichlorobenzene .....
1,2-Dichloroethane .....
1,1-Dichloroethylene ....
2,4-Dinitrotoluene .....
Endrin .....
Heptachlor (and its hydroxide) .....
Hexachlorobenzene .....
Hexachlorobutadiene .....
Hexachloroethane .....
Isobutanol .....

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Lindane .................
Methoxychlor ............
Methylene chloride ......
Methyl ethyl ketone .....
Nitrobenzene ............
Pentachlorophenol .......
Phenol ..................
Pyridine ................
1,1,1,2-Tetrachloroethane
1,1,2,2-Tetrachloroethane
Tetrachloroethylene .....
2,3,4,6-Tetrachlorophenol
Toluene .................
Toxaphene ...............
1,1,1-Trichloroethane ...
1,1,2-Trichloroethane ...
Trichloroethylene .......
2,4,5-Trichlorophenol ...
2,4,6-Trichlorophenol ...
2,4,5-TP (Silvex) .......
Vinyl chloride ..........
-------------------------
1...#...10....#...20....#
********************************************************************************
******* This is piece 2. -- It begins at character 26 of table line 1. ********
********************************************************************************
Attenuation Factors for Toxicity Characteristic Organic
Constituents
-------------------------------------------------------------
LOG Kow Ka [FN2] Kb [FN2] Kn [FN2] D/A
[FN1] factor
[FN3]
-------------------------------------------------------------
........ 0.07 >1/yr ..... >1/yr ..... >1/yr ........... 14.4
........ 2.13 NHYF [FN4] NHYF ...... NHYF ............ 14.4
........ 1.04 NH [FN5] .. NH ........ 8E-5/hr ......... 14.4
........ 2.16 NH ........ >10/yr .... NH .............. 14.4
........ 2.96 NH ........ NH ........ NH .............. 14.4
....... [FN7] NH ........ >10/yr .... NH .............. 14.4
5.48
........ 2.87 NH ........ 1E-6/hr ... NH .............. 14.4
........ 1.96 NH ........ 0.23/hr ... 3E-9/hr ......... 14.4
........ 2.15 NHYF ...... NHYF ...... NHYF ............ 14.4
........ 2.15 NHYF ...... NHYF ...... NHYF ............ 14.4
........ 2.15 NHYF ...... NHYF ...... NHYF ............ 14.4
........ 2.70 NHYF ...... NHYF ...... NHYF ............ 14.4
........ 3.56 NH ........ 1E-5/hr ... NH .............. 14.4
........ 3.56 NLFG [FN6] NLFG ...... NLFG ............ 14.4
........ 1.40 NH ........ NH ........ 7.2E-5/hr ....... 75.0
........ 2.13 NLFG ...... NLFG ...... NLFG ............ 14.4
........ 2.30 NLFG ...... NLFG ...... NLFG ............ 14.4
....... [FN7] >1/yr ..... >1/yr ..... >1/yr ........... 14.4
3.54
....... [FN7] NLFG ...... NLFG ...... NLFG ............ 14.4
4.61
........ 6.42 <1/yr ..... <1/yr ..... <1/yr ........... 14.4
........ 4.24 NLFG ...... NLFG ...... NLFG ............ 14.4
........ 4.22 >1/yr ..... >1/yr ..... >1/yr ........... 14.4
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........ 0.74 >1/yr ..... >1/yr ..... >1/yr ........... 14.4
........ 3.40 >1/yr ..... >1/yr ..... >1/yr ........... 14.4
....... [FN7] NH ........ 1.4/hr .... 7.5E-5/hr ....... 14.4
4.30
........ 1.26 NH ........ NH ........ 1.18E-8/hr ...... 14.4
........ 0.30 NLFG ...... NLFG ...... NLFG ............ 14.4
........ 1.90 NLFG ...... NLFG ...... NLFG ............ 14.4
........ 5.06 NH ........ >1E-4/hr .. NH ............... 14.4
........ 1.49 NHYF ...... NHYF ...... NHYF ............ 14.4
........ 0.68 NLFG ...... NLFG ...... NLFG ............ 14.4
....... 2.81 NH ........ 1.3/hr .... 2.2E-7/hr ....... 14.4
....... 2.42 NH ........ 2.6E# 3/hr NH ............... 65.0
........ 3.03 NLFG ...... NLFG ...... NLFG ............ 14.4
....... 4.33 NH ........ 1E-5/hr ... NH ............... 14.4
........ 2.82 NHYF ...... NHYF ...... NHYF ............ 14.4
....... [FN7] NH ........ >10/yr .... NH ............... 14.4
5.30
........ 2.50 NH ........ NH ........ 1.1E-4/hr ...... 150.0
........ 1.91 NH ........ 13/hr ..... 4.3E-7/hr ....... 20.0
........ 2.28 NLFG ...... NLFG ...... NLFG ............ 14.4
........ 3.86 NH ........ 1E-5/hr ... NH ............... 14.4
........ 3.58 NH ........ 1E-5/hr ... NH ............... 14.4
........ 3.45 NLFG ...... NLFG ...... NLFG ............ 14.4
........ 1.38 NH ........ 1E-5/hr ... 1E-7/hr ......... 14.4
-------------------------------------------------------------
26.......#...40....#...50....#...60....#...70....#...80....#.
******************************************************************************
******* This is piece 3. -- It begins at character 1 of table line 59. ********
******************************************************************************
1 Logarithm of the octanol/water partition coefficient.
2 Acid, base and neutral hydrolysis rate constants.
3 Dilution/attenuation factor derived from ground water transport system.
4 NHYF = No Hydrolyzable Functional Group.
5 NH = Negligible Hydrolysis.
6 NLFG = No Liable Functional Group.
7 Estimated value.
1...#...10....#...20....#...30....#...40....#...50....#...60....#...70....#....
```

***11817** In the monte carlo simulation, values for each parameter are based upon the frequency distribution for each parameter (where such data exists) rather than the selection of a single value for each parameter. The model is then run a sufficient number of times (typically several thousand) to produce the frequency distribution of the model's output. This overall frequency distribution is, effectively, a combination of the frequency distributions for each individual parameter. This approach avoids the compounding effects of conservatism inherent in choosing single, reasonable-worst-case values for each parameter. Monte carlo simulation was chosen as the preferred method to analyze the full range of possible environmental conditions for the land disposal scenario. The wide range of environmental conditions (e.g., ground water velocities, pH, temperatures, exposure point locations) that can exist in locations across the nation where the wastes in question may be disposed precludes a priori specification of a reasonable worst case for these parameters. Another important reason to use the monte carlo method is the very complex manner in which the many model variables and parameters interact. Unless many (hundreds to thousands) combinations of variables are investigated, it is simply not possible to anticipate those physical settings that lead to unacceptably high exposure levels. Accordingly, the monte carlo method was chosen to ensure that a conservative but not physically unrealistic or impossible analysis was completed.

The EPASMOD, as described in the proposed rule, was based on a number of key assumptions pertaining to the features of ground water flow, properties of the porous medium, and the behavior of hazardous wastes in ground water. These assumptions included the following:

- Saturated soil conditions (no attenuation of chemicals in the unsaturated zone);

- Flow regions of infinite extent in the longitudinal direction, semi-infinite extent in the lateral direction, and finite in the vertical direction;

- Aquifer can be characterized by homogeneous and isotropic properties and the aquifer thickness is constant;

- Ground water flow is uniform and continuous in direction and velocity;

- Degradation is limited to hydrolysis and the by-products of hydrolysis are assumed to be nonhazardous;

- Contaminants follow a linear equilibrium adsorption isotherm;

- An infinite source supplies a constant mass flux of chemical into the aquifer;

- Recharge due to precipitation supplies water to the disposal unit and the aquifer;

- The ground water upstream of the disposal site is initially free of contamination;

- The receptor well is directly in line with the source and the ground water flow direction;

- The receptor well is located 500 feet from the unit; and

- Hydraulic conductivity does not vary with temperature.

In the June proposed rule, the Agency also proposed using the 85th cumulative percentile level of the back-calculated dilution attenuation factors obtained using the monte carlo simulation technique as an appropriate regulatory level for the TC. Selection of this level means that downgradient ***11818** concentrations will not exceed the allowable health-based concentrations in more than 15 percent of all possible analyzed settings of subtitle D disposal units. (This proposal referenced other proposals dealing with the ground water transport model, such as the January 14, l986 Land Disposal Restrictions notice, and notices published by the delisting program; relevant comments received in response to those notices are also discussed in this rulemaking.)

b. August 1, 1988 Notice of Data Availability and Request for Comments; Supplement to Proposed Rule (52 FR 28892). On August 1, 1988, the Agency presented new data related to subtitle D municipal landfills, soil characteristics, and chemical-specific hydrolysis rates to be used with the subsurface fate and transport model to calculate DAFs for each of the organic constituents in the TC. These new data became available to the Agency after the June 13, 1986 proposal. The August 1, 1988 Notice also requested comments on several major revisions to EPASMOD that were being considered by the Agency, subsequently referred to as EPA's Composite Model for Landfills (EPACML). As a result of comments received on the January 14, 1986, and June 13, 1986 proposals, as well as the August 1, 1988 Notice, the Agency has used EPACML to support the choice of appropriate DAFs for this rulemaking.

These modifications and data are described in greater detail below (section III.E.2). The reader is referred to the Response-to-Comments Background Document for the Subsurface Fate and Transport Module (Ref. 1), which presents, in detail, each of the technical issues addressed in the public comments on the model and the Agency's response to these issues.

2. Modifications of the Subsurface Fate and Transport Model (EPASMOD) in Response to Comments

In today's rule, the Agency has used EPACML to estimate the attenuation and dilution of specific constituents during their migration through the unsaturated zone beneath a municipal landfill and their transport through the saturated zone to a potential drinking water source (exposure point). EPACML accounts for dispersion in the longitudinal, lateral, and vertical

directions; one-dimensional steady and uniform advective flow; sorption; and chemical degradation from hydrolysis. The major enhancements that were made to EPASMOD to produce EPACML, the substantive comments that led to these changes, and important assumptions made to develop analytical solutions are described in subsection (a) below.

In addition, the Agency used the EPACML model to corroborate its conclusions on dilution/attenuation factors for surface impoundments. For this exercise, data inputs typical of surface impoundments rather than landfills were used. These procedures are described in subsection (b) below.

a. General Modifications—i. Unsaturated Zone. The EPASMOD model discussed in the June 13, 1986 proposal assumed that there was no unsaturated zone (i.e., the bottom of the landfill is directly connected to the top of the aquifer). Several commenters stated that the assumption that the facility is located directly at the top of the saturated zone is unrealistic because an unsaturated zone usually exists above the aquifer and that retardation, dilution, and degradation effects in the unsaturated zone should be considered. The commenters also suggested that, when incorporating the unsaturated zone, the depth to the water table should be incorporated as part of the monte carlo analysis.

The Agency is in agreement with the commenters and has now included an unsaturated zone as part of the subsurface model. The Agency believes that this modification to the model is reasonable, based in part on a survey of existing municipal landfills that indicated that an unsaturated zone exists beneath 95 percent of the surveyed landfills. Incorporating an unsaturated zone into the model accounts for any retardation and degradation of chemicals in the unsaturated zone and provides a more realistic scenario.

To account for the unsaturated zone, the Agency developed unsaturated zone flow and transport modules and implemented them using the monte carlo (probabilistic) framework that has already been used in conjunction with the saturated zone modeling approach in EPASMOD; these unsaturated zone modules are incorporated into EPACML. The input concentration to the unsaturated zone transport module of EPACML corresponds to the leachate concentration at the bottom of the landfill.

The unsaturated zone model was reviewed by EPA's Science Advisory Board (SAB). The SAB endorsed the use of the model for applications for the development of regulations; however, the SAB recommended that it not be used for site-specific applications because the model has limitations imposed by the simplifying assumptions (those necessary for regulatory use), and the limitations of the use of site-specific data. The unsaturated zone model consists of two modules: a flow component and solute transport component. These two components were developed in a form to allow for their incorporation in the monte carlo simulation. The major assumptions and consequences of the flow module are:

- Flow is steady in the vertical direction, and lateral and transverse movement of the leachate is negligible. Because there is little or no lateral flow in the unsaturated zone, these assumptions are appropriate. In any case, this procedure will tend to maximize the concentration of leachate leaving the unsaturated zone and therefore represents a conservative assumption.

- No vapor phase or immiscible liquid flow occurs, and the water phase is the only flowing material. EPA acknowledges that some constituents in some situations may undergo phase shifts and be emitted in vapors. Because this rule is essentially directed to risks from drinking water and because of the uncertainties in accurately computing emissions and their relationship to the currently available leaching tests, this conservative assumption was adopted. Under certain conditions, particularly very high constituent concentrations, immiscible liquid flow can occur. For such situations, the model's inability to account for the immiscible flow condition may lead to higher downgradient concentrations (i.e., the model would underestimate the receptor well concentrations).

- Flow is isothermal (not affected by temperature variations). In reality, temperature variations at any given site are not dramatic because the source of infiltrating liquid is precipitation. Thus, this assumption is not expected to influence the results to any appreciable degree.

- Effects of variations in the unsaturated zone hydraulic properties caused by alternating moisture conditions are negligible (i.e., hysteresis effects). Many soils, especially the more porous ones for which infiltration rates are high, do not present important hysteresis effects. In other cases, little and often no data are available to characterize the effects. Failure to include hysteresis is not expected to affect the results to any appreciable extent.

- The flow field is uniform and continuous in direction and velocity. Precipitation-driven infiltration can be a dynamic process where much of the vertical movement occurs during relatively short periods of time. Time- ***11819** averaged values of infiltration derived from dynamic water balance calculations (as described in the Background Technical Support Document) are often used to enable solution of analytical, steady-flow models. The unsteady-flow conditions could lead to higher downgradient concentrations than predicted by EPACML. However, the effect is expected to be significant only for rapidly degrading constituents. For the constituents regulated in this rule, no appreciable impact is expected because none of the constituents are expected to hydrolyze to any significant extent during transport.

- The unsaturated zone is homogeneous and isotropic. This assumption is typically required to enable mathematical solutions amenable to exhaustive sensitivity analyses and monte carlo implementation. In any one application (one model run) of this assumption, the result can either under- or over-predict downgradient concentrations. The monte carlo implementation, however, results in a very wide range of possible conditions, and thus the total analysis, when taken together, accounts for a wide variety of unsaturated zone conditions.

The major assumptions and consequences of the unsaturated zone transport module are:

- Chemical transport is vertical; lateral and transverse movement of the chemical is negligible. This follows from the first assumption for the flow module described above.

- Chemical sorption is modeled as a reversible, linear equilibrium process. This is a standard modeling assumption which is accurate for systems having relatively low solute concentrations, and conservative at higher concentrations.

- Degradation is limited to hydrolysis. This assumption was made to be consistent with the similar approach adopted for the saturated zone. Thus, the model includes only those degradation mechanisms that can be reliably characterized in laboratory studies of each individual constituent. This assumption remains a major conservative component of the overall model.

- Chemical transport in the vapor phase has been assumed to be negligible. This follows from the second assumption for the flow module described above.

- The unsaturated zone transport model is solved for the steady-state condition. This is a conservative assumption that has been investigated for its impact on all the originally proposed constituents. The extent to which this assumption is appropriate is discussed in section III.E.4(b)(iii).

The details of the unsaturated zone module are provided in the background documents (Ref. 1, 9), which also describe the data sources and analyses that were performed to obtain the data distributions.

ii. Source Characterization. In EPASMOD, the input leachate to the saturated zone was assumed to be instantaneously mixed in the vertical direction over a pre-specified depth of source penetration, and the concentration in the leachate was equal to the maximum source contaminant concentration in the saturated zone below the facility. Mass balance considerations required that the lateral extent of the leachate directly underneath the facility be adjusted to ensure that leachate was neither gained nor lost in the transition from the facility (or unsaturated zone) to the aquifer. A number of commenters criticized the treatment of the source. A major concern was that the method was inadequate because of an overly conservative assumption, which equated the concentration of the contaminant in the saturated zone to the landfill leachate concentration. Thus, commenters argued that EPA had not given adequate consideration to mixing and dispersion under the landfill. The commenters also pointed out that

this treatment of the source could result in modeling physically unrealistic boundary conditions (e.g., by modeling a source of small cross-sectional area with a very large width of the Gaussian source, and vice versa).

The Agency agrees with the commenters that the method used to characterize the source-boundary conditions for the saturated zone transport needed to be improved. Thus, the method has been revised to consider the mass balance requirements, geometrical configurations, and physical processes that are occurring in the mixing zone below the facility and within the saturated zone. An important characteristic of the revised method is the plume restriction in the lateral extent. That is, the method no longer permits physically unrealistic situations where the plume source width exceeds the facility width. In addition, the current method of computing the source-boundary conditions represents the mixing and dilution effect on the leachate below the source and ensures that the concentration of the contaminant in the saturated zone will be less than or equal to the landfill leachate concentration.

iii. Treatment of Dilution from Recharge. In EPASMOD, the dilution effect of ground water recharge on contaminant transport in the saturated zone was taken into account by including recharge as a dilution term in the governing equation. Dilution of leachate concentrations from recharge was calculated by dividing the infiltration (recharge) rate by the source penetration depth. A number of commenters were concerned that the influence of recharge on the ground water flow field had not been properly accounted for in the model. In addition, several commenters alerted the Agency to an error in the equation used to evaluate the recharge dilution parameter.

In response to these comments, the Agency has modified the model to calculate dilution from recharge by dividing the recharge rate by the total saturated thickness of the aquifer, the aquifer porosity, and the effective retardation factor in this zone. This revision represents a more realistic assessment of the dilution potential of recharge by considering changes in the entire volume of water in the contaminated aquifer and the effectiveness of contaminant and recharge flow and mixing in the aquifer.

The Agency recognizes that recharge effects on ground water flow fields are not rigorously considered in the model and that the assumption of uniform, constant, horizontal ground water velocity neglects the possible effects of local mounding of the water table underneath the land disposal unit. However, the constant velocity assumption can be interpreted as an averaging of the velocity field over the spatial area affected by recharge; in addition, the uniform, horizontal flow assumption was necessary to make the three-dimensional transport equation analytically solvable. The effect of recharge on ground water velocity is difficult to account for directly in the model. To assist in the analysis, EPA has conducted a sensitivity analysis comparing EPACML results with recharge effects as predicted by a two-dimensional numerical model that rigorously accounts for recharge. The results (which can be found in Ref. 9) indicated that as long as recharge values are significantly less than the natural flow velocity, there was no major effect on the ground water flow fields. Based on this analysis, and on evidence of typically low rates of ground water recharge, the Agency believes that the revised treatment of the dilution effect from recharge is reasonable. In addition, the error, as pointed out by several commenters, in the equation used to evaluate the recharge dilution ***11820** parameters was corrected, and the correction is included in EPACML.

iv. Location of the Receptor Well. In EPASMOD, the receptor well was assumed to be located downgradient from the landfill along the centerline of the plume (direction of ground water-flow) at a fixed distance of 500 feet (152.4 m). In addition, the receptor well was assumed to be tapping water from the top of the aquifer, and no mixing of water in the well or effects of drawdown in the well were considered in EPASMOD.

Many commenters argued that the assumptions concerning the location of the receptor well were too conservative and suggested that well locations should be considered in a probabilistic manner as part of the monte carlo simulation in the model. These commenters noted that well locations other than on the centerline should be considered. Several commenters also stated that the well locations should not be restricted to lying within the areal extent of the plume and suggested that wells located outside of the plume should be considered in the calculation of the dilution/attenuation factors.

The Agency agrees that the proposed location of the well was unrealistic and that affected wells located at points other than on the centerline should be considered. Therefore, the model now considers well locations anywhere within the areal extent of

the contaminant plume. In order to incorporate these locations, a distribution of distances to downgradient wells was developed based upon a subtitle D municipal landfill survey (Ref. 6). These distances were used as part of the monte carlo analysis. Also, to incorporate locations other than on the centerline, the Y values (see Figure 1) were selected randomly over a 180° domain but the X-Y pairs were constrained to values that were located within the areal extent of the plume.

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***11822** The Agency disagrees with those commenters who stated that well locations outside of the areal extent of the plume should be considered. The purpose of the Toxicity Characteristic is to answer the question "if the management of this waste continues to be uncontrolled, what are the consequences in terms of human exposure via ingestion of contaminated drinking water?" In performing the exposure assessment to answer this question, the Agency believes it appropriate to consider only wells that could be affected by the disposal of the waste. Wells that could not be affected by the migration of constituents from the wastes are obviously irrelevant to the exposure assessment and, thus, not considered.

Commenters also stated that it was unrealistic to assume that the well tapped water from only the uppermost point of the aquifer. These commenters stated that, in practice, the intake portion of a well is located below the top of the water table and that mixing and drawdown will occur.

The Agency agrees that the proposed well intake location was unrealistic and that it ignored the effects of vertical mixing and the possibility that the well intake would likely be at some point other than the top of the aquifer. In response, the assumptlon has been modified to consider well intake at any point throughout the depth of the aquifer. This modification largely takes into account the above-described mixing and drawdown effects.

In determining how to account for well drawdown more realistically in the model, the Agency considered the mechanics of well construction. Generally, wells are screened from near the top of the aquifer to a sufficient depth (into the aquifer) to allow delivery of the needed water supply. Thus, the ranges of values for the length of the screens and their locations relative to the top of the aquifer are very large. In recognition of this variability, especially in screen length, the Agency has employed a simplifying assumption that the concentrations of constituents at various depths of the aquifer represent the concentrations at the exposure point. That is, the concentration of constituents in the water drawn from the well is assumed to be equal to the concentration of the constituents at the depth which is selected in the monte carlo simulation. (The well depth is randomly selected from all points within the vertical range of the aquifer's thickness.)

To evaluate the model's sensitivity to this assumption, the Agency evaluated the case in which wells were assumed to be screened from the top of the aquifer to the monte-carlo-selected depth. The exposure point concentration was then calculated as the average concentration over the screened depth. This case is considered to be more representative of the most likely well design, although in many cases the well will not extend to the bottom of the aquifer nor will it always be constrained to intersect the plume as is implemented in the monte carlo simulation. This scenario is considered to be more conservative (i.e., resulting in lower DAFs) than the EPACML-as-implemented scenario. When one considers other possibilities like well location factors up gradient and outside the plume, the range of DAFs from the two scenarios can be expected to bound the actual exposures.

In evaluating the model predictions over the range of cumulative frequency values considered in interpreting the model's results in today's rule (see Section III.E.4—DAF Evaluation), the dilution/attenuation factors for the two scenarios are not sufficiently different to warrant separate conclusions regarding the appropriate value for use in today's rule. (Model results for the two scenarios are compared in the background document for the model—Ref. 9.)

v. Dispersivity Values. Dispersivity controls the degree of spreading of dissolved contaminants in the subsurface. The saturated-zone fate and transport model includes dispersion in the longitudinal, transverse (horizontal), and vertical directions. The model thus requires values of the longitudinal, transverse, and vertical dispersivities in the saturated zone. In EPASMOD, the distance x from the downgradient edge of the landfill to the receptor well was assumed to be fixed at 152 m (500 feet). Consequently, fixed values of the longitudinal and transverse dispersivities were used in the model. The values of vertical dispersivity were assumed to vary uniformly.

Several commenters criticized the assumption that dispersivity values did not vary and reflected only the fixed distance selected in the model. They also suggested that the ratio of longitudinal to transverse dispersivity used in the model was too low. The basis of their comments is that field values of dispersivities have been shown to depend on, and usually increase with, the travel distance.

The Agency agrees with the commenters and now calculates the three components of dispersivity based on a detailed analysis of data gathered from field tests (the model background document [Ref. 9] presents a detailed discussion on dispersivity values and provides references to the field data). The Agency believes that the revised approach, reflecting the distance-dependent nature of the dispersivity values and different relationships between the dimensional dispersivities, is more realistic and consistent with the available data.

EPACML also requires the specification of a dispersivity parameter for transport in the unsaturated zone. Since the transport equation in the unsaturated zone is one-dimensional, only the longitudinal (vertical) dispersivity value is required and is calculated as a function of the distance (i.e., the depth to water table) traveled in the unsaturated zone.

vi. Hydraulic Conductivity. In EPASMOD, the value of hydraulic conductivity in the saturated zone was estimated using the Kozeny-Carmen (Ref. 9) expression, which relates hydraulic conductivity to porosity, the mean particle diameter of the aquifer material, and the fluid properties (density and viscosity). This relationship was based on an assumed ground water temperature of 15 degrees C and did not reflect changes in the fluid properties with temperature.

Commenters expressed concern with this assumption because ground water temperature is known to typically range in temperature from 4 degrees C to 30 degrees C. A few commenters also expressed concern regarding the validity of using this empirical relationship.

In response to these comments, the Agency generalized the expression to include the effects of changes in temperature on fluid viscosity and fluid density. That is, the fluid viscosity and density are now considered as functions of temperature rather than as constants. The Agency realizes that the hydraulic conductivity also depends on physical properties, such as grain shape, grain size distribution, packing, and tortuosity of the porous media. Porosity measurements reflect the composite result of these textural characteristics on the structural arrangement of the porous media. The range of porosity values derived in EPACML indirectly reflect the impact of these properties. Therefore, in view of the Agency's objective to represent the wide variations expected from site to site, the Agency decided to retain the Kozeny-Carmen equation, except for the modification described above.

vii. Hydrolysis. As already discussed in section III.E.2., the EPACML model accounts for reduction in constituent concentrations due to hydrolysis. This results in higher DAFs for constituents that hydrolyze during transport than for ***11823** constituents that do not. The DAF predicted by the model for some of these constituents ranges up to one million. Thus, in some cases, wastes would not be considered hazardous unless they contain large amounts of these toxicants; still, in other cases, no amount of toxicant in the waste would define it as hazardous under this scenario. Therefore, the Agency did not believe it appropriate to include these constituents in the TC (see Table E-2 for list of constituents that appreciably hydrolyze). Furthermore, the model does not account for the degradation products that are produced as the original constituents hydrolyze. That is, while the decrease in the concentration of the original constituent is accounted for, the resultant increase in concentration

of the hydrolysis products is not. Several commenters stated that the toxicity and transport of the potential hydrolysis products should be considered to fully assess the hazards posed by the constituents that hydrolyze.

The Agency agrees with the commenters and is (1) determining which byproducts result from hydrolysis and (2) developing an appropriate protocol for predicting the concentration of hydrolysis byproducts (see Table E-2). Once this protocol is developed, the Agency will determine whether any of these toxicants should be added to the list of constituents. While the Agency considered including these constituents at a higher dilution and attenuation factor until this work was completed, the Agency does not have sufficient information at this time to determine which of the constituents listed in Table E-2 will eventually be added to the TC and at what level.

Table E-2--Hydrolyzing Constituents Listed in the June 13, 1986 Proposed Rule
Acrylonitrile
Bis(2-chloroethyl) ether
Methylene chloride
1,1,1,2-Tetrachloroethane
1,1,2,2-Tetrachloroethane
1,1,1-Trichloroethane
1,1,2-Trichloroethane

viii. Steady-State Assumption. As implemented for today's rule, EPACML was solved for the steady-state condition. Thus, the solution represents the case where leaching has occurred for a period of time that is sufficiently long to allow the concentration at the receptor well to become constant. Several commenters noted that, in certain circumstances, use of the steady-state solution would lead to unreasonably low DAFs. In particular, in situations where the mass of a constituent is relatively low in the source facility (i.e., the landfill has a very limited quantity of the constituent available to contaminate leachate), the steady-state model will continue to assume the existence of a very large quantity of the constituent and, hence, over-predict the resulting concentration at the downgradient well. Under such circumstances, the commenters argue, the Agency should accommodate this phenomenon by using a transient solution in deriving appropriate DAFs.

The Agency agrees with the commenters and has initiated a study to thoroughly investigate the problem described above. Based upon preliminary investigations already complete, however, the Agency continues to believe that application of the steady-state model to many constituents is appropriate and is promulgating regulatory levels for those constituents based upon the results of the steady-state model. The preliminary investigations have also led to a decision to postpone the promulgation of regulatory levels for constituents that are believed to be more appropriately evaluated with a transient solution. The Agency is continuing to refine the approach required to implement the transient solution but results to date suggest that this latter group of constituents require unreasonably large quantities in the source facility to insure that the steady-state solution is appropriate. For example, under some conditions even when the constituents exist at concentrations in excess of 1000 ppm of the solid waste within the entire volume of the landfill, the steady-state condition is not realized. Therefore, based upon the preliminary analysis, regulation of these constituents based upon the DAFs predicted by the steady-state model may not be appropriate.

Preliminary investigation of this condition was completed for all of the originally proposed constituents. All constituents were assumed to exist in the “tested” waste at 1000 ppm. Furthermore, the “tested” waste was assumed to occupy 100% of the available facility capacity (i.e., the “tested” waste is the only solid waste in the facility). As a reasonable worst case scenario, the DAF was derived by the transient model for each constituent under these conditions. Because the above assumptions are very conservative, most of the DAFs derived for the constituents were found to coincide with the steady-state values. That is, sufficient mass was available to insure that steady-state conditions were reached. Accordingly, regulatory levels for these constituents are being promulgated in this rule. For the following constituents, however, the steady-state condition was not achieved under this scenario:

phenol

1,2-dichlorobenzene

carbon disulfide

isobutanol

2,3,4,6-tetrachlorophenol

toluene

Accordingly, the Agency is postponing the promulgation of regulatory levels for these six constituents until such time as the investigations are complete. Once these investigations are completed, the Agency will take the appropriate action.
ix. Biodegradation. The subsurface fate and transport model does not account for biodegradation processes in the subsurface environment. EPA recognizes, however, that biodegradation is an important process that can reduce concentrations under either aerobic or anaerobic conditions. Accordingly, the EPA has constructed the model so that it can theoretically be modified to include these processes for experimentally derived biodegradation rates. Biodegradation processes have not been included because the data bases to support this portion of the model are currently insufficient.

The first major data deficiency is that the model incorporates many diverse subsurface environmental conditions where as constituent-specific biodegradation rate data typically exist for only a few (if any) subsurface environments. EPA also recognizes that although the kinetic equations describing the degradation of hazardous organic chemicals in many environments are available, these equations have not been sufficiently evaluated in the subsurface environment (Ref. 10, 11, 12). Second, the Agency considers data on the formation of transformation products to be insufficient. Third, the key processes that can affect the subsurface biodegradation rate are not well understood. These processes include sorption, pH, temperature, nutrient availability, toxicity, and others. For example, while nutrient levels in the environment are generally considered sufficient for low populations of microorganisms, the microorganic population at which the nutrient availability in the environment becomes a limiting factor is not known. Additionally, while sorption is well understood for hydrophobic compounds at low concentrations (Ref. 13), at concentrations where the compounds can form small droplets or become entrained in the micropores of the ***11824** subsurface matrix, sorption effects are not well understood. The effects of temperature have been characterized in innumerable studies of isolated microorganisms, but the kinetics of these effects have only recently been investigated in environmental samples (Ref. 14). Finally, the toxicity of hazardous chemicals to the microorganisms themselves is only now being investigated (Ref. 15).

Accordingly, the Agency is continuing to gather data to refine the modeling of biodegradation, but has not been able to include biodegradation in the ground water transport model at this time. In this regard, EPA has published guidelines for developing anaerobic microbiological biodegradation rate data for chemicals in the subsurface environment (see 40 CFR 795.54). Results developed under these guidelines will provide data on kinetic rates of degradation, and to a lesser extent, on the effects of pH and temperature on these rates. Similar guidelines have not been developed for aerobic systems at this time. Data developed under 40 CFR 795.54 may be considered for use in the model at some future time.

x. Summary of General Modifications. The Technical Background Document (Ref. 9) describes in detail the model revisions, including options developed but not implemented for the purposes of establishing the regulatory levels for today's rule. A summary of the major model options and procedures implemented for the rule follows:

- The model was run for the steady-state case. The initial condition was a constant concentration. The equations were solved for infinite time.

- The unsaturated zone module was included in the analysis.

- Concentrations can be predicted at wells placed at any position. The wells can be allowed to draw from any selected depth.

- The updated method of computing dispersivities as a function of random longitudinal well locations was used (designated in the model as the “Gelhar procedure”).

- The option implemented for setting the boundary conditions between the unsaturated zone and the aquifer was the one that limits the lateral extent of the plume to the downgradient facility width, computes vertical mixing and dispersion underneath the facility, and estimates the maximum source concentration within the plume based on mass balance requirements. Any combination of conditions that violated these requirements and, thus is not physically realistic, was rejected.

The above options and additional options are listed in the background document for the model (Ref. 9). Specifically, the model input and control variables, as required and accepted by the computer code, are listed for each computer run used to set regulatory levels in today's rule.

By incorporating these modifications, the EPACML, as applied to landfills, models the following basic features:

- The landfills are filled to capacity and covered with native soil.

- Caps are characterized as being in a failed or deteriorated state. Thus, permeabilities are set to be higher than would be typical of landfills with an undamaged cap. It is assumed that liners are not present.

- All wells (exposure points) are considered to be downgradient in every model run. The longitudinal distance parallel to the direction of ground water flow is determined from data described later in section III.E.3.

- Lateral well location is determined by allowing the position to uniformly vary at random within the plume width and with the additional constraint that the location also must be within an area defined by lines at 90-degree angles from the direction of ground water flow at the midpoint of the downgradient boundary of the facility.

- Vertical well location is determined by allowing the position of the well intake point to uniformly vary at random over the entire aquifer depth.

- The landfill storage capacity is assumed to be sufficient to accommodate sufficient mass of each constituent to allow a steady-state condition to exist. This produces an infinite source initial condition.

- Constituents contained within the landfill do not degrade.

- Infiltration rates are represented as annually averaged flows based on 20-year climatic records and concomitant water balance calculations.

b. Use of the EPACML for Surface Impoundments. Because some wastes are managed in surface impoundments rather than landfills, several commenters indicated the need to analyze and include the results obtained by considering a surface impoundment mismanagement scenario. They argued that dilution/attenuation factors (DAFs) generated by modeling a landfill scenario would be too stringent for wastes managed in surface impoundments. Based upon these comments, the Agency decided to investigate whether surface impoundment DAFs would be significantly different from landfill DAFs. EPA requested comment on the use of this data in the August 1, 1988 notice.

Based upon this investigation, the Agency has concluded that the use of DAFs based on a landfill scenario is appropriate in establishing the regulatory levels for wastes managed in surface impoundments. EPA used the EPACML model to confirm this analysis by modeling a surface impoundment mismanagement scenario.

This conclusion is based on the Agency's evaluation of the physical parameters that would lead to different DAFs for surface impoundments than for landfills. A key factor that could lead to differences in the DAFs from these two types of management units (surface impoundments and landfills) is the difference in total leachate infiltration rates. The infiltration rate is equal to the product of the leachate mass flux (mass per unit area per unit time) and the area of the management unit. For surface impoundments, the mass flux can be considerably greater than for landfills. However, to the extent that the area of surface impoundments is typically smaller than the area of landfills (although some atypical surface impoundments can be as large, if not larger than landfills), the effects of the greater leachate flux are somewhat offset. That is, while the flux is greater, the area is smaller, resulting in relatively similar leachate infiltration rates.

A second factor that affects the DAFs is the situation in which the leachate flux is large and the ground water velocity is relatively small. In these situations, a ground water mound may form below the management unit. This effect is more typically associated with surface impoundments because of their higher leachate fluxes; this effect should result in smaller DAFs (and, thus, more stringent regulatory levels) than would be predicted if the mounding did not occur. As a result of these factors, the Agency concluded that DAFs from a surface impoundment scenario would be equivalent to or less than DAFs from a landfill scenario.

To confirm this conclusion, EPA used EPACML to evaluate a surface impoundment scenario. The main features of the surface impoundment scenario, as simulated using EPACML, are as follows:

- The surface impoundments are filled to their fluid capacity and are assumed to operate on a continuous basis.

- Bottom layers are characterized as being in a more permeable state (typically ten times greater) than those found in field studies.

- Location rules for downgradient well positions and lateral and vertical ***11825** locations are identical to landfills. The data base for longitudinal distances is different, however.

- The operating life of the surface impoundment is assumed to be sufficient to accommodate a sufficient mass of constituent to allow a steady-state condition to exist. This assumption produces an infinite source initial condition.

- The leaching rate from a surface impoundment depends on, among other factors, the ponding depth in the impoundment and the characteristics of the bottom materials. The Hydrologic Evaluation of Landfill Performance (HELP) model used in evaluating the landfill data is inadequate to determine the leaching rates from surface impoundments. Therefore, the leaching rates from subtitle D surface impoundments were estimated by considering the relationship between the velocity in the vertical direction and the substrate's porosity and permeability and the solution of the nonlinear steady state flow problem. To be conservative, the Agency used a permeability value ten times higher than the value typically reported in field studies as an input for calculating leaching rates (the source of these data are discussed below).

- The Agency has not yet conducted a detailed survey for subtitle D surface impoundments, but the Agency conducted a review and analysis of data on subtitle D units in RCRA Facility Assessment (RFA) Reports (Ref 16). A set of data on subtitle D surface impoundments was obtained from this analysis and used as inputs to the EPACML. Additional data were compiled from aerial photographs by EPA's Environmental Photographic Interpretation Center (EPIC).

- The data extracted from RFSs included the area of the surface impoundments and the distance to downgradient drinking water wells as determined by EPIC.

- The ponding depth data for the subtitle D surface impoundments were reported by E. C. Jordan (Ref. 9). The hydraulic conductivity of the bottom materials was chosen as 1.0 E-6 cm/sec. This value reflects the effect of gradual settlement and compaction of sediments at the bottom, because surface impoundments tend to fill up with sediments over a period of about 20 years or so. The Agency believes that the hydraulic conductivity value of 1.0 E-6 cm/sec represents a reasonable worst-case value. These values were used in conjunction with EPACML to estimate DAFs for the surface impoundment data.

As expected, DAFs predicted for surface impoundments are somewhat smaller than the corresponding values for landfills (see section III.E.4). However, because the EPACML does not incorporate the mounding effect, the surface impoundment evaluation was restricted to include only those cases where mounding would be minimal and, thus, reasonably ignored. As a consequence of limiting the evaluation to these cases, the modeling results tend to omit some worst case scenarios. That is, if all possible cases were included, rather than just the “no mounding” cases, the DAFs for surface impoundments could be somewhat lower and, thus, the downgradient concentrations may be higher than those estimated by the EPACML model. The Agency thus believes that the omitted surface impoundment conditions should be further investigated and may result in more stringent regulatory levels. The Agency believes, however, that the DAFs produced by the EPACML analysis properly delineate wastes that are clearly hazardous wastes.

3. Newly Acquired Data

As previously described, the DAFs proposed on June 13, 1986, were calculated based on the subtitle D landfill scenario. However, subtitle D landfill data were not available to the Agency at that time, and instead, subtitle C landfill data were used.

Several commenters criticized the use of subtitle C (hazardous waste) landfill data. The Agency agreed with the commenters and has based the final rule on data from a survey of solid waste subtitle D landfills.

a. Landfill Data. The Agency conducted a survey of municipal solid waste landfills in the U.S. (Ref. 6). The survey used a stratified design based on facility size. The results were tabulated based on 1,102 completed questionnaires. The survey yielded data on area of landfills, distance to the nearest downgradient drinking water wells, and thickness of the unsaturated zone. These data are site-specific, corresponding to individual solid waste landfills located throughout the United States. The survey data were analyzed to develop distributions of these site-specific parameters and used as inputs to EPACML, as described in the model background document (Ref. 9). The input frequency distributions are also presented in the background document.

EPA also collected additional data on leachate generation at municipal landfills. EPASMOD requires, as input, the leachate distribution from the bottom of the landfill. The leaching rate distributions for the June 13, 1986, proposal were based on the use of a single soil type, loam, as the cover soil for the landfill. These distributions were estimated using climatologic data for a total of 30 cities nationwide, representing the median range for each of 18 climatological conditions or zones identified in the 48 contiguous states.

The assumptions of a single soil type and 18 climatic zones were criticized as not being realistic and resulting in an overly optimistic cap performance. The commenters suggested enhancing the data base by including simulation of different soil covers.

In response to these comments, the Agency has implemented a number of changes. The Agency believes that these modifications significantly improve the validity of the leachate flux distribution and make it more realistic.

Soil Type

The Soil Conservation Service (SCS) has a county-by-county soil mapping program underway. More than 90 percent of the land area in the U.S. has been mapped, and soil data representing approximately 51 percent of the total land area in the U.S. have been entered into a computer data base. Using this data base, the soil classifications were grouped according to the U.S. Department of Agriculture's definitions of coarse, medium, and fine textures. These three categories are represented in EPACML by soils equivalent in properties to sandy loam, silt loam, and silty clay loam for the landfill cover materials. The latest results show that coarse grained soils, medium grained soils, and fine grained soils represent 15.4, 56.6, and 28.0 percent, respectively, of the soils that have been mapped thus far.

Climatic Zones

The number of cities representing climatic variations that were used to develop frequency distributions for the leachate generation has been increased from 30 to 100. The reason for this change was to reduce the chance that any one city would provide an unrepresentative percolation rate in its climatic range.

The climatic data base used in EPACML was enhanced to include six precipitation ranges and five ranges of pan evaporation rates, thereby resulting in 30 climatic ranges as opposed to the 18 described in the earlier proposal. For the climatic ranges so defined, the percentage of the area of the 48 states represented by each range was calculated, and the percent areal average was used to weight the percolation (recharge and/or infiltration) rate estimated for the selected cities in each range according ***11826** to probable relative occurrence in the U.S. The effect of these changes is to provide more representative values of the overall national distribution of the leachate flux.

After the percolation data for the landfill were calculated using the HELP model (Ref. 9), the climatic ranges were further subdivided to account for wide variations in percolation within a range. This resulted in separate subranges being established for some California cities (Los Angeles, Sacramento, San Diego, and Santa Maria), and two Oregon cities (Medford and Astoria).

Percolation rates for each of the selected cities in the 48 contiguous states were determined using silt loam, sandy loam, and silty clay loam cover soils. These soils, based on data obtained from the SCS, appear to represent the most common soil types in the U.S., and thus the most common soil to be used as covers for landfills. They also span the range of likely cover soils, from fine-grained to coarse-grained, or from low to high percolation rates. Simulations were performed for each of these soil types, and the results weighted according to the frequency of occurrence for each type.

The leaching rate flux was determined by using the average, weighted percolation rate from the cities in each climatic range. The model background document (Ref. 9) presents the data used and the accompanying changes to the June 13, 1986 proposal runs.

b. Chemical-Specific Parameters. In the EPASMOD proposal, chemical parameters, such as hydrolysis rates, were used to calculate the relative retardation factors and degradation rates for selected compounds. Some of the chemical-specific parameters used in that model were estimated based on a brief review of the existing chemical data. Some commenters criticized some of the parameter values selected and used for that proposal as being nonrepresentative of the range of parameter values.

The Agency has an ongoing program for the measurement of constituent-specific parameters and for the review of new constituent-specific data as reported in the current scientific literature. Some hydrolysis rate constants and octanol-water partition coefficients used in the proposal have been revised to reflect the most recent laboratory measurements and recent values reported in the literature. The updated parameter values are given in the background document (Ref. 9) and represent either measured or best available values.

4. DAF Evaluation

a. Selection of an Appropriate Percentile. As described earlier, the EPACML was used to investigate the expected range of DAFs associated with mismanagement of solid wastes. As generated by EPACML, the DAF represents the expected reduction in the concentration of a constituent during transport through soil and ground water from the leachate release point (bottom of the waste management unit) to an exposure point (a well serving as a drinking-water supply). The wide range of possible environmental settings (e.g., ground water velocities, pH, temperatures, etc.) and the multitude of possible scenario configurations (e.g., facility area, distance to downgradient wells, etc.) result in an extremely wide range of DAFs. Monte carlo simulation was used to implement EPACML, and the resulting cumulative frequency distribution can be viewed as a ranked order of increasingly higher downgradient concentrations expected from the “best-case” situations (large DAFs) to the “worst-case” situations (small DAFs) for the scenario being investigated.

The Agency's proposed approach was to define DAFs representative of reasonable worst-case conditions as those corresponding to the 85th percentile of the cumulative frequency distribution. The Agency received numerous comments on the selection of the 85th percentile, which are addressed in Section d, following.

b. Resulting DAFs for Landfills. The DAF values corresponding to various cumulative frequency levels for landfills are as follows:

Percentile	80	85	90	95
All nondegrading constituents	328	134	47	12
Chloroform [FN1]	385	152	52	14

1 The DAFs for chloroform are slightly higher than for the other nondegrading constituents because chloroform is expected to hydrolyze slightly during transport.

The similar DAF values for nondegrading constituents and chloroform arises because all these constituents either do not degrade at all or only degrade slightly.

c. Resulting DAFs for Surface Impoundments. The DAF values corresponding to various cumulative frequency levels for the surface impoundment investigations described in E.2.b of this section are as follows:

Percentile	80	85	90	95
All nondegrading constituents	226	111	51	19
Chloroform	227	111	52	19

As with the landfills, the constant DAF for all constituents reflects the fact that nondegraders and very slow degraders have virtually identical environmental fate for the scenario investigated. As the resulting numbers indicate, within a reasonable degree of accuracy, the DAFs for waste managed in surface impoundments are equivalent to the corresponding landfill DAFs.

d. Final DAF Selection. The Agency's purpose in developing dilution/attenuation factors (DAFs) is to identify wastes whose leaching behavior indicates that they may pose a hazard to human health unless they are controlled under subtitle C management standards. Thus, the Agency developed a subsurface fate and transport model that simulates a subtitle D management unit (i.e., a municipal landfill) and the subsurface environment that would be encountered by toxic constituents as they migrate from the management unit to a drinking-water well. In order to make the model's output (DAFs) as realistic as possible, the Agency implemented the model using real-world distributions for parameter values (e.g., areas of landfills, properties of the subsurface environment, etc.) whenever possible. The monte carlo structure of the simulation allowed the modeling results to be presented as a cumulative frequency distribution or probability. That is, the model expresses the probability that a toxic constituent disposed of in a municipal solid waste landfill will undergo certain dilution/attenuation as it moves through a subsurface environment to an exposure point. Thus, there is a different DAF for each selected probability.

In its June 13, 1986 proposal notice, the Agency proposed the use of the DAF corresponding to the 85th percentile cumulative frequency level and requested comment on the use of other percentile levels. Comments were received urging the use of both higher and lower levels. Recommendations for using the 80th percentile cumulative frequency were justified by assertions that the assumptions used in the model were already unduly conservative. One commenter noted that EPA could still rely on the listing program to regulate wastes whose leachate concentrations would not exceed the regulatory levels derived from the lower percentile DAF but that are still considered hazardous. ***11827** Other commenters argued that the 85th percentile was not adequately protective of human health and the environment. One commenter, claiming that assumptions in the model were not conservative enough, recommended that the 95th percentile be used.

In selecting the appropriate level, the Agency recognizes that there is no consensus “correct” level for interpreting modeling results. This has resulted in a particular challenge in developing today's rule, wherein a quantitative approach is being used

for guidance in answering what is a partly qualitative question—namely, “what is the human health impact of unregulated management of certain types of wastes in a ‘reasonable worst-case’ disposal scenario?” While the Agency believes that the 85th percentile is an appropriate choice to represent a reasonable worst-case result, consideration of the relationship of the 85th percentile DAF to other percentile DAFs is also appropriate. That is, the Agency believes that the behavior, or shape, of the upper portion of the cumulative frequency distribution curve should also be evaluated in order to determine how critical the selection of a particular frequency level is to the DAF.

Another consideration in determining the appropriate DAF value, independent of the selected cumulative frequency level, is the accuracy inherent in the data set used. Given that there is some uncertainty associated with any data set used to represent possible values for any parameter, and that the model requires values for many parameters, the Agency believes that the selected DAF value should not imply an undue degree of accuracy.

After considering the above factors, the Agency has concluded that a DAF value of 100 is appropriate for establishing the regulatory levels for the constituents included in today's rule.[FN1] First, the Agency believes that, considering the number of parameters for which distributions of values were established (in order to represent a “generalized” scenario), a DAF with an order-of-magnitude precision is appropriate.[FN2] Second, in selecting this DAF value of 100, the Agency noted that the 80th and 90th percentile DAFs, as well as the 85th percentile DAFs, indicate that constituents migrating in the modeled disposal scenario will be diluted by approximately two orders of magnitude. This is also true of the predicted DAFs from the data used for surface impoundments. Thus, EPA believes that a DAF data used for indicating dilution by two orders of magnitude (i.e. 100) is appropriate. Moreover, as the data indicate, on an order-of-magnitude scale, the predicted DAF is not extremely sensitive to the exact cumulative frequency value that was selected.

The Agency points out that the considerations leading to the use of 100 to represent the model-predicted dilution/attenuation factors are unique to today's promulgation. In other cases, different conclusions may be more appropriate. For example, when parameter values can be more narrowly defined (as in site-specific evaluations), the higher degree of precision may be appropriately ascribed to the model-predicted DAFs. Likewise, where the program goals are different (i.e. other than to identify levels that are indicative of wastes that clearly are hazardous), the selection of a value that represents a cumulative frequency value other than the 85th percentile may be warranted.

F. Toxicity Characteristic Leaching Procedure (TCLP) (Method 1311)

1. Introduction

The development of the TCLP and the role of the test in identifying a waste as hazardous were discussed at length in the June 1986 proposal (51 FR 21648). Today, EPA is promulgating the TCLP, with some improvements and modifications, as a replacement to the EP for use in the identification of hazardous waste. (The revised TCLP is promulgated in Appendix II to 40 CFR part 261 and has been designated as EPA Method 1311 and will be incorporated in “Test Methods for Evaluating Solid Waste Physical/Chemical Methods—SW-846”.)

The Agency received numerous comments in response to the Federal Register notices (51 FR 1602, 51 FR 21648, 51 FR 24856, 51 FR 33297, 51 FR 40593, 51 FR 40643 and 53 FR 18792) related to the TCLP procedure. ln particular, EPA received close to 140 comments on the application of the TCLP in response to the June 1986 proposal. The comments covered general issues such as the relationship to the EP, the adequacy of research supporting TCLP development and specifically, the statistical treatment of data. Commenters also addressed technical issues including the suitability of the zero head space extraction (ZHE) vessel; the types of filters, reagents, and leaching media; the quality assurance requirements; and the multiple extraction and oily waste extraction procedures. In addition, comments were received on the use of quantitation limits for establishing regulatory levels. All the comments were categorized and summarized by issue and are presented in the technical background document along with the Agency's response to these comments (Ref. 4).

In this preamble, only certain comments are discussed, which include (a) the applicability of the TCLP to specific types of waste (i.e., solidified wastes); (b) the analytical difficulties encountered during the analysis of the TCLP extract for phenolic compounds and phenoxy acid herbicides; and (c) the use of quantitation limits. The first two comment issues are presented below while the last comment and the Agency's response is given in section IV.C. of this preamble.

2. Adoption in the LDR Rulemaking and Modification from the Proposed Rule

The TCLP was promulgated in Appendix I to 40 CFR part 268 on November 7, 1986 (51 FR 40593), as part of the Land Disposal Restrictions Rule for Solvents and Dioxins. The TCLP is used in the Land Disposal Restrictions (LDR) program to determine whether certain wastes require treatment prior to land disposal and to determine whether certain treated wastes meet the applicable treatment standards. In today's rule, the Agency has incorporated two other clarifications to the TCLP as proposed on May 24, 1988 (53 FR 18792) for use in both the LDR and the TC programs.

The Agency modified the proposed TCLP as a result of the Agency's own research and comments received on the January 14, 1986 (51 FR 1602) proposal for the LDR program and the June 13, 1986 (51 FR 21648) proposal for the TC. These modifications to the TCLP were promulgated on November 7, 1986 for the LDR program. On May 24, 1988, the Agency proposed additional modifications to the TCLP for both the LDR and the TC. In today's rule, the Agency has adopted two of these proposed changes, and is promulgating the revised TCLP for use in both the LDR and TC programs.

***11828** The first change is the insertion of a more detailed method flow chart to explain how analysts are to perform the test. Comments expressed confusion regarding the original flow chart (e.g., that it was difficult to follow), so the Agency has added this new chart to eliminate confusion. The second change is the addition of new equipment suppliers to provide more information on the availability of suitable testing equipment. The new equipment suppliers include two manufacturers of rotary agitation devices, Environmental Machine and Design, Inc., of Lynchburg, VA, and Millipore Corporation of Bedford, MA; two manufacturers of a zero-headspace extractor (ZHE) vessel, Lars Lande of Whitmore Lake, MI and Environmental Machine and Design, Inc., of Lynchburg, VA; and three manufacturers of filter media, Millipore Corporation of Bedford, MA; Nucleopore Corporation of Pleasanton, CA; and Micro Filtration Systems of Dublin, CA. These manufacturers are listed in Tables 2, 3, and 5, respectively, of the method (i.e., Appendix II of 40 CFR 261), along with company telephone numbers and equipment model numbers.

Another more substantial proposed modification, the addition of a stainless steel cage insert to the bottle extractor, will not be added by the Agency at this time for the reasons discussed below. The Agency had proposed this modification to eliminate the requirement for particle size reduction for certain types of wastes (e.g., solidified materials).

3. Applicability of TCLP to Solidified Wastes

Some commenters expressed reservations regarding the applicability of the TCLP to specific types of wastes. The wastes of concern were solidified wastes. Numerous commenters supported the reinstatement of the structural integrity procedure (SIP) or some other stability criterion for solidified wastes. They argued that particle size reduction (i.e., “grinding”) would be inappropriate in those instances where solidification of the waste is needed to meet the best demonstrated available technology (BDAT) provisions of the law and that grinding may not adequately represent the weathering process or the effect of vehicular traffic. Commenters recommended that the Agency retain the SIP. Others agreed that particle size reduction is inappropriate for stabilized monolithic wastes and produces unrepresentative results. Specifically, commenters stated that particle size reduction alters the physical character of many solidified wastes by destroying the cementitious property of these wastes in such a way that the leaching rate increases unrealistically. By increasing the surface area that is available to attack by a leaching medium, the amount and rate at which substances may be leached increases. Inasmuch as waste grinding is not normally employed in municipal landfills, particle size reduction renders the TCLP a less accurate model of leaching in a municipal landfill environment.

Since the June 13, 1986, proposal, the Agency has reviewed the use of the SIP, which uses a drop-hammer to test the integrity of the waste and to reduce its size if it fractures. The Agency found that although the SIP may simulate the potential of a monolithic waste to be degraded by vehicular traffic on a landfill, it cannot address certain other stresses acting on the waste (e.g., wet-dry and freeze-thaw cycles). In addition, the SIP can only be used for wastes that can be prepared in a sample of specified dimensions.

While evaluating the use of the SIP, the Agency found that dense, hard materials would occasionally break the glass extractor bottle. To prevent breakage of the bottles, the Agency developed a cage insert for the extractor bottle. The cage, which is designed to prevent contact between the hard sample and the sides of the bottle, is constructed of 0.25-inch stainless steel woven mesh. Experiments have shown that the use of the cage prevents bottle breakage.

While evaluating the utility of the cage, the Agency noticed that wastes that were believed to be well-solidified retained their monolithic nature in the cage during extraction, whereas wastes that were believed to be less well-stabilized (even though some of them had passed the SIP) were broken into small pieces during the extraction. Thus, these experiments led to the proposed use of the stainless steel wire cage in the extraction apparatus (53 FR 28792, May 24, 1988). The use of this device, the Agency believed, tested the physical integrity of the sample and reduces particle size appropriately.

Commenters expressed support for the cage modification—that it is a step in the appropriate direction toward a more realistic assessment of the environmental leaching potential of a solidified waste. However, commenters also had concerns that the cage was proposed prematurely—that not enough evaluation of waste samples using the cage had been done. Specifically, commenters argued that the cage could possibly leach significant quantities of nickel and chromium to contaminate metals analysis; that it would be difficult to collect representative samples in some cases; that there were problems with the configuration of the cage so that it could not be accommodated to fit a large array of bottles; that the cage's construction provided numerous crevices and a significant amount of surface area for waste residue to collect, making effective cage cleaning difficult; and that solidified samples could be molded into a shape that would cause less material to be sloughed off during extraction, leading to a less aggressive test. The Agency agrees with these commenters and has decided not to go forward with the cage modification at this time. The Agency currently has work underway to evaluate all these concerns, and will continue to evaluate modifications of the TCLP and will propose further improvements as they are developed.

4. Analytical Methods

Several comments addressed the analytical difficulties of analyzing the TCLP extract for phenolic compounds and phenoxy acid herbicides by gas chromatography/mass spectroscopy, SW-846 Method 8250 (GC/MS). These analytical difficulties include the interference of the acetate ion in the TCLP leach fluid with the column packing material of Method 8250. Removal of the acetate ion is often difficult, and equipment damage may result if the acetate is not removed (i.e., the acetate ion can destroy the column packing material).

The Agency agrees that analysis for acidic compounds by GC methods may be difficult, but not impossible. The Agency suggests the use of a bonded-phase capillary column (Method 8270) to reduce the interference from acetate. In addition, the Agency is investigating other methods for removal of the acetate ion from the extract before analysis for the phenolics and herbicide and welcomes alternative suggestions, especially when accompanied by supporting data.

The Agency had suggested the use of HPLC as an alternative to GC/MS analysis of phenolics and phenoxy acid herbicides. However, several commenters believed that an HPLC method is generally regarded as more expensive and not as readily available as GC/MS. In addition, some commenters indicated that GC/MS is a better method analytically than HPLC, and that HPLC would be more difficult to implement. The commenters expressed that, at the very least, a lengthy verification process would be ***11829** required to determine an HPLC method's ruggedness and reproducibility and to determine the most effective cleanup steps. The commenters further suggested that even if an effective HPLC cleanup procedure is developed and approved by the Agency, it is bound to increase the analytical costs and slow down the analytical throughput. Even without considering this restriction, the procedure of leaching the organics into an aqueous medium, followed by extraction, recovery,

and concentration, is bound to require more manpower and thus more money than a more direct solvent extraction of the solid itself. The commenters indicated that methods for analyzing solid waste for semi-volatile organics and phenoxyacid herbicides are already described in SW-846 and should be the preferred methods, both for practicality and as a way of providing a reliable test.

The Agency agrees that the GC/MS or GC/electron capture (GC/EC) analysis is more advantageous for the analysis of phenolics and phenoxy acid herbicides because the equipment is more readily and widely available than HPLC, despite the associated difficulties. HPLC methods for phenolic compounds are not included in the third edition of SW-846 because of a lack of validation data. The Agency will allow only the use of the GC/MS method until such time that the Agency proposes an HPLC method.

G. Testing and Recordkeeping Requirements

1. Existing Requirements for Generators

Under existing regulations, persons who generate solid waste are not specifically required to test their wastes to determine whether they exhibit the characteristic of EP toxicity or any other characteristic. Instead, solid waste generators are required to make a determination as to whether or not their wastes are hazardous (40 CFR 262.11).

If a waste is found to be excluded from regulation under § 261.4, or if it is found to be a listed hazardous waste under subpart D of 40 CFR part 261, no further determination of hazardousness is necessary. On the other hand, if a waste is neither excluded nor listed, the solid waste generator must determine whether it exhibits any of the hazardous waste characteristics in subpart C of 40 CFR part 261. This determination may be made by either testing the waste or applying knowledge of the waste, the raw materials, and the processes used in its generation.

If a waste is determined to be hazardous, the generator must keep records establishing the basis for that determination (40 CFR 262.40(c)). These records must be maintained for at least 3 years after the generator no longer handles the waste in question. Neither of these recordkeeping requirements, however, applies to solid waste generators who do not generate hazardous wastes.

Other provisions in the hazardous waste regulations make generators responsible for knowing the properties of their wastes and for documenting that knowledge. For example, generators who declare that their wastes are hazardous must nevertheless have sufficient knowledge of their wastes to complete the Uniform Hazardous Waste Manifest, to use proper labels, containers, and placards, and to satisfy all applicable reporting and recordkeeping requirements (see 45 FR 12728, February 26, 1980). In addition, all generators of hazardous waste are required under 40 CFR part 268 to determine whether their wastes are restricted from land disposal.

2. Changes Considered

In the June 13, 1986 proposal, EPA expressed concern that the current system for determining whether a solid waste is hazardous may be inadequate to ensure that wastes are characterized properly as hazardous or nonhazardous. Because of the importance of accurate hazard determinations to the RCRA subtitle C program, the Agency discussed the possibility of requiring solid waste generators to test their wastes periodically.

In the proposed rule, EPA identified three general approaches that might be adopted in the TC final rule. In the first approach, the Agency would retain the current approach, allowing generators to rely on their knowledge of materials and processes used in generating wastes as a basis for their determination. In the second approach, EPA would require the testing of wastes, at a frequency specified by regulation. Finally, in the third approach, the Agency would require testing but without specifying a particular testing frequency. Under this third approach, generators would be required to develop an appropriate testing frequency, based on Agency guidance, and to document the basis for their choice.

Commenters were heavily divided on the issue of testing and recordkeeping requirements. Many commenters, including waste management firms and a few generators, favored mandatory testing of solid wastes. Most of these commenters argued that generators typically lack sufficient information to determine accurately the composition of their wastes without testing. Indeed, one commenter claimed that with 52 constituents regulated at the part-per-million level or lower, a generator could never be sure whether a waste exhibits the TC without performing the TCLP test. The commenters concluded that testing is the only reliable method for ensuring that potentially hazardous wastes are properly identified and managed.

A few commenters offered somewhat different reasons for supporting testing requirements. For example, some commenters pointed out that mandatory testing would facilitate EPA enforcement efforts. Others claimed that mandatory testing would reduce uncertainty by making it clear to generators precisely what EPA expects of them with respect to performing hazardous waste determinations.

Another group of commenters, however, opposed the imposition of a formal testing requirement. These commenters argued that mandatory testing would place an inordinate burden on the regulated community without providing significant benefit for human health and the environment. In particular, the commenters claimed that mandatory testing is unlikely to identify wastes that were improperly characterized as nonhazardous when generators relied exclusively on their knowledge. According to these commenters, generators rely on their knowledge only when the wastes they produce are clearly hazardous or clearly nonhazardous. Whenever uncertainty exists, these commenters stated, generators either declare their wastes hazardous or perform appropriate tests. The commenters emphasized that this cautioned response results from generators' liability for making incorrect determinations, regardless of whether they test their wastes. The commenters concluded that requiring testing of all wastes would deplete resources and place a strain on limited laboratory capacity.

The Agency recognizes that there are many difficult issues related to the imposition of a testing requirement, both for the Toxicity Characteristic and the other hazardous waste characteristics. While the Agency believes that a testing requirement could improve the Agency's enforcement tools, the Agency believes that the current requirements for hazardous waste determinations are not ineffective because many generators do have sufficient knowledge to make a determination without a test. The Agency further believes that liability for incorrect determinations provides a strong incentive for not misclassifying hazardous wastes as non-hazardous. Although EPA thinks that the current ***11830** system set forth in 40 CFR 262.11 is effective, the Agency believes that imposing a testing requirement does have some merit, in that it could increase the accuracy of determinations, could clarify the responsibilities of generators, and could facilitate compliance monitoring.

The Agency will continue to evaluate the comments on this issue as well as explore other options for a testing requirement. At present, however, the Agency is not yet ready to go forward with a testing requirement based on any of the options it has evaluated thus far. Should the Agency decide that an appropriate approach is available, it will propose and solicit comment upon the details of that approach in a separate rulemaking. In the meantime, the Agency believes that the existing determination requirement (as specified at 40 CFR 262.11), as well as the liability for incorrect determinations, is effective and practical.

H. Applicability to Wastes Managed in Surface Impoundments

As discussed above, in response to the proposed TC, EPA received many comments questioning the validity of applying the TC to wastes, including wastewaters, likely to be managed in surface impoundments. In response to commenters' concerns, on May 18, 1987, EPA published a Supplemental Notice of Proposed Rulemaking in the Federal Register, which requested comments and data on several issues related to the regulation of wastes managed in surface impoundments under the TC rule. The Agency also requested comment (assuming such an approach) on: (1) The criteria to be used to determine whether the surface impoundment scenario should apply to a particular waste, (2) the point at which concentration measurements should be made (e.g., at the point of generation or within the impoundment), and (3) how multiple surface impoundments should be handled under the TC rule.

Comments received in response to the notice concerning the surface impoundment management scenario are summarized and addressed in section III.A.2.c. Comments received in response to the notice, which addressed sampling point and multiple impoundment issues, are discussed below.

1. Sampling Point

In the May 18, 1987 notice, EPA requested comments on whether evaluations of wastes managed in surface impoundments should be based on measurements of the concentration in the impoundment or at the inlet to the impoundment. In response, some commenters supported sampling at the inlet to the impoundment and stated that sampling the waste within the impoundment is not only contrary to Congressional intent, but conflicts with EPA's own regulations that require the determination of hazard to be made at the point of generation.

Other commenters, however, argued that wastes should be sampled within the impoundment or that the impoundment effluent should be sampled. Many of these commenters argued that measuring the concentrations in the impoundment more accurately represents the concentrations of hazardous constituents that pose a threat to ground water. Some commenters argued that evaluation of hazard should be based on impoundment effluent because concentrations of the wastewaters within the impoundment are approximately the same as the concentrations in the impoundment effluent.

If the Agency were to allow persons to make their determinations on the waste in the impoundment, it would raise questions that the Agency has not yet evaluated completely nor taken comment on. For example, in this situation, should the Agency actually require testing; if so, how often and what should be tested? Would such a result allow persons to land dispose of wastes that (but for the point of hazard determination) would be hazardous, contrary to Congressional intent? Would such a result allow persons to treat wastes without a permit and thus be inconsistent with Congressional intent? EPA concedes that, for some activities (e.g., closure), leachate quality may be more appropriately assessed by measuring concentrations at multiple sites within the impoundment.

The current rules require that the determination of whether a waste is hazardous be made at the point of generation (i.e., when the waste becomes a solid waste). (A waste must be a solid waste before it can be classified as a hazardous waste under RCRA.) EPA believes that determination of the regulatory status of a waste at the point of generation continues to be appropriate, especially since the Agency is not developing a separate mismanagement scenario or set of regulatory levels for wastewaters. To be consistent with other hazardous waste regulations and until the Agency addresses the above questions, EPA is retaining the existing approach of requiring sampling at the point of generation.

2. Multiple Surface Impoundments

In the May 18, 1987 notice, EPA requested comment on how multiple surface impoundments or “treatment trains” should be handled under the TC rule. Some commenters favored regulating all surface impoundments in a treatment train as a single unit—if the first impoundment treats a hazardous waste, all impoundments would be required to comply with the RCRA regulations for hazardous waste treatment facilities. Other commenters, however, suggested that each impoundment should be regulated individually. Still other commenters stated that owners and operators should be required to determine whether the most upstream surface impoundment is treating wastes that exhibit the TC, but they should only be required to evaluate downstream impoundments if an upstream impoundment exhibits the TC.

As discussed above, the Agency has decided not to develop a separate regulatory scheme for surface impoundments. Thus, the Agency will continue to regulate all surface impoundments as individual units and will not pursue any of the other options discussed by commenters. Currently, under 40 CFR part 261, each surface impoundment in a series of multiple surface impoundments is regulated separately. If a surface impoundment receives or generates a hazardous waste, the owner or operator of the impoundment is required to comply with the RCRA regulations governing hazardous waste treatment, storage, and disposal facilities. On the other hand, if a downstream impoundment is not treating or generating a characteristically hazardous

waste and upstream units have not managed, listed wastes, then the downstream unit is not subject to RCRA subtitle C requirements.

I. Relationship to Other RCRA Regulations

1. Hazardous Waste Identification Regulations

a. Hazardous Waste Listings. Under the June 13, 1986, proposal, the hazardous waste listings in subpart D of 40 CFR part 261 would not be affected. All the listings would remain in effect, including those listings that were based on the presence of TC constituents. It is EPA's intention that the hazardous waste listings would continue to complement the revised TC as they had the EPTC.

A number of commenters, however, argued that the TC should supersede certain hazardous waste listings. In ***11831** particular, they suggested that the TC should be the only basis for regulating wastes that have been identified as hazardous solely because of the presence of a TC constituent. Such an approach, according to the commenters, would establish a more rational basis for identifying hazardous wastes. Wastes failing the TC test would be regulated as hazardous wastes, whether or not they have previously been listed, because they have demonstrated the potential to pose a threat to human health and the environment. Wastes passing the TC test, in contrast, would not be subject to subtitle C regulation. The commenters claimed that, by definition, if the extract from a waste that was listed because of the presence of a TC constituent does not contain the constituent in a concentration greater than or equal to the regulatory level, the waste can safely be managed at a subtitle D facility.

EPA does not agree that the TC revisions justify elimination of any of the hazardous waste listings. The Agency has consistently maintained that individual waste streams may be listed regardless of whether the waste is defined as hazardous by the TC. Exhibiting a characteristic can constitute the basis for listing a waste. In fact, prior to today's action, approximately 25 listings were based on the presence of metals or pesticides covered by the EPTC.

There are a number of reasons for continuing this approach. First, listed wastes frequently contain hazardous constituents other than the ones cited in Appendix VII of 40 CFR part 261 as the basis for the listings. It is for this reason that Congress directed EPA, in evaluating delisting petitions, to consider constituents other than those for which the wastes were listed, assuming that there is a reasonable basis to believe that such constituents might render the wastes hazardous (see RCRA section 3001(f)). In many cases, the additional hazardous constituents that are present in a waste may not be on the list of TC constituents. The listings may therefore serve to identify wastes that pass the TC test but are nevertheless hazardous. Removing wastes from a hazardous waste listing without an evaluation of additional constituents would appear to be inconsistent with the intent of section 3001(f).

Another reason for retaining the hazardous waste listings is that TC constituents may continue to pose a threat to human health and the environment even when they are present in concentrations lower than the regulatory levels. The regulatory levels have not been designed to address the problems of phytotoxicity, aquatic toxicity, or bioaccumulation potential. Moreover, they have not been designed to identify the full range of wastes that may be toxic to human beings. Instead, the characteristic levels have been established at concentrations where there is a high degree of certainty that any wastes with constituents at levels equal to or exceeding the regulatory levels pose a potential threat to human health. Individual wastes may continue to be hazardous, despite the fact that they may contain TC constituents in concentrations below the regulatory levels. This is particularly true for wastes that have the potential to be exposed to more aggressive leaching conditions than those modeled in the TCLP. As a result, EPA believes that wastes previously listed as hazardous should continue to be considered hazardous, whether or not they exhibit the characteristic.

b. “Mixture” and “Derived From” Rules. Because the TC will not supersede the listings for hazardous wastes, it also will not affect the regulatory status of wastes that are hazardous by virtue of the “mixture” rule of 40 CFR 262.3(a)(2)(iv) or the “derived from” rule of 40 CFR 261.3(c). The “mixture” rule provides that any mixture of a listed hazardous waste and a solid waste is

itself a RCRA hazardous waste.[FN3] The “derived from” rule states that any waste derived from the treatment, storage, or disposal of a listed hazardous waste is hazardous.

Several commenters contended that the current regulatory scheme encompasses wastes that contain de minimis quantities of leachable organic chemicals. The commenters acknowledged that mixtures and treatment residues posing insignificant threats to human health and the environment may be excluded from regulation through the delisting process. However, they claimed that delisting is unduly expensive, time-consuming, and, in some cases, impractical. The commenters suggested as an alternative that mixtures and treatment residues from listed wastes containing TCLP constituents not be considered hazardous unless they fail the TC test. They contended that this approach would adequately protect human health and the environment. Moreover, it would be “self-implementing,” in the sense that it would eliminate the need for the current process of petitions and Agency review for delisting.

EPA recognizes that the “mixture” and “derived from” rules may create some inequities by including wastes that contain very small amounts of hazardous wastes that have been mixed so as to render them nonhazardous. However, the Agency has consistently maintained that the mixture and derived from rules are an appropriate regulatory approach for dealing with waste mixtures and treatment residues.

When the rules were promulgated in 1980, EPA stated that it was essential to regulate waste mixtures to prevent generators from evading subtitle C requirements by simply co-mingling listed wastes with nonhazardous wastes. The Agency also determined that because of the infinite potential combinations of listed wastes and other wastes, it was unable at that time to devise any workable, broadly applicable formula that was capable of distinguishing between hazardous and nonhazardous mixtures. The Agency acknowledged that the “mixture” rule might be overly broad, but noted that generators could avoid any inequities either by segregating their wastes or by obtaining a waste-specific exclusion under the delisting program (see 45 FR 33095, May 19, 1980).

EPA also believed that it was important to regulate wastes from the treatment, storage, or disposal of listed hazardous wastes on the basis that these “derived from” wastes might themselves be hazardous. Once again, however, the Agency found that because of the large number of listed wastes and treatment processes (some of which introduce new hazardous constituents into the treatment residues), it was unable to prescribe standards that could properly distinguish between hazardous and nonhazardous residues. (It should be noted that the definition of treatment is not confined to rendering a waste non-hazardous, but also includes any method designed to change the nature of a waste to render the waste (1) less hazardous; (2) safer to transport, store, or dispose; (3) amenable for recovery; or (4) reduced in volume (see 40 CFR 260.10).) Therefore, the Agency concluded that wastes generated during the treatment of listed wastes should be presumed to be hazardous. Delisting was provided as the mechanism for excluding these wastes from subtitle C regulation (45 FR 33096, May 19, 1980).

EPA is sympathetic to the commenters' concerns regarding use of delisting to exclude wastes that are ***11832** hazardous under the “mixture” and “derived from” rules. The Agency does not believe, however, that the alternative suggested by the commenters (i.e., relying on the TC to regulate mixtures and treatment residues) would adequately protect human health and the environment. As noted above, wastes that pass the characteristic test may nevertheless be hazardous, either because they contain listed constituents at concentrations below the TC regulatory levels but at levels and under circumstances that nevertheless render the waste hazardous or because they contain hazardous constituents that are not covered by the TC rule. As noted above, the TC regulatory levels are not threshold levels defining all hazardous waste, but are levels that are set to clearly define hazardous waste. Wastes containing constituents falling below these levels may still present a hazard in more limited situations.

Nevertheless, the Agency recognizes that some inequities may result by the application of the “mixture” and “derived from” rules to certain dilute listed wastes. The Agency therefore is considering proposing an amendment to the definition of hazardous waste which would establish self-implementing de minimis exemption levels for hazardous constituents found in listed wastes. Listed wastes that meet these exemption levels would no longer be listed hazardous wastes and thus would not need to be managed as hazardous wastes unless they exhibit a hazardous waste characteristic.

c. Mixture Rule Exemption. The mixture rule under 40 CFR 261.3(a)(2)(iv) provides an exemption from RCRA subtitle C regulation for mixtures of wastewaters and certain listed spent solvents. The mixture rule exemption is applicable only if the maximum weekly usage of the solvents (other than solvents that can be demonstrated not to be discharged to wastewater) divided by the average weekly flow of wastewater does not exceed specified values. The mixture rule exemption does not apply to wastewaters that exhibit a characteristic of hazardous waste or to wastewaters that contain listed hazardous wastes not specified in the mixture rule exemption.

A number of commenters claimed that the proposed TC conflicts with the mixture rule exemption. The commenters noted that the mixture rule exemption levels are higher than the corresponding TC regulatory levels for solvent constituents. Because of this difference in regulatory levels, the commenters stated that the proposed TC rule will bring large quantities of currently exempted wastewaters into the hazardous waste management system. In effect, the commenters argued that the TC rule will revoke the mixture rule exemption. Commenters disapproved of this result, stating that the mixture rule exemption was promulgated in recognition that small amounts of certain spent solvents are often most efficiently managed by being discharged to a plant's wastewater treatment system and that this method of management does not pose risks to human health and the environment.

EPA acknowledges that the TC rule may bring some currently exempted wastewaters into the subtitle C regulatory system; however, the mixture rule exemption is an exemption from the hazardous waste listings, not the characteristics. Thus, there is no inconsistency between this rule and the mixture rule exemption. In addition, it should be noted that the TC regulatory levels are based on state-of-the-art toxicological data and risk assessment methodologies. Consequently, EPA believes that the TC regulatory levels are the best measures available to identify wastewater mixtures that pose a threat to human health and the environment. In contrast, the mixture rule exemption levels are based upon less current risk information.

Even though some wastewaters presently covered by the mixture rule exemption will become hazardous wastes as a result of the TC rule, EPA believes that the exemption will continue to serve an important purpose by ensuring that mixtures of wastewaters and certain listed spent solvents will not be considered hazardous unless they exhibit a characteristic of hazardous waste. To clarify the mixture rule exemption and make it more consistent with current risk information, EPA is considering proposing in the future that the mixture rule exemption levels be reduced so that they are equivalent to the TC regulatory levels.

d. Delisting. While the June 13, 1986 proposal did not specifically address the effect that the TC might have on the hazardous waste delisting program under 40 CFR 260.22, a number of comments were received claiming that the TC rule would be inconsistent with existing EPA policies regarding case-by-case exclusions. In the August 1, 1988 proposal, however, the Agency solicited comment on the use of the EPACML model in the delisting program.

The commenters noted that each major element of the delisting program is different from the corresponding element in the original TC proposal. For example, the chronic toxicity reference levels that are used to establish “no hazard” levels under the delisting program appear to differ from the levels that were used to establish the proposed TC regulatory standards. In addition, the delisting program uses (as appropriate) a different ground water transport model (i.e., the Vertical and Horizontal Spread (VHS) Model), which generates generic DAFs rather than compound-specific factors. Finally, the delisting program employs (as appropriate) the Organic Leachate Model (OLM) rather than the EP or the TCLP to determine the degree to which various organic constituents are likely to leach from solid wastes. The commenters urged the Agency to use the same reference levels, DAFs, and leaching procedures in both the characteristic and delisting programs. A few commenters expressed a particular preference for adopting the delisting elements as part of the revised TC.

There were a number of differences between the various elements of the proposed TC and the corresponding elements in the delisting program. However, regarding Chronic Toxicity Reference Levels, the only difference between the levels used in the delisting program and those in the TC final rule is the use of different risk levels for the carcinogens (i.e., delisting uses a more conservative risk factor of 10-6 for carcinogens, compared to the use of a 10-5 risk factor in the TC rule). Many of the differences between the chronic toxicity reference levels used in the TC rule and those in the delisting program have been

eliminated as a result of decisions concerning risk levels and apportionment. Furthermore, the health-based levels used in the delisting program and in the TC rule have been updated to incorporate recent Agency evaluations (see 53 FR 18024).

EPA believes that the risk factors being used for each program are appropriate, and does not think that risk levels used to set regulatory levels should necessarily be the same in the two programs because each serves a separate purpose. Delisting evaluates the hazard posed by specific individual wastestreams that have been listed as hazardous. Characteristics identify broad classes of clearly hazardous wastes; specific wastes that may pose a substantial identified hazard in a lower risk range may be listed as hazardous. As discussed below, EPA believes it is appropriate that the delisting program is, in certain cases, more stringent than the characteristic program.

***11833** A number of commenters focused on the overall stringency of the characteristic and delisting programs. In particular, the commenters stated that the proposed TC regulatory levels were sometimes greater than and sometimes less than the concentration standards used by the Agency's delisting program in determining when listed wastes may properly be managed in subtitle D facilities. Most of the commenters argued that EPA, in the interest of consistency, should adopt the same concentration standards under the characteristic and delisting programs. Other commenters, however, urged the Agency to establish higher concentration standards under the revised characteristic. The latter group of commenters noted that characteristics are designed to identify broad classes of solid wastes that are “clearly” hazardous, while listings are designed to identify wastes that may not exhibit a characteristic, yet are nevertheless hazardous. The commenters concluded that, in light of the different functions of listings and characteristics, it should be more difficult for a waste to pass the delisting standards (i.e., to be eligible for delisting) than for the same waste to pass the characteristic test.

EPA does not agree with those commenters who argued that the Agency must use the same concentration standards in the characteristic and delisting programs or, that the concentration standards for characteristics must be higher than those for delisting. These programs have very different purposes. While hazardous waste characteristic levels are those equal to or above which a waste is clearly hazardous due to a particular property, delisting levels are those below which a waste is not hazardous. Thus, it is reasonable that these two levels may or may not coincide. Delisting decisions are based on an extensive evaluation of a particular waste which requires specific information on the waste. The characteristics approach to defining a hazardous waste is much more broad. Only one mismanagement scenario is used and it is based on “reasonable worse-case” assumptions resulting in a “generic” regulatory level to be applied to all solid waste. And, of course, section 260.22 of the RCRA regulations specifies that a waste may not be delisted if it exhibits a characteristic of hazardous waste (e.g., the characteristic of EP toxicity). Thus, the delisting program could never be less stringent than the characteristic program.

In regard to the use of different models in the delisting and characteristic programs, in the August 1, 1988 Federal Register notice, the Agency specifically solicited comment on the use of the Toxicity Characteristics model (EPACML) in place of the model currently used in the delisting program (the VHS model). All of the commenters supported the use of EPACML instead of the VHS model in the delisting program, although one commenter supported this only if it would not add complexity and thereby increase the time required for delisting petition evaluation. Another commenter stated that the EPACML model should be used in the delisting program but that petition evaluations should not be restricted to the use of any single specific model. Finally, several of the commenters stated that the Agency should present details as to how the EPACML model would be used for delisting in a separate Federal Register notice.

In response to these comments, the Agency will use the EPACML model and the TCLP in the delisting program. Also, as suggested, the Agency will explain how the model and the TCLP will be used in a future Federal Register notice.

A few commenters expressed concern about the applicability of the TC to wastes that have previously been delisted. The commenters argued that once EPA has ruled (through the waste-specific delisting process) that a particular waste stream poses no threat to human health and the environment, the Agency should be barred from using a generic rule to declare the same waste as being “clearly” hazardous. One commenter claimed that it would be especially unfair to alter the regulatory status of

a waste stream after the person managing it has been granted an exclusion and has acted in reliance on that exclusion (e.g., by changing the production process or waste management practices).

EPA has consistently maintained that wastes "excluded" from subtitle C regulation under the delisting program may nevertheless be hazardous if they exhibit a characteristic of hazardous waste (see 40 CFR 260.22). While the TC rule will apply to previously delisted waste, EPA does not, in general, expect that such wastes will become hazardous because of application of the revised TC. The Agency believes that, because delisting levels are more stringent than the final TC levels, the impact of the TC rule on previously delisted wastes will be minimal. Nevertheless, if a previously delisted waste exhibits the TC, it will again be subject to subtitle C requirements (i.e., delisted wastes are treated no differently than any other solid waste).

2. Land Disposal Restrictions

a. Risk Levels and Frequency Interval. The approach used to develop regulatory levels in the proposed TC rule was similar to the original approach suggested for developing treatment standards in the proposed Land Disposal Restrictions (LDR) rule (51 FR 1602, January 14, 1986). Both proposals began with health-based concentration thresholds at the point of exposure and used subsurface fate and transport models to back-calculate allowable constituent concentrations in the leachate. In the June 13, 1986 TC proposal, the Agency requested comments on whether the risk levels and cumulative frequency level used in the TC should be the same as those used to develop the treatment standards in the proposed LDR rule.

Several commenters supported the use of different risk levels and cumulative frequency levels in the two proposals. These commenters stressed that different statutory mandates for the two rules and the entirely different functions of the TC regulatory levels and the LDR treatment standards warranted different approaches. However, other commenters contended that the frequency level and risk levels in the TC rule should be the same as or more stringent than those used in the LDR proposal. Some of these commenters argued that the more stringent risk levels and frequency level in the LDR proposal provided a more appropriate degree of protection for human health and the environment than the corresponding levels and frequency interval in the TC proposal.

The issue of consistency of risk levels and frequency level for the TC and the LDR program is now moot. The LDR final rule (51 FR 40572, November 7, 1986) abandoned the use of screening levels based on risk methodology and subsurface fate and transport modeling, and promulgated an approach to establishing treatment standards based entirely on technology-based standards expressed as Best Demonstrated Available Technology (BDAT). Today's rule continues to be based upon health-based concentration levels and dilution/attenuation factors, the values for which are based upon the predictions of a subsurface fate and transport model.

b. Treatment Standards for TC Wastes. Under RCRA section 3004(g)(4), EPA is required to make an LDR determination for all TC wastes within 6 months of today's action, as discussed in the following section. Several commenters were concerned that the LDR treatment standards that will ***11834** eventually be established for the TC wastes may be inconsistent with TC regulatory levels. Some of these commenters noted that the proposed LDR treatment standards for listed spent solvents were in many cases lower than the proposed TC regulatory levels for the identical constituents in unlisted characteristic wastes. The commenters feared that if LDR treatment standards are applied to unlisted TC wastes in the same manner as they are applied to similar listed wastes, the characteristic wastes may require treatment to below the TC level before subtitle C land disposal is permissible. This means that unlisted wastes no longer exhibiting the TC must continue to be managed as hazardous wastes. Some commenters who voiced concerns over potential differences between TC regulatory levels and LDR treatment standards suggested that there should be a clear continuum of regulatory levels, with the higher standards being those that deem a waste hazardous in the first place (i.e., the TC regulatory levels).

Wastes deemed hazardous under the TC will not immediately become subject to the LDR program on the effective date of the TC rule, except perhaps by operation of the California List restrictions (i.e., halogenated organic compounds are subject to the LDR if they exhibit a characteristic, see 52 FR 25770, July 8, 1987). However, the Agency has not yet determined whether the existing LDR California List restrictions should be applicable to newly identified TC wastes. The Agency specifically

requested comment on the appropriateness of applying the California List prohibitions to newly identified hazardous wastes in the November 22, 1989 proposed rule for the "Third Third" of scheduled wastes (54 FR 48499). The Agency will fully address this issue as part of the "Third Third" final rule.

Since the Agency is not today proposing LDR treatment standards for the TC wastes, the Agency believes that it is more appropriate to address these comments when the LDR treatment standards are proposed. However, in response to comments that proposed treatment standards for listed solvents were lower than proposed TC levels, the Agency would like to point out that the treatment standards for TC wastes will not necessarily be the same as the corresponding LDR treatment standards for spent solvents. Indeed, if the TC wastes belong to a different treatability group, one can expect that the treatment standards will be different.

c. Schedule for LDR Determinations. For wastes already listed or identified at the time of enactment of HSWA, the Agency must make LDR determinations according to the schedule set forth in RCRA section 3004(g)(4). If EPA fails to make the determinations by the established schedule, the wastes are automatically subject to the land disposal restrictions on the scheduled date. EPA must also make LDR determinations for all wastes that are identified or listed as hazardous after November 1984 (when HSWA was enacted) within six months after the wastes are identified or listed.

On November 22, 1989 (54 FR 48372), EPA proposed treatment standards for those wastes that exhibit the EPTC, as well as any of the other characteristics. Upon the effective date of today's rule, the TC will include the 14 EPTC constituents in addition to the 25 organics, and the TCLP will replace the EP. EPA proposed that the BDAT levels for wastes that exhibit the EPTC for the 14 constituents remain the same when the TC becomes effective. By May 8, 1990 the Agency will establish the final BDAT levels for the 14 constituent currently identified by the EPTC. Newly identified TC wastes are subject to the six-month listing deadline. However, wastes are not automatically prohibited from land disposal if EPA fails to make this required determination within six months.

Some commenters argued that the six-month deadline would accelerate the LDR determinations for listed wastes that contain TC constituents. For example, some commercial chemical products are currently scheduled to be reviewed by May 8, 1990 (51 FR 19300, May 28, 1986). However, these wastes also may exhibit the TC. Commenters were concerned that these wastes may be subject to the six-month deadline and claimed that this would effectively accelerate the determinations in a manner that would be contrary to Congressional intent.

Wastes that are newly identified as hazardous by today's rule will be subject to the six-month deadline for LDR determinations. However, even if EPA were to complete LDR determinations for TC wastes before May, 1990, the Agency disagrees with commenters that this has the potential to accelerate the determinations in a manner that would be contrary to Congressional intent. The dates set forth in RCRA section 3004(g)(4) are deadlines by which EPA must make LDR determinations or the wastes are automatically restricted from land disposal. EPA is in no way prevented or discouraged by the statute from making LDR determinations before any of its deadlines (RCRA section 3004(g)(5), "Not later than * * *"). lndeed, other determinations are being made ahead of schedule; the final rule for restricting "second third" wastes includes treatment standards and prohibitions for some "third third" wastes (54 FR 26594).

3. RCRA Corrective Action and Closure Requirements

Today's rule will have no direct effect on either the action levels of RCRA corrective action or the cleanup standards of RCRA closure requirements. However, to the extent that the TC brings more facilities under the RCRA program as hazardous waste management facilities, additional facilities will be newly subject to the subtitle C corrective action and closure requirements.

Although the corrective action program under subtitle C addresses remediation of releases of hazardous constituents from waste at facilities subject to RCRA permitting, the TC levels will be neither action levels (i.e., concentrations that, if exceeded, signal the need for corrective action) nor cleanup standards. Rather, corrective action, as a process, encompasses trigger levels and

cleanup standards that are developed from site-specific information gathered during the investigatory and evaluative phases of the process (i.e., the RCRA Facility Investigation and the Corrective Measures Study).

Thus, the levels or concentrations associated with today's TC rule are largely independent from levels associated with corrective action. Similarly, the closure requirements are unaffected by today's rule. The TC is not used to determine whether a facility has met the requirements for clean closure. However, it must be noted that solid wastes generated as a result of remediation of releases or in pursuance of closure requirements that exhibit the TC must be handled as a hazardous waste.

4. Minimum Technology Requirements

a. Applicability. HSWA added section 3004(o) to RCRA which imposes minimum technology requirements on owners and operators of certain landfills and surface impoundments seeking permits. HSWA also added a new section 3015 imposing similar requirements on certain interim status waste piles, landfills, and surface impoundments. Finally, HSWA section 3005(j) requires surface impoundments to be retrofitted to meet minimum technology requirements. EPA codified the statutory language in the Agency's ***11835** Codification Rule promulgated on July 25, 1985 (50 FR 28705). Facilities that will face new RCRA regulation following the promulgation of the TC will need to comply with the minimum technology requirements in order to remain in operation.

b. Scope of Minimum Technology Requirements—1. Permitted Facilities. Section 3004(o)(1)(A) requires that after November 8, 1984, certain landfills and surface impoundments must meet minimum technology requirements. The minimum technology requirements for 1andfills and surface impoundments appear in 40 CFR 264.301(c) and 264.221(c), respectively. They require the owner or operator of each new unit and each replacement unit or lateral expansion of an existing unit to install two or more liners and a leachate collection system between and, for landfills, above the liners.

2. Interim Status Facilities. Section 3015 of RCRA requires that certain waste piles, landfills, and surface impoundments meet minimum technology requirements. The minimum technology requirements for interim status waste piles, landfills, and surface impoundments appear in 40 CFR 265.254, 265.301, and 265.221, respectively. They require that the owner or operator of each new unit, replacement of an existing unit, or lateral expansion of an existing unit that is within the area identified in the part A permit application install liners and a leachate collection system or equivalent protection. Existing surface impoundments (i.e., surface impoundments regulated under subtitle C prior to November 8, 1984) had to be retrofitted to meet the minimum technology requirements by November 8, 1988.

c. Compliance with Minimum Technology Requirements. Facilities or units newly regulated as a result of the TC will have to meet the minimum technology requirements of sections 3004(o) and 3015 if and when they add a new unit, replace an existing unit, or laterally expand an existing unit. Surface impoundments must comply with the retrofitting requirement in section 3005(j)(6)(A), which requires the owner or operator of a newly-regulated surface impoundment to retrofit that impoundment 4 years from the date of promulgation of the additional listings or characteristics, that made it subject to regulation. Thus, surface impoundments that become regulated under subtitle C because of the TC will need to meet the minimum technology requirements on March 29, 1994. (However, retrofitting may be expedited due to the minimum technology requirements imposed under the capacity variance for land disposal under section 3004.) This extension applies only to those impoundments that contain solely the newly listed/characteristic wastes. Any impoundments that already contained listed/characteristic wastes currently are subject to RCRA regulations, including the minimum technology requirements. Other existing land disposal units (besides surface impoundments) that already contained wastes that exhibit the TC will not require retrofitting unless they are expanded or are replacement units.

5. RCRA Subtitle D (Solid Wastes)

a. Municipal Waste Combustion Ash. Several commenters requested that ash from municipal waste combustion (MWC) units be exempt from regulation under the TC. Many of these commenters argued that the regulation of MWC ash would be in direct conflict with RCRA section 3001(i), which provides that resource recovery facilities engaging in MWC “shall not be

deemed to be treating, storing, disposing of, or otherwise managing hazardous wastes." Other commenters indicated that the high costs associated with subtitle C regulation would discourage the recovery of energy values from MSW. They claimed that this result would run counter to the clear Congressional intent to encourage resource recovery as a beneficial alternative to the landfilling of MSW.

EPA articulated its position on the scope of section 3001(i) when the Agency codified the 1984 HSWA (see 50 FR 28725, July 15, 1985). However, two recent Court decisions have rejected EPA's 1985 interpretation. EDF v. City of Chicago, No. 88C769 (N.D. Ill.) (slip op. Nov. 29, 1989) and EDF v. Wheelabrator Technologies Inc., No. 88Civ.0560 (S.D. N.Y.) (slip op. Nov. 21, 1989). The Agency is considering the appropriate response to these two decisions.

b. Impact on Wastes Excluded from Subtitle C Regulation. Another group of commenters asked for assurances that the TC rule would not affect the existing exclusions for specific wastes under 40 CFR 261.4(b). One commenter expressed particular concern about the exclusion for mixtures of household and other nonhazardous solid wastes. Another commenter raised questions about applying the TC to wastes that are usually considered to be non-hazardous solid wastes. Other commenters focused on the exemptions for "special wastes," primarily mining and mineral processing wastes and oil and gas production wastes. A utility company consortium addressed the exemption for wood treated with arsenic, commonly used as a fungicide for utility poles. The commenter noted that cresols and pentachlorophenol, also used as fungicides for wood, are proposed as TC constituents; the commenter asserted that the exemption for arsenic-treated wood should be extended to creosote- and pentachlorophenol-treated wood as well.

The TC rule will not apply to wastes that are already excluded from subtitle C regulation under § 261.4(b). These wastes will continue to be exempt from regulation as hazardous wastes, even if they would exhibit the TC. Likewise, the TC rule does not add any exclusions to the applicability of previously promulgated hazardous waste characteristics. With respect to the issue of creosote- and pentachlorophenol-treated wood, EPA does not at this time intend to expand the list of exemptions under § 261.4(b) to include these wastes. This is discussed further in section III.J.4.b.

It should be noted, however, that the special waste exclusions are currently being reevaluated in accordance with the criteria and procedures mandated by Congress. After completing the studies required by RCRA section 8002, EPA may determine that one or more special wastes should be regulated under RCRA subtitle C (see RCRA section 3001(b)). Such wastes would then be listed or the generators required to determine whether the wastes exhibit a hazardous waste characteristic.

A few commenters argued that even if special wastes are brought into the subtitle C system, they should not be subject to the TC. These commenters claimed that codisposal of special wastes with MSW is implausible because special wastes, by definition, are generated in very large quantities. The commenters recommended that EPA develop a separate mismanagement scenario and leaching procedure for special wastes.

At this time, the Agency cannot agree that the TC should not be applicable to special wastes; rather, the applicability to these wastes will be determined on a case-by-case basis. If EPA makes a determination that any special wastes should be regulated under RCRA subtitle C, the Agency will at that time make a separate determination concerning the applicability of the TC to such wastes.

6. RCRA Subtitle I (Underground Storage Tanks)

a. Scope of the Underground Storage Tank Program. Subtitle I of RCRA provides for the establishment of a ***11836** regulatory program for underground storage tanks containing "regulated substances." Regulated substances are defined under RCRA section 9001(2) as (1) petroleum and (2) hazardous substances listed under section 101(14) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund), excluding hazardous wastes regulated under subtitle C of RCRA.

Except as discussed below, today's action will change the regulatory status of TC wastes that were previously subject to RCRA subtitle I. Because these wastes will be RCRA hazardous wastes, they are excluded from regulation under subtitle I (see 40 CFR part 280.10(b)(1)). For this reason, underground storage tanks that contain TC wastes will be subject to the subtitle C tank requirements rather than those promulgated under subtitle I.

b. Deferral for Petroleum-Contaminated Media and Debris Subject to Part 280 Corrective Action Requirements. As part of its underground storage tank (UST) program, the Agency has recently promulgated regulations which address releases from USTs containing petroleum (see 53 FR 37082, September 23, 1988 and 53 FR 43322, October 26, 1988). Among other requirements, these rules require petroleum UST owners and operators to install leak detection, to report leaks from their tanks and piping, to undertake corrective action to address such releases, and to demonstrate financial assurance for corrective action and third party liability resulting from such releases. These requirements started going into effect in December, 1988, and the Agency estimates that over the next few years more than 300,000 petroleum UST releases will be discovered and be subject to the subtitle I corrective action requirements. In addition, the Agency has, through cooperative agreements, provided funding to states from the Leaking Underground Storage Tank (LUST) Trust Fund under RCRA to undertake the necessary response actions where petroleum UST owners and operators are unable or unwilling to do so. Hundreds of petroleum UST cleanups have been initiated to date under this program.

As noted in the preamble to the final UST rules, due to the large regulated community affected by the UST regulations, the UST program is based on self-implementing requirements and is highly dependent upon voluntary compliance to attain the environmental performance objectives of the program. However, because petroleum contains several of the hazardous constituents for which regulatory levels are being established today (e.g., benzene) some of the petroleum-contaminated media and debris may exhibit the Toxicity Characteristic under today's rule. While the amount and type of media and debris that may exhibit the characteristic at any particular UST site will depend upon the petroleum product, soil type, and the size of the release, it is likely that many sites where petroleum UST releases have occurred will contain some media that exhibits the Toxicity Characteristic. The management of any such media and debris would be subject to subtitle C requirements for hazardous waste management.

The Agency has insufficient information concerning the full impact of this rule on UST cleanups, but the information available to date suggests that the impact may be severe in terms of the administrative feasibility of both the subtitle C and subtitle I programs. Thus, the Agency has decided to defer a final decision on the application of the TC to media and debris contaminated with petroleum from USTs subject to the part 280 requirements. The application of today's rule to these cleanups will be delayed while the Agency evaluates the extent and nature of this impact and alternative administrative mechanisms for implementing the UST cleanups in accordance with subtitle C requirements. The Agency believes that the UST regulations governing cleanups at these sites will be adequate in the interim to protect human health and the environment.

The deferral of a final decision concerning application of this rule to UST cleanups is necessary for several reasons. First, while the actual number of sites and amount of media and debris at each site that would exhibit the toxicity characteristic under today's rule is unclear, based on a preliminary assessment, the number and amount could be extremely high. As noted above, EPA expects hundreds of thousands of UST releases to be uncovered in the next few years. Subjecting each of these sites to subtitle C requirements could overwhelm the hazardous waste permitting program and the capacity of existing hazardous waste treatment, storage, and disposal facilities. Imposition of the subtitle C requirements is also likely to delay cleanups significantly and severely discourage the self-monitoring and voluntary reporting essential to implementation of the UST program. Moreover, the UST cleanup activities involving the most contaminated media and debris are also likely to involve free product recovery. Free product recovery would not be subject to subtitle C requirements because the material being recovered is not a waste.

Because of the uncertainties of the impacts on the UST cleanups as a result of this rule, including the amount of contaminated media that would become hazardous waste and the type of management feasible and appropriate for such waste (i.e., on-site treatment, off-site disposal), EPA cannot determine whether the application of this rule to these cleanups will have the severe consequences on implementation of these RCRA programs that preliminary information suggests. Also, because this issue did

not come to the Agency's attention until late in the development of this rulemaking, the Agency has not had an opportunity to obtain public input on this issue, the implications of the subtitle C requirements when applied to UST cleanups, or any alternative regulatory mechanisms to make feasible the implementation of UST cleanups while meeting subtitle C hazardous waste requirements. Thus, the Agency believes that further evaluation of the impacts of applying the TC to soils and ground water contaminated by petroleum from USTs and subject to the subtitle I program is necessary in order to determine whether an exemption for such materials is warranted or whether additional regulatory or administrative changes can or should be made in order to make the application of the TC to UST cleanups feasible.

In order to make a final decision concerning the applicability of this rule to UST sites, the Agency intends to undertake several activities. First, the Agency will attempt to more specifically define the impact of the TC through studies of petroleum UST sites, focusing upon the potential hazard from these sites. More specifically, the Agency will study the characteristics of UST sites (number of UST sites by media type, volumes of media and debris typically removed, fraction of this media and debris that exhibits the TC, if any, etc.), current practices and requirements for management of these media and debris, and how contaminated media and debris from these sites are managed under the new subtitle I state programs. As currently envisioned, these studies will include: (1) A survey of tank vendors, contractors, and others knowledgeable about UST site characteristics and contaminated media and debris management practices; (2) a survey of current state and local programs; and (3) a sampling program conducted in conjunction with one or ***11837** more selected states. The Agency also plans to evaluate the impact that subtitle C management of petroleum-contaminated media and debris from USTs would have on the Agency's and states' hazardous waste management programs. In addition, the inclusion of these media and debris in the subtitle C management system will be evaluated in comparison to the available capacity for commercial hazardous waste treatment, storage, and disposal.

Second, the Agency will evaluate whether and how the subtitle C requirements can be feasibly implemented for UST cleanups. This evaluation will include an investigation of regulatory streamlining, phased compliance, or other administrative changes to increase the feasibility of implementing UST cleanups in accordance with subtitle C requirements. As part of this effort and the larger issue of the application of subtitle C requirements to contaminated media, EPA intends to convene a public forum to discuss the relationship between subtitle C and subtitle I requirements, the impacts of the subtitle C program on UST cleanups, and how the subtitle C requirements can feasibly be applied to the UST cleanups.

EPA requests data and comment from the public on these issues. Upon completion of the evaluations described above, EPA will determine whether to retain the temporary exemption for UST cleanups provided in this rule or to remove the exemption and make the TC fully applicable to corrective actions under subtitle I.

7. RCRA Section 3004(n) Air Regulations

In HSWA, Congress directed EPA to "* * * promulgate such regulations for the monitoring and control of air emissions at hazardous waste treatment, storage, and disposal facilities, including but not limited to open tanks, surface impoundments, and landfills, as may be necessary to protect human health and the environment." This provision was added as section 3004(n) of RCRA. In response, the Agency proposed the first of a multi-phased set of air regulations for TSDFs on February 5, 1987 (53 FR 3748). This first phase is intended to apply to equipment that would be used to treat wastes that would first be subject to the Land Disposal Restrictions (LDR) standards to ensure that the LDR treatment did not result in cross-media transfer of hazardous constituents to the air (see III.I.2., above, for a discussion of the LDR program). This first phase is to be followed by proposals for more comprehensive air regulations for TSDFs. Once these air standards are promulgated, they are expected to apply to many of the wastes newly regulated by today's rule.

The February 5, 1987 proposal would limit air emissions of organics as a class from certain treatment units. The proposed rule would apply to specified equipment that contains or is in contact with certain hazardous wastes, which are identified based upon their potential to emit organics. The proposed standards contain two major features. First, a 95% reduction in process emissions from units distilling or stripping (air or steam) organic wastes would be required. Second, leak detection and repair programs would be required for certain valves, pumps, compressors, pressure relief devices, and closed-vent systems. If wastes

that exhibit the TC also have concentrations of organic constituents exceeding the regulatory threshold, they will be subject to this first phase of regulation for air emissions.

J. Relationship to Other Regulatory Authorities

1. Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

Although promulgated in fulfillment of a RCRA mandate, today's rule may affect, to varying degrees, remediations performed under CERCLA authority. Such effects or interactions, when they arise, will be associated with section 121(d) of CERCLA, which requires CERCLA remedial actions to comply with all applicable or relevant and appropriate requirements (ARARs) of other federal and state laws, including RCRA.

Several commenters questioned the applicability of the TC to CERCLA sites and argued that the TC would constrain the discretion of Remedial Project Managers and On-Scene Coordinators. However, CERCLA section 121(d) is clear that CERCLA remediations must comply with Federal and State ARARs. Accordingly, RCRA regulations, including today's TC, are incorporated into the CERCLA decision-making and remediation process to augment controls already in place under the CERCLA program.

In addition, a few commenters argued that as a result of today's rule, a greater number of hazardous waste determinations would be made during CERCLA remediations. Consequently, “thousands of additional Superfund sites” would be created, attributable in large part, one commenter notes, to petroleum and petrochemical waste that will exceed TC levels. The Agency disagrees with the commenters. While it is clear that CERCLA remediations must comply with Federal and State ARARs, the TC is not used by CERCLA to determine whether or not to undertake a clean-up action. Rather, the TC will apply to decisions concerning the management of solid wastes (e.g., soil and debris) generated during cleanup activities.

2. Clean Water Act

a. Conflict with NPDES Effluent Guidelines and Pretreatment Standards. Many commenters argued that the regulatory levels in the proposed TC conflict with NPDES effluent guidelines and pretreatment standards under the Clean Water Act (CWA). Several commenters stated that in many cases, the proposed TC regulatory levels are lower than the concentrations allowed in wastewaters directly discharged to surface waters in compliance with NPDES effluent guidelines. Commenters also stated that many wastewaters that are indirectly discharged to publicly owned treatment works in compliance with pretreatment standards will exhibit the TC.

Most of the commenters argued that it would be difficult to justify labeling a wastewater as “hazardous” under RCRA, but “safe” under the CWA. One commenter claimed that differential treatment of identical wastewaters is particularly difficult to justify because leaks from on-site wastewater management operations normally migrate to the same bodies of water that receive NPDES-permitted discharges.

EPA acknowledges the possibility that some wastewaters that meet NPDES effluent guidelines or pretreatment standards may exhibit the TC. However, because the statutory bases for setting regulatory levels are different under the CWA and RCRA, the treatment standards and effluent limitations established under the CWA are not inconsistent with the TC rule. The CWA requires EPA to set effluent limitations to control discharges of toxic pollutants “* * * which shall require application of the best available technology economically achievable * * *” and to set more stringent effluent limitations where necessary to meet applicable water quality standards (see CWA section 301(b)). RCRA, however, mandates that EPA identify wastes which may be a threat to human health or the environment. The criteria for the identification and listing of hazardous waste requires EPA to take into account “* * * toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous ***11838** characteristics” (see RCRA section 3001(a)). These criteria are different from those used under the CWA.

Accordingly, the two statutory programs have different goals. EPA believes that the TC regulatory levels represent concentrations above which a wastewater poses a potential hazard to human health and the environment, if mismanaged, even if it has been treated to some degree. Therefore, owners and operators of wastewater treatment facilities that treat wastewaters exhibiting the TC will be required to comply with all applicable regulations under RCRA and the CWA.

b. Permit Requirements for Wastewater Treatment Facilities. Many commenters stated that under the proposed TC, many wastewater treatment facilities will become hazardous waste treatment facilities subject to full RCRA permitting requirements. These commenters were concerned that the costs to industry of preparing permit applications and complying with RCRA regulations for hazardous waste treatment facilities will be prohibitive. Some commenters argued that EPA has insufficient resources to process permit applications from all of the wastewater treatment facilities that will require permits.

Although owners and operators of some wastewater treatment facilities that use newly-regulated surface impoundments could be subject to RCRA permitting requirements, EPA believes that the actual number of facilities requiring permits will not be large. The Regulatory Impact Analysis for this rule indicates that other options available to wastewater treatment facilities treating wastewaters exhibiting the TC are likely to be more cost-effective than obtaining an RCRA permit (see section VI. B for a more detailed discussion). In particular, an alternative that the Agency expects may be attractive to many owners and operators is the replacement of surface impoundments with tanks. Retrofitting existing surface impoundments to meet RCRA requirements for hazardous waste management facilities will often be more expensive than building tanks that are subject to CWA requirements in lieu of RCRA permitting requirements. (“Wastewater treatment units” are exempt from the hazardous waste management standards under 40 CFR 264.1(g)(6) and 265.1(c)(10). Similarly, “totally enclosed treatment facilities” are exempt under 40 CFR 264.1(g)(5) and 265.1(c)(9).) Thus, there are options available to owners/operators for whom RCRA standards may be too costly.

There may be some wastewater treatment facilities that opt to continue using surface impoundments to manage wastewaters exhibiting the TC, and these facilities will enter the RCRA permitting system. However, the Agency does not believe that there will be such a large number of facilities that it will overwhelm the Agency's permitting capabilities.

c. Sludges from Publicly Owned Treatment Works (POTW). The preamble to the June 13, 1986 proposed rule requested comments on the regulation of sewage sludge under RCRA and under the CWA. The preamble stated that EPA was considering an exemption from RCRA regulation for sludges from publicly owned treatment works (POTW sludges) upon the promulgation of sewage sludge management standards pursuant to section 405(d) of the CWA.

A number of commenters, including many municipalities, responded to this request for comments. Although a few commenters opposed an exemption from RCRA for POTW sludges, the commenting municipalities supported an exemption from RCRA. These municipalities stated that sewage sludge management regulations, in addition to pretreatment standards, are sufficient to protect human health and the environment without additional regulation under RCRA. Commenters stated that regulating POTW sludge under RCRA will place a significant economic burden on municipalities and will cause municipalities and EPA to face duplicative administrative costs and regulatory confusion.

EPA does not agree with commenters that regulation of POTW sludge under RCRA will place a significant economic burden on municipalities or increase the burden of implementation. EPA's office of Water tested 18 POTW sludge samples using the TCLP; none of the samples tested exhibited the TC at the proposed regulatory levels (Ref. 18). Because the final TC regulatory levels are higher than the proposed regulatory levels, the Agency believes that few, if any, POTW sludges will exhibit the TC. Thus, most POTW sludges will not be classified as hazardous waste under RCRA.

Although EPA does not believe it is necessary to exempt POTW sludges from RCRA at this time, the Agency may reconsider this decision after the sewage sludge management regulations are promulgated. In the unlikely event that a particular POTW sludge does exhibit the TC, the municipality may use the pretreatment program under the CWA to eliminate the indirect discharges of the pollutants that are causing the sludge to exhibit the TC.

3. Safe Drinking Water Act

Several commenters noted that the proposed regulatory level for chloroform is lower than the primary drinking water standard for trihalomethanes (a class of organic chemicals that includes chloroform) established under the Safe Drinking Water Act (SDWA). Most of these commenters consequently declared that the regulatory level had been set too low, and they argued that it would be unreasonable to regulate ordinary drinking water as a hazardous waste. Some commenters asserted that an industrial facility taking water from a public water supplier (a facility supplying drinking water in compliance with the SDWA rules) could find that its noncontact cooling water becomes a hazardous waste after it is passed through the plant and is disposed.

In today's final rule, the regulatory level for chloroform has been raised from that proposed in the June 13, 1986, notice of proposed rulemaking. The change is because of two modifications to the data originally used to set the regulatory level: first, the chronic toxicity reference level for chloroform is roughly 12 times higher than when originally proposed (see 53 FR 18024) and, second, due to the changes in the model, the DAF is about 7 times higher than the one originally proposed. Together, these two changes result in a regulatory level that is higher than both the original regulatory level and the SDWA standard for trihalomethanes. Non-contact cooling water or other wastewaters derived from public water supplies complying with the SDWA thus should not exhibit the TC for chloroform unless these wastewaters are contaminated by other sources.

4. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

a. Pesticide Wastes. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA regulation of pesticide sale, distribution, use, and disposal. Since RCRA regulations cover solid wastes which include pesticide product wastes, these wastes may be regulated under both FIFRA and RCRA.

Until recently, pesticide disposal under FIFRA was primarily controlled by mandating that product labeling include instructions for the proper disposal of the pesticide and its container. Recent amendments to FIFRA, effective October 25, 1988, authorize the Administrator to impose additional requirements relating to storage, transportation, and disposal of certain pesticides. For example, EPA under FIFRA may issue requirements ***11839** and procedures for the storage, transportation, and disposal of suspended or cancelled pesticides and of rinsates or containers associated with the pesticides. Also, EPA may require that applicants for registration of a pesticide submit information regarding methods for safe storage and disposal of the pesticide, and that applicants for registration provide evidence of sufficient financial resources to provide for disposal in the event of suspension or cancellation.

A number of pesticide-related wastes are listed as hazardous under 40 CFR part 261. The listings include four groups: The first, at § 261.31, includes certain discarded unused pesticide formulations containing tri-, tetra-, and pentachlorophenols (F027) or certain compounds derived from the chlorophenols; these are listed as acute hazardous waste. This listing includes approximately 20 phenoxy pesticides and their salts and esters. Today's rule will add the constituent 2,4,6-trichlorophenol, which is used as an active ingredient in pesticide products, to the TC list. Because products containing this constituent are separately listed under F027, the promulgation of specific toxicity limits will not affect their regulation under RCRA (i.e., they will continue to be regulated as acute hazardous wastes at all concentrations, both above and below the TC level).

The second group, at § 262.32, consists of “K” wastes from the production of specific pesticides, such as wastewater treatment sludges from the production of the pesticide chlordane (K032); these are listed as toxic wastes. Again, however, because these wastes are listed, they will not be affected by the regulatory levels of the TC, but will continue to be subject to regulation regardless of concentration levels.

The third grouping, at § 261.33 (e) and (f), consists of “P” and “U” wastes. Section 261.33 lists certain commercial chemical products as hazardous when discarded or intended for discard. Approximately 50 pesticide active ingredients are listed as acute hazardous wastes under § 261.33(e), while 83 pesticide active ingredients are listed under § 261.33(f) as toxic hazardous wastes. Pesticide products containing these chemicals as sole active ingredients or the pure or technical grade of these chemicals are

regulated under both RCRA and FIFRA when they become wastes. Generally, products containing these ingredients as one of multiple active ingredients are not regulated (at this time) as hazardous wastes under subtitle C of RCRA unless they meet one of the characteristics; their disposal is still subject to any applicable FIFRA and RCRA subtitle D requirements. For the majority of the 133 listed pesticides, today's rule will not change their status under RCRA; waste pesticides that are either pure, technical grade, or sole active ingredient products will continue to be subject to regulation as hazardous at all concentrations under RCRA subtitle C. Wastes from multiple active ingredient products that do not exhibit a characteristic will still be regulated under any applicable FIFRA and RCRA subtitle D requirements.

Six pesticide wastes that are currently regulated on a concentration basis under the existing EPTC at § 261.24, form the fourth group. These six pesticides (endrin, lindane, methoxychlor, toxaphene, 2,4-D, and silvex) will be retained in the new rule with their current concentration limits, which are based on a DAF of 100. The significant difference between the listings and the TC is that, while multiple active ingredient products are not covered by the listings, they are covered under the characteristic. Thus, increasing the number of pesticidal constituents encompassed by the TC (whether or not they are also listed), brings more multiple active ingredient formulations into the subtitle C system. Consequently, today's rule is expanding regulation of pesticide wastes under RCRA.

Although EPA is adding pesticides to the TC list of constituents, today's rule will not have a significant effect on many pesticide users who generate wastes. RCRA regulations contain special requirements that affect the extent to which pesticide users will become subject to additional RCRA regulation:

- Household pesticide wastes are, like other household wastes, exempt from RCRA.

- Farmers who triple rinse their containers and dispose of the rinsate on their own farm in a manner consistent with 40 CFR 262.51 and label instructions are exempt from RCRA requirements.

- Other small quantity generators under § 261.5 need comply only with reduced requirements. Many pesticide users are small quantity generators.

- Under § 261.7, properly emptied containers may be exempted from further RCRA requirements. Thus, many pesticide containers may not be subject to regulation as hazardous wastes.

As a result, the principal effects of today's final rule will be felt by commercial applicators, such as aerial applicators and pest control operators, who are not eligible for the special requirements applicable to farmers and who may use sufficiently large volumes of pesticides that they exceed the small quantity generator limitations. If they use large quantities of multiple active ingredient pesticide products that have not previously been regulated, such commercial applicators may be newly subject to the RCRA hazardous waste management requirements.

b. Treated Wood Wastes. The Agency is promulgating TC regulatory levels for certain chemicals—for example, cresols and pentachlorophenol—that are commonly used as wood preservatives. In its review of wood preservative chemicals under FIFRA, EPA concluded that these wood preservatives may continue to be used under certain circumstances, and the Agency decided to allow disposal of treated wood by means of ordinary trash collection, burial, or incineration (49 FR 28666, July 13, 1984, and 51 FR 1334, January 10, 1986). However, the mandates of FIFRA and RCRA are different. EPA has previously stated that even if it were determined that certain ground uses of treated wood did not pose unreasonable risks, wood wastes might still be regulated under RCRA subtitle C (45 FR 78531, November 25, 1980). Under FIFRA, the Agency may determine that the economic benefits of continued use of a pesticide outweigh any potential risks posed by the pesticide. This does not mean, however, that materials treated with pesticides should not be managed in a controlled manner under RCRA at the end of their useful lives, to ensure that long-term risks are minimized.

Some treated wood that is hazardous solely because it fails the EP toxicity test for arsenic which is not a hazardous waste for any other reason or reasons is exempt from regulation as hazardous (40 CFR 261.4(b)(9)). The exemption is limited to wood wastes generated by persons who use wood products for their intended end use. Several commenters claimed that large quantities of treated wood wastes will be newly regulated as hazardous under the TC, and they argued that this result is inconsistent with other EPA policies and regulations. Most of these commenters recommended that EPA expand the existing exemption for arsenic-treated wood waste to encompass all treated wood that exhibits the TC.

EPA has decided not to expand the existing exemption for arsenic-treated wood. If a wood waste does exhibit the TC for a constituent other than arsenic, or if the waste is hazardous waste for any other reasons or reasons, the ***11840** Agency believes that the waste should be regulated as hazardous, in order to protect human health and the environment. The arsenic-treated wood exemption is not being revoked at this time, but it may be reevaluated in the future.

5. Food, Drug, and Cosmetic Act (FDCA)

a. Food Wastes. Several commenters noted that allowable levels set by the Food and Drug Administration (FDA) under the Food, Drug, and Cosmetics Act (FDCA) are, in some cases, higher than the proposed TC regulatory levels for the same chemicals. Most of these commenters then asserted that if it is safe to consume substances containing pesticides or additives, it must also be safe to place such substances in municipal landfills. Some commenters expressed concern that food wastes that comply with FDCA pesticide tolerance or action levels may nevertheless have to be handled as hazardous wastes as a result of the TC. One food processing industry trade association requested that the final TC rule state that any waste from food already in compliance with a tolerance or action level set by EPA or FDA is nonhazardous.

The Agency acknowledges that for certain chemicals in waste, it proposed TC regulatory levels lower than FDCA tolerances or action levels in food. However, it is inappropriate to make a direct comparison of these two sets of levels. FDCA levels are set for concentrations in food products, while TC levels apply to concentrations in the leachate from waste materials. Because not all toxic constituents leach from the waste, levels in the leachate are lower than in the waste material itself. Accordingly, for a food waste to be hazardous, the waste would have to have constituent concentrations higher than the TC levels. The Agency is unaware of any food-related wastes that will be regulated as hazardous under the TC rule. (In addition, unlike the FDCA, RCRA does not allow consideration of economic factors in establishing regulatory levels of concern.)

If any food waste does exhibit the TC, it may be subject to lesser requirements as household waste (40 CFR 261.4(b)(1)) or under the small quantity generator provisions (40 CFR 261.5). For non-household food wastes that fail the TC (i.e., leachate from the waste contains contaminants in levels equal to or above the regulatory levels promulgated in today's rule) and that are generated in large quantities, it is appropriate that they be managed in a controlled manner to protect human health and the environment. Because EPA sees no conflict between the TC rule and tolerance or action levels under FDCA, this rule contains no exemption for wastes that meet the FDCA standards.

b. Pharmaceutical and Cosmetic Wastes. Several commenters, arguing that the proposed TC levels were too low, pointed out that the proposed regulatory levels are lower than FDCA-allowed levels for the same chemicals in drugs or cosmetics.

Although the proposed TC regulatory levels for certain chemicals were lower than the FDCA levels for the same chemicals in drug and cosmetic products, the levels are higher in the final rule. Moreover, it is clear that different factors must be taken into account when regulating these constituents in drugs and cosmetics rather than in solid wastes, as confirmed by different statutory mandates. The constituents in drugs and cosmetics products, often used in very small quantities, serve a useful function and may be therapeutic in certain quantities and under proper circumstances. However, this does not mean that these same constituents should not be controlled where found at TC levels in waste materials.

Of course, drug and cosmetic wastes generated in households are not subject to subtitle C regulation (40 CFR 261.4(b)(1)) nor are wastes generated by small quantity generators (less than 100 kg/mo of non-acute hazardous waste—see 40 CFR 261.5). However, drug and cosmetic products when discarded may present risks to human health and the environment if disposed

in large volumes. Thus, EPA maintains that regulation of large quantities of drug or cosmetic wastes exhibiting the TC is appropriate and not in conflict with the existing FDCA program.

6. Used Oil Recycling Act

The Used Oil Recycling Act of 1980 (UORA), which amended RCRA, was intended to increase safe recycling and reuse of used oil. It established that it is in the national interest to recycle used oil in a manner that both protects public health and the environment and conserves energy and materials. The UORA has been incorporated in section 3014 of RCRA.

Section 3014 of RCRA, as amended by HSWA, requires EPA to make a determination of whether to list or identify used oil as a hazardous waste (see RCRA section 3014(b)). In response to this statutory directive, EPA proposed to list most types of used oil, including recycled used oil, as a hazardous waste on November 29, 1985 (see 50 FR 49258). EPA subsequently decided in November, 1986 not to list used oil because the Agency believed that the listing would discourage recycling of used oil and could result in an increase in the amount of used oil that is disposed of or illegally dumped. The Agency decided to continue to study whether used oil that is disposed should be listed as a hazardous waste under RCRA or regulated under different statutes (see 51 FR 41900 (November 19, 1986)). EPA's decision to withdraw the proposed listing of used oils was invalidated by the D.C. Circuit Court of Appeals in 1988. The Agency was directed by the Court to reconsider the listing of used oil as a hazardous waste based on the technical criteria contained in RCRA section 3001.

Some commenters claimed that used oil would be brought into the subtitle C system under the TC proposal. They stated that used oil is likely to fail the TC test for both aromatic hydrocarbons (e.g., benzene) and chlorinated solvents (e.g., trichloroethylene and tetrachloroethylene). The commenters argued that regulating used oil as a hazardous waste would be inconsistent with the intent of the UORA, as well as with current Agency policies regarding used oil.

Under today's rule, used oil will be regulated as a hazardous waste only: (1) If it exhibits one or more of the hazardous waste characteristics defined in subpart C of 40 CFR part 261 (including the TC as finalized today) and (2) if it is disposed of (rather that recycled). On the other hand, used oil that exhibits one or more of the hazardous waste characteristics and is recycled is exempt from regulation (see 40 CFR 261.6(a)(3)(iii)) except as provided in subpart E of 40 CFR part 266. In addition, RCRA prohibits the use of used oil as a dust suppressant or for road treatment if it is contaminated with dioxin or mixed with a hazardous waste. Thus, used oil that exhibits one or more of the characteristics (except for ignitability) cannot be used as a dust suppressant. ln particular, the regulations have the following effect:

- Solid waste that is hazardous waste because it fails a characteristic and that is recycled (except by burning or use as a dust suppressant) is exempt from regulation.

- Characteristically hazardous used oil that is disposed of (or incinerated without recovery of energy value) is subject to full RCRA subtitle C regulation.

- Characteristically hazardous used oil that is being burned for energy recovery is subject to subpart E of part 266—i.e., off-specification used oil is subject to certain administrative requirements, while specification used ***11841** oil is subject only to the analysis and recordkeeping requirements of 40 CFR 266.43(b) (1) and (6).

- Characteristically hazardous used oil is prohibited from being used as a dust suppressant, unless it is hazardous solely for exhibiting the ignitability characteristic (see 40 CFR 266.23(b)).

- Characteristically hazardous used oil that is recycled in any manner other than being burned for energy recovery (e.g., by being rerefined) is exempt from subtitle C regulation.

Therefore, today's rule will not affect the regulatory status of most recycled used oil. In fact, today's rule should encourage the recycling of used oil, and not discourage its recycling as suggested by some commenters. It should also be noted that some percentage of used oil already is defined as hazardous (i.e., exhibits one or more of the hazardous waste characteristics and is disposed). Consequently, the amount of used oil that is affected by this rule and is either disposed of or recycled by being burned for energy recovery or used as a dust suppressant will be even less.
The Agency is currently determining how best to deal with used oil listing and management issues. Section 3014 of RCRA also requires EPA to promulgate management standards for used oil that is recycled. Standards for controlling used oil which is recycled were proposed on November 29, 1985 (50 FR 49212), but have not been finalized. The Agency will be addressing these issues as well as addressing the listing determination in the near future.

7. Toxic Substances Control Act (TSCA)
EPA has decided to exempt from the application of this rule certain polychlorinated biphenyl (PCB) wastes that are regulated under the Toxic Substances Control Act (TSCA) and would be identified as hazardous because of today's rule. Specifically, PCB-containing dielectric fluids removed from electrical transformers, capacitors, and associated PCB-contaminated electrical equipment may exhibit the TC, and thus become hazardous wastes when disposed, not because they contain PCBs (which are not among the constituents regulated under the TC) but because they may contain other TC constituents, such as chlorinated benzenes. The Agency has decided to exempt such wastes from the subtitle C management standards because new regulation of these wastes under RCRA may be disruptive to the mandatory phaseout of PCBs in certain electrical transformers and capacitors. In addition, the Agency believes that the regulation of these wastes under TSCA is adequate to protect human health and the environment. However, the exemption applies only to those dielectric fluids (as described above) that are fully regulated under TSCA. Other PCB-containing wastes that are hazardous (i.e., listed or exhibit a hazardous waste characteristic including the existing EPTC wastes—waste codes D004 through D017) are subject to all applicable subtitle C standards. Furthermore, these non-TC hazardous wastes that are (1) liquids containing PCBs at concentration greater than 50 ppm, or (2) solids containing PCBs listed in Appendix III of part 268 at concentrations greater than 1000 mg/Kg, are prohibited from land disposal under 40 CFR part 268.

The disposal and storage of PCB wastes is regulated under TSCA section 6(e)(1) authority rather than under subtitle C of RCRA. Since the enactment of TSCA, the manufacture, processing, and distribution in commerce of PCBs (without an exemption) has been banned and the use of PCB without authorization has been banned. In addition, EPA has developed comprehensive PCB disposal regulations under TSCA. This regulatory framework includes specific disposal requirements for defined classes of PCB wastes, specific marking requirements for PCB items, facility recordkeeping requirements, approval requirements for disposers, and a proposed notification and manifesting system modeled on the subtitle C “cradle to grave” tracking system.

One commenter stated that utility transformer dielectric fluids are likely to exhibit the revised TC and urged the Agency to exempt PCB-containing utility transformer dielectric fluids from the rule. The commenter noted that the regulation of PCBs is unique because the manufacture of PCBs (without an exemption) has been banned. Thus, the critical regulatory concern with respect to these PCB wastes is the need to expedite safe disposal of the chemical. The commenter stressed that if PCB wastes were to be regulated now under RCRA as well as under TSCA, serious legal, practical and administrative complications could result.

The Agency agrees with the commenter. The most significant potential negative impact of dual regulation of these wastes under both RCRA subtitle C and TSCA results from the unique scope and timing of PCB disposal. The Agency estimates that approximately 312 million pounds of PCBs are dispersed among nearly 30 million discrete units of electrical equipment. The TSCA regulations require the phaseout of certain PCB-containing electrical transformers, and EPA expects that the TSCA mandatory phaseout requirements and restrictions will render the next three years a peak period for PCB disposal. Under the authority of the TSCA mandatory phaseout, by October 1, 1990, owners of secondary network higher voltage transformers located in or near commercial buildings are required to either remove or reclassify these transformers. (Reclassification necessitates draining of all PCB fluids from the unit, and replacing them with non-PCB fluids or low concentration PCB

fluids, and keeping the transformer in full service, under loaded conditions, for a minimum of three months.) In addition, the phaseout restrictions affect lower secondary voltage network units of PCB-containing electrical transformers located in or near commercial buildings; by October 1, 1993, such transformers must either be removed or be reclassified, or an alternative option for lower voltage units allows for providing enhanced electrical protection on such units by October 1, 1990. Radial PCB-containing electrical transformers must either have enhanced electrical protection or be removed.

The TSCA program, with which the regulated community is familiar, is specifically tailored to deal with the problem of widely dispersed waste generation and the timely disposal of a chemical that is no longer commercially produced. The confusion that could result from the addition of requirements under a separate regulatory disposal system, and the RCRA disincentives to waste production, would cause significant disruption to the expeditious disposal of large quantities of these PCB wastes if these wastes were to become subject to the RCRA hazardous waste regulations.

In addition, the Agency believes that the existing system for PCB disposal, including the existing TSCA disposal regulations and recent additions to the program (e.g., the proposed notification and manifesting rule, published at 53 FR 37436), are adequate to protect human health and the environment with respect to the disposal of these wastes. Thus, further regulation under RCRA for PCB-containing dielectric fluids and associated PCB-contaminated electrical equipment does not appear to be necessary at this time. The Agency will also evaluate the integration of the TSCA PCB regulations with the RCRA hazardous waste regulations for other PCB-containing wastes which are identified or listed as hazardous.

11842** ***K. Implementation Issues

EPA received many comments concerning implementation of the TC rule. The comments addressed issues including the schedule for companies and municipalities to come into compliance with subtitle C requirements, exemptions and applicability, implications for permit modifications, and administrative requirements. Major comments on implementation are summarized and addressed below. Section V of this preamble further discusses how the Agency will implement today's rule.

1. Notification

In the June 13, 1986 Federal Register notice, EPA proposed to waive the RCRA section 3010 notification requirement for persons who manage TC wastes and have already: (1) Notified the Agency that they manage other hazardous wastes and (2) received an EPA identification number. Virtually all commenters who addressed the notification requirement supported EPA's proposal. However, one state agency opposed the proposal, on the grounds that a waiver would hinder efforts to develop a more accurate and complete understanding of hazardous waste management practices within the United States.

EPA has decided, as proposed, to waive the notification requirement for TC waste handlers that have already notified the Agency that they manage hazardous wastes and have received an EPA identification number. The Agency believes that, given the vast scope of the TC rule, a notification requirement for persons already identified within the hazardous waste management universe would present an administrative burden without providing any significant benefits to human health and the environment.

2. Effective Date

Several commenters claimed that the 6-month effective date of the TC rule would not provide them with sufficient time to come into compliance with the full array of hazardous waste regulations. Some commenters argued that it would be impossible for generators of TC wastes to test their wastes, obtain EPA identification numbers, arrange for transport and off-site management of their wastes, modify their short-term storage (i.e., accumulation) practices, and institute the necessary recordkeeping and reporting procedures within a 6-month time frame. The commenters stated that the time constraints are especially unreasonable in light of the shortages of laboratory and TSDF capacity that can be expected to result from the TC revisions. Other commenters claimed that TSDFs will require more than 6 months to come into compliance with the interim status standards of 40 CFR part 265 (e.g., personnel training, contingency planning, and financial responsibility).

EPA appreciates the concerns of the commenters, and the Agency is aware that all of the commenters addressing the effective date for the TC rule encouraged EPA to adopt a delayed effective date for most, if not all, requirements. However, RCRA section 3010(b) requires that hazardous waste regulations become effective 6 months after the date of promulgation unless EPA has good cause to establish an earlier effective date. Thus, the effective date for the final TC rule will be 6 months from the date of promulgation.

However, EPA is promulgating different compliance dates for two different categories of waste generators: (1) All generators of more than 100 and less than 1,000 kg/month of hazardous waste (small-quantity generators) must come into compliance with subtitle C requirements for management of their TC waste within one year of today; and (2) all generators of 1,000 kg/month or more of hazardous waste are required to comply with all subtitle C requirements for TC wastes within six months of today, on the effective date of the rule.

All generators of over 1,000 kg/month of hazardous waste are required to comply with all applicable RCRA regulations for their TC wastes on the effective date of this rule. (The generator quantity refers to all of a generator's hazardous waste, not just newly hazardous TC waste.) The Agency recognizes that this compliance category will include two groups of generators: current hazardous waste generators, including small quantity hazardous waste generators who will be generating additional hazardous wastes and generators of large quantities of solid wastes who will be regulated as hazardous waste generators for the first time. EPA believes that both of these groups of generators should predominantly be large businesses and either be familiar with the waste management regulations or be in a position to come into compliance with the requirements within the six month period. These persons should have been aware of the Agency's statutory commitment and have had ample notice of the impending TC rule through the proposed rule and supplemental notices.

On the other hand, the Agency is allowing an additional six months from the effective date (i.e., one year from today) for generators of greater than 100 but less than 1,000 kg/month of hazardous waste (small quantity generators) to comply with all applicable subtitle C regulations. (As with the over 1,000 kg/month category, this quantity refers to the total quantity of a generator's hazardous waste, not just newly hazardous TC waste.) The TC has the potential to affect an extremely large number of handlers that never before have been subject to the hazardous waste regulations; many of these firms are small businesses. Handlers that will assume small quantity generator status as a result of the TC rule are most likely not regulated under subtitle C at the present time. Thus, these handlers are less likely to be familiar with the waste management regulations, or because of their small business status, will need more than six months to come into compliance with the regulations.

As already indicated, these handlers are likely to be small entities and may be unaware that their practices, which were not regulated in the past, will now be regulated as a result of today's rule. The Agency recognizes that these new handlers of small quantities of TC wastes (over 100 but less than 1,000 kg/month) may have to test their wastes, obtain EPA identification numbers, arrange for transport and off-site management of their wastes, modify their short-term storage (i.e., accumulation) practices, and institute the necessary recordkeeping and reporting procedures. As recognized by the Agency in establishing special requirements for small quantity generators, the burden of initial compliance may fall relatively harder on these generators (see 51 FR 10146, March 24, 1986). Thus, to lessen the burden on the handlers of small quantities of TC wastes, the Agency has developed an outreach program targeted for the small quantity generators which will inform new generators of the required steps necessary to enter the hazardous waste management system. Effective program outreach, however, will take more than 6 months.

In amending RCRA in 1984, Congress, in requiring EPA to promulgate regulations for small quantity generators, indicated that the Agency should consider the impacts on small businesses, while still providing protection to human health and the environment. While this rule is not promulgated pursuant to this provision, we believe the intent of Congress is for the Agency (in promulgating any rule substantially affecting small quantity ***11843** generators) to consider such impacts and to provide procedural adjustments where appropriate. EPA believes that extending the compliance date for this group of generators will allow the Agency time to provide necessary assistance and outreach to these generators and will allow sufficient time for small quantity generators to comply with the full range of applicable subtitle C requirements. Finally, by delaying the effective date of

the TC for small quantity generators, the Agency will be able to concentrate its initial implementation efforts on large quantity generators, who will generate the vast majority of waste brought into the RCRA subtitle C system under this rule. Thus, because the delayed compliance date for small quantity generators enables the Agency to focus its attention on the waste generators expected to produce the largest volumes of waste, it maximizes protection of human health and the environment.

In summary, the Agency believes that allowing an additional six months for small quantity generators to come into full compliance with the TC will serve two purposes. First, it will allow the Agency time to educate small quantity generators on the RCRA rules, while at the same time, allowing the Agency to focus immediate implementation efforts on large generators of hazardous waste. Second, it will provide the necessary time for small quantity generators to comply with subtitle C requirements as a result of the TC.

3. Permitting

Several commenters expressed concern that they would not be able to submit required permit modifications before the effective date of the rule. Some commenters also expressed concern that the TC revisions could place a significant burden on the system for permitting hazardous waste treatment, storage, and disposal facilities.

The commenters recommended a number of different mechanisms for reducing the prospective burdens on the permitting system, such as (1) Allowing permitted facilities to operate under interim status with respect to newly regulated wastes; (2) handling requests from permitted facilities to manage TC wastes as minor permit modifications, rather than as major permit modifications (especially in the case of facilities that are already permitted to manage listed wastes containing TC constituents); (3) requiring permitted facilities to apply for major permit modifications by the effective date of the TC rule, but not requiring them to actually obtain the modification until a later date; or (4) delaying the effective date of the final rule.

EPA has promulgated amendments to the procedures for permit modifications for treatment, storage, and disposal facilities on September 28, 1988 (53 FR 37934). These changes to the regulations should generally allay the concerns expressed by the commenters. Although the new permit modifications rule will not automatically be effective in authorized states, EPA expects that many authorized states will adopt the provisions and EPA plans to use the new permit modification procedures to implement the TC. The new permit modification procedures are further explained in section V.

IV. Regulatory Levels

The regulatory levels established in today's rule are based on two elements—the toxicity of each constituent and the expected fate of the constituent when released into the environment. The latter element is expressed as a dilution/attenuation factor (DAF), which, when multiplied by the toxicity value, results in the regulatory level. It is this level that, when compared to the results of the TCLP, defines a waste as hazardous. If the waste leachate generated through the TCLP contains constituents equal to or above the regulatory levels in today's rule, the waste is a hazardous waste.

This section summarizes the Agency's basis for selecting the final list of constituents and the regulatory levels that are being promulgated in today's rule.

A. List of Constituents

1. Proposed List

The Agency initially proposed regulatory levels for 38 new organic constituents, proposed to modify the regulatory levels for the six organic constituents that are regulated under the existing EPTC, and proposed to retain the existing levels for the eight inorganic constituents regulated in the existing EPTC (see Table IV-1).

2. Constituents for Which Final Regulatory Levels Are Not Now Being Promulgated

The model used to predict DAFs for today's rule accounts for hydrolysis, which may occur during the transport of a constituent through the environment. If a constituent hydrolyzes during transport, its concentration will decrease more rapidly than it would if it were influenced by dispersion alone. Therefore, the DAF for a constituent that hydrolyzes during transport will be higher than that for a constituent that does not hydrolyze. However, the products that are formed because of hydrolysis of the constituent also may be toxic.

Table IV-1.--TC Constituents and Regulatory Levels Proposed June 13, 1986

HWNO [FN1]	Constituents	CASNO [FN2]	Regulatory level (mg/L)
D016	Acrylonitrile	107-13-1	5.0
D004	Arsenic	7440-38-2	5.0
D005	Barium	7440-39-3	100.0
D019	Benzene	71-43-2	0.07
D020	Bis(2-chloroethyl) ether	111-44-4	0.05
D006	Cadmium	7440-43-9	1.0
D021	Carbon disulfide	75-15-0	14.4
D022	Carbon tetrachloride	58-23-5	0.07
D023	Chlordane	57-74-9	0.03
D024	Chlorobenzene	108-90-7	1.4
D025	Chloroform	67-66-3	0.07
D007	Chromium	1333-82-0	5.0
D026	o-Cresol	95-46-7	10.0
D027	m-Cresol	106-39-4	10.0
D028	p-Cresol	106-44-5	10.0
D016	2,4-D	94-75-7	1.4
D029	1,2-Dichlorobenzene	96-50-1	4.3
D030	1,4-Dichlorobenzene	106-46-7	10.8
D031	1,2-Dichloroethane	107-08-2	0.40
D032	1,1-Dichloroethylene	75-35-4	0.1
D033	2,4-Dinitrotoluene	121-14-2	0.13
D012	Endrin	72-20-8	0.003
D034	Heptachlor (and its hydroxide)	76-44-2	0.001
D035	Hexachlorobenzene	118-74-1	0.13
D036	Hexachlorobutadiene	87-68-3	0.72
D037	Hexachloroethane	67-72-1	4.3
D038	Isobutanol	78-83-1	36.0
D008	Lead	7439-92-1	5.0
D013	Lindane	58-89-9	0.06
D009	Mercury	7439-97-6	0.2
D014	Methoxychlor	72-43-5	1.4
D039	Methylene chloride	75-09-2	8.6
D040	Methyl ethyl ketone	78-93-3	7.2
D041	Nitrobenzene	96-95-3	0.13
D042	Pentachlorophenol	87-86-5	3.6
D043	Phenol	106-95-2	14.4
D044	Pyridine	110-86-1	5.0
D010	Selenium	7782-49-2	1.0
D011	Silver	7440-22-4	5.0
D045	1,1,2,2-Tetrachloroethane	630-20-6	10.0
D046	1,1,2,2-Tetrachloroethane	79-34-5	1.3
D047	Tetrachloroethylene	127-18-4	0.1
D048	2,3,4,6-Tetrachlorophenol	58-90-2	1.5
D049	Toluene	106-88-3	14.4
D015	Toxaphene	8001-35-2	0.07
D050	1,1,1-Trichloroethane	71-55-6	30.0

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D051 ..... 1,1,2-Trichloroethane ................. 79-00-5 1.2
D052 ..... Trichloroethylene ..................... 79-01-6 0.07
D053 ..... 2,4,5-Trichlorophenol ................. 95-95-4 5.8
D054 ..... 2,4,6-Trichlorophenol ................. 88-06-2 0.30
D017 ..... 2,4,5-TP (Silvex) ..................... 93-76-5 0.14
D066 ..... Vinyl chloride ....................... 75-01-4 0.05
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1 EPA Hazardous Waste Code Number.
2 Chemical Abstracts Service number.
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***11844** As explained in section III.E.2.a.vii, the Agency does not have sufficient data to address the formation and toxicity of hydrolysis products. Therefore, in today's rule, the Agency is not establishing regulatory levels for those new organic constituents that are expected to appreciably hydrolyze and thereby form potentially toxic by-products. Rather, the Agency expects to address these constituents in a future Federal Register notice.

Three of the organic constituents currently regulated by the EPTC may hydrolyze to a significant extent. However, due to uncertainties associated with this mechanism, the Agency believes that it would not be prudent to remove these constituents from regulation on a temporary basis (i.e., until their hydrolysis products can be assessed). Therefore, these constituents (endrin, methoxychlor, and toxaphene) will continue to be regulated at the existing EPTC levels in the interim.

Also, as explained in section III.E.2.a, the Agency has concluded that the steady-state assumption used in the ground water transport model may not be appropriate for all constituents. The constituents for which a steady-state solution may not be appropriate are being deferred from the list of proposed constituents. EPA will promulgate or repropose (as warranted) regulatory levels for these constituents in a future Federal Register notice.

3. Final List of Constituents

a. Organic Constituents. The organic constituents for which the Agency is today establishing regulatory levels (i.e., those that are on the current EP list, and those that do not appreciably hydrolyze and for which a steady-state assumption is appropriate) are presented in Table IV-2.

Table IV-2.--Organic Constituents

EPA HW number [FN1]	Contaminant	CAS number [FN2]
D018	Benzene	71-43-2
D019	Carbon tetrachloride	56-23-5
D020	Chlordane	57-74-9
D021	Chlorobenzene	106-90-7
D022	Chloroform	67-66-3
D023	o-Cresol	95-46-7
D024	m-Cresol	106-39-4
D025	p-Cresol	106-44-5
D016	2,4-D	94-75-7
D027	1,4-Dichlorobenzene	106-46-7
D028	1,2-Dichloroethane	107-06-2
D029	1,1-Dichloroethylene	75-35-4
D030	2,4-Dinitrotoluene	121-14-2
D012	Endrin	72-20-8
D031	Heptachlor (and its hydroxide)	76-44-2
D032	Hexachlorobenzene	118-74-1
D033	Hexachloro-1,3-butadiene	87-68-3
D034	Hexachloroethane	67-72-1
D013	Lindane	58-89-9
D014	Methoxychlor	72-43-5

D035	Methyl ethyl ketone	78-93-3
D036	Nitrobenzene	96-95-3
D037	Pentachlorophenol	87-86-5
D038	Pyridine	110-86-1
D039	Tetrachloroethylene	127-18-4
D015	Toxaphene	8001-35-2
D040	Trichloroethylene	79-01-6
D041	2,4,5-Trichlorophenol	95-95-4
D042	2,4,6-Trichlorophenol	88-06-2
D017	2,4,5-TP (Silvex)	93-76-5
D043	Vinyl chloride	75-01-4

1 Hazardous waste number.
2 Chemical abstracts service number.

b. Inorganic Constituents. Among the constituents that were proposed for inclusion in the TC were eight inorganic constituents that are currently regulated in the EPTC. Because EPACML does not currently accommodate metallic species, it cannot be used to predict DAFs for these constituents. Therefore, the Agency is today retaining the regulatory ***11845** levels for these constituents at their current levels. When the MINTEQ model (see III.B.5.c) is available to accommodate these constituents, the Agency will reconsider their regulatory levels and propose new ones, if so warranted.

B. Selection of DAFs

The selection of the appropriate DAF for the constituents addressed in today's rule is based on the municipal landfill scenario, as proposed. However, based on comments on fate processes that were not appropriately considered in the model, several constituents have been omitted from the proposed list of constituents—specifically, those that may hydrolyze to more than a negligible extent and those for which the steady-state assumption may not be appropriate.

For the remaining constituents, the Agency believes that a DAF of 100 is appropriate for establishing regulatory levels in today's rule. The basis for this conclusion is explained in Section III.E.4.d.

C. Analytical Constraints

The regulatory levels for the compounds proposed for inclusion in the TC span approximately five orders of magnitude (i.e., from the low parts per billion to 100 parts per million). The calculated regulatory levels for three of these compounds (2,4-dinitrotoluene, hexachlorobenzene, and pyridine) are below the concentrations measurable using currently available methods.

EPA believes that the appropriate way to deal with a calculated regulatory level that is below the analytical detection limit is to use (for the regulatory level) the lowest level of detection that can be attained. The lowest level of a particular chemical that can be reliably measured within acceptable limits of precision and accuracy under routine laboratory operating conditions is that chemical's "quantitation limit." A quantitation limit is determined through such studies as method performance evaluations.

If data from interlaboratory studies are unavailable, quantitation limits are estimated based on the detection limits and an estimated multiplier that represents a practical and routinely achievable level with relatively high certainty that the reported value is reliable. EPA proposed to use a value of five times the analytical detection limit as the quantitation limit and to set the regulatory level at the quantitation limit for those compounds for which the calculated regulatory level is below the quantitation limit, and interlaboratory studies were not available.

Because TCLP extracts are aqueous in nature, the quantitation limits used in this rule are based on the presence of these compounds in a water matrix. The Agency received many comments on the use of the quantitation limit as the regulatory level for the three compounds with health-based thresholds below that level. Most commenters expressed concern that quantitation limits based on analysis of the constituent in a water matrix may not be achievable in more complex samples. The comments

discussed potential complications that could hamper analysis of various kinds of wastes and recommended that EPA work toward determining actual quantitation limits on real wastes.

The Agency agrees that the ability to achieve the quantitation levels listed in the proposed rule is strongly influenced by the type of waste that is being analyzed. However, determination of a matrix-dependent quantitation limit would require analysis of a wide variety of wastes. EPA believes that it would be impractical to perform such waste-specific analyses at this time. Therefore, EPA has chosen to use the proposed definition (i.e., five times the method detection limit) for the quantitation limit.

A number of commenters addressed the issue of the generic multiplier used to derive the quantitation limit. Several commenters recommended using 10 to 25 times the detection limit as the regulatory level, while a few commenters supported setting the regulatory level at the detection limit itself, to provide what they believe would be greater environmental protection.

The Agency is working to improve the sensitivity of analytical methods to provide increased protection of human health and the environment. Analytical detection limits are, by definition, not routinely achievable under average laboratory conditions. Thus, a regulatory level set at the detection limit would be difficult for the Agency to enforce and would make it difficult for the regulated community to demonstrate compliance. To provide a consistently enforceable regulatory limit while providing assurance that those wastes that clearly pose hazards are subject to subtitle C requirements, the Agency will set the regulatory level at five times the detection limit. The Agency has a high degree of confidence in setting the regulatory level at the quantitation limit (i.e., five times the detection limit) because other programs within the Agency have successfully used this method in the past to set regulatory levels (e.g., the Contract Laboratory Program under the Superfund Program).

Comments on the use of the quantitation limit are addressed more extensively in the testing methods background document.

D. Final Regulatory Levels

The regulatory levels being promulgated today are equal to the product of each constituent's toxicity threshold and the DAF or the quantitation limit. These regulatory levels are presented in Table IV-3. These levels are designed to identify wastes that clearly pose a hazard and define those wastes as hazardous. However, it should be noted that wastes that do not exhibit this characteristic (e.g., result in TCLP levels that are less than the regulatory levels) are not necessarily nonhazardous and may be listed as a hazardous waste or become hazardous under other hazardous waste characteristics.

Table IV-3.--Toxicity Characteristic Constituents and Regulatory Levels

EPA HW number [FN1]	Constituent	CAS Number	Regulatory level (mg/L) [FN2]
D004	Arsenic	7440-38-2	5.0
D005	Barium	7440-39-3	100.0
D018	Benzene	71-43-2	0.5
D006	Cadmium	7440-43-9	1.0
D019	Carbon tetrachloride	56-23-5	0.5
D020	Chlordane	57-74-9	0.03
D021	Chlorobenzene	108-90-7	100.0
D022	Chloroform	67-66-3	6.0
D007	Chromium	7440-47-3	5.0
D023	o-Cresol	95-48-7	[FN4] 200.0
D024	m-Cresol	108-39-4	[FN4] 200.0
D025	p-Cresol	106-44-5	[FN4] 200.0
D026	Cresol	----------	[FN4] 200.0
D016	2,4-D	94-75-7	10.0
D027	1,4-Dichlorobenzene	106-46-7	7.5
D028	1,2-Dichloroethane	107-06-2	0.5
D029	1,1-Dichloroethylene	75-35-4	0.7

D030 ..... 2,4-Dinitrotoluene ..... 121-14-2 [FN3] 0.13
D012 ..... Endrin 72-20-8 0.02
D031 ..... Heptachlor (and its
hydroxide) 76-44-8 0.008
D032 ..... Hexachlorobenzene ..... 118-74-1 [FN3] 0.13
D033 ..... Hexachloro-1,3-butadiene 87-68-3 0.5
D034 ..... Hexachloroethane 67-72-1 3.0
D008 ..... Lead 7439-92-1 5.0
D013 ..... Lindane 58-89-9 0.4
D009 ..... Mercury 7439-97-6 0.2
D014 ..... Methoxychlor 72-43-5 10.0
D035 ..... Methyl ethyl ketone 78-93-3 200.0
D036 ..... Nitrobenzene 98-95-3 2.0
D037 ..... Pentachlorophenol 87-86-5 100.0
D038 ..... Pyridine ..... 110-86-1 [FN3] 5.0
D010 ..... Selenium 7782-49-2 1.0
D011 ..... Silver 7440-22-4 5.0
D039 ..... Tetrachloroethylene 127-18-4 0.7
D015 ..... Toxaphene 8001-35-2 0.5
D040 ..... Trichloroethylene 79-01-6 0.5
D041 ..... 2,4,5-Trichlorophenol 95-95-4 400.0
D042 ..... 2,4,6-Trichlorophenol 88-06-2 2.0
D017 ..... 2,4,5-TP (Silvex) 93-72-1 1.0
D043 ..... Vinyl chloride 75-01-4 0.2

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1 Hazardous waste number.
2 Chemical abstracts service number.
3 Quantitation limit is greater than the calculated regulatory level. The quantitation limit therefore becomes the regulatory level.
4 If o-m-, and p-cresol concentrations cannot be differentiated, the total cresol (D026) concentration is used. The regulatory level for total cresol is 200 mg/l.

***11846 V. Implementation**

This section is intended to assist the regulated community in understanding their regulatory obligations for managing TC wastes. Responses to comments and an analysis of issues related to implementation were presented in section III.K.

The first step in a solid waste generator's decision making process must be to determine whether or not particular wastes are hazardous (40 CFR 262.11). If a waste is excluded from regulation under 40 CFR 261.4, or if it is a listed hazardous waste under subpart D of 40 CFR part 261, then no further determination is necessary. If a waste is neither excluded nor listed, a generator must determine whether the waste exhibits any of the characteristics of hazardous waste; the Toxicity Characteristic is one such characteristic of hazardous waste. A generator may determine if a waste exhibits a characteristic either by testing the waste or applying knowledge of the waste, the raw materials, and the processes used in its generation.

When a waste is determined to be hazardous, handlers of that waste must comply with any applicable standards in parts 262, 263, 264, 265, 266, 267, 268 and 270 of chapter 40. Table V-1 presents an implementation timeline for the TC. The remainder of this section illuminates five implementation concerns: state authority, integration of today's TC with the existing EPTC, notification, permitting, and compliance date.

Table V-1.—IMPLEMENTATION TIMELINE FOR THE TOXICITY CHARACTERISTIC

0 Months: Publication in the Federal Register.

3 Months:

Generators of 1000 kg/mo or more and TSDFs who have not previously notified submit 3010 Notification to EPA.

6 Months:

Facilities wishing to avoid entering the RCRA program cease managing newly regulated TC hazardous wastes. Units that were receiving TC hazardous wastes must cease further receipt in order to avoid regulation under Subtitle C.

Large quantity generators begin to comply with all applicable Subtitle C regulations for newly regulated TC wastes.

Newly regulated facilities.

—Submit Part A permit application.

Already regulated facilities.

—Interim Status Facilities: submit amended Part A permit application.

—Permitted TSDFs: submit Class 1 permit modification.

12 Months:

Small quantity generators begin to comply with all applicable Subtitle C regulations for newly regulated TC wastes.

Already regulated facilities.

—Permitted TSDFs: submit Class 2 or Class 3 permit modifications.

18 Months:

Newly regulated land disposal units: submit Part B permit application and certifications to EPA—Interim Status terminates for those land disposal units that did not submit their Part B permit application and certifications by this date.

A. State Authority

1. Applicability of Final Rule in Authorized States

Under section 3006 of RCRA, EPA may authorize qualified states to ***11847** administer and enforce the RCRA program within the state (see 40 CFR part 271 for the standards and requirements for authorization). Following authorization, EPA retains enforcement authority under sections 3008, 7003 and 3013 of RCRA, although authorized states have primary enforcement responsibility. Prior to HSWA, a state with final authorization administered its hazardous waste program entirely in lieu of the federal program. The federal requirements no longer applied in the authorized state, and EPA could not issue permits for any facilities in a state that was authorized to issue permits. When new, more stringent federal requirements were promulgated or enacted, the state was obligated to enact equivalent authority within specified time frames. New federal requirements did not take effect in an authorized state until the state adopted the requirements as state law.

In contrast, under section 3006(g) of RCRA, 42 U.S.C. 6926(g), new requirements and prohibitions imposed by HSWA take effect in authorized states at the same time that they take effect in nonauthorized states. EPA is directed to carry out those requirements and prohibitions in authorized states, including the issuance of permits, until the state is granted authorization to

do so. While states must still adopt HSWA-related provisions as state law to retain final authorization, the HSWA requirements are implemented by EPA in authorized states in the interim.

Today's rule is promulgated pursuant to RCRA section 3001(g) and (h). These provisions were added by HSWA. Therefore, the Agency is adding the requirement to Table 1 in § 271.1(j), which identifies the federal program requirements that are promulgated pursuant to HSWA and that take effect in all states, regardless of their authorization status. States may apply for either interim of final authorization for the HSWA provisions identified in Table 1, as discussed in the following section of this preamble.

2. Effect on State Authorization

As noted above, EPA will implement today's rule in authorized states until they modify their programs to adopt these rules and the modifications are approved by EPA. Because the rule is promulgated pursuant to HSWA, a state submitting a program modification may apply to receive either interim or final authorization under section 3006(g)(2) or 3006(b), respectively, on the basis of requirements that are substantially equivalent or equivalent to EPA's. The procedures and schedule for state program modifications for either interim or final authorization are described in 40 CFR 271.21. It should be noted that all HSWA interim authorizations will expire January 1, 1993 (see 40 CFR 271.24(c)).

40 CFR 271.21(e)(2) requires that states with final authorization must modify their programs to reflect federal program changes, and they must subsequently submit the modifications to EPA for approval. The deadline for state program modifications for this rule is July 1, 1991 (or July 1, 1992, if a state statutory change is needed). These deadlines can be extended in certain cases (40 CFR 271.21(e)(3)). Once EPA approves the modification, the state requirements become subtitle C RCRA requirements. States with authorized RCRA programs may already have requirements similar to those in today's rule. These state regulations have not been assessed against the federal regulations being promulgated today to determine whether they meet the tests for authorization. Thus, a state is not authorized to implement these requirements in lieu of EPA until the state program modification is approved. Of course, states with existing standards may continue to administer and enforce their standards as a matter of state law. In implementing the federal program, EPA will work with states under cooperative agreements to minimize duplication of efforts. In many cases, EPA will be able to defer to the states in their program implementation efforts, rather than take separate actions under federal authority.

States that submit their official applications for final authorization less than 12 months after the effective date of these standards are not required to include standards equivalent to these standards in their application. However, the state must modify its program by the deadline set forth in § 271.21(e). States that submit official applications for final authorization 12 months after the effective date of these standards must include standards equivalent to these standards in their application. The process and schedule for final state authorization applications is described in 40 CFR 271.3.

B. Integration of Today's Final Rule with Existing EPTC

As explained above, because this rule is promulgated pursuant to HSWA, it will be effective six months from today in both authorized and unauthorized states and will be implemented by EPA until states receive authorization for this rule. Thus, beginning on the effective date, large quantity generators that generate TC waste in all states are responsible for complying with the appropriate requirements. However, the rule promulgated today also revises an existing RCRA rule defining hazardous wastes that authorized states have been implementing for some time. The two principal changes in the rule are the revision to the leaching procedure, by replacing the EP with the TCLP, and the addition of constituents for which the leachate will be analyzed. The discussion below and Table V-2 describe how state implementation of the existing EPTC will be integrated with EPA implementation of the TC as promulgated today.

1. Facilities Located in Authorized States

There are three types of facilities located in authorized states which are affected by today's rule: facilities which are already operating under a RCRA permit, facilities which are already operating under interim status, and facilities which are subject to RCRA permit requirements for the first time as a result of today's rule. Permitted and interim status facilities can also be affected by today's rule in three distinct ways: (1) The facility may already be managing wastes that are hazardous under the existing EPTC, (2) the facility may already be managing wastes that are hazardous under the existing EPTC but which also exhibit the toxicity characteristic for a new constituent(s) under today's rule (and thus the waste would have a new waste code), or (3) the facility may be managing a solid waste which is newly subject to regulation as a result of today's revision of the TC. Table V-2 summarizes the initial filing requirements and applicable standards for each category of facility.

[Note: The following TABLE/FORM is too wide to be displayed on one screen. You must print it for a meaningful review of its contents. The table has been divided into multiple pieces with each piece containing information to help you assemble a printout of the table. The information for each piece includes: (1) a three line message preceding the tabular data showing by line # and character # the position of the upper left-hand corner of the piece and the position of the piece within the entire table; and (2) a numeric scale following the tabular data displaying the character positions.]

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Table V-2.--Integration of TC With Existing EPTC

Status of State authorization	Facility status	Type of waste	What to file	Where to file
I. Authorized State	A. Permitted	1. Regulated EPA waste w/no new constituents under revised TC	NA	NA
		2. Regulated EP waste w/new constituents	Class 1 permit modification under 40 CFR 270.42	EPA Regional Office and State
		3. Previously unregulated waste in:	... Class 1 permit modification under 40 CFR 270.42.	[FN1] EPA Regional Office and State
		-Already regulated unit		
		-Previously		

unregulated
unit ..... ---------- ----------
B. Interim Status 1. Regulated
EP waste
w/no new
constituents
under
revised TC .. NA ..... NA .....
---------- 2. Regulated
EP waste
w/new
constituents
under
revised TC .. Revised Part A
under 40 CFR
270.72 ..... EPA
Regional
Office
and
State ...
---------- 3. Previously
unregulated
waste ..... Revised Part A
under 40 CFR
270.72.
[FN2] ..... EPA
Regional
Office
and
State ...
C.
Newly-regulated ---------- Part A and
3010 under
40 CFR
270.70.
[FN3] ..... EPA
Regional
Office ..
II.
Nonauthorized
State ..... A. Permitted ..... 1. Regulated
EP waste
w/no new
constituents
under
revised TC .. NA ..... NA .....
---------- 2. Regulate EP
waste w/new
constituents
under
revised TC .. Class 1 permit
modification
under 40 CFR
270.42 ..... EPA
Regional
Office ..
---------- 3. Previously
unregulated

waste in: ... Class 1 permit
modification
under 40 CFR
270.42.
[FN1] ..... EPA
Regional
Office ..
---------- -Already
regulated
unit ..... ---------- ----------
---------- -Previously
unregulated
unit ..... ---------- ----------
B. Interim Status 1. Regulated
EP waste
w/no new
constituents
under
revised TC .. NA ..... NA .....
---------- 2. Regulated
EP waste
w/new
constituents
under
revised TC .. Revised Part A
under 40 CFR
270.72 ..... EPA
Regional
Office ..
---------- 3. Previously
unregulated
waste ..... Revised Part A
under 40 CFR
270.72.
[FN2] ..... EPA
Regional
Office ..
C.
Newly-regulated ---------- Part A and
3010 under
40 CFR
270.70.
[FN3] ..... EPA
Regional
Office ..
---

1 Facility may also need to receive a Class 2 or Class 3 modification under CFR 270.42.

2 If newly regulated waste is being managed in a land disposal unit, facility may need to submit certification of compliance within one year under 40 CFR 270.73.

3 If facility is a land disposal facility, Part B permit application and certfication of compliance must be submitted within one year under RCRA Section 3005(e)(3) and 40 CFR 270.73.

1...#...10....#...20....#...30....#...40....#...50....#...60....#...70....#....
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******* This is piece 2. -- It begins at character 80 of table line 1. ********
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Applicable
permitting
standards
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State permit
standards.
State permit
standards.
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State permit
standards.
40 CFR Part
265.
State interim
status
standards.
State interim
status
standards.
40 CFR Part
265.
40 CFR Part
265.
40 CFR Part
264.
40 CFR Part
265.
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40 CFR Part
264.
40 CFR Part
265.
40 CFR Part
265.
40 CFR Part
265.
40 CFR Part
265.
40 CFR Part
265.
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80..#...90....#.
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***11848** For facilities which have been managing EPTC wastes under an authorized state program and the constituents exhibited by the wastes are unchanged under today's rule, (i.e., no waste code change is necessary), such interim status and permitted facilities have no changes to file with permitting authorities. Similarly, since the regulatory status of the waste is unchanged, management of that waste will continue to be regulated under the authorized state standards. The only effect of today's rule on such facilities is that the facility must use the TCLP when testing for toxic constituents. However, use of the EP in addition to the TCLP may continue to be required as a matter of state law.

For facilities which have been managing EPTC wastes under an authorized state program and the constituents exhibited by the wastes have changed as a result of today's rule, the facility will need to change the waste code assigned to its TC wastes. Permitted facilities must submit permit modifications to EPA reflecting the new wastes codes. Because EPA must implement this rule until the state is authorized to do so, the permittee must comply with federal permit modification procedures under 40 CFR 270.42 rather than state permit modification procedures. However, because the permit undergoing modification is most likely a joint EPA-state RCRA permit, a copy of the modification request should also be submitted to the authorized state.

Similarly, interim status facilities must submit a revised part A permit application to EPA pursuant to 40 CFR 270.72, with a copy to state permitting authorities. Although these facilities must make appropriate waste code modifications to reflect the new TC constituents, the wastes are already regulated as EP wastes under the authorized state program. Accordingly, such wastes are not subject to any new management requirements as a result of this rule and must continue to comply with appropriate authorized state ***11849** requirements for management of these wastes.

Some permitted and interim status facilities in authorized states will be managing wastes which will become hazardous as a result of today's rule. These facilities must also submit permit modifications or part A permit application revisions to EPA. However, because these wastes were previously unregulated under RCRA, they also were not regulated under the authorized state program. As a result, if these wastes are in a previously unregulated unit, they will be subject to the self-implementing Federal standards for hazardous wastes management at 40 CFR part 265 until permit issuance (for interim status facilities) or modification (for permitted facilities). After permit issuance or modification, the Federal permitting standards at 40 CFR part 264 will apply to these wastes (or the state permitting standards if the permit is ultimately issued or modified by a state authorized for the TC). However, if the wastes are at a permitted facility in a unit that is already regulated, that unit will continue to comply with the applicable 40 CFR part 264 (or state equivalent) standards.

Facilities in authorized states which are newly subject to RCRA permit requirements as a result of today's rule must obtain an EPA identification number and submit their part A permit application and section 3010 notification to EPA in order to obtain interim status (see 40 CFR 270.70). Such facilities are subject to regulation under 40 CFR part 265 until a permit is issued by EPA or a state authorized for the TC.

2. Facilities Located in Unauthorized States

There are also three types of facilities located in unauthorized states which are affected by today's rule: already permitted facilities, facilities operating under interim status, and facilities newly subject to RCRA permit requirements under today's rule. As in authorized states, some of the permitted and interim status facilities have been managing EPTC wastes.

For interim status and permitted facilities which have been managing EPTC wastes that will exhibit no new constituents as a result of the replacement of the EP with the TCLP and the addition of constituents to the TC, there will be no waste code changes. Accordingly, such facilities do not need to submit permit modifications or revised permit applications to EPA and will continue to be subject to the applicable federal standards for hazardous waste management.

Facilities which have been managing EPTC wastes which exhibit the toxicity characteristic for new constituents as a result of today's changes to the TC must notify EPA of the waste code changes for its TC wastes. Permitted facilities must submit permit modifications to EPA as required under 40 CFR 270.42 that reflect the new wastes codes. Interim status facilities must submit revised part A permit applications in accordance with 40 CFR 270.72. These facilities must continue to comply with the applicable federal standards for hazardous waste management.

Permitted and interim status facilities which manage waste that is newly defined as hazardous waste as a result of today's rule must also submit permit modification requests or part A permit application revisions to EPA. Facilities must manage these wastes in accordance with 40 CFR part 265 or 40 CFR part 264 until permit modification or issuance, depending on whether the waste is managed in a newly regulated or previously regulated unit.

Facilities which are newly subject to RCRA permit requirements as a result of today's rule must get an EPA identification number and a part A permit application to EPA in order to obtain interim status. Such facilities are subject to regulation under 40 CFR part 265 until a permit is issued.

C. Notification

Pursuant to RCRA section 3010, the Administrator may require all persons who handle hazardous wastes to notify EPA of their hazardous waste management activities within 90 days after the wastes are identified or listed as hazardous. This requirement may be applied even to those generators, transporters, and TSDFs who have previously notified EPA with respect to the management of other hazardous wastes.

In the June 13, 1986, Federal Register notice, EPA proposed to waive the notification requirement for persons who manage TC wastes and have already (1) notified the Agency that they manage other hazardous wastes and (2) received an EPA identification number. EPA has decided to waive the notification requirement as proposed. The Agency believes that, given the vast scope of the TC rule, a notification requirement for persons already identified within the hazardous waste management universe is unnecessary.

EPA is not waiving the notification requirement for TC waste handlers that have neither notified the Agency that they manage hazardous wastes nor received an EPA identification number. Those persons must notify EPA no later than June 27, 1990 of these activities pursuant to section 3010 of RCRA. Notification instructions are set forth in 45 FR 12746, February 26, 1980.

D. Permitting

Currently permitted facilities that manage TC wastes must submit Class 1 permit modifications if they are to continue managing the newly regulated wastes in units that require a permit. The facilities must obtain the necessary modification by the effective date of the rule, or they will be prohibited from accepting additional TC wastes.

Interim status facilities that manage TC wastes in units that require a permit must file an amended part A permit application under 40 CFR 270.10(g) if they are to continue managing newly regulated wastes. The facilities must file the necessary amendments by the effective date of the rule, or they will not receive interim status with respect to the TC wastes (i.e., they will be prohibited from accepting additional TC wastes until permitted).

Newly regulated facilities (i.e., facilities at which the only hazardous wastes that are managed are newly regulated TC wastes) must qualify for interim status by the compliance date of the rule in order to continue managing TC wastes prior to receiving a permit. Under 40 CFR 270.70, an existing facility may obtain interim status by getting an EPA identification number and submitting a part A permit application. To retain interim status, a newly-regulated land disposal facility must submit a part B permit application within one year after the effective date of the rule and certify that the facility is in compliance with all applicable ground water monitoring and financial responsibility requirements (see RCRA section 3005(e)(3)).

EPA recently promulgated amendments to the procedures for permit modifications for treatment, storage, and disposal facilities (see 53 FR 37934, September 28, 1988). The following discussion assumes implementation in accordance with the new rule. EPA will implement the TC by using the new permit modification procedures, consistent with EPA policy (see 53 FR 37933, September 28, 1988).

Under the new regulation in § 270.42, there are now three classes of permit modifications with different submittal and public participation requirements for each class. In § 270.42(g), which concerns newly listed or identified wastes, a permitted facility that is “in existence” as a hazardous waste facility for the newly listed or identified waste on the effective date of the notice must ***11850** submit a Class 1 modification by that date. Essentially, this modification is a notification to the Agency that the facility is handling the waste. As part of the procedure, the permittee must also notify the public within 90 days of submittal to the Agency.

Next, within 180 days of the effective date, the permittee must submit a Class 2 or 3 modification to the Agency. A permittee may submit a Class 2 modification if the newly regulated waste will be disposed in existing TSD units and will not require additional or different management practices from those authorized in the permit. A Class 2 modification requires public notice by the facility owner of the modification request, a 60 day public comment period, and an informal meeting between the owner and the public within the 60 day period. The rule includes a “default provision,” so that for Class 2 modifications, if the Agency

does not make a decision within 120 days, the modification is automatically authorized for 180 days. If the Agency does not reach a decision by the end of that period, the modification is permanently authorized. If the newly regulated waste requires additional or different management practices, a Class 3 modification is required. The initial public notification and public meeting requirements are the same as for Class 2. However, after the end of the public comment period, the Agency will develop a draft permit modification, open a public comment period of 45 days and hold a public hearing.

E. Compliance Date

The Agency is promulgating two different compliance dates for two different categories of TC waste generators: (1) All generators of greater than 100 and less than 1,000 kg/month of hazardous waste (small-quantity generators) must come into compliance with subtitle C requirements for management of their TC waste within one year from today; and (2) all generators of 1,000 kg/month or more of hazardous waste and TSDFs are required to comply with all subtitle C requirements for TC wastes within six months from today, on the effective date of the rule. Thus the EPTC remains in effect until six months after today's date for large quantity generators and TSDFs, and remains in effect for 12 months after today's date for small quantity generators. The generator quantity refers to all of a generator's hazardous waste, not just newly hazardous TC waste.

Further discussion of the Agency's reasons for promulgating an extended compliance date for small-quantity generators is provided in section III.K of this preamble. In summary, the Agency believes that allowing an additional six months for small quantity generators to come into full compliance with the TC will serve two purposes. First, it will allow the Agency time to educate small quantity generators on the RCRA rules while, at the same time, allowing the Agency to focus immediate implementation efforts on large volumes of hazardous waste. Second, it will provide the necessary time for small quantity generators to comply with subtitle C requirements as a result of the TC.

VI. Regulatory Requirements

A. Introduction

This portion of the preamble discusses the analyses required by Executive Order No. 12291 and the Regulatory Flexibility Act. The Agency is required under the Executive Order to estimate the costs, economic impacts, and benefits of “major” rules by conducting a regulatory impact analysis (RIA). Recognizing the potential of the Toxicity Characteristic (TC) rule to affect a broad spectrum of American industry, EPA prepared an RIA comparing several regulatory alternatives. Based on the results of this analysis, the Agency concluded that this final regulation is a major rule. Section VI.B presents the methodology and results of the RIA.

The Regulatory Flexibility Act requires the Agency to assess small business impacts resulting from regulations. The analysis of small business impacts indicated that the TC rule would not have a significant impact on small businesses, and therefore a formal regulatory flexibility analysis was not prepared. Section VI.C addresses potential effects on small businesses.

The Agency received many comments on the RIA for the June 13, 1986 proposal. A summary of comments, along with Agency responses, is included as section VI.D. Section VI.E discusses requirements under the Paperwork Reduction Act.

Details of the regulatory impact analysis and small business analysis are available in the RIA document for the final rule (Ref. 8). This final rule was submitted to the Office of Management and Budget for review as required by E.O. No. 12291.

B. Regulatory lmpact Analysis

1. Executive Order No. 12291

Executive Order No. 12291 requires EPA to assess the effect of Agency actions during the development of regulations. Such an assessment consists of a quantification of the potential costs, economic impacts, and benefits of a rule, as well as a description of any beneficial or adverse effects that cannot be quantified in monetary terms. ln addition, Executive Order No. 12291 requires

that regulatory agencies prepare a regulatory impact analysis (RlA) for major rules. Major rules are defined as those likely to result in (1) an annual cost to the economy of $100 million or more; (2) a major increase in costs or prices for consumers or individual industries; or (3) significant adverse effects on competition, employment, investment, innovation, or international trade.

EPA prepared an RIA comparing the final TC rule with several regulatory alternatives. Based on the RIA, EPA estimates that the final TC rule is a major rule with annual compliance costs of between $130 million and $400 million. The analysis was conducted based on the Office of Management and Budget's “Interim Regulatory Impact Analysis Guidance” and EPA's “Guidelines for Performing Regulatory Impact Analyses.”

2. Basic Approach

In the final rule, EPA is amending its hazardous waste identification regulations under Subtitle C of the Resource Conservation and Recovery Act (RCRA) by refining and expanding the existing Extraction Procedure Toxicity Characteristic (EPTC). The resulting TC includes a new extraction procedure (the Toxicity Characteristic Leaching Procedure or TCLP) and 25 new organic constituents in addition to the 14 existing EPTC constituents. Wastes exhibiting the TC, based on concentrations of constituents in the TCLP extract, are designated as hazardous wastes and are brought under subtitle C regulation.

EPA estimated the costs, economic impacts, and benefits of the final rule and of a number of major regulatory alternatives to the rule. Only the anticipated effects of the final rule are presented in this preamble; results for the regulatory alternatives are discussed in the RIA. In presenting the results of the analysis, the Agency has presented range estimates for costs, economic impacts, and benefits to express the uncertainty associated with certain analytical assumptions.

In order to gauge the effects of the final rule, EPA first identified wastes and industries which would be affected by the rule. Incremental costs for affected facilities were estimated based on the change in waste management practices which would be required once ***11851** the wastes became hazardous. These incremental costs were aggregated to estimate national costs of the rule.

Economic impacts on facilities were based on a comparison of facility compliance costs with costs of production and cash from operations. The potential for facility closures was also examined.

Benefits, like costs, were based on required changes in waste management practices. Benefit measures included human health risk reduction, resource damage reduction, and cleanup costs avoided. Facility-level benefit estimates were aggregated to obtain national benefits.

Section VI.B.3, below, presents the methodology used to estimate costs, economic impacts, and benefits. It also briefly describes the sensitivity analyses that were conducted to determine the significance of key analytical assumptions; these sensitivity analyses are discussed in more detail in the RIA. Limitations of the analytical approach (e.g., assumptions which are likely to overstate, understate, or create uncertainty in results) are discussed in the RIA. Results of the analysis of costs, economic impacts, and benefits are provided in section VI.B.4.

3. Methodology

The methodology for the RIA is presented in several parts. First, the procedure for identifying wastes and facilities affected by the TC is discussed. Next, the development of national cost estimates is presented. The section on economic impact methodology describes the criteria used in gauging impacts on the regulated community. Following that is a section that presents several alternative measures of benefits of the rule. The last section describes the methodology for analysis of used oil.

a. Determination of Affected Wastes and Facilities. The first step in estimating the impacts of the rule was to determine which wastes and facilities would be affected by the rule, based on waste characteristics, quantities, and management practices. No

single data source contained all of this information, and none of the data were facility-specific. Therefore, the Agency assembled aggregated data (e.g., by industrial sector) from separate sources and used it to draw inferences on facility-level impacts.

Data on waste characterization and volume came primarily from a series of TC industry studies. (Ref. 19 through 29) These studies were conducted for major industrial categories identified as likely to generate significant quantities of TC wastes; other sectors, generating smaller quantities of potentially affected waste, were not addressed. Standard Industrial Classifications (SICs) for the industrial sectors studied range between the two-digit and four-digit levels. The industries profiled are shown in Table VI-1.

Table VI-1.--Potentially Affected Industries Considered in RIAs for the Proposed and Final TC Rules

Industry	SIC [FN1]	Proposed	Final
Textile Mills [FN2]	22		X
Lumber and Wood Products. [FN2]	2421, 2499		X
Pulp and Paper [FN2]	261, 262, 263, 266		X
Printing and Publishing	27		X
Plastics Materials and Resins. [FN2]	2821	X	X
Synthetic Rubber. [FN2]	2822	X	X
Synthetic Fibers. [FN2]	2823, 2824		X
Pharmaceuticals. [FN2]	283	X	X
Soaps and Other Detergents	2841	X	
Surface Active Agents	2843	X	
Paints and Allied Products	2851	X	
Organic Chemicals. [FN2]	2865, 2869	X	X
Agricultural Chemicals	2879	X	
Petroleum Refining. [FN2]	2911	X	X
Miscellaneous Petroleum and Coal Products. [FN2]	2992		X
Rubber and Miscellaneous Plastics Products. [FN2]	30		X
Non-Ferrous Wire Drawing and Insulation	3357	X	
Machinery and Mechanical Products	34 through 39		X
Pipelines, except Natural Gas. [FN2]	461		X
Electrical Services	4911		X
Wholesale Petroleum Marketing. [FN2]	517		X

1 SICs listed are those defining the group considered in this analysis. SICs given at the two-digit or three-digit SIC level indicate that the analysis applies to all four-digit SICs contained within the broader category

2 Included in detailed quantitative analysis for the final RIA.

The industry studies provided data including waste type (wastewater, sludge, solid process residual, or organic liquid), waste quantity, constituent concentration ranges and distributions, and number of generating facilities. The data in the studies were based primarily on EPA's effluent guidelines reports, supplemented by best engineering judgement and data received in comments on the proposed rule or in follow-up correspondence (Refs. 30 and 31). Most of the wastes which were included were related to wastewater treatment; there was relatively little data on process residuals. Wastes which were already hazardous by virtue of a listing or characteristic (e.g., the EPTC) were not included. Due to lack of data, certain types of wastes were not included in the analysis (e.g., contaminated soil, off-spec products, contaminated debris).

It is particularly difficult to predict the behavior of oily wastes in the TCLP test. For the purpose of deriving upper bound estimates of costs, economic impacts, and benefits, one assumption that EPA adopted was that oily non-liquid wastes would

not present filtration problems in the TCLP (i.e., that the oily phase passes through the filter and hazardous constituents in the oil phase leach to the test extract) and that if extract concentrations exceeded regulatory levels, these wastes would fail the TC. As a basis for lower bound estimates for costs, economic impacts and benefits, the Agency assumed that no oily wastes will be caught by TC regulation because the oily phase (and corresponding high levels of toxic constituents) would not filter through to the extract in the TCLP.

Due to the lack of facility-specific waste generation data, certain assumptions had to be made to derive the quantity of each wastestream per facility. First, potentially affected facilities within each industrial sector were split between small (with less than 50 employees) and large (with 50 employees or more) facility size categories based on 1982 Census of Manufacturers data on the number of facilities by size category. (The 1982 Census data were the most recent available.) Second, the total quantity of potentially affected waste was distributed between small and large facilities based on Census of Manufacturers data on the value of shipments for the small and large size categories. Using the distribution of facilities and of total waste quantity between small and large size categories, EPA estimated wastestream quantity per facility for small and large facilities.

EPA conducted a sensitivity analysis in order to test the sensitivity of results to the assumed distribution of wastes based on value of shipments. Since the division of waste quantities based on value of shipments resulted in most waste being generated by large facilities, EPA tested the alternative assumption that waste quantities were split evenly between the large and small facility size categories in each industry. (Results of sensitivity analyses are presented in section VI.B.4.)

***11852** Baseline management practices (i.e., management practices in the absence of the regulation) were derived primarily from the Screening Survey of Industrial subtitle D Establishments. (Ref. 16.) This survey provided information on the percent of facilities, by industrial sector, which manage non-hazardous wastes on-site in landfills, surface impoundments, waste piles, and land application units. Other baseline management practices were not specifically identified in the survey; therefore, EPA had to use knowledge of potentially affected TC wastes to identify these other practices and estimate the percentage of facilities using them.

In the case of non-wastewaters, the other practices considered included management in off-site landfills and land application units. For wastewaters, the other baseline practices included management in tanks as part of a wastewater treatment system, direct discharge under a NPDES permit, or indirect discharge to a Publicly Owned Treatment Works. These other wastewater management practices were assumed to be permissible under subtitle C; therefore it was assumed that facilities using these practices for wastes which were identified as hazardous by the TC would not be affected by the TC rule. EPA examined the sensitivity of results to this assumption by assuming, alternatively, that all wastewaters were managed on site in subtitle D surface impoundments.

For organic liquids, EPA determined, based on the Office of Solid Waste's Industry Studies Database, that the most likely baseline management practices were recycling and burning. EPA assumed that incremental management costs for these wastes would not be significant and therefore did not include the wastes in the analysis.

By combining the waste characterization and volume data with the management practice data, it was possible to estimate, by industrial sector, the amount of waste and the number of facilities potentially affected by the TC.

In order to determine the quantity of each wastestream which would be affected by the TC, the regulatory levels for constituents in the waste were compared with the estimated concentration distributions, derived from the TC industry studies, for constituents in the waste leachate. The constituent which caused the largest percentage of the wastestream to fail the TC was designated as the “cost-driving” constituent, and the quantity exhibiting the TC due to the presence of that constituent was used as the affected quantity. EPA tested the sensitivity of results to the assumption that waste would fail for a single driving constituent by adding the percentages failing for all constituents (up to 100 percent).

Due to the lack of facility-specific data, it was assumed that the percentage of facilities affected by the TC for a particular wastestream would equal the percentage of the total waste failing the TC. (For example, if 25 percent of a wastestream failed, it was assumed that 25 percent of the facilities generating the waste would be affected and that all of the wastestream at each affected facility would fail.) In order to test the importance of this assumption, EPA adopted two alternative assumptions as sensitivity analyses: for any percentage of waste failing (except for 0 and 100 percent, where clearly no facilities or all facilities would be affected), the percentage of facilities affected would be 10 percent or, alternatively, 90 percent.

The effects of potential production process changes in response to the rule were not addressed.

b. Cost Methodology. EPA estimated both the social costs and the compliance costs of the final rule. Social costs do not include transfer payments between different parties within society (i.e., they do not include tax payments or above-average profits); the social costs therefore represent the real resource costs imposed by the rule on society as a whole. Compliance costs, which include the effects of taxes and above-average profits, more accurately reflect the effect of the rule on particular entities within society.

1. Social Costs

EPA estimated the national social costs of the final rule by calculating before-tax incremental management costs for affected wastes at model facilities and then summing the facility costs across industrial sectors.

Before-tax incremental costs were calculated by subtracting baseline management costs from post-regulatory costs. Baseline management practices were determined as discussed previously. Post-regulatory management practices were developed based on waste types and quantities; the least-cost practice among those feasible for a waste was chosen as discussed below. The post-regulatory practices did not include potential waste treatment practices under the land disposal restrictions program since land disposal restrictions requirements for TC wastes will not come into effect until after the TC rule is promulgated. Possible post-regulatory management practices, as well as baseline practices, for TC wastes are shown in Table VI-2.

Table VI-2.--Baseline and Post-Regulatory Management Practices

Waste type	Baseline practice	Post-regulatory practice
Wastewater	On-site Subtitle D surface impoundment	On-site tank exempt from Subtitle C, Subtitle C surface impoundment. [FN1] or Practice permissible under Subtitle. [FN2] .....
Same as baseline. [FN3]		
Non-wastewater	On-site Subtitle D landfill or land application unit or off-site Subtitle D landfill	On-site or off-site Subtitle C landfill or land application unit.
Organic liquid	Burning, recycling	Same as baseline. [FN3]

1 Dilution and deep-well injection were also considered as post-regulatory practices but were found to be more expensive than tank management.
2 Includes management in Subtitle C-exempt tanks, direct discharge under a NPDES permit, or indirect discharge to a Publicly Owned Treatment Works.
3 Since the post-regulatory practice was the same as the baseline practice, the rule would not affect management of these wastes.

To estimate before-tax baseline and post-regulatory costs for wastes, EPA first estimated the cost per metric ton for the different on-site and off-site waste management practices. Before-tax costs for on-site management units include operation and maintenance (O&M) and capital costs. O&M costs are incurred annually for operation and maintenance of waste treatment or disposal units. Capital costs include costs for construction of the unit and for depreciable assets; these costs, which assumed an average operating life of 20 years, were restated as annual values by using a capital recovery factor based on a discount rate of three percent. RCRA-related costs such as personnel training, financial assurance, and liability insurance were included as indirect capital costs.

For the subset of subtitle D facilities which could potentially become subtitle C TSDFs in order to manage TC wastes on-site, post-regulatory costs for on-site management also included corrective action costs. Corrective action costs for units were based on data from the to-be-proposed corrective action subpart S rule RIA, which indicated the probability of a unit requiring a RCRA facility assessment, RCRA facility investigation, and corrective action cleanup. Corrective action costs were ***11853** not assigned to facilities which were determined to already be subtitle C treatment, storage, and disposal facilities, since units at these facilities would already be subject to corrective action requirements under subparts S and F. Like capital costs, corrective action costs were converted to annual values.

The annualized capital and (as appropriate) corrective action costs were added to yearly O&M costs to derive overall annualized costs for on-site units of various sizes. These annualized costs were then divided by the waste management capacities of the units to obtain the costs per metric ton for on-site management in different units.

Off-site management costs were based on commercial hazardous waste management prices, adjusted for the effects of above-average profits. Shipping costs were included for wastes sent off-site. Neither the on-site nor off-site costs included the cost of waste testing.

Since no data were available on the combinations of wastestreams generated at particular facilities, EPA used an algorithm to create model facilities. In estimating costs for the model facilities, wastes that were amenable to co-management were grouped to identify economies of scale.

Once the costs per metric ton for different types of on-site and off-site management had been developed and waste quantities for the model facilities had been determined, EPA estimated each facility's baseline cost based on the quantities of waste and the cost per metric ton for the baseline management practices identified for the wastes. The post-regulatory cost for each facility was estimated in a similar way. The post-regulatory management practices for facilities were selected by comparing the cost per metric ton for different feasible post-regulatory practices for wastes and selecting the least expensive alternative. (This comparison was made based on compliance costs, rather than social costs, as discussed below). EPA then subtracted baseline costs from post-regulatory costs to obtain the before-tax incremental cost for each facility. These before-tax incremental costs were then added across industrial sectors to obtain the total (national) social costs of the rule.

EPA examined the possibility that some facilities managing wastewaters would incur costs over and above the cost of switching from management in unlined surface impoundments to management in wastewater treatment tanks that are exempt from subtitle C. To calculate upper bound costs, the Agency assumed that facilities generating large quantities of TC wastewater (over 400,000 metric tons per year) would not be able to convert existing non-hazardous surface impoundments to tanks by the effective date of the rule (i.e., October 1, 1990) and therefore would become interim status facilities under RCRA and subject to subtitle C closure of any impoundments. The upper bound cost estimates included costs for subtitle C “landfill closure” of the surface impoundments currently used to manage TC waste. Costs for surface impoundment subtitle C closure included pumping of free liquid, solidification of sludges, construction of a cover system, installation of upgradient and downgradient ground water monitoring wells, closure certification, and potential corrective action costs triggered by bringing facilities with TC surface impoundments into the subtitle C system.

2. Compliance Costs

EPA used the same basic approach to estimate compliance costs that was used to estimate social costs except that the after-tax costs (or revenue requirements) of management practices were used rather than the before-tax costs, and the price of off-site management was used rather than the cost of off-site management (to address above-average profits). Since the compliance costs reflect the cost of the rule for particular entities within society more accurately than the social costs do, compliance costs were used in determining whether it would be less expensive for facilities to use on-site or off-site post-regulatory management practices.

Based on the cost analysis discussed above, EPA estimated the number of existing subtitle C treatment, storage, and disposal facilities (TSDFs) electing to manage TC non-wastewaters on site and the number of subtitle D facilities which would be likely to become subtitle C TSDFs in order to manage their non-wastewaters on-site. (The focus was on on-site management of non-wastewaters, since it was assumed that most facilities would be able to manage wastewaters on site without becoming subtitle C TSDFs.) This was done by first determining the number of facilities that would be likely to choose on-site management as the least-cost management practice for non-wastewaters and then estimating how many of these would be likely to already be subtitle C TSDFs. EPA also estimated the number of new subtitle C generators, by determining how many facilities would generate in excess of 100 kilograms per month of TC waste and then calculating how many of these facilities would be likely to already be subtitle C generators.

c. Economic Impact Methodology. To gauge impacts, EPA compared compliance costs (discussed previously) with average facility costs of production and with cash from operations. Financial data were obtained primarily from the Census and Annual Survey of Manufacturers (U.S. Department of Commerce, Bureau of Census) and were organized by Standard Industrial Classification (SIC) code and facility size. Impacts were estimated at the facility level rather than the firm level, due to lack of data on specific facilities and the firms owning them.

Two ratios were used to identify facilities likely to experience adverse economic effects: compliance cost divided by cost of production (the COP ratio) and cash from operations divided by compliance cost (the CFO ratio). These ratios bound possible effects on individual facilities by examining impacts assuming complete pass-through of compliance costs to customers, on the one hand, and assuming no pass-through of costs, on the other. The COP ratio represents the percentage product price increase for facility output that would be necessary if the entire compliance cost, accompanied by facility profit, were to be passed through to customers in the form of higher prices. A change exceeding five percent is considered an indication of a significant adverse economic impact on a facility. The CFO ratio represents the number of times that a facility's gross margin (profit) would cover the compliance cost if the facility were to fully absorb the cost. For this ratio, a value of less than 20 is considered to represent a significant adverse impact.

EPA then performed an analysis on the facilities experiencing significant economic impacts to identify the potential for facility closures. Those facilities for which the CFO ratio was less than two were considered likely to close.

Impacts on significantly affected product markets were addressed qualitatively by examining market structure and the ability of facilities to pass compliance costs on to customers.

d. Benefits Methodology. The benefits of the final rule were evaluated by considering the reduction in human health risk, the reduction in resource damage, and future cleanup costs avoided that would result from required changes in management practices for affected wastes. These benefits ***11854** measures centered primarily on the exposure to contaminants via the ground water medium, since this was the route of exposure addressed by the TC rule; however, a screening analysis of risks via air, due to emissions from surface impoundments, was also conducted to gauge the significance of these risks.

It is important to point out that the benefits measures should not be added. The measures provide alternative ways of evaluating benefits of the rule, and significant overlap between measures does occur.

EPA estimated benefits on a wastestream-by-wastestream basis. To simplify the analysis of benefits, EPA employed a screening analysis to identify two “risk-driving” constituents in each wastestream, one a carcinogen and one a non-carcinogen. These constituents were then used in developing benefit estimates.

A Monte Carlo modeling approach was used to simulate fate and transport of the constituents and subsequent exposure to them under a variety of waste characterizations, hydrogeologic settings, and exposure scenarios. Based on data from EPA's National Survey of Solid Waste Municipal Landfill Facilities (the “Municipal Landfill Survey”), it was assumed that only 46 percent of facilities had down-gradient wells. EPA examined the sensitivity of results to this assumption by assuming, alternatively, that all facilities had down-gradient wells.

Due to the way in which fate and transport of constituents was modeled (using an infinite source, steady-state model), benefits estimates were primarily a function of the number of facilities estimated to manage each wastestream and constituent concentrations in the waste; wastestream volumes did not affect benefits estimates. In contrast, cost analysis results were a function of the number of facilities, waste constituent concentrations, and wastestream volumes.

Worst-case estimates of baseline risk, resource damage, and cleanup costs were developed by assuming that the baseline management practice for both wastewaters and non-wastewaters was an unlined, non-hazardous waste landfill. This is the same assumption that was employed by the Agency in determining regulatory levels for TC constituents. Post-regulatory risk, resource damage, and cleanup costs were estimated by assuming that the wastes managed as hazardous under the TC would be effectively prevented from contaminating ground water and would therefore result in no risk, resource damage, or cleanup costs; only those wastes continuing to be managed as non-hazardous would pose a threat to human health or the environment.

For wastewaters, the baseline risk, resource damage, and cleanup cost due to ground water contamination were based on concentrations of constituents in the influents to waste management units. Consequently, since volatilization of constituents from waste management units was not accounted for, benefits due to reduction in ground water contamination may be overstated.

The three benefits measures used in this analysis are discussed separately below.

1. Human Health Risk Reduction

EPA estimated two types of human health risk: risk to the most exposed individual (MEI) and population risk. Human health risk is defined herein as the probability of injury, disease, or death over a given time (70 years) due to responses to doses of disease-causing agents. The human health risk posed by a waste management practice is a function of the toxicity of the chemical constituents in the wastestream and the extent of human exposure to the constituents. The likelihood of exposure is dictated by hydrogeologic and climatic settings at land disposal units and by the fate and transport of chemical constituents in environmental media.

a. MEI Risk Reduction. MEI risk was based on exposure to the risk-driving constituents. Concentrations of the risk-driving constituents in the waste leachate were selected randomly from the constituents' concentration distributions. A dilution-attenuation factor (DAF), derived from EPA's subsurface fate and transport model (EPACML), was then randomly selected and used to model the fate and transport of the constituents in ground water. (The DAFs were developed using data from the Municipal Landfill Survey on landfill size, hydrogeology, and distance from the unit to the closest drinking water well; see section III.E for further discussion of the model.) By dividing the initial leachate concentrations of the risk-driving constituents by the DAF, exposure concentrations at a down-gradient well were estimated. Risks from ingestion of contaminated ground water were then calculated. The carcinogenic MEI risk was expressed as the probability of the MEI contracting cancer over a 70-year lifetime, and the non-carcinogenic MEI risk was expressed as an exceedance of the health-effects threshold.

Risk estimates were developed in this way for baseline conditions and for the final rule. The difference between the final rule and baseline risk estimates yielded the MEI risk reduction (or benefit).

EPA conducted a separate screening analysis of baseline MEI risks due to air emissions from surface impoundments in order to assess whether potential air risks were significant. This was done by assuming that constituents in wastewaters would potentially volatilize to the air rather than leach to ground water. EPA's Liner Location Model (Ref. 32) was used to estimate concentrations of constituents at an exposure point 200 meters from the edge of the surface impoundment. Both carcinogenic and non-carcinogenic risks were estimated.

b. Population Risk Reduction. Population risk was estimated in much the same way as MEI risk, with the exception that ground water plume areas for risk-driving constituents were used to model the exposure of populations located downgradient from units. The plume areas were developed for a representative hydrogeologic environment, based on data from the Municipal Landfill Survey.

Each plume area contained a gradient of exposure concentrations, with the highest concentration near the unit boundary and the lowest concentration near the outside edge of the plume. By assuming a uniform population density of 1.6 persons per acre, based on the Municipal Landfill Survey, it was possible to estimate the number of persons exposed to each of the concentration levels within each plume.

The population risk for the carcinogenic constituent, based on the constituent's risk-specific dose (RSD), was expressed as the number of cancer cases over a 70-year lifetime. The population risk for the non-carcinogenic constituent, based on the constituent's reference dose (RfD), was expressed as the number of persons exposed to average daily concentrations exceeding the RfD over a 70-year period.

2. Resource Damage Avoided

Resource damage measures the cost associated with replacing contaminated ground water that had been used as a source of drinking water. Resource damage was assumed to result from any contamination of ground water which would render it unsuitable for human consumption; other potential foregone uses, such as industrial or agricultural uses, were not addressed.

If the concentration of a constituent in ground water exceeded a maximum contaminant level (MCL), the ground water was assumed to be damaged. If ***11855** the contaminant did not have an MCL but the concentration exceeded a taste and odor threshold or a health effects threshold, the ground water was also assumed to be damaged. Areas of damaged ground water were derived based on a comparison of the constituent's concentration within the plume with the constituent's MCL, taste and odor threshold, or health-based number, in an approach similar to that used to estimate plume areas for population risk.

To place a value on the damaged resource, EPA assumed that an alternative water supply system would have to be built to provide water to persons living above the area of the damaged ground water. The costs of constructing the water supply system included capital and O&M costs; these costs were discounted to the present at a rate of three percent to obtain the resource damage per facility. Addition of resource damage across facilities provided a national estimate.

3. Cleanup Costs Avoided

As an alternative measure of benefits, EPA estimated the cleanup costs avoided as a result of the TC rule. Costs of cleanup of contaminated ground water were estimated by assuming that sites with resource damage in the baseline would eventually require cleanups. To develop an upper bound estimate, it was assumed that sites with resource damage greater than $1,000,000 (present value) would require cleanup.

Cleanup costs were based on an average cost of $15 million per site, with cleanups beginning in 15 years. EPA estimated the average cost of cleanup by examining recent Superfund records of decision (RODs) for sites contaminated with TC constituents that required substantial ground water cleanup efforts. Costs were discounted to present values using a discount rate of three percent.

e. Used Oil Methodology. EPA addressed the impacts of the TC on used oil separately from other wastes for several reasons. First, used oil is generated across a wide variety of industrial sectors. Second, unlike other wastes, it has economic value and can be sold in intermediate or end-use markets; this complicates any analysis of the costs of regulating it as a hazardous waste. Also, data on used oil are quite limited. Finally, it is difficult to accurately estimate quantities of used oil that may exhibit the TC because in practice TCLP filtration is sample-specific and difficult to predict.

The analysis of costs, economic impacts, and benefits associated with used oil was qualitative in nature; no attempt was made to develop national estimates. In determining the quantity of used oil potentially affected, EPA excluded used oil that was: (1) Already hazardous because it exhibits a hazardous waste characteristic (e.g., ignitability); (2) recycled; or (3) generated by "do-it-yourselfers" (i.e., auto owners disposing of crankcase oil). In order to develop worst-case estimates of impacts on used oil, it was assumed that used oil would filter in the TCLP. It was also assumed that the facilities managing used oil were subtitle D facilities. Finally, estimated impacts on used oil did not account for the possible stigma associated with management of used oil as a hazardous waste.

4. Results

Results of the RIA are presented below. These results are approximations that are intended to identify the most significant impacts of the TC rule. As discussed previously, there were no data on the waste types and quantities generated by specific facilities in the different industrial sectors. Therefore, EPA used more aggregated data and focused on those industrial sectors which were most likely to generate significant quantities of TC wastes.

a. Affected Wastes and Facilities. EPA estimated the amount of waste and the number of facilities that would be "affected" by the rule, i.e., that would incur any incremental costs due to required changes in management practices for newly hazardous wastes.

1. Affected Wastes

The overall quantity of waste affected by the TC was driven by wastewaters. EPA estimated the quantity of affected wastewaters to be approximately 730 million metric tons (MMT) per year and the quantity of affected non-wastewaters (sludges and solids) would range from approximately 0.85 MMT/year to 1.8 MMT/year. It should be noted that the affected wastewaters, which would be hazardous wastes, are assumed to be exempt from subtitle C regulation in the post-regulatory scenario due to their management in exempt tanks. However, they would be affected wastes because a change in management practice (from surface impoundments to tanks) would be required.

The industrial sectors with the largest quantities of affected wastewaters were Petroleum Refining (SIC 2911), Organic Chemicals (SIC 286), Synthetic Rubber (SIC 2822), and Cellulosic and Non-Cellulosic Synthetic Fibers (SICs 2823 and 2824). For the lower bound estimate of 0.85 MMT/year of non-wastewaters affected, the sectors with the largest quantities of affected non-wastewaters were Pulp and Paper (SIC 26), Synthetic Fibers, Organic Chemicals, and Pharmaceuticals (SIC 283). For the upper bound estimate of 1.8 MMT/year, industry sectors generating the largest quantities of affected non-wastewaters were Petroleum Refining, Pulp and Paper, Synthetic Fibers, Organic Chemicals, and Wholesale Petroleum Marketing (SIC 517). Certain sectors generate significant quantities of both wastewaters and non-wastewaters due to the wastewater treatment sludges associated with wastewater streams. Most of the affected wastewaters and non-wastewaters are believed to be generated by large facilities.

A total of twelve constituents appeared as "cost-driving" constituents in the analysis. However, benzene was the driving constituent for over 60 percent of the affected waste quantity. Other volume-driving constituents include chloroform (25%), vinyl chloride (17%), and trichloroethylene (15%).

2. Affected Facilities

EPA estimated that between 15,000 and 17,000 generators would be affected by the rule. Costs and additional requirements among these affected facilities will vary (e.g., some may already be RCRA generators or TSDFs, others may need to apply for RCRA permits or send wastes off-site). Over 90 percent of these were small facilities (with fewer than 50 employees). The industries with the most affected large facilities were Hosiery and Knit Fabric Finishing (SIC 225), Wholesale Petroleum Marketing, Organic Chemicals, Petroleum Refining, and Plastics Materials and Resins (SIC 2821). The industries with the most affected small facilities were Wholesale Petroleum Marketing, Hosiery and Knit Fabric Finishing, Miscellaneous Petroleum and Coal Products (SIC 2992), Organic Chemicals, and Plastics Materials and Resins.

3. Sensitivity Analysis of Affected Wastes and Facilities

Changes in certain analytical assumptions had significant effects on the quantity of waste and number of facilities affected by the TC final rule. (Refer to section VI.B.3.a for discussion of the sensitivity analyses which were conducted.) Some of the changes also affected cost and benefit results, as discussed below under cost results and benefit results.

Assuming that oily wastes would not filter in the TCLP, rather than assuming that they would, would have a very significant effect on the quantity of non- ***11856** wastewaters affected by the TC. This effect can be seen in the difference between lower bound (assuming oily wastes do not filter) and upper bound (assuming oily wastes filter without complications) estimates of affected quantities of non-wastewaters. Nearly all of the non-wastewaters from Petroleum Refining (including a very large-volume primary treatment sludge), Wholesale Petroleum Marketing, and Petroleum Pipelines are oily wastes.

Assuming that all wastewaters were managed in surface impoundments, rather than some portion being managed by practices exempt under subtitle C, increased affected wastewater quantity significantly to approximately 1,900 MMT/year. lt also increased the number of facilities affected in certain sectors.

Finally, assuming that only 10 percent of the facilities would be affected for a waste failing the TC, rather than using the percent of the waste failing, significantly reduced the number of facilities affected by the TC in most industrial sectors.

b. Cost Results—1. Social Costs and Compliance Costs. EPA estimated the total social costs of the TC rule (excluding taxes and above-average profits) to be approximately $90 million to $310 million per year (present value $1.3 billion to $5.7 billion); this does not include costs associated with used oil. Compliance costs (which include taxes and above-average profits) ranged from $130 million to $400 million per year (present value $1.9 billion to $6.0 billion). While affected waste quantities were driven by wastewaters, compliance costs (for the scenario where oily wastes fail the TC and no surface impoundment closure costs are incurred) were driven by non-wastewaters due to the significantly higher incremental costs of managing non-wastewaters. Non-wastewaters accounted for over 95 percent of compliance costs.

For the lower bound cost estimate, the industrial sectors with the largest compliance costs were Pulp and Paper, Synthetic Fibers, Organic Chemicals, and Synthetic Rubber. For the upper bound cost estimate, the industrial sectors with the largest compliance costs were Petroleum Refining, Pulp and Paper, Synthetic Fibers, Wholesale Petroleum Marketing, and Organic Chemicals. Constituents driving the cost results were: benzene, chloroform, trichloroethylene, vinyl chloride, and carbon tetrachloride.

Approximately 90 percent of the compliance costs (for the scenario where oily wastes fail the TC and no surface impoundment closure costs are incurred) were incurred by large facilities and 10 percent by small facilities across industrial sectors. A relatively small number of large facilities incurs the majority of compliance costs because large facilities are believed to have much greater waste generation rates than small facilities.

The estimated number of subtitle D facilities seeking permits to become non-commercial subtitle C TSDFs was 40 to 250; this does not include facilities seeking permits for storage or treatment only. Most of the expected permit applicants were in the Pulp and Paper Industry in the lower bound estimate. Most of these new TSDFs in the upper bound estimate were in Petroleum Refining.

The number of existing subtitle C non-commercial TSDFs expected to seek permit modifications to handle TC wastes was between 45 and 220, depending on whether permits are considered for only disposal or for treatment, storage, and disposal. Most of these facilities in the upper bound estimate were in the Wholesale Petroleum Marketing and Petroleum Refining industries.

The number of subtitle C commercial TSDFs (SIC 4953) seeking permit modifications or changes to interim status could be as high as 360, the estimated number of existing commercial TSDFs. Many of these commercial TSDFs are primarily storage facilities.

In addition, the TC rule would result in as many as 15,000 new subtitle C generators. Most of the new generators would be in Wholesale Petroleum Marketing and Hosiery and Knit Fabric Finishing.

2. Sensitivity Analysis of Costs. Changes in certain analytical assumptions had significant effects on the social costs and compliance costs of the TC final rule. (Refer to section VI.B.3.a for discussion of the sensitivity analyses which were conducted.) Some of the changes also affected benefit results, as discussed below under benefits results.

Assuming that oily wastes would not filter in the TCLP, rather than assuming that they would, would have a significant effect on both social costs and compliance costs. The Agency estimated, as a lower bound assuming that no oily wastes will fail the TC test, social costs of about $90 million per year and compliance costs of about $130 million per year. By comparison, if it were assumed for the purpose of predicting TCLP results that oily wastes behave like other non-liquid wastes, social costs would be $190 million per year and compliance costs would be $250 million per year.

Assuming that not all facilities would be able to convert within six months from surface impoundments to tanks for management of their TC wastewaters, rather than assuming that all facilities would be able to convert, significantly increased the cost of the rule. Based on landfill closure of impoundments, this assumption added approximately $120 million to annual social costs and $140 million to annual compliance costs.

Splitting wastestream quantity evenly between small and large facility size categories, rather than based on value of shipments, shifted wastes from large to small facilities. While this did not affect the overall costs greatly, it significantly decreased compliance costs for large facilities and increased them for small facilities.

Finally, assuming that only 10 percent of the facilities would be affected for a waste failing the TC, rather than using the percent of the waste failing, significantly reduced social costs and compliance costs due to the larger quantities of waste being managed at a smaller number of facilities and the resultant economies of scale. The estimated number of new subtitle0 C TSDFs, existing TSDFs seeking permit modifications, and new subtitle C generators also decreased significantly.

c. Economic Impact Results—1. Significantly Affected Facilities. Based on the economic impact criteria discussed previously the estimated total number of significantly affected facilities was 65 to 81, of which most (51 to 66) are large. The fact that most of the significantly affected facilities are large can be partially explained by the fact that data indicate there are no small facilities in certain sectors (e.g., Cellulosic Synthetic Fibers). Another reason for the preponderance of significantly affected large facilities is that for some wastes, total compliance costs are less for small facilities than for large facilities because large facilities are believed to generate significantly more waste.

In the lower bound estimates, significantly affected facilities were expected in four industrial sectors: Pulp and Paper, Synthetic Rubber, Synthetic Fibers, and Organic Chemicals. In the lower bound estimates the Pulp and Paper industry was predicted to have the greatest number of significantly affected facilities (35), of which 30 are large facilities. The synthetic rubber industry had the highest number of significantly affected small facilities (8), out of a total of 14 significantly affected small facilities. None of the industries examined were expected to suffer facility closures as a result of the TC.

***11857** In the upper bound estimates, significantly affected facilities were expected in seven industries: Pulp and Paper, Synthetic Rubber, Synthetic Fibers, Organic Chemicals, Textiles, Pharmaceuticals, and Plastics and Resins. Pulp and paper had the largest number of significantly affected facilities—36 out of 80 for all facilities.

2. Effects on Product and Capital Markets

The industries with significantly affected facilities have very little potential to pass compliance costs on to consumers in the form of higher prices. These industries produce primarily intermediate goods (e.g., rubber, paper, fibers, and chemicals) which are used in a number of subsequent processes (e.g., manufacturing and fabrication) before they reach consumer markets. The users of these intermediate products have access to similar or identical products from U.S. suppliers that are not significantly affected by the TC and from foreign suppliers; because substitutes are available, these users would not be forced to pay higher prices for the intermediate products.

While results suggest that prices in product markets will not be affected, at least some impact is likely on capital markets. Because affected facilities will not be able to pass compliance costs through to buyers in the form of higher prices, they will experience lower profits. Lower profits will reduce the value of capital tied up in these facilities. However, as most of the affected facilities are part of integrated production systems and are owned by large firms with significant asset holdings, the effect on capital markets (i.e., stock prices and bond ratings) should be relatively small.

3. Sensitivity Analysis of Economic Impacts.

A change in one of the analytical assumptions had significant effects on economic impacts due to the TC final rule. Refer to section VI.B.3.a for discussion of the sensitivity analyses which were conducted.

Splitting wastestream quantity evenly between small and large facility size categories, rather than based on value of shipments, shifted wastes from large to small facilities. Under the scenario where oily wastes fail the TC and no surface impoundment closure costs are incurred, this resulted in nearly 40 additional small facilities with significant economic impacts and 10 small facility closures.

d. Benefits Results. EPA estimated the benefits of regulating TC wastes on a wastestream by wastestream basis; results of this analysis are presented in Table VI-3. As discussed in the benefits methodology section, results for different benefit measures (human health risk, resource damage, and cleanup costs avoided) are likely to overlap and should not be added.

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Table VI-3.--Benefits of the TC Rule
Reduction in MEI Risk:
- Reduction in Carcinogenic Risk (number of facilities with risk
greater than 1x10E-5 at down-gradient well) ..................... 370 to
780.
- Reduction in Non-Carcinogenic Risk (number of facilities with
exposure above a health-based threshold at downgradient well) ..... 8.
Reduction in Population Risk:
- Reduction in Carcinogenic Risk (number of cancer cases over 70
years) ........................................................... 6.
- Reduction in Non-Carcinogenic Risk (number of persons with
exposure above a health-based threshold at downgradient wells) ..... 320.
Reduction in Resource Damage (present value, millions of 1988
dollars) ....................................................... 3,800.
Cleanup Costs Avoided (present value, millions of 1988 dollars) ..... Up to
15,000.
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1. MEI Risk

As can be seen from the table, there is a potentially significant reduction under the final rule in the carcinogenic risk to the most exposed individual (MEI). There are from 370-780 fewer facilities managing wastes that present risks to the most exposed individual (MEI) greater than 1x10E-5 under the final rule than there were under baseline conditions. The industrial sectors driving these benefits include Wholesale Petroleum Marketing (SIC 517) and Miscellaneous Plastics Products (SIC 3079). The constituent driving most of these benefits is benzene. The difference between the lower and upper bounds results from certain oily wastes that are unregulated in the lower bound.

For non-carcinogenic MEI risk, there are 8 fewer facilities managing wastewaters where the exposure to a non-carcinogenic constituent exceeds the reference dose (RfD) under the final rule than under baseline conditions. Wastes from Wholesale Petroleum Marketing drive these benefits results. Cresols are the risk-driving constituents.

The Wholesale Petroleum Marketing sector presents significant risks due to the large number of facilities managing wastewaters and non-wastewaters. The number of facilities in this sector estimated to manage wastewaters and non-wastewaters are 1,290 and 1,050 facilities, respectively; this compares with 1,900 and 8,600 facilities, respectively, managing affected wastewaters and non-wastewaters across all industrial sectors.

A screening analysis of MEI risks due to air emissions from surface impoundments was conducted to gauge the potential risk via the air medium. This analysis indicated that in sectors other than Wholesale Petroleum Marketing approximately 20 percent of modeled facilities had carcinogenic risks greater than 1x10E-5 and 5 percent had non-carcinogenic doses greater than the RfD; MEI air risks from Wholesale Petroleum Marketing were less than 1x10E-6. Benzene contributed most of the carcinogenic risks while phenol was responsible for most of the non-carcinogenic risks.

The industries generating wastes with high MEI air risks differ to some extent from those generating wastes with high MEI ground water risks. The industries generating wastes with high MEI air risks include Pulp and Paper, Plastics Materials and Resins, Synthetic Rubber, Cellulosic and Non-Cellulosic Synthetic Fibers (SICs 2823 and 2824), and Organic Chemicals.

There is some potential overlap in estimates of air and ground water risk. The wastewater MEI risks via ground water were based on the assumption that all the constituent mass was available for leaching to ground water; in contrast, the air risks assumed some percentage of constituent mass would volatilize from impoundments. As a result, the wastewater MEI risks via ground water are likely to be overstated.

2. Population Risk

Based on a very limited analysis of population risk, EPA estimates that there would be six fewer cancer cases over the 70-year modeling period due to the final rule. Wholesale Petroleum Marketing (constituent: benzene) and Plastics and Resins (SIC 2821) (constituent: vinyl chloride) drive these benefits. The reduction in number of persons exposed to non-carcinogens at concentrations greater than the RfDs was estimated to be 320 over a 70-year period. Sawmills and Planing Mills (SIC 2421) and Organic Chemicals (pentachlorophenol and methyl ethyl keytone) drive these results.

3. Resource Damage

The total reduction in resource damage would be approximately $3.8 billion (present value). Wholesale Petroleum Marketing and Miscellaneous Plastics Products are the industrial sectors driving resource damage benefits. Benzene is the driving constituent.

***11858 4. Cleanup Costs Avoided**

Estimated cleanup costs avoided due to the final rule ranged up to $15 billion (present value). Under the assumption that all sites with significant resource damage (i.e., resource damage greater than $1,000,000 (present value)) would require cleanup, approximately 1,600 facilities would require cleanup.

5. Sensitivity Analysis of Benefits

Changes in certain analytical assumptions had significant effects on the benefits of the TC final rule. (Refer to sections VI.B.3. a and d for discussion of the sensitivity analyses which were conducted.) Some of the changes also affected cost results, as discussed under cost results.

Assuming that oily wastes would not filter in the TCLP, rather than assuming that they would, would reduce the benefits associated with non-wastewaters, as can be seen in the lower bound estimates indicated in the results above. This would result primarily from the significant reduction in the number of facilities managing non-wastewaters in Wholesale Petroleum Marketing.

Assuming that all wastewaters were managed in surface impoundments, rather than some portion being managed by practices exempt under subtitle C, would increase the number of facilities affected in many sectors and increase benefits significantly. Benefits for wastewaters could increase by approximately 10 times since there would be 10 times as many facilities with surface impoundments.

Assuming that only 10 percent of the facilities would be affected for a waste failing the TC, rather than using the percent of the waste failing, significantly reduced the number of facilities affected by the TC in all industrial sectors. This would significantly reduce benefits as a result, since fewer facilities would be managing wastes.

Assuming that all facilities have down-gradient wells, rather than assuming only 46% have down-gradient wells, would increase benefit results by a factor of approximately two.

e. Cost-Effectiveness. The Agency estimated the cost-effectiveness of the final rule and of several regulatory alternatives. This discussion is presented in the regulatory impact analysis document, which is part of the public docket for the rule.

f. Used Oil Results. Used oil is generated across a wide variety of industrial sectors. Some generators manage or dispose of their used oil directly while others provide their used oil to the used oil management system (UOMS), a system of intermediate collectors and processors (Ref. 33). Firms in the UOMS then re-refine or process the used oil and/or sell it for various end uses.

Under the worst-case assumption that used oil would not create TCLP filtration problems, EPA found based on constituent concentration data (see Ref. 8), that virtually all used oil would fail the TC. EPA determined that three end-use management practices for used oil would be affected: landfilling/incineration, dumping, and road oiling.

Once used oil became TC hazardous, it would have to be shifted to other end-use management practices. Much of the used oil that is currently dumped or applied directly to roads by generators would probably be collected and sold to the UOMS. Firms in the UOMS that currently sell used oil for road oiling would generally shift this oil to other management practices, such as re-refining or burning as a fuel. Used oil that is managed by landfilling or incineration in subtitle D units would likely be shifted to management in subtitle C units.

The shift in management practices would impose costs on used oil generators, the UOMS, and end-users of used oil. Used oil generators currently providing used oil to the UOMS would be likely to pay somewhat higher collection costs due to pass-through of compliance costs by firms in the UOMS. Generators that currently manage their wastes by road oiling would incur storage and collection costs for their used oil as well as costs for a road-oiling substitute. Generators directly managing their wastes by dumping would incur costs for storage and collection. Firms in the UOMS that sell used oil for road oiling would be forced to sell the oil in less profitable markets, and some firms could close if unable to enter another market. Firms in the UOMS could also incur costs for disposal of low quality used oil and related wastes in subtitle C (rather than subtitle D) units if these wastes were TC hazardous; as discussed above, some of these costs could be passed on to used oil generators. Firms that

re-refine used oil could benefit from the TC rule, since a greater volume of used oil would potentially be available at a lower price. Finally, end-users that purchase used oil for road oiling would incur costs for an alternative dust suppressant.

The shift in management practices could also result in certain benefits. A previous study of carcinogenic risks from used oil management practices (Ref. 34) indicates that dumping of used oil may present significant risks relative to other management practices (with the possible exception of burning in boilers, where risks are more comparable). Road oiling appears to present more significant risks than recycling and comparable or fewer risks relative to burning in boilers or landfill disposal. It is difficult to draw definitive conclusions concerning benefits due to the different constituent profiles and population densities associated with each of the management practices in the risk analysis.

C. Regulatory Flexibility Analysis

1. Approach

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) requires that whenever an agency publishes a notice of rulemaking, it must prepare a Regulatory Flexibility Analysis (RFA) that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions). An RFA is unnecessary, however, if the Agency's administrator certifies that the rule will not have a significant economic effect on a substantial number of small entities.

EPA examined the final rule's potential effects on small entities as required by the Regulatory Flexibility Act. Three measures, based on EPA guidelines for conducting an RFA, were used to determine whether the rule would have a “significant economic effect” on small entities: the ratio of compliance cost to cost of production, the ratio of compliance cost to value of sales, and the ratio of cash from operations to compliance cost (the last ratio being used to assess potential closures). Two of the three criteria, the ratio of compliance cost to cost of production and the ratio of cash from operations to compliance cost, are discussed in section VI.B.3.c. The third, the ratio of compliance cost to value of sales, was estimated for small and large facilities; if the difference between these ratios was greater than ten percent, this indicated a significant impact.

The guidelines for conducting RFAs are somewhat ambiguous with respect to evaluating impacts based on the third criterion. Determining whether the difference between ratios exceeds ten percent can be done by subtracting the large facility ratio from the small facility ratio or by dividing the small facility ratio by the large facility ratio. Dividing the small facility ratio by the large facility ratio may incorrectly indicate siqnificant impacts on small facilities when both ratios are very small but the small facility ratio is larger than the large facility ratio. (For example, a small ***11859** facility ratio of 0.00002 divided by a large facility ratio of 0.00001 would indicate a significant impact on small businesses based on the division approach, despite the fact that the very low ratio of compliance cost to value of sales for small facilities indicates little impact on small facilities.) Therefore, the division approach must be interpreted with caution.

A “substantial number” of small entities was assumed to be 20 percent or more of the population of small businesses, small organizations, or small government jurisdictions within the universe of facilities affected by the rule.

The Agency defined a small business as a business employing 50 employees or less. (Standard Small Business Administration criterion is 500 employees.) EPA decided to use the 50 employee definition of a small business because the RIA estimates facility-level impacts, and the SBA definition applies to entire firms. The SBA definition would designate most of the facilities in the examined industries as small businesses, which would obscure differential impacts on smaller facilities.

Impacts on small businesses related to costs of compliance for used oil and contaminated soils were not examined due to lack of data on the facilities experiencing those costs.

2. Results

The only entities found to be affected by the final rule were small businesses, defined here as businesses employing fewer than 50 persons. No small organizations or small government jurisdictions were identified as potential TC waste generators in the TC industry studies which form the foundation for this analysis.

The Agency did not identify any industries in which 20 percent or more of the small businesses were significantly affected based on the ratio of compliance cost to cost of production, the ratio of cash from operations to compliance cost, or the ratio of compliance cost to value of sales (using the subtraction approach). Using the division approach for the ratio of compliance cost to value of sales indicated that small businesses in four sectors (including Pulp and Paper, Synthetic Rubber, Organic Chemicals, and Wholesale Petroleum Marketing) would be significantly affected. However, since the small facility and large facility ratios were both quite small (small facility ratios were less than 0.03), the Agency does not expect significant small business impacts in these sectors. Based on these results, EPA has concluded that today's final rule will not have a significant effect on a substantial number of small entities. As a result of this finding, EPA has not prepared a formal RFA in support of the rule. More detailed information on small business impacts is available in the RIA for this rule.

D. Response to Comments on RIA for June 13, 1986 Proposal

EPA received many comments on the RIA for the proposed TC rule. This section presents a general summary and analysis of the public comments concerning the original RIA; all of the comments are addressed in the background document for this final rule. Major issues addressed by commenters included consideration of particular industries, specific aspects of cost and benefit methodologies, cost and benefit estimates, and the assessment of small business impacts.

1. Industries Included in the Analysis

The majority of comments on the RIA for the proposed rule concerned the absence of specific industrial sectors from the group examined for potential impacts. Other commenters criticized the RIA for not considering the effects of the TC on end users of products and on facilities such as Publicly Owned Treatment Works and Municipal Landfills.

Industries that commenters suggested should have been evaluated included natural gas production, manufacturing of a variety of products, including forest products, pharmaceuticals, automobiles, plastics, metals, polyvinyl chloride, semi-conductors, wire and cables, and waste management. The Agency agrees with commenters that a number of industrial sectors were not addressed in the RIA for the proposed rule. The Agency notes, however, that several of the wastestreams that commenters believed should have been included in the RIA (based upon the proposed regulatory levels) are not expected to be defined as hazardous based upon the final regulatory levels being promulgated today. One of the fundamental problems with determining which industries would potentially be affected by the TC is lack of data on currently non-hazardous wastes. Since these wastes are currently outside the subtitle C system, requirements for information gathering related to them are minimal.

The Agency made extensive efforts, in preparing the RIA for the TC final rule, to obtain data on the industrial sectors potentially affected by the TC. These data were derived from a variety of sources. The Agency contacted numerous trade associations and individual facilities and collected pertinent EPA and other government publications. In addition, EPA prepared a series of TC industry study reports on those sectors most likely to generate significant quantities of TC wastes.

In preparing its TC industry studies, EPA first conducted preliminary studies which examined a large number of industries, with emphasis on identifying whether or not TC constituents would be likely to be present in industry wastes. Based on the preliminary studies, EPA completed detailed profiles of potentially affected industries for use in the final RIA. The Agency examined the potential for impacts on a number of industries that were not considered in the RIA for the proposed rule, as well as reconsidering some that were addressed in that RIA. Table VI-1 in section VI.B compares the coverage of industries for both the proposed rule RIA and the final rule RIA and indicates the industries for which detailed quantitative analysis was conducted.

Commenters also criticized the proposed rule RIA for not considering effects on end-users of products containing TC constituents. Examples of such end-user industries include agricultural chemical users, transporters, automotive maintenance

facilities, petroleum retailers, medical facilities, and research laboratories. The Agency recognizes that TC toxicants exist in a variety of substances, and that end-users as well as producers of products containing TC constituents could be affected by the rule. Some end-users not identified in the RIA may be affected, but there is no information to quantify these potential impacts. The Agency believes that some of the impacts on affected end users may be mitigated by small quantity generator regulations under 40 CFR 261.5.

Finally, several commenters questioned EPA's assessment of impacts on Publicly Owned Treatment Works (POTWs), resource recovery facilities, public water suppliers, municipal landfills, the electrical services industry, and currently regulated RCRA facilities. As discussed previously in section III.K.2, the Agency has tested a number of POTW sludges to determine whether or not these sludges would be considered hazardous under the TC; the data generally indicate that these wastes would not be affected by the TC (Ref. 8). Because the final regulatory level for chloroform is significantly higher than originally proposed, EPA believes that public water suppliers also are unlikely to generate TC wastes. The Agency analyzed wastestreams generated by the Electrical Services ***11860** industry. These wastes were excluded from the RIA because they are fossil fuel combustion wastes, which are exempt from subtitle C regulation until a determination is made as to whether they should be regulated as hazardous. The Agency acknowledges that some waste generated by waste management facilities may exhibit the TC; however, most of these wastestreams that commenters believed should be included are not expected to exhibit the TC under the final regulatory levels. Finally, impacts on currently regulated RCRA facilities (in the industries included in the RIA) were addressed in the RIA.

2. Estimation of Costs and Economic Impacts

Many commenters expressed concern that the compliance cost estimates for facilities included in the economic impact analysis did not capture many of the expenditures faced by handlers of hazardous waste. The most common criticism was directed at the omission of the cost for actually performing the TCLP. Other commenters mentioned insurance costs and costs associated with RCRA permit applications. Another large group of comments concerned the costs for permitting and retrofitting the large universe of surface impoundments containing wastewaters which would exhibit the TC. In addition, a number of commenters contended that the RIA significantly underestimated potential economic impacts of the TC.

Other commenters claimed that the expense of the highly sophisticated equipment and specially trained personnel necessary for the testing of wastes would pose a significant burden on many firms, especially those without on-site laboratory facilities. The Agency recognizes that testing of wastes could pose a significant expense for firms that choose to test their wastes. On the other hand, there is currently no RCRA requirement for generators to test their wastes; the determination of hazardousness may be made based on either laboratory analysis of the waste or on knowledge of the waste, raw materials, and production processes. The Agency expects that many generators will rely on the latter method, and elect not to perform the TCLP. The Agency is still considering promulgating a testing requirement at a future date. If a testing requirement is proposed, potential costs of testing will be analyzed in detail.

Recognizing that administrative and insurance costs can constitute a significant portion of waste management costs, the Agency considered these in cost estimates in the final RIA. In addition, the cost of preparing RCRA permit applications is considered in the cost of subtitle C waste management, as are items such as liability insurance, personnel training, and contingency planning.

In response to comments that surface impoundment impacts were understated, the Agency examined the effect of the TC rule on wastewaters and estimated the costs of compliance with subtitle C requirements. The Agency assumed in the final RIA that, based on least-cost management practices, surface impoundments would not have to be retrofitted. Instead, it was assumed that affected wastewaters would be segregated and treated in a separate tank system, while remaining non-hazardous wastewaters could continue to be managed in the impoundments. In deriving an upper bound estimate of costs, it was assumed that some impoundments would have to undergo subtitle C clean closure.

Given the broad scope of the TC rule and the general lack of data on industries and facilities managing currently non-hazardous wastes, the Agency agrees that economic impacts on certain sectors may have been underestimated in the RIA for the proposed

rule. As discussed above, the Agency has made significant efforts in the final RIA to more accurately characterize the sectors potentially affected by the TC and to estimate the actual impacts on affected facilities.

3. Estimation of Benefits

Several commenters remarked on the original methodology used for the estimation of benefits. The most frequent target of criticism was the assumption that all contaminated aquifers would be cleaned up as a result of the TC. Commenters also questioned the validity of assuming that ground water resource conditions in North Carolina were representative of conditions across the entire United States.

Commenters on the use of aquifer cleanup as the basis for estimating benefits of the proposed rule asked for justification of the assumption that all aquifers would be cleaned up and an explanation of the benefits to human health and the environment which would result from the cleanup. The Agency used a different methodology to estimate benefits for the final RIA than was used for the original RIA. For the final RIA, EPA examined three potential types of benefits: human health risk reduction, resource damage avoided, and cleanup costs avoided. The assumption that all aquifers would be cleaned up was not used in the final RIA. In estimating benefits based on cleanup costs avoided through controlled subtitle C management of TC wastes, EPA assumed in the RIA for the final rule that, for the near term, the subtitle D facilities with down-gradient wells and with at least some resource damage (as predicted by the resource damage analysis) would be the most likely candidates for cleanup.

The Agency agrees with the comments that ground water resource conditions in North Carolina may not be representative of conditions across the entire United States. As a result, in the final RIA EPA used distributions of hydrogeologic parameters which were representative of nationwide conditions, rather than relying on hydrogeologic information from one state.

4. Cost-Benefit Comparisons

In general, commenters argued that the RIA overestimated likely benefits of the proposed rule while underestimating the potential impacts. Commenters believed that the TC would bring large quantities of waste into the subtitle C system with little or no attendant environmental or health benefit. One commenter claimed that, after all indirect impacts are considered, the net benefits of the rule could be negative. Another commenter, however, stated that benefits were actually underestimated because of assumptions in the baseline scenario.

The Agency has used an improved methodology and additional data in the final RIA. EPA believes that the final RIA provides reasonable estimates of the potential costs and benefits of the rule. As presented in this section, the final RIA does indicate that the TC will bring relatively large quantities of waste into the subtitle C system, and also indicates that there will be attendant benefits. The Agency used cost and benefit estimates to compare relative costs and benefits of the various regulatory options. The analyses were conducted separately using approaches constructed to make the best possible use of available data. The separate analyses were not meant to be used to produce absolute measures of cost effectiveness. The RIA contains discussion of the Agency's evaluation and comparison of cost and benefit results.

5. Small Business Analysis

The Agency received many comments on its assessment of the effects of the proposed TC on small businesses. One group of comments focused on the definition chosen by EPA for small businesses. The Agency was also criticized for its threshold for ***11861** determining if a “substantial number” of small businesses would suffer significant economic impacts, and therefore necessitate the preparation of a full Regulatory Flexibility Analysis. Finally, many commenters felt that the analysis severely underestimated the impact of the rule on small businesses.

Commenters asked why the Agency did not use the standard Small Business Administration (SBA) criterion of 500 employees to define a small business. The Agency decided to use the 50 employee definition of a small business because the RIA estimates facility-level impacts, and the SBA definition applies to entire firms. In the absence of data to estimate firm-level impacts,

the Agency chose the 50 employee cutoff as an appropriate small facility definition for the RIA. The SBA definition would designate most of the establishments in most of the examined industries as small facilities, which would obscure differential impacts on smaller facilities.

The Agency was criticized for using a 20 percent threshold for determining if a "substantial number" of small businesses would be significantly affected. Commenters claimed that it was arbitrary to consider the small business impact negligible if "only 19.9 percent" of small business were significantly affected. The Agency recognizes that, for an individual facility, the magnitude of impacts is not altered by the number of other facilities which are significantly affected. Nevertheless, the Agency believes that 20 percent is a reasonable benchmark for defining a "substantial number" of small businesses. The 20 percent threshold is commonly applied in RIAs conducted by EPA.

A large number of commenters criticized the overall conclusions of the small business analysis, declaring that the analysis severely underestimated the economic effects of the TC on small businesses. Commenters maintained that the universe of small businesses was inadequately addressed. Examples of small businesses not included in the analysis which commenters felt should have been considered included service stations and vehicle maintenance facilities. Commenters also mentioned the expense of performing the TCLP, claiming that it was an especially significant hardship for small businesses.

As explained in the general discussion of the industrial sectors included in the RIA, the Agency made extensive efforts to identify and include sectors potentially affected by the TC rule, including end users of products. And, as discussed under the comments on incorporating testing costs, these costs were not included since generators are not currently required to test their wastes. Although EPA maintains that a full RFA is not necessary for the TC rule, it realizes that the impact of the rule could be significant for individual small enterprises.

E. Paperwork Reduction Act

The information collection requirements in this rule have been approved by the Office of Management and Budget (OMB) under the Paper Reduction Act, 44 U.S.C. 3501 et seq., and have been assigned the following OMB control numbers: 2050-0007, Land Disposal Permitting Standards; 2050-0008, RCRA Closure/Post-Closure; 2050-0009, Hazardous Waste Storage and Treatment Facilities; 2050-0011, Contingency Plans for Hazardous Waste Facilities; 2050-0012, General Facility Operating Requirements; 2050-0013, Operating Record for Hazardous Waste Facilities; 2050-0028, Notification of a Hazardous Waste Activity; 2050-0033, Reporting, Recordkeeping, and Planning for Ground-Water Monitoring; 2050-0034, RCRA Hazardous Waste Permit Application Part A; 2050-0036, RCRA Financial Assurance Requirements; 2050-0037, Recordkeeping and Reporting for RCRA Permitees; and 2050-0039, Uniform Hazardous Waste Manifest for Generators and Transporters.

VII. References

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List of Subjects in 40 CFR Parts 261, 264, 265, 268, 271, and 302

Administrative practice and procedure, Air pollution control, Chemicals, Confidential business information, Hazardous materials transportation, Hazardous substances, Hazardous waste, Indian lands, Intergovernmental relations, Natural resources, Nuclear materials, Penalties, Pesticides and pests, Radioactive materials, Recycling, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply, Waste treatment and disposal.

Dated: March 5, 1990.

William K. Reilly,

Administrator.

For the reasons set out in the preamble, Chapter I of Title 40 of the Code of Federal Regulations is amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6922.

2. Section 261.4 is amended by revising paragraphs (b)(6)(i) introductory text, and (b)(9) and by adding paragraph (b)(10) to read as follows:

§ 261.4 Exclusions.

* * * * *

(b) * * *

(6)(i) Wastes which fail the test for the Toxicity Characteristic because chromium is present or are listed in subpart D due to the presence of chromium, which do not fail the test for the Toxicity Characteristic for any other constituent or are not listed due to the presence of any other constituent, and which do not fail the test for any other characteristic, if it is shown by a waste generator or by waste generators that:

* * * * *

(9) Solid waste which consists of discarded wood or wood products which fails the test for the Toxicity Characteristic solely for arsenic and which is not a hazardous waste for any other reason or reasons, if the waste is generated by persons who utilize the arsenical-treated wood and wood products for these materials' intended end use.

(10) Petroleum-contaminated media and debris that fail the test for the Toxicity Characteristic of § 261.24 and are subject to the corrective action regulations under part 280 of this chapter.

3. Section 261.8 is added to subpart A to read as follows:

§ 261.8 PCB Wastes Regulated Under Toxic Substance Control Act

The disposal of PCB-containing dielectric fluid and electric equipment containing such fluid authorized for use and regulated under part 761 of this chapter and that are hazardous only because they fail the test for the Toxicity Characteristic (Hazardous Waste Codes D018 through D043 only) are exempt from regulation under parts 261 through 265, and parts 268, 270, and 124 of this chapter, and the notification requirements of section 3010 of RCRA.

4. Section 261.24 is revised to read as follows:

§ 261.24 Toxicity characteristic.

(a) A solid waste exhibits the characteristic of toxicity if, using the test methods described in Appendix II or equivalent methods approved by the Administrator under the procedures set forth in §§ 260.20 and 260.21, the extract from a representative sample of the waste contains any of the contaminants listed in Table 1 at the concentration equal to or greater than the respective value given in that Table. Where the waste contains less than 0.5 percent filterable solids, the waste itself, after filtering using the methodology outlined in Appendix II, is considered to be the extract for the purpose of this section.

(b) A solid waste that exhibits the characteristic of toxicity, but is not listed as a hazardous waste in subpart D, has the EPA Hazardous Waste Number specified in Table 1 which corresponds to the toxic contaminant causing it to be hazardous.

Table 1.--Maximum Concentration of Contaminants for the Toxicity Characteristic

EPA HW No. [FN1]	Contaminant	CAS No. [FN2]	Regulatory Level (mg/L)
D004	Arsenic	7440-38-2	5.0
D005	Barium	7440-39-3	100.0
D018	Benzene	71-43-2	0.5
D006	Cadmium	7440-43-9	1.0
D019	Carbon tetrachloride	56-23-5	0.5
D020	Chlordane	57-74-9	0.03
D021	Chlorobenzene	108-90-7	100.0
D022	Chloroform	67-66-3	6.0
D007	Chromium	7440-47-3	5.0.
D023	o-Cresol	95-48-7 [FN4]	200.0
D024	m-Cresol	108-39-4 [FN4]	200.0
D025	p-Cresol	106-44-5 [FN4]	200.0
D026	Cresol	---------- [FN4]	200.0
D016	2,4-D	94-75-7	10.0
D027	1,4-Dichlorobenzene	106-46-7	7.5
D028	1,2-Dichloroethane	107-06-2	0.5
D029	1,1-Dichloroethylene	75-35-4	0.7
D030	2,4-Dinitrotoluene	121-14-2 [FN3]	0.13
D012	Endrin	72-20-8	0.02
D031	Heptachlor (and its hydroxide)	76-44-8	0.008
D032	Hexachlorobenzene	118-74-1 [FN3]	0.13
D033	Hexachlorobutadiene	87-68-3	0.5

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D034 ..... Hexachloroethane ..... 67-72-1 3.0
D008 ..... Lead ..... 7439-92-1 5.0
D013 ..... Lindane ..... 58-89-9 0.4
D009 ..... Mercury ..... 7439-97-6 0.2
D014 ..... Methoxychlor ..... 72-43-5 10.0
D035 ..... Methyl ethyl ketone ..... 78-93-3 200.0
D036 ..... Nitrobenzene ..... 98-95-3 2.0
D037 ..... Pentrachlorophenol ..... 87-86-5 100.0
D038 ..... Pyridine ..... 110-86-1 [FN3] 5.0
D010 ..... Selenium ..... 7782-49-2 1.0
D011 ..... Silver ..... 7440-22-4 5.0
D039 ..... Tetrachloroethylene ..... 127-18-4 0.7
D015 ..... Toxaphene ..... 8001-35-2 0.5
D040 ..... Trichloroethylene ..... 79-01-6 0.5
D041 ..... 2,4,5-Trichlorophenol ..... 95-95-4 400.0
D042 ..... 2,4,6-Trichlorophenol ..... 88-06-2 2.0
D017 ..... 2,4,5-TP (Silvex) ..... 93-72-1 1.0
D043 ..... Vinyl chloride ..... 75-01-4 0.2
--------------------------------------------------------------------------------
1 Hazardous waste number.
2 Chemical abstracts service number.
3 Quantitation limit is greater than the calculated regulatory level. The
quantitation limit therefore becomes the regulatory level.
4 If o-, m-, and p-Cresol concentrations cannot be differentiated, the total
cresol (D026) concentration is used. The regulatory level of total cresol is
200 mg/l.
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***11863** 5. Section 261.30 is amended by revising paragraph (b) to read as follows:

§ 261.30 General.

* * * * *

(b) The Administrator will indicate his basis for listing the classes or types of wastes listed in this subpart by employing one or more of the following Hazard Codes:

```
Ignitable Waste ..... (I)
Corrosive Waste ..... (C)
Reactive Waste ..... (R)
Toxicity Characteristic Waste ..... (E)
Acute Hazardous Waste ..... (H)
Toxic Waste ..... (T)
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Appendix VII identifies the constituent which caused the Administrator to list the waste as a Toxicity Characteristic Waste (E) or Toxic Waste (T) in §§ 261.31 and 261.32.

* * * * *

6. Appendix II of part 261 is revised to read as follows:

Appendix II—Method 1311 Toxicity Characteristic Leaching Procedure (TCLP)

1.0 Scope and Application

1.1 The TCLP is designed to determine the mobility of both organic and inorganic contaminants present in liquid, solid, and multiphasic wastes.

1.2 If a total analysis of the waste demonstrates that individual contaminants are not present in the waste, or that they are present but at such low concentrations that the appropriate regulatory thresholds could not possibly be exceeded, the TCLP need not be run.

1.3 If an analysis of any one of the liquid fractions of the TCLP extract indicates that a regulated compound is present at such high levels that even after accounting for dilution from the other fractions of the extract the concentration would be above the regulatory threshold for that compound, then the waste is hazardous and it is not necessary to analyze the remaining fractions of the extract.

1.4 If an analysis of extract obtained using a bottle extractor shows that the concentration of any regulated volatile contaminant exceeds the regulatory threshold for that compound, then the waste is hazardous and extraction using the ZHE is not necessary. However, extract from a bottle extractor cannot be used to demonstrate that the concentration of volatile compounds is below the regulatory threshold.

2.0 Summary of Method (see Figure 1)

2.1 For liquid wastes (i.e., those containing less than 0.5 percent dry solid material), the waste, after filtration through a 0.6 to 0.8-um glass fiber filter, is defined as the TCLP extract.

2.2 For wastes containing greater than or equal to 0.5 percent solids, the liquid, if any, is separated from the solid phase and stored for later analysis; the solid phase, if necessary, is reduced in particle size. The solid phase is extracted with an amount of extraction fluid equal to 20 times the weight of the solid phase. The extraction fluid employed is a function of the alkalinity of the solid phase of the waste. A special extractor vessel is used when testing for volatile contaminants (see Table 1 for a list of volatile compounds). Following extraction, the liquid extract is separated from the solid phase by filtration through a 0.6 to 0.8-um glass fiber filter.

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BILLING CODE 6560-50-C

Table 1.--Volatile Contaminants [FN1]

Compound	CAS no.
Acetone	67-64-1
Benzene	71-43-2
n-Butyl alcohol	71-36-3
Carbon disulfide	75-15-0
Carbon tetrachloride	56-23-5
Chlorobenzene	108-90-7
Chloroform	67-66-3
1,2-Dichloroethane	107-06-2
1,1-Dichloroethylene	75-35-4
Ethyl acetate	141-78-6
Ethyl benzene	100-41-4
Ethyl ether	60-29-7
lsobutanol	78-83-1
Methanol	67-56-1
Methylene chloride	75-09-2
Methyl ethyl ketone	78-93-3
Methyl isobutyl ketone	108-10-1

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Tetrachloroethylene ..................................................... 127-18-4
Toluene ................................................................. 108-88-3
1,1,1-Trichloroethane ................................................... 71-55-6
Trichloroethylene ....................................................... 79-01-6
Trichlorofluoromethane .................................................. 75-69-4
1,1,2-Trichloro-1,2,2-trifluoroethane ................................... 76-13-1
Vinyl chloride .......................................................... 75-01-4
Xylene ................................................................ 1330-20-7
--------------------------------------------------------------------------------
1 When testing for any or all of these contaminants, the zero-headspace
extractor vessel shall be used instead of the bottle extractor.
```

2.3 If compatible (i.e., multiple phases will not form on combination), the initial liquid phase of the waste is added to the liquid extract, and these are analyzed together. If incompatible, the liquids are analyzed separately and the results are mathematically combined to yield a volume-weighted average concentration.

3.0 Interferences

3.1 Potential interferences that may be encountered during analysis are discussed in the individual analytical methods.

4.0 Apparatus and Materials

4.1 Agitation apparatus: The agitation apparatus must be capable of rotating the extraction vessel in an end-over-end fashion (see Figure 2) at 30 +2 rpm. Suitable devices known to EPA are identified in Table 2.

4.2 Extraction Vessel:

4.2.1 Zero-Headspace Extraction Vessel (ZHE). This device is for use only when the waste is being tested for the mobility of volatile constituents (i.e., those listed in Table 1). The ZHE (depicted in Figure 3) allows for liquid/solid separation within the device, and effectively precludes headspace. This type of vessel allows for initial liquid/solid separation, extraction, and final extract filtration without opening the vessel (see step 4.3.1). The vessels shall have an internal volume of 500-600 mL and be equipped to accommodate a 90-110 mm filter. The devices contain VITON R [FN1] O-rings which should be replaced frequently. Suitable ZHE devices known to EPA are identified in Table 3.

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TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

BILLING CODE 6560-50-C

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Table 2.--Suitable Rotary Agitation Apparatus [FN1]
--------------------------------------------------------------------------------
Company Location Model no.
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Analytical Testing and
Consulting Services,
Inc ................. Warrington, PA (215)
343-4490 .......... 2-ZHE or 4-bottle extractor
(DC20S); 4-ZHE or 8-bottle
extractor (DC20); 6-ZHE or
12-bottle extractor (DC20B).
Associated Design and
Manufacturing
Company ............. Alexandria, VA (703)
549-5999 .......... 2-vessel (3740-2). 4-vessel
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(3740-4). 6-vessel (3740-6).
8-vessel (3740-8). 12-vessel
(3740-12). 24-vessel (3740-24).
Environmental Machine
and Design, Inc ..... Lynchburg, VA (804)
845-6424 ..... 8-vessel (08-00-00). 4-vessel
(04-00-00).
IRA Machine Shop and
Laboratory ..... Santurce, PR (809)
752-4004 ..... 8-vessel (011001).
Lars Lande
Manufacturing ..... Whitmore Lake, MI
(313) 449-4116 .... 10-vessel (10VRE). 5-vessel (5
VRE).
Millipore Corp..... Bedford, MA (800)
225-3384 ..... 4-ZHE or 4 1-liter bottle
extractor (YT30ORAHW).

---

1 Any device that rotates the extraction vessel in an end-over-end fashion at
30 #2 rpm is acceptable.

BILLING CODE 6560-50-M

TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE

BILLING CODE 6560-50-C

Table 3.--Suitable Zero-Headspace Extractor Vessels [FN1]

Company Location Model no.

Analytical Testing &
Consulting Services, Inc Warrington, PA (215)
343-4490 ..... C102, Mechanical Pressure
Device.
Associated Design and
Manufacturing Company ... Alexandria, VA (703)
549-5999 ..... 3745-ZHE, Gas Pressure
Device.
Lars Lande Manufacturing
[FN2] ..... Whitmore Lake, MI (313)
449-4116 ..... ZHE-11, Gas Pressure
Device.
Millipore Corporation ..... Bedford, MA (800)
225-3384 ..... YT3009OHW, Gas Pressure
Device.
Environmental Machine and
Design, Inc ..... Lynchburg, VA (804)
845-6424 ..... VOLA-TOX1, Gas Gas
Pressure Device.

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1 Any device that meets the specifications listed in Section 4.2.1 of the
method is suitable.
2 This device uses a 110 mm filter.

For the ZHE to be acceptable for use, the piston within the ZHE should be able to be moved with approximately 15 psi or less. If it takes more pressure to move the piston, the O-rings in the device should be replaced. If this does not solve the problem, the ZHE is unacceptable for TCLP analyses and the manufacturer should be contacted.

The ZHE should be checked for leaks after every extraction. If the device contains a built-in pressure gauge, pressurize the device to 50 psi, allow it to stand unattended for 1 hour, and recheck the pressure. If the device does not have a built-in pressure gauge, pressurize the device to 50 psi, submerge it in water, and check for the presence of air bubbles escaping from any of the fittings. If pressure is lost, check all fittings and inspect and replace O-rings, if necessary. Retest the device. If leakage problems cannot be solved, the manufacturer should be contacted.

Some ZHEs use gas pressure to actuate the ZHE piston, while others use mechanical pressure (see Table 3). Whereas the volatiles procedure (see section 9.0) refers to pounds-per-square-inch (psi), for the mechanically actuated piston, the pressure applied is measured in torque-inch-pounds. Refer to the manufacturer's instructions as to the proper conversion.

4.2.2 Bottle Extraction Vessel. When the waste is being evaluated using the nonvolatile extraction, a jar with sufficient capacity to hold the sample and the extraction fluid is needed. Headspace is allowed in this vessel.

The extraction bottles may be constructed from various materials, depending on the contaminants to be analyzed and the nature of the waste (see Step 4.3.3). It is recommended that borosilicate glass bottles be used instead of other types of glass, especially when inorganics are of concern. Plastic bottles, other than polytetrafluoro-ethylene, shall not be used if organics are to be investigated. Bottles are available from a number of laboratory suppliers. When this type of extraction vessel is used, the filtration device discussed in Step 4.3.2 is used for initial liquid/solid separation and final extract filtration.

4.3 Filtration Devices: It is recommended that all filtrations be performed in a hood.

4.3.1 Zero-Headspace Extractor Vessel (ZHE): When the waste is evaluated for volatiles, the zero-headspace extraction vessel described in section 4.2.1 is used for filtration. The device shall be capable of supporting and keeping in place the glass fiber filter and be able to withstand the pressure needed to accomplish separation (50 psi).

Note: When it is suspected that the glass fiber filter has been ruptured, an in-line glass fiber filter may be used to filter the material within the ZHE.

4.3.2 Filter Holder: When the waste is evaluated for other than volatile compounds, any filter holder capable of supporting a glass fiber filter and able to withstand the pressure needed to accomplish separation may be used. Suitable filter holders range from simple vacuum units to relatively complex systems capable of exerting pressures of up to 50 psi or more. The type of filter holder used depends on the properties of the material to be filtered (see Step 4.3.3). These devices shall have a minimum internal volume of 300 mL and be equipped to accommodate a minimum filter size of 47 mm (filter holders having an internal capacity of 1.5 L or greater and equipped to accommodate a 142 mm diameter filter are recommended). Vacuum filtration can only be used for wastes with low solids content (<10 percent) and for highly granular liquid-containing wastes. All other types of wastes should be filtered using positive pressure filtration. Suitable filter holders known to EPA are shown in Table 4.

4.3.3 Materials of Construction: Extraction vessels and filtration devices shall be made of inert materials which will not leach or absorb waste components. Glass, polytetrafluoroethylene (PTFE), or type 316 stainless steel equipment may be used when evaluating the mobility of both organic and inorganic components. Devices made of high-density polyethylene (HDPE), polypropylene, or polyvinyl chloride may be used only when evaluating the mobility of metals. Borosilicate glass bottles are recommended for use over other types of glass bottles, especially when inorganics are constituents of concern.

Table 4.--Suitable Filter Holders [FN1]

Company	Location	Model/Catalogue no.	Size (um)
Nucleopore Corporation	..... Pleasanton, CA	(800)	

882-7711 ..... 425910 410400 142 mm 47 mm
Micro Filtration
Systems ..... Dublin, CA (800)
334-7132 (415)
828-6010 ..... 302400 311400 142 mm 47 mm
Millipore
Corporation ..... Bedford, MA (800)
225-3384 ..... YT30142HW XX1004700 . 142 mm 47 mm

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1 Any device capable of separating the liquid from the solid phase of the waste is suitable, providing that it is chemically compatible with the waste and the constituents to be analyzed. Plastic devices (not listed above) may be used when only inorganic contaminants are of concern. The 142 mm size filter holder is recommended.

4.4 Filters: Filters shall be made of borosilicate glass fiber, shall contain no binder materials, and shall have an effective pore size of 0.6 to 0.8-um or equivalent. Filters known to EPA which meet these specifications are identified in Table 5. Pre-filters must not be used. When evaluating the mobility of metals, filters shall be acid-washed prior to use by rinsing with 1N nitric acid followed by three consecutive rinses with deionized distilled water (a minimum of 1-L per rinse is recommended). Glass fiber filters are fragile and should be handled with care.

4.5 pH meters: The meter should be accurate to +0.05 units at 25 °C.

Table 5.--Suitable Filter Media [FN1]

Company Location Model Pore size

Millipore Corporation ... Bedford, MA (800) 225-3384 . AP40 ..... 0.7
Nucleopore Corporation .. Pleasanton, CA (415)
463-2530 ..... 211625 0.7
Whatman Laboratory
Products, Inc ..... Clifton, NJ (201) 773-5800 . GFF 0.7
Micro Filtration Systems Dublin, CA (800) 334-7132
(415) 828-6010 ..... GF75 ..... 0.7

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1 Any filter that meets the specifications in Section 4.4 of the Method is suitable.

***11870** 4.6 ZHE extract collection devices: TEDLARR[FN2] bags or glass, stainless steel or PTFE gas-tight syringes are used to collect the initial liquid phase and the final extract of the waste when using the ZHE device. The devices listed are recommended for use under the following conditions:

4.6.1 If a waste contains an aqueous liquid phase or if a waste does not contain a significant amount of nonaqueous liquid (i.e., <1 percent of total waste), the TEDLARR bag or a 600 mL syringe should be used to collect and combine the initial liquid and solid extract.

4.6.2 If a waste contains a significant amount of nonaqueous liquid in the initial liquid phase (i.e., >1 percent of total waste), the syringe or the TEDLARR bag may be used for both the initial solid/liquid separation and the final extract filtration. However, analysts should use one or the other, not both.

4.6.3 If the waste contains no initial liquid phase (is 100 percent solid) or has no significant solid phase (is 100 percent liquid), either the TEDLARR bag or the syringe may be used. If the syringe is used, discard the first 5 mL of liquid expressed from the device. The remaining aliquots are used for analysis.

4.7 ZHE extraction fluid transfer devices: Any device capable of transferring the extraction fluid into the ZHE without changing the nature of the extraction fluid is acceptable (e.g., a positive displacement or peristaltic pump, a gas tight syringe, pressure filtration unit (See Step 4.3.2), or other ZHE device).

4.8 Laboratory balance: Any laboratory balance accurate to within +0.01 grams may be used (all weight measurements are to be within +0.1 grams).

5.0 Reagents

5.1 Reagent water. Reagent water is defined as water in which an interferant is not observed at or above the methods detection limit of the analyte(s) of interest. For nonvolatile extractions, ASTM Type II water or equivalent meets the definition of reagent water. For volatile extractions, it is recommended that reagent water be generated by any of the following methods. Reagent water should be monitored periodically for impurities.

5.1.1 Reagent water for volatile extractions may be generated by passing tap water through a carbon filter bed containing about 500 grams of activated carbon (Calgon Corp., Filtrasorb-300 or equivalent).

5.1.2 A water purification system (Millipore Super-Q or equivalent) may also be used to generate reagent water for volatile extractions.

5.1.3 Reagent water for volatile extractions may also be prepared by boiling water for 15 minutes. Subsequently, while maintaining the water temperature at 90 +5 °C, bubble a contaminant-free inert gas (e.g., nitrogen) through the water for 1 hour. While still hot, transfer the water to a narrow mouth screw-cap bottle under zero-headspace and seal with a Teflon-lined septum and cap.

5.2 Hydrochloric acid (1N), HCl, made from ACS reagent grade.

5.3 Nitric acid (1N), HNO3 , made from ACS reagent grade.

5.4 Sodium hydroxide (1N), NaOH, made from ACS reagent grade.

5.5 Glacial acetic acid, HOAc, ACS reagent grade.

5.6 Extraction fluid.

5.6.1 Extraction fluid 1: Add 5.7 mL glacial HOAc to 500 mL of the appropriate water (See Step 5.1), add 64.3 mL of 1N NaOH, and dilute to a volume of 1 liter. When correctly prepared, the pH of this fluid will be 4.93 +0.05.

5.6.2 Extraction fluid 2: Dilute 5.7 mL glacial HOAc with ASTM Type II water (See Step 5.1) to a volume of 1 liter. When correctly prepared, the pH of this fluid will be 2.88+0.05.

Note: These extraction fluids should be monitored frequently for impurities. The pH should be checked prior to use to ensure that these fluids are made up accurately. If impurities are found or the pH is not within the above specifications, the fluid shall be discarded and fresh extraction fluid prepared.

5.7 Analytical standards prepared according to the appropriate analytical method.

6.0 Sample Collection, Preservation, and Handling

6.1 All samples shall be collected using an appropriate sampling plan.

6.2 The TCLP may place requirements on the minimal size of the field sample depending upon the physical state or states of the waste and the contaminants of concern. An aliquot is needed for preliminary evaluation of which extraction fluid is to be used for the nonvolatile contaminant extraction procedure. Another aliquot may be needed to actually conduct the nonvolatile extraction (see section 1.4 concerning the use of this extract for volatile organics). If volatile organics are of concern, another aliquot may be needed. Quality control measures may require additional aliquots. Further, it is always wise to collect more sample just in case something goes wrong with the initial attempt to conduct the test.

6.3 Preservatives shall not be added to samples.

6.4 Samples may be refrigerated unless refrigeration results in irreversible physical change to the waste. If precipitation occurs, the entire sample (including precipitate) should be extracted.

6.5 When the waste is to be evaluated for volatile contaminants, care shall be taken to minimize the loss of volatiles. Samples shall be taken and stored in a manner to prevent the loss of volatile contaminants (e.g., samples should be collected in Teflon-lined septum capped vials and stored at 4 °C, until ready to be opened prior to extraction).

6.6 TCLP extracts should be prepared for analysis and analyzed as soon as possible following extraction. Extracts or portions of extracts for metallic contaminant determinations must be acidified with nitric acid to a pH <2, unless precipitation occurs (see section 8.14 if precipitation occurs). Extracts or portions of extracts for organic contaminant determinations shall not be allowed to come into contact with the atmosphere (i.e., no headspace) to prevent losses. See section 10.0 (QA requirements) for acceptable sample and extract holding times.

7.0 Preliminary Evaluations

Perform preliminary TCLP evaluations on a minimum 100 gram aliqout of waste. This aliquot may not actually undergo TCLP extraction. These preliminary evaluations include: (1) determination of the percent solids; (2) determination of whether the waste contains insignificant solids and is, therefore, its own extract after filtration; (3) determination of whether the solid portion of the waste requires particle size reduction; and (4) determination of which of the two extraction fluids are to be used for the nonvolatile TCLP extraction of the waste.

7.1 Preliminary determination of percent solids: Percent solids is defined as that fraction of a waste sample (as a percentage of the total sample) from which no liquid may be forced out by an applied pressure, as described below.

7.1.1 If the waste will obviously yield no free liquid when subjected to pressure filtration (i.e., is 100% solids) proceed to Step 7.3.

7.1.2 If the sample is liquid or multiphasic, liquid/solid separation to make a preliminary determination of percent solids is required. This involves the filtration device described in Step 4.3.2 and is outlined in Steps 7.1.3 through 7.1.9.

7.1.3 Pre-weigh the filter and the container that will receive the filtrate.

7.1.4 Assemble the filter holder and filter following the manufacturer's instructions. Place the filter on the support screen and secure.

***11871** 7.1.5 Weigh out a subsample of the waste (100 gram minimum) and record the weight.

7.1.6 0Allow slurries to stand to permit the solid phase to settle. Wastes that settle slowly may be centrifuged prior to filtration. Centrifugation is to be used only as an aid to filtration. If used, the liquid should be decanted and filtered followed by filtration of the solid portion of the waste through the same filtration system.

7.1.7 Quantitatively transfer the waste sample to the filter holder (liquid and solid phases). Spread the waste sample evenly over the surface of the filter. If filtration of the waste at 4 °C reduces the amount of expressed liquid over what would be expressed at room temperature then allow the sample to warm up to room temperature in the device before filtering.

Note: If waste material (>1 percent of original sample weight) has obviously adhered to the container used to transfer the sample to the filtration apparatus, determine the weight of this residue and subtract it from the sample weight determined in Step 7.1.5 to determine the weight of the waste sample that will be filtered.

Gradually apply vacuum or gentle pressure of 1-10 psi, until air or pressurizing gas moves through the filter. If this point is not reached under 10 psi, and if no additional liquid has passed through the filter in any 2-minute interval, slowly increase the pressure in 10-psi increments to a maximum of 50 psi. After each incremental increase of 10-psi, if the pressurizing gas has not moved through the filter, and if no additional liquid has passed through the filter in any 2-minute interval, proceed to the next 10-psi increment. When the pressurizing gas begins to move through the filter, or when liquid flow has ceased at 50 psi (i.e., filtration does not result in any additional filtrate within any 2-minute period), stop the filtration.

Note: Instantaneous application of high pressure can degrade the glass fiber filter and may cause premature plugging.

7.1.8 The material in the filter holder is defined as the solid phase of the waste, and the filtrate is defined as the liquid phase.

Note: Some wastes, such as oily wastes and some paint wastes, will obviously contain some material that appears to be a liquid. Even after applying vacuum or pressure filtration, as outlined in Step 7.1.7, this material may not filter. If this is the case, the material within the filtration device is defined as a solid. Do not replace the original filter with a fresh filter under any circumstances. Use only one filter.

7.1.9 Determine the weight of the liquid phase by subtracting the weight of the filtrate container (see Step 7.1.3) from the total weight of the filtrate-filled container. Determine the weight of the solid phase of the waste sample by subtracting the weight of the liquid phase from the weight of the total waste sample, as determined in Step 7.1.5 or 7.1.7.

Record the weight of the liquid and solid phases. Calculate the percent solids as follows:

```
Percent = Weight of solid (Step 7.1.9) X 100
solids
--------------------------------
Total weight of waste (Step 7.1.5
or 7.1.7)
```

7.2 If the percent solids determined in Step 7.1.9 is equal to or greater than 0.5%, then proceed either to Step 7.3 to determine whether the solid material requires particle size reduction or to Step 7.2.1 if it is noticed that a small amount of the filtrate is entrained in wetting of the filter. If the percent solids determined in Step 7.1.9 is less than 0.5%, then proceed to Step 8.9 if the nonvolatile TCLP is to be performed and to section 9.0 with a fresh portion of the waste if the volatile TCLP is to be performed.

7.2.1 Remove the solid phase and filter from the filtration apparatus.

7.2.2 Dry the filter and solid phase at 100 +20 °C until two successive weighing yield the same value within +1 percent. Record the final weight.

Note: Caution should be taken to ensure that the subject solid will not flash upon heating. It is recommended that the drying oven be vented to a hood or other appropriate device.

7.2.3 Calculate the percent dry solids as follows:

```
Percent dry = (Weight of dry X 100
solids waste#filter)-tared weight of
filter
--------------------------------
Initial weight of waste (Step
7.1.5 or 7.1.7)
```

7.2.4 lf the percent dry solids is less than 0.5 percent, then proceed to Step 8.9 if the nonvolatile TCLP is to be performed, and to Section 9.0 if the volatile TCLP is to be performed. If the percent dry solids is greater than or equal to 0.5%, and if the nonvolatile TCLP is to be performed, return to the beginning of this Section (7.0) and, with a fresh portion of waste, determine whether particle size reduction is necessary (Step 7.3) and determine the appropriate extraction fluid (Step 7.4). If only the volatile TCLP is to be performed, see the note in Step 7.4.

7.3 Determination of whether the waste requires particle-size reduction (particle-size is reduced during this step): Using the solid portion of the waste, evaluate the solid for particle size. Particle-size reduction is required, unless the solid has a surface area per gram of material equal to or greater than 3.1 cm2 , or is smaller than l cm in its narrowest dimension (i.e., is capable of passing through a 9.5 mm (0.375 inch) standard sieve). If the surface area is smaller or the particle size larger than described above, prepare the solid portion of the waste for extraction by crushing, cutting, or grinding the waste to a surface area or particle-size as described above. If the solids are prepared for organic volatiles extraction, special precautions must be taken, see Step 9.6.

Note: Surface area criteria are meant for filamentous (e.g., paper, cloth, and similar) waste materials. Actual measurement of surface area is not required, nor is it recommended. For materials that do not obviously meet the criteria, sample-specific methods would need to be developed and employed to measure the surface area. Such methodology is currently not available.

7.4 Determination of appropriate extraction fluid: If the solid content of the waste is greater than or equal to 0.5 percent and if TCLP extraction for nonvolatile constituents will take place (Section 8.0), perform the determination of the appropriate fluid (Step 5.6) to use for the nonvolatiles extraction as follows:

Note: TCLP extraction for volatile constituents uses only extraction fluid 1 (Step 5.6.1). Therefore, if TCLP extraction for nonvolatiles is not required, proceed to Section 9.0.

7.4.1 Weigh out a small subsample of the solid phase of the waste, reduce the solid (if necessary) to a particle-size of approximately 1 mm in diameter or less, and transfer 5.0 grams of the solid phase of the waste to a 500-mL beaker or Erlenmeyer flask.

7.4.2 Add 96.5 mL of reagent water (ASTM Type II) to the beaker, cover with a watchglass, and stir vigorously for 5 minutes using a magnetic stirrer. Measure and record the pH. If the pH is <5.0, use extraction fluid 1. Proceed to Section 8.0.

7.4.3 If the pH from Step 7.4.2 is >5.0, add 3.5 mL 1N HCl, slurry briefly, cover with a watchglass, heat to 50 °C, and hold at 50 °C for 10 minutes.

7.4.4 Let the solution cool to room temperature and record the pH. If the pH is <5.0, use extraction fluid 1. If the pH is >5.0, use extraction fluid 2. Proceed to Section 8.0.

7.5 If the aliquot of the waste used for the preliminary evaluation (Steps 7.1-7.4) was determined to be 100% solid at Step 7.1.1, then it can be used for the Section 8.0 extraction (assuming at least 100 grams ***11872** remain), and the section 9.0 extraction (assuming at least 25 grams remain). If the aliquot was subjected to the procedure in Step 7.1.7, then another aliquot shall be used for the volatile extraction procedure in Section 9.0. The aliquot of the waste subjected to the procedure in Step 7.1.7 might be appropriate for use for the section 8.0 extraction if an adequate amount of solid (as determined by Step 7.1.9) was

obtained. The amount of solid necessary is dependent upon whether a sufficient amount of extract will be produced to support the analyses. If an adequate amount of solid remains, proceed to Step 8.10 of the nonvolatile TCLP extraction.

8.0 Procedure When Volatiles Are Not Involved

A minimum sample size of 100 grams (solid and liquid phases) is required. In some cases, a larger sample size may be appropriate, depending on the solids content of the waste sample (percent solids, See Step 7.1), whether the initial liquid phase of the waste will be miscible with the aqueous extract of the solid, and whether inorganics, semivolatile organics, pesticides, and herbicides are all analytes of concern. Enough solids should be generated for extraction such that the volume of TCLP extract will be sufficient to support all of the analyses required. If the amount of extract generated by a single TCLP extraction will not be sufficient to perform all of the analyses, more than one extraction may be performed and the extracts from each combined and aliquoted for analysis.

8.1 If the waste will obviously yield no liquid when subjected to pressure filtration (i.e., is 100 percent solid, see Step 7.1), weigh out a subsample of the waste (100 gram minimum) and proceed to Step 8.9.

8.2 If the sample is liquid or multiphasic, liquid/solid separation is required. This involves the filtration device described in Step 4.3.2 and is outlined in Steps 8.3 to 8.8.

8.3 Pre-weigh the container that will receive the filtrate.

8.4 Assemble the filter holder and filter following the manufacturer's instructions. Place the filter on the support screen and secure. Acid wash the filter if evaluating the mobility of metals (see Step 4.4).

Note: Acid washed filters may be used for all nonvolatile extractions even when metals are not of concern.

8.5 Weigh out a subsample of the waste (100 gram minimum) and record the weight. If the waste contains <0.5 percent dry solids (Step 7.2), the liquid portion of the waste, after filtration, is defined as the TCLP extract. Therefore, enough of the sample should be filtered so that the amount of filtered liquid will support all of the analyses required of the TCLP extract. For wastes containing >0.5 percent dry solids (Step 7.1 or 7.2), use the percent solids information obtained in Step 7.1 to determine the optimum sample size (100 gram minimum) for filtration. Enough solids should be generated by filtration to support the analyses to be performed on the TCLP extract.

8.6 Allow slurries to stand to permit the solid phase to settle. Wastes that settle slowly may be centrifuged prior to filtration. Use centrifugation only as an aid to filtration. If the waste is centrifuged, the liquid should be decanted and filtered followed by filtration of the solid portion of the waste through the same filtration system.

8.7 Quantitatively transfer the waste sample (liquid and solid phases) to the filter holder (see Step 4.3.2). Spread the waste sample evenly over the surface of the filter. If filtration of the waste at 4 °C reduces the amount of expressed liquid over what would be expressed at room temperature, then allow the sample to warm up to room temperature in the device before filtering.

Note: If waste material (>1 percent of the original sample weight) has obviously adhered to the container used to transfer the sample to the filtration apparatus, determine the weight of this residue and subtract it from the sample weight determined in Step 8.5, to determine the weight of the waste sample that will be filtered.

Gradually apply vacuum or gentle pressure of 1-10 psi, until air or pressurizing gas moves through the filter. If this point is not reached under 10 psi, and if no additional liquid has passed through the filter in any 2-minute interval, slowly increase the pressure in 10-psi increments to a maximum of 50 psi. After each incremental increase of 10 psi, if the pressurizing gas has not moved through the filter, and if no additional liquid has passed through the filter in any 2-minute interval, proceed to the

next 10-psi increment. When the pressurizing gas begins to move through the filter, or when the liquid flow has ceased at 50 psi (i.e., filtration does not result in any additional filtrate within a 2-minute period), stop the filtration.

Note: Instantaneous application of high pressure can degrade the glass fiber filter and may cause premature plugging.

8.8 The material in the filter holder is defined as the solid phase of the waste, and the filtrate is defined as the liquid phase. Weigh the filtrate. The liquid phase may now be either analyzed (See Step 8.12) or stored at 4 °C until time of analysis.

Note: Some wastes, such as oily wastes and some paint wastes, will obviously contain some material that appears to be a liquid. Even after applying vacuum or pressure filtration, as outlined in Step 8.7, this material may not filter. If this is the case, the material within the filtration device is defined as a solid and is carried through the extraction as a solid. Do not replace the original filter with a fresh filter under any circumstances. Use only one filter.

8.9 If the waste contains <0.5 percent dry solids (see Step 7.2), proceed to Step 8.13. If the waste contains >0.5 percent dry solids (see Step 7.1 or 7.2), and if particle-size reduction of the solid was needed in Step 7.3, proceed to Step 8.10. If the waste as received passes a 9.5 mm sieve, quantitatively transfer the solid material into the extractor bottle along with the filter used to separate the initial liquid from the solid phase, and proceed to Step 8.11.

8.10 Prepare the solid portion of the waste for extraction by crushing, cutting, or grinding the waste to a surface area or particle-size as described in Step 7.3. When the surface area or particle-size has been appropriately altered, quantitatively transfer the solid material into an extractor bottle. Include the filter used to separate the initial liquid from the solid phase.

Note: Sieving of the waste is not normally required. Surface area requirements are meant for filamentous (e.g., paper, cloth) and similar waste materials. Actual measurement of surface area is not recommended. If sieving is necessary, a Teflon-coated sieve should be used to avoid contamination of the sample.

8.11 Determine the amount of extraction fluid to add to the extractor vessel as follows:

```
Weight of = 20 X percent solids (Step 7.1) weight of
extraction waste filtered (Step 8.5 or 8.7)
fluid
-----------------------------------------
100
```

Slowly add this amount of appropriate extraction fluid (see Step 7.4) to the extractor vessel. Close the extractor bottle tightly (it is recommended that Teflon tape be used to ensure a tight seal), secure in rotary agitation device, and rotate at 30+2 rpm for 18+2 hours. Ambient temperature (i.e., temperature of room in which extraction takes place) shall be maintained at 22 +3 °C during the extraction period.

Note: As agitation continues, pressure may build up within the extractor bottle for some types of wastes (e.g., limed or calcium carbonate containing waste may evolve gases such as carbon dioxide). To relieve excess pressure, the extractor bottle may be periodically opened (e.g., after 15 minutes, 30 minutes, and 1 hour) and vented into a hood.

8.12 Following the 18+2 hour extraction, separate the material in the extractor vessel into its component liquid and solid phases by filtering through a new glass fiber filter, as outlined in Step 8.7. For final filtration of the TCLP extract, the glass fiber filter may be changed, if necessary, to facilitate filtration. Filter(s) shall be acid-washed (see Step 4.4) if evaluating the mobility of metals.

8.13 Prepare the TCLP extract as follows:

8.13.1 If the waste contained no initial liquid phase, the filtered liquid material obtained from Step 8.12 is defined as the TCLP extract. Proceed to Step 8.14.

***11873** 8.13.2 If compatible (e.g., multiple phases will not result on combination), combine the filtered liquid resulting from Step 8.12 with the initial liquid phase of the waste obtained in Step 8.7. This combined liquid is defined as the TCLP extract. Proceed to Step 8.14.

8.13.3 If the initial liquid phase of the waste, as obtained from Step 8.7, is not or may not be compatible with the filtered liquid resulting from Step 8.12, do not combine these liquids. Analyze these liquids, collectively defined as the TCLP extract, and combine the results mathematically, as described in Step 8.14.

8.14 Following collection of the TCLP extract, the pH of the extract should be recorded. Immediately aliquot and preserve the extract for analysis. Metals aliquots must be acidified with nitric acid to pH<2. If precipitation is observed upon addition of nitric acid to a small aliquot of the extract, then the remaining portion of the extract for metals analyses shall not be acidified and the extract shall be analyzed as soon as possible. All other aliquots must be stored under refrigeration (4 °C) until analyzed. The TCLP extract shall be prepared and analyzed according to appropriate analytical methods. TCLP extracts to be analyzed for metals shall be acid digested except in those instances where digestion causes loss of metallic contaminants. If an analysis of the undigested extract shows that the concentration of any regulated metallic contaminant exceeds the regulatory level, then the waste is hazardous and digestion of the extract is not necessary. However, data on undigested extracts alone cannot be used to demonstrate that the waste is not hazardous. If the individual phases are to be analyzed separately, determine the volume of the individual phases (to +0.5 percent), conduct the appropriate analyses, and combine the results mathematically by using a simple volume-weighted average:

```
Final analyte concentration = (V1)(C1) (V2)(C2)
----------------------
V1 V2
```

where:

V1 =The volume of the first phase (L).

C1 =The concentration of the contaminant of concern in the first phase (mg/L).

V2 =The volume of the second phase (L).

C2 =The concentration of the contaminant of concern in the second phase (mg/L).
8.15 Compare the contaminant concentrations in the TCLP extract with the thresholds identified in the appropriate regulations. Refer to § 10.0 for quality assurance requirements.

9.0 Procedure When Volatiles Are Involved
Use the ZHE device to obtain TCLP extract for analysis of volatile compounds only. Extract resulting from the use of the ZHE shall not be used to evaluate the mobility of nonvolatile analytes (e.g., metals, pesticides, etc.).

The ZHE device has approximately a 500-mL internal capacity. The ZHE can thus accommodate a maximum of 25 grams of solid (defined as that fraction of a sample from which no additional liquid may be forced out by an applied pressure of 50 psi), due to the need to add an amount of extraction fluid equal to 20 times the weight of the solid phase.

Charge the ZHE with sample only once and do not open the device until the final extract (of the solid) has been collected. Repeated filling of the ZHE to obtain 25 grams of solid is not permitted.

Do not allow the waste, the initial liquid phase, or the extract to be exposed to the atmosphere for any more time than is absolutely necessary. Any manipulation of these materials should be done when cold (4 °C) to minimize loss of volatiles.

9.1 Pre-weigh the (evacuated) filtrate collection container (See Step 4.6) and set aside. If using a TEDLARR bag, express all liquid from the ZHE device into the bag, whether for the initial or final liquid/solid separation, and take an aliquot from the liquid in the bag for analysis. The containers listed in Step 4.6 are recommended for use under the conditions stated in 4.6.1-4.6.3.

9.2 Place the ZHE piston within the body of the ZHE (it may be helpful first to moisten the piston O-rings slightly with extraction fluid). Adjust the piston within the ZHE body to a height that will minimize the distance the piston will have to move once the ZHE is charged with sample (based upon sample size requirements determined from Section 9.0, Step 7.1 and/or 7.2). Secure the gas inlet/outlet flange (bottom flange) onto the ZHE body in accordance with the manufacturer's instructions. Secure the glass fiber filter between the support screens and set aside. Set liquid inlet/outlet flange (top flange) aside.

9.3 If the waste is 100 percent solid (see Step 7.1), weigh out a subsample (25 gram maximum) of the waste, record weight, and proceed to Step 9.5.

9.4 If the waste contains <0.5 percent dry solids (Step 7.2), the liquid portion of waste, after filtration, is defined as the TCLP extract. Filter enough of the sample so that the amount of filtered liquid will support all of the volatile analyses required. For wastes containing >0.5 percent dry solids (Steps 7.1 and/or 7.2), use the percent solids information obtained in Step 7.1 to determine the optimum sample size to charge into the ZHE. The recommended sample size is as follows:

9.4.1 For wastes containing <0.5 percent solids (see Step 7.1), weigh out a 500-gram subsample of waste and record the weight.

9.4.2 For wastes containing >0.5 percent solids (see Step 7.1), determine the amount of waste to charge into the ZHE as follows:

```
Weight of waste to = 25 X 100
change ZHE
-------------------------
Percent solids (Step 7.1)
```

Weigh out a subsample of the waste of the appropriate size and record the weight.

9.5 If particle-size reduction of the solid portion of the waste was required in Step 7.3, proceed to Step 9.6. If particle-size reduction was not required in Step 7.3, proceed to Step 9.7.

9.6 Prepare the waste for extraction by crushing, cutting, or grinding the solid portion of the waste to a surface area or particle-size as described in Step 7.3.1. Wastes and appropriate reduction equipment should be refrigerated, if possible, to 4 °C prior to particle-size reduction. The means used to effect particle-size reduction must not generate heat in and of itself. If reduction of the solid phase of the waste is necessary, exposure of the waste to the atmosphere should be avoided to the extent possible.

Note: Sieving of the waste is not recommended due to the possibility that volatiles may be lost. The use of an appropriately graduated ruler is recommended as an acceptable alternative. Surface area requirements are meant for filamentous (e.g., paper, cloth) and similar waste materials. Actual measurement of surface area is not recommended.

When the surface area or particle-size has been appropriately altered, proceed to Step 9.7.

9.7 Waste slurries need not be allowed to stand to permit the solid phase to settle. Do not centrifuge wastes prior to filtration.

9.8 Quantitatively transfer the entire sample (liquid and solid phases) quickly to the ZHE. Secure the filter and support screens onto the top flange of the device and secure the top flange to the ZHE body in accordance with the manufacturer's instructions.

Tighten all ZHE fittings and place the device in the vertical position (gas inlet/outlet flange on the bottom). Do not attach the extract collection device to the top plate.

Note: If waste material (>1% of original sample weight) has obviously adhered to the container used to transfer the sample to the ZHE, determine the weight of this residue and subtract it from the sample weight determined in Step 9.4 to determine the weight of the waste sample that will be filtered.

Attach a gas line to the gas inlet/outlet valve (bottom flange) and, with the liquid ***11874** inlet/outlet valve (top flange) open, begin applying gentle pressure of 1-10 psi (or more if necessary) to force all headspace slowly out of the ZHE device into a hood. At the first appearance of liquid from the liquid inlet/outlet valve, quickly close the valve and discontinue pressure. If filtration of the waste at 4 °C reduces the amount of expressed liquid over what would be expressed at room temperature, then allow the sample to warm up to room temperature in the device before filtering. If the waste is 100 percent solid (see Step 7.1), slowly increase the pressure to a maximum of 50 psi to force most of the headspace out of the device and proceed to Step 9.12.

9.9 Attach the evacuated pre-weighed filtrate collection container to the liquid inlet/outlet valve and open the valve. Begin applying gentle pressure of 1-10 psi to force the liquid phase of the sample into the filtrate collection container. If no additional liquid has passed through the filter in any 2-minute interval, slowly increase the pressure in 10-psi increments to a maximum of 50 psi. After each incremental increase of 10 psi, if no additional liquid has passed through the filter in any 2-minute interval, proceed to the next 10-psi increment. When liquid flow has ceased such that continued pressure filtration at 50 psi does not result in any additional filtrate within a 2-minute period, stop the filtration. Close the liquid inlet/outlet valve, discontinue pressure to the piston, and disconnect and weigh the filtrate collection container.

Note: Instantaneous application of high pressure can degrade the glass fiber filter and may cause premature plugging.

9.10 The material in the ZHE is defined as the solid phase of the waste and the filtrate is defined as the liquid phase.

Note: Some wastes, such as oily wastes and some paint wastes, will obviously contain some material that appears to be a liquid. Even after applying pressure filtration, this material will not filter. If this is the case, the material within the filtration device is defined as a solid and is carried through the TCLP extraction as a solid.

If the original waste contained <0.5 percent dry solids (see Step 7.2), this filtrate is defined as the TCLP extract and is analyzed directly. Proceed to Step 9.15.

9.11 The liquid phase may now be either analyzed immediately (See Steps 9.13 through 9.15) or stored at 4 °C under minimal headspace conditions until time of analysis. Determine the weight of extraction fluid 1 to add to the ZHE as follows:

```
Weight of = 20 X percent solids (Step 7.1) weight of
extraction waste filtered (Step 9.4 or 9.8)
fluid
-------------------------------------------
100
```

9.12 The following steps detail how to add the appropriate amount of extraction fluid to the solid material within the ZHE and agitation of the ZHE vessel. Extraction fluid 1 is used in all cases (See Step 5.6).

9.12.1 With the ZHE in the vertical position, attach a line from the extraction fluid reservoir to the liquid inlet/outlet valve. The line used shall contain fresh extraction fluid and should be preflushed with fluid to eliminate any air pockets in the line. Release gas pressure on the ZHE piston (from the gas inlet/outlet valve), open the liquid inlet/outlet valve, and begin transferring extraction fluid (by pumping or similar means) into the ZHE. Continue pumping extraction fluid into the ZHE until the appropriate amount of fluid has been introduced into the device.

9.12.2 After the extraction fluid has been added, immediately close the liquid inlet/outlet valve and disconnect the extraction fluid line. Check the ZHE to ensure that all valves are in their closed positions. Manually rotate the device in an end-over-end fashion 2 or 3 times. Reposition the ZHE in the vertical position with the liquid inlet/outlet valve on top. Pressurize the ZHE to 5-10 psi (if necessary) and slowly open the liquid inlet/outlet valve to bleed out any headspace (into a hood) that may have been introduced due to the addition of extraction fluid. This bleeding shall be done quickly and shall be stopped at the first appearance of liquid from the valve. Re-pressurize the ZHE with 5-10 psi and check all ZHE fittings to ensure that they are closed.

9.12.3 Place the ZHE in the rotary agitation apparatus (if it is not already there) and rotate at 30+2 rpm for 18+2 hours. Ambient temperature (i.e., temperature of room in which extraction occurs) shall be maintained at 22+3 °C during agitation.

9.13 Following the 18 +2 hour agitation period, check the pressure behind the ZHE piston by quickly opening and closing the gas inlet/outlet valve and noting the escape of gas. If the pressure has not been maintained (i.e., no gas release observed), the device is leaking. Check the ZHE for leaking as specified in Step 4.2.1, and perform the extraction again with a new sample of waste. If the pressure within the device has been maintained, the material in the extractor vessel is once again separated into its component liquid and solid phases. If the waste contained an initial liquid phase, the liquid may be filtered directly into the same filtrate collection container (i.e., TEDLARR bag) holding the initial liquid phase of the waste. A separate filtrate collection container must be used if combining would create multiple phases, or there is not enough volume left within the filtrate collection container. Filter through the glass fiber filter, using the ZHE device as discussed in Step 9.9. All extract shall be filtered and collected if the TEDLARR bag is used, if the extract is multiphasic, or if the waste contained an initial liquid phase (see Steps 4.6 and 9.1).

Note: An in-line glass fiber filter may be used to filter the material within the ZHE if it is suspected that the glass fiber filter has been ruptured.

9.14 If the original waste contained no initial liquid phase, the filtered liquid material obtained from step 9.13 is defined as the TCLP extract. If the waste contained an initial liquid phase, the filtered liquid material obtained from Step 9.13 and the initial liquid phase (Step 9.9) are collectively defined as the TCLP extract.

9.15 Following collection of the TCLP extract, immediately prepare the extract for analysis and store with minimal headspace at 4 °C until analyzed. Analyze the TCLP extract according to the appropriate analytical methods. If the individual phases are to be analyzed separately (i.e., are not miscible), determine the volume of the individual phases (to 0.5%), conduct the appropriate analyses, and combine the results mathematically by using a simple volume-weighted average:

```
Final analyte concentration (V1)(C1) (V2)(C2)
----------------------
V1 V2
```

***11875** where:

V1 =The volume of the first phases (l).

C1 =The concentration of the contaminant of concern in the first phase (mg/l).

V2 =The volume of the second phase (l).

C2 =The concentration of the contaminant of concern in the second phase (mg/l).

9.16 Compare the contaminant concentrations in the TCLP extract with the thresholds identified in the appropriate regulations. Refer to section 10.0 for quality assurance requirements.

10.0 Quality Assurance Requirements

10.1 Maintain all data, including quality assurance data, and keep it available for reference or inspection.

10.2 A minimum of one blank (extraction fluid 1) for every 10 extractions that have been conducted in an extraction vessel shall be employed as a check to determine if any memory effects from the extraction equipment are occurring.

10.3 A matrix spike shall be performed for each waste unless the result exceeds the regulatory level and the data is being used solely to demonstrate that the waste property exceeds the regulatory level. If more than one sample of the same waste is being tested, a matrix spike needs to be performed for every twenty samples and the average percent recovery applied to the waste characterization.

10.3.1 Matrix spikes are to be added after filtration of the TCLP extract and before preservation. Matrix spikes should not be added prior to TCLP extraction of the sample.

10.3.2 Matrix spike levels should be made at the appropriate regulatory threshold limits. However, if the extract contaminant concentration is less than one half the threshold limit, the spike level may be one half the contaminant concentration but not less than the quantitation limit or a fifth of the threshold limit.

10.3.3 The purpose of the matrix spike is to monitor the adequacy of the analytical methods used on the TCLP extract and to determine whether matrix interferences exist in analyte detection. If the matrix spike recoveries are less than 50%, then the analytical methods are not performing adequately or use of the methods is inadequate. Use of internal calibration quantitation methods, modification of the analytical methods, or use of alternate analytical methods may be needed to accurately measure the contaminant concentration in the TCLP extract.

10.3.4 Use of internal quantitation methods is also required when the contaminant concentration is within 20% of the regulatory level. (See section 10.5 concerning the use of internal calibration methods.)

10.3.5 Matrix spike recoveries are calculated by the following formula:

```
Percent recovery = A-B X 100%
--------
C
```

where A=the concentration of the spiked sample,

B=the concentration of the unspiked sample, and

C=the spike level

10.4 All quality control measures described in the appropriate analytical methods shall be followed.

10.5 The use of internal calibration quantitation methods shall be employed for a contaminant if: (1) Recovery of the contaminant from the TCLP extract is not at least 50% and the concentration does not exceed the regulatory level, and (2) The concentration of the contaminant measured in the extract is within 20% of the appropriate regulatory level.

10.5.1 The method of standard additions shall be employed as the internal calibration quantitation method for each metallic contaminant.

10.5.1.1 The method of standard additions requires preparing calibration standards in the sample matrix rather than reagent water or blank solution. It requires taking four identical aliquots of the solution and adding known amounts of standard to three of these aliquots. The fourth aliquot is the unknown. Preferably, the first addition should be prepared so that the resulting concentration is approximately 50% of the expected concentration of the sample. The second and third additions should be

prepared so that the concentrations are approximately 100% and 150% of the expected concentration of the sample. All four aliquots are maintained at the same final volume by adding reagent water or a blank solution, and may need dilution adjustment to maintain the signals in the linear range of the instrumental technique. All four aliquots are analyzed.

10.5.1.2 Prepare a plot, or subject data to linear regression, of instrumental signals or external-calibration-derived concentrations as the dependent variable (y-axis) versus concentrations of the additions of standard as the independent variable (x-axis). Solve for the intercept of the abscissa (the independent variable, x-axis) which is the concentration in the unknown.

10.5.1.3 Alternately, subtract the instrumental signal or external-calibration-derived concentration of the unknown (unspiked) sample from the instrumental signals or external-calibration-derived concentrations of the standard additions. Plot or subject data to linear regression of the corrected instrumental signals or external-calibration-derived concentrations as the dependent variable versus the independent variable. Derive concentrations for unknowns using the internal calibration curve as if it were an external calibration curve.

10.6 Samples must undergo TCLP extraction within the following time periods:

Sample Maximum Holding Times [Days]			
From: Field collection To: TCLP extraction	From: TCLP extraction To: Preparative extraction	From: Preparative extraction To: Determinative analysis	Total elapsed time
Volatiles	14	NA	14 28
Semi-volatiles	7	7 40	54
Mercury	28	NA	28 56
Metals, except mercury	180	NA	180 360

NA = Not applicable.

If sample holding times are exceeded, the values obtained will be considered minimal concentrations. Exceeding the holding time is not acceptable in establishing that a waste does not exceed the regulatory level. Exceeding the holding time will not invalidate characterization if the waste exceeds the regulatory level.

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

7. The authority citation for part 264 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912, 6924, and 6925.

8. Section 264.301 is amended by revising paragraph (e)(1) to read as follows:

§ 264.301 Design and operating requirements.

* * * * *

***11876** (e) * * *

(1) The monofill contains only hazardous wastes from foundry furnace emission controls or metal casting molding sand, and such wastes do not contain constituents which would render the wastes hazardous for reasons other than the Toxicity Characteristic in § 261.24 of this chapter, with EPA Hazardous Waste Numbers D004 through D017; and

* * * * *

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT STORAGE, AND DISPOSAL FACILITIES

9. The authority citation of part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, 6925, and 6935.

10. Section 265.221 is amended by revising paragraph (d)(1) to read as follows:

§ 265.221 Design requirements.

* * * * *

(d) * * *

(1) The monofill contains only hazardous wastes from foundry furnace emission controls or metal casting molding sand, and such wastes do not contain constituents which would render the wastes hazardous for reasons other than the Toxicity Characteristic in § 261.24 of this chapter, with EPA Hazardous Waste Numbers D004 through D017; and

* * * * *

11. Section 265.273 is amended by revising paragraph (a) to read as follows:

§ 265.273 Waste analysis.

* * * * *

(a) Determine the concentrations in the waste of any substances which equal or exceed the maximum concentrations contained in Table 1 of § 261.24 of this chapter that cause a waste to exhibit the Toxicity Characteristic;

* * * * *

PART 268—LAND DISPOSAL RESTRICTIONS

12. The authority citation for part 268 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6924.

13. Appendix I of part 268 is revised to read as follows:

Appendix I—Toxicity Characteristic Leaching Procedure (TCLP)

Note: The TCLP is published in Appendix II of part 261.

PART 271—REQUIREMENTS FOR AUTHORIZATION OF STATE HAZARDOUS WASTE PROGRAMS

14. The authority citation for part 271 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), and 6926.

15. Section 271.1, paragraph (j), the heading of Table 1 is republished, and Table 1 is amended by adding the following entry in chronological order by date of promulgation to read as follows:

§ 271.1 Purpose and scope.

* * * * *

(j) * * *

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[Note: The following TABLE/FORM is too wide to be displayed on one screen. You must print it for a
meaningful review of its contents. The table has been divided into multiple pieces with each piece containing
information to help you assemble a printout of the table. The information for each piece includes: (1) a
three line message preceding the tabular data showing by line # and character # the position of the upper
left-hand corner of the piece and the position of the piece within the entire table; and (2) a numeric
scale following the tabular data displaying the character positions.]
******************************************************************************
******** This is piece 1. -- It begins at character 1 of table line 1. ********
******************************************************************************
Table 1.--Regulations Implementing the Hazardous and Solid Waste
-----------------------------------------------------------------
Promulgation date Title of regulation Federal Register
reference
-----------------------------------------------------------------
* * * *
March 29, 1990 ..... Toxicity
characteristic .... [Insert FR
reference on date
of publication] ..
-----------------------------------------------------------------
1...#...10....#...20....#...30....#...40....#...50....#...60....
******************************************************************************
******* This is piece 2. -- It begins at character 65 of table line 1. ********
******************************************************************************
Amendments of 1984
--------------------
Effective date
--------------------
*
September 25, 1990
--------------------
65..70....#...80....
```

PART 302—DESIGNATION, REPORTABLE QUANTITIES, AND NOTIFICATION

16. The authority citation for part 302 continues to read as follows:

Authority: 42 U.S.C. 9602; 33 U.S.C. 1321 and 1361.

17. Section 302.4 is amended by revising under the column Hazardous Substance the entry “Unlisted Hazardous Wastes Characteristic of EP Toxicity” to read “Unlisted Hazardous Wastes Characteristics:” and by revising the entry “Characteristic of EP Toxicity” and its sub entries to read as follows:

§ 302.4 Designation of hazardous substances.

* * * * *

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[Note: The following TABLE/FORM is too wide to be displayed on one screen. You must print it for a
meaningful review of its contents. The table has been divided into multiple pieces with each piece containing
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information to help you assemble a printout of the table. The information for each piece includes: (1) a three line message preceding the tabular data showing by line # and character # the position of the upper left-hand corner of the piece and the position of the piece within the entire table; and (2) a numeric scale following the tabular data displaying the character positions.]

****

******** This is piece 1. -- It begins at character 1 of table line 1. ********

****

Table 302.4.--List of Hazardous Substances

Hazardous substance	CASRN	Regulatory synonyms	RQ
* * * * *			
Characteristic of Toxicity:			
Arsenic (D004)	N.A.		*1
Barium (D005)	N.A.		*1
Benzene (D018)	N.A.		1000
Cadmium (D006)	N.A.		*1
Carbon tetrachloride (D019)	N.A.		5,000
Chlordane (D020)	N.A.		1
Chlorobenzene (D021)	N.A.		100
Chloroform (D022)	N.A.		5,000
Chromium (D007)	N.A.		*1
o-Cresol (D023)	N.A.		1,000
m-Cresol (D024)	N.A.		1,000
p-Cresol (D025)	N.A.		1,000
Cresol (D026)	N.A.		1,000
2,4-D (D016)	N.A.		100
1,4-Dichlorobenzene (D027)	N.A.		100
1,2-Dichloroethane (D028)	N.A.		5,000
1,1-Dichloroethylene (D029)	N.A.		5,000
2,4-Dinitrotoluene (D030)	N.A.		1,000
Endrin (D012)	N.A.		1
Heptachlor (and hydroxide) (D031)	N.A.		1
Hexachlorobenzene (D032)	N.A.		*1
Hexachlorobutadiene (D033)	N.A.		*1
Hexachloroethane (D034)	N.A.		*1
Lead (D008)	N.A.		*1
Lindane (D013)	N.A.		1
Mercury (D009)	N.A.		*1
Methoxychlor (D014)	N.A.		1
Methyl ethyl ketone (D035)	N.A.		*1
Nitrobenzene (D036)	N.A.		1,000
Pentachlorophenol (D037)	N.A.		10
Pyridine (D038)	N.A.		*1
Selenium (D010)	N.A.		*1
Silver (D011)	N.A.		*1
Tetrachloroethylene			

```
(D039) ................. N.A....... --------------- *1
Toxaphene (D015) ......... N.A....... --------------- 1
Thrichloroethylene (D040) N.A....... --------------- 1000
2,4,5-Trichloroethylene
(D041) ................. N.A....... --------------- 10
2,4,6-Trichlorophenol
(D042) ................. N.A....... --------------- 10
2,4,5-TP (D017) .......... N.A....... --------------- 100
Vinyl chloride (D043) .... N.A....... --------------- *1
* * * *
*
------------------------------------------------------------
1...#...10....#...20....#...30....#...40....#...50....#...60..
********************************************************************************
******* This is piece 2. -- It begins at character 63 of table line 1. ********
********************************************************************************
and Reportable Quantities
-------------------------------------------
Statutory Final RQ
-------------------------------------------
Code RCRA Category Pounds (Kg)
waste
number
-------------------------------------------
* * -
4 D004 ..... X ............ 1 (0.454)
4 D005 ..... C .......... 1,000 (454)
1, 2, D018 ..... A ............ 10 (4.54)
3, 4
4 D006 ..... A ............ 10 (4.54)
1, 2, 4 D019 ..... A ............ 10 (4.54)
1, 2, 4 D020 ..... X ............ 1 (0.454)
1, 2, 4 D021 ..... B ............ 100 (45.4)
1, 2, 4 D022 ..... A ............ 10 (4.54)
4 D007 ..... A ............ 10 (4.54)
1, 4 D023 ..... C .......... 1,000 (454)
1, 4 D024 ..... C .......... 1,000 (454)
1, 4 D025 ..... C .......... 1,000 (454)
1, 4 D026 ..... C .......... 1,000 (454)
1, 4 D016 ..... B ............ 100 (45.4)
1, 2, 4 D027 ..... B ............ 100 (45.4)
1, 2, 4 D028 ..... B ............ 100 (45.4)
1, 2, 4 D029 ..... B ............ 100 (45.4)
1, 2, 4 D030 ..... A ............ 10 (4.54)
1, 4 D012 ..... X ............ 1 (0.454)
1, 2, 4 D031 ..... X ............ 1 (0.454)
2, 4 D032 ..... A ............ 10 (4.54)
2, 4 D033 ..... X ............ 1 (0.454)
2, 4 D034 ..... B ............ 100 (45.4)
4 D008 ..... ---------- ()
1, 4 D013 ..... X ............ 1 (0.454)
4 D009 ..... X ............ 1 (0.454)
1, 4 D014 ..... X ............ 1 (0.454)
4 D035 ..... D ................ 5,000
(2270)
1, 2, 4 D036 ..... C .......... 1,000 (454)
1, 2, 4 D037 ..... A ............ 10 (4.54)
4 D038 ..... C .......... 1,000 (454)
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4 D010 ..... A ............ 10 (4.54)
4 D011 ..... X ............ 1 (0.454)
2, 4 D039 ..... B ........... 100 (45.4)
1, 4 D015 ..... X ............ 1 (0.454)
1, 2, 4 D040 ..... B ........... 100 (45.4)
1, 4 D041 ..... A ............ 10 (4.54)
1, 2, 4 D042 ..... A ............ 10 (4.54)
1, 4 D017 ..... B ........... 100 (45.4)
2, 3, 4 D043 ..... X ............ 1 (0.454)
* * -
*
-------------------------------------------
63....70....#...80....#...90....#....0....#...
*******************************************************************************
******* This is piece 3. -- It begins at character 1 of table line 68. ********
*******************************************************************************
--indicates the statutory source as defined by 1, 2, 3, or 4 below.
*1 --indicates that the 1-pound RQ is a CERCLA statutory RQ.
--indicates that the RQ is subject to change when the assessment of potential
carcinogenicity is completed.
1...#...10....#...20....#...30....#...40....#...50....#...60....#...70....#....
```

***11877** [FR Doc. 90-6104 Filed 3-28-90; 8:45 am]

BILLING CODE 6560-50-M

Footnotes

1 As explained previously, the Agency is not, in today's rule, promulgating regulatory levels for several of the constituents for which regulatory levels were proposed. These constituents include those that are expected to hydrolyze appreciably and those for which it has not yet been determined whether the steady-state solution to the subsurface fate and transport model is appropriate. Once the issues associated with these constituents are resolved, the Agency will promulgate or repropose (as warranted) regulatory levels for these constituents. For cases where regulatory levels are reproposed, they may incorporate dilution/ attenuation factors other than 100. FN2 The health data is only valid to one order of magnitude precision and thus may control the total number of significant figures.

3 The exception to this rule is a mixture of solid waste and a waste that is listed solely because it exhibits a characteristic of hazardous waste. If such a mixture does not exhibit any characteristic of hazardous waste, the mixture is not defined as hazardous [40 CFR 261.3(a)(2)(iii)].

1 VITON R is a trademark of Du Pont.

2 TEDLARR is a registered trademark of Du Pont.

57 FR 22888-01
NOTICES
ENVIRONMENTAL PROTECTION AGENCYI41(FRL-4129-5)

Guidelines for Exposure Assessment

*22888 Friday, May 29, 1992

AGENCY: U.S. Environmental Protection Agency

ACTION: Final guidelines for exposure assessment

SUMMARY: The U.S. Environmental Protection Agency (EPA) is today issuing final guidelines for exposure assessment. The Guidelines for Exposure Assessment (hereafter "Guidelines") are intended for risk assessors in EPA, and those exposure and risk assessment consultants, contractors, or other persons who perform work under Agency contract or sponsorship. In addition, publication of these Guidelines makes information on the principles, concepts, and methods used by the Agency available to all interested members of the public. These Guidelines supersede and replace both the Guidelines for Estimating Exposures published September 24, 1986 (51 FR 34042-34054) (hereafter "1986 Guidelines") and the Proposed Guidelines for Exposure-Related Measurements published for comment on December 2, 1988 (53 FR 48830-48853) (hereafter "1988 Proposed Guidelines"). In response to recommendations from the Science Advisory Board (SAB) and the public, the 1986 Guidelines were updated and combined with the 1988 Proposed Guidelines and retitled as the current Guidelines for Exposure Assessment.

These Guidelines establish a broad framework for Agency exposure assessments by describing the general concepts of exposure assessment including definitions and associated units, and by providing guidance on the planning and conducting of an exposure assessment. Guidance is also provided on presenting the results of the exposure assessment and characterizing uncertainty. Although these Guidelines focus on exposures of humans to chemical substances, much of the guidance contained herein also pertains to assessing wildlife exposure to chemicals, or to human exposures to biological, noise, or radiological agents. Since these latter four areas present unique challenges, assessments on these topics must consider additional factors beyond the scope of these Guidelines. The Agency may, at a future date, issue additional specific guidelines in these areas.

EFFECTIVE DATE: The Guidelines will be effective May 29, 1992.

FOR FURTHER INFORMATION CONTACT: Michael A. Callahan, Director, Exposure Assessment Group, Office of Health and Environmental Assessment (RD-689), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, 202-260-8909.

SUPPLEMENTARY INFORMATION: In its 1983 book Risk Assessment in the Federal Government: Managing the Process, the National Academy of Sciences recommended that Federal regulatory agencies establish "inference guidelines" to promote consistency and technical quality in risk assessment, and to ensure that the risk assessment process is maintained as a scientific effort separate from risk management. A task force within EPA accepted that recommendation and requested that Agency scientists begin to develop such guidelines.

In 1984, EPA scientists began work on risk assessment guidelines for carcinogenicity, mutagenicity, suspect developmental toxicants, chemical mixtures, and estimating exposures. Following extensive scientific and public review, these guidelines were issued on September 24, 1986 (51 FR 33992-34054). Subsequent work resulted in the publishing of four additional proposals (one of which has recently become final): Proposed Guidelines for Assessing Female Reproductive Risk (53 FR 24834-24847), Proposed Guidelines for Assessing Male Reproductive Risk (53 FR 24850-24869), Proposed Guidelines for Exposure-Related Measurements (53 FR 48830-48853), and Proposed Amendments to the Guidelines for the Health Assessment of Suspect

Developmental Toxicants (54 FR 9386-9403). The final Guidelines for Developmental Toxicity Risk Assessment, published December 5, 1991 (56 FR 63798-63826), supersede and replace the proposed amendments.

The Guidelines issued today continue the guidelines development process initiated in 1984. Like the guidelines issued in 1986, the Guidelines issued today set forth principles and procedures to guide EPA scientists in the conduct of Agency risk assessments and to inform Agency decision makers and the public about these procedures. In particular, the Guidelines standardize terminology used by the Agency in exposure assessment and in many areas outline the limits of sound scientific practice. They emphasize that exposure assessments done as part of a risk assessment need to consider the hazard identification and dose-response parts of the risk assessment in the planning stages of the exposure assessment so that these three parts can be smoothly integrated into the risk characterization. The Guidelines discuss and reference a number of approaches and tools for exposure assessment, along with discussion of their appropriate use. The Guidelines also stress that exposure estimates along with supporting information will be fully presented in Agency risk assessment documents, and that Agency scientists will identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions, and limitations, as well as the scientific basis and rationale for each assessment.

Work on these Guidelines began soon after publication of the 1986 Guidelines. At that time, the SAB recommended that the Agency develop supplementary guidelines for conducting exposure studies. This supplementary guidance was developed by an Agency work group composed of scientists from throughout the Agency, a draft was peer reviewed by experienced professionals from environmental groups, industry, academia, and other governmental agencies, and proposed for comment on December 2, 1988 (as Proposed Guidelines for Exposure-Related Measurements). In the public notice, the Agency asked for comment on whether the proposed guidelines should be combined with the 1986 guidelines in order to have a single Agency guideline for exposure assessment. Comments from the public and the SAB were heavily in favor of combining the two guidelines.

Since proposal, the Agency has reformatted the 1988 Proposed Guidelines to allow incorporation of the information in the 1986 Guidelines, and incorporated revisions resulting from additional public and SAB comments, to establish the current Guidelines. The current Guidelines were reviewed by the Risk Assessment Forum and the Risk Assessment Council, subjected to an external peer review, and presented to the SAB on September 12, 1991 for final comment (EPA-SAB-IAQC-92-015). In addition, the Guidelines were reviewed by the Working Party on Exposure Assessment, an interagency working group under the Subcommittee on Risk Assessment of the Federal Coordinating Committee on Science, Engineering and Technology. Comments of these groups have been considered in the revision of these Guidelines. The full text of the final Guidelines for Exposure Assessment is published here.

These Guidelines were developed as part of an interoffice guidelines development program under the auspices of the Risk Assessment Forum and the Office of Health and Environmental Assessment in the Agency's Office of Research and ***22889** Development. The Agency is continuing to study risk assessment issues raised in these Guidelines, and will revise them in line with new information as appropriate.

Following this preamble are two parts: Part A is the Guidelines and Part B is the Response to the Public and Science Advisory Board comments submitted in response to the 1988 Proposed Guidelines.

References, supporting documents, and comments received on the 1988 Proposed Guidelines, as well as a copy of these final Guidelines for Exposure Assessment are available for inspection at the ORD Public Information Shelf, EPA Headquarters Library (202-260-5926), 401 M Street, SW., Washington, DC, between the hours of 8 a.m. and 4:30 p.m.

Dated: April 28, 1992.

William K. Reilly,

Administrator.

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Abbreviations and Acronyms

ADD—Average daily dose

AF—Absorption fraction

AT—Averaging time

BW—Body weight

C—Exposure concentration

C(t)—Exposure concentration as a function of time

CO—Carbon monoxide

CT—Contact time

D—Dose

D_{app}—Applied dose

D_{int}—Internal dose

D_{pot}—Potential dose

DQO—Data quality objective

E—Exposure

ED—Exposure duration

EPA—U.S. Environmental Protection Agency

F_{adh}—Adherence factor for soil

f(t)—Absorption function

IR—Intake rate (also ingestion or inhalation rate)

J—Flux

K_p—Permeability coefficient

***22890** LADD—Lifetime average daily dose

LOAEL—Lowest observable adverse effect level

LOD—Limit of detection

LT—Lifetime

M_{medium}—Amount (mass) of carrier medium material applied to the skin

MDL—Method detection limit

MEI—Maximally exposed individual or most exposed individual

ND—Not detected

PMN—Premanufacture notice

QA—Quality assurance

QAP_jP—Quality assurance project plan

QC—Quality control

QL—Quantification limit

RfC—Reference concentration

RfD—Reference dose

SA—Surface area

SAB—Science Advisory Board

TEAM—Total exposure assessment methodology

TUBE—Theoretical upper bounding estimate

UCL—Upper confidence limit (often used to refer to the upper confidence limit of the mean)

UR—Uptake rate

Part A: Guidelines for Exposure Assessment

1. Introduction

In 1984, the U. S. Environmental Protection Agency (EPA) initiated a program to ensure scientific quality and technical consistency of Agency risk assessments. One of the goals of the program was to develop risk assessment guidelines that would be used Agencywide. The guidelines development process includes a public review and comment period for all proposed guidelines as well as Agency Science Advisory Board review. Following the review process, the guidelines are revised if needed and then issued as final guidelines. The Guidelines for Estimating Exposures (hereafter "1986 Guidelines") were one of five guidelines issued as final in 1986 (U.S. EPA, 1986a). In 1988, the Proposed Guidelines for Exposure-Related Measurements (hereafter "1988 Proposed Guidelines") were published in the Federal Register for public review and comment (U.S. EPA, 1988a). The 1988 Proposed Guidelines were intended to be a companion and supplement to the 1986 Guidelines.

When proposing the 1988 guidelines, the Agency asked both the EPA Science Advisory Board (SAB) and the public for comments on combining the 1986 and 1988 exposure guidelines into a larger, more comprehensive guideline; the majority of comments received were in favor of doing so. Thus, these 1992 Guidelines for Exposure Assessment (hereafter "Guidelines") combine, reformat, and substantially update the earlier guidelines. These guidelines make use of developments in the exposure assessment field since 1988, both revising the previous work and adding several topics not covered in the 1986 or 1988 guidelines. Therefore, the 1992 guidelines are being issued by the Agency as a replacement for both the 1986 Guidelines and the 1988 Proposed Guidelines.

1.1. Intended Audience

This document is intended for exposure and risk assessors in the Agency and those exposure and risk assessment consultants, contractors, or other persons who perform work under Agency contract or sponsorship. Risk managers in the Agency may also benefit from this document since it clarifies the terminology and methods used by assessors, which in some cases could strengthen the basis for decisions. In addition, publication of these guidelines makes information on the principles, concepts, and methods used by the Agency available to other agencies, States, industry, academia, and all interested members of the public.

1.2. Purpose and Scope of the Guidelines

There are a number of different purposes for exposure assessments, including their use in risk assessments, status and trends analysis, and epidemiology. These Guidelines are intended to convey the general principles of exposure assessment, not to serve as a detailed instructional guide. The technical documents cited here provide more specific information for individual exposure assessment situations. As the Agency performs more exposure assessments and incorporates new approaches, these Guidelines will be revised.

Agency risk assessors should use these Guidelines in conjunction with published guidelines for assessing health effects such as cancer (U.S. EPA, 1986b), developmental toxicity (U.S. EPA, 1991a), mutagenic effects (U.S. EPA, 1986c), and reproductive effects (U.S. EPA, 1988b; U.S. EPA, 1988c). These exposure assessment guidelines focus on human exposure to chemical substances. Much of the guidance contained herein also applies to wildlife exposure to chemicals, or human exposure to biological, physical (i.e., noise), or radiological agents. Since these areas present unique challenges, however, assessments on these topics must consider additional factors beyond the scope of these Guidelines.

For example, ecological exposure and risk assessment may deal with many species which are interconnected via complex food webs, while these guidelines deal with one species, humans. While these guidelines discuss human exposure on the individual and population levels, ecological exposure and risk assessments may need to address community, ecosystem, and landscape levels, also. Whereas chemical agents may degrade or be transformed in the environment, biological agents may of course grow and multiply, an area not covered in these guidelines. The Agency may, at a future date, issue specific guidelines in these areas.

Persons subject to these Guidelines should use the terms associated with chemical exposure assessment in a manner consistent with the glossary in Section 8. Throughout the public comment and SAB review process, the Agency has sought definitions that have consensus within the scientific community, especially those definitions common to several scientific fields. The Agency is aware that certain well understood and widely accepted concepts and definitions in the area of health physics (such as the definition of exposure) differ from the definitions in this glossary. The definitions in this glossary are not meant to replace such basic definitions used in another field of science. It was not possible, however, to reconcile all the definitions used in various fields of science, and the ones used in the glossary are thought to be the most appropriate for the field of chemical exposure assessment.

The Agency may, from time to time, issue updates of or revisions to these Guidelines.

1.3. Organization of the Guidelines

These Guidelines are arranged in an order that assessors commonly use in preparing exposure assessments. Section 2 deals with general concepts, section 3 with planning, section 4 with data development, section 5 with calculating exposures, section 6 with uncertainty evaluation, and section 7 with presenting the results. In addition, these Guidelines include a glossary of terms (section 8) and references to other documents (section 9).

2. General Concepts in Exposure Assessment

Exposure assessment in various forms dates back at least to the early twentieth century, and perhaps before, particularly in the fields of epidemiology (World Health Organization (WHO), 1983), industrial hygiene (Cook, 1969; Paustenbach, 1985), and health physics (Upton, 1988). Epidemiology is the study of disease occurrence and the causes of disease, while the latter fields deal primarily with occupational exposure. ***22891** Exposure assessment combines elements of all three disciplines. This has become increasingly important since the early 1970s due to greater public, academic, industrial, and governmental awareness of chemical pollution problems.

Because there is no agreed-upon definition of the point on or in the body where exposure takes place, the terminology used in the current exposure assessment literature is inconsistent. Although there is reasonable agreement that human exposure means contact with the chemical or agent (Allaby, 1983; Environ Corporation, 1988; Hodgson et al., 1988; U.S. EPA, 1986a), there has not yet been widespread agreement as to whether this means contact with (a) the visible exterior of the person (skin and openings into the body such as mouth and nostrils), or (b) the so-called exchange boundaries where absorption takes place (skin, lung, gastrointestinal tract). [FN1] These different definitions have led to some ambiguity in the use of terms and units for quantifying exposure.[FN2]

Comments on the 1986 Guidelines and the 1988 Proposed Guidelines suggested that EPA examine how exposure and dose were defined in Agency assessments and include guidance on appropriate definitions and units. After internal discussions and external

peer review, it is the Agency's position that defining exposure as taking place at the visible external boundary, as in (a) above, is less ambiguous and more consistent with nomenclature in other scientific fields. This is a change from the 1986 Guidelines.

Under this definition, it is helpful to think of the human body as having a hypothetical outer boundary separating inside the body from outside the body. This outer boundary of the body is the skin and the openings into the body such as the mouth, the nostrils, and punctures and lesions in the skin. As used in these Guidelines, exposure to a chemical is the contact of that chemical with the outer boundary. An exposure assessment is the quantitative or qualitative evaluation of that contact; it describes the intensity, frequency, and duration of contact, and often evaluates the rates at which the chemical crosses the boundary (chemical intake or uptake rates), the route by which it crosses the boundary (exposure route; e.g., dermal, oral, or respiratory), and the resulting amount of the chemical that actually crosses the boundary (a dose) and the amount absorbed (internal dose).

Depending on the purpose for which an exposure assessment will be used, the numerical output of an exposure assessment may be an estimate of either exposure or dose. If exposure assessments are being done as part of a risk assessment that uses a dose-response relationship, the output usually includes an estimate of dose. [FN3] Other risk assessments, for example many of those done as part of epidemiologic studies, use empirically derived exposure-response relationships, and may characterize risk without the intermediate step of estimating dose.

2.1. Concepts of Exposure, Intake, Uptake, and Dose

The process of a chemical entering the body can be described in two steps: contact (exposure), followed by actual entry (crossing the boundary). Absorption, either upon crossing the boundary or subsequently, leads to the availability of an amount of the chemical to biologically significant sites within the body (internal dose[FN4]). Although the description of contact with the outer boundary is simple conceptually, the description of a chemical crossing this boundary is somewhat more complex.

There are two major processes by which a chemical can cross the boundary from outside to inside the body. Intake involves physically moving the chemical in question through an opening in the outer boundary (usually the mouth or nose), typically via inhalation, eating, or drinking. Normally the chemical is contained in a medium such as air, food, or water; the estimate of how much of the chemical enters into the body focuses on how much of the carrier medium enters. In this process, mass transfer occurs by bulk flow, and the amount of the chemical itself crossing the boundary can be described as a chemical intake rate. The chemical intake rate is the amount of chemical crossing the outer boundary per unit time, and is the product of the exposure concentration times the ingestion or inhalation rate. Ingestion and inhalation rates are the amount of the carrier medium crossing the boundary per unit time, such as m3 air breathed/hour, kg food ingested/day, or liters of water consumed/day. Ingestion or inhalation rates typically are not constant over time, but often can be observed to vary within known limits. [FN5]

The second process by which a chemical can cross the boundary from outside to inside the body is uptake. Uptake involves absorption of the chemical through the skin or other exposed tissue such as the eye. Although the chemical is often contained in a carrier medium, the medium itself typically is not absorbed at the same rate as the chemical, so estimates of the amount of the chemical crossing the boundary cannot be made in the same way as for intake (see section 2.1.3.). Dermal absorption is an example of direct uptake across the outer boundary of the body.[FN6] A chemical uptake rate is the amount of chemical absorbed per unit time. In this process, mass transfer occurs by diffusion, so uptake can depend on the concentration gradient across the boundary, permeability of the barrier, and other factors. Chemical uptake rates can be expressed as a function of the exposure concentration, permeability coefficient, and surface area exposed, or as a flux (see section 2.1.4.).

The conceptual process of contact, then entry and absorption, can be used to derive the equations for exposure and dose for all routes of exposure.

2.1.1. Exposure

The condition of a chemical contacting the outer boundary of a human is exposure. Most of the time, the chemical is contained in air, water, soil, a product, or a transport or carrier medium; the chemical concentration at the point of contact is the exposure

***22892** concentration. Exposure over a period of time can be represented by a time-dependent profile of the exposure concentration. The area under the curve of this profile is the magnitude of the exposure, in concentration-time units (Lioy, 1990; NRC, 1990):

where E is the magnitude of exposure, C(t) is the exposure concentration as a function of time, and t is time, t_2- t_1 being the exposure duration (ED). If ED is a continuous period of time (e.g., a day, week, year, etc.), then C(t) may be zero during part of this time. [FN7] Integrated exposures are done typically for a single individual, a specific chemical, and a particular pathway or exposure route over a given time period. [FN8]

The integrated exposures for a number of different individuals (a population or population segment, for example), may then be displayed in a histogram or curve (usually, with integrated exposure increasing along the abscissa or x-axis, and the number of individuals at that integrated exposure increasing along the ordinate or y-axis). This histogram or curve is a presentation of an exposure distribution for that population or population segment. The utility of both individual exposure profiles and population exposure distributions is discussed in Section 2.3.

2.1.2. Applied Dose and Potential Dose

Applied dose is the amount of a chemical at the absorption barrier (skin, lung, gastrointestinal tract) available for absorption. It is useful to know the applied dose if a relationship can be established between applied dose and internal dose, a relationship that can sometimes be established experimentally. Usually, it is very difficult to measure the applied dose directly, as many of the absorption barriers are internal to the human and are not localized in such a way to make measurement easy. An approximation of applied dose can be made, however, using the concept of potential dose[FN9] (Lioy, 1990; NRC, 1990).

Potential dose is simply the amount of the chemical ingested, inhaled, or in material applied to the skin. It is a useful term or concept for those instances in which there is exposure to a discrete amount of chemical or transport medium, such as eating a certain amount of food or applying a certain amount of material to the skin. [FN10]

The potential dose for ingestion and inhalation is analogous to the administered dose in a dose-response experiment. Human exposure to environmental chemicals is generally inadvertent rather than administered, so in these Guidelines it is termed potential dose rather than administered dose. Potential dose can be used for dose-response relationships based on administered dose.

For the dermal route, potential dose is the amount of chemical applied, or the amount of chemical in the medium applied, for example as a small amount of particulate deposited on the skin. Note that as all of the chemical in the particulate is not contacting the skin, this differs from exposure (the concentration in the particulate times the time of contact) and applied dose (the amount in the layer actually touching the skin).

The applied dose, or the amount that reaches the exchange boundaries of the skin, lung, or gastrointestinal tract, may often be less than the potential dose if the material is only partly bioavailable. Where data on bioavailability are known, adjustments to the potential dose to convert it to applied dose and internal dose may be made. [FN11]

2.1.3. Internal Dose

The amount of a chemical that has been absorbed and is available for interaction with biologically significant receptors is called the internal dose. Once absorbed, the chemical can undergo metabolism, storage, excretion, or transport within the body. The amount transported to an individual organ, tissue, or fluid of interest is termed the delivered dose. The delivered dose may be only a small part of the total internal dose. The biologically effective dose, or the amount that actually reaches cells, sites, or membranes where adverse effects occur (NRC, 1990, p. 29), may only be a part of the delivered dose, but it is obviously the crucial part. Currently, most risk assessments dealing with environmental chemicals (as opposed to pharmaceutical assessments) use dose-response relationships based on potential (administered) dose or internal dose, since the pharmacokinetics necessary

to base relationships on the delivered dose or biologically effective doses are not available for most chemicals. This may change in the future, as more becomes known about the pharmacokinetics of environmental chemicals.

Doses are often presented as dose rates, or the amount of a chemical dose (applied or internal) per unit time (e.g., mg/day), or as dose rates on a per-unit-body-weight basis (e.g., mg/kg/day).

Distributions of individual doses within a population or population segment may be displayed in a histogram or curve analogous to the exposure distributions described in section 2.1.1. The utility of individual dose profiles, as well as the utility of population distributions of dose are described more fully in section 2.3.

2.1.4. Exposure and Dose Relationships

Depending on the use of the exposure assessment, estimates of exposure and dose in various forms may be required.

- Exposure concentrations are useful when comparing peak exposures to levels of concern such as short-term exposure limits (STELs). They are typically expressed in units such as MUg/m3, mg/m3, mg/kg, MUg/L, mg/L, ppb, or ppm.

- Exposure or dose profiles describe the exposure concentration or dose as a function of time. Concentration and time are used to depict exposure, while amount and time characterize dose; ***22893** graphical or tabular presentations may be used for either type of profile.

Such profiles are very important for use in risk assessment where the severity of effect is dependent on the pattern by which the exposure occurs rather than the total (integrated) exposure. For example, a developmental toxin may only produce effects if exposure occurs during a particular stage of development. Similarly, a single acute exposure to very high contaminant levels may induce adverse effects even if the average exposure is much lower than apparent no-effect levels. Such profiles will become increasingly important as biologically based dose-response models become available.

- Integrated exposures are useful when a total exposure for a particular route (i.e., the total for various pathways leading to exposure via the same route) is needed. Units of integrated exposure are concentration times time. The integrated exposure is the total area under the curve of the exposure profile (Equation 2-1). Note that an exposure profile (a picture of exposure concentration over time) contains more information than an integrated exposure (a number), including the duration and periodicity of exposure, the peak exposure, and the shape of the area under the time-concentration curve.

- Time-weighted averages are widely used in exposure assessments, especially as part of a carcinogen risk assessment. A time-weighted average exposure concentration (units of concentration) is the integrated exposure divided by the period where exposure occurs, and is useful in some of the equations discussed below in estimating dose. A time-weighted average dose rate is the total dose divided by the time period of dosing, usually expressed in units of mass per unit time, or mass/time normalized to body weight (e.g., mg/kg/day). Time-weighted average dose rates such as the lifetime average daily dose (LADD) are often used in dose-response equations to estimate effects or risk. [FN12]

The discussion in the next three sections focuses on exposure via inhalation, oral intake, and dermal absorption. Other exposure routes are possible, however, including direct introduction into the bloodstream via injection or transfusion, contamination of exposed lesions, placental transfer, or use of suppositories. The exposures and doses for these routes can be calculated in a similar manner, depending on whether an intake or uptake process is involved.

Although equations for calculating exposure, dose, and their various averages are in widespread use in exposure assessment, the assessor should consider the implications of the assumptions used to derive the equations. Simplifying assumptions used in deriving the equations may mean that variations in exposure concentration, ingestion or inhalation rate, permeability coefficient, surface area exposed, and absorption fraction can introduce error into the estimate of dose if average values are used, and this must be considered in the evaluation of uncertainty (section 6).

2.1.4.1. Calculating Potential Dose for Intake Processes

The general equation for potential dose for intake processes, e.g., inhalation and ingestion (see Figure 2-1 for illustration of various exposures and doses) is simply the integration of the chemical intake rate (concentration of the chemical in the medium times the intake rate of the medium, C times IR) over time:

where D_{pot} is potential dose and IR(t) is the ingestion or inhalation rate.

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***22895** The quantity t_2-t_1, as before, represents the period of time over which exposure is being examined, or the exposure duration (ED). The exposure duration may contain times where the chemical is in contact with the person, and also times when C(t) is zero. Contact time represents the actual time period where the chemical is in contact with the person. For cases such as ingestion, where actual contact with food or water is intermittent, and consequently the actual contact time may be small, the intake rate is usually expressed in terms of a frequency of events (e.g., 8 glasses of water consumed per day) times the intake per event (e.g., 250 mL of water/glass of water consumed). Intermittent air exposures (e.g., 8 hours exposed/day times one cubic meter of air inhaled/hour) can also be expressed easily using exposure duration rather than contact time. Hereafter, the term exposure duration will be used in the examples below to refer to the term t_2-t_1, since it occurs frequently in exposure assessments and it is often easier to use.

Equation 2-2 can also be expressed in discrete form as a summation of the doses received during various events i:

where ED_i is the exposure duration for event i. If C and IR are nearly constant (which is a good approximation if the contact time is very short), Equation 2-3 becomes:

where ED is the sum of the exposure durations for all events, and C#8 and IR#8 are the average values for these parameters. Equation 2-4 will not necessarily hold in cases where C and IR vary considerably. In those cases, Equation 2-3 can be used if the exposure can be broken out into segments where C and IR are approximately constant. If even this condition cannot be met, Equation 2-2 may be used.

For risk assessment purposes, estimates of dose should be expressed in a manner that can be compared with available dose-response data. Frequently, dose-response relationships are based on potential dose (called administered dose in animal studies), although dose-response relationships are sometimes based on internal dose.

Doses may be expressed in several different ways. Solving Equations 2-2, 2-3, or 2-4, for example, gives a total dose accumulated over the time in question. The dose per unit time is the dose rate, which has units of mass/time (e.g., mg/day). Because intake and uptake can vary, dose rate is not necessarily constant. An average dose rate over a period of time is a useful number for many risk assessments.

Exposure assessments should take into account the time scale related to the biological response studied unless the assessment is intended to provide data on the range of biological responses (NRC, 1990, p. 28). For many noncancer effects, risk assessments consider the period of time over which the exposure occurred, and often, if there are no excursions in exposure that would lead to acute effects, average exposures or doses over the period of exposure are sufficient for the assessment. These averages are often in the form of average daily doses (ADDs).

An ADD can be calculated from Equation 2-2 by averaging D_{pot} over body weight and an averaging time, provided the dosing pattern is known so the integral can be solved. It is unusual to have such data for human exposure and intake over extended periods of time, so some simplifying assumptions are commonly used. Using Equation 2-4 instead of 2-2 or 2-3 involves making steady-state assumptions about C and IR, but this makes the equation for ADD easier to solve.[FN13] For intake processes, then, using Equation 2-4, this becomes:

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where ADD_{pot} is the average daily potential dose, BW is body weight, and AT is the time period over which the dose is averaged (converted to days). As with Equation 2-4, the exposure concentration C#8 is best expressed as an estimate of the arithmetic mean regardless of the distribution of the data. Again, using average values for C and IR in Equation 2-5 assumes that C and IR are approximately constant.

For effects such as cancer, where the biological response is usually described in terms of lifetime probabilities, even though exposure does not occur over the entire lifetime, doses are often presented as lifetime average daily doses (LADDs). The LADD takes the form of Equation 2-5, with lifetime (LT) replacing the averaging time (AT):

The LADD is a very common term used in carcinogen risk assessment where linear nonthreshold models are employed.

2.1.4.2. Calculating Internal Dose for Uptake Processes (Especially via the Dermal Route)

For absorption processes, there are two methods generally in use for calculating internal dose. The first, commonly used for dermal absorption from a liquid where at least partial immersion occurs, is derived from the equation for internal dose, D_{int}, which is analogous to Equation 2-2 except that the chemical uptake rate (C - Kp - SA) replaces the chemical intake rate (C - IR). Thus,

***22896** where K_p is the permeability coefficient, and SA is the surface area exposed. Both C and SA will vary over time, and although K_p may not vary over time, it may vary over different parts of the body. Unlike the intake processes, where the rate of the carrier medium crossing the boundary can be observed or measured, the carrier may or may not cross the absorption barrier; the equations must be in terms of the chemical itself crossing. The flow of the chemical across the barrier (or flux, J) is not directly measurable, and is dependent on many factors including the nature of the chemical, the nature of the barrier, active transport versus passive diffusion processes, and the concentration of the chemical contacting the barrier. The relationship between the flux and the exposure concentration[FN14] is usually expressed as a permeability coefficient, K_p, which is experimentally measurable.[FN15] The internal dose that is analogous to the potential dose in Equation 2-4 would be:

where SA#8 is the average surface area exposed and the ADD_{int} (average daily internal dose) becomes:

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(The corresponding $LADD_{int}$ would be obtained by substituting LT for AT.) This is the method to use when calculating internal dose for a swimmer. The total body surface area (SA) is assumed to be exposed to a layer of water with an average chemical concentration C#8 for a period of time (ED). It is not necessary to know the mass of the chemical that comes in contact with the skin. The assumptions necessary in going from Equation 2-7 to Equation 2-9 are comparable to those made in deriving Equation 2-5. Recall that both C and SA will vary over time, and K_p may not be constant over different parts of the body. If the assumption used to derive Equation 2-5 (that these variables are nearly constant) does not hold, a different form of the equation having several terms must be used.

The second method of calculating internal dose uses empirical observations or estimates of the rate that a chemical is absorbed when a dose is administered or applied. It is useful when a small or known amount of material (such as a particulate) or a chemical (such as a pesticide) contacts the skin. The potential dose of a chemical to the skin, D_{pot}, can often be calculated from knowing the concentration (C) and the amount of carrier medium applied (M_{medium}), either as a whole or on a unit surface area basis. For example, potential dose from dermal contact with soil can be calculated using the following equation:

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where D_{pot} is potential dose, M_{medium} is amount of soil applied, and F_{adh} is the adherence factor for soil (the amount of soil applied to and adhering to the skin on a unit surface area per unit time).
The relationship between potential dose and applied dose for dermal exposures is that potential dose includes the amount of the chemical in the total amount of medium contacting the skin, e.g., the amount of chemical in the soil whether or not all the chemical itself ever comes in direct contact, and applied dose includes only that amount of the chemical which actually directly touches the skin. Theoretically, the relationship between the applied dose (D_{app}) and the internal (or absorbed) dose (D_{int}) can be thought of as:

where f(t) is a complicated nonlinear absorption function, usually not measurable, having the dimensions of mass absorbed per mass applied per unit time. The absorption function will vary due to a number of factors (concentration gradient of chemical, carrier medium, type of skin, skin moisture, skin condition, etc.). If f(t) could be integrated over time from the start of exposure until time T, it would yield the absorption fraction, AF, which is the fraction of the applied dose that is absorbed after time T. The absorption fraction is a cumulative number and can increase with time to a possible maximum of 1 (or 100% absorption), but due to competing processes may reach steady state long before reaching 100% absorption. Equation 2-11 then becomes:

***22897** where AF is the absorption fraction in units of mass absorbed/mass applied (dimensionless).
If one assumes that all the chemical contained in the bulk material will eventually come in contact with the skin, then D_{app} equals D_{pot} and using Equation 2-12, the D_{int} equation becomes:

and (using Equations 2-9 and 2-10) consequently:

where M_{medium} is the mass of the bulk material applied to the skin. For reasons explained below, this approximation will by no means always give credible results. The key is whether all the chemical contained in the bulk medium can actually contact the skin. Although with certain liquids or small amounts of material, the applied dose may be approximately equal to the potential dose, in cases where there is contact with more than a minimal amount of soil, there is research that indicates that using this approximation may cause serious error (Yang et al., 1989). When this approximation does not hold, the assessor must make assumptions about how much of the bulk material actually contacts the skin, or use the first method of estimating internal dose outlined above.
Unfortunately, almost no data are available concerning the relationship between potential dose and applied dose for dermal exposures. Experimental data on absorption fractions derived for soil commonly use potential dose rather than applied dose, which may make the experimental data at least in part dependent on experimental conditions such as how much soil was applied. If the exposure assessment conditions are similar to those in the experiment, this would not usually introduce much error, but if the conditions vary widely, the error introduced may be difficult to determine.

As a practical matter, estimates of absorption fraction are often crude approximations and may be difficult to refine even if some data from experiments are available in the published literature. Typically, absorption experiments report results as an absorption fraction after a given time (e.g., 50% after 24 hours). Since absorption fraction is a function of several variables such as skin temperature, pH, moisture content, and exposed surface area, as well as characteristics of the matrix in which the

chemical occurs (e.g., soil particle size distribution, organic matter content, and moisture content), it is often difficult to make comparisons between experimental data and conditions being considered for an assessment.

With single data points, it may not be clear whether the experiment reached steady state. If several data points are available from different times in the experiment, a plot of absorption fraction vs. time may be instructive. For chemicals where data are available for steady-state conditions, the steady-state value will probably be a good approximation to use in assessments where exposure duration is at least this long, provided the conditions in the experiment are similar to those of the case being assessed. Assessors should be very cautious in applying absorption fractions for moderately absorbed chemicals (where observed experimental absorption fractions are not in the steady-state part of the cumulative curve), or in using experimental data for estimates of absorption over a much shorter duration than in the experiment.

In almost all cases, the absorption fraction method of estimating internal dose from applied dose gives only an approximation of the internal dose. The interested reader is referred to U.S. EPA (1992b) for more thorough guidance on dermal exposure assessment.

2.1.4.3. Calculating Internal Dose for Intake Processes (Especially via Respiratory and Oral Routes)

Chemicals in air, food, or drinking water normally enter the body through intake processes, then are subsequently absorbed through internal uptake processes in the lung or gastrointestinal tract. Sometimes it is necessary to estimate resulting internal dose, D_{int}, after intake. In addition, if enough is known about the pharmacokinetics of the chemical to make addition of doses across routes a meaningful exercise, the doses must be added as internal dose, not applied dose, potential dose, or exposure.

Theoretically, one could calculate D_{int} in these cases by using an equation similar to Equation 2-7; but C in that equation would become the concentration of the chemical in the lung or gastrointestinal tract, SA would be the internal surface area involved, and K_p would be the permeability coefficient of the lung or gastrointestinal tract lining. Although data from the pharmaceutical field may be helpful in determining, for example, internal surface areas, all of the data mentioned above are not known, nor are they measurable with current instrumentation.

Because Equations 2-2 through 2-4 estimate the potential dose D_{pot}, which is the amount ingested or inhaled, and Equations 2-11 and 2-12 provide relationships between the applied dose (D_{app}) and internal dose (D_{int}), all that is necessary is a relationship between potential dose and applied dose for intake processes. Again, data on this topic are virtually nonexistent, so a common assumption is that for intake processes, the potential dose equals the applied dose. Although arguments can be made that this assumption is likely to be more nearly accurate than for the case of soil contact, the validity of this assumption is unknown at this point. Essentially, the assumption of equality means that whatever is eaten, drunk, or inhaled touches an absorption barrier inside the person.

Assuming potential dose and applied dose are approximately equal, the internal dose after intake can be estimated by combining Equations 2-2 or 2-3 and 2-10 or 2-11. Using Equations 2-3 and 2-11, this becomes:

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***22898** The ADD_{int} for the two-step intake/uptake process becomes:

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Using average values for C#8 and IR#8 in Equations 2-15 and 2-16 involves the same assumptions and cautions as were discussed in deriving the ADD and LADD equations in the previous two sections, and of course, the same cautions apply to the use of the absorption fraction as were outlined in section 2.1.4.2.

2.1.5. Summary of Exposure and Dose Terms With Example Units

Table 2-1 provides a summary of the exposure and dose terms discussed in section 2.1, along with examples of units commonly used.

Table 2-1.—Explanation of Exposure and Dose Terms.

Term	Refers to	Generic units	Specific example units
Exposure	Contact of chemical with outer boundary of a person, e.g., skin, nose, mouth	Concentration x time	Dermal: (mg chem/L water) x (hrs of contact) (mg chem/kg soil) x (hrs of contact) Respiratory: (ppm chem in air) x (hrs of contact) (MUg/m^3 air) x (days of contact) Oral: (mg chem/L water) x (min of contact) (mg chem/kg food) (min of contact)
Potential Dose	Amount of a chemical contained in material ingested, air breathed, or bulk material applied to the skin	Mass of the chemical: Dose rate is mass of the chemical/time; The dose rate is sometimes normalized to body weight: mass of chemical/unit body weight x time	Dermal: (mg chem/kg soil) x (kg soil on skin) = mg chem in soil applied to skin Respiratory: (MUg chem/m3 air) x (m3 air breathed/min) x (min exposed) = MUg chemical in air breathed Oral: (mg chem/L water) x (L water consumed/day) x days exposed = mg chemical ingested in water (also dose rate: mg/day)
Applied Dose	Amount of chemical in contact with the primary	As above	Dermal: (mg chem/kg soil) x (kg soil directly touching

	absorption boundaries (e.g., skin, lungs, gastrointestinal tract) and available for absorption		skin) x (% of chem in soil actually touching skin) = mg chem actually touching skin Respiratory: (MUg chem/ m^3 air) x (m^3 air directly touching lung) (% of chemical actually touching lung) = mg chemical actually touching lung absorption barrier Oral:(mg chem/kg food) x (kg food consumed/day) x (% of chemical touching g.i. tract) = mg chemical actually touching g.i. tract absorption barrier (also absorbed dose rate: mg/day) chemical available to organ or cell (dose rate: mg chemical available to organ/day)
Internal (Absorbed) Dose	The amount of a chemical penetrating across an absorption barrier or exchange boundary via either physical or biological processes	As above	Dermal: mg chemical absorbed through skin Respiratory: mg chemical absorbed via lung Oral: mg chemical absorbed via g.i. tract (dose rate: mg chemical absorbed/day or mg/kg x day)
Delivered Dose	Amount of chemical available for interaction with any particular organ or cell	As above	mg chemical available to organ or cell (dose rate: mg chemical available to organ/day)

2.2. Approaches to Quantification of Exposure

Although exposure assessments are done for a variety of reasons (see Section 3), the quantitative exposure estimate can be approached from three different ways:[FN16]

***22899** 1. The exposure can be measured at the point of contact (the outer boundary of the body) while it is taking place, measuring both exposure concentration and time of contact and integrating them (point-of-contact measurement),

2. The exposure can be estimated by separately evaluating the exposure concentration and the time of contact, then combining this information (scenario evaluation),

3. The exposure can be estimated from dose, which in turn can be reconstructed through internal indicators (biomarkers,[FN17] body burden, excretion levels, etc.) after the exposure has taken place (reconstruction).

These three approaches to quantification of exposure (or dose) are independent, as each is based on different data. The independence of the three methods is a useful concept in verifying or validating results. Each of the three has strengths and weaknesses; using them in combination can considerably strengthen the credibility of an exposure or risk assessment. Sections 2.2.1 through 2.2.3 briefly describe some of the strengths and weaknesses of each approach.

2.2.1. Measurement of Exposure at the Point-of-Contact

Point-of-contact exposure measurement evaluates the exposure as it occurs, by measuring the chemical concentrations at the interface between the person and the environment as a function of time, resulting in an exposure profile. The best known example of the point-of-contact measurement is the radiation dosimeter. This small badge-like device measures exposure to radiation as it occurs and provides an integrated estimate of exposure for the period of time over which the measurement has been taken. Another example is the Total Exposure Assessment Methodology (TEAM) studies (U.S. EPA, 1987a) conducted by the EPA. In the TEAM studies, a small pump with a collector and absorbent was attached to a person's clothing to measure his or her exposure to airborne solvents or other pollutants as it occurred. A third example is the carbon monoxide (CO) point-of-contact measurement studies where subjects carried a small CO measuring device for several days (U.S. EPA, 1984a). Dermal patch studies and duplicate meal studies are also point-of-contact measurement studies. In all of these examples, the measurements are taken at the interface between the person and the environment while exposure is occurring. Use of these data for estimating exposures or doses for periods that differ from those for which the data are collected (e.g., for estimates of lifetime exposures) will require some assumptions, as discussed in Section 5.3.1.

The strength of this method is that it measures exposure directly, and providing that the measurement devices are accurate, is likely to give the most accurate exposure value for the period of time over which the measurement was taken. It is often expensive, however, and measurement devices and techniques do not currently exist for all chemicals. This method may also require assumptions to be made concerning the relationship between short-term sampling and long-term exposures, if appropriate. This method is also not source-specific, a limitation when particular sources will need to be addressed by risk managers.

2.2.2. Estimates of Exposure from Scenario Evaluation

In exposure scenario evaluation, the assessor attempts to determine the concentrations of chemicals in a medium or location and link this information with the time that individuals or populations contact the chemical. The set of assumptions about how this contact takes place is an exposure scenario. In evaluating exposure scenarios, the assessor usually characterizes the chemical concentration and the time of contact separately. This may be done for a series of events, e.g., by using Equation 2-3, or using a steady-state approximation, e.g., using Equation 2-4.

The goal of chemical concentration characterization is to develop estimates of exposure concentration. This is typically accomplished indirectly by measuring, modeling, or using existing data on concentrations in the bulk media, rather than at the point of contact. Assuming the concentration in the bulk medium is the same as the exposure concentration is a clear source of potential error in the exposure estimate and must be discussed in the uncertainty analysis. Generally, the closer the medium can be measured to the point of contact (in both space and time), the less uncertainty there is in the characterization of exposure concentration.

The goal of characterizing time of contact is to identify who is exposed and to develop estimates of the frequency and duration of exposure. Like chemical concentration characterization, this is usually done indirectly by use of demographic data, survey statistics, behavior observation, activity diaries, activity models, or, in the absence of more substantive information, assumptions about behavior.

The chemical concentration and population characterizations are ultimately combined in an exposure scenario, and there are various ways to accomplish this. One of the major problems in evaluating dose equations such as Equations 2-4 through 2-6 is that the limiting assumptions or boundary conditions used to derive them (e.g., steady-state assumptions; see section 2.1.4.) do not always hold true. Two major approaches to this problem are (1) to evaluate the exposure or dose equation under conditions where the limiting assumptions do hold true, or (2) to deal with the uncertainty caused by the divergence from the boundary conditions. As an example of the first way, the microenvironment method, usually used for evaluating air exposures, evaluates segments of time and location where the assumption of constant concentration is approximately true, then sums over all such time segments for a total exposure for the respiratory route, effectively removing some of the boundary conditions by falling back to the more general Equation 2-3. While estimates of exposure concentration and time-of-contact are still derived indirectly by this method, the concentration and time-of-contact estimates can be measured for each microenvironment. This avoids much of the error due to using average values in cases where concentration varies widely along with time of contact.ng18ng

As examples of the second approach, there are various tools used to describe uncertainty caused by parameter variation, such as Monte Carlo analysis (see section 5). Section 6 discusses some of these techniques in more detail.

One strength of the scenario evaluation approach is that it is usually the least expensive method of the three. ***22900** Also, it is particularly suited to analysis of the risk consequences of proposed actions. It is both a strength and a weakness of scenario development that the evaluation can be performed with little or no data; it is a technique that is best used when some knowledge exists about the soundness, validity, and uncertainty of the underlying assumptions.

2.2.3. Exposure Estimation by Reconstruction of Internal Dose

Exposure can also be estimated after it has taken place. If a total dose is known, or can be reconstructed, and information about intake and uptake rates is available, an average past exposure rate can be estimated. Reconstruction of dose relies on measuring internal body indicators after exposure and intake and uptake have already occurred, and using these measurements to back-calculate dose. However, the data on body burden levels or biomarkers cannot be used directly unless a relationship can be established between these levels or biomarker indications and internal dose, and interfering reactions (e.g., metabolism of unrelated chemicals) can be accounted for or ruled out. Biological tissue or fluid measurements that reveal the presence of a chemical may indicate directly that an exposure has occurred, provided the chemical is not a metabolite of other chemicals.

Biological monitoring can be used to evaluate the amount of a chemical in the body by measuring one or more of the following items. Not all of these can be measured for every chemical:

- The concentration of the chemical itself in biological tissues or sera (blood, urine, breath, hair, adipose tissue, etc.),

- The concentration of the chemical's metabolite(s),

- The biological effect that occurs as a result of human exposure to the chemical (e.g., alkylated hemoglobin or changes in enzyme induction), or

- The amount of a chemical or its metabolites bound to target molecules.

The results of biomonitoring can be used to estimate chemical uptake during a specific interval if background levels do not mask the marker and the relationships between uptake and the marker selected are known. The time of sampling for biomarkers

can be critical. Establishing a correlation between exposure and the measurement of the marker, including pharmacokinetics, can help optimize the sampling conditions.

The strengths of this method are that it demonstrates that exposure to and absorption of the chemical has actually taken place, and it theoretically can give a good indication of past exposure. The drawbacks are that it will not work for every chemical due to interferences or the reactive nature of the chemical, it has not been methodologically established for very many chemicals, data relating internal dose to exposure are needed, and it may be expensive.

2.3. Relationships of Exposure and Dose to Risk

Exposure and dose information are often combined with exposure-response or dose-response relationships to estimate risk, the probability of an adverse effect occurring. There are a variety of risk models, with various mathematical relationships between risk and dose or (less frequently) exposure. A major function of the exposure assessment as part of a risk assessment is to provide the exposure or dose values, and their interpretations.

The exposure and dose information available will often allow estimates of individual risk or population risk, or both. Presentation of risks in a risk assessment involves more than merely a numerical value, however. Risks can be described or characterized in a number of different ways. This section discusses the relationships between exposure and dose and a series of risk descriptors.

In preparing exposure information for use in a risk assessment, the use of several descriptors, including descriptors of both individual and population risk, often provides more useful information to the risk manager than a single descriptor or risk value. Developing several descriptors may require the exposure assessor to analyze and evaluate the exposure and dose information in several different ways. The exposure assessor should be aware of the purpose, scope, and level of detail of the assessment (see Sections 3.1 through 3.3) before gathering data, since the types and amounts of data needed may differ. The questions that need to be addressed as a result of the purpose of the assessment determine the type of risk descriptors used in the assessment.

2.3.1. Individual Risk

Individual risk is risk borne by individual persons within a population. Risk assessments almost always deal with more than a single individual. Frequently, individual risks are calculated for some or all of the persons in the population being studied, and are then put into the context of where they fall in the distribution of risks for the entire population. Descriptions of individual risk can take various forms, depending on the questions being addressed. For the risk manager, there are often key questions in mapping out a strategy for dealing with individual risk. For cancer (or when possible, noncancer) assessments, the risk manager may need answers to questions such as:

- Are individuals at risk from exposure to the substances under study? Although for substances, such as carcinogens, that are assumed to have no threshold, only a zero dose would result in no excess risk; for noncarcinogens, this question can often be addressed. In the case of the use of hazard indices, where exposures or doses are compared to a reference dose or some other acceptable level, the risk descriptor would be a statement based on the ratio between the dose incurred and the reference dose.

- To what risk levels are the persons at the highest risk subjected?

- Who are these people, what are they doing, where do they live, etc., and what might be putting them at this higher risk?

- Can people with a high degree of susceptibility be identified?

- What is the average individual risk?

In addressing these questions, risk descriptors may take any of several forms:

- An estimate of the probability that an individual in the high end of the distribution may suffer an adverse effect, along with an explanation (to the extent known) of the (exposure or susceptibility) factors which result in their being in the high end;

- An estimate of the probability that an individual at the average or median risk may suffer an adverse effect; or

- An estimate of the probability that an individual will suffer an adverse effect given a specific set of exposure circumstances.

Individuals at the high end of the risk distribution are often of interest to risk managers when considering various actions to mitigate risk. These individuals often are either more susceptible to the adverse health effect than others in the population or are highly exposed individuals, or both.

Higher susceptibility may be the result of a clear difference in the way the chemical is processed by the body, or it may be the result of being in the extreme part of the normal range in metabolism for a population. It may not always be possible to identify persons or subgroups who are more susceptible than the general population. If groups of individuals who have clearly different susceptibility characteristics can be identified, they can be treated as a separate subpopulation, and the risk assessment for this subgroup may require a different dose-response relationship from the one used for the ***22901** general population. When highly susceptible individuals can be identified, but when a different dose-response relationship is not appropriate or feasible to develop, the risks for these individuals are usually treated as part of the variability of the general population.

Highly exposed individuals have been described in the literature using many different terms. Due to unclear definitions, terms such as most exposed individual,[FN19] worst case exposure,[FN20] and reasonable worst case exposure [FN21] have sometimes been applied to a variety of ad hoc estimates with unclear target ranges. The term most exposed individual has often been used synonymously with worst case exposure, that is, to estimate the exposure of the individual with the highest actual or possible exposure. An accurate estimate of the exposure of the person in the distribution with the highest exposure is extremely difficult to develop; uncertainty in the estimate usually increases greatly as the more extreme ends of the distribution are approached. Even using techniques such as Monte Carlo simulations can result in high uncertainty about whether the estimate is within, or above, the actual exposure distribution.

For the purpose of these guidelines, a high end exposure estimate is a plausible estimate of the individual exposure for those persons at the upper end of an exposure distribution. The intent of this designation is to convey an estimate of exposures in the upper range of the distribution, but to avoid estimates that are beyond the true distribution. Conceptually, the high end of the distribution means above the 90th percentile of the population distribution, but not higher than the individual in the population who has the highest exposure. High-end dose estimates are described analogously.

The concept of the high end exposure, as used in this guidance, is fundamentally different from terms such as worst case, in that the estimate is by definition intended to fall on the actual (or in the case of scenarios dealing with future exposures, probable) exposure distribution.

Key Point: The primary objective when developing an estimate of high-end exposure or dose is to arrive at an estimate that will fall within the actual distribution, rather than above it. (Estimates above the distribution are bounding estimates; see section 5.3.4.1.) Often this requires professional judgment when data are sparse, but the primary objective of this type of estimator is to be within this fairly wide conceptual target range.

The relationship between answering the questions about high-end individual risk and what the exposure assessor must do to develop the descriptors is discussed in section 3.4. Individual risk descriptors will generally require the assessor to make estimates of high-end exposure or dose, and sometimes additional estimates (e.g., estimates of central tendency such as average or median exposure or dose).

Another type of individual risk descriptor results from specific sets of circumstances that can be hypothesized as part of a scenario, for example:

- What if a homeowner lives at the edge of this site for his entire life?

- What if a pesticide applicator applies this pesticide without using protective equipment?

- What if a consumer uses this product every day for ten years? Once a month? Once a week?

- What risk level will occur if we set the standard at 100 ppb?

The assumptions made in answering these assessment-specific postulated questions should not be confused with the approximations made in developing an exposure estimate for an existing population or with the adjustments in parameter values made in performing a sensitivity analysis. The assumptions in these specific questions address a purer “if/then” relationship and, as such, are more helpful in answering specific hypothetical or anecdotal questions. The answers to these postulated questions do not give information about how likely the combination of values might be in the actual population or about how many (if any) persons might actually be subjected to the calculated risk.

Exposure scenarios employing these types of postulated questions are encountered often in risk assessments, especially in those where actual exposure data are incomplete or nonexistent. Although the estimates of individual exposure derived from these assumptions provide numerical values for calculating risk, they do so more as a matter of context than a determination of actual exposure. They are not the same types of estimates as high-end exposure or risk, where some statement must be made about the likelihood of their falling within a specified range in the actual exposure or risk distribution.

2.3.2. Population Risk

Population risk refers to an estimate of the extent of harm for the population or population segment being addressed. Risk managers may need questions addressed such as the following:

- How many cases of a particular health effect might be probabilistically estimated for a population of interest during a specified time period?

- For noncarcinogens, what portion of the population exceeds the reference dose (RfD), the reference concentration (RfC), or other health concern level?

- For carcinogens, how many persons are above a certain risk level such as 10^{-6} or a series of risk levels such as 10^{-5}, 10^{-4}, etc?

- How do various subgroups fall within the distributions of exposure, dose, and risk?

- What is the risk for a particular population segment?

- Do any particular subgroups experience a high exposure, dose, or risk?

The risk descriptors for population risk can take any of several forms:

- A probabilistic projection of the estimated extent of occurrence of a particular effect for a population or segment (sometimes called “number of cases” of effect);

- A description of what part of the population (or population segment) is above a certain risk value of interest; or

- A description of the distribution of risk among various segments or subgroups of the population.

In theory, an estimate of the extent of effects a population might incur (e.g., the number of individual cases that might occur during a specified time) can be calculated by summing the individual risks for all individuals within the population or population segment of interest. The ability to calculate this estimate depends on whether the individual risks are in terms of probabilities for each individual, rather than a hazard index or other ***22902** nonprobabilistic risk. The calculation also requires a great deal more information than is normally available.

For some assessments, an alternate method is used, provided certain conditions hold. An arithmetic mean dose is usually much easier to estimate than the individual doses of each person in the population or population segment, but calculating the hypothetical number of cases by using mean doses, slope factors, and population size must be done with considerable caution. If the risk varies linearly with dose, and there is no threshold below which no effect ever occurs, an estimate of the number of cases that might occur can be derived from the definition of arithmetic mean. If A = T/n, where A is the arithmetic mean of n numbers, and T is the sum of the same n numbers, simple rearrangement gives T = A x n. If the arithmetic mean risk for the population (A) can be estimated, and the size of the population (n) is known, then this relationship can be used to calculate a probabilistic estimate of the extent of effects (T).[FN22] Even so, several other cautions apply when using this method.

Individual risks are usually expressed on an upper bound basis, and the resulting number of cases estimated in this manner will normally be an upper bound estimate due to the nature of the risk model used. This method will not work at all for nonlinear dose-response models, such as many noncancer effects or for nonlinear carcinogenic dose-response models.

In practice, it is difficult even to establish an accurate mean health effect risk for a population. This is due to many complications, including uncertainties in using animal data for human dose-response relationships, nonlinearities in the dose-response curve, projecting incidence data from one group to another dissimilar group, etc. Although it has been common practice to estimate the number of cases of disease, especially cancer, for populations exposed to chemicals, it should be understood that these estimates are not meant to be accurate predictions of real (or actuarial) cases of disease. The estimate's value lies in framing hypothetical risk in an understandable way rather than in any literal interpretation of the term “cases.”

Another population risk descriptor is a statement regarding how many people are thought to be above a certain risk level or other point of demarcation. For carcinogens, this might be an excess risk level such as 10^{-6} (or a series of levels, i.e., 10^{-5}, 10^{-4}, etc.). For noncarcinogenic risk, it might be the portion of the population that exceeds the RfD (a dose), the RfC (an exposure concentration), an effect-based level such as a lowest observed adverse effect level (LOAEL), etc. For the exposure assessor, this type of descriptor usually requires detailed information about the distribution of exposures or doses.

Other population risk descriptors address the way the risk burden is distributed among various segments of the subject population. The segments (or subgroups) could be divided by geographic location, age, sex, ethnic background, lifestyle, economic factors, or other demographic variables, or they could represent groups of persons with a typical sensitivity or susceptibility, such as asthmatics.

For assessors, this means that data may need to be evaluated for both highly exposed population segments and highly sensitive population segments. In cases involving a highly exposed population segment, the assessor might approach this question by having this segment of the population in mind when developing the descriptors of high-end exposure or dose. Usually, however, these segments are identified (either a priori or from inspection of the data) and then treated as separate, unique populations in themselves, with segment-specific risk descriptors (population, individual, etc.) analogous to those used for the larger population.

2.3.3. Risk Descriptors

In summary, exposure and dose information developed as part of an exposure assessment may be used in constructing risk descriptors. These are statements to convey information about risk to users of that information, primarily risk managers. Risk descriptors can be grouped as descriptors of individual risk or population risk, and within these broad categories, there are several types of descriptors. Not all descriptors are applicable to all assessments. As a matter of policy, the Agency or individual program offices within the Agency may require one or more of these descriptors to be included in specific risk assessments. Because the type of descriptor translates fairly directly into the type of analysis the exposure assessor must perform, the exposure assessor needs to be aware of these policies. Additional information on calculating and presenting exposure estimates and risk descriptors is found in sections 5 and 7 of these Guidelines.

3. Planning an Exposure Assessment

Exposure assessments are done for a variety of purposes, and for that reason, cannot easily be regimented into a set format or protocol. Each assessment, however, uses a similar set of planning questions, and by addressing these questions the assessor will be better able to decide what is needed to perform the assessment and how to obtain and use the information required. To facilitate this planning, the exposure assessor should consider some basic questions:

Purpose: Why is the study being conducted? What questions will the study address and how will the results be used?

Scope: Where does the study area begin and end? Will inferences be made on a national, regional, or local scale? Who or what is to be monitored? What chemicals and what media will be measured, and for which individuals, populations, or population segments will estimates of exposure and dose be developed?

Level of Detail: How accurate must the exposure or dose estimate be to achieve the purpose? How detailed must the assessment be to properly account for the biological link between exposure, dose, effect, and risk, if necessary? How is the depth of the assessment limited by resources (time and money), and what is the most effective use of those resources in terms of level of detail of the various parts of the assessment?

Approach: How will exposure or dose be measured or estimated, and are these methods appropriate given the biological links among exposure, dose, effect, and risk? How will populations be characterized? How will exposure concentrations be estimated? What is known about the environmental and biological fate of the substance? What are the important exposure pathways? What is known about expected concentrations, analytical methods, and detection limits? Are the presently available analytical methods capable of detecting the chemical of interest and can they achieve the level of quality needed in the assessment? How many samples are needed? When will the samples be collected? How frequently? How will the data be handled, analyzed, and interpreted?

By addressing each of these questions, the exposure assessor will develop a clear and concise definition of study ***22903** objectives that will form the basis for further planning.

3.1. Purpose of the Exposure Assessment

The particular purpose for which an exposure assessment will be used will often have significant implications for the scope, level of detail, and approach of the assessment. Because of the complex nature of exposure assessments, a multidisciplinary approach that encompasses the expertise of a variety of scientists is necessary. Exposure assessors should seek assistance from other scientists when they lack the expertise necessary in certain areas of the assessment.

3.1.1. Using Exposure Assessments in Risk Assessment

The National Research Council (NRC, 1983) described exposure assessment as one of the four major areas of risk assessment (the others are hazard identification, dose-response assessment, and risk characterization). The primary purpose of an exposure assessment in this application is often to estimate dose, which is combined with chemical-specific dose-response data (usually

from animal studies) in order to estimate risk. Depending on the purpose of the risk assessment, the exposure assessment will need to emphasize certain areas in addition to quantification of exposure and dose.

If the exposure assessment is part of a risk assessment to support regulations for specific chemical sources, such as point emission sources, consumer products, or pesticides, then the link between the source and the exposed or potentially exposed population is important. In this case, it is often necessary to trace chemicals from the source to the point of exposure by using source and fate models and exposure scenarios. By examining the individual components of a scenario, assessors can focus their efforts on the factors that contribute the most to exposure, and perhaps use the exposure assessment to select possible actions to reduce risk. For example, exposure assessments are often used to compare and select control or cleanup options. Most often the scenario evaluation is employed to estimate the residual risk associated with each of the alternatives under consideration. These estimates are compared to the baseline risk to determine the relative risk reduction of each alternative. These types of assessments can also be employed to make screening decisions about whether to further investigate a particular chemical. These assessments can also benefit from verification through the use of personal or biological monitoring techniques.

If the exposure assessment is part of a risk assessment performed to set standards for environmental media, usually the concentration levels in the medium that pose a particular risk level are important. Normally, these assessments place less emphasis on the ultimate source of the chemical and more emphasis on linking concentration levels in the medium with exposure and dose levels of those exposed. A combination of media measurements and personal exposure monitoring could be very helpful in assessments for this purpose, since what is being sought is the relationship between the two. Modeling may also support or supplement these assessments.

If the exposure assessment is part of a risk assessment used to determine the need to remediate a waste site or chemical spill, the emphasis is on calculating the risk to an individual or small group, comparing that risk to an acceptable risk level, and if necessary determining appropriate cleanup actions to reach an acceptable risk. The source of chemical contamination may or may not be known. Although personal exposure monitoring can give a good indication of the exposure or dose at the present time, often the risk manager must make a decision that will protect health in the future. For this reason, modeling and scenario development are the primary techniques used in this type of assessment. Emphasis is usually placed on linking sources with the exposed individuals. Biological monitoring may also be helpful (in cases where the methodology is established) in determining if exposure actually results in a dose, since some chemicals are not bioavailable even if intake occurs.

If the exposure assessment is part of a risk assessment used as a screening device for setting priorities, the emphasis is more on the comparative risk levels, perhaps with the risk estimates falling into broad categories (e.g., semi-quantitative categories such as high, medium, and low). For such quick-sorting exercises, rarely are any techniques used other than modeling and scenario development. Decisions made in such cases rarely involve direct cleanup or regulatory action without further refinement of the risk assessment, so the scenario development approach can be a cost-effective way to set general priorities for future investigation of worst risk first.

If the exposure assessment is part of a risk assessment that is wholly predictive in nature, such as for the premanufacture notice (PMN) program, a modeling and scenario development approach is recommended. In such cases, measurement of chemicals yet to be manufactured or in the environment is not possible. In this case again, the link between source and exposed individuals is emphasized.

Not only are risk assessments done for a variety of purposes, but the toxic endpoints being assessed (e.g., cancer, reproductive effects, neurotoxic effects) can also vary widely. Endpoints and other aspects of the hazard identification and dose-response relationships can have a major effect on how the exposure information must be collected and analyzed for a risk assessment. This is discussed in more detail in section 3.5.1.

3.1.2. Using Exposure Assessments for Status and Trends

Exposure assessments can also be used to determine whether exposure occurs and to monitor status and trends. The emphasis in these exposure assessments is on what the actual exposure (or dose) is at one particular time, and how the exposure changes over time. Examples of this type of assessment are occupational studies. Characteristics and special considerations for occupational studies have been discussed by the National Institute for Occupational Safety and Health (NIOSH, 1988).

Exposure status is the snapshot of exposure at a given time, usually the exposure profile of a population or population segment (perhaps a segment or statistical sample that can be studied periodically). Exposure trends show how this profile changes with time. Normally, status and trends studies make use of statistical sampling strategies to assure that changes can be interpreted meaningfully. These data are particularly useful if actions for risk amelioration and demonstration of the effectiveness of these actions can be made through exposure trend measurements.

Measurement is critical to such assessments. Personal monitoring can give the most accurate picture of exposure, but biological or media monitoring can indicate exposure levels, provided a strong link is established between the biological or media levels and the exposure levels. Usually this link is established first by correlating biological or media levels with personal monitoring data for the same population over the same period.

22904** ***3.1.3. Using Exposure Assessments in Epidemiologic Studies

Exposure assessments can also be important components of epidemiologic studies, where the emphasis is on using the exposure assessment to establish exposure-incidence (or dose-effect) relationships. For this purpose, personal monitoring, biological monitoring, and scenario development have all been used. If the population under study is being currently exposed, personal monitoring or biological monitoring may be particularly helpful in establishing exposure or dose levels. If the exposure took place in the past, biological monitoring may provide useful data, provided the chemical is amenable to detection without interference or degradation, and the pharmacokinetics are known. More often, however, scenario development techniques are used to estimate exposure in the past, and often the accuracy of the estimate is limited to classifying exposure as high, medium, or low. This type of categorization is rather common, but sometimes it is very difficult to determine who belongs in a category, and to interpret the results of the study. Although epidemiologic protocols are beyond the scope of these Guidelines, the use of exposure assessment for epidemiology has been described by the World Health Organization (WHO, 1983).

3.2. Scope of the Assessment

The scope of an assessment refers to its comprehensiveness. For example, an important limitation in many exposure assessments relates to the specific chemical(s) to be evaluated. Although this seems obvious, where exposure to multiple chemicals or mixtures is possible, it is not always clear whether assessing “all” chemicals will result in a different risk value than if only certain significant chemicals are assessed and the others assumed to contribute only a minor amount to the risk. This may also be true for cases where degradation products have equal or greater toxicological concerns. In these cases, a preliminary investigation may be necessary to determine which chemicals are likely to be in high enough concentrations to cause concern, with the possibile contribution of the others discussed in the uncertainty assessment. The assessor must also determine geographical boundaries, population exposed, environmental media to be considered, and exposure pathways and routes of concern.

The purpose of the exposure assessment will usually help define the scope. There are characteristics that are unique to national exposure assessments as opposed to industry-wide or local exposure assessments. For example, exposure assessments in support of national regulations must be national in scope; exposure assessments to support cleanup decisions at a site will be local in scope. Exposure assessments to support standards for a particular medium will often concentrate on that medium's concentration levels and typical exposure pathways and routes, although the other pathways and routes are also often estimated for perspective.

3.3. Level of Detail of the Assessment

The level of detail, or depth of the assessment, is measured by the amount and resolution of the data used, and the sophistication of the analysis employed. It is determined by the purpose of the exposure assessment and the resources available to perform

the assessment. Although in theory the level of detail needed can be established by determining the accuracy of the estimate required, this is rarely the case in practice. To conserve resources, most assessments are done in an iterative fashion, with a screening done first; successive iterations add more detail and sophistication. After each iteration, the question is asked, is this level of detail or degree of confidence good enough to achieve the purpose of the assessment? If the answer is no, successive iterations continue until the answer is affirmative, new input data are generated, or as is the case for many assessments, the available data, time, or resources are depleted. Resource-limited assessments should be evaluated in terms of what part of the original objectives have been accomplished, and how this affects the use of the results.

The level of detail of an exposure assessment can also be influenced by the level of sophistication or uncertainty in the assessment of health effects to be used for a risk assessment. If only very weak health information is available, a detailed, costly, and in-depth exposure assessment will in most cases be wasteful, since the most detailed information will not add significantly to the certainty of the risk assessment.

3.4. Determining the Approach for the Exposure Assessment

The intended use of the exposure assessment will generally favor one approach to quantifying exposure over the others, or suggest that two or more approaches be combined. These approaches to exposure assessment can be viewed as different ways of estimating the same exposure or dose. Each has its own unique characteristics, strengths, and weaknesses, but the estimate should theoretically be the same, independent of the approach taken.

The point-of-contact approach requires measurements of chemical concentrations at the point where they contact the exposed individuals, and a record of the length of time of contact at each concentration. Some integrative techniques are inexpensive and easy to use (radiation badges), while others are costly and may present logistical challenges (personal continuous-sampling devices), and require public cooperation.

The scenario evaluation approach requires chemical concentration and time-of-contact data, as well as information on the exposed persons. Chemical concentration may be determined by sampling and analysis or by use of fate and transport models (including simple dilution models). Models can be particularly helpful when some analytical data are available, but resources for additional sampling are limited. Information on human behavior and physical characteristics may be assumed or obtained by interviews or other techniques from individuals who represent the population of interest.

For the reconstruction of dose approach, the exposure assessor usually uses measured body burden or specific biomarker data, and selects or constructs a biological model that uses these data to account for the chemical's behavior in the body. If a pharmacokinetic model is used, additional data on metabolic processes will be required (as well as model validation information). Information on exposure routes and relative source strengths is also helpful.

One of the goals in selecting the approach should include developing an estimate having an acceptable amount of uncertainty. In general, estimates based on quality-assured measurement data, gathered to directly answer the questions of the assessment, are likely to have less uncertainty than estimates based on indirect information. The approach selected for the assessment will determine which data are needed. All three approaches also require data on intake and uptake rates if the final product of the assessment is a calculated dose.

Sometimes more than one approach is used to estimate exposure. For example, the TEAM study combines point-of-contact measurement with the microenvironment (scenario evaluation) approach and breath measurements for the reconstruction of dose approach (U.S. EPA, 1987a). If more than one ***22905** approach is used, the assessor should consider how using each approach separately can verify or validate the others. In particular, point-of-contact measurements can be used as a check on assessments made by scenario evaluation.

3.5. Establishing the Exposure Assessment Plan

Before starting work on an exposure assessment, the assessor should have determined the purpose, scope, level of detail, and approach for the assessment, and should be able to translate these into a set of objectives. These objectives will be the foundation for the exposure assessment plan. The exposure assessment plan need not be a lengthy or formal document, especially for assessments that have a narrow scope and little detail. For more complex exposure assessments, however, it is helpful to have a written plan.

For exposure assessments being done as part of a risk assessment, the exposure assessment plan should reflect (in addition to the objectives) an understanding of how the results of the exposure assessment will be used in the risk assessment. For some assessments, three additional components may be needed: the sampling strategy (section 3.5.2), the modeling strategy (section 3.5.3), and the communications strategy (section 7.1.3).

3.5.1. Planning an Exposure Assessment as Part of a Risk Assessment

For risk assessments, exposure information must be clearly linked to the hazard identification and dose-response relationship (or exposure-response relationship; see section 3.5.4). The toxic endpoints (e.g., cancer, reproductive effects, neurotoxic effects) can vary widely, and along with other aspects of the hazard identification and dose-response relationships, can have a major effect on how the exposure information must be collected and analyzed for a risk assessment. Some of these aspects include implications of limited versus repeated exposures, dose-rate considerations, reversibility of toxicological processes, and composition of the exposed population.

- Limited versus Repeated Exposures. Current carcinogen risk models often use lifetime time-weighted average doses in the dose-response relationships owing to their derivation from lifetime animal studies. This does not mean cancer cannot occur after single exposures (witness the A-bomb experience), merely that exposure information must be consonant with the source of the model. Some toxic effects, however, occur after a single or a limited number of exposures, including acute reactions such as anesthetic effects and respiratory depression or certain developmental effects following exposure during pregnancy. For developmental effects, for example, lifetime time-weighted averages have little relevance, so different types of data must be collected, in this case usually shorter-term exposure profile data during a particular time window. Consequently, the exposure assessors and scientists who conduct monitoring studies need to collaborate with those scientists who evaluate a chemical's hazard potential to assure the development of a meaningful risk assessment. If short-term peak exposures are related to the effect, then instruments used should be able to measure short-term peak concentrations. If cumulative exposure is related to the effect, long-term average sampling strategies will probably be more appropriate.

- Dose-Rate Effects. The use of average daily dose values (e.g., ADD, LADD) in a dose-response relationship assumes that within some limits, increments of C times T (exposure concentration times time) that are equal in magnitude are equivalent in their potential to cause an effect, regardless of the pattern of exposure (the so-called Haber's Rule; see Atherley, 1985). In those cases where toxicity depends on the dose rate, one may need a more precise determination of the time people are exposed to various concentrations and the sequence in which these exposures occur.

- Reversibility of Toxicological Processes. The averaging process for daily exposure assumes that repeated dosing continues to add to the risk potential. In some cases, after cessation of exposure, toxicological processes are reversible over time. In these cases, exposure assessments must provide enough information so that the risk assessor can account for the potential influence of episodic exposures.

- Composition of the Exposed Population. For some substances, the type of health effect may vary as a function of age or sex. Likewise, certain behaviors (e.g., smoking), diseases (e.g., asthma), and genetic traits (e.g., glucose-6-phosphate dehydrogenase deficiency) may affect the response of a person to a chemical substance. Special population segments, such as children, may also call for a specialized approach to data collection (WHO, 1986).

3.5.2. Establishing the Sampling Strategy

If the objectives of the assessment are to be met using measurements, it is important to establish the sampling strategy before samples are actually taken. The sampling strategy includes setting data quality objectives, developing the sampling plan and design, using spiked and blank samples, assessing background levels, developing quality assurance project plans, validating previously generated data, and selecting and validating analytical methods.

3.5.2.1. Data Quality Objectives

All measurements are subject to uncertainty because of the inherent variability in the quantities being measured (e.g., spatial and temporal variability) and analytical measurement variability introduced during the measurement process through sampling and analysis. Some sources of variability can be expressed quantitatively, but others can only be described qualitatively. The larger the variability associated with individual measurements, the lower the data quality, and the greater the probability of errors in interpretation. Data quality objectives (DQOs) describe the degree of uncertainty that an exposure assessor and other scientists and management are willing to accept.

Realistic DQOs are essential. Data of insufficient quality will have little value for problem solving, while data of quality vastly in excess of what is needed to answer the questions asked provide few, if any, additional advantages. DQOs should consider data needs, cost-effectiveness, and the capability of the measurement process. The amount of data required depends on the level of detail necessary for the purpose of the assessment. Estimates of the number of samples to be taken and measurements to be made should account for expected sample variability. Finally, DQOs help clarify study objectives by compelling the exposure assessor to establish how the data will be used before they are collected.

The exposure assessor establishes data criteria by proposing limits (based on best judgment or perhaps a pilot study) on the acceptable level of uncertainty for each conclusion to be drawn from new data, considering the resources available for the study. DQOs should include:

- A clear statement of study objectives, to include an estimation of the key study parameters, identifying the hypotheses being tested, the specific aims of the study, and how the results will be used.

- The scope of study objectives, to include the minimum size of subsamples from which separate results may be calculated, and the largest unit (area, ***22906** time period, or group of people) the data will represent.

- A description of the data to be obtained, the media to be sampled, and the capabilities of the analytical methodologies.

- The acceptable probabilities and uncertainties associated with false positive and false negative statements.

- A discussion of statistics used to summarize the data; any standards, reference values, or action levels used for comparison; and a description and rationale for any mathematical or statistical procedures used.

- An estimate of the resources needed.

3.5.2.2. Sampling Plan

The sampling plan specifies how a sample is to be selected and handled. An inadequate plan will often lead to biased, unreliable, or meaningless results. Good planning, on the other hand, makes optimal use of limited resources and is more likely to produce valid results.

The sampling design specifies the number and types of samples needed to achieve DQOs. Factors to be considered in developing the sampling design include study objectives, sources of variability (e.g., temporal and spatial heterogeneity, analytical differences) and their relative magnitudes, relative costs, and practical limitations of time, cost, and personnel.

Sampling design considers the need for temporal and spatial replication, compositing (combining several samples prior to analysis), and multiple determinations on a single sample. A statistical or environmental process model may be used to allocate sampling effort in the most efficient manner.

Data may be collected using a survey or an experimental approach. It may be desirable to stratify the sample if it is suspected that differences exist between segments of the statistical population being sampled. In such cases, the stratified sampling plan assures representative samples of the obviously different parts of the sample population while reducing variance in the sample data. The survey approach estimates population exposure based on the measured exposure of a statistically representative sample of the population. In some situations the study objectives are better served by an experimental approach; this approach involves experiments designed to determine the relationship between two or more factors, (e.g., between house construction and a particular indoor air pollutant). In the experimental approach, experimental units are selected to cover a range of situations (e.g., different housing types), but do not reflect the frequency of those units in the population of interest. An understanding of the relationship between factors gained from an experiment can be combined with other data (e.g., distribution of housing types) to estimate exposure. An advantage of the experimental approach is that it may provide more insight into underlying mechanisms which may be important in targeting regulatory action. However, as in all experimental work, one must argue that the relationships revealed apply beyond that particular experiment.

A study may use a combination of survey and experimental techniques and involve a variety of sampling procedures. A summary of methods for measuring worker exposure is found in Lynch (1985). Smith et al. (1987) provide guidance for field sampling of pesticides. Relevant EPA reference documents include Survey Management Handbook, Volumes I and II (U.S. EPA, 1984b); Soil Sampling Quality Assurance User's Guide (U.S. EPA, 1990a); and A Rationale for the Assessment of Errors in the Sampling of Soils (U.S. EPA, 1989a). A detailed description of methods for enumerating and characterizing populations exposed to chemical substances is contained in Methods for Assessing Exposure to Chemical Substances, Volume 4 (U.S. EPA, 1985a).

Factors to be considered in selecting sampling locations include population density, historical sampling results, patterns of environmental contamination and environmental characteristics such as stream flow or prevailing wind direction, access to the sample site, types of samples, and health and safety requirements.

The frequency and duration of sample collection will depend on whether the risk assessor is concerned with acute or chronic exposures, how rapidly contamination patterns are changing, ways in which chemicals are released into the environment, and whether and to what degree physical conditions are expected to vary in the future.

There are many sources of information on methods for selecting sampling locations. Schweitzer and Black (1985) and Schweitzer and Santolucito (1984) give statistical methods for selecting sampling locations for ground water, soil, and hazardous wastes. A practical guide for ground-water sampling (U.S. EPA, 1985b) and a handbook for stream sampling (U.S. EPA, 1986d) are also available.

The type of sample to be taken and the physical and chemical properties of the chemical of concern usually dictate the sampling frequency. For example, determining the concentration of a volatile chemical in surface water requires a higher sampling frequency than necessary for ground water because the chemical concentration of the surface water changes more rapidly. Sampling frequency might also depend on whether the health effects of concern result from acute or chronic exposures. More frequent sampling may be needed to determine peak exposures versus average exposure.

A preliminary survey is often used to estimate the optimum number, spacing, and sampling frequency. Factors to be considered include technical objectives, resources, program schedule, types of analyses, and the constituents to be evaluated. Shaw et al. (1984), Sanders and Adrian (1978), and Nelson and Ward (1981) discuss statistical techniques for determining the optimal number of samples.

Sampling duration depends on the analytical method chosen, the limits of detection, the physical and chemical properties of the analyte, chemical concentration, and knowledge of transport and transformation mechanisms. Sampling duration may be extended to ensure adequate collection of a chemical at low concentration or curtailed to prevent the breakthrough of one at high concentration. Sampling duration is directly related to selection of statistical procedures, such as trend or cross-sectional analyses.

Storage stability studies with periodic sample analysis should normally be run concurrently with the storage of treated samples. However, in certain situations where chemicals are prone to break down or have high volatility, it is advisable to run a storage stability study in advance so that proper storage and maximum time of storage can be determined prior to sample collection and storage. Unless storage stability has been previously documented, samples should be analyzed as soon as possible after collection to avoid storage stability problems. Individual programs may have specific time limits on storage, depending on the types of samples being analyzed.

3.5.2.3. Quality Assurance Samples

Sampling should be planned to ensure that the samples are not biased by the introduction of field or laboratory contaminants. If sample validity is in question, all associated analytical data will be suspect. Field- and laboratory-spiked samples and blank samples should be analyzed concurrently to validate results. The plan should provide instructions clear enough so that ***22907** each worker can collect, prepare, preserve, and analyze samples according to established protocols.

Any data not significantly greater than blank sample levels should be used with considerable caution. All values should be reported as measured by the laboratory, but with appropriate caveats on blank sample levels. The method for interpreting and using the results from blank samples depends on the analyte and should be specified in the sampling plan. The following guidance is recommended:

- For volatiles and semivolatiles, no positive sample results should be reported unless the concentration of the compound in the sample exceeds 10 times the amount in any blank for the common laboratory contaminants methylene chloride, acetone, toluene, 2-butanone, and common phthalate esters. The amount for other volatiles and semivolatiles should exceed 5 times the amount in the blank (U.S. EPA, 1988d).

- For pesticides and polychlorinated biphenyls (PCBs) no positive sample results should be reported unless the concentration in the sample exceeds 5 times that in the blank (U.S. EPA, 1988d). If a pesticide or PCB is found in a blank but not in a sample, no action is taken.

- For inorganics, no positive sample results should be reported if the results are less than 5 times the amount in any blank (U.S. EPA, 1988e).

3.5.2.4. Background Level

Background presence may be due to natural or anthropogenic sources. At some sites, it is significant and must be accounted for. The exposure assessor should try to determine local background concentrations by gathering data from nearby locations clearly unaffected by the site under investigation.

When differences between a background (control area) and a target site are to be determined experimentally, the control area must be sampled with the same detail and care as the target.

3.5.2.5. Quality Assurance and Quality Control

Quality assurance (QA) assures that a product meets defined standards of quality with a stated level of confidence. QA includes quality control.

Quality assurance begins with the establishment of DQOs and continues throughout the measurement process. Each laboratory should have a QA program and, for each study, a detailed quality assurance project plan, with language clear enough to preclude confusion and misunderstanding. The plan should list the DQOs and fully describe the analytes, all materials, methods, and procedures used, and the responsibilities of project participants. The EPA has prepared a guidance document (U.S. EPA, 1980) that describes all these elements and provides complete guidance for plan preparation.

Quality control (QC) ensures a product or service is satisfactory, dependable, and economical. A QC program should include development and strict adherence to principles of good laboratory practice, consistent use of standard operational procedures, and carefully-designed protocols for each measurement effort. The program should ensure that errors have been statistically characterized and reduced to acceptable levels.

3.5.2.6. Quality Assurance and Quality Control for Previously Generated Data

Previously generated data may be used by the exposure assessor to fulfill current needs. Any data developed through previous studies should be validated with respect to both quality and extrapolation to current use. One should consider how long ago the data were collected and whether they are still representative. The criteria for method selection and validation should also be followed when analyzing existing data. Other points considered in data evaluation include the collection protocol, analytical methods, detection limits, laboratory performance, and sample handling.

3.5.2.7. Selection and Validation of Analytical Methods

There are several major steps in the method selection and validation process. First, the assessor establishes methods requirements. Next, existing methods are reviewed for suitability to the current application. If a net method must be developed, it is subjected to field and laboratory testing to determine its performance; these tests are then repeated by other laboratories using a round robin test. Finally, the method is revised as indicated by laboratory testing. The reader is referred to Guidance for Data Useability in Risk Assessment (U.S. EPA, 1990b) for extensive discussion of this topic.

3.5.3. Establishing the Modeling Strategy

Often the most critical element of the assessment is the estimation of pollutant concentrations at exposure points. This is usually carried out by a combination of field data and mathematical modeling results. In the absence of field data, this process often relies on the results of mathematical models (U.S. EPA, 1986e, 1987b, 1987c, 1988f, 1991b). EPA's Science Advisory Board (U.S. EPA, 1989b) has concluded that, ideally, modeling should be linked with monitoring data in regulatory assessments, although this is not always possible (e.g., for new chemicals).

A modeling strategy has several aspects, including setting objectives, model selection, obtaining and installing the code, calibrating and running the computer model, and validation and verification. Many of these aspects are analogous to the QA/QC measures applied to measurements.

3.5.3.1. Setting the Modeling Study Objectives

The first step in using a model to estimate concentrations and exposure is to clearly define the goal of the exposure assessment and how the model can help address the questions or hypotheses of the assessment. This includes a clear statement of what information the model will help estimate, and how this estimate will be used. The approach must be consistent with known project constraints (i.e., schedule, budget, and other resources).

3.5.3.2. Characterization and Model Selection

Regardless of whether models are extensively used in an assessment and a formal modeling strategy is documented in the exposure assessment plan, when computer simulation models such as fate and transport models and exposure models are used

in exposure assessments, the assessor must be aware of the performance characteristics of the model and state how the exposure assessment requirements are satisfied by the model.

If models are to be used to simulate pollutant behavior at a specific site, the site must be characterized. Site characterization for any modeling study includes examining all data on the site such as source characterization, dimensions and topography of the site, location of receptor populations, meteorology, soils, geohydrology, and ranges and distributions of chemical concentrations. For exposure models that simulate both chemical concentration and time of exposure (through behavior patterns) data on these two parameters must be evaluated.

For all models, the modeler must determine if databases are available to support the site, chemical, or population characterization, and that all parameters required by the model can be obtained or reasonable default values are ***22908** available. The assessment goals and the results of the characterization step provide the technical basis for model selection.

Criteria are provided in U.S. EPA (1987b, 1988f) for selection of surface water models and ground-water models respectively; the reader is referred to these documents for details. Similar selection criteria exist for air dispersion models (U.S. EPA, 1986e, 1987c, 1991b).

A primary consideration in selecting a model is whether to perform a screening study or to perform a detailed study. A screening study makes a preliminary evaluation of a site or a general comparison between several sites. It may be generic to a type of site (i.e., an industrial segment or a climatic region) or may pertain to a specific site for which sufficient data are not available to properly characterize the site. Screening studies can help direct data collection at the site by, for example, providing an indication of the level of detection and quantification that would be required and the distances and directions from a point of release where chemical concentrations might be expected to be highest.

The value of the screening-level analysis is that it is simple to perform and may indicate that no significant contamination problem exists. Screening-level models are frequently used to get a first approximation of the concentrations that may be present. Often these models use very conservative assumptions; that is, they tend to overpredict concentrations or exposures. If the results of a conservative screening procedure indicate that predicted concentrations or exposures are less than some predetermined no-concern level, then a more detailed analysis is probably not necessary. If the screening estimates are above that level, refinement of the assumptions or a more sophisticated model are necessary for a more realistic estimate.

Screening-level models also help the user conceptualize the physical system, identify important processes, and locate available data. The assumptions used in the preliminary analysis should represent conservative conditions, such that the predicted results overestimate potential conditions, limiting false negatives. If the limited field measurements or screening analyses indicate that a contamination problem may exist, then a detailed modeling study may be useful.

A detailed study is one in which the purpose is to make a detailed evaluation of a specific site. The approach is to use the best data available to make the best estimate of spatial and temporal distributions of chemicals. Detailed studies typically require much more data of higher quality and models of greater sophistication.

3.5.3.3. Obtaining and Installing the Computer Code

It may be necessary to obtain and install the computer code for a model on a specific computer system. Modern computer systems and software have a variety of differences that require changes to the source code being installed. It is essential to verify that these modifications do not change the way the model works or the results it provides. If the model is already installed and supported on a computer system to which the user has access, this step is simplified greatly.

Criteria for using a model include its demonstrated acceptability and the ease with which the model can be obtained. Factors include availability of specific models and their documentation, verification, and validation. These so-called implementation

criteria relate to the practical considerations of model use and may be used to further narrow the selection of technically acceptable models.

3.5.3.4. Calibrating and Running the Model

Calibration is the process of adjusting selected model parameters within an expected range until the differences between model predictions and field observations are within selected criteria. Calibration is highly recommended for all operational, deterministic models. Calibration accounts for spatial variations not represented by the model formulation; functional dependencies of parameters that are either nonquantifiable, unknown, or not included in the model algorithms; or extrapolation of laboratory measurements to field conditions. Extrapolation of laboratory measurements to field conditions requires considerable care since many unknown factors may cause differences between laboratory and field.

The final step in the modeling portion of an exposure assessment is to run the model and generate the data needed to answer the questions posed in the study objectives.

Experience and familiarity with a model can also be important. This is especially true with regard to the more complex models. Detailed models can be quite complex with a large number of input variables, outputs, and computer-related requirements. It frequently takes months to years of experience to fully comprehend all aspects of a model. Consequently, it is suggested that an exposure assessor select a familiar model if it possesses all the selection criteria, or seek the help of experienced exposure modelers.

3.5.3.5. Model Validation

Model validation is a process by which the accuracy of model results is compared with actual data from the system being simulated. There are numerous levels of validation of an environmental fate model, for example, such as verifying that the transport and transformation concepts are appropriately represented in the mathematical equations, verifying that the computer code is free from error, testing the model against laboratory microcosms, running field tests under controlled conditions, running general field tests, and repeatedly comparing field data to the modeling results under a variety of conditions and chemicals. In essence, validation is an independent test of how well the model (with its calibrated parameters) represents the important processes occurring in the natural system. Although field and environmental conditions are often different during the validation step, parameters fixed as a result of calibration are not readjusted during validation.[FN23]

The performance of models (their ability to represent measured data) is often dramatically influenced by site characterization and how models represent such characteristics. Characterizing complex, heterogenous physical systems presents major challenges; modeling representations of such systems must be evaluated in light of that difficulty. In many cases, the apparent inability to model a system is caused by incomplete physical characterization of the system. In other cases the uncertainties cannot be readily apportioned between the model per se and the model's input data.

In addition to comparing model results with actual data (thus illustrating accuracy, bias, etc.), the model validation process provides information about conditions under which a simulation will be acceptable and accurate, and under what conditions it should not be used at all. All models have specific ranges of application and specific classes of chemicals for which they are appropriate. Assessors should be aware of these limitations as they develop modeling strategies.

22909** ***3.5.4. Planning an Exposure Assessment to Assess Past Exposures

In addition to the considerations discussed in sections 3.5.1 through 3.5.3, if the data are being collected to assess past exposures, such as in epidemiologic studies, they need to be representative of the past exposure conditions, which may have changed with time. The scope and level of detail of the assessment depends greatly on the availability and quality of past data. Several approaches for determining and estimating past exposure are provided in the literature (Waxweiler et al., 1988; Stern et al., 1986; NIOSH, 1988; Greife et al., 1988; Hornung and Meinhardt, 1987).

4. Gatherring and Developing Data for Exposure Assessments

The information needed to perform an exposure assessment will depend on the approach(es) selected in the planning stage (section 3). For those assessments using point-of-contact measurements, the information includes:

- Measured exposure concentrations and duration of contact.

For assessments using the scenario evaluation method for estimating exposures, the needed information includes:

- Information on chemical concentrations in media, usually desirable in the format of a concentration-time-location profile.

- Information on persons who are exposed and the duration of contact with various concentrations.

For assessments estimating exposure from dose, the information includes:

- Biomarker data.

- Pharmacokinetic relationships, including the data to support pharmacokinetic models.

If dose is to be calculated, data are needed on:

- Intake and uptake, usually in the form of rates.

Information on both natural and anthropogenic sources is usually helpful. If the agent has natural sources, the contribution of these to environmental concentrations may be relevant. These background concentrations may be particularly important when the results of toxicity tests show a threshold or distinctly nonlinear dose-response relationship. In a situation where only relative or additional risk is considered, background levels may not be relevant.

4.1. Measurement Data for Point-of-Contact Assessments

This approach requires that chemical concentrations be measured at the interface between the person and the environment, usually through the use of personal monitors; there are currently no models to assist in the process of obtaining the concentration-time data itself. The chemical concentrations contacted in the media are measured by sampling the individual's breathing zone, food, and water. These methodologies were originally developed for occupational monitoring; they may have to be modified for exposures outside the workplace. An example of this is the development of a small pump and collector used in the TEAM studies (U.S. EPA, 1987a). In order to conduct these studies, a monitoring device had to be developed that was sufficiently small and lightweight so that it could be worn by the subjects.

The Total Human Exposure and Indoor Air Quality (U.S. EPA, 1988h) report is a useful bibliography covering models, field data, and emerging research methodologies, as well as new techniques for accurately determining exposure at nonoccupational levels.

New data for a particular exposure assessment may be developed through the use of point-of-contact methods, or data from prior studies can sometimes be used. In determining whether existing point-of-contact monitoring data can be used in another assessment, the assessor must consider the factors that existed in the original study and that influenced the exposure levels measured. Some of these factors are proximity to sources, activities of the studied individuals, time of day, season, and weather conditions.

Point-of-contact data are valuable in evaluating overall population exposure and checking the credibility of exposure estimates generated by other methods.

4.2. Obtaining Chemical Concentration Information

The distribution of chemical concentrations is used to estimate the concentration that comes in contact with the individual(s) at any given time and place. This can be done through personal monitoring, but for a variety of reasons, in a given assessment, personal monitoring may not be feasible. Alternative methods involve measuring the concentration in the media, or modeling the concentration distribution based on source strength, media transport, and chemical transformation processes. For exposure scenario evaluation, measurements and modeling of media concentrations are often used together.

Many types of measurements can be used to help determine the distribution of chemical concentrations in media. They can be measurements of the concentrations in the media themselves, measurements of source strength, or measurements of environmental fate processes which will allow the assessor to use a model to estimate the concentration in the media at the point of contact. Table 4-1 illustrates some of the types of measurements used by exposure assessors, along with notes concerning what additional information is usually needed to use these measurements in estimating exposure or dose. For epidemiologic studies, questionnaires are often used when data are not measureable or are otherwise unavailable.

Table 4-1.—Examples of types of measurements to characterize exposure-related media and parameters. [a]

Type of measurement (sample)	Usually attempts to characterize (whole)	Examples	Typical information needed to characterize exposure
A. For Use in Exposure Scenario Evaluation:			
1. Fixed-Location Monitoring	Environmental medium; samples used to establish long-term indications of media quality and trends	National Stream Quality Accounting Network (NASQAN), [b] water quality networks, air quality networks	Population location and activities relative to monitoring locations; fate of pollutants over distance between monitoring and point of exposure; time variation of pollutant concentration at point of exposure
2. Short-Term Media Monitoring	Environmental or ambient medium; samples used to establish a snapshot of quality of medium over relatively short time	Special studies of environmental media, indoor air	Population location and activities (this is critical since it must be closely matched to variations in concentrations due to short period of study); fate of pollutants between measurement point and point of exposure; time variation of pollutant concentration at point of exposure.
3. Source Monitoring of Facilities	Release rates to the environment from sources (facilities). Often given in terms of relationships between release amounts and	Stack sampling, effluent sampling, leachate sampling from landfills, incinerator ash sampling, fugitive emissions sampling,	Fate of pollutants from point of entry into the environment to point of exposure; population location and activities; time variation of release.

	various operating parameters of the facilities	pollution control device sampling	
4. Food Samples (also see #11 below)	Concentrations of contaminants in food supply	FDA Total Diet Study Program, [c] market basket studies, shelf studies, cooked-food diet sampling	Dietary habits of various age, sex, or cultural groups. Relationship between food items sampled and groups (geographic, ethnic, demographic) studied. Relationships between concentrations in uncooked versus prepared food.
5. Drinking Water Samples	Concentrations of pollutants in drinking water supply	Ground Water Supply Survey, [d] Community Water Supply Survey, [e] tap water	Fate and distribution of pollutants from point of sample to point of consumption. Population served by specific facilities and consumption rates. For exposure due to other uses (e.g., cooking and showering), need to know activity patterns and volatilization rates.
6. Consumer Products	Concentration levels of various products	Shelf surveys, e.g., solvent concentration in household cleaners [f]	Establish use patterns and/or market share of particular products, individual exposure at various usage levels, extent of passive exposure.
7. Breathing Zone Measurements	Exposure to airborne chemicals	Industrial hygiene studies, occupational surveys, indoor air studies.	Location, activities, and time spent relative to monitoring locations. Protective measures/avoidance.
8. Microenvironmental Studies	Ambient medium in a defined area, e.g., kitchen, automobile interior, office setting, parking lot	Special studies of indoor air, house dust, contaminated surfaces, radon measurements, office building studies	Activities of study populations relative to monitoring locations and time exposed.
9. Surface Soil Sample	Degree of contamination of soil available for contact	Soil samples at contaminated sites	Fate of pollution on/in soil; activities of potentially exposed populations.
10. Soil Core	Soil including pollution available for ground-water contamination; can be an indication of quality and trends over time	Soil sampling at hazardous waste sites	Fate of substance in soil; speciation and bioavailability, contact and ingestion rates as a function of activity patterns and age.
11. Fish Tissue	Extent of contamination of edible fish tissue	National Shellfish Survey [g]	Relationship of samples to food supply for individuals or population of interest; consumption habits; preparation habits.

B. For Use in Point-of-Contact Measurement			
1. Air Pump/Particulates and Vapors	Exposure of an individual or population via the air medium	TEAM study, [h] carbon monoxide study. [i] Breathing zone sampling in industrial settings	Direct measurement of individual exposure during time sampled. In order to characterize exposure to population, relationships between individuals and the population must be established as well as relationships between times sampled and other times for the same individuals, and relationships between sampled individuals and other populations. In order to make these links, activities of the sampled individuals compared to populations characterized are needed in some detail.
2. Passive Vapor Sampling	Same as above	Same as above	Same as above.
3. Split Sample Food/Split Sample Drinking Water	Exposures of an individual or population via ingestion.	TEAM study [j]	Same as above.
4. Skin Patch Samples	Dermal exposure of an individual or population	Pesticide Applicator Survey [k]	(1) Same as above. (2) Skin penetration.
C. For Use in Exposure Estimation from Reconstructed Dose:			
1. Breath	Total internal dose for individuals or population (usually indicative of relatively recent exposures)	Measurement of volatile organic chemicals (VOCs), alcohol. (Usually limited to volatile compounds)	(1) Relationship between individuals and population; exposure history (i.e., steady-state or not) pharmacokinetics (chemical half-life), possible storage reservoirs within the body. (2) Relationship between breath content and body burden.
2. Blood	Total internal dose for individuals or population (may be indicative of either relatively recent exposures to fat-soluble organics or long term body burden for metals)	Lead studies, pesticides, heavy metals (usually best for soluble compounds, although blood lipid analysis may reveal lipophilic compounds)	(1) Same as above.

			(2) Relationship between blood content and body burden.
3. Adipose	Total internal dose for individuals or population (usually indicative of long-term averages for fat-soluble organics).	NHATS,[l] dioxin studies, PCBs (usually limited to lipophilic compounds)	1) Same as above.
			(2) Relationship between adipose content and body burden.
4. Nails, Hair	Total internal dose for individuals or population (usually indicative of past exposure in weeks to months range; can sometimes be used to evaluate exposure patterns)	Heavy metal studies (usually limited to metals)	(1) Same as above.
			(2) Relationship between nails, hair content and body burden.
5. Urine	Total internal dose for individuals or population (usually indicative of elimination rates); time from exposure to appearance in urine may vary, depending on chemical	Studies of tetrachloroethylene[m] and trichloroethylene[n]	(1) Same as above.
			(2) Relationship between urine content and body burden.

22911** ***4.2.1. Concentration Measurements in Environmental Media

Measured concentration data can be generated for the exposure assessment by a new field study, or by evaluating concentration data from completed field study results and using them to estimate concentrations. Media measurements taken close to the point of contact with the individual(s) in space and time are preferable to measurements far removed geographically or temporally. As the distance from the point of contact increases, the certainty of the data at the point of contact usually decreases, and the obligation for the assessor to show relevance of the data to the assessment at hand becomes greater. For example, an outdoor air measurement, no matter how close it is taken to the point of contact, cannot by itself adequately characterize indoor exposure.

Concentrations can vary considerably from place to place, seasonally, and over time due to changing emission and use patterns. This needs to be considered not only when designing studies to collect new data, but especially when evaluating the applicability of existing measurements as estimates of exposure concentrations in a new assessment. It is a particular concern when the measurement data will be used to extrapolate to long time periods such as a lifetime. Transport and dispersion models are frequently used to help answer these questions.

The exposure assessor is likely to encounter several different types of measurements. One type of measurement used for general indications and trends of concentrations is outdoor fixed-location monitoring. This measurement is used by EPA and other

groups to provide a record of pollutant concentration at one place over time. Nationwide air and water monitoring programs have been established so that baseline values in these environmental media can be documented. Although it is not practical to set up a national monitoring network to gather data for a particular exposure assessment, the data from existing networks can be evaluated for relevance to an exposure assessment. These data are usually somewhat removed, and often far removed, from the point of contact. Adapting data from previous studies usually presents challenges similar to those encountered when using network data. If new data are needed for the assessment, studies measuring specific chemicals at specific locations and times can be conducted.

Contaminant concentrations in indoor air can vary as much or more than those in outdoor air. Consequently, indoor exposure is best represented by measurements taken at the point of contact. However, because pollutants such as carbon monoxide can exhibit substantial indoor penetration, indoor exposure estimates should consider potential outdoor as well as indoor sources of the contaminant(s) under evaluation.

Food and drinking water measurements can also be made. General characterization of these media, such as market basket studies (where representative diets are characterized), shelf studies (where foodstuffs are taken from store shelves and analyzed), or drinking water quality surveys, are usually far removed from the point of contact for an individual, but may be useful in evaluating exposure concentrations over a large population. Closer to the point of contact would be measurements of tap water or foodstuffs in a home, and how they are used. In evaluating the relevance of data from previous studies, variations in the distribution systems must be considered as well as the space-time proximity.

Consumer or industrial product analysis is sometimes done to characterize the concentrations of chemicals in products. The formulation of products can change substantially over time, similar products do not ***22912** necessarily have similar formulations, and regional differences in product formulation can also occur. These should be considered when determining relevance of extant data and when setting up sampling plans to gather new data.

Another type of concentration measurement is the microenvironmental measurement. Rather than using measurements to characterize the entire medium, this approach defines specific zones in which the concentration in the medium of interest is thought to be relatively homogenous, then characterizes the concentration in that zone. Typical microenvironments include the home or parts of the home, office, automobile, or other indoor settings. Microenvironments can also be divided into time segments (e.g., kitchen-day, kitchen-night). This approach can produce measurements that are closely linked with the point of contact both in location and time, especially when new data are generated for a particular exposure assessment. The more specific the microenvironment, however, the greater the burden on the exposure assessor to establish that the measurements are representative of the population of interest. Adapting existing data bases in this area to a particular exposure assessment requires the usual evaluation discussed throughout this section.

The concentration measurement that provides the closest link to the actual point of contact uses personal monitoring, which is discussed in section 4.3.

4.2.2. Use of Models for Concentration Estimation

If concentrations in the media cannot be measured, they can frequently be estimated indirectly by using related measurements and models. To accomplish this, source and fate information are usually needed. Source characterization data are used as input to transport and transformation models (environmental fate models). These models use a combination of general relationships and situation-specific information to estimate concentrations. In exposure assessments, mathematical models are used extensively to calculate environmental fate and transport, concentrations of chemicals in different environmental media, the distribution of concentrations over space and time, indoor air levels of chemicals, concentrations in foods, etc. In determining the relevance of this type of model for estimating concentrations, the same rules apply as for the measurements of concentrations discussed in the previous section. When concentrations in the media are available, models can be used to interpolate concentrations between measurements. Because models rely on indirect measurements and data remote from the point of contact, statistically valid

analytical measurements take precedence when discrepancies arise. When it is necessary to estimate contributions of individual sources to overall concentrations, models are commonly used.

Source characterization measurements usually determine the rate of release of chemicals into the environment from a point of emission such as an incinerator, landfill, industrial facility, or other source. Often these measurements are used to estimate emission factors, or a relationship between releases and facility operations. Since emission factors are usually averages over time, the assessor must determine whether given emission factors from previous work are relevant to the time specificity and source type needed for the exposure assessment. Generally, emission factors are more useful for long-term average emission calculations, and become less useful when applied to intermittent or short-term exposures.

Environmental fate measurements can be either field measurements (field degradation studies, for example) or laboratory measurements (partition coefficients, hydrolysis, or biodegradation rates, etc.). Approximations for these can sometimes also be calculated (Lyman et al., 1982).

Environmental fate models calculate estimated concentrations in media that in turn are linked to the concentrations at the point of contact. The use of estimated properties or rates adds to the uncertainty in the exposure concentration estimate. When assessors use these methods to estimate exposures, uncertainties attributable to the model and the validation status of the model must be clearly discussed in the uncertainty section (see discussion in section 6).

4.2.3. Selection of Models for Environmental Concentrations

Selection of an appropriate model is essential for successful simulation of chemical concentrations. In most cases assessors will be able to choose between several models, any of which could be used to estimate environmental concentrations. There is no right model; there may not even be a best model. There are, however, several factors that will help in selecting an appropriate model for the study. The assessor should consider the objectives of the study, the technical capabilities of the models, how readily the models can be obtained, and how difficult each is to use (U.S. EPA, 1987b, 1988f, 1991b).

The primary consideration in selecting a model is the objective of the exposure assessment. The associated schedule, budget, and other resource constraints will also affect model selection options. Models are available to support both screening-level and detailed, site-specific studies. Screening models can provide quick, easy, and cost-effective estimates of environmental concentrations. They can support data collection efforts at the site by indicating the required level of detection and quantification and the locations where chemical concentrations are expected to be highest. They are also used to interpolate chemical concentrations between measurements. Where study objectives require the best estimates of spatial and temporal distributions of chemicals, more sophisticated models are available. These models require more and better data to characterize the site, and therefore site-specific data may be needed in order to use them.

The technical capabilities of a model are expressed in its ability to simulate site-specific contaminant transport and transformation processes. The model must be able to simulate the relevant processes occurring within the specified environmental setting. It must adequately represent the physical setting (e.g., the geometric configuration of hydrogeological systems, river widths and depths, soil profiles, meteorological patterns, etc.) and the chemical transformation processes. Field data from the area where doses are to be estimated are necessary to define the input parameters required to use the models. In cases in which these data are not available, parameter values representative of field conditions should be used as defaults. Assumptions of homogeneity and simplification of site geometry may allow use of simpler models.

In addition, it is important to thoroughly understand the performance characteristics of the model used. This is especially true with regard to the more complex models. Detailed models can be quite complex with a large number of input variables, outputs, and computer-related requirements.

4.3. Estimating Duration of Contact

As discussed in section 2, the duration of contact is linked to a particular exposure concentration to estimate exposure. Depending on the purpose of the assessment and the confidence ***22913** needed in the accuracy of the final estimate, several approaches for obtaining estimates of duration of contact can be used.

Ideally, the time that the individual is in contact with a chemical would be observed and recorded, and linked to the concentrations of the chemical during those time segments. Although it is sometimes feasible to do this (by point-of-contact measurement, see section 4.1.), many times it is not. In those cases, as in concentration characterization, the duration of contact must be estimated by using data that may be somewhat removed from the actual point of contact, and assumptions must be made as to the relevance of the data.

It is common for the estimate of duration of contact at a given concentration to be the single largest source of uncertainty in an exposure assessment. [FN24] The exposure assessor, in developing or selecting data for making estimates of duration of contact, must often assume that the available data adequately represent exposure.

4.3.1. Observation and Survey Data

Observation and recording of activities, including location-time data, are likely to be the types of data collection closest to the point of contact. This can be done by an observer or the person(s) being evaluated for exposure, and can be done for an individual, a population segment, or a population. The usual method for obtaining these data for population segments or populations is survey questionnaires. Surveys can be performed as part of the data-gathering efforts of the exposure assessment, or existing survey data can be used if appropriate.

There are several approaches used in activity surveys, including diaries, respondent or third-party estimates, momentary sampling, videomonitoring, and behavioral meters. The diary approach, probably the most powerful method for developing activity patterns, provides a sequential record of a person's activities during a specified time period. Typical time-diary studies are done across a day or a week. Diary forms are designed to have respondents report all their activities and locations for that period. Carefully designed forms are especially important for diary studies to ensure that data reported by each individual are comparable. The resulting time budget is a sample of activity that can be used to characterize an individual's behavior, activities, or other features during the observation period. Sequential activity monitoring forms the basis of an activity profile.

Several studies have demonstrated the reliability of the diary method in terms of its ability to produce similar estimates. One study (Robinson, 1977) found a 0.85 correlation between diary estimates using the yesterday and tomorrow approaches and a 0.86 correlation between overall estimates. However, no definitive study has established the validity of time-diary data.

Questionnaires are used for direct questions to collect the basic data needed. Questionnaire design is a complex and subtle process, and should only be attempted with the help of professionals well-versed in survey techniques. A useful set of guidelines is provided in the Survey Management Handbook (U.S. EPA, 1984b).

Respondent estimates are the least expensive and most commonly used questionnaire alternative. Respondents are simply asked to estimate the time they spend at a particular activity. Basically, the question is, how many hours did you spend doing this activity (or in this location or using a certain product)? In exposure studies, respondents may be asked how often they use a chemical or product of interest or perform a specific activity. These data are less precise and likely to be somewhat less accurate than a carefully conducted diary approach.

At a less demanding level, respondents may be asked whether their homes contain items of interest (pesticides, etc.). Since this information is not time-of-activity data, it is more useful in characterizing whether the chemical of interest is present. It does, however, give the assessor some indication that use may occur.

Estimates from other respondents (third parties) use essentially the same approach, except that other informants respond for that individual. Here the question is how many hours per week does the target person spend doing this activity?

Momentary (beeper) sampling or telephone-coincidental techniques ask respondents to give only brief reports for a specific moment — usually the moment the respondent's home telephone or beeper sounds. This approach is limited to times when people are at home or able to carry beepers with them.

Methods that use behavioral meter or monitoring devices are probably the most expensive approach, since they require the use or development of equipment, respondent agreement to use such equipment, and technical help to install or adjust the equipment.

The Exposure Factors Handbook (U.S. EPA, 1989c) contains a summary of published data on activity patterns along with citations. Note that the summary data and the mean values cited are for the data sets included in the Handbook, and may or may not be appropriate for any given assessment.

4.3.2. Developing Other Estimates of Duration of Contact

When activity surveys cannot be used to estimate duration of contact, it may be estimated from more indirect data. This is the least expensive and most commonly used approach for generating estimates of duration of contact; it is also the least accurate. But for some situations, such as assessing the risk to new chemicals being introduced into the marketplace or in assessing future possible uses of contaminated sites, it is the only approach that can be used.

In general, the methods used to make these estimates fall into two areas: (1) those where the time it takes to perform an activity is itself estimated, and (2) those where an average duration of contact is estimated by combining the time of a unit activity with data on the use of a product or commodity.

Methods that try to estimate the time of a particular activity include general time-and-motion studies that might be adapted for use in an exposure assessment, general marketing data which include time of use, anecdotal information, personal experience, and assumptions about the amount of time it takes to perform an activity.

Methods that estimate average times for activities from product or commodity use usually interpret data on product sales or marketing surveys, water use, general food sales, etc. Information on use can be combined with an estimate of the number of persons using the product to estimate the average consumption of the product. If an estimate of the duration of contact with one unit (product, gallon of water, etc.) can be made, this can then be multiplied by the average number of units consumed to arrive at an estimate of average duration of contact for each individual.

Duration-of-contact estimates based on data collected close to the actual point of contact are preferable to those based on indirect measurements; both of these are preferred to estimates based on assumptions alone. This hierarchy is ***22914** useful in both the data-gathering process and uncertainty analysis.

4.4. Obtaining Data on Body Burden or Biomarkers

Body burden or biomarker data denote the presence of the chemical inside the body of exposed individuals. In a reconstructive assessment, these data, in conjunction with other environmental monitoring data, may provide a better estimate of exposure.

A biomarker of exposure has been defined as an exogenous substance or its metabolite or the product of an interaction between a xenobiotic agent and some target molecule or cell that is measured in a compartment within an organism (NRC, 1989a). Examples of simple direct biomarkers include the chemical itself in body fluid, tissue, or breath. Measurable changes in the physiology of the organism can also constitute markers of exposure. Examples include changes in a particular enzyme synthesis and activity. The interaction of xenobiotic compounds with physiological receptors can produce measurable complexes which also serve as exposure biomarkers. Other markers of exposure include xenobiotic species adducted to protein or DNA, as well as a variety of genotoxicity endpoints, such as micronuclei and mutation. Some biomarkers are specific to a given chemical while others may result from exposure to numerous individual or classes of compounds.

Biomarker data alone do not usually constitute a complete exposure assessment, since these data must be associated with external exposures. However, biomarker data complement other environmental monitoring data and modeling activities in estimating exposure.

4.5. Obtaining Data for Pharmacokinetic Relationships

To estimate dose from exposure, one must understand the pharmacokinetics of the chemical of interest. This is particularly true when comparing risks resulting from different exposure situations. Two widely different exposure profiles for the same chemical may have the same integrated exposure (area under the curve), but may not result in the same internal dose due to variations in disposition of the chemical under the two profiles. For example, enzymes that normally could metabolize low concentrations of a chemical may be saturated when the chemical is absorbed in high doses, resulting in a higher dose delivered to target tissues. The result of these two exposures may even be a different toxicological endpoint, if pharmacokinetic sensitivities are severe enough.

An iterative approach, including both monitoring and modeling, is necessary for proper data generation and analysis. Data collection includes monitoring of environmental media, personal exposure, biomarkers, and pharmacokinetic data. It may involve monitoring for the chemical, metabolites, or the target biomarker. Monitoring activities must be designed to yield data that are useful for model formulation and validation. Modeling activities must be designed to simulate processes that can be monitored with available techniques. The pharmacokinetic data necessary for model development are usually obtained from laboratory studies with animals. The data are generated in experiments designed to estimate such model parameters as the time course of the process, absorption, distribution, metabolism, and elimination of the chemical. These data, and the pharmacokinetic models developed from them, are necessary to interpret field biomarker data.

4.6. Obtaining Data on Intake and Uptake

The Exposure Factors Handbook (U.S. EPA, 1989c) presents statistical data on many of the factors used in assessing exposure, including intake rates, and provides citations for the primary references. Some of these data were developed by researchers using approaches discussed in Section 4.2.1 (for example, Pao et al. (1982) used the diary approach in a study of food consumption). Intake factors included are:

- Drinking water consumption rates;

- Consumption rates for homegrown fruits, vegetables, beef, and dairy products;

- Consumption rates for recreationally caught fish and shellfish;

- Incidental soil ingestion rates;

- Pulmonary ventilation rates; and

- Surface areas of various parts of the human body.

The Exposure Factors Handbook is being updated to encompass additional factors and to include new research data on the factors currently covered. It also provides default parameter values that can be used when site-specific data are not available. Obviously, general default values should not be used in place of known, valid data that are more relevant to the assessment being done.

5. Using Data to Determine or Estimate Exposure and Dose

Collecting and assembling data, as discussed in the previous section, is often an iterative process. Once the data are assembled, inferences can be made about exposure concentrations, times of contact, and exposures to persons other than those for whom data are available. During this process, there usually will be gaps in information that can be filled by making a series of assumptions. If these gaps are in areas critical to the accuracy of the assessment, further data collection may be necessary.

Once an acceptable data set[FN25] is available, the assessor can calculate exposure or dose. Depending on the method used to quantify exposure, there are several ways to calculate exposure and dose. This chapter will discuss making inferences (section 5.1), assumptions (section 5.2), and calculations (section 5.3).

5.1. Use of Data in Making Inferences for Exposure Assessments

Inferences are generalizations that go beyond the information contained in a data set. The credibility of an inference is often related to the method used to make it and the supporting data. Anecdotal information is the source of one type of inference, but the assessor has only limited knowledge of how well one anecdote represents the realm of possibilities, so anecdotes as a basis for inference should be used only with considerable caution. Professional judgment is usually preferred to anecdotes assuming that it is based on experience representing a variety of conditions. Statistical inferences also are generalizations that go beyond the data set. They may take any of several forms (see any statistics textbook for examples), but unlike those described above, a statistical inference will usually include a measure of how certain it is. For that reason, statistical inferences are often preferable to anecdotes or professional judgment provided the data are shown to be relevant and adequate.

As discussed above, the primary use of data from exposure-related measurements is to infer more general information about exposure concentrations, contact times, exposures, or doses. For example, measured concentrations in a medium can be used to infer what the concentration might be at the point of contact, which may not have been measured directly. Point-of-contact measurement data for one group of people may be used to infer the ***22915** exposures of a similar group, or to infer what the exposures of the same group might be at different times.

In all cases, the exposure assessor must have a clear picture of the relationship between the data at hand and what is being characterized by inference. For example, surface water concentration data alone, although essential for characterizing the medium itself, are not necessarily useful for inferring exposures from surface water, since other information is necessary to complete the link between surface water and exposure. But the medium's characteristics (over space and time) can be used, along with the location and activities of individuals or populations, to estimate exposures. Samples taken for exposure assessment may be designed to characterize different aspects (or components) of exposure. For example, a sample taken as a point-of-contact exposure measurement is qualitatively different from a sample of an environmental medium or body fluid.

Different measurements taken under the general category of exposure-related measurements cannot necessarily all be used in the same way. The exposure assessor must explain the relationship between the sample data and the inferences or conclusions being drawn from them. In order to do this, data relevance, adequacy, and uncertainty must be evaluated.

5.1.1. Relevance of Data for the Intended Exposure Assessment

When making inferences from a data set, the assessor must establish a clear link between the data and the inference. When statistically based sampling is used to generate data, relevance is a function of how well the sample represents the medium or parameter being characterized. When planning data collection for an exposure assessment, the assessor can use information about the inferences that will be made to select the best measurement techniques. In many cases data are also available from earlier studies. The assessor must determine (and state) how relevant the available data are to the current assessment; this is usually easier for new data than for previously collected information.

5.1.2. Adequacy of Data for the Intended Assessment

Table 4-1 in the previous section illustrated how different types of measurements may be used to characterize a variety of concentrations, contact times, and intake or uptake parameters. Nevertheless, just because certain types of measurements generally can be used to make certain inferences, there is no guarantee that this can always be done. The adequacy of the data to make inferences is determined by evaluating the amount of data available and the accuracy of the data. Evaluation of the adequacy of data will ensure that the exposure assessment is conducted with data of known quality.

In general, inadequate data should not be used, but when it can be demonstrated that the inadequacies do not affect results, it is sometimes possible to use such data. In these cases, an explanation should be given as to why the inadequacies do not invalidate conclusions drawn from them. In some cases, even seriously inadequate or only partially relevant data may be the only data available, and some information may be gained from their consideration. It may not be possible to discard these data entirely unless better data are available. If these data are used, the uncertainties and resulting limitations of the inferences should be clearly stated. If data are rejected for use in favor of better data, the rationale for rejection should be clearly stated and the basis for retaining the selected data should be documented. QA/QC considerations are paramount in considerations of which data to keep and which to discard.

Outliers should not be eliminated from data analysis procedures unless it can be shown that an error has occurred in the sample collection or analysis phases of the study. Very often outliers provide much information to the study evaluators. Statistical tests such as the Dixon test exist to determine the presence of outliers (Dixon, 1950, 1951, 1953, 1960).

5.1.2.1. Evaluation of Analytical Methods

Analytical methods are evaluated in order to develop a data set based on validated analytical methods and appropriate QA/QC procedures. In a larger sense, analytical methods can be evaluated to determine the strength of the inferences made from them, and in turn, the confidence in the exposure assessment itself. Consequently, it is just as important to evaluate analytical methods used for data generated under another study as it is to evaluate the methods used to generate new data.

The EPA has established extensive QA/QC procedures (U.S. EPA, 1980). Before measurement data are used in the assessment, they should be evaluated against these procedures and the results stated. If this is not possible, the assessor must consider what effect the unknown quality of the data has on the confidence placed on the inferences and conclusions of the assessment.

5.1.2.2. Evaluation of Analytical Data Reports

An assortment of qualifiers is often used in data validation. These qualifiers are used to indicate QA/QC problems such as uncertain chemical identity or difficulty in determining chemical concentration. Qualifiers usually appear on a laboratory analysis report as a letter of the alphabet next to the analytical result. Some examples of data qualifiers, applied by U.S. EPA regional reviewers for Contract Laboratory Program (CLP) data include:

B (blank)—the analyte was found in blank samples;

J (judgment)—the compound is present but the concentration value is estimated;

U (undetected)—the chemical was analyzed for but not detected at the detection limit;

R (reject)—the quality control indicates that the data are unusable.

The exposure assessor may contact the laboratory or the person who validated the data if the definitions of the qualifiers are unclear. Since the exposure assessment is only as good as the data supporting it, it is essential to interpret these types of data properly to avoid misrepresenting the data set or biasing the results.

5.1.2.2.1. Evaluation of Censored Data Sets

Exposure assessors commonly encounter data sets containing values that are lower than limits deemed reliable enough to report as numerical values (i.e., quantification limits (QL)). These data points are often reported as nondetected and are referred to as censored. The level of censoring is based on the confidence with which the analytical signal can be discerned from the noise. While the concentration may be highly uncertain for substances below the reporting limit, it does not necessarily mean that the concentration is zero. As a result the exposure assessor is often faced with the problem of having to estimate values for the censored data. Although a variety of techniques have been described in the literature, no one procedure is appropriate under all exposure assessment circumstances; thus, the exposure assessor will need to decide on the appropriate method for a given situation. Techniques for analyzing censored data sets can be grouped into three classes (Helsel, 1990): Simple substitution methods, distributional methods, and robust methods.

Simple substitution methods, the most commonly encountered technique, ***22916** involve substitution of a single value as a proxy for each nondetected data value. Frequently used values have included zero, the QL, QL/2, and

QL/§2.[FN26]

In the worst-case approach, all nondetects are assigned the value of the QL, which is the lowest level at which a chemical may be accurately and reproducibly quantitated. This approach biases the mean upward. On the other hand, assigning all nondetects the value of zero biases the mean downward. The degree to which the results are biased will depend on the relative number of detects and nondetects in the data set and the difference between the reporting limit and the measured values above it.

In an effort to minimize the obvious bias introduced by choosing either zero or the QL as the proxy, two other values have been suggested, i.e., QL/2 and QL/§2. Assigning all nondetects as QL/2 (Nehls and Akland, 1973) assumes that all values between the QL and zero are equally likely; therefore, an average value would result if many samples in this range were measured. Hornung and Reed (1990) discuss the merits of assigning a value of QL/§2 for nondetects rather than QL/2 if the data are not highly skewed (geometric standard deviation < 3.0); otherwise they suggest using QL/2.

Based on reported analyses of simulated data sets that have been censored to varying degrees (Gleit, 1985; Horning and Reed, 1990; Gilliom and Helsel, 1986; Helsel and Cohn, 1988), it can be concluded that substitution with QL/2 or QL/§ 2 for nondetects will be adequate for most exposure assessments provided that the nondetects do not exceed 10% to 15% of the data set or the data are not highly skewed. When such situations arise, the additional effort to make use of more sophisticated methods as discussed below is recommended. On the other hand, the exposure assessor may encounter situations in which the purpose of the assessment is only to serve as a screen to determine if a health concern has been triggered or if a more detailed study is required, then assigning the value of the QL to all nondetect values can be justified. If, when using this conservative approach, no concern is indicated, then no further effort is warranted. This method cannot be used to prove an unacceptable risk exists, and any exposure values calculated using this method should be caveated and clearly presented as “less than” estimates.

Distributional methods, unlike simple substitution methods, make use of the data above the reporting limit to extrapolate below it. One such technique is the use of log-probit analysis. This approach assumes a lognormal probability distribution of the data. In the probit analysis, the detected values are plotted on the scale and the nondetectable values are treated as unknowns, but their percentages are accounted for. The geometric mean is determined from the 50th percentile. As discussed by Travis and Land (1990), limitations of the method have been pointed out, but it is less biased and more accurate than the frequently used substitution methods. This method is useful in situations where the data set contains enough data points above the reporting limit to define the distribution function for the exposure values (i.e., lognormal) with an acceptable degree of confidence. The treatment of the nondetectable samples is then straightforward, assuming the nondetectable samples follow the same distribution as those above the reporting limit.

Robust methods have an advantage over distributional methods in so far as they do not assume that the data above the reporting limit follow a defined distribution (e.g., lognormal) and they are not subject to transformation bias in going from logarithms

back to original units. Gilliom and Helsel (1986) have described the application of several approaches to data sets of varying sample size and degree of censoring. These methods involve somewhat more data manipulation than the log-probit method discussed earlier in this Section, but they may be more appropriate to use when the observed data do not fit a lognormal distribution. Generally, these methods only assume a distributional form for the censored values rather than the entire data set, and extrapolation from the uncensored data is done by using regression techniques.

In summary, when dealing with censored data sets, a variety of approaches can be used by the exposure assessor. Selecting the appropriate method requires consideration of the degree of censoring, the goals of the exposure assessment, and the accuracy required. Regardless of the method selected, the assessor should explain the choice made and how it may affect the summary statistics. Presenting only the summary statistics developed by one of these methods should be avoided. It is always useful to include a characterization of the data by the percentage of detects and nondetects in language such as "in 37% of the samples the chemical was detected above the quantitation limit; of these 37%, the mean concentration was 47 ppm, the standard deviation was 5 ppm, etc."

5.1.2.2.2. Blanks and Recovery

Blank samples should be compared with the results from their corresponding samples. When comparing blank samples to the data set, the following rules should be followed (outlined in section 3):

- Sample results should be reported only if the concentrations in the sample exceed 10 times the maximum amount detected in the blank for common laboratory contaminants. Common laboratory contaminants include: acetone, 2-butanone (or methyl ethyl ketone), methylene chloride, toluene, and phthalate esters.

- Sample results should be reported only if the concentrations in the sample exceed 5 times the maximum amount detected in a blank for chemicals that are not common laboratory contaminants.

In general, for other types of qualifiers, the exposure assessor may include the data with qualifiers if they indicate that a chemical's concentration is uncertain, but its identity is known. If possible, the uncertainties associated with the qualifier should be noted.

Chemical spike samples that show abnormally high or low recoveries may result in qualified or rejected data. Assessors should not use rejected data; these samples should be treated as if the samples were not taken, since the resulting data are unreliable. Typically, analytical results are reported from the laboratory unadjusted for recovery, with the recovery percentage also reported. The assessor must determine how these data should be used to calculate exposures. If recovery is near 100%, concentrations are not normally adjusted (although the implicit assumption of 100% recovery should be mentioned in the uncertainty section). However, the assessor may need to adjust the data to account for consistent, but abnormally high or low recovery. The rationale for such adjustments should be clearly explained; individual program offices may develop guidance on the acceptable percent recovery limits before data adjustment or rejection is necessary.

5.1.3. Combining Measurement Data Sets from Various Studies

Combining data from several sources into a single data set must be done cautiously. The circumstances under which each set of data was collected (target population, sampling design, ***22917** location, time, etc.) and quality (precision, accuracy, representativeness, completeness, etc.) must be evaluated. Combining summary statistics of the data sets (e.g., means) into a single set may be more appropriate than combining the original values. Statistical methods are available for combining results from individual statistical tests. For example, it is sometimes possible to use several studies with marginally significant results to justify an overall conclusion of a statistically significant effect.

The best way to report data is to provide sufficient background information to explain what was done and why, including clear documentation of the source of the data and including any references.

5.1.4. Combining Measurement Data and Modeling Results

Combining model results with measurement data must be done with an understanding of how this affects the resulting inferences, conclusions, or exposure estimates. If model results are used in lieu of additional data points, they must be evaluated for accuracy and representativeness as if they were additional data, and the uncertainty associated with this data combination must be described fully, as discussed in section 5.1.3.

On the other hand, measurement data are often used within the context of the model itself, as calibration and verification points, or as a check on the plausibility of the model results. If measurements are used within the model, the uncertainty in these measurements affects the uncertainty of the model results, and should be discussed as part of the uncertainty of the model results.

5.2. Dealing With Data Gaps

Even after supplementing existing measurement data with model results, there are likely to be gaps in the information base to be used for calculating exposures and doses. There are several ways to deal with data gaps. None are entirely satisfactory in all situations, but they can be useful depending on the purposes of the assessment and the resources available. The following options can be used singly or in combination:

- New data can be collected. This may be beyond the reach of the assessor's resources, but promises the best chance for getting an accurate answer. It is most likely to be a useful option if the new data are quick and easy to obtain.

- The scope of the assessment can be narrowed. This is possible if the data gaps are in one pathway or exposure route, and the others have adequate data. It may be a viable option if the pathway or route has values below certain bounds, and those bounds are small relative to the other pathways being evaluated. This is unlikely to be satisfactory if the part of the assessment deleted is an important exposure pathway or route and must be evaluated.

- Conservative[FN27] assumptions can be used. This option is useful for establishing bounds on exposure parameters, but limits how the resulting exposures and doses can be expressed. For example, if one were to assume that a person stays at home 24 hours a day as a conservative assumption, and used this value in calculations, the resulting contact time would have to be expressed as an upper limit rather than a best estimate. When making conservative assumptions, the assessor must be aware of (and explain) how many of these are made in the assessment, and how they influence the final conclusions of the assessment.[FN28]

- Models may be used in some cases, not only to estimate values for concentrations or exposures, but also to check on how conservative certain assumptions are.

- Surrogate data may also be used in some cases. For example, for pesticide applicators' exposure to pesticides, the EPA Office of Pesticide Programs (U.S. EPA, 1987d) assumes that the general parameters of application (such as the human activity that leads to exposure) are more important than the properties of the pesticide in determining the level of exposure.[FN29] This option assumes that surrogate data are available and that the differences between the chemical and the surrogate are small. If a clear relationship can be determined between the concentration of a chemical and the surrogate (usually termed an indicator chemical) in a medium, this relationship could also be used to fill data gaps. In any case, the strength and character of the relationship between the chemical and the surrogate must be explained.

- Professional judgment can be used. The utility of this option depends on the confidence placed in the estimate. Expert opinion based on years of observation of similar circumstances usually carries more weight than anecdotal information. The assessor must discuss the implications of these estimates in the uncertainty analysis.

5.3. Calculating Exposure and Dose

Depending on the approach used to quantify exposure and dose, various types of data will have been assembled. In calculating exposures and doses from these data, the assessor needs to direct attention specifically to certain aspects of the data. These aspects include the use of short-term data for long-term projections, the role of personal monitoring data, and the particular way the data might be used to construct scenarios. Each of these aspects is covered in turn below.

5.3.1. Short-Term Versus Long-Term Data for Population Exposures

Short-term data, for the purposes of this discussion, are data representing a short period of time measured (or modeled) relative to the time period covered in the exposure assessment. For example, a 3-day sampling period would produce short-term data if the exposure assessment covered a period of several years to a lifetime. The same 3-day sampling period would not be considered short-term if the assessment covered, say, a few days to a week.

Short-term data can provide a snapshot of concentrations or exposures during that time, and an inference must be made about what that means for the longer term if the exposure assessment covers a long period. The assessor must determine how well the short-term data represent the longer period.

Even when short-term population data are statistically representative (i.e., they describe the shape of the distribution, the mean, and other statistics), use of these short-term data to infer long-term exposures and risks must be done with caution. Using short-term data to estimate long-term exposures has a tendency to underestimate the number of people exposed, but to overestimate the exposure levels to the upper end of the distribution, even though the mean will remain the same.[FN30] Both ***22918** concentration variation at a single point and population mobility will drive the estimates of the levels of exposure for the upper tail of the distribution toward the mean. If short-term data are used for long-term exposure or dose estimates, the implications of this on the estimated exposures must be discussed in the assessment. Likewise, use of long-term monitoring data for specific short-term assessments can miss significant variations due to short-term conditions or activities. Long-term data should be used cautiously when estimating short-term exposures or doses, and the implications should be discussed in the assessment.

5.3.2. Using Point-of-Contact Data to Calculate Exposure and Dose

Point-of-contact exposure assessments are often done with the intent of protecting the individuals, often in an occupational setting. When exposures are being evaluated to determine whether they exceed an action level or other benchmark, point-of-contact measurements are the most relevant data.

Typically, point-of-contact measurement data reflect exposures over periods of minutes to perhaps a week or so. For individuals whose exposures have been measured, these data may be used directly as an indication of their exposure during the sampling period, provided they are of adequate quality, measure the appropriate chemical, and actually measure exposure while it occurs. This is the only case in which measurement data may be used directly as exposure data.

When using point-of-contact measurements, even with statistically based data, several inferences still must be made to calculate exposure or dose:

- Inferences must be made to apply short-term measurements of exposure to long-term estimates of exposure; these are subject to the cautions outlined in section 5.3.1.

- Inferences must be made about the representativeness of the individual or persons sampled for the individual or population segment for which the assessment is done.

- Inferences must be made about the factors converting measured exposure to potential or internal dose for use in a risk assessment.

- If the assessment requires it, inferences must be made about the relationship between the measured chemical exposures and the presence and relative contribution of various sources of the chemical.

5.3.3. The Role of Exposure Scenarios in Exposure Assessment

Exposure scenarios have several functions in exposure and risk assessments. First, they are calculational tools to help the assessor develop estimates of exposure, dose, and risk. Whatever combination of data and models is used, the scenario will help the assessor to picture how the exposure is taking place, and will help organize the data and calculations. Second, the estimates derived from scenarios are used to develop a series of exposure and risk descriptors, which were discussed in section 2.3. Finally, exposure scenarios can often help risk managers make estimates of the potential impact of possible control actions. This is usually done by changing the assumptions in the exposure scenario to the conditions as they would exist after the contemplated action is implemented, and reassessing the exposure and risk. These three uses of exposure assessments are explained in sections 5.3.3.1, 5.3.3.2, and 5.3.3.3, respectively.

An exposure scenario is the set of information about how exposure takes place. An exposure scenario generally includes facts, data, assumptions, inferences, and sometimes professional judgment about the following:

- The physical setting where exposure takes place (exposure setting)

- The exposure pathway(s) from source(s) to exposed individual(s) (exposure pathways)

- The characterization of the chemical, i.e., amounts, locations, time variation of concentrations, source strength, environmental pathways from source to exposed individuals, fate of the chemical in the environment, etc. (characterization of the chemical)

- Identification of the individual(s) or population(s) exposed, and the profile of contact with the chemical based on behavior, location as a function of time, characteristics of the individuals, etc. (characterization of the exposed population)

- If the dose is to be estimated, assumptions about the transfer of the chemical across the boundary, i.e., ingestion rates, respiration rates, absorption rates, etc. (intake and uptake rates)

It usually is necessary to know whether the effect of concern is chronic, acute, or dependent on a particular exposure time pattern.

The risk characterization, the link between the development of the assessment and the use of the assessment, is usually communicated in part to the risk manager by means of a series of “risk descriptors,” which are merely different ways to describe the risk. Section 2.3 outlined two broad types of descriptors: individual risk descriptors and population risk descriptors, with several variations for each. To the exposure or risk assessor, different types of risk information require different risk descriptors and different analyses of the data. The following paragraphs discuss some of the aspects of developing and using exposure scenarios in various functions for exposure assessment.

5.3.3.1. Scenarios as a Means to Quantify Exposure and Dose

When using exposure scenario evaluation as a means to quantify exposure and dose, it is possible to accumulate a large volume of data and estimated values, and both the amount and type of information can vary widely. The exposure scenario also contains the information needed to calculate exposure, since the last three bullets above (section 5.3.3) are the primary variables in most exposure and dose equations.

As an example, consider Equation 2-5, the equation for lifetime average daily potential dose ($LADD_{pot}$). This equation uses the variables of exposure concentration (C), intake rate (IR), and exposure duration (ED) as the three primary variables. Body weight (BW) and averaging time (AT) (in this case, lifetime, LT) are not related to the exposure or dose per se, but are averaging variables used to put the resulting dose in convenient units of lifetime average exposure or dose per kg of body weight.

In looking at the three primary variables (C, IR, and ED), the exposure assessor must determine what value to use for each to solve the equation. In actuality, the information available for a variable like C may consist of measurements of various points in an environmental medium, source and fate characterizations, and model results. There will be uncertainty in the values for C for any individual; there will also be variability among individuals. Each ***22919** of these primary variables will be represented by a range of values, even though at times, the boundaries of this range will be unknown. How exposure or dose is calculated depends on how these ranges are treated.

In dealing with these ranges in trying to solve the equation for LADD, the assessor has at least two choices. First, statistical tools, such as the Monte Carlo analysis, can be used to enter the values as frequency distributions, which results in a frequency distribution for the LADD. This is an appropriate strategy when the frequency distributions are known for C, IR, and ED (or for the uptake analogs, C, K_p, SA, and ED introduced in section 2), and when these variables are independent.

A second approach is to select or estimate discrete values from the ranges of each of the variables and use these values to solve the LADD equation. This approach usually results in a less certain estimate, but may be easier to do. Which values are used determines how the resulting estimate will be described. Several terms for describing such estimates are discussed in section 5.3.3.2.

Since exposure to chemicals occurs through a variety of different pathways, contact patterns, and settings, sufficient perspective must be provided to the users of the assessment (usually risk managers) to help them make an informed decision. Providing this perspective and insight would be relatively straightforward if complete and accurate information were known about the exposure, dose, and risk for each and every person within the population of interest. In this hypothetical situation, these individual data could actually be arrayed next to the name of each person in the population, or the data could be compiled into frequency distribution curves. From such distributions, the average, median, maximum, or other statistical values could easily be read off the curves and presented to the risk manager. In addition, accurate information could be provided about how many persons are above certain exposure, dose, or risk levels as well as information about where various subgroups fall within the subject distribution.

Unfortunately, an assessor rarely has these kinds of data; the reality an assessor faces usually falls far short of this ideal. But it is precisely this kind of information about the distribution of exposure, dose, and risk that is needed many times by the risk assessor to characterize risk, and by the risk manager to deal with risk-related issues.

In the absence of comprehensive data, or if the scenario being evaluated is a possible future use or post-control scenario, an assessor must make assumptions in order to estimate what the distribution would look like if better data were available, or if the possible future use becomes a reality. Communicating this estimated distribution to the risk manager can be difficult. The assessor must not only estimate exposure, dose, and risk levels, but must also estimate where those levels might fall on the actual distributions or estimated distributions for potential future situations. To help communicate where on the distribution the estimate might fall, loosely defined terms such as reasonable worst case, worst case, and maximally exposed individual have been used by assessors. Although these terms have been used to help describe the exposure assessor's perceptions of where estimated exposures fall on the actual or potential distribution for the future use, the ad hoc nature of the historical definitions used has led to some inconsistency. One of the goals of these Guidelines is to promote greater consistency in the use of terms describing exposure and risk. 5.3.3.2. Exposure Scenarios and Exposure Estimators as Input to Risk Descriptors

As discussed in section 2.3, risk descriptors convey information about risk to users of that information, primarily risk managers. This information usually takes the form of answers to a relatively short set of questions, not all of which are applicable to all assessments. Section 5.3.5 provides more detail on how the exposure assessor's analysis leads to construction of the risk descriptors.

5.3.3.3. Exposure Scenarios as a Tool for Option Evaluation

A third important use for exposure scenarios is as a tool for evaluating proposed options for action. Risk managers often have a number of choices for dealing with environmental problems, from taking no action on one extreme to a number of different actions, each with different costs, on the other. Often the exposure scenarios developed as part of the baseline risk assessment provide a powerful tool to evaluate the potential reduction of exposure and risk for these various options, and consequently are quite useful in many cost-benefit analyses.

There are several additional related uses of exposure scenarios for risk managers. They may help establish a range of options for cleanup by showing the sensitivity of the risk estimates to the changes in assumed source or exposure levels. The exposure assessor can use the sensitivity analysis of the exposure scenario to help evaluate and communicate the uncertainty of the assumptions, and what can be done to reduce that uncertainty. Well-crafted and soundly based exposure scenarios may also help communicate risks and possible options to community groups.

Although it is beyond the scope of these Guidelines to detail the methods used for option evaluation and selection, the assessor should be aware of this potential use. Discussing strategy (and specific information needs) with risk managers is usually prudent before large resource expenditures are made in the risk assessment area.

5.3.4. General Methods for Estimating Exposure and Dose

A variety of methods are used to obtain estimates of dose necessary for risk characterization. These range from quick screening level calculations and rules of thumb to more sophisticated techniques. The technique to be used in a given case is a matter of the amount of information available and the purpose of the assessment. Several of the methods are outlined in the following sections.

Normally it is neither practical nor advisable to immediately develop detailed information on all the potential pathways, since not all may contribute significantly to the outcome of the assessment.[FN31] Rather, evaluation of the scenario is done in an iterative manner. First, screening or bounding techniques are used to ascertain which pathways are unimportant, then the information for the remaining pathways is refined, iteratively becoming more accurate, until the quantitative objectives of the assessment are met (or resources are depleted).

In beginning the evaluation phase of any assessment, the assessor should have a scenario's basic assumptions (setting, scope, etc.) well identified, one or more applicable exposure pathways defined, an equation for evaluating the exposure or dose for each of those exposure pathways, and the data and information requirements pertinent to solving the equations. Quality and quantity of data and information needed to substitute quantitative values or ***22920** ranges into the parameters of the exposure equation will often vary widely, from postulated assumptions to actual high-quality measurements. Many times, there are several exposure pathways identified within the scenario, and the quality of the data and information may vary for each.

A common approach to estimating exposure and dose is to do a preliminary evaluation, or screening step, during which bounding estimates are used, and then to proceed to refine the estimates for those pathways that cannot be eliminated as of trivial importance.

5.3.4.1. Preliminary Evaluation and Bounding Estimates

The first step that experienced assessors usually take in evaluating the scenario involves making bounding estimates for the individual exposure pathways. The purpose of this is to eliminate further work on refining estimates for pathways that are clearly not important.

The method used for bounding estimates is to postulate a set of values for the parameters in the exposure or dose equation that will result in an exposure or dose higher than any exposure or dose expected to occur in the actual population. The estimate of

exposure or dose calculated by this method is clearly outside of (and higher than) the distribution of actual exposures or doses. If the value of this bounding estimate is not significant, the pathway can be eliminated from further refinement.[FN32]

The theoretical upper bounding estimate (TUBE) is a type of bounding estimate that can be easily calculated and is designed to estimate exposure, dose, and risk levels that are expected to exceed the levels experienced by all individuals in the actual distribution. The TUBE is calculated by assuming limits for all the variables used to calculate exposure and dose that, when combined, will result in the mathematically highest exposure or dose (highest concentration, highest intake rate, lowest body weight, etc.). The theoretical upper bound is a bounding estimate that should, if the limits of the parameters used are known, ensure that the estimate is above the actual exposures received by all individuals in the population. It is not necessary to go to the formality of the TUBE to assure that the exposure or dose calculated is above the actual distribution, however, since any combination that results in a value clearly higher than the actual distribution can serve as a suitable upper bound.

The bounding estimate (a limit of individual exposure, dose or risk) is most often used only to eliminate pathways from further consideration. This is often done in screening-level assessments, where bounding estimates of exposure, dose, or risk provide a quick and relatively easy check on whether the levels to be assessed are trivial relative to a level that would cause concern. If acceptably lower than the concern level, then additional assessment work is not necessary.

Bounding estimates also are used in other types of assessments. They can be used for deregulation of chemicals when pathways or concentrations can be shown to present insignificant or de minimis risk. They can be used to determine whether more information is needed to determine whether a pathway is significant; if the pathway's significance cannot be ruled out by a bounding estimate, test data may be needed to refine the estimate.

There are two important points about bounding estimates. First, the only thing the bounding estimate can establish is a level to eliminate pathways from further consideration. It cannot be used to make a determination that a pathway is significant (that can only be done after more information is obtained and a refinement of the estimate is made), and it certainly cannot be used for an estimate of actual exposure (since by definition it is clearly outside the actual distribution). Second, when an exposure scenario is presented in an assessment, it is likely that the amount of refinement of the data, information, and estimates will vary by pathway, some having been eliminated by bounding estimates, some eliminated after further refinement, and others fully developed and quantified. This is an efficient way to evaluate scenarios. In such cases, bounding estimates must not be considered to be equally as sophisticated as an estimate of a fully developed pathway, and should not be described as such.

Experienced assessors can often eliminate some obvious pathways more or less by inspection as they may have evaluated these pathways many times before.[FN33] In these cases, the assessor must still explain why the pathway is being eliminated. For less experienced assessors, developing bounding estimates for all pathways is instructive and will be easier to defend.

5.3.4.2. Refining the Estimates of Exposure and Dose

For those pathways not eliminated by bounding estimates or judged trivial, the assessor will then evaluate the resulting exposure or dose. At this point, the assessor will make estimates of exposure or dose that are designed to fall on the actual distribution. The important point here is that unlike a bounding estimate, these estimates of exposure or dose should focus on points in the actual distribution. Both estimates of central tendency and estimates of the upper end of the distribution curve are useful in crafting risk descriptors.

Consider Equation 2-6 for the lifetime average daily potential dose ($LADD_{pot}$), an equation often used for linear, nonthreshold carcinogen risk models. The assessor will use the data, ranges of data, distributions of data, and assumptions about each of the factors needed to solve the equation for dose. Generally, both central estimates and high-end estimates are performed. Each of these estimates has uncertainty (perhaps unquantifiable uncertainty), and the better the quality and comprehensiveness of data used as input to the equation, the less uncertainty.

After solving the equation, the assessor will determine whether the uncertainty associated with the answer is sufficiently narrow to allow the risk descriptors to be developed (see section 3.4) and to answer satisfactorily the questions posed in the exposure assessment statement of purpose. Evaluating whether the data, uncertainty, risk descriptors, and answers to the questions are good enough is usually a joint responsibility of the risk assessor and the risk manager.

Should the estimates of exposure or dose have sufficiently narrow uncertainty, the assessor can then proceed to develop the descriptors and finish the assessment. If not, the data or assumptions used usually will have to be refined, if resources allow, in an attempt to bring the estimated exposure or dose closer to what the assessor believes are the actual values in the population. Refining the estimates usually requires that new data be brought into consideration [FN34]; this new ***22921** information can be other studies from the literature, information previously developed for another, related purpose that can be adapted, or new survey, laboratory, or field data. The decision about which particular parts of the information base to refine should be based both on which data will most significantly reduce the uncertainty of the overall exposure or dose estimate, and on which data are in fact obtainable either technologically or within resource constraints.

After refinement of the estimate, the assessor and risk manager again determine whether the estimates provided will be sufficient to answer the questions posed to an acceptable degree, given the uncertainties that may be associated with those estimates. Refinements proceed iteratively until the assessment provides an adequate answer within the resources available.

5.3.5. Using Estimates for Developing Descriptors

Risk assessors and risk managers are encouraged to explore a range of ways to describe exposure and risk information, depending on the purpose of the assessment and the questions for which the risk manager must have answers. Section 2.3 outlines a series of risk descriptors; in the sections below, these are discussed in the context of how an exposure assessor's analysis of the data would lead to various descriptors for risk.

5.3.5.1. Individual Exposure, Dose, and Risk

Questions about individual risk are an important component of any assessment, especially an estimate of the high end of the distribution. Section 5.3.4.1 indicated that bounding estimates are actually a useful but limited form of individual risk estimate, a form which is by definition beyond the highest point on the population distribution. This section deals with estimates that are actually on the distribution of exposure, dose, or risk.

There are several approaches for arriving at an individual risk estimate. Since calculation of risk involves using information from fields other than exposure assessment, the reader is advised to consult other Agency guidelines for more detailed discussions (e.g., U.S. EPA, 1986b, 1986c, 1988b, 1988c, 1991a). The uncertainty in the risk estimate will depend heavily on the quality of the information used. There are several steps in the process:

First, the question of unusual susceptibility of part of the population must be addressed. If equal doses result in widely different responses in two individuals, it may be necessary to consult with scientists familiar with the derivation of the dose-response relationship for the chemical in question in order to ascertain whether this is normal variability among members of a population. Normal variability should have been considered as part of the development of the dose-response relationship; unusual susceptibility may not have been. If such a highly susceptible subgroup can be identified, it is often useful to assess their risk separately from the general population. It will not be common, given the current data availability, to clearly identify such susceptible subgroups. If none can be identified, the default has usually been to assume the dose-response relationship applies to all members of the population being assessed. Where no information shows the contrary, this assumption may be used provided it is highlighted as a source of uncertainty.

Second, after the population or population segment can be represented by a single dose-response relationship, the appropriate dose for use in the dose-response relationship (absorbed/internal dose, potential dose, applied dose, effective dose) must be identified. For dose-response relationships based on administered dose in animal studies, potential dose will usually be the

human analogue. If the dose-response relationship is based on internal dose, then that is the most appropriate human dose. If the estimates of exposure and dose from the exposure assessment are in an inappropriate form (say, potential dose rather than internal dose), they must be converted before they are used for risk calculations. This may involve analysis of bioavailability, absorption rates as a function of form of the chemical and route, etc. If these data are not available, the default has been to assume the entire potential dose becomes the internal dose.[FN35] As more data become available concerning absorption for different chemicals, this conservative assumption may not always be the best, or even a credible, default. Whatever assumption is made concerning absorption (or the relationships among any of the different dose terms if used, for that matter), it should be highlighted in the uncertainty section.

Once the first two steps have been done, and the dose-response relationship and type of dose have been identified, the exposure and dose information needs to be put in the appropriate form. Ideally, this would be a distribution of doses of the appropriate type across the population or population subgroup of interest. This may involve converting exposures into potential doses or converting potential doses into internal, delivered, or biologically effective doses. Once this is accomplished, the high-end estimate of dose will often (but not always) lead fairly directly to the high-end estimate of risk. The method used to develop the high-end estimate for dose depends on the data available. Because of the skewed nature of exposure data, there is no exact formula that will guarantee an estimate will fall into this range in the actual population if only sparse data are available.

The high-end risk is a plausible estimate of the individual risk for those persons at the upper end of the risk distribution. The intent of this descriptor is to convey an estimate of risk in the upper range of the distribution, but to avoid estimates that are beyond the true distribution. Conceptually, high-end risk means risks above the 90th percentile of the population distribution, but not higher than the individual in the population who has the highest risk. This descriptor is intended to estimate the risks that are expected to occur in small but definable high-end segments of the subject population. The use of “above the 90th percentile” in the definition is not meant to precisely define the range of this descriptor, but rather to clarify what is meant conceptually by high end.

The high-end segments of the exposure, dose, and risk populations may represent different individuals. Since the location of individuals on the exposure, dose, and risk distributions may vary depending on the distributions of bioavailability, absorption, intake rates, susceptability, and other variables, a high exposure does not necessarily result in a high dose or risk, although logically one would expect a moderate to highly positive correlation among exposure, dose, and risk.

When the complete data on the population distributions of exposures and doses are available, and the significance of the factors above (bioavailability, etc.) are known to the ***22922** extent to allow a risk distribution to be constructed, the highend risk estimate can be represented by reporting risks at selected percentiles of the distributions, such as the 90th, 95th, or 98th percentile. When the complete distributions are not available, the assessor should conceptually target something above the 90th percentile on the actual distribution.

In developing estimates of high-end individual exposure and dose, the following conditions must be met:

- The estimated exposure or dose is on the expected distribution, not above the value one would expect for the person with the highest estimated risk in the population. This means that when constructing this estimate from a series of factors (environmental concentrations, intake rates, individual activities, etc.), not all factors should be set to values that maximize exposure or dose, since this will almost always lead to an estimate that is much too conservative.

- The combination of values assigned to the exposure and dose factors can be expected to be found in the actual population. In estimating high-end exposures or doses for future use or post-control scenarios, the criterion to be used should be that it is expected to be on the distribution provided the future use or control measure occurs.[FN36]

Some of the alternative methods for determining a high-end estimate of dose are:

- If sufficient data on the distribution of doses are available, take the value directly for the percentile(s) of interest within the high end. If possible, the actual percentile(s) should be stated, or the number of persons determined in the high end above the estimate, in order to give the risk manager an idea of where within the high end-range the estimate falls.

- If data on the distribution of doses are not available, but data on the parameters used to calculate the dose are available, a simulation (such as an exposure model or Monte Carlo simulation) can sometimes be made of the distribution. In this case, the assessor may take the estimate from the simulated distribution. As in the method above, the risk manager should be told where in the high-end range the estimate falls by stating the percentile or the number of persons above this estimate.

The assessor and risk manager should be cautioned that unless a great deal is known about exposures or doses at the high end of the distribution, simulated distributions may not be able to differentiate between bounding estimates and high-end estimates. Simulations often include low-probability estimates at the upper end that are higher than those actually experienced in a given population, due to improbability of finding these exposures or doses in a specific population of limited size, or due to nonobvious correlations among parameters at the high ends of their ranges.[FN37] Using the highest estimate from a Monte Carlo simulation may therefore overestimate the exposure or dose for a specific population, and it is advisable to use values somewhat less than the highest Monte Carlo estimated value if one is to defend the estimate as being within the actual population distribution and not above it.

Simulations using finite ranges for parameters will result in a simulated distribution with a calculable finite maximum exposure, and the maximum exposures calculated in repeated simulations will not exceed this theoretical maximum.[FN38] When unbounded default distributions, such as lognormal distributions, are used for input parameters to generate the simulated exposure distributions, there will not be a finite maximum exposure limit for the simulation, so the maximum value of the resulting simulated distribution will vary with repeated simulations. The EPA's Science Advisory Board (SAB) (U.S. EPA, 1992a) has recommended that values above a certain percentile in these simulations be treated as if they were bounding estimates, not estimates of high-end exposures (see Figure 5-1). The SAB noted that for large populations, simulated exposures, doses, and risks above the 99.9th percentile may not be meaningful when unbounded lognormal distributions are used as a default.

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***22923** Although the Agency has not specifically set policy on this matter, exposure assessors should observe the following caution when using simulated distributions. The actual percentile cutoff above which a simulation should be considered a bounding estimate may be expected to vary depending on the size of the population. Since bounding estimates are established to develop statements that exposures, doses, and risks are “not greater than . . .,” it is prudent that the percentile cutoff bound expected exposures for the size of the population being evaluated. For example, if there are 100 persons in the population, it may be prudent to consider simulated exposures above the 1 in 500 level or 1 in 1000 level (i.e., above the 99.5^{th} or 99.9^{th} percentile, respectively) to be bounding estimates. Due to uncertainties in simulated distributions, assessors should be cautious about using estimates above the 99.9^{th} percentile for estimates of high-end exposure regardless of the size of the population. The Agency or individual program offices may issue more direct policy for setting the exact cutoff value for use as high-end and bounding estimates in simulations.

- If some information on the distribution of the variables making up the exposure or dose equation (e.g., concentration, exposure duration, intake or uptake rates) is available, the assessor may estimate a value which falls into the high end by meeting the defining criteria of “high end”: An estimate that will be within the distribution, but high enough so that less than 1 out of 10 in the distribution will be as high. The assessor often constructs such an estimate by using maximum or near-maximum values for one or more of the most sensitive ***22924** variables, leaving others at their mean values. [FN39] The exact method used to calculate the estimate of high-end exposure or dose is not critical; it is very important that the exposure assessor explain why the estimate, in his or her opinion, falls into the appropriate range, not above or below it.

- If almost no data are available, it will be difficult, if not impossible, to estimate exposures or doses in the high end. One method that has been used, especially in screening-level assessments, is to start with a bounding estimate and back off the limits used until the combination of parameter values is, in the judgment of the assessor, clearly in the distribution of exposure or dose. Obviously, this method results in a large uncertainty. The availability of pertinent data will determine how easily and defensibly the high-end estimate can be developed by simply adjusting or backing off from the ultra conservative assumptions used in the bounding estimates. This estimate must still meet the defining criteria of "high end," and the assessor should be ready to explain why the estimate is thought to meet the defining criteria.

A descriptor of central tendency may be either the arithmetic mean risk (average estimate) or the median risk (median estimate), but should be clearly labeled as such. Where both the arithmetic mean and the median are available, but differ substantially, it is helpful to present both.

Exposure and dose profiles often fall in a skewed distribution that many times appears to be approximately lognormally distributed, although statistical tests for lognormality may fail. The arithmetic mean and the median are the same in a normal distribution, but exposure data are rarely normally distributed. As the typical skewness in the distribution increases, the exposure or dose distribution comes to resemble a lognormal curve where the arithmetic mean will be higher than the median. It is not unusual for the arithmetic mean to be located at the 75^{th} percentile of the distribution or higher. Thus, the arithmetic mean is not necessarily a good indicator of the midpoint (median, 50_{th} percentile) of a distribution.

The average estimate, used to describe the arithmetic mean, can be approximated by using average values for all the factors making up the exposure or dose equation. It does not necessarily represent a particular individual on the distribution, but will fall within the range of the actual distribution. Historically, this calculation has been referred to as the average case, but as with other ad hoc descriptors, definitions have varied widely in individual assessments.

When the data are highly skewed, it is sometimes instructive to approximate the median exposure or dose, or median estimate. This is usually done by calculating the geometric mean of the exposure or dose distribution, and historically this has often been referred to as the typical case, although again, definitions have varied widely. Both the average estimate and median estimate are measures of the central tendency of the exposure or dose distribution, but they must be clearly differentiated when presenting the results.

It will often be useful to provide additional specific individual risk information to provide perspective for the risk manager. This specific information may take the form of answers to what if questions, such as, what if a consumer should use this product without adequate ventilation? For the risk manager, these questions are likely to put bounds on various aspects of the risk question. For the assessor, these are much less complicated problems than trying to estimate baseline exposure or dose in an actual population, since the answers to these questions involve choosing values for various parameters in the exposure or risk equations and solving them for the estimate.

This type of risk descriptor is a calculation of risk to specific hypothetical or actual combinations of factors postulated within the exposure assessment. It is often valuable to ask and answer specific questions of the "what if" nature to add perspective to the risk assessment.

Each assessment may have none, one, or several of these specific types of descriptors. The answers to these questions might be a point estimate or a range, but are usually fairly simple to calculate. The answers to these types of postulated questions, however, do not directly give information about how likely that combination of values might be in the actual population, so there are some limits to the applicability of these descriptors.

5.3.5.2. Population Exposure, Dose, and Risk

Questions about population exposure, dose, and risk are central to any risk assessment. Ideally, given the time and methods, the assessor might strive to construct a picture of exposure, dose, and risk in which each individual exposure, dose and risk is known. These data could then be displayed in a frequency distribution.

The risk manager, perhaps considering what action might be necessary for this particular situation, might ask how many cases of the particular effect might be probabilistically estimated in a population during a specific time period, or what percentage of the population is (or how many people are) above a certain exposure, dose, or risk level.

For those who do the assessments, answering these questions requires some knowledge of the population frequency distribution. This information can be obtained or estimated in several ways, leading to two descriptors of population risk.

The first is the probabilistic number of health effect cases estimated in the population of interest over a specified time period. This descriptor can be obtained either by summing the individual risks over all the individuals in the population, or by multiplying the slope factor obtained from a carcinogen dose-response relationship, the arithmetic mean of the dose, and the size of the population. The latter approach may be used only if the risk model assumes a single linear, nonthreshold response to dose, and then only with some caution.[FN40] If risk varies ***22925** linearly with dose, knowing the arithmetic mean risk and the population size can lead to an estimate of the extent of harm for the population as a whole, excluding sensitive subgroups for which a different dose-response curve may need to be used. For noncarcinogens, or for nonlinear, nonthreshold carcinogen models, using the arithmetic mean exposure or dose, multiplying by a slope factor to calculate an average risk, and multiplying by the population size is not appropriate, and risks should be summed over individuals.[FN41]

Obviously, the more relevant information one has, the less uncertain this descriptor, but in any case, the estimate used to develop the descriptor is also limited by the inherent uncertainties in risk assessment methodology, e.g., the risk estimates often being upper confidence level bounds. With the current state of the science, this descriptor should not be confused with an actuarial prediction of cases in the population (which is a statistical prediction based on a great deal of empirical data).

The second type of population risk descriptor is an estimate of the percentage of the population, or the number of persons, above a specified level of risk, RfD, RfC, LOAEL, or other specific level of interest. This descriptor must be obtained by measuring or simulating the population distribution, which can be done in several ways.

First, if the population being studied is small enough, it may be possible to measure the distribution of exposure or dose. Usually, this approach can be moderately to highly costly, but it may be the most accurate. Possible problems with this approach are lack of measuring techniques for the chemical of interest, the availability of a suitable population subset to monitor, and the problem of extrapolating short-term measurements to long-term exposures.

Second, the distribution itself may be simulated from a model such as an exposure model (a model that reports exposures or doses by linking concentrations with contact times for subsets of the population, such as those living various distances from a source) or a Monte Carlo simulation. Although this may be considerably less costly than measurements, it will probably be less accurate, especially near the high end of the distribution. Although models and statistical simulations can be fairly accurate if the proper input data are available, these data are often difficult to obtain and assumptions must be made; use of assumptions may reduce the certainty of the estimated results.

Third, it may be possible to estimate how many people are above a certain exposure, dose, or risk level by identifying and enumerating certain population segments known to be at higher exposure, dose, sensitivity, or risk than the level of interest.

For those who use the assessments, this descriptor can be used in the evaluation of options if a level can be identified as an exposure, dose, or risk level of concern. The options can then be evaluated by estimating how many persons would go from the higher category to the lower category after the option is implemented.

Questions about the distribution of exposure, dose, and risk often require the use of additional risk descriptors. In considering the risks posed by the particular situation being evaluated, a risk manager might want to know how various subgroups fall within the distribution, and if there are any particular subgroups at disproportionately high risk.

It is often helpful for the risk assessor to describe risk by an identification, and if possible, characterization and quantification of the magnitude of the risk for specific highly exposed subgroups within the population. This descriptor is useful when there is (or is expected to be) a subgroup experiencing significantly different exposures or doses from that of the larger population.

It is also helpful to describe risk by an identification, and if possible, characterization and quantification of the magnitude of risk for specific highly sensitive or highly susceptible subgroups within the population. This descriptor is useful when the sensitivity or susceptibility to the effect for specific subgroups within the population is (or is expected to be) significantly different from that of the larger population. In order to calculate risk for these subgroups, it will sometimes be necessary to use a different dose-response relationship.

Generally, selection of the subgroups or population segments is a matter of either a priori interest in the subgroup, in which case the risk manager and risk assessor can jointly agree on which subgroups to highlight, or a matter of discovery of a subgroup during the assessment process. In either case, the subgroup can be treated as a population in itself and characterized the same way as the larger population using the descriptors for population and individual risk.

Exposures and doses for highly-exposed subpopulations can be calculated by defining the population segment as a population, then estimating the doses as for a population. The assessor must make it clear exactly which population was considered.

A special case of a subpopulation is that of children. For exposures that take place during childhood, when low body weight results in a higher dose rate than would be calculated using the $LADD_{pot}$ (Equation 2-6), it is appropriate to average the dose rate (intake rate/body weight) rather than dose. The $LADD_{pot}$ equation then becomes

where $LADD_{pot}$ is the lifetime average daily potential dose, ED_i is the exposure duration (time over which the contact actually takes place), $C\#8_i$ is the average exposure concentration during period of calendar time ED_i, IR_i is the average ingestion or inhalation rate during ED_i, BW_i is body weight during exposure duration ED_i, and LT is the averaging time, in this case, a lifetime (converted to days). This form of the $LADD_{pot}$ equation, if applied to an exposure that occurs primarily in childhood (for example, inadvertent soil ingestion), may result in an $LADD_{pot}$ calculation somewhat higher than that obtained by using Equation 2-6, but there is some evidence that it is more defensible (Kodell et al., 1987; additional discussion in memorandum from Hugh McKinnon, EPA, to Michael Callahan, EPA, November 9, 1990).

6. Assessing Uncertainty

Assessing uncertainty may involve simple or very sophisticated techniques, depending on the requirements of the assessment. Uncertainty characterization and uncertainty assessment are two activities that lead to different degrees of sophistication in describing uncertainty. Uncertainty characterization generally involves a qualitative discussion of the thought processes that lead to the selection and rejection of specific data, estimates, scenarios, etc. For simple exposure assessments, where not much quantitative information is available, uncertainty characterization may be all that is necessary.

The uncertainty assessment is more quantitative. The process begins with simpler measures (i.e., ranges) and simpler analytical techniques (i.e., sensitivity analysis), and progresses, to the extent needed to support the decision for which the exposure ***22926** assessment is conducted, to more complex measures and techniques. The development and implementation of an appropriate uncertainty assessment strategy can be viewed as a decision process. Decisions are made about ways to characterize and analyze uncertainties, and whether to proceed to increasingly more complex levels of uncertainty assessment.

6.1. Role of Uncertainty Analysis in Exposure Assessment

Exposure assessment uses a wide array of information sources and techniques. Even where actual exposure-related measurements exist, assumptions or inferences will still be required (see section 5.2). Most likely, data will not be available for all aspects of the exposure assessment and those data that are available may be of questionable or unknown quality. In these situations, the exposure assessor will have to rely on a combination of professional judgment, inferences based on analogy with similar chemicals and conditions, estimation techniques, and the like. The net result is that the exposure assessment will be based on a number of assumptions with varying degrees of uncertainty.

The decision analysis literature has focused on the importance of explicitly incorporating and quantifying scientific uncertainty in risk assessments (Morgan, 1983; Finkel, 1990). Reasons for addressing uncertainties in exposure assessments include:

- Uncertain information from different sources of different quality must be combined.

- A decision must be made about whether and how to expend resources to acquire additional information (e.g., production, use, and emissions data; environmental fate information; monitoring data; population data) to reduce the uncertainty.

- There is considerable empirical evidence that biases may result in so-called best estimates that are not actually very accurate. Even if all that is needed is a best-estimate answer, the quality of that answer may be improved by an analysis that incorporates a frank discussion of uncertainty.

- Exposure assessment is an iterative process. The search for an adequate and robust methodology to handle the problem at hand may proceed more effectively, and to a more certain conclusion, if the associated uncertainty is explicitly included and can be used as a guide in the process of refinement.

- A decision is rarely made on the basis of a single piece of analysis. Further, it is rare for there to be one discrete decision; a process of multiple decisions spread over time is the more common occurrence. Chemicals of concern may go through several levels of risk assessment before a final decision is made. Within this process, decisions may be made based on exposure considerations. An exposure analysis that attempts to characterize the associated uncertainty allows the user or decision-maker to better evaluate it in the context of the other factors being considered.

- Exposure assessors have a responsibility to present not just numbers but also a clear and explicit explanation of the implications and limitations of their analyses. Uncertainty characterization helps carry out this responsibility.

Essentially, the construction of scientifically sound exposure assessments and the analysis of uncertainty go hand in hand. The reward for analyzing uncertainties is knowing that the results have integrity or that significant gaps exist in available information that can make decision-making a tenuous process.

6.2. Types of Uncertainty

Uncertainty in exposure assessment can be classified into three broad categories:

1. Uncertainty regarding missing or incomplete information needed to fully define the exposure and dose (scenario uncertainty).

2. Uncertainty regarding some parameter (parameter uncertainty).

3. Uncertainty regarding gaps in scientific theory required to make predictions on the basis of causal inferences (model uncertainty).

Identification of the sources of uncertainty in an exposure assessment is the first step toward eventually determining the type of action necessary to reduce that uncertainty. The three types of uncertainty mentioned above can be further defined by examining some principal causes for each.

Exposure assessments often are developed in a phased approach. The initial phase usually involves some type of broad-based screening in which the scenarios that are not expected to pose a risk to the receptor are eliminated from a more detailed, resource-intensive review, usually through developing bounding estimates. These screening-level scenarios often are constructed to represent exposures that would fall beyond the extreme upper end of the expected exposure distribution. Because the screening-level assessments for these nonproblem scenarios usually are included in the final exposure assessment document, this final document may contain scenarios that differ quite markedly in level of sophistication, quality of data, and amenability to quantitative expressions of uncertainty. These also can apply to the input parameters used to construct detailed exposure scenarios.

The following sections will discuss sources, characterization, and methods for analyzing the different types of uncertainty.

6.2.1. Scenario Uncertainty

The sources of scenario uncertainty include descriptive errors, aggregation errors, errors in professional judgment, and incomplete analysis.

Descriptive errors include errors in information, such as the current producers of the chemical and its industrial, commercial, and consumer uses. Information of this type is the foundation for the eventual development of exposure pathways, scenarios, exposed populations, and exposure estimates.

Aggregation errors arise as a result of lumping approximations. Included among these are assumptions of homogeneous populations, and spatial and temporal approximations such as assumptions of steady-state conditions.

Professional judgment comes into play in virtually every aspect of the exposure assessment process, from defining the appropriate exposure scenarios, to selecting the proper environmental fate models, to determining representative environmental conditions, etc. Errors in professional judgment also are a source of uncertainty.

A potentially serious source of uncertainty in exposure assessments arises from incomplete analysis. For example, the exposure assessor may overlook an important consumer exposure due to lack of information regarding the use of a chemical in a particular product. Although this source of uncertainty is essentially unquantifiable, it should not be overlooked by the assessor. At a minimum, the rationale for excluding particular exposure scenarios should be described and the uncertainty in those decisions should be characterized as high, medium, or low. The exposure assessor should discuss whether these decisions were based on actual data, analogues, or professional judgment. For situations in which the uncertainty is high, one should perform a reality check where credible upper limits on the exposure are established by a “what if” analysis.

Characterization of the uncertainty associated with nonnumeric assumptions (often relating to setting the assessment's direction and scope) will ***22827** generally involve a qualitative discussion of the rationale used in selecting specific scenarios. The discussion should allow the reader to make an independent judgment about the validity of the conclusions reached by the assessor by describing the uncertainty associated with any inferences, extrapolations, and analogies used and the weight of evidence that led the assessor to particular conclusions.

6.2.2. Parameter Uncertainty

Sources of parameter uncertainty include measurement errors, sampling errors, variability, and use of generic or surrogate data.

Measurement errors can be random or systematic. Random error results from imprecision in the measurement process. Systematic error is a bias or tendency away from the true value.

Sampling errors concern sample representativeness. The purpose of sampling is to make an inference about the nature of the whole from a measurement of a subset of the total population. If the exposure assessment uses data that were generated for another purpose, for example, consumer product preference surveys or compliance monitoring surveys, uncertainty will arise if the data do not represent the exposure scenario being analyzed.

The inability to characterize the inherent variability in environmental and exposure-related parameters is a major source of uncertainty. For example, meteorological and hydrological conditions may vary seasonally at a given location, soil conditions can have large spatial variability, and human activity patterns can vary substantially depending on age, sex, and geographical location.

The use of generic or surrogate data is common when site-specific data are not available. Examples include standard emission factors for industrial processes, generalized descriptions of environmental settings, and data pertaining to structurally related chemicals as surrogates for the chemical of interest. This is an additional source of uncertainty, and should be avoided if actual data can be obtained.

The approach to characterizing uncertainty in parameter values will vary. It can involve an order-of-magnitude bounding of the parameter range when uncertainty is high, or a description of the range for each of the parameters including the lower- and upper-bound and the best estimate values and justification for these based on available data or professional judgment. In some circumstances, characterization can take the form of a probabilistic description of the parameter range. The appropriate characterization will depend on several factors, including whether a sensitivity analysis indicates that the results are significantly affected by variations within the range. When the results are significantly affected by a particular parameter, the exposure assessor should attempt to reduce the uncertainty by developing a description of the likely occurrence of particular values within the range. If enough data are available, standard statistical methods can be used to obtain a meaningful representation. If available data are inadequate, then expert judgments can be used to develop a subjective probabilistic representation. Expert judgments should be developed in a consistent, well-documented manner. Examples of techniques to solicit expert judgments have been described (Morgan et al., 1979; Morgan et al., 1984; Rish, 1988).

Most approaches for analyzing uncertainty have focused on techniques that examine how uncertainty in parameter values translates into overall uncertainty in the assessment. Several published reports (Cox and Baybutt, 1981; U.S. EPA, 1985f; Inman and Helton, 1988; Seller, 1987; Rish and Marnicio, 1988) have reviewed the many techniques available; the assessor should consult these for details. In general, these approaches can be described, in order of increasing complexity and data requirements, as either sensitivity analysis, analytical uncertainty propagation, probabilistic uncertainty analysis, or classical statistical methods.

Sensitivity analysis is the process of changing one variable while leaving the others constant and determining the effect on the output. The procedure involves fixing each uncertain quantity, one at a time, at its credible lower-bound and then its upper-bound (holding all others at their medians), and then computing the outcomes for each combination of values. These results are useful to identify the variables that have the greatest effect on exposure and to help focus further information gathering. The results do not provide any information about the probability of a quantity's value being at any level within the range; therefore, this approach is most useful at the screening level when deciding about the need and direction of further analyses.

Analytical uncertainty propagation involves examining how uncertainty in individual parameters affects the overall uncertainty of the exposure assessment. Intuitively, it seems clear that uncertainty in a specific parameter may propagate very differently through a model than another variable having approximately the same uncertainty. Some parameters are more important than others, and the model structure is designed to account for the relative sensitivity. Thus, uncertainty propagation is a function of both the data and the model structure. Accordingly, both model sensitivity and input variances are evaluated in this procedure.

Application of this approach to exposure assessment requires explicit mathematical expressions of exposure, estimates of the variances for each of the variables of interest, and the ability either analytically or numerically to obtain a mathematical derivative of the exposure equation.

Although uncertainty propagation is a powerful tool, it should be applied with caution, and the assessor should consider several points. It is difficult to generate and solve the equations for the sensitivity coefficients. In addition, the technique is most accurate for linear equations, so any departure from linearity must be carefully evaluated. Assumptions, such as independence of variables and normality of errors in the variables, need to be checked. Finally, this approach requires estimates of parameter variance, and the information to support these may not be readily available.

Probabilistic uncertainty analysis is generally considered the next level of refinement. The most common example is the Monte Carlo technique where probability density functions are assigned to each parameter, then values from these distributions are randomly selected and inserted into the exposure equation. After this process is completed many times, a distribution of predicted values results that reflects the overall uncertainty in the inputs to the calculation.

The principal advantage of the Monte Carlo method is its very general applicability. There is no restriction on the form of the input distributions or the nature of the relationship between input and output; computations are also straightforward. There are some disadvantages as well as inconveniences, however. The exposure assessor should only consider using this technique when there are credible distribution data (or ranges) for most key variables. Even if these distributions are known, it may not be necessary to apply this technique. For example, if only average exposure values are needed, these can often be computed as accurately by using average values for each of the input parameters. Another ***22928** inconvenience is that the sensitivity of the results to the input distributions is somewhat cumbersome to assess. Changing the distribution of only one value requires rerunning the entire calculation (typically, several hundreds or thousands of times). Finally, Monte Carlo results do not tell the assessor which variables are the most important contributors to output uncertainty. This is a disadvantage since most analyses of uncertainty are performed to find effective ways to reduce uncertainty.

Classical statistical methods can be used to analyze uncertainty in measured exposures. Given a data set of measured exposure values for a series of individuals, the population distribution may be estimated directly, provided that the sample design was developed properly to capture a representative sample. The measured exposure values also may be used to directly compute confidence interval estimates for percentiles of the exposure distribution (American Chemical Society, 1988). When the exposure distribution is estimated from measured exposures for a probability sample of population members, confidence interval estimates for percentiles of the exposure distribution are the primary uncertainty characterization. Data collection survey design should also be discussed, as well as accuracy and precision of the measurement techniques.

Often the observed exposure distribution is skewed; many sample members have exposure distributions at or below the detection limit. In this situation, estimates of the exposure distribution may require a very large sample size. Fitting the data to a distribution type can be problematic in this situation because data are usually scant in the low probability areas (the tails) where numerical values vary widely. As a consequence, for data sets for which the sampling has been completed, means and standard deviations may be determined to a good approximation, but characterization of the tails of the distribution will have much greater uncertainty. This difference should be brought out in the discussion. For data sets for which sampling is still practical, stratification of the statistical population to oversample the tail may give more precision and confidence in the information in the tail area of the distribution.

6.2.3. Model Uncertainty

At a minimum, the exposure assessor should describe in qualitative terms the rationale for selection of any conceptual and mathematical models. This discussion should address the status of these approaches and any plausible alternatives in terms of their acceptance by the scientific community, how well the model(s) represents the situation being assessed, e.g., high end estimate, and to what extent verification and validation have been done. Relationship errors and modeling errors are the primary sources of modeling uncertainty.

Relationship errors include errors in correlations between chemical properties, structure-reactivity correlations, and environmental fate models. In choosing to use these tools, the exposure assessor must decide among the many possible functional forms available. Even though statistics on the performance of the methodology for a given test set of chemicals may be available and can help guide in the selection process, the exposure assessor must decide on the most appropriate methodology for the chemical of interest based on the goals of the assessment.

Modeling errors are due to models being simplified representations of reality, for example approximating a three-dimensional aquifer with a two-dimensional mathematical model. Even after the exposure assessor has selected the most appropriate model for the purpose at hand, one is still faced with the question of how well the model represents the real situation. This question is compounded by the overlap between modeling uncertainties and other uncertainties, e.g., natural variability in environmental inputs, representativeness of the modeling scenario, and aggregation errors. The dilemma facing exposure assessors is that many existing models (particularly the very complex ones) and the hypotheses contained within them cannot be fully tested (Beck, 1987), although certain components of the model may be tested. Even when a model has been validated under a particular set of conditions, uncertainty will exist in its application to situations beyond the test system.

A variety of approaches can be used to quantitatively characterize the uncertainty associated with model constructs. One approach is to use different modeling formulations (including the preferred and plausible alternatives) and consider the range of the outputs to be representative of the uncertainty range. This strategy is most useful when no clear best approach can be identified due to the lack of supporting data or when the situations being assessed require extrapolation beyond the conditions for which the models were originally designed.

Where the data base is sufficient, the exposure assessor should characterize the uncertainty in the selected model by describing the validation and verification efforts. Validation is the process of examining the performance of the model compared to actual observations under situations representative of those being assessed. Approaches for model validation have been discussed (U.S. EPA 1985e). Verification is the process of confirming that the model computer code is producing the proper numerical output. In most situations, only partial validation is possible due to data deficiencies or model complexity.

6.3. Variability Within a Population Versus Uncertainty in the Estimate

For clarity, it should be emphasized that variability (the receipt of different levels of exposure by different individuals) is being distinguished from uncertainty (the lack of knowledge about the correct value for a specific exposure measure or estimate). Most of the exposure and risk descriptors discussed in this report deal with variability directly, but estimates must also be made of the uncertainty of these descriptors. [FN42] This may be done qualitatively or quantitatively, and it is beyond the scope of this report to discuss the mechanics of uncertainty analysis in detail. It is an important distinction, however, since the risk assessor and risk manager need to know if the numbers being reported for exposures take variability, uncertainty, or both, into consideration.

Not all approaches historically used to construct measures or estimates of exposure attempted to distinguish variability and uncertainty. In particular, in many cases in which estimates were termed worst case, focusing on the high end of the exposed population and also selection of high-end values for uncertain physical quantities resulted in values that were seen to be quite conservative. By using both the high-end individuals (variability) and upper confidence bounds[FN43] on data or physical parameters ***22929** (uncertainty), these estimates might be interpreted as “not exceeding an upper bound on exposures received by certain high-end individuals.”

Note that this approach will provide an estimate that considers both variability and uncertainty, but by only reporting the upper confidence bound, it appears to be merely a more conservative estimate of the variability. High end estimates which include consideration of uncertainty should be presented with both the upper and lower uncertainty bounds on the high end estimate. This provides the necessary information to the risk manager. Without specific discussion of what was done, risk managers may view the results as not having dealt with uncertainty. It is fundamental to exposure assessment that assessors have a clear

distinction between the variability of exposures received by individuals in a population, and the uncertainty of the data and physical parameters used in calculating exposure.

The discussion of estimating exposure and dose presented in Section 5.3.4 addresses the rationale and approaches for constructing a range of measures or estimates of exposure, with emphasis on how these can be used for exposure or risk characterization. The distinction between these measures or estimates (e.g., average versus high end) is often a difference in anticipated variability in the exposures received by individuals (i.e., average exposure integrates exposures across all individuals, while high-end exposure focuses on the upper percentiles of the exposed group being assessed.) Although several measures can be used to characterize risk in different ways, this does not address which of these measures or characterizations is used for decisions. The selection of the point or measure of exposure or risk upon which regulatory decisions are made is a risk management decision governed by programmatic policy, and is therefore beyond the scope of these guidelines.

7. Presenting the Results of the Exposure Assessment

One of the most important aspects of the exposure assessment is presenting the results. It is here that the assessment ultimately succeeds or fails in meeting the objectives laid out in the planning as discussed in section 3. This section discusses communication of the results, format considerations, and suggested tips for reviewing exposure assessments either as a final check or as a review of work done by others.

7.1. Communicating the Results of the Assessment

Communicating the results of an exposure assessment is more than a simple summary of conclusions and quantitative estimates for the various pathways and routes of exposure. The most important part of an exposure assessment is the overall narrative exposure characterization, without which the assessment is merely a collection of data, calculations, and estimates. This exposure characterization should consist of discussion, analysis, and conclusions that synthesize the results from the earlier portions of the document, present a balanced representation of the available data and its relevancy to the health effects of concern, and identify key assumptions and major areas of uncertainty. Section 7.1.1 discusses the exposure characterization, and section 7.1.2 discusses how this is used in the risk characterization step of a risk assessment.

7.1.1. Exposure Characterization

The exposure characterization is the summary explanation of the exposure assessment. In this final step, the exposure characterization:

- Provides a statement of purpose, scope, level of detail, and approach used in the assessment, including key assumptions;

- Presents the estimates of exposure and dose by pathway and route for individuals, population segments, and populations in a manner appropriate for the intended risk characterization;

- Provides an evaluation of the overall quality of the assessment and the degree of confidence the authors have in the estimates of exposure and dose and the conclusions drawn;

- Interprets the data and results; and

- Communicates results of the exposure assessment to the risk assessor, who can then use the exposure characterization, along with characterizations of the other risk assessment elements, to develop a risk characterization.

As part of the statement of purpose, the exposure characterization explains why the assessment was done and what questions were asked. It also reaches a conclusion as to whether the questions posed were in fact answered, and with what degree

of confidence. It should also note whether the exposure assessment brought to light additional or perhaps more appropriate questions, if these were answered, and if so, with what degree of confidence.

The statement of scope discusses the geographical or demographic boundaries of the assessment. The specific populations and population segments that were the subjects of the assessment are clearly identified, and the reasons for their selection and any exclusions are discussed. Especially sensitive groups or groups that may experience unusual exposure patterns are highlighted.

The characterization also discusses whether the scope and level of detail of the assessment were ideal for answering the questions of the assessment and whether limitations in scope and level of detail were made because of technical, practical, or financial reasons, and the implications of these limitations on the quality of the conclusions.

The methods used to quantify exposure and dose are clearly stated in the exposure characterization. If models are used, the basis for their selection and validation status is described. If measurement data are used, the quality of the data is discussed. The strengths and weaknesses of the particular methods used to quantify exposure and dose are described, along with comparison and contrast to alternate methods, if appropriate.

In presenting the exposure and dose estimates, the important sources, pathways, and routes of exposure are identified and quantified, and reasons for excluding any from the assessment are discussed.

A variety of risk descriptors, and where possible, the full population distribution is presented. Risk managers should be given some sense of how exposure is distributed over the population and how variability in population activities influences this distribution. Ideally, the exposure characterization links the purpose of the assessment with specific risk descriptors, which in turn are presented in such a way as to facilitate construction of a risk characterization.

A discussion of the quality of the exposure and dose estimates is critical to the credibility of the assessment. This may be based in part on a quantitative uncertainty analysis, but the exposure characterization must explain the results of any such analysis in terms of the degree of confidence to be placed in the estimates and conclusions drawn.

Finally, a description of additional research and data needed to improve the exposure assessment is often helpful to risk managers in making decisions about improving the quality of the assessment. For this reason, the exposure characterization should identify key data gaps that can help ***22930** focus further efforts to reduce uncertainty.

Additional guidance on communicating the results of an exposure assessment can be found in the proceedings of a recent workshop on risk communication (American Industrial Health Council, 1989).

7.1.2. Risk Characterization

Most exposure assessments will be done as part of a risk assessment, and the exposure characterization must be useful to the risk assessor in constructing a risk characterization. Risk characterization is the integration of information from hazard identification, dose-response assessment, and exposure assessment into a coherent picture. A risk characterization is a necessary part of any Agency report on risk whether the report is a preliminary one prepared to support allocation of resources toward further study or a comprehensive one prepared to support regulatory decisions.

Risk characterization is the culmination of the risk assessment process. In this final step, the risk characterization:

- Integrates the individual characterizations from the hazard identification, dose-response, and exposure assessments;

- Provides an evaluation of the overall quality of the assessment and the degree of confidence the authors have in the estimates of risk and conclusions drawn;

- Describes risks to individuals and populations in terms of extent and severity of probable harm; and

- Communicates results of the risk assessment to the risk manager.

It provides a scientific interpretation of the assessment. The risk manager can then use the risk assessment, along with other risk management elements, to make public health decisions. The following sections describe these four aspects of the risk characterization in more detail.

7.1.2.1. Integration of Hazard Identification, Dose-Response, and Exposure Assessments

In developing the hazard identification, dose-response, and exposure portions of the risk assessment, the assessor makes many judgments concerning the relevance and appropriateness of data and methodology. These judgments are summarized in the individual characterizations for hazard identification, dose-response, and exposure. In integrating the parts of the assessment, the risk assessor determines if some of these judgments have implications for other parts of the assessment, and whether the parts of the assessment are compatible. For example, if the hazard identification assessment determines that a chemical is a developmental toxicant but not a carcinogen, the dose-response and exposure information is presented accordingly; this differs greatly from the way the presentation is made if the chemical is a carcinogen but not a developmental toxicant.

The risk characterization not only examines these judgments, but also explains the constraints of available data and the state of knowledge about the phenomena studied in making them, including:

- The qualitative, weight-of-evidence conclusions about the likelihood that the chemical may pose a specific hazard (or hazards) to human health, the nature and severity of the observed effects, and by what route(s) these effects are seen to occur. These judgments affect both the dose-response and exposure assessments;

- For noncancer effects, a discussion of the dose-response behavior of the critical effect(s), data such as the shapes and slopes of the dose-response curves for the various other toxic endpoints, and how this information was used to determine the appropriate dose-response assessment technique; and

- The estimates of the magnitude of the exposure, the route, duration and pattern of the exposure, relevant pharmacokinetics, and the number and characteristics of the population exposed. This information must be compatible with both the hazard identification and dose-response assessments.

The presentation of the integrated results of the assessment draws from and highlights key points of the individual characterizations of hazard, dose-response, and exposure analysis performed separately under these Guidelines. The summary integrates these component characterizations into an overall risk characterization.

7.1.2.2. Quality of the Assessment and Degree of Confidence

The risk characterization summarizes the data brought together in the analysis and the reasoning upon which the assessment is based. The description also conveys the major strengths and weaknesses of the assessment that arise from data availability and the current limits of understanding of toxicity mechanisms.

Confidence in the results of a risk assessment is consequently a function of confidence in the results of analysis of each element: hazard, dose-response, and exposure. Each of these three elements has its own characterization associated with it. For example, the exposure assessment component includes an exposure characterization. Within each characterization, the important uncertainties of the analysis and interpretation of data are explained so that the risk manager is given a clear picture of any consensus or lack thereof about significant aspects of the assessment. For example, whenever more than one view of dose-response assessment is supported by the data and by the policies of these Guidelines, and choosing between them is difficult,

the views are presented together. If one has been selected over another, the rationale is given; if not, then both are presented as plausible alternatives.

If a quantitative uncertainty analysis is appropriate, it is summarized in the risk characterization; in any case a qualitative discussion of important uncertainties is appropriate. If other organizations, such as other Federal agencies, have published risk assessments, or prior EPA assessments have been done on the substance or an analogous substance and have relevant similarities or differences, these too are described.

7.1.2.3. Descriptors of Risk

There are a number of different ways to describe risk in quantitative or qualitative terms. Section 2.3 explains how risk descriptors are used. It is important to explain what aspect of the risk is being described, and how the exposure data and estimates are used to develop the particular descriptor.

7.1.2.4. Communicating Results of a Risk Assessment to the Risk Manager

Once the risk characterization is completed, the focus turns to communicating results to the risk manager. The risk manager uses the results of the risk characterization, technologic factors, and socioeconomic considerations in reaching a regulatory decision. Because of the way these risk management factors may impact different cases, consistent, but not necessarily identical, risk management decisions must be made on a case-by-case basis. Consequently, it is entirely possible and appropriate that a chemical with a specific risk characterization may be regulated differently under different statutes. These Guidelines are not intended to give guidance on the nonscientific aspects of risk management decisions.

***22931** *7.1.3. Establishing the Communication Strategy*

For assessments that must be explained to the general public, a communication strategy is often required. Although risk communication is often considered a part of risk management, it involves input from the exposure and risk assessors; early planning for a communication strategy can be very helpful to the ultimate risk communication.

The EPA has guidance on preparing communication strategies (U.S. EPA, 1988g). Additional sources of information are the New Jersey Department of Environmental Protection (1988a, 1988b) and the NRC (1989b). These documents, and the sources listed within them, are valuable resources for all who will be involved with the sensitive issues of explaining environmental health risks. The NRC (1989b, p. 148) states:

“It is a mistake to simply consider risk communication to be an add-on activity for either scientific or public affairs staffs; both elements should be involved. There are clear dangers if risk messages are formulated ad hoc by public relations personnel in isolation from available technical expertise; neither can they be prepared by risk analysts as a casual extension of their analytic duties.”

7.2. Format for Exposure Assessment Reports

The Agency does not require a set format for exposure assessment reports, but individual program offices within the Agency may have specific format requirements. Section 3 illustrates that exposure assessments are performed for a variety of purposes, scopes, and levels of detail, and use a variety of approaches. While it is impractical for the Agency to specify an outline format for all types of assessments being performed within the Agency, program offices are encouraged to use consistent formats for similar types of assessments within their own purview.

All exposure assessments must, at a minimum, contain a narrative exposure characterization section that contains the types of information discussed in section 7.1. For the purpose of consistency, this section should be titled exposure characterization.

Placement of this section within the assessment is optional, but it is strongly suggested that it be prominently featured in the assessment. It is not, however, an executive summary and should not be used interchangeably with one.

7.3. Reviewing Exposure Assessments

This section provides some suggestions on how to effectively review an exposure assessment and highlights some of the common pitfalls. The emphasis in these Guidelines has been on how to properly conduct exposure assessments; this section can serve as a final checklist in reviewing the completed assessment. An exposure assessor also may be called upon to critically review and evaluate exposure assessments conducted by others; these suggestions should be helpful in this regard.

Reviewers of exposure assessments are usually asked to identify inconsistences with the underlying science and with Agency-developed guidelines, factors, and methodologies, and to determine the effect these inconsistences might have on the results and conclusions of the exposure assessment. Often the reviewer can only describe whether these inconsistencies or deficiencies might underestimate or overestimate exposure.

Some of the questions a reviewer should ask to identify the more common pitfalls that tend to underestimate exposure are:

Has the pathways analysis been broad enough to avoid overlooking a significant pathway?

For example, in evaluating exposure to soil contaminated with PCBs, the exposure assessment should not be limited only to evaluating the dermal contact pathway. Other pathways, such as inhalation of dust and vapors or the ingestion of contaminated gamefish from an adjacent stream receiving surface runoff containing contaminated soil, should also be evaluated as they could contribute higher levels of exposure from the same source.

Have all the contaminants of concern in a mixture been evaluated?

Since risks resulting from exposures to complex mixtures of chemicals with the same mode of toxic action are generally treated as additive (by summing the risks) in a risk assessment, failure to evaluate one or more of the constituents would neglect its contribution to the total exposure and risk. This is especially critical for relatively toxic or potent chemicals that tend to drive risk estimates even when present in relatively low quantities.

Have exposure levels or concentration measurements been compared with appropriate background levels?

Contaminant concentrations or exposure levels should not be compared with other contaminated media or exposed populations. When comparing with background levels, the exposure assessor must determine whether these concentrations or exposure levels are also affected by contamination from anthropogenic activities.

Were the detection limits sensitive enough to make interpretations about exposures at levels corresponding to health concerns? Were the data interpreted correctly?

Because values reported as not detected (ND) mean only that the chemical of interest was not found at the particular detection limit used in the laboratory analysis, ND does not rule out the possibility that the chemical may be present in significant concentrations. Depending on the purpose and the degree of conservatism warranted in the exposure assessment, results reported as ND should be handled as discussed in Section 5.

Has the possibility of additive pathways been considered for the population being studied?

If the purpose of the exposure assessment is to evaluate the total exposure and risk of a population, then exposures from individual pathways within the same route may be summed in cases which concurrent exposures can realistically be expected to occur.

Some questions a reviewer should ask to avoid the more prevalent errors that generally tend to overestimate exposure are:

Have unrealistically conservative exposure parameters been used in the scenarios?

The exposure assessor must conduct a reality check to ensure that the exposure cases used in the scenario(s) (except bounding estimates) could actually occur.

Have potential exposures been presented as existing exposures?

In many situations, especially when the scenario evaluation approach is used, the objective of the assessment is to estimate potential exposures. (That is, if a person were to be exposed to these chemicals under these conditions, then the resultant exposure would be this much.) In determining the need and urgency for regulatory action, risk managers often weigh actual exposures more heavily than higher levels of potential exposures. Therefore, the exposure assessment should clearly note whether the results represent actual or potential exposures.

Have exposures derived from “not detected” levels been presented as actual exposures?

For some exposure assessments it may be appropriate to assume that a chemical reported as not detected is present at either the detection limit or ***22932** one-half the detection limit. The exposure estimates derived from these nondetects, however, should be clearly labeled as hypothetical since they are based on the conservative assumption that chemicals are present at or below the detection limit, when, in fact, they may not be present at all. Exposures, doses, or risks estimated from data using substituting values of detection limits for “not detected” samples must be reported as “less than” the resulting exposure, dose, or risk estimate.

Questions a reviewer should ask to identify common errors that may underestimate or overestimate exposure are:

Are the results presented with an appropriate number of significant figures?

The number of significant figures should reflect the uncertainty of the numeric estimate. If the likely range of the results spans several orders of magnitude, then using more than one significant figure implies more confidence in the results than is warranted.

Have the calculations been checked for computational errors?

Obviously, calculations should be checked for arithmetic errors and mistakes in converting units. This is overlooked more often than one might expect.

Are the factors for intake rates, etc. used appropriately?

Exposure factors should be checked to ensure that they correspond to the site or situation being evaluated.

Have the uncertainties been adequately addressed?

Exposure assessment is an inexact science, and the confidence in the results may vary tremendously. It is essential the exposure assessment include an uncertainty assessment that places these uncertainties in perspective.

If Monte Carlo simulations were used, were correlations among input distributions known and properly accounted for? Is the maximum value simulated by this method in fact a bounding estimate? Was Monte Carlo simulation necessary?

(A Monte Carlo simulation randomly selects the values from the input parameters to simulate an individual. If data already exist to show the relationship between variables for the actual individuals, it makes little sense to use Monte Carlo simulation, since one already has the answer to the question of how the variables are related for each individual. A simulation is unnecessary.)

8. Glossary of Terms

Absorbed dose—See internal dose.

Absorption barrier—Any of the exchange barriers of the body that allow differential diffusion of various substances across a boundary. Examples of absorption barriers are the skin, lung tissue, and gastrointestinal tract wall.

Accuracy—The measure of the correctness of data, as given by the difference between the measured value and the true or standard value.

Administered dose—The amount of a substance given to a test subject (human or animal) in determining dose-response relationships, especially through ingestion or inhalation. In exposure assessment, since exposure to chemicals is usually inadvertent, this quantity is called potential dose.

Agent—A chemical, physical, mineralogical, or biological entity that may cause deleterious effects in an organism after the organism is exposed to it.

Ambient—The conditions surrounding a person, sampling location, etc.

Ambient measurement—A measurement (usually of the concentration of a chemical or pollutant) taken in an ambient medium, normally with the intent of relating the measured value to the exposure of an organism that contacts that medium).

Ambient medium—One of the basic categories of material surrounding or contacting an organism, e.g., outdoor air, indoor air, water, or soil, through which chemicals or pollutants can move and reach the organism. (See also biological medium, environmental medium)

Applied dose—The amount of a substance in contact with the primary absorption boundaries of an organism (e.g., skin, lung, gastrointestinal tract) and available for absorption.

Arithmetic mean—The sum of all the measurements in a data set divided by the number of measurements in the data set.

Background level (environmental)—The concentration of substance in a defined control area during a fixed period of time before, during, or after a data-gathering operation.

Breathing zone—A zone of air in the vicinity of an organism from which respired air is drawn. Personal monitors are often used to measure pollutants in the breathing zone.

Bias—A systematic error inherent in a method or caused by some feature of the measurement system.

Bioavailability—The state of being capable of being absorbed and available to interact with the metabolic processes of an organism. Bioavailability is typically a function of chemical properties, physical state of the material to which an organism is exposed, and the ability of the individual organism to physiologically take up the chemical.

Biological marker of exposure (sometimes referred to as a biomarker of exposure)—Exogenous chemicals, their metabolites, or products of interactions between a xenobiotic chemical and some target molecule or cell that is measured in a compartment within an organism.

Biological measurement—A measurement taken in a biological medium. For the purpose of exposure assessment via reconstruction of dose, the measurement is usually of the concentration of a chemical/metabolite or the status of a biomarker, normally with the intent of relating the measured value to the internal dose of a chemical at some time in the past. (Biological measurements are also taken for purposes of monitoring health status and predicting effects of exposure.) (See also ambient measurement)

Biological medium—One of the major categories of material within an organism, e.g., blood, adipose tissue, or breath, through which chemicals can move, be stored, or be biologically, physically, or chemically transformed. (See also ambient medium, environmental medium)

Biologically effective dose—The amount of a deposited or absorbed chemical that reaches the cells or target site where an adverse effect occurs, or where that chemical interacts with a membrane surface.

Blank (blank sample)—An unexposed sampling medium, or an aliquot of the reagents used in an analytical procedure, in the absence of added analyte. The measured value of a blank sample is the blank value.

Body burden—The amount of a particular chemical stored in the body at a particular time, especially a potentially toxic chemical in the body as a result of exposure. Body burdens can be the result of long-term or short-term storage, for example, the amount of a metal in bone, the amount of a lipophilic substance such as PCB in adipose tissue, or the amount of carbon monoxide (as carboxyhemoglobin) in the blood.

Bounding estimate—An estimate of exposure, dose, or risk that is higher than that incurred by the person in the population with the highest exposure, dose, or risk. Bounding estimates are useful in developing statements that exposures, doses, or risks are “not greater than” the estimated value.

Comparability—The ability to describe likenesses and differences in the quality and relevance of two or more data sets.

***22933** Data quality objectives (DQO)—Qualitative and quantitative statements of the overall level of uncertainty that a decision-maker is willing to accept in results or decisions derived from environmental data. DQOs provide the statistical framework for planning and managing environmental data operations consistent with the data user's needs.

Dose—The amount of a substance available for interaction with metabolic processes or biologically significant receptors after crossing the outer boundary of an organism. The potential dose is the amount ingested, inhaled, or applied to the skin. The applied dose is the amount of a substance presented to an absorption barrier and available for absorption (although not necessarily having yet crossed the outer boundary of the organism). The absorbed dose is the amount crossing a specific absorption barrier (e.g., the exchange boundaries of skin, lung, and digestive tract) through uptake processes. Internal dose is a more general term denoting the amount absorbed without respect to specific absorption barriers or exchange boundaries. The amount of the chemical available for interaction by any particular organ or cell is termed the delivered dose for that organ or cell.

Dose rate—Dose per unit time, for example in mg/day, sometimes also called dosage. Dose rates are often expressed on a per-unit-body-weight basis, yielding units such as mg/kg/day (mg/kg-day). They are also often expressed as averages over some time period, for example a lifetime.

Dose-response assessment—The determination of the relationship between the magnitude of administered, applied, or internal dose and a specific biological response. Response can be expressed as measured or observed incidence, percent response in groups of subjects (or populations), or the probability of occurrence of a response in a population.

Dose-response curve—A graphical representation of the quantitative relationship between administered, applied, or internal dose of a chemical or agent, and a specific biological response to that chemical or agent.

Dose-response relationship—The resulting biological responses in an organ or organism expressed as a function of a series of different doses.

Dosimeter—Instrument to measure dose; many so-called dosimeters actually measure exposure rather than dose.

Dosimetry—Process of measuring or estimating dose.

Ecological exposure—Exposure of a nonhuman receptor or organism to a chemical, or a radiological or biological agent.

Effluent—Waste material being discharged into the environment, either treated or untreated. Effluent generally is used to describe water discharges to the environment, although it can refer to stack emissions or other material flowing into the environment.

Environmental fate—The destiny of a chemical or biological pollutant after release into the environment. Environmental fate involves temporal and spatial considerations of transport, transfer, storage, and transformation.

Environmental fate model—In the context of exposure assessment, any mathematical abstraction of a physical system used to predict the concentration of specific chemicals as a function of space and time subject to transport, intermedia transfer, storage, and degradation in the environment.

Environmental medium—One of the major categories of material found in the physical environment that surrounds or contacts organisms, e.g., surface water, ground water, soil, or air, and through which chemicals or pollutants can move and reach the organisms. (See ambient medium, biological medium)

Exposure— Contact of a chemical, physical, or biological agent with the outer boundary of an organism. Exposure is quantified as the concentration of the agent in the medium in contact integrated over the time duration of that contact.

Exposure assessment—The determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure.

Exposure concentration—The concentration of a chemical in its transport or carrier medium at the point of contact.

Exposure pathway—The physical course a chemical or pollutant takes from the source to the organism exposed.

Exposure route—The way a chemical or pollutant enters an organism after contact, e.g., by ingestion, inhalation, or dermal absorption.

Exposure scenario—A set of facts, assumptions, and inferences about how exposure takes place that aids the exposure assessor in evaluating, estimating, or quantifying exposures.

Fixed-location monitoring—Sampling of an environmental or ambient medium for pollutant concentration at one location continuously or repeatedly over some length of time.

Geometric mean—The nth root of the product of n values.

Guidelines—Principles and procedures to set basic requirements for general limits of acceptability for assessments.

Hazard identification—A description of the potential health effects attributable to a specific chemical or physical agent. For carcinogen assessments, the hazard identification phase of a risk assessment is also used to determine whether a particular agent or chemical is, or is not, causally linked to cancer in humans.

High-end exposure (dose) estimate—A plausible estimate of individual exposure or dose for those persons at the upper end of an exposure or dose distribution, conceptually above the 90th percentile, but not higher than the individual in the population who has the highest exposure or dose.

High-end Risk Descriptor—A plausible estimate of the individual risk for those persons at the upper end of the risk distribution, conceptually above the 90th percentile but not higher than the individual in the population with the highest risk. Note that persons in the high end of the risk distribution have high risk due to high exposure, high susceptibility, or other reasons, and therefore persons in the high end of the exposure or dose distribution are not necessarily the same individuals as those in the high end of the risk distribution.

Intake—The process by which a substance crosses the outer boundary of an organism without passing an absorption barrier, e.g., through ingestion or inhalation. (See also potential dose)

Internal dose—The amount of a substance penetrating across the absorption barriers (the exchange boundaries) of an organism, via either physical or biological processes. For the purpose of these Guidelines, this term is synonymous with absorbed dose.

Limit of detection (LOD) (or Method detection limit (MDL))—The minimum concentration of an analyte that, in a given matrix and with a specific method, has a 99% probability of being identified, qualitatively or quantitatively measured, and reported to be greater than zero.

Matrix—A specific type of medium (e.g., surface water, drinking water) in which the analyte of interest may be contained.

Maximally exposed individual (MEI)—The single individual with the highest exposure in a given population (also, most exposed individual). This term has historically been defined various ways, including as defined here and also synonymously with worst case or bounding estimate. Assessors are cautioned to look for contextual ***22934** definitions when encountering this term in the literature.

Maximum exposure range—A semiquantitative term referring to the extreme uppermost portion of the distribution of exposures. For consistency, this term (and the dose or risk analogues) should refer to the portion of the individual exposure distribution that conceptually falls above about the 98th percentile of the distribution, but is not higher than the individual with the highest exposure.

Median value—The value in a measurement data set such that half the measured values are greater and half are less.

Microenvironment method—A method used in predictive exposure assessments to estimate exposures by sequentially assessing exposure for a series of areas (microenvironments) that can be approximated by constant or well-characterized concentrations of a chemical or other agent.

Microenvironments—Well-defined surroundings such as the home, office, automobile, kitchen, store, etc. that can be treated as homogeneous (or well characterized) in the concentrations of a chemical or other agent.

Mode—The value in the data set that occurs most frequently.

Monte Carlo technique—A repeated random sampling from the distribution of values for each of the parameters in a generic (exposure or dose) equation to derive an estimate of the distribution of (exposures or doses in) the population.

Nonparametric statistical methods—Methods that do not assume a functional form with identifiable parameters for the statistical distribution of interest (distribution-free methods).

Pathway—The physical course a chemical or pollutant takes from the source to the organism exposed.

Personal measurement—A measurement collected from an individual's immediate environment using active or passive devices to collect the samples.

Pharmacokinetics—The study of the time course of absorption, distribution, metabolism, and excretion of a foreign substance (e.g., a drug or pollutant) in an organism's body.

Point-of-contact measurement of exposure—An approach to quantifying exposure by taking measurements of concentration over time at or near the point of contact between the chemical and an organism while the exposure is taking place.

Potential dose—The amount of a chemical contained in material ingested, air breathed, or bulk material applied to the skin.

Precision—A measure of the reproducibility of a measured value under a given set of conditions.

Probability samples—Samples selected from a statistical population such that each sample has a known probability of being selected.

Quality assurance (QA)—An integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

Quality control (QC)—The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of the users. The aim is to provide quality that is satisfactory, adequate, dependable, and economical.

Quantification limit (QL)—The concentration of analyte in a specific matrix for which the probability of producing analytical values above the method detection limit is 99%.

Random samples—Samples selected from a statistical population such that each sample has an equal probability of being selected.

Range—The difference between the largest and smallest values in a measurement data set.

Reasonable worst case—A semiquantitative term referring to the lower portion of the high end of the exposure, dose, or risk distribution. The reasonable worst case has historically been loosely defined, including synonymously with maximum exposure or worst case, and assessors are cautioned to look for contextual definitions when encountering this term in the literature. As a semiquantitative term, it is sometimes useful to refer to individual exposures, doses, or risks that, while in the high end of the distribution, are not in the extreme tail. For consistency, it should refer to a range that can conceptually be described as above the 90th percentile in the distribution, but below about the 98th percentile. (compare maximum exposure range, worst case).

Reconstruction of dose—An approach to quantifying exposure from internal dose, which is in turn reconstructed after exposure has occurred, from evidence within an organism such as chemical levels in tissues or fluids or from evidence of other biomarkers of exposure.

Representativeness—The degree to which a sample is, or samples are, characteristic of the whole medium, exposure, or dose for which the samples are being used to make inferences.

Risk—The probability of deleterious health or environmental effects.

Risk characterization—The description of the nature and often the magnitude of human or nonhuman risk, including attendant uncertainty.

Route—The way a chemical or pollutant enters an organism after contact, e.g., by ingestion, inhalation, or dermal absorption.

Sample—A small part of something designed to show the nature or quality of the whole. Exposure-related measurements are usually samples of environmental or ambient media, exposures of a small subset of a population for a short time, or biological samples, all for the purpose of inferring the nature and quality of parameters important to evaluating exposure.

Sampling frequency—The time interval between the collection of successive samples.

Sampling plan—A set of rules or procedures specifying how a sample is to be selected and handled.

Scenario evaluation—An approach to quantifying exposure by measurement or estimation of both the amount of a substance contacted, and the frequency/duration of contact, and subsequently linking these together to estimate exposure or dose.

Source characterization measurements—Measurements made to characterize the rate of release of agents into the environment from a source of emission such as an incinerator, landfill, industrial or municipal facility, consumer product, etc.

Standard operating procedure (SOP)—A procedure adopted for repetitive use when performing a specific measurement or sampling operation.

Statistical control—The process by which the variability of measurements or of data outputs of a system is controlled to the extent necessary to produce stable and reproducible results. To say that measurements are under statistical control means that there is statistical evidence that the critical variables in the measurement process are being controlled to such an extent that the system yields data that are reproducible within well-defined limits.

Statistical significance—An inference that the probability is low that the observed difference in quantities being measured could be due to variability in the data rather than an actual difference in the quantities themselves. The inference that an observed difference is statistically significant is typically based on a test to reject one hypothesis and accept another.

Surrogate data—Substitute data or measurements on one substance used to ***22935** estimate analogous or corresponding values of another substance.

Uptake—The process by which a substance crosses an absorption barrier and is absorbed into the body.

Worst case—A semiquantitative term referring to the maximum possible exposure, dose, or risk, that can conceivably occur, whether or not this exposure, dose, or risk actually occurs or is observed in a specific population. Historically, this term has been loosely defined in an ad hoc way in the literature, so assessors are cautioned to look for contextual definitions when encountering this term. It should refer to a hypothetical situation in which everything that can plausibly happen to maximize exposure, dose, or risk does in fact happen. This worst case may occur (or even be observed) in a given population, but since it is usually a very unlikely set of circumstances, in most cases, a worst-case estimate will be somewhat higher than occurs in a specific population. As in other fields, the worst-case scenario is a useful device when low probability events may result in

a catastrophe that must be avoided even at great cost, but in most health risk assessments, a worst-case scenario is essentially a type of bounding estimate.

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Part B: Response to Public and Science Advisory Board Comments

1. Introduction

This section summarizes the major issues raised in public comments on the Proposed Guidelines for Exposure-Related Measurements (hereafter "1988 Proposed Guidelines") published December 2, 1988 (53 FR 48830-48853). In addition to general comments, reviewers were requested to comment specifically on the guidance for interpreting contaminated blanks versus field data, the interpretation of data at or near the limit of detection, approaches to assessing uncertainty, and the Glossary of Terms. Comment was also invited on the following questions: Should the 1988 Proposed Guidelines be combined with the 1986 Guidelines for Estimating Exposures (hereafter "1986 Guidelines")? Is the current state-of-the-art in making measurements of population activities for the purpose of exposure assessment advanced to the point where the Agency can construct guidelines in this area? Given that EPA Guidelines are not protocols or detailed literature reviews, is the level of detail useful and appropriate, especially in the area of statistics?

The Science Advisory Board (SAB) met on December 2, 1988, and provided written comments in a May, 1989 letter to the EPA Administrator (EPA-SAB-EETFC-89-020). The public comment period extended until March 2, 1989. Comments were received from 17 individuals or organizations.

After the SAB and public comment, Agency staff prepared summaries of the comments and analyses of major issues presented by the commentors. These were considered in the development of these final Guidelines. In response to the comments, the Agency has modified or clarified most of the sections of the Guidelines. For the purposes of this discussion, only the most significant issues reflected by the public and SAB comments are discussed. Several minor recommendations, which do not warrant discussion here, were considered and adopted by the Agency in the revision of these Guidelines.

The EPA revised the 1988 Proposed Guidelines in accordance with the public and SAB comments, retitling them Guidelines for Exposure Assessment (hereafter "Guidelines"). The Agency presented the draft final Guidelines to the SAB at a public meeting on September 12, 1991, at which time the SAB invited public comment for a period of 30 days on the draft. The SAB discussed the final draft in a January 13, 1992 letter to the Administrator of the EPA (EPA-SAB-IAQC-92-015). There were no additional public comments received.

2. Response to General Comments

In general, the reviewers were complementary regarding the overall quality of the 1988 Proposed Guidelines. Several reviewers requested that the ***22938** Agency better define the focus and intended audiences and refine the Guidelines with regard to treatment of nonhuman exposure. The Agency has refined its approach and coverage in these Guidelines. Although these Guidelines deal specifically with human exposures to chemicals, additional supplemental guidance may be developed

for ecological exposures, and exposures to biological or radiological entities. The Agency is currently developing separate guidelines for ecological risk assessment.

Concerns were expressed about the Agency's use of the terms exposure and dose. Consequently, the Agency reviewed its definitions and uses of these terms and evaluated their use elsewhere in the scientific community. The Agency has changed its definitions and uses of these terms from that in both the 1986 Guidelines and the 1988 Proposed Guidelines. It is believed that the definitions contained in the current Guidelines are now in concert with the definitions suggested by the National Academy of Sciences and others in the scientific field.

Many reviewers urged the Agency to be more explicit in its recommendations regarding uncertainty in statistics, limits of detection, censored data sets, and the use of models. Some reviewers felt the level of detail was appropriate for statistical uncertainty while others wanted additional methods for dealing with censored data. Several commended the Agency for its acknowledgement of uncertainty in exposure assessments and the call for its explicit description in all exposure assessments, while others expressed concern for lack of acknowledgement of model uncertainty. Accordingly, these areas have been revised and an entire section has been devoted to uncertainty. We agree with the reviewers that much more work remains to be done in this area, particularly with evaluating overall exposure assessment uncertainty, not only with models but also with the distributions of exposure parameters. The Agency may issue additional guidance in this area in the future.

Some reviewers submitted extensive documentation regarding detection limits and statistical representations. Several submitted comments arguing against data reporting conventions that result in censored data sets and recommended that the Agency issue a guidance document for establishing total system detection limits. The Agency found the documentation to be helpful and has revised the sections of the Guidelines accordingly. Unfortunately, several of the other suggestions go beyond the scope of this document.

The reviewers generally commented that the glossary was useful, presenting many technical terms and defining them in an appropriate manner. The glossary has been expanded to include the key terms used in the Guidelines, while at the same time correcting some definitions that were inconsistent or unclear. In particular, the definitions for exposure and dose have been revised.

3. Response to Comments on the Specific Questions

3.1. Should the 1988 Proposed Guidelines Be combined with the 1986 Guidelines?

The SAB and several other commentors recommended that the 1986 Guidelines and the 1988 Proposed Guidelines be combined into an integrated document. The Agency agrees with this recommendation and has made an effort to produce a single guideline that progresses logically from start to finish. This was accomplished through an extensive reformatting of the two sets of guidelines as an integrated document, rather than a simple joining together of the previous versions.

In integrating the two previous guidelines, the Agency has revised and updated the section in the 1986 Guidelines that suggests an outline for an exposure assessment. A more complete section (section 7 of the current Guidelines) now discusses how assessments should be presented and suggests a series of points to consider in reviewing assessments.

The Agency has also expanded the section in the 1986 Guidelines that discussed exposure scenarios, partly by incorporating material from the 1988 Proposed Guidelines, and partly as a result of comments requesting clarification of the appropriate use of certain types of scenario (e.g., “worst case”). Section 5.3 of the current Guidelines extensively discusses the appropriateness of using various scenarios, estimates, and risk descriptors, and defines certain scenario-related terms for use in exposure assessments.

3.2. Is the Current State-of-the-Art in Making Measurements of Population Activities for the Purpose of Exposure Assessment Advanced to the Point Where the Agency Can Construct Guidelines in This Area?

Both the SAB and public comments recommended the inclusion of demographics, population dynamics, and population activity patterns in the exposure assessment process. In response, the Agency has included additional discussion on use of activity patterns in the current Guidelines, while recognizing that more research has to be done in this area.

3.3. Is the Level of Detail of the Guidelines Useful and Appropriate, Especially in the Area of Statistics?

As might be expected, there was no clear consensus of opinion on what constitutes appropriate coverage. Regarding quality assurance (QA) and quality control (QC), it was felt that a strong statement on the need for QA/QC followed by reference to appropriate EPA documents was a suitable level of detail. Statistical analyses, sampling issues, limit of detection, and other analytical issues all elicited many thoughtful comments. Where the recommendations did not exceed the scope of the document or the role of EPA, the Agency has attempted to blend the various recommendations into the current Guidelines. In all these areas, therefore, the previous sections have been revised in accordance with comments.

(FR Doc. 92-10425 Filed 5-28-92; 8:45 am)

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Footnotes

1 A third, less common, scheme is that exposure is contact with any boundary outside or inside of the body, including internal boundaries around organs, etc. This scheme is alluded to, for example, in an article prepared by the National Research Council (NRC, 1985, p. 91). One could then speak of exposure to the whole person or exposure to certain internal organs.

FN2 For example, the amount of food ingested would be a dose under scheme (a) and an exposure under scheme (b). Since the amount ingested in an animal toxicology study is usually termed administered dose, this leads to the use of both exposure and dose for the same quantity under scheme (b). There are several such ambiguities in any of the currently used schemes. Brown (1987) provides a discussion of various units used to describe exposures due to multiple schemes.

3 The National Research Council's 1983 report Risk Assessment in the Federal Government: Managing the Process often addresses the output of an exposure assessment as an exposure or a dose (NRC 1983, pp. 32, 35-36).

4 These guidelines use the term internal dose to refer to the amount of a chemical absorbed across the exchange boundaries, such as the skin, lung, or gastrointestinal tract. The term absorbed dose is often used synonymously for internal dose, although the connotation for the term absorbed dose seems to be more related to a specific boundary (the amount absorbed across a membrane in an experiment, for example), while the term internal dose seems to connote a more general sense of the amount absorbed across one or more specific sites. For the purpose of these guidelines, the term internal dose is used for both connotations. The term internal dose as used here is also consistent with how it is generally applied to a discussion of biomarkers (NRC, 1989a). It is also one of the terms used in epidemiology (NRC, 1985).

5 Ingestion of food or water is an intermittent rather than continuous process, and can be expressed as (amount of medium per event) x (events per unit clock or calendar time) (the frequency of contact); (e.g., 250 mL of water/glass of water ingested x 8 glasses of water ingested/day).

6 Uptake through the lung, gastrointestinal tract, or other internal barriers also can occur following intake through ingestion or inhalation.

7 Contact time (CT) is that part of the exposure duration where C(t) does not equal zero; that is, the actual time periods (events, episodes) during which actual exposure is taking place. The exposure duration as defined here, on the other hand, is a time interval of interest for assessment purposes during which exposure occurs, either continuously or intermittently.

FN8 An exposure pathway is the course a chemical takes from its source to the person being contacted. An exposure route is the particular means of entry into the body, e.g., inhalation, ingestion, or dermal absorption.

9 Potential dose is the potential amount of the chemical that could be absorbed if it were 100% bioavailable. Note, however, that this does not imply that 100% bioavailability or 100% absorption is assumed when using potential dose. The equations and discussion in this chapter use potential dose as a measurable quantity that can then be converted to applied or absorbed dose by the use of the

appropriate factors. Potential dose is a general term referring to any of the exposure routes. The terms respiratory dose, oral dose, or dermal dose are sometimes used to refer to the route-specific potential doses.

10 It is not useful to calculate potential doses in cases where there is partial or total immersion in a fluid such as air or water. In these cases, it is more useful to describe the situation in terms of exposure (concentration of the chemical in the medium times the time of contact) or absorbed dose. For cases such as contact with water in a swimming pool, the person is not really exposed to the entire mass of the chemical that would be described by a potential dose. Nor is it useful to calculate dermal applied doses because the boundary layer is being constantly renewed. The use of alternate ways to calculate a dose that might occur while swimming is discussed in Section 2.1.4.2., in conjunction with Equations 2-7 and 2-8.

11 This may be done by adding a bioavailability factor (range: 0 to 1) to the dose equation. The bioavailability factor would then take into account the ability of the chemical to be extracted from the matrix, absorption through the exchange boundary, and any other losses between ingestion and contact with the lung or gastrointestinal tract. When no data or information are available to indicate otherwise, the bioavailability factor is usually assumed to be 1.

12 Current carcinogen risk models, such as the linearized multistage procedure and other linear nonthreshold models, use lifetime exposures to develop the dose-response relationships, and therefore use lifetime time-weighted average exposures to estimate risks. Within the range of linearity for risk, this procedure effectively treats exposures and doses as a series of “units,” with each unit of dose being equal to any other unit of dose in terms of risk potential without respect to prior exposure or dose patterns. Current research in the field of dose-response modeling is focusing on biologically based dose-response models which may take into account the effects of the exposure or dose patterns, making use of all of the information in an exposure or dose profile. For a more indepth discussion on the implications of the use of time-weighted averages, see Atherley (1985).

13 The assessor should keep in mind that this steady state assumption has been made when using Equation 2-5, and should be able to discuss what effect using average values for C, IR, and ED has on the resulting estimate.

14 This relationship is described by Fick's Law, where $J = K_p \cdot C$ where C represents the steady-state concentration of the chemical, J is the steady-state flux, and K_p is the permeability coefficient.

FN15 The permeability coefficient, K_p, can be experimentally calculated for a chemical and a particular barrier (e.g., skin type) by observing the flux rate in vitro (typical units: mg chemical crossing/sec-cm 2), and dividing it by the concentration of the chemical in the medium in contact with the barrier (typical units: mg chemical/cm^3). This allows the relationship between bulk concentration and the crossing of the chemical itself to be made. K_p has the advantage of being fairly constant over a range of concentrations and can be used for concentrations other than the one used in the experiment. The chemical uptake rate, relating the crossing of the barrier of the chemical itself in terms of the bulk concentration, then becomes C times K_p times the surface area exposed (SA).

16 These three ways are approaches for arriving at a quantitative estimate of exposure. Sometimes the approaches to assessing exposure are described in terms of “direct measures” and “indirect measures” of exposure (e.g., NRC, 1990). Measurements that actually involve sampling on or within a person, for example, use of personal monitors and biomarkers, are termed “direct measures” of exposure. Use of models, microenvironmental measurements, and questionnaires, where measurements do not actually involve personal measurements, are termed “indirect measures” of exposure. The direct/indirect nomenclature focuses on the type of measurements being made; the scenario evaluation/point-of-contact/reconstruction nomenclature focuses on how the data are used to develop the dose estimate. The three-term nomenclature is used in these guidelines to highlight the point that three independent estimates of dose can be developed.

17 Biomarkers can be used to study exposure, effects, or susceptibility. The discussion of biomarkers in these guidelines is limited to their use in indicating exposure.

18 This technique still may not deal effectively with the problem of short-term “peak concentrations” exceeding some threshold leading to an acute effect. Even the averaging process used in a microenvironment may miss significant concentration spikes and average them out to lower concentrations which are apparently less toxicologically significant. A similar problem exists when evaluating sources; a “peak release” of a toxic chemical for a short time may cause serious acute effects, even though the average concentration over a longer period of time might not indicate serious chronic effects.

19 The uppermost portion of the high-end exposure range has generally been the target for terms such as “most exposed individual,” although actual usage has varied.

FN20 The term “worst case exposure” has historically meant the maximum possible exposure, or where everything that can plausibly happen to maximize exposure, happens. While in actuality, this worst case exposure may fall on the uppermost point of the population distribution, in most cases, it will be somewhat higher than the individual in the population with the highest exposure. The worst case represents a hypothetical individual and an extreme set of conditions; this will usually not be observed in an actual population. The worst case and the so-called maximum exposed individual are therefore not synonymous, the former describing a statistical possibility that may or may not occur in the population, and the latter ostensibly describing an individual that does, or is thought to, exist in the population.

FN21 The lower part of the high-end exposure range, e.g., conceptually above the 90th percentile but below about the 98th percentile, has generally been the target used by those employing the term “reasonable worst case exposure.” Above about the 98th percentile has been termed the “maximum exposure” range. Note that both these terms should refer to estimates of exposure on the actual distribution, not above it.

22 Since the geometric mean (G) is defined differently, use of the geometric mean individual risk (where G does not equal A, such as is often found in environmental situations) in the above relationship will obviously give an erroneous (usually low) estimate of the total. Geometric means have appropriate uses in exposure and risk assessment, but estimating population risk in this way is not one of them.

23 In other words, a fundamental rule is that a model should not be validated using data that were already used to generate or calibrate the model, since doing so would not be an independent test.

a To characterize dose, intake or uptake information is also needed (see Section 2). U.S. EPA (1985c).

[e f] c U.S. EPA (1986f). U.S. EPA (1985c). U.S. EPA (1985d). U.S. EPA (1985a).

[i j] g U.S. EPA (1986f). U.S. EPA (1987a). U.S. EPA (1987a). U.S. EPA (1987a).

[m n] k U.S. EPA (1987d). U.S. EPA (1986g). U.S. EPA (1986h). U.S. EPA (1987e).

24 Conversely, it may be stated that the largest source of uncertainty is the concentration for a given exposure duration. Often, however, the concentration in the media is known with more certainty than the activities of the individual(s) exposed.

25 An acceptable data set is one that is consistent with the scope, depth, and purpose of the assessment, and is both relevant and adequate as discussed in Section 5.1.

26 Some programs, such as the U.S. Department of Energy (1991), do not recommend this procedure at all, if it can be avoided.

27 “Conservative” assumptions are those which tend to maximize estimates of exposure or dose, such as choosing a value near the high end of the concentration or intake rate range.

FN28 Obviously, the mathematical product of several conservative assumptions is more conservative than any single assumption alone. Ultimately, this could lead to unrealistically conservative bounding estimates (see section 5.3).

29 Note that when using a passive dosimetry monitoring method, what is measured is the amount of chemical impinging on the skin surface or available for inhalation, that is, exposure, not the actual dose received. Factors such as dermal penetration, are, of course, expected to be highly chemical dependent.

30 Consider, for example, a hypothetical set of 100 rooms (microenvironments) where the concentration of a particular pollutant is zero in 50 of them, and ranges stepwise from 1 to 50 (nominal concentration units) in the remainder. If one person were in each room, short-term “snapshot” monitoring would show that 50 people were unexposed and the others were exposed to concentrations ranging from 1 to 50. If the concentration in each room remained constant and people were allowed to visit any room at random, long-term monitoring would indicate that all 100 were exposed to a mean concentration of 12.75. The short-term data would tend to overestimate concentration and underestimate the number of persons exposed if applied to long-term exposures. If only average values were available, the long-term data would tend to underestimate concentration and overestimate the number exposed if applied to short-term exposures. Because populations are not randomly mobile or static, the exposure assessor should determine what effect this has on the exposure estimate.

31 There are some important exceptions to this statement. First, the public or other concerned groups may express particular interest in certain pathways, which will not normally be dropped entirely at this point. Second, for routine repetitive assessments using a certain standard scenario for many chemicals, once the general bounding has been done on the various possible pathways, it may become standard operating procedure to immediately begin developing information for particular pathways as new chemicals are assessed.

32 “Not significant” can mean either that it is so small relative to other pathways that it will not add perceptibly to the total exposure being evaluated or that it falls so far below a level of concern that even when added to other results from other pathways, it will be trivial. Note that a “level of concern” is a risk management term, and the assessor must discuss and establish any such levels of concern with risk managers (and in some cases, concerned groups such as the local community) before eliminating pathways as not significant.

33 Experienced assessors may also be able to determine quickly that a pathway requires refined estimation.

34 It also can involve new methods or additional methods for analyzing the old data.

35 The unstated assumption is often made that the relationship between administered dose and absorbed dose in the animal is the same as that between potential dose and internal dose in humans, provided a correction is made for body weight/surface area. In other words, the bioavailability and absorption fractions are assumed to be the same in the human as in the animal experiment. If no correction is made for absorption, this leads to the assumption that the absorption percent is the same as in the animal experiment from which the dose-response relationship was derived. Note this uncorrected conversion of potential dose to internal dose does not assume “100% absorption” unless there was 100% absorption in the animal study.

36 This means that estimates of high-end exposure or dose for future uses are limited to the same conceptual range as current uses. Although a “worst-case” combination of future conditions or events may result in an exposure that is conceivably possible, the

assessor should not merely use a worst-case combination as an estimate of high-end exposure for possible future uses. Rather, the assessor must use judgment as to what the range of exposures or doses would plausibly be, given the population size and probability of certain events happening.

37 For example, although concentration breathed, frequency, duration, and breathing rate may be independent for a consumer painting rooms in a house under most normal circumstances, if the concentration is high enough, it may affect the other parameters such as duration or breathing rate. These types of high-end correlations are difficult to quantify, and techniques such as Monte Carlo simulations will not consider them unless relationships are known and taken into account in the simulation. If extreme concentration in this case resulted in lower breathing rate or duration, a non-corrected Monte Carlo simulation could overestimate the exposure or dose at the high end. Far less likely, due to self-preservation processes, would seem the case where high concentration increases duration or intake rate, although this theoretically might also occur.

38 This maximum is the theoretical upper bounding estimate (TUBE).

39 Maximizing all variables, as is done in bounding estimates, will result in virtually all cases in an estimate that is above the bounds of this range, that is, above the actual values seen in the population.

40 For example, when calculating risks using doses and “slope factors,” the risk is approximately linear with dose until relatively high individual risks (about 10^{-1}) are attained, after which the relationship is no longer even approximately linear. This results from the fact that no matter how high the dose, the individual risk cannot exceed 1, and the dose-risk curve approaches 1 asymptotically. This can result in artifacts when calculating population risk from average individual doses and population size if there are individuals in the population in this nonlinear risk range. Consider a population of five persons, only one of whom is exposed. As an example, assume a lifetime average daily dose of 100 mg/kg/day corresponds to an individual risk of 4×10^{-1}. Increasing the dose fivefold, to 500 mg/kg/day, would result in a higher individual risk for that individual, but due to the nonlinearity of the dose-risk curve, not yet a risk of 1. The average dose for the five persons in the population would then be 100 mg/kg/day. Multiplying the “average risk” of 4×10^{-1} by the population size of five results in an estimate of two cases, even though in actuality only one person is exposed. Although calculating average individual dose, estimating individual risk from it, and multiplying by the population size is a useful approximation if all members of the population are within the approximately linear range of the dose-risk curve, this method should not be used if some members of the population have calculated individual risks higher than about 10^{-1}, since it will overestimate the number of cases.

FN41 In these cases, a significant problem can be the lack of a constant (or nearly constant) “slope factor” that would be appropriate over a wide exposure/dose range, since the dose-response curve may have thresholds, windows, or other discontinuities.

42 Each measure or estimate of exposure will have its associated uncertainty which should be addressed both qualitatively and quantitatively. For example, if population mean exposure is being addressed by use of direct personal monitoring data, qualitative issues will include the representativeness of the population monitored to the full population, the representativeness of the period selected for monitoring, and confidence that there were not systematic errors in the measured data. Quantitative uncertainty could be addressed through the use of confidence intervals for the actual mean population exposure.

43 The confidence interval is interpreted as the range of values within which the assessor knows the true measure lies, with specified statistical confidence. The upper bound confidence limit is the higher of the two ends of the confidence interval.

End of Document

60 FR 15366-01
RULES and REGULATIONS
ENVIRONMENTAL PROTECTION AGENCY
40 CFR Parts 9, 122, 123, 131, and 132
[FRL-5173-7]
RIN 2040-AC08

Final Water Quality Guidance for the Great Lakes System

Thursday, March 23, 1995

***15366** AGENCY: U.S. Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: EPA is publishing Final Water Quality Guidance for the Great Lakes System. Great Lakes States and Tribes will use the water quality criteria, methodologies, policies, and procedures in the Guidance to establish consistent, enforceable, long-term protection for fish and shellfish in the Great Lakes and their tributaries, as well as for the people and wildlife who consume them.

The Guidance was initially developed by the Great Lakes States, EPA, and other Federal agencies in open dialogue with citizens, local governments, and industries in the Great Lakes ecosystem. It will affect all types of pollutants, but will target especially the types of long-lasting pollutants that accumulate in the food web of large lakes.

The Guidance consists of water quality criteria for 29 pollutants to protect aquatic life, wildlife, and human health, and detailed methodologies to develop criteria for additional pollutants; implementation procedures to develop more consistent, enforceable water quality-based effluent limits in discharge permits, as well as total maximum daily loads of pollutants that can be allowed to reach the Lakes and their tributaries from all sources; and antidegradation policies and procedures.

Under the Clean Water Act, the States of Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin must adopt provisions into their water quality standards and NPDES permit programs within two years (by March 23, 1997) that are consistent with the Guidance, or EPA will promulgate the provisions for them. The Guidance for the Great Lakes System will help establish consistent, enforceable, long-term protection from all types of pollutants, but will place short-term emphasis on the types of long-lasting pollutants that accumulate in the food web and pose a threat to the Great Lakes System. The Guidance includes minimum water quality criteria, antidegradation policies, and implementation procedures that provide a coordinated ecosystem approach for addressing existing and possible pollutant problems and improves consistency in water quality standards and permitting procedures in the Great Lakes System. In addition, the Guidance provisions help establish consistent goals or minimum requirements for Remedial Action Plans (RAPs) and Lakewide Management Plans (LaMPs) that are critical to the success of international multi-media efforts to protect and restore the Great Lakes ecosystem.

EFFECTIVE DATE: April 24, 1995.

ADDRESSES: The public docket for this rulemaking, including applicable Federal Register documents, public comments in response to these documents, the Final Water Quality Guidance for the Great Lakes System, Response to Comments Document, other major supporting documents, and the index to the docket are available for inspection and copying at U.S. EPA Region 5, 77 West Jackson Blvd., Chicago, IL 60604 by appointment only. Appointments may be made by calling Wendy Schumacher (telephone 312-886-0142).

Information concerning the Great Lakes Initiative (GLI) Clearinghouse is available from Ken Fenner, Water Quality Branch Chief, (WQS-16J), U.S. EPA Region 5, 77 W. Jackson Blvd., Chicago, IL 60604 (312-353-2079).

Copies of the Information Collection Request for the Guidance are available by writing or calling Sandy Farmer, Information Policy Branch, EPA, 401 M St., S.W. (Mail Code 2136), Washington, DC 20460 (202-260-2740).

Selected documents supporting the Guidance are also available for viewing by the public at locations listed in section XI of the preamble.

Selected documents supporting the Guidance are available by mail upon request for a fee. Selected documents are also available in electronic format at no incremental cost to users of the Internet. See section XI of the preamble for additional information.

FOR FURTHER INFORMATION CONTACT: Kenneth A. Fenner, Water Quality Branch Chief (WQS-16J), U.S. EPA Region 5, 77 W. Jackson Blvd., Chicago, IL 60604 (312-353-2079).

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I. Introduction

Section 118(c)(2) of the Clean Water Act (CWA) (Pub. L. 92-500 as amended by the Great Lakes Critical Programs Act of 1990 (CPA), Pub. L. 101-596, November 16, 1990) required EPA to publish proposed and final water quality guidance on minimum water quality standards, antidegradation policies, and implementation procedures for the Great Lakes System. In response to these requirements, EPA published the Proposed Water Quality Guidance for the Great Lakes System (proposed Guidance) in the Federal Register on April 16, 1993 (58 FR 20802). EPA also published four subsequent documents in the Federal Register identifying corrections and requesting comments on additional related materials (April 16, 1993, 58 FR 21046; August 9, 1993, 58 FR 42266; September 13, 1993, 58 FR 47845; and August 30, 1994, 59 FR 44678). EPA received over 26,500 pages of comments, data, and information from over 6,000 commenters in response to ***15367** these documents and from meetings with members of the public.

After reviewing and analyzing the information in the proposal and these comments, EPA has developed the Final Water Quality Guidance for the Great Lakes System (final Guidance), published in this document and codified in 40 CFR part 132, which includes six appendixes of detailed methodologies, policies, and procedures. This preamble describes the background and purpose of the final Guidance, and briefly summarizes the major provisions. Detailed discussion of EPA's reasons for issuing the final Guidance, analysis of comments and issues, description of specific changes made to the proposed Guidance, and further description of the final Guidance, are provided in “Final Water Quality Guidance for the Great Lakes System: Supplementary Information Document” (SID), (EPA, 1995, 820-B-95-001) and in additional technical and supporting documents which are available in the docket for this rulemaking. Copies of the SID and other supporting documents are also available from EPA in electronic format, or in printed form for a fee upon request; see section XI of this preamble.

II. Background

The Great Lakes are one of the outstanding natural resources of the world. They have played a vital role in the history and development of the United States and Canada, and have physical, chemical, and biological characteristics that make them a unique ecosystem. The Great Lakes themselves—Lakes Superior, Huron, Michigan, Erie and Ontario and their connecting channels—plus all of the streams, rivers, lakes and other bodies of water that are within the drainage basin of the Lakes collectively comprise the Great Lakes System.

The System spans over 750 miles across eight States—New York, Pennsylvania, Ohio, Michigan, Indiana, Illinois, Wisconsin and Minnesota—and the Province of Ontario. The Lakes contain approximately 18 percent of the world's and 95 percent of the United States' fresh surface water supply. The Great Lakes are a source of drinking water and energy, and are used for recreational, transportation, agricultural and industrial purposes by the more than 46 million Americans and Canadians who inhabit the Great Lakes region, including 29 Native American tribes. Over 1,000 industries and millions of jobs are dependent upon water from the Great Lakes. The Great Lakes System also supports hundreds of species of aquatic life, wildlife and plants along more than 4,500 miles of coastline which boast six National Parks and Lakeshores, six National Forests, seven National Wildlife Refuges, and hundreds of State parks, forests and sanctuaries.

Because of their unique features, the Great Lakes are viewed as important to the residents of the region, and to the Nation as a whole. The natural resources of the region have contributed to the development of its economy. The Lakes' natural beauty and aquatic resources form the basis for heavy recreational activity. The Great Lakes Basin Ecosystem—the interacting components of air, land, water and living organisms, including humans, that live within the Great Lakes drainage basin—is a remarkably diverse and unique ecosystem important in the global ecology.

In the past few decades, the presence of environmental contaminants in the Great Lakes has been of significant concern. In spite of the fact that the Great Lakes contain 5,500 cubic miles of water that cover a total surface area of 94,000 square miles, they have proved to be sensitive to the effects of pollutants that accumulate in them. The internal responses and processes that operate in the Great Lakes because of their depth and long hydraulic residence times cause pollutants to recycle between biota, sediments and the water column.

The first major basin-wide environmental problem in the Great Lakes emerged in the late 1960s, when increased nutrients had dramatically stimulated the growth of green plants and algae, reduced dissolved oxygen levels, and accelerated the process of eutrophication. As oxygen levels continued to drop, certain species of insects and fish were displaced from affected areas of the Great Lakes Basin Ecosystem. Environmental managers determined that a lakewide approach was necessary to adequately control accelerated eutrophication. From the late 1960s through the late 1970s, United States and Canadian regulatory agencies agreed on measures to limit the loadings of phosphorus, including effluent limits on all major municipal sewage treatment facilities, limitations on the phosphorus content in household detergents, and reductions in nonpoint source runoff loadings. As a result of all of these efforts, open lake phosphorus concentrations have declined, and phosphorus loadings from municipal sewage treatment facilities have been reduced by an estimated 80 to 90 percent. These reductions have resulted in dramatic improvements in nearshore water quality and measurable improvements in open lake conditions.

More recently, scientists and public leaders have reached a general consensus that the presence of environmentally persistent, bioaccumulative contaminants is a serious environmental threat to the Great Lakes Basin Ecosystem. Beginning in 1963, adverse environmental impacts in the form of poor reproductive success and high levels of the pesticide DDT were observed in herring gulls in Lake Michigan. Through ongoing research, scientists have detected 362 contaminants in the Great Lakes System. Of these, approximately one third have toxicological data showing that they can have acute or chronic toxic effects on aquatic life, wildlife and/or human health. Chemicals that have been found to bioaccumulate at levels of concern in the Great Lakes include, but are not limited to, polychlorinated biphenyls (PCBs), mercury, DDT, dioxin, chlordane, and mirex. The main route of exposure to these chemicals for humans is through the consumption of Great Lakes fish.

Potential adverse human health effects by these pollutants resulting from the consumption of fish include both the increased risk of cancer and the potential for systemic or noncancer risks such as kidney damage. EPA has calculated health risks to populations in the Great Lakes basin from consumption of contaminated fish based on exposure to eight bioaccumulative pollutants: chlordane, DDT, dieldrin, hexachlorobenzene, mercury, PCBs, 2,3,7,8-TCDD, and toxaphene. These chemicals were chosen based on their potential to cause adverse human health effects (i.e., cancer or disease) and the availability of information on fish tissue contaminant concentrations from the Great Lakes.

Based on these data, EPA estimates that the lifetime cancer risks for Native Americans in the Great Lakes System due to ingestion of contaminated fish at current concentrations range from $1.8\ 10^{-3}$ (Lake Superior) (1.8 in one thousand) to $3.7\ 10^{-2}$ (Lake Michigan) (3.7 in 100). Estimated risks to low income minority sport anglers range from $2.5\ 10^{-3}$ (2.5 in one thousand) (Lake Superior) to $1.2\ 10^{-2}$ (1.2 in 100) (Lake Michigan). Estimated risks for other sport anglers range from $9.7\ 10^{-4}$ (9.7 in ten thousand) (Lake Superior) to $4.5\ 10^{-3}$ (4.5 in one thousand) (Lake Michigan). (See section I.B.2.a of the SID.) In comparison, EPA has long maintained that $1\ 10^{-4}$ (one in ten thousand) to $1\ 10^{-6}$ (one in 1 million) is an appropriate range of risk to protect human health.

***15368** EPA also estimates a high potential risk of systemic (noncancer) injury to populations in the Great Lakes basin due to ingestion of fish contaminated with these pollutants at current concentrations. The systemic adverse health effects associated with the assessed contaminants are described in section I.B of the SID.

Although the Great Lakes States and EPA have moved forward to deal with these problems, control of persistent, bioaccumulative pollutants proved to be more complex and difficult than dealing with nutrients. As a result, inconsistencies began to be apparent in the ways various States developed and implemented controls for the pollutants. By the mid-1980s, such inconsistencies became of increasing concern to EPA and State environmental managers.

EPA began the Great Lakes Water Quality Initiative (“Initiative”) in cooperation with the Great Lakes States to establish a consistent level of environmental protection for the Great Lakes ecosystem, particularly in the area of State water quality standards and the National Pollutant Discharge Elimination System (NPDES) programs. In the spring of 1989, the Council of Great Lakes Governors unanimously agreed to participate in the Initiative with EPA, because the Initiative supported the principles and goals of the Great Lakes Toxic Substances Control Agreement (Governors' Agreement). Signed in 1986 by the Governors of all eight Great Lakes States, the Governors' Agreement affirmed the Governors' intention to manage and protect the resources of the Great Lakes basin through the joint pursuit of unified and cooperative principles, policies and programs enacted and adhered to by each Great Lakes State.

The Initiative provided a forum for a regional dialogue to establish minimum requirements that would reduce disparities between State water quality controls in the Great Lakes basin. The scope of the Initiative included development of proposed Great Lakes water quality guidance—Great Lakes-specific water quality criteria and methodologies to protect aquatic life, wildlife and human health, procedures to implement water quality criteria, and an antidegradation policy.

Three committees were formed to oversee the Initiative. A Steering Committee (composed of directors of water programs from the Great Lakes States' environmental agencies and EPA's National and Regional Offices) discussed policy, scientific, and technical issues, directed the work of the Technical Work Group and ratified final proposals. The Technical Work Group (consisting of technical staff from the Great Lakes States' environmental agencies, EPA, the U.S. Fish and Wildlife Service, and the National Park Service) prepared proposals on elements of the Guidance for consideration by the Steering Committee. The Public Participation Group (consisting of representatives from environmental groups, municipalities, industry and academia) observed the deliberations of the other two committees, advised them of the public's concerns, and kept its various constituencies apprised of ongoing activities and issues. These three groups were collectively known as the Initiative Committees. From the start, one goal of the Initiative Committees was to develop the Guidance elements in an open public forum, drawing upon the extensive expertise and interest of individuals and groups within the Great Lakes community.

The Initiative efforts were well underway when Congress amended section 118 of the CWA in 1990 through the CPA. The general purpose of these amendments was to improve the effectiveness of EPA's existing programs in the Great Lakes by identifying key treaty provisions agreed to by the United States and Canada in the Great Lakes Water Quality Agreement (GLWQA), imposing statutory deadlines for the implementation of these key activities, and increasing Federal resources for program operations in the Great Lakes System.

Section 118(c)(2) requires EPA to publish proposed and final water quality guidance for the Great Lakes System. This Guidance must conform with the objectives and provisions of the GLWQA (a binational agreement establishing common water quality objectives for the Great Lakes) and be no less restrictive than provisions of the CWA and National water quality criteria and guidance. The Guidance must specify minimum requirements for the waters in the Great Lakes System in three areas: (1) water quality standards (including numerical limits on pollutants in ambient Great Lakes waters to protect human health, aquatic life and wildlife); (2) antidegradation policies; and (3) implementation procedures.

The Great Lakes States must adopt water quality standards, antidegradation policies and implementation procedures for waters within the Great Lakes System which are consistent with the final Guidance within two years of EPA's publication. In the absence of such action, EPA is required to promulgate any necessary requirements within that two-year period. In addition, when an Indian Tribe is authorized to administer the NPDES or water quality standards program in the Great Lakes basin, it will also need to adopt provisions consistent with the final Guidance into their water programs.

On December 6, 1991, the Initiative Steering Committee unanimously recommended that EPA publish the draft Guidance ratified by that group in the Federal Register for public review and comment. The agreement that the draft Great Lakes Guidance was ready for public notice did not represent an endorsement by every State of all of the specific proposals. Rather, all parties agreed on the importance of proceeding to publish the draft Great Lakes Guidance in order to further solicit public comment. State Steering Committee members indicated their intent to develop and submit specific comments on the proposed Guidance during the public comment period. EPA worked to convert the agreements reached in principle by the Steering Committee into a formal package suitable for publication in the Federal Register as proposed Guidance. EPA generally used the draft proposal ratified by the Steering Committee as the basis for preparing the Federal Register proposal package. Modifications were necessary, however, to reflect statutory and regulatory requirements and EPA policy considerations, to propose procedures for State and Tribal adoption of the final Guidance, to provide suitable discussion of various alternative options, and to accommodate necessary format changes. Where modifications were made, the preamble to the proposal described both the modification and the original Steering Committee-approved guidelines, and invited public comment on both. All elements approved by the Steering Committee were either incorporated in the proposed rule or discussed in the preamble to the proposal.

III. Purpose of the Guidance

The final Guidance represents a milestone in the 30 years of effort described above on the part of the Great Lakes stakeholders to define and apply innovative, comprehensive environmental programs in protecting and restoring the Great Lakes. In particular, this publication of the final Guidance culminates six years of intensive, cooperative effort that included participation by the eight Great Lakes States, the environmental community, academia, industry, municipalities and EPA Regional and National offices.

***15369** The final Guidance will help establish consistent, enforceable, long-term protection with respect to all types of pollutants, but will place short-term emphasis on the types of long-lasting pollutants that accumulate in the food web and pose a threat to the Great Lakes System. The final Guidance will establish goals and minimum requirements that will further the next phase of Great Lakes programs, including the Great Lakes Toxic Reduction Effort's integrated, multi-media ecosystem approach.

EPA and State development of the Guidance—from drafting through proposal and now final publication—was guided by several general principles that are discussed below.

A. Use the Best Available Science to Protect Human Health, Aquatic Life, and Wildlife

EPA and the Initiative Committees have been committed throughout the Initiative to using the best available science to develop programs to protect the Great Lakes System. In the 1986 Governors' Agreement, the Governors of the Great Lakes States recognized that the problem of persistent toxic substances was the foremost environmental issue confronting the Great Lakes. They also recognized that the regulation of toxic contaminants was scientifically complex because the pollutants are numerous, their pathways into the Lakes are varied, and their effects on the environment, aquatic life and human health are not completely understood. Based on the importance of the Great Lakes Basin Ecosystem and the documented adverse effects from toxic contamination, however, the Governors directed their environmental administrators to jointly develop an agreement and procedure for coordinating the control of toxic releases and achieving greater uniformity of regulations governing such releases within the Great Lakes basin.

As discussed further above, the Initiative was subsequently created to begin work on these goals. EPA and the Great Lakes States, with input from interested parties in the basin, began collecting and analyzing data, comparing regulatory requirements and technical guidance in their various jurisdictions, and drafting specific methodologies and procedures to control the discharge of toxic contaminants. The provisions of the final Guidance were based in large part on these prior efforts of the Initiative Committees, and incorporate the best available science to protect human health, wildlife and aquatic life in the Great Lakes System. For example, the final Guidance includes new criteria and a methodology developed by the Initiative Committees to specifically protect wildlife; incorporates recent data on the bioavailability of metals into the aquatic life criteria and methodologies; incorporates Great Lakes-specific data on fish consumption rates and fish lipid contents into the human health criteria; and provides a methodology to determine the bioaccumulation properties of individual pollutants. Additionally, EPA understands that the science of risk assessment is rapidly improving. Therefore, in order to ensure that the scientific basis for the criteria methodologies is always current and peer reviewed, EPA will review the methodologies and revise them as appropriate every three years.

B. Recognize the Unique Nature of the Great Lakes Basin Ecosystem

The final Guidance also reflects the unique nature of the Great Lakes Basin Ecosystem by establishing special provisions for chemicals of concern. EPA and the Great Lakes States believe it is reasonable and appropriate to establish special provisions for the chemicals of most concern because of the physical, chemical and biological characteristics of the Great Lakes System, and the documented environmental harm to the ecosystem from the past and continuing presence of these types of pollutants. The Initiative Committees devoted considerable effort to identifying the chemicals of most concern to the Great Lakes System —persistent, bioaccumulative pollutants termed “bioaccumulative chemicals of concern (BCCs)”—and developing the most appropriate criteria, methodologies, policies, and procedures to address them. The special provisions for BCCs, initially developed by the Initiative Committees and incorporated into the final Guidance, include antidegradation procedures, to ensure that future problems are minimized; general phase-out and elimination of mixing zones for BCCs, except in limited circumstances, to reduce their overall loadings to the Lakes; more extensive data generation requirements to ensure that they are not under-regulated for lack of data; and development of water quality criteria that will protect wildlife that feed on aquatic prey.

The final Guidance is designed not only to begin to address existing problems, but also to prevent emerging and potential problems posed by additional chemicals in the future which may damage the overall health of the Great Lakes. The experience with such pollutants as DDT and PCBs indicates that it takes many decades to overcome the damage to the ecosystem caused by even short-term discharges, and that prevention would have been dramatically less costly than clean-up. Issuance of the final Guidance alone will not solve the existing long-term problems in the Great Lakes System from these contaminants. Full implementation of provisions consistent with the final Guidance will, however, provide a coordinated ecosystem approach for addressing possible pollutant problems before they produce adverse and long-lasting basin-wide impacts, rather than waiting to see what the future impacts of the pollutants might be before acting to control them. The comprehensive approach used in the development of the final Guidance provides regulatory authorities with both remedial and preventive ways of gauging the actions and potential effects of chemical stressors upon the Great Lakes Basin Ecosystem. The methodologies, policies and procedures contained in the final Guidance provide mechanisms for appropriately addressing both pollutants that have been or may in the future be documented as chemicals of concern.

C. Promote Consistency in Standards and Implementation Procedures While Allowing Appropriate Flexibility to States and Tribes

Promoting consistency in standards and implementation procedures while providing for appropriate State flexibility was the third principle in State and EPA development of the final Guidance. The underlying rationale for the Governors' Agreement, the Initiative, and the requirements set forth in the CPA was a recognition of the need to promote consistency through adoption of minimum water quality standards, antidegradation policies, and implementation procedures by Great Lakes States and Tribes to protect human health, aquatic life and wildlife. Although provisions in the CWA provide for the adoption of and periodic revisions to State water quality criteria, such provisions do not necessarily ensure that water quality criteria of adjoining States are consistent within a shared water body. For example, ambient water quality criteria in place in six of the eight Great Lakes States to protect aquatic life from acute effects range from 1.79 MUg/L to 15.0 MUg/L for cadmium, and from 0.21 MUg/L to 1.33 MUg/L for dieldrin. Other examples of variations in acute aquatic life criteria include nickel, which ranges from 290.30 MUg/L to 852.669 MUg/L; lindane, ***15370** with a range of no criteria in place to 1.32 MUg/L; and mercury, ranging from 0.5 MUg/L to 2.4 MUg/L. Similar ranges and disparities exist for chronic aquatic life criteria, and for water quality criteria to protect human health.

Disparities also exist among State procedures to translate water quality criteria into individual discharge permits. Wide variations exist, for example, in procedures for the granting of mixing zones, interpretation of background levels of pollutants, consideration of pollutants present in intake waters, controls for pollutants present in concentrations below the level of detection, and determination of appropriate levels for pollutants discharged in mixtures with other pollutants. Additionally, when addressing the accumulation of chemicals by fish that will be consumed by humans and wildlife, some States consider accumulation through multiple steps in the food chain (bioaccumulation) while others consider only the single step of concentration from the water column (bioconcentration). Further disparities exist in different translator methodologies in deriving numeric values for implementing narrative water quality criteria; different assumptions when calculating total maximum daily loads (TMDLs) and wasteload allocations (WLAs), including different assumptions about background concentrations, mixing zones, receiving water flows, or environmental fate; and different practices in deciding what pollutants need to be regulated in a discharge, what effect detection limits have on compliance determinations, and how to develop whole effluent toxicity limitations.

These inconsistencies in State standards and implementation procedures have resulted in the disparate regulation of point source discharges. In the Governors' Agreement, the Governors recognized that the water resources of the basin transcend political boundaries and committed to taking steps to manage the Great Lakes as an integrated ecosystem. The Great Lakes States, as participants in the Initiative Committees, recommended provisions, based on their extensive experience in administering State water programs and knowledge of the significant differences in these programs within the basin, that were ultimately included in the proposed Guidance. The final Guidance incorporates the work begun by the Initiative Committees to identify these disparities and improve consistency in water quality standards and permit procedures in the Great Lakes System.

Although improved consistency in State water programs is a primary goal of the final Guidance, it is also necessary to provide appropriate flexibility to States and Tribes in the development and implementation of water programs. In overseeing States' implementation of the CWA, EPA has found that reasonable flexibility is not only necessary to accommodate site-specific situations and unforeseen circumstances, but is also appropriate to enable innovation and progress as new approaches and information become available. Many commenters, including the Great Lakes States, urged EPA to evaluate the appropriate level of flexibility provided to States and Tribes in the proposed Guidance provisions. EPA reviewed all sections of the proposed Guidance and all comments received to determine the appropriate level of flexibility needed to address these concerns while still providing a minimum level of consistency between the State and Tribal programs. Based on this review, the final Guidance provides flexibility for State and Tribal adoption and implementation of provisions consistent with the final Guidance in many areas, including the following:

—Antidegradation: Great Lakes States and Tribes may develop their own approaches for implementing the prohibition against deliberate actions of dischargers that increase the mass loading of BCCs without an approved antidegradation demonstration. Furthermore, States and Tribes have flexibility in adopting antidegradation provisions regarding non-BCCs.

—TMDLs: Great Lakes States and Tribes may use assessment and remediation plans for the purposes of appendix F to part 132 if the State or Tribe certifies that the assessment and remediation plan meets certain TMDL-related provisions in the final Guidance and public participation requirements applicable to TMDLs, and if EPA approves such plan. Thus, States have the flexibility in many cases to use LAMPs, RAPs and State Water Quality Management Plans in lieu of TMDLs.

—Intake Credits: Great Lakes States and Tribes may consider the presence of intake water pollutants in establishing water quality-based effluent limits (WQBELs) in accordance with procedure 5 of appendix F.

—Site-Specific Modifications: Great Lakes States and Tribes may adopt either more or less stringent modifications to human health, wildlife, and aquatic life criteria and bioaccumulation factors (BAFs) based on site-specific circumstances specified in procedure 1 of appendix F. All criteria, however, must be sufficient not to cause jeopardy to threatened or endangered species listed or proposed to be listed under the Federal Endangered Species Act.

—Variances: Great Lakes States and Tribes may grant variances from water quality standards based on the factors identified in procedure 2 of appendix F.

—Compliance Schedules: Great Lakes States and Tribes may allow existing Great Lakes dischargers additional time to comply with permit limits in order to collect data to derive new or revised Tier I criteria and Tier II values in accordance with procedure 9 of appendix F.

—Mixing Zones: Great Lakes States and Tribes may authorize mixing zones for existing discharges of BCCs after the 10-year phase-out period in accordance with procedure 3.B of appendix F, if the permitting authority determines, among other things, that the discharger has reduced its discharge of the BCC for which a mixing zone is sought to the maximum extent possible. Water conservation efforts that result in overall reductions of BCCs are also allowed even if they result in higher effluent concentrations.

—Scientific Defensibility Exclusion: Great Lakes States and Tribes may apply alternate procedures consistent with Federal, State, and Tribal requirements upon demonstration that a provision in the final Guidance would not be scientifically defensible if applied to a particular pollutant in one or more sites. This provision is in §132.4(h) of the final Guidance.

—Reduced Detail: In many instances, EPA has revised the proposed Guidance to reduce the amount of detail in the provisions without sacrificing the objectives of the provisions. Examples of such revisions include simplification of procedures for developing TMDLs in procedure 3 of appendix F, and simplification of procedures for determining reasonable potential to exceed water quality standards in procedure 5.B of appendix F.

—Other Provisions: Flexibility is also present in provisions for the exercise of best professional judgment by the Great Lakes States and Tribes when implementing many individual provisions in the final Guidance including: determining the appropriate uncertainty factors in the human health and wildlife criteria methodologies; selection of data sets for establishing water quality criteria; identifying reasonable and prudent ***15371** measures in antidegradation provisions; and specifying appropriate margins of safety when developing TMDLs. In all cases, of course, State and Tribal provisions would need to be scientifically defensible and consistent with all applicable regulatory requirements.

D. Establish Equitable Strategies to Control Pollution Sources

Many commenters argued that the proposed Guidance unfairly focused on point source discharges. They asserted that nonpoint sources or diffuse sources of pollution, such as air emissions, are responsible for most of the loadings of some pollutants of concern in the Great Lakes, that increased regulation of point sources will be inequitable and expensive, and that the final Guidance will not result in any environmental improvement given the large, continuing contribution of toxic pollutants by nonpoint sources.

EPA recognizes that regulation of point source discharges alone cannot address all existing or future environmental problems from toxic pollutants in the Great Lakes. In addition to discharges from point sources, toxic pollutants are also contributed to the Great Lakes from industrial and municipal emissions to the air, resuspension of pollutants from contaminated sediments, urban and agricultural runoff, hazardous waste and Superfund sites, and spills. Restoration and maintenance of a healthy ecosystem will require significant efforts in all of these areas. EPA, Canada and the Great Lakes States and Tribes are currently implementing or developing many voluntary and regulatory programs to address these and other nonpoint sources of environmental contaminants in the Great Lakes.

Additionally, EPA intends to use the scientific data developed in the final Guidance and new or revised water quality criteria subsequently adopted by Great Lakes States and Tribes in evaluating and determining appropriate levels of control in other environmental programs. For example, EPA's future biennial reports under section 112(m) of the Clean Air Act will consider the extent to which air discharges cause or contribute to exceedances of water quality criteria in assessing whether additional air emission standards or control measures are necessary to prevent serious adverse effects. Similarly, once provisions consistent with the final Guidance are adopted by the Great Lakes States or Tribes, they will serve as applicable or relevant and appropriate requirements (ARARs) for on-site responses under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). EPA will also consider the data and criteria developed for the final Guidance, including the information on BCCs, in developing or evaluating LaMPs and RAPs under section 118 of the CWA and Article VI, Annex 2 of the GLWQA; determination of corrective action requirements under sections 3004(u), 3008(h), or 7003 of the Solid Waste Disposal Act; new or existing chemical reviews under the Toxic Substances Control Act (TSCA); pesticide reviews under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and reporting requirements for toxic releases under the Emergency Planning and Community Right-to-Know Act (EPCRA).

The final Guidance also includes provisions to address the contribution of pollutants by nonpoint sources. First, the water quality criteria to protect human health, wildlife and aquatic life, and the antidegradation provisions apply to the waters in the Great Lakes System regardless of whether discharges to the water are from point or nonpoint sources. Accordingly, any regulatory programs for nonpoint sources that require compliance with water quality standards would also be subject to the criteria and antidegradation provisions of the final Guidance once they are adopted into State or Tribal standards.

Second, several elements of the final Guidance would, after State, Tribal or Federal promulgation, require or allow permitting authorities to consider the presence of pollutants in ambient waters—including pollutants from nonpoint source dischargers—in establishing WQBELs for point sources. For example, permit authorities may consider the presence of other point or nonpoint source discharges when evaluating whether to grant a variance from water quality criteria. Additionally, the provisions for TMDLs address nonpoint sources by specifying that the loading capacity of a receiving water that does not meet water quality standards for a particular pollutant be allocated, where appropriate, among nonpoint as well as point sources of the pollutant, including, at a minimum, a margin of safety to account for technical uncertainties in establishing the TMDL.

The development of TMDLs is the preferred mechanism for addressing equitable division of the loading capacities of these nonattained waters. Because TMDLs have not been completed for most nonattained waters, however, the final Guidance promotes the development of TMDLs through a phased approach, where appropriate, and provides for short-term regulatory relief to point source dischargers in the absence of TMDLs through intake credits, variances, and other water quality permitting procedures.

EPA received numerous comments on the problem posed in controlling mercury in particular. Many commenters stated that since the primary source of mercury is now atmospheric deposition, point sources contribute only a minor portion of the total loading of mercury to the Great Lakes System and further restriction of point source discharges would have no apparent effect in improving water quality. Although EPA believes that there is sufficient flexibility in the Guidance to handle the unique problems posed by mercury (e.g., water quality variances, phased TMDLs, intake credits), EPA is committed to developing a mercury permitting strategy to provide a holistic, comprehensive approach for dealing with this pollutant. EPA will publish this strategy no later than two years following publication of this Guidance.

There are also many ongoing voluntary and regulatory activities that address nonpoint sources of toxic pollutants to the Great Lakes System, including activities taken under the Clean Air Act Amendments of 1990 (CAAA), the CWA, and State regulatory and voluntary programs. Some of these activities are summarized in the preamble to the proposed Guidance (58 FR 20826-32) and section I.D of the SID.

In addition to the many ongoing activities, EPA and the Great Lakes States, Tribes, and other federal agencies are pursuing a multi-media program to prevent and to further reduce toxic loadings from all sources of pollution to the Great Lakes System, with an emphasis on nonpoint sources. This second phase of the Great Lakes Water Quality Initiative, called the Great Lakes Toxic Reduction Effort (GLTRE), will build on the open, participative public dialogue established during the development of the final Guidance. Through the GLTRE, the Federal, State, and Tribal agencies intend to coordinate and enhance the effectiveness of ongoing actions and existing tools to prevent and reduce nonpoint source and wet-weather point source contributions of toxic pollutants in the Great Lakes System. A special emphasis will be placed on BCCs identified in the final Guidance.

A partial list of ongoing actions that are being or could be focused on BCCs includes: implementation of the CAAA to reduce atmospheric deposition of toxics; Resource Conservation and Recovery Act and CERCLA remedial actions to reduce loadings of toxics from ***15372** hazardous waste sites; increased focus (through the GLTRE) on toxic pollutants emanating from combined sewer overflows and stormwater outfalls; application in the Great Lakes basin of the National Contaminated Sediment Management Strategy; implementation of spill prevention planning practices to minimize this potential source of loadings to the Great Lakes; improved reporting of toxic pollutants under the Toxic Release Inventory; public education on the dangers of mercury and other BCCs; pesticide registration and re-registration processes; development of a "mass balance" model for fate and transport of pollutants in the Great Lakes; and, development of a "virtual elimination strategy." These programs will prevent and further reduce mass loadings of pollutants and facilitate equitable division of the costs of any necessary control measures between point and nonpoint sources.

In addition to the GLTRE, which is basin-wide in scope, a primary vehicle for coordinating Federal and State programs at the local level for meeting water quality standards and restoring beneficial uses for the open waters of the Great Lakes are LaMPS. LaMPs will define media specific program actions to further reduce loadings of toxic substances, assess whether these programs will ensure restoration and attainment of water quality standards and designated beneficial uses, and recommend any media-specific program enhancements as necessary. Additionally, LaMPs will be periodically updated and revised to assess progress in implementing media-specific programs, assess the reductions in toxic loadings to the Great Lakes System through these programs, incorporate advances in the understanding of the System based on new data and information, and recommend specific adjustments to media programs as appropriate.

E. Promote Pollution Prevention Practices

The final Guidance also promotes pollution prevention practices consistent with EPA's National Pollution Prevention Strategy and the Pollution Prevention Action Plan for the Great Lakes. The Pollution Prevention Act of 1990 declares as National policy that reducing the sources of pollution is the preferred approach to environmental protection. When source reductions are not possible, however, recycling, treating and properly disposing of pollutants in an environmentally safe manner complete the hierarchy of management options designed to prevent pollution from entering the environment.

Consistent with the goals of the Pollution Prevention Act, EPA developed the Great Lakes Pollution Prevention Action Plan (April, 1991). The Great Lakes Pollution Prevention Action Plan highlights how EPA, in partnership with the States, will incorporate pollution prevention into actions designed to reduce the use and release of toxic substances in the Great Lakes basin.

The final Guidance builds upon these two components of the Great Lakes program by promoting the development of pollution prevention analysis and activities in the level of detection, mixing zone, and antidegradation sections of the final Guidance. Also, the decision to provide special provisions for BCCs implements EPA's commitment to pollution prevention by reducing the discharge of these pollutants in the future. This preventive step not only makes good environmental management sense, but is appropriate based on the documented adverse effects that the past and present discharge of these pollutants has produced in the Great Lakes basin.

F. Provide Accurate Assessment of Costs and Benefits

In developing the final Guidance, EPA identified and carefully evaluated the anticipated costs and benefits from implementation of the major provisions. EPA received many comments on the draft cost and benefit studies conducted as part of the proposed Regulatory Impact Analysis (RIA) required by Executive Order 12291, and its successor, Executive Order 12866. Based upon consideration of those comments and further analysis, EPA has revised the RIA. The results of this analysis are summarized in section V of this preamble.

IV. Summary of the Final Guidance

The final Guidance will establish minimum water quality standards, antidegradation policies, and implementation procedures for the waters of the Great Lakes System in the States of Illinois, Indiana, Michigan, Minnesota, New York, Pennsylvania, Ohio and Wisconsin, including waters within the jurisdiction of Indian Tribes. Specifically, the final Guidance specifies numeric criteria for selected pollutants to protect aquatic life, wildlife and human health within the Great Lakes System and provides methodologies to derive numeric criteria for additional pollutants discharged to these waters. The final Guidance also contains minimum procedures to translate the proposed ambient water quality criteria into enforceable controls on discharges of pollutants, and a final antidegradation policy.

The provisions of the final Guidance are not enforceable requirements until adopted by States or Tribes, or promulgated by EPA for a particular State or Tribe. The Great Lakes States and Tribes must adopt water quality standards, antidegradation policies, and implementation procedures for waters within the Great Lakes System consistent with the (as protective as) final Guidance or be subject to EPA promulgation. Great Lakes Tribes include any Tribe within the Great Lakes basin for which EPA has approved water quality standards under section 303 or has authorized to administer a NPDES program under section 402 of the CWA. No Indian Tribe has been authorized to administer these water programs in the Great Lakes basin as of this time. If a Great Lakes State fails to adopt provisions consistent with the final Guidance within two years of this publication in the Federal Register (that is, by March 23, 1997), EPA will publish a final rule at the end of that time period identifying the provisions of the final Guidance that will apply to waters and discharges within that jurisdiction. Additionally, when an Indian Tribe is authorized to administer the NPDES or water quality standards program in the Great Lakes basin, it will also need to adopt provisions consistent with the final Guidance into their water programs.

The following sections provide a brief summary of the provisions of the final Guidance. A more complete discussion of the final Guidance, including EPA's analysis of major comments, issues, and a description of specific changes made to the proposed Guidance, are contained in the SID.

The parenthetical note at the beginning of each section provides references to the primary provisions in the final Guidance being discussed in the section, and to discussions in the SID. The final Guidance is codified as 40 CFR 132, including appendixes A through F. Note that appendix F consists of procedures 1 through 9. For ease of reference, sections in appendix F may be referred to by appending the section designation to the procedure number. For example, section A.1 of procedure 1 may be referred to as procedure 1.A.1 of appendix F.

15373** ***A. Water Quality Criteria and Methodologies

1. Protection of Aquatic Life
(§§132.3(a), 132.3(b), 132.4(a)(2); Tables 1 and 2 to part 132; appendix A to part 132; section III, SID)

The final Guidance contains numeric criteria to protect aquatic life for 15 pollutants, and a two-tiered methodology to derive criteria (Tier I) or values (Tier II) for additional pollutants discharged to the Great Lakes System. Aquatic life criteria are derived to establish ambient concentrations for pollutants, which, if not exceeded in the Great Lakes System, will protect fish, invertebrates, and other aquatic life from adverse effects due to that pollutant. The final Guidance includes both acute and chronic criteria to protect aquatic life from acute and chronic exposures to pollutants.

Tier I aquatic life criteria for each chemical are based on laboratory toxicity data for a variety of aquatic species (e.g., fish and invertebrates) which are representative of species in the freshwater aquatic environment as a whole. The Guidance also includes a Tier II methodology to be used in the absence of the full set of data needed to meet Tier I data requirements. For pollutants for which Tier I criteria have not been adopted into State or Tribal water quality standards, States must use methodologies consistent with either the Tier I or Tier II methodologies, depending on the data available, in conjunction with whole effluent toxicity requirements in the final Guidance (see section IV.B.5 of this preamble), to implement their existing narrative water quality criteria that prohibit toxic pollutants in toxic amounts in all waters. The Great Lakes States and Tribes are not required to use the Tier II methodology to adopt numeric criteria into their water quality standards.

Use of the two-tiered final Guidance methodologies in these situations will enable regulatory authorities to translate narrative criteria to derive TMDLs and individual NPDES permit limits on a more uniform basis. EPA and the States determined that there is a need to regulate pollutants more consistently in the Great Lakes System when faced with limited numbers of criteria. Many of the Great Lakes States are already employing procedures similar to the approach in the final Guidance to implement narrative criteria. EPA determined the Tier II approach improves upon existing mechanisms by utilizing all available data.

The two-tiered methodology allows the application of the final Guidance to all pollutants, except those listed in Table 5 of part 132 (see section IV.E of this preamble). The Tier I aquatic life methodology includes data requirements very similar to those used in current guidelines for developing National water quality criteria guidance under section 304(a) of the CWA. For example, both require that acceptable toxicity data for aquatic species in at least eight different families representing differing habitats and taxonomic groups must exist before a Tier I numeric criterion can be derived. The Tier II aquatic life methodology is used to derive Tier II values which can be calculated with fewer toxicity data than Tier I. Tier II values can, in certain instances, be based on toxicity data from a single taxonomic family, provided the data are acceptable. The Tier II methodology generally produces more stringent values than the Tier I methodology, to reflect greater uncertainty in the absence of additional toxicity data. As more data become available, the derived Tier II values tend to become less conservative. That is, they more closely approximate Tier I numeric criteria. EPA and the States believe it is desirable to continue to supplement toxicity data to ultimately derive Tier I numeric criteria.

One difference from the existing National water quality criteria guidelines is that the final Guidance methodology for aquatic life deletes the provision in the National guidelines to use a Final Residue Value (FRV) in deriving a criterion. The FRV is intended to prevent concentrations of pollutants in commercially or recreationally important aquatic species from affecting the marketability of those species or affecting wildlife that consume them by preventing the exceedance of applicable Food

and Drug Administration action levels and concentrations that affect wildlife. The final Guidance provides specific, separate methodologies to protect wildlife and human health (discussed below) which EPA believes will provide more accurate and appropriate levels of protection than the FRVs.

For pollutants without Tier I criteria but with enough data to derive Tier II values for aquatic life, the proposal would have required permittees to meet permit limits based on both Tier II values and whole effluent toxicity (WET) testing. In response to comments, the final Guidance clarifies that States and Tribes may adopt provisions allowing use of indicator parameter limits consistent with 40 CFR 122.44(d)(1)(vi)(C). When deriving limits to meet narrative criteria, States and Tribes have the option of using an indicator parameter limit, including use of a WET limit under appropriate conditions, in lieu of a Tier II-based limit. If use of an indicator parameter is allowed, the State or Tribe must ensure that the indicator parameter will attain the "applicable water quality standard" (as described in 40 CFR 122.44(d)(1)(vi)(C). The "applicable water quality standard" in this instance would be the State's or Tribe's narrative water quality standard that protects aquatic life.

Finally, the aquatic criteria for metals in the proposed Guidance were expressed as total recoverable concentrations. The final Guidance expresses the criteria for metals in dissolved form because the dissolved metal more closely approximates the bioavailable fraction of metal in the water column than does the total recoverable metal. The dissolved criteria are obtained by multiplying the chronic and/or acute criterion by appropriate conversion factors in Table 1 or 2. This is consistent with many comments on the issue and with the policy on metals detailed in "Office of Water Policy and Technical Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria" (October 1, 1993). A document describing the methodology to convert total recoverable metals criteria to dissolved metals criteria was published in the Federal Register on August 30, 1994 (59 FR 44678). If a State or Tribe fails to adopt approvable aquatic life criteria for metals, EPA will promulgate criteria expressed as dissolved concentrations.

EPA Region 5, in cooperation with EPA Regions 2 and 3 and Headquarters offices, and the Great Lakes States and Tribes, will establish a Great Lakes Initiative (GLI) Clearinghouse to assist States and Tribes in developing numeric Tier I water quality criteria for aquatic life, human health and wildlife and Tier II water quality values for aquatic life and human health. As additional toxicological data and exposure data become available or additional Tier I numeric criteria and Tier II values are calculated by EPA, States, or Tribes, Region 5 will ensure that this information is disseminated to the Great Lakes States and Tribes. EPA believes operation of the GLI Clearinghouse will help ensure consistency during implementation of the final Guidance.

2. Protection of Human Health
(§§132.3(c), 132.4(a)(4); Table 3 to part 132; appendix C to part 132; section V of the SID)

The final Guidance contains numeric human health criteria for 18 pollutants, and includes Tier I and Tier II methodologies to derive cancer and ***15374** non-cancer human health criteria for additional pollutants. The proposed Guidance contained numeric criteria for 20 pollutants, but two pollutants were deleted because they do not meet the more restrictive minimum data requirements for BAFs used in the final Guidance.

Tier I human health criteria are derived to establish ambient concentrations of chemicals which, if not exceeded in the Great Lakes System, will protect individuals from adverse health impacts from that chemical due to consumption of aquatic organisms and water, including incidental water consumption related to recreational activities in the Great Lakes System. For each chemical, chronic criteria are derived to reflect long-term consumption of food and water from the Great Lakes System. Tier II values are intended to provide a conservative, interim level of protection in the establishment of a permit limit, and are distinguished from the Tier I approach by the amount and quality of data used for derivation.

The final Guidance differs from current National water quality criteria guidelines when calculating the assumed human exposure through consumption of aquatic organisms. The final Guidance uses BAFs predicted from biota-sediment accumulation factors (BSAFs) in addition to field-measured BAFs, and uses a food chain multiplier (FCM) to account for biomagnification when using measured or predicted bioconcentration factors (BCFs). BAFs are discussed further in section IV.A.4. of this preamble.

Human health water quality criteria for carcinogens are typically expressed in concentrations associated with a plausible upper bound of increased risk of developing cancer. In practice, the level of cancer risk generally accepted by EPA and the States typically ranges between 10^{4} (one in one thousand) and 10^{6} (one in one million). In contrast, as discussed in section II above, the cancer risk from ingestion of contaminated fish at current concentrations in the Great Lakes System are as high as 1.2 10^{2} (1.2 in 100). The proposed and final Guidance establishes 10^{5} (one in one hundred thousand) as the risk level used for deriving criteria and values for individual carcinogens. This is within the range historically used in EPA actions, and approved for State actions, designed to protect human health. The majority of the Great Lakes States use 10^{5} as a baseline risk level in establishing their water quality standards.

The methodology is designed to protect humans who drink water or consume fish from the Great Lakes System. The portion of the methodology addressing fish consumption includes a factor describing how much fish humans consume per day. The final Guidance includes a Great Lakes-specific fish consumption rate of 15 grams per day, based upon several fish consumption surveys from the Great Lakes, including a recent study by West et al. that was discussed in a Federal Register document on August 30, 1994 (59 FR 44678). This rate differs from the 6.5 grams per day rate which is used in the National water quality criteria guidelines as a National average consumption value. The 15 grams per day represents the mean consumption rate of regional fish caught and consumed by the Great Lakes sport fishing population.

Commenters argued that a 15 gram per day assumption in the methodology would not adequately protect populations that consume greater than this amount (e.g., low-income minority anglers and Native Americans), and that such an approach therefore would be inconsistent with Executive Order 12898 regarding environmental justice (February 16, 1994, 59 FR 7629). EPA believes that the human health criteria methodology, including the fish consumption rate, will provide adequate health protection for the public, including more highly exposed sub-populations. In carrying out regulatory actions under a variety of statutory authorities, including the CWA, EPA has generally viewed an upper bound incremental cancer risk in the range of 10^{4} to 10^{6} as adequately protective of public health. As discussed above, the human health criteria methodology is based on a risk level of 10^{5}. Therefore, if fish are contaminated at the level permitted by criteria derived under the final Guidance, individuals eating up to 10 times (i.e., 150 grams per day) the assumed fish consumption rate would still be protected at the 10^{4} risk level. Available data indicate that, even among low-income minorities who as a group consume more fish than the population on average, the overwhelming majority (approximately 95 percent) consume less than 150 grams per day. The final Guidance requires, moreover, that States and Tribes modify the human health criteria on a site-specific basis to provide additional protection appropriate for highly exposed sub-populations. Thus, where a State or Tribe finds that a population of high-end consumers would not be adequately protected by criteria derived using the 15 gram per day assumption (e.g., where the risk was greater than 10^{4}), the State or Tribe would be required to modify the criteria to provide appropriate additional protection. The final Guidance also requires States and Tribes to adopt provisions to protect human health from the potential adverse effects of mixtures of pollutants in effluents, specifically including mixtures of carcinogens. Understood in the larger context of the human health methodology and the final Guidance as a whole, therefore, EPA believes that the 15 gram per day fish consumption rate provides adequate health protection for the public, including highly exposed populations, and that the final Guidance is therefore consistent with Executive Order 12898.

In developing bioaccumulation factors, the proposed Guidance used a 5.0 percent lipid value for fish consumed by humans, based on Great Lakes-specific data. The current National methodology uses a 3.0 percent lipid value. The final Guidance uses a 3.10 percent lipid value for trophic level 4 fish and 1.82 for trophic level 3 fish. These percent lipid values are based on an analysis of the West et al. study cited above and data from State fish contaminant monitoring programs.

The final Guidance contains specific technical guidelines concerning the range of uncertainty factors that may be applied by the State and Tribal agencies on the basis of their best professional judgment. The final Guidance places a cap of 30,000 on the combined product of uncertainty factors that may be applied in the derivation of non-cancer Tier II values and a combined

uncertainty factor of 10,000 for Tier I criteria. The likely maximum combined uncertainty factor for Tier I criteria in most cases is 3,000. The SID discusses further the use of the uncertainty factors in the derivation of human health criteria and values.

The proposed Guidance used an 80 percent relative source contribution (RSC) from surface water pathways for BCCs, and a 100 percent RSC for all other pollutants, in deriving noncancer criteria. The RSC concept is applied in the National drinking water regulations and is intended to account, at least in part, for exposures from other sources for those bioaccumulative pollutants for which surface water pathways are likely to be major contributors to human exposure. The final Guidance uses the more protective 80 percent RSC for all pollutants in deriving noncancer criteria. This change was made because of concern that for non-BCCs as well as ***15375** BCCs, there may be other sources of exposures for noncarcinogens.

3. Protection of Wildlife

(§§132.3(d), 132.4(a)(5); Table 4 to part 132; appendix D to part 132; section VI of the SID)

The final Guidance contains numeric criteria to protect wildlife for four pollutants and a methodology to derive Tier I criteria for additional BCCs. Wildlife criteria are derived to establish ambient concentrations of chemicals which, if not exceeded, will protect mammals and birds from adverse impacts from that chemical due to consumption of food and/or water from the Great Lakes System.

These are EPA's first water quality criteria specifically for the protection of wildlife. The methodology is based largely on the noncancer human health paradigm. It focuses, however, on endpoints related to reproduction and population survival rather than the survival of individual members of a species. The methodology incorporates pollutant-specific effect data for a variety of mammals and birds and species-specific exposure parameters for two mammals and three birds representative of mammals and birds resident in the Great Lakes basin which are likely to experience significant exposure to bioaccumulative contaminants through the aquatic food web.

In the proposal, EPA included a two-tiered approach similar to that for aquatic life and human health. In response to comments, the final Guidance requires States and Tribes to adopt provisions consistent with only the Tier I wildlife methodology, and only to apply this methodology for BCCs (see section IV.A.4 below). The TSD provides discretionary guidelines for the use of Tier I and Tier II methodologies for other pollutants. The wildlife methodology was limited to the BCCs because these are the chemicals of greatest concern to the higher trophic level wildlife species feeding from the aquatic food web in the Great Lakes basin. This decision is consistent with comments made by the EPA Science Advisory Board (SAB) who agreed that the initial focus for wildlife criteria development should be on persistent, bioaccumulative organic contaminants (USEPA, 1994, EPA-SAB-EPEC-ADV-94-001).

Numerous commenters were concerned that the mercury criterion for wildlife was not scientifically appropriate. After review of all comments and a reevaluation of all the data, the mercury criterion for wildlife has been increased from 180 pg/L to 1300 pg/L. EPA believes the 1300 pg/L is protective of wildlife in the Great Lakes System.

In developing bioaccumulation factors, the proposed Guidance used a 7.9 percent lipid value for fish consumed by wildlife. The final Guidance uses a 10.31 percent lipid value for trophic level 4 fish and 6.46 for trophic level 3 fish. These percent lipid values are based on the actual prey species consumed by the representative wildlife species specified in the methodology, and are used to estimate the BAFs for the trophic levels which those species consume. The percent lipid is based on the preferential consumption patterns of wildlife and cross-referenced with fish weight and size and appropriate percent lipid. This approach is a more accurate reflection of the lipid content of the fish consumed by wildlife species than the approach used in the proposal.

4. Bioaccumulation Methodology

(§132.4(a)(3); appendix B to part 132; section IV of the SID)

The proposed Guidance incorporated BAFs in the derivation of criteria and values to protect human health and wildlife. Bioaccumulation refers to the uptake and retention of a substance by an aquatic organism from its surrounding medium and from food. For certain chemicals, uptake through the aquatic food chain is the most important route of exposure for wildlife and humans. The wildlife criteria and the human health criteria and values incorporate appropriate BAFs in order to more accurately account for the total exposure to a chemical. Current EPA guidelines for the derivation of human health water quality criteria use BCFs, which measure only uptake from water, when field-measured BAFs are not available. EPA believes, however, that the BAF is a better predictor of the concentration of a chemical within fish tissues in the Great Lakes System because it includes consideration of the uptake of contaminants from all routes of exposure.

The proposed Guidance included a hierarchy of three methods for deriving BAFs for non-polar organic chemicals: field-measured BAFs; predicted BAFs derived by multiplying a laboratory-measured BCF by a food-chain multiplier; and BAFs predicted by multiplying a BCF calculated from the log K_{ow} by a food-chain multiplier. For inorganic chemicals, the proposal would have required either a field-measured BAF or laboratory-measured BCF. On August 30, 1994, EPA published a document in the Federal Register (59 FR 44678) requesting comments on revising the hierarchy of methods for deriving BAFs for organic chemicals, and issues pertaining to the model used to assist in predicting BAFs when a field-measured BAF is not available. Based on the comments received, the final Guidance modifies the proposed hierarchy by adding a predicted BAF based on a BSAF as the second method in the hierarchy. BSAFs may be used for predicting BAFs from concentrations of chemicals in surface sediments. In addition, the final Guidance uses a model to assist in predicting BAFs that includes both benthic and pelagic food chains thereby incorporating exposures of organisms to chemicals from both the sediment and the water column. The model used in the proposal only included the pelagic food chain, and therefore, did not account for exposure to aquatic organisms from sediment.

The proposed Guidance used the total concentration of a chemical in the ambient water when deriving BAFs for organic chemicals. In the preamble to the proposed Guidance and in the Federal Register document cited above, EPA requested comments on deriving BAFs in terms of the freely dissolved concentration of the chemical in the ambient water. Based on comments received from the proposal and the document, the final Guidance uses the freely dissolved concentration of a chemical instead of the total concentration in the derivation of BAFs for organic chemicals. Use of the freely dissolved concentration will improve the accuracy of extrapolations between water bodies.

Finally, as discussed in section II of this preamble, bioaccumulation of persistent pollutants is a serious environmental threat to the Great Lakes Basin Ecosystem. Because of these concerns, the proposed Guidance would have required that pollutants with human health BAFs greater than 1000 receive increased attention and more stringent controls within the Great Lakes System. These pollutants are termed BCCs. EPA identified 28 BCCs in the proposed Guidance. The additional controls for BCCs are specified in certain of the implementation procedures and the antidegradation procedures, and are discussed further in the SID. The final Guidance continues to include increased attention on and more stringent controls for BCCs within the Great Lakes System. The final Guidance identifies 22 BCCs that are targeted for special controls instead of the 28 in the proposed Guidance. Six BCCs were deleted from the proposed list because of concern that the methods used to estimate the BAFs may not ***15376** account for the metabolism or degradation of the pollutants in the environment. States and Tribes may identify more BCCs as additional BAF data become available. The final Guidance designates as BCCs only those chemicals with human health BAFs greater than 1000 that were derived from either a field-measured BAF or a predicted BAF based on a field-measured BSAF (for non-metals) or from a field-measured BAF or a laboratory-measured BCF (for metals). Field-measured BAFs and BSAFs, unlike BAFs based only on laboratory analyses or calculations, account for the effects of metabolism.

B. Implementation Procedures

(§§132.4(a)(7), 132.4(e); appendix F to part 132; section VIII of the SID)
This section of the preamble discusses nine specific procedures contained in the final Guidance for implementing water quality standards and developing NPDES permits to attain the standards.

1. Site-Specific Modifications

(Procedure 1 of appendix F to part 132; section VIII.A of the SID)
The proposed Guidance would have allowed States and Tribes to adopt site-specific modifications to water quality criteria and values under certain circumstances. States and Tribes could modify aquatic life criteria to be either more stringent or less stringent when local water quality characteristics altered the biological availability or toxicity of a pollutant, or where local species' sensitivities differed from tested species. Less stringent modifications to chronic aquatic life criteria could also be made to reflect local physical and hydrological conditions. States and Tribes could also modify BAFs and human health and wildlife criteria to be more stringent, but not less stringent than the final Guidance.

The final Guidance retains most of the above provisions, but in addition allows less stringent modifications to acute aquatic life criteria and values to reflect local physical and hydrological conditions, less stringent modifications to BAFs in developing human health and wildlife criteria, and the use of fish consumption rates lower than 15 grams per day if justified. The final Guidance also specifies that site-specific modifications must be made to prevent water quality that would cause jeopardy to endangered or threatened species that are listed or proposed under the ESA, and prohibits any less-stringent site-specific modifications that would cause such jeopardy. Other issues related to the ESA are discussed in section IX of this preamble.

2. Variances from Water Quality Standards for Point Sources

(Procedure 2 of appendix F to part 132; section VIII.B of the SID)
The final Guidance allows Great Lakes States and Tribes to adopt variances from water quality standards, applicable to individual existing Great Lakes dischargers for up to five years, where specified conditions exist. For example, a variance may be granted when compliance with a criterion would result in substantial and widespread social and economic impacts or where certain stream conditions prevent the attainment of the criterion. No significant changes were made in this section from the proposed Guidance.

3. TMDLs and Mixing Zones

(Procedure 3 of appendix F to part 132; section VIII.C of the SID)
Section 303(d) of the CWA and implementing regulations at 40 CFR 130.7 require the establishment of TMDLs for waters not attaining water quality standards after implementation of existing or planned pollution controls. The TMDL quantifies the maximum allowable loading of a pollutant to a water body and allocates the loading capacity to contributing point and nonpoint sources (including natural background) such that water quality standards for that pollutant will be attained. A TMDL must incorporate a margin of safety (MOS) that accounts for uncertainty about the relationship between pollutant loads and water quality. TMDLs may involve single point sources or multiple sources (e.g., point sources and nonpoint sources) and may be established for geographic areas that range in size from large watersheds to relatively small water body segments.

The proposal attempted to develop a single, consistent approach for developing TMDLs to be used by all States and Tribes in the Great Lakes System. Current practice in the eight Great Lakes States includes distinct technical procedures and program approaches that differ in scale, emphasis, scope and level of detail. Two options for TMDL development were proposed. One, Option A, focused on first evaluating the basin as a whole and then conducting individual site-by-site adjustments as necessary to ensure attainment of water quality standards at each location in the basin. The other, Option B, focused on evaluating limits needed for individual point sources with supplemental emphasis on basin-wide considerations as necessary. Both approaches are consistent with the CWA, but result in different methodologies for TMDL development.

Both options proposed that within 10 years of the effective date of the final Guidance (i.e., two five-year NPDES permit terms), mixing zones would be prohibited for BCCs for existing point source discharges to the Great Lakes System. Further, both proposed that mixing zones be denied for new point source discharges of BCCs as of the effective date of the final Guidance.

Both options also specified procedures for determining background levels of pollutants present in ambient waters. In addition, the proposal would have tightened the relationship between TMDL development and NPDES permit issuance by providing that TMDLs be established for each pollutant causing an impairment in a water body prior to the issuance or reissuance of any NPDES permits for that pollutant.

The final Guidance merges both Options A and B into one single set of minimum regulatory requirements for TMDL development. In general, the final TMDL procedures are less detailed than the proposal, and offer more flexibility for States and Tribes in establishing TMDLs. The final TMDL procedures contain elements from both Options A and B that were deemed critical for a minimum level of consistency among the Great Lakes States and Tribes. These critical elements include: mixing zone specifications, design flows, and procedures for determining background concentrations.

The final Guidance also includes a prohibition on mixing zones for BCCs after 12 years in most circumstances. Maintaining these restrictions on the availability of mixing zones is consistent with both the Steering Committee's policy views and the bi-national GLWQA goal of virtual elimination of persistent, bioaccumulative toxics. Because of the unique nature of the Great Lakes ecosystem, documented ecological impacts, and the need for consistency, EPA believes that the general prohibition on mixing zones for BCCs is reasonable and appropriate. However, a new exception is allowed if a facility with an existing BCC discharge can demonstrate that it is reducing that discharge to the maximum extent feasible (considering technical and economic factors) but cannot meet WQBELs for that discharge without a mixing zone. EPA, in conjunction with stakeholders within the Great Lakes Basin, will develop guidance for use by ***15377** States and Tribes in exercising the exception provision with special focus on the technical and economic feasibility criteria. This guidance will also consider the notice, public hearing, monitoring and pollution prevention demonstration elements of the exception criteria.

The final Guidance also retains many of the proposed provisions for calculating background concentrations used in TMDLs and WLAs established in the absence of TMDLs. The procedure addressing data points below the level of detection, however, has been modified so that it no longer specifies the use of default values (i.e., half of the level of detection).

The final TMDL procedures do not require that TMDLs be established for point sources prior to the issuance/reissuance of NPDES permits. The final Guidance defers to the existing National program for determining when a TMDL is required. Lastly, the final Guidance allows assessment and remediation plans that are approved by EPA under 40 CFR 130.6 to be used in lieu of a TMDL for purposes of appendix F as long as they meet the general conditions of a TMDL as outlined by procedure 3 of appendix F, and the public participation requirements applicable to TMDLs.

4. Additivity

(Procedure 4 of appendix F to part 132; section VIII.D of the SID)
EPA has traditionally developed numeric water quality criteria on a single pollutant basis. While some potential environmental hazards involve significant exposure to only a single compound, most instances of contamination in surface waters involve mixtures of two or more pollutants. The individual pollutants in such mixtures can act or interact in various ways which may affect the magnitude and nature of risks or effects on human health, aquatic life and wildlife. WET tests are available to generally address interactive effects of mixtures on aquatic organisms. EPA's 1986 “Guidelines for the Health Risk Assessment of Chemical Mixtures” set forth principles and procedures for human health risk assessment of chemical mixtures. There are currently no technical guidelines on how to assess effects on wildlife from chemical mixtures.

The preamble for the proposed Guidance discussed several possible approaches to address additive effects from multiple pollutants. Proposed regulatory language was provided for two specific options, each with separate provisions related to aquatic life, wildlife and human health. One approach was developed by the Initiative Committees, modified to delete the application of toxicity equivalency factors (TEFs) for PCBs to wildlife. The other approach was developed by EPA. Neither approach addressed the possible toxicologic interactions between pollutants in a mixture (e.g., synergism or antagonism) because of the limited data available on these interactive effects. In the absence of contrary data, both approaches recommended that the risk

to human health from individual carcinogens in a mixture be considered additive, and that a 10^{-5} risk level be adopted as a cap for the cancer risk associated with mixtures. Both approaches also proposed using TEFs to assess the risk to humans and wildlife from certain chemical classes. The TEF approach converts the concentration of individual components in a mixture of chemicals to an "equivalent" concentration expressed in terms of a reference chemical. Both approaches used the 17 TEFs for dioxins and furans identified in the 1989 EPA document, "Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-Dioxins and -Dibenzofurans," and the 1989 update.

The final Guidance includes a general requirement for States and Tribes to adopt an additivity provision consistent with procedure 4 of appendix F to protect human health from the potential additive adverse effects from both the noncarcinogenic and carcinogenic components of chemical mixtures in effluents. The final Guidance also requires the use of the 17 TEFs included in the proposed Guidance to protect human health from the potential additive adverse effects in effluents.

5. Determining the Need for WQBELs (Reasonable Potential)

(Procedure 5 of appendix F to part 132; section VIII.E of the SID)
EPA's existing regulations require NPDES permits to include WQBELs to control all pollutants or pollutant parameters which the permitting authority determines are or may be discharged at a level which will cause, have the reasonable potential to cause or contribute to an excursion of any applicable water quality standard. If the permitting authority determines that a discharge has the reasonable potential to cause or contribute to an excursion of an applicable numeric water quality criterion, it must include a WQBEL for the individual pollutant in the permit. In the absence of an adopted numeric water quality criterion for an individual pollutant, the permitting authority must derive appropriate WQBELs from the State or Tribal narrative water quality criterion by either calculating a numeric criterion for the pollutant; applying EPA's water quality criteria developed under section 304(a) of the CWA, supplemented with other information where necessary; or establishing effluent limitations on an indicator pollutant. See 40 CFR 122.44(d)(1).

The final Guidance implements these National requirements by specifying procedures for determining whether a discharge has the reasonable potential to cause or contribute to an exceedance of Tier I criteria or Tier II values based on facility-specific effluent data. The final Guidance also specifies procedures for determining whether permitting authorities must generate or require permittees to generate data sufficient to calculate Tier II values when specified pollutants of concern in the Great Lakes System are known or suspected of being discharged, but neither Tier I criteria nor Tier II values have been derived due to a lack of toxicological data. EPA believes that the data necessary to calculate Tier II values for aquatic life, wildlife and human health currently exists for most of the specified pollutants of concern.

The final Guidance maintains all the basic requirements from the proposed procedure. Some minor changes are that the procedure no longer includes a special provision for effluent dominated streams, and the procedure allows a broader range of statistical approaches to be used when evaluating effluent data, which provides added simplicity and flexibility to States and Tribes.

Another change from the proposal is the relationship in the final Guidance between the reasonable potential and TMDL procedures. Numerous commenters pointed out that the proposed Guidance indicated that TMDLs would be required for any water receiving effluent from a discharger found to exhibit reasonable potential. Given the fact that there are many waterbodies in the Great Lakes basin for which TMDLs have not been developed, and the obvious need for permitting to proceed in the interim until TMDLs are completed, the final Guidance provides that the permitting authority can establish waste load allocations and WQBELs in the absence of a TMDL or an assessment and remediation plan developed and approved in accordance with procedure 3.A of appendix F. A more detailed discussion of the assessment and remediation plan and its relationship to a TMDL can be found in section VIII.C.2 of the SID. Procedures for establishing such WLAs are therefore addressed in the final Guidance.

***15378 6. Intake Pollutants**

(Procedures 5.D and 5.E of appendix F to part 132; section VIII.E of the SID)
The proposed Guidance allowed a permitting authority to determine that the return of an identified intake water pollutant to the same body of water under specified circumstances does not cause, have the reasonable potential to cause, or contribute to an excursion above water quality standards, and therefore, that a WQBEL would not be required for that pollutant. Under the proposal, this "pass through" of intake water pollutants would be allowed if the facility returns the intake water containing the pollutant of concern to the same waterbody; does not contribute additional mass of pollutant; does not increase the concentration of the intake water pollutant; and does not discharge at a time or location, or alter the pollutant in a manner which would cause adverse impacts to occur that would not occur if the pollutant were left in-stream.

EPA received numerous comments on the proposal. Some commenters argued that the proposed provision was too narrow because relief would not be available if the facility added any amount of the pollutant to the discharge, even where the facility was not contributing any additional mass or concentration to the waterbody than was contained in the intake water. After consideration of public comments, EPA decided to expand the intake pollutant provisions to include not only a reasonable potential procedure like the one contained in the proposal, but also a provision that allows the permitting authority to take into account the presence of pollutants in intake water in deriving WQBELs. Specifically, the final Guidance authorizes the permitting authority to establish limits based on a principle of "no net addition" (i.e., the limit would allow the mass and concentration of the pollutant in the discharge up to the mass and concentration of the pollutant in the intake water). This provision would be available where the facility's discharge is to the same body of water as the intake water, and could be applied for up to 12 years after publication of the final Guidance. After that time, if a TMDL or comparable plan that meets the requirements of procedure 3 of appendix F has not been completed, the facility's WQBEL must be established in accordance with the "baseline" provisions in procedure 5.F.2 of appendix F. This time limit provides a period of relief for dischargers that are not causing increased impacts on the waterbody by virtue of their discharge that would not have occurred had the pollutant remained in-stream, while maintaining the incentive for development of a comprehensive assessment and remediation plan for achieving attainment of water quality standards, which EPA believes is a critical element of the final Guidance for addressing pollutants for which a large contributor to non-attainment is nonpoint source pollution.

The final Guidance allows States and Tribes to address intake pollutants in a manner consistent with assessment and remediation plans that have been developed through mechanisms other than TMDLs in order to provide flexibility where such plans comprehensively address the point and non-point sources of non-attainment in a waterbody and the means for attaining compliance with standards.

EPA believes that 12 years provides sufficient time for States to develop and complete the water quality assessments that would serve as the basis for establishing effluent limits (including "no net addition" limits, where appropriate) under procedure 3.A of appendix F. However, EPA also recognizes that unforeseen events could delay State completion of these assessments, and therefore will, at 7 years following promulgation, in consultation with the States, evaluate the progress of the assessments. If this evaluation shows that completion of the assessments may not be accomplished by the 12 year date, EPA will revisit these provisions, and consider proposing extensions if appropriate.

Under the final Guidance, the permitting authority can permit the discharge of intake pollutants to a different body of water that is in non-attainment provided limitations require the discharge to meet a WQBEL for the pollutant equal to the pollutant's water quality criterion. Because inter-waterbody transfers of pollutants introduce pollutants to the receiving water that would not be present in that waterbody in the absence of the facility's discharge, EPA does not believe that relief for such pollutants comparable to the "no net addition" approach would be appropriate. However, to address the concern raised by commenters about facilities with multiple sources of intake water, the permitting authority may use a flow-weighted combination of these approaches when the facility has co-mingled sources of intake water from the same and different bodies of water.

EPA maintains that the preferred approach to deal with non-attainment waters, particularly when multiple sources contribute a pollutant for which the receiving water exceeds the applicable criterion, is development of a TMDL or comparable assessment and remediation plan. The above “no net addition” permitting approach provides additional flexibility in situations where a TMDL or comparable plan has not yet been developed. Other existing relief mechanisms include variances to water quality standards, removal of non-existing uses, and site-specific criteria.

7. WET

(Procedure 6 of appendix F to part 132; section VIII.F of the SID)
Existing EPA regulations define WET as “the aggregate toxic effect of an effluent measured directly by a toxicity test.” These regulations require WET limits to be included in permits in most circumstances in which the WET of a discharge has the reasonable potential to cause or contribute to an in-stream excursion above either a State's numeric criteria for toxicity or narrative criteria for water quality (40 CFR 122.2, 122.44(d)(1)). The regulations allow States and Tribes the flexibility to control for WET with either numeric or narrative criteria. Current technical guidelines recommend that no discharge should exceed 0.3 acute toxic units (TUa = 100/LC50) at the edge of an acute mixing zone and 1.0 chronic toxic units (TUc = 100/NOEC, the No Observed Effect Concentration) at the edge of a chronic mixing zone.

The proposed Guidance would have continued to allow States and Tribes the flexibility to choose to control WET with either numeric or narrative criteria, but specified that no discharge could exceed 1.0 TU_a at the point of discharge (i.e., no acute mixing zones) and 1.0 TU_c at the edge of a chronic mixing zone (with some exceptions). In addition, the proposal contained minimum requirements for appropriate test methods to measure WET and for permit conditions, and procedures for determining whether or not limits for WET are necessary.

The final Guidance differs principally from the proposal in requiring States and Tribes to adopt 0.3 TU_a and 1.0 TU_c either as numeric criteria or as an equivalent numeric interpretation of narrative criteria. The final Guidance also allows the use of acute mixing zones for the application of the acute criterion. This approach will promote consistency among States and Tribes in controlling WET, while still permitting considerable flexibility regarding implementation measures, consistent with current National policies and guidelines.

***15379 8. Loading Limits**

(Procedure 9 of appendix F to part 132; section VIII.G of the SID)
The final Guidance provides that WQBELs be expressed in terms of both concentration and mass loading rate, except for those pollutants that cannot appropriately be expressed in terms of mass. These provisions clarify the application of existing Federal regulations at 40 CFR 122.45(f), and are consistent with current EPA guidance which requires the inclusion of any limits determined necessary based on best professional judgment to meet water quality standards, including, where appropriate, mass loading rate limits. They are also consistent with the antidegradation policy for the Great Lakes System in appendix E of the final Guidance.

9. Levels of Quantification

(Procedure 8 of appendix F to part 132; section VIII.H of the SID)
Many of the pollutants of concern in the Great Lakes System cause unacceptable toxic effects at very low concentrations. This results in instances where WQBELs are below levels of reliable quantification. When this occurs, the permitting authority may not be able to determine whether the pollutant concentration is above or below the WQBEL. The final Guidance requires adoption of pollutant minimization programs (PMPs) for such permits to increase the likelihood that the concentration of the pollutant is as close to the effluent limit as possible. The PMP is an ongoing, iterative process that requires, among other things,

internal wastestream monitoring and submission of status reports. The use of PMPs for facilities with pollutants below the level of quantification is consistent with existing EPA guidance.

Unlike the proposal, however, the final Guidance eliminates additional minimum requirements for BCCs. For example, the final Guidance recommends but does not require bio-uptake studies that had been proposed to assess impacts to the receiving water and evaluate the effectiveness of the PMP.

10. Compliance Schedules

(Procedure 9 of appendix F to part 132; section VIII.I of the SID)
The final Guidance includes a procedure that allows Great Lakes States and Tribes to include schedules of compliance in permits for existing Great Lakes dischargers for effluent limitations based on new water quality criteria and certain other requirements. Generally, compliance schedules may provide for up to five years to comply with the effluent limitation in question and may, in specified cases, allow the compliance schedule to go beyond the term of the permit. Existing Great Lakes dischargers are those whose construction commenced before March 23, 1997. Thus the term, existing Great Lakes discharges, covers expanding dischargers who were ineligible for compliance schedules under the proposal. The final Guidance also provides the opportunity for States and Tribes to allow dischargers additional time to comply with effluent limitations based on Tier II values while conducting studies to justify modifications of those limitations.

C. Antidegradation Provisions

(§132.4(a)(6); appendix E to part 132; section VII of the SID)
EPA's existing regulations, at 40 CFR 131.6, establish an antidegradation policy as one of the minimum requirements of an acceptable water quality standards submittal. Section 131.12 describes the required elements of an antidegradation policy. These are: protection of water quality necessary to maintain existing uses, protection of high quality waters (those where water quality exceeds levels necessary to support propagation of fish, shellfish, and wildlife and recreation in and on the waters) and protection of water quality in those water bodies identified as outstanding National resources.

The proposed Guidance provided detailed procedures for implementing antidegradation that were not part of the existing regulations. The detailed implementation procedures were intended to result in greater consistency in how antidegradation was applied throughout the Great Lakes System. The proposed Guidance specified, among other things, how high quality waters should be identified, what activities should and should not require review under antidegradation, and the information necessary to support a request to lower water quality and the procedures to be followed by a Tribe or State in making a decision whether or not to allow a lowering of water quality.

The final Guidance maintains the overall structure of the proposed Guidance while allowing Tribes and States greater flexibility in how antidegradation is implemented. As in the proposal, the final Guidance is composed of an antidegradation standard, antidegradation implementation procedures, antidegradation demonstration and antidegradation decision. However, many of the detailed requirements found in the proposed Guidance appear in the SID accompanying the final Guidance as nonbinding guidelines, including provisions specific to non-BCCs.

Key elements of the proposed Guidance that are retained in the final Guidance for BCCs include: identification of high quality waters on a pollutant-by-pollutant basis; requirements for States and Tribes to adopt an antidegradation standard consistent with the final Guidance for BCCs; minimum requirements for conducting an antidegradation review of any activity expected to result in a significant lowering of water quality due to BCCs, minimum requirements for notifying permitting authorities of increases in discharges of BCCs; and, minimum requirements for an antidegradation demonstration consisting of a pollution prevention analysis, an alternative treatment analysis and a showing that the significant lowering of water quality will allow for important social and economic development. Significant changes from the proposed Guidance include: encouraging, but not

requiring, States and Tribes to adopt provisions consistent with the antidegradation standard and implementation procedures for non-BCCs; replacement of numeric existing effluent quality-based (EEQ) limits as a means of implementing antidegradation for BCCs with a narrative description of the types of activities that will trigger an antidegradation review; and greater flexibility in the implementation, demonstration and decision components. A detailed discussion of the basis for each of the changes is provided in Section VII the SID.

D. Regulatory Requirements

(Part 132; Tables 5 and 6 to part 132; section II of the SID)
The Great Lakes States must adopt water quality standards, anti-degradation policies, and implementation procedures for waters within the Great Lakes System which are consistent with the final Guidance within two years of this publication. If a Great Lakes State fails to adopt such standards, policies, and procedures, section 118(c)(2)(C) of the CWA requires EPA to promulgate them not later than the end of that two-year period. Additionally, when an Indian Tribe is authorized to administer the NPDES or water quality standards program in the Great Lakes basin, it will also need to adopt provisions consistent with the final Guidance into its water program.

Part 132 establishes requirements and procedures to implement section 118(c)(2)(C). Sections 132.3 and 132.4 ***15380** require Great Lakes States and Tribes to adopt criteria, methodologies, policies, and procedures consistent with the criteria, methodologies, policies, and procedures contained in part 132—that is, the definitions in §132.2, the numeric criteria in Tables 1 through 4, the criteria development methodologies in appendixes A through D, the antidegradation policy in appendix E, and the implementation procedures in appendix F. Section 132.5 specifies the procedures for States and Tribes to make their submissions to EPA, and for EPA to approve or disapprove the submissions. The section specifies that in reviewing submissions, EPA will consider provisions of State and Tribal submissions to be "consistent with" the final Guidance if each provision is as protective as the corresponding provision of the final Guidance. If a State or Tribe fails to make a submission, or if provisions of the submission are not consistent with the final Guidance, §132.5 provides that EPA will publish a final rule in the Federal Register identifying the final Guidance provisions that will apply to discharges within the particular State or Federal Indian Reservation.

Section 132.4 specifies that water quality criteria adopted by States and Tribes consistent with the final Guidance will apply to all waters of the Great Lakes System, regardless of designated uses of the waters in most cases, with some variations in human health criteria depending on whether the waters are designated for drinking water use. Section 132.4 also contains certain exceptions in applying the final Guidance methodologies and procedures. First, States and Tribes do not have to adopt and apply the final Guidance methodologies and procedures for the 14 pollutants listed in Table 5 of part 132. EPA believes that some or all of the methodologies and procedures are not scientifically appropriate for these pollutants. Second, if a State or Tribe demonstrates that the final Guidance methodologies or procedures are not scientifically defensible for a particular pollutant, the State or Tribe may use alternate methodologies or procedures so long as they meet all applicable Federal, State, and Tribal laws. Third, §132.4 specifies that for wet-weather point sources, States and Tribes generally do not have to adopt and apply the final Guidance implementation procedures. The exception is the TMDL general condition for wet weather events. Fourth, pursuant to section 510 of the CWA, part 132 specifies that nothing in the final Guidance prohibits States or Tribes from adopting provisions more stringent than the final Guidance.

As discussed further in section IX of this preamble, §132.4 also provides that State and Tribal submissions will need to include any provisions that EPA determines, based on EPA's authorities under the CWA and the results of consultation with the U.S. Fish and Wildlife Service (FWS) under section 7 of the ESA, are necessary to ensure that water quality is not likely to cause jeopardy to any endangered or threatened species listed under the ESA.

Part 132 extends the requirements of section 118(c)(2)(C) to Indian Tribes within the Great Lakes basin for which EPA has approved water quality standards under section 303 of the CWA or which EPA has authorized to administer an NPDES program under section 402 of the CWA. EPA believes that inclusion of Great Lakes Tribes in this way is necessary and appropriate to be

consistent with section 518 of the CWA. The reasons for EPA's proposal are discussed further in the preamble to the proposed Guidance (58 FR 20834), and section II.D.3 of the SID. As a practical matter, no Great Lakes Tribes currently have approved water quality standards or authorized NPDES programs, so the submission requirements of part 132 do not apply to any Great Lakes Tribes. Tribes that are approved or authorized in the future, however, will need to adopt provisions consistent with the final Guidance in their water programs.

V. Costs, Cost-Effectiveness and Benefits

(Section IX of the SID)
Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether the regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a "significant regulatory action" because it raises novel policy issues arising out of the development of a comprehensive ecosystem-based approach for a large geographic area involving several States, Tribal governments, local governments, and a large number of regulated dischargers. This approach, including the Great Lakes Water Quality Initiative which developed the core concepts of the final Guidance, is a unique and precedential approach to the implementation of environmental programs. As such, this action was submitted to OMB for review pursuant to Executive Order 12866. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

The following is a summary of major elements of the "Regulatory Impact Analysis of the Final Great Lakes Water Quality Guidance" (RIA) (EPA 820-B-95-011) that has been prepared in compliance with Executive Order 12866. Further discussion is included in section IX of the SID, and in the full RIA, which is available in the docket for this rulemaking.

The provisions of the final Guidance are not enforceable requirements until adopted by States or Tribes, or promulgated by EPA for a particular State or Tribe. Therefore, this publication of the final Guidance does not have an immediate effect on dischargers. Until actions are taken to promulgate and implement these provisions (or equally protective provisions consistent with the final Guidance), there will be no economic effect on any dischargers. For the purposes of the RIA, EPA's analysis of costs and benefits assumes that either State or EPA promulgations occur consistent with the final Guidance within the next two years.

Under the CWA, costs cannot be a basis for adopting water quality criteria that will not be protective of designated uses. If a range of scientifically defensible criteria that are protective can be identified, however, costs may be considered in selecting a particular criterion within that range. Costs may also be relevant under the antidegradation standard as applied to high quality waters.

EPA has assessed compliance costs for facilities that could be affected by provisions adopted by States or Tribes consistent with the final Guidance. EPA has also assessed basin-wide risk reduction benefits to sport anglers and Native American subsistence

anglers in the basin, and benefits for three case study sites in the Great Lakes System. ***15381** The methodology used in each assessment and the results of these assessments are discussed below.

EPA solicited public comment and supporting data on the RIA methodology used to estimate both costs and benefits for implementation of the proposed Guidance. EPA evaluated these comments and supporting data as well as comments provided by OMB and revised the RIA methodology prior to performing these assessments for the final Guidance.

A. Costs

Based on the information provided by each State and a review of the permit files, EPA identified about 3,800 direct dischargers that could be affected by State or Tribal adoption or subsequent EPA promulgation, if necessary, of requirements consistent with the final Guidance. Of these, about 590 are major dischargers and the remaining 3,210 are minor dischargers. Of the 590 majors, about 275 are industrial facilities and 315 are publicly owned treatment works (POTWs). Out of these dischargers, EPA used a stratified random sampling procedure to select 59 facilities (50 major and nine minor) that it considered representative of all types and sizes of facilities in the basin.

EPA divided the major facilities into nine industrial categories and a category for POTWs. The nine industrial categories are: mining, food and food products, pulp and paper, inorganic chemical manufacturing, organic chemical manufacturing/petroleum refining, metals manufacturing, electroplating/metal fabrication, steam electric power plants, and miscellaneous facilities.

For each major and minor facility in the sample, EPA estimated incremental costs to comply with subsequently promulgated provisions consistent with the final Guidance, using a baseline of compliance with the requirements of section 303(c)(2)(B) of the CWA. Using a decision matrix, costs were developed for two different scenarios—a “low-end” cost scenario and a “high-end” cost scenario—to account for the range of regulatory flexibility available to States and Tribes when adopting and implementing provisions consistent with the final Guidance. In addition, the decision matrix specified assumptions used for selection of control options in the cost analysis such as optimization of existing treatment processes and operations, in-plant pollutant minimization and prevention, and “end of pipe” effluent treatment.

The annualized costs for direct and indirect dischargers to implement the final Guidance are estimated to be between $60 million (low end) and $380 million (high end) (first quarter 1994 dollars). EPA believes the costs for implementing the final Guidance, which balance pollution prevention, “end-of-pipe” treatment and regulatory flexibility, will approach the low end of the cost range. Costs are unlikely to reach the high end of the cost range because State and Tribal authorities are likely to choose implementation options that provide some degree of relief to point source dischargers, especially because in many cases the nonpoint source contributions will be significant. Furthermore, cost estimates for both scenarios, but especially for the high-end scenario, may be overstated because in cases where the final Guidance provides States and Tribes flexibility in selecting less costly approaches when implementing provisions consistent with the final Guidance, the most costly approach was used to estimate the costs. This approach was used to reduce uncertainty in the cost analysis for the final Guidance.

Under the low-end cost scenario, major industrial facilities and POTWs would account for about 65 percent of the costs, indirect dischargers about 33 percent, and minor dischargers about two percent. Among the major dischargers three categories would account for most of the costs—POTWs (39 percent), pulp and paper (14 percent), and miscellaneous (eight percent). The average per plant costs for different industry categories range from zero to $168,000. The two highest average cost categories are pulp and paper ($151,000) and miscellaneous ($168,000). Although major POTWs make up a large portion of the total cost, the average cost per plant under the low-end scenario is not among the highest at $75,000 per facility. About half of the low-end costs are associated with pollution prevention activities, and about half are for capital and operating costs for wastewater treatment.

For the high-end cost scenario, direct dischargers account for 98 percent of the total estimated cost, and indirect dischargers account for two percent. This shift in proportion of costs between direct and indirect dischargers and between the low and the high estimates are due to the assumption that more direct dischargers will need to use end-of-pipe treatment under the high-end

scenario. In addition, it was assumed that a smaller proportion of indirect dischargers (10 percent) would be impacted under the high-end scenario, since municipalities are adding end-of-pipe treatment which should reduce the need for source controls (i.e., reduce the need for increased pretreatment program efforts) by indirect discharges. Less than 10 percent of the high-end costs are associated with pollution prevention activities, and over 90 percent are for capital and operating costs for wastewater treatment.

Under the high-end scenario for the direct dischargers, municipal major dischargers are expected to incur just under 70 percent of total costs, and industrial major dischargers account for 29 percent of total costs. Minor direct dischargers are estimated to incur less than one percent of the total costs. The two major industrial categories with the largest total annualized cost are the pulp and paper (23 percent of total) and miscellaneous (three percent) categories. The food and food products and metal finishing categories are estimated to incur less than 1 percent of the total annualized cost.

Under the high-end scenario, the average annual cost per major municipal facility is just over $822,000 per facility. Average annualized costs for industrial majors vary widely across categories, with the highest average cost estimated for pulp and paper ($1,583,000 per plant) and miscellaneous ($433,700 per plant) categories. Regardless of the scenario, the average costs for minor facilities are negligible at an estimated $500 per facility.

The costs described above account for the costs of eliminating mixing zones for BCCs except in narrow circumstances, costs related to implementation of Tier II values, and specific calculated costs related to intake credits. The cost assessment also projects the potential cost savings across the different scenarios that facilities may realize if States or Tribes use existing regulatory relief mechanisms to modify or eliminate the need for a WQBEL for an identified pollutant (e.g., variances, TMDLs, site-specific modifications to criteria, and changes in designated uses).

In addition to the cost estimates described above, EPA estimated the cost to comply with requirements consistent with the antidegradation provisions of the final Guidance. This potential future cost is expressed as a “lost opportunity” cost for facilities impacted by the antidegradation requirements. This cost could result in the addition of about $22 million each year.

B. Cost-Effectiveness

EPA estimated the cost-effectiveness of the final Guidance in terms of the cost of reducing the loadings of toxic pollutants from point sources. The cost-effectiveness (cost per pound removed) is derived by dividing the annualized costs of implementing the final ***15382** Guidance by the toxicity-weighted pounds (pound-equivalents) of pollutants removed. Pound-equivalents are calculated by multiplying pounds of each pollutant removed by the toxic weight (based on the toxicity of copper) for that pollutant.

It is estimated that implementation of provisions consistent with the final Guidance would be responsible for the reduction of about six to eight million toxic pounds per year, or 16 to 22 percent of the toxic-weighted baseline for the low- and high-end scenarios, respectively. The cost-effectiveness of the scenarios, over the baseline, is quite good, ranging from $10 to $50 per pound-equivalent.

Approximately 80 percent of the pollutant load reduction from implementation of the final Guidance, regardless of the scenario, is attributable to reducing BCCs as a result of PMPs and end-of-pipe treatment. The largest pollutant load reductions occur for chlordane, dieldrin, heptachlor, lead, and pentachlorobenzene.

In a separate analysis, EPA also investigated the cost-effectiveness of regulating point and nonpoint sources of mercury and PCBs, two contaminants associated with fish advisories in the Great Lakes basin. Although data and resource constraints limited the findings from these analyses, the preliminary results indicate that point sources may factor cost-effectively into pollutant reduction scenarios. For both contaminants, the cost-effectiveness of point and nonpoint source controls are likely to be highly site-specific.

C. Benefits

The benefits analysis is intended to provide insight into both the types and potential magnitude of the economic benefits expected to arise as a result of implementation of provisions adopted by States and Tribes consistent with the final Guidance. To the extent feasible, empirical estimates of the potential magnitude of the benefits are developed and then compared to the estimated costs of implementing provisions adopted by States and Tribes consistent with the final Guidance.

The benefits analysis is based on a case study approach, using benefits transfer applied to three case studies. The case study approach was used because it is more amenable to meaningful benefit-cost analyses than are studies of larger aggregate areas. Although the results obtained for a case study site may not apply uniformly to the entire Great Lakes basin, the case study approach does provide a pragmatic and realistic perspective of how implementation of the final Guidance can generate benefits, the types of benefits anticipated, and how these benefits compare to costs.

The case studies include: (1) the lower Fox River drainage, including Green Bay, located on Lake Michigan in northeastern Wisconsin; (2) the Saginaw River and Saginaw Bay, located on Lake Huron in northeastern Michigan; and (3) the Black River, located on Lake Erie in north-central Ohio. The case studies were selected from a list of candidate sites (i.e., designated Areas of Concern (AOCs) in the Great Lakes basin) on the basis of data availability and the relevance of the water quality problems to the final Guidance (i.e., areas in which problems were more likely to be associated with on-going point source discharges rather than historic loadings from Superfund sites and other sources). Geographic diversity was also considered in selecting the sites so that the analyses might better promote a broad perspective of the final Guidance's benefits and costs.

For each of the three case studies, EPA estimated future toxics-oriented water quality benefits, and then attributed a percentage of these benefits to implementation of the final Guidance. The attribution of benefits was based only on the estimated reduction in loadings from point sources at the case study sites and information on the relative contribution of point sources to total loadings in the basin. EPA did not attempt to calculate the longer-term benefits to human health, wildlife, and aquatic life once the final Guidance provisions are fully implemented by nonpoint sources as well as point sources and the minimum protection levels are attained in the ambient water.

In the Fox River and Green Bay case study, total annual undiscounted benefits attributable to the final Guidance range from $0.3 million to $8.5 million (first quarter 1994 dollars). Human health benefits account for between 29 percent and 72 percent of the estimated benefits, recreational fishing accounts for between eight percent and 45 percent, and nonuse/ecologic benefits account for between nine percent and 23 percent. Municipal and industrial dischargers in this case study are estimated to incur annualized costs of about $3.6 million.

In the Saginaw River/Bay case study, total annual undiscounted benefits range from $0.2 million to $7.7 million. Recreational fishing benefits account for between 36 percent and 60 percent of the estimated benefits, non-use benefits account for between 18 percent and 30 percent, and human health benefits account for between eight percent and 36 percent. Total annualized costs to municipal and industrial dischargers are estimated to be about $2.6 million.

In the Black River case study, total annual undiscounted benefits range from $0.4 million to $1.5 million. Recreational fishing benefits account for between 48 percent and 63 percent of the estimated benefits, and nonuse benefits account for between 32 percent and 44 percent. Total annualized costs to municipal and industrial dischargers are estimated to be $2.1 million.

An inherent limitation of the case study approach is the inability to extrapolate from a limited set of river-based sites to the Great Lakes basin as a whole. Accordingly, extrapolation of the case study results to the Great Lakes basin is not recommended. However, as noted above, the three case studies were selected on the basis of data availability, the relative importance of point source discharges to the watersheds' problems, and an attempt to portray spatial diversity throughout the Great Lakes basin. Thus, there is no reason to conclude that the selected sites are not reflective of the basin, even though benefits (and costs) tend to be highly site-specific. In addition, the benefits extend from the case study rivers into the larger, open-water environment of the Great Lakes.

The representativeness of the case study sites was assessed by comparing the percentage of total benefits estimated to accrue in the case study areas to the percentage of basin-wide costs incurred by the case study sites. Benefits-related measures (such as population, recreational angling days, and nonconsumptive recreation days) were used in place of total benefits for this analysis because there is no estimate of benefits for the entire Great Lakes basin. The three case studies combine to account for nearly 14 percent of the total cost of the final Guidance, nearly 17 percent of the loadings reductions, and from four percent to 10 percent of the benefits proxies (i.e., basin-wide population, recreational angling, nonconsumptive recreation, and commercial fishery harvest). Thus, the three case studies may represent a reasonably proportionate share of costs and benefits.

In addition to the case study analyses, a basin-wide risk assessment was conducted for Great Lakes anglers. EPA collected data and information on the consumption of Great Lakes basin fish to estimate baseline risk levels and reductions in risks due to implementation of the final Guidance for two populations at risk: Great Lakes sport anglers (including minority and ***15383** low-income anglers) and Native Americans engaged in subsistence fishing in the basin. For sport anglers, EPA estimated that the projected reduction in loadings from point sources based on controls consistent with the final Guidance would result in a reduction of annual excess lifetime cancer cases (potential cancer cases assuming a 70-year lifetime exposure period) of 2.2 to 4.1 for low-income minorities in lakeshore counties; 0.4 to 0.8 for other minorities in lakeshore counties; and 21.9 to 41.9 for all other sport anglers. For Native American subsistence anglers, EPA estimated that reductions from point source loadings attributable to the final Guidance would result in a reduction of excess lifetime cancer cases of between 0.1 and 0.3 using a low fish ingestion scenario and 0.5 to 1.1 using a high fish ingestion scenario. Note that these estimates do not include the long-term benefits (including reduced cancer cases) that will result once the final Guidance provisions are fully implemented and the minimum protection levels are attained in the ambient water.

In total, using the most conservative consumption scenario for Native Americans, these reductions represent between 0.35 and 0.67 excess cancer cases per year, and potential basin-wide benefits of the final Guidance for this one benefits category of between $0.7 million and $6.7 million per year, based on the estimated value of a statistical life of between $2.0 million and $10.0 million. Comparison to case study results, which were based on a more comprehensive sample of facilities within case study areas than was possible for the entire basin, indicates these values likely underestimate the potential risk reduction benefits of the final Guidance at the basin level. For example, if the average percentage load reduction for PCBs for the three case studies is used to reflect reductions in PCBs for the basin, the reduction in excess cancer cases increases to between three and six cases per year, and potential benefits increase to between $6.6 and $60 million per year.

The reduction in pollutant loadings for PCBs was likely understated in the basin-wide analysis because the analysis did not count pollutant load reduction benefits when the current State-based permit limit and the final Guidance-based permit limit were both below the pollutant analytical method detection limit (MDL). Only three sample facilities in the population of 59 sample facilities used to project basin-wide costs and human health benefits had State-based permit limits for PCBs. Since the current State-based permit limit and the final Guidance-based permit limit were below the MDL in all three facilities, “zero” reduction in PCB loadings for the basin was estimated. This, of course, is an artifact of the methodology and the size of the sample population selected for the analysis, and would not occur, as demonstrated in the case study analysis, if a larger sample population had been used.

VI. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), EPA generally is required to conduct a final regulatory flexibility analysis (FRFA) describing the impact of the regulatory action on small entities as part of the final rulemaking. However, under section 605(b) of the RFA, if EPA certifies that the rule will not have a significant economic impact on a substantial number of small entities, EPA is not required to prepare a FRFA.

Implementation of the final Guidance is dependent upon future promulgation of provisions consistent with it by State or Tribal agencies or, if necessary, EPA. Until actions are taken to promulgate and implement these provisions, or equally protective provisions consistent with the final Guidance, there will be no economic effect of this rule on any entities, large or small. For

that reason, and pursuant to Section 605(b) of the RFA, EPA is certifying that this rule itself will not have a significant economic impact on a substantial number of small entities.

Although EPA is certifying that this rule will not have a significant economic impact on a substantial number of small entities, and therefore is not required to prepare a FRFA, it is nevertheless including for public information in the RIA a discussion of the possible economic effects to small entities that could result from State or Tribal adoption of provisions consistent with the final Guidance or subsequent EPA promulgation, if necessary. As discussed above, small facilities are projected to incur costs of only approximately $500 per facility to comply with subsequently promulgated requirements that are consistent with the final Guidance. Accordingly, EPA believes there will be no significant economic impact on a substantial number of small entities as a result of State or Tribal implementation of the final Guidance.

VII. Enhancing the Intergovernmental Partnership Under Executive Order 12875

In compliance with Executive Order 12875 (58 FR 58093, October 28, 1993), EPA has involved State, Tribal, and local governments in the development of the final Guidance.

As described in section II above, the core elements of the final Guidance were developed by the Great Lakes States, EPA, and other Federal agencies in open dialogue with citizens, local governments, and industries in the Great Lakes ecosystem over a five-year period through the Initiative. The Initiative process marks the first time that EPA has developed a major rulemaking effort in the water program through a regional public forum. The Initiative process is described further in the preamble to the proposed Guidance (58 FR 20820-23) and section II of this preamble.

In addition to the participation by State and local governments in the initial development of the proposed Guidance and in the public comment process, several activities have been carried out since the publication of the proposed Guidance. These include:

(1) On April 26, 1994, EPA held a public meeting to solicit additional information from interested parties on the proposed Guidance. As part of EPA's outreach efforts to State, Tribal and local governments, a special invitation was sent inviting elected officials and other State, Tribal and local representatives to participate in the public meeting. EPA specifically welcomed Tribal and local officials and opened the floor to them to hear and discuss their specific concerns and views on the final Guidance.

(2) A series of meetings and teleconferences were held with Great Lakes States in early 1994 to discuss their comments on several issues, including development of water quality criteria, State adoption requirements, WET, BAFs, additivity, compliance schedules, anti-backsliding, nonpoint sources, and international concerns.

(3) In October, 1994, EPA met with each individual State in the Great Lakes basin to discuss the nature, form, and scope of the proposed Guidance, and State concerns with implementation of the provisions under consideration. The following issues were discussed at each of the meetings: intake credits, antidegradation and EEQ, wildlife criteria, excluded pollutants (e.g., ammonia and chlorine), elimination of mixing zones, site-specific modifications, fish consumption, appropriate degrees of flexibility for implementation (e.g., guidance vs. regulation), and implementation procedures.

(4) In 1994 and 1995, EPA met with representatives of the National Wildlife Federation to discuss EPA's activities in developing the final Guidance in ***15384** accordance with the terms of a consent decree governing the schedule for development of the final Guidance.

(5) In 1994, EPA also met with elected officials and other representatives from several local communities in the Great Lakes basin to discuss issues regarding the economic impact of the proposed Guidance on local communities and POTWs. Issues discussed include cost impacts associated with implementing water quality criteria, methodologies, and implementation procedures; dealing with pollution from nonpoint sources; public outreach to control pollutants such as mercury instead of costly end-of-pipe treatment; and applicability of provisions in the final Guidance to the National water quality program.

(6) EPA held an additional 18 consultations with the regulated community throughout 1994. Such meetings allowed representatives of dischargers to share additional data, which has been placed in the docket for this rulemaking, and concerns about a range of issues, including cost concerns, that the dischargers expect to arise in implementation of the final Guidance.

(7) In 1994, EPA met with State representatives to conduct initial planning for implementation of the GLI Clearinghouse. All Great Lakes States agreed to participate in this effort, which will involve the sharing of toxicological and other data to assist in the development of additional water quality criteria and values.

The results of the above efforts have assisted in the development of the final Guidance through broad communication with a full range of interested parties, sharing of additional information, and incorporation of features to improve the implementation of the final Guidance.

EPA has estimated the total annual State government burden to implement the final Guidance as approximately 5,886 hours, resulting in a State government cost of $175,992 annually. Such burden and costs were estimated based upon the burden and costs associated with developing water quality criteria, review of antidegradation policy demonstrations, review of approvable control strategies and BCC monitoring data, and review of variance requests. The total annual local government burden is estimated to be 42,296 hours with an associated cost of $2,008,624. All of the burden and costs to local governments are associated with being a regulated entity as an operator of a POTW.

VIII. Paperwork Reduction Act

The information collection requirements in this final Guidance have been approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., and have been assigned OMB control number 2040-0180. EPA has prepared an Information Collection Request (ICR) document (ICR No. 1639.02). A copy of ICR 1639.02 may be obtained by writing to Ms. Sandy Farmer, Information Policy Branch, EPA 2136, Washington, D.C. 20460, or by calling (202) 260-2740.

The annual public reporting and record keeping burden for this regulation is estimated to be 128,787 hours for the affected 3,795 permittees, or an average of 34 hours. This includes the total annual burden to local governments as POTW operators, estimated to be 45,296 hours. The total annual burden to State governments is estimated to be 5,886 hours. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

In this rulemaking EPA is also amending the table of currently approved ICR control numbers issued by OMB for various regulations into 40 CFR 9.1. This amendment updates the table to accurately display those information requirements promulgated under the CWA. The affected regulations are codified at 40 CFR parts 122, 123, 131, and 132. EPA will continue to present OMB control numbers in a consolidated table format. The table will be codified in 40 CFR part 9 of EPA's regulations and in each 40 CFR volume containing EPA regulations. The table lists the section numbers with reporting and recordkeeping requirements, and the current OMB control numbers. This display of the OMB control numbers and their subsequent codification in the CFR satisfies the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.) and OMB's implementing regulations at 5 CFR part 1320.

The ICR for this rulemaking was previously subject to public notice and comment prior to OMB approval. As a result, EPA finds that there is “good cause” under section 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(B)) to amend this table without prior notice and comment. Due to the technical nature of the table, further notice and comment would be unnecessary.

IX. Endangered Species Act

Pursuant to section 7(a)(2) of the ESA, EPA consulted with the FWS concerning EPA's publication of the final Guidance. EPA and the FWS have now completed both informal and formal consultation conducted over a two-year period.

As a result of the consultation, as well as an analysis of comments, EPA modified several provisions of the final Guidance. The procedure for site-specific modifications provides that Great Lakes States and Tribes must make site-specific modifications to criteria and values where necessary to ensure the resulting water quality does not cause jeopardy to listed or proposed species. Similarly, the antidegradation policy and implementation procedures restrict certain actions States and Tribes may take to allow lowering of water quality in high quality waters, or to adopt variances or mixing zones. Additionally, the regulatory requirements were modified to require Great Lakes States and Tribes to include in their part 132 submissions any provisions that EPA determines, based on EPA's authorities under the CWA and the results of consultation under section 7 of the ESA, are necessary to ensure that water quality is not likely to cause jeopardy to listed species. EPA and the FWS also agreed on how further consultations will be conducted as the final Guidance is implemented. The two agencies also agreed that EPA will undertake a review of water quality standards and implementation of those standards for ammonia and chlorine in the Great Lakes basin as part of EPA's responsibilities under section 303(c) of the CWA.

During the consultation, two issues were identified that required formal consultation, as defined in 40 CFR part 402. These issues were: the absence of toxicological data concerning effects of contaminants on three species of freshwater mussels in the Great Lakes basin, and the adequacy of the wildlife criteria methodology to protect three endangered or threatened wildlife species in the basin. On February 21, 1995, the FWS provided EPA with a written Biological Opinion (Opinion) on these issues. The Opinion is available in the docket for this rulemaking. On both issues, the FWS concluded that the water quality resulting from implementation of the final Guidance will not cause jeopardy to the listed species. To minimize the amount or extent of any incidental take that might ***15385** occur, the FWS consulted closely with EPA to develop a coordinated approach. The final Opinion specified reasonable and prudent measures that the FWS considers necessary or appropriate to minimize such impact. EPA has agreed to implement the measures, and the FWS and EPA will continue to work cooperatively during the implementation.

X. Judicial Review of Provisions Not Amended

In some situations, EPA has renumbered or included other editorial changes to regulations that have been promulgated in past rulemakings. Additionally, to provide for ease in reading changes to existing regulations, EPA has in some cases repeated entire sections, including portions not changed. The promulgation of this final rule, however, does not provide another opportunity to seek judicial review on the substance of the existing regulations.

XI. Supporting Documents

All documents that are referenced in this preamble are available for inspection and photocopying in the docket for this rulemaking at the address listed at the beginning of this preamble. A reasonable fee will be charged for photocopies.

Selected documents supporting the final Guidance are also available for viewing by the public at locations listed below:

Illinois: Illinois State Library, 300 South 2nd Street, Springfield, IL 62701 (217-785-5600)

Indiana: Indiana Department of Environmental Management, Office of Water Management, 100 North Senate Street, Indianapolis, IN 46204 (317-232-8671)

Michigan: Library of Michigan, Government Documents Service, 717 West Allegan, Lansing, MI 48909 (517-373-1300); Detroit Public Library, Sociology and Economics Department, 5201 Woodward Avenue, Detroit, MI 48902 (313-833-1440)

Minnesota: Minnesota Pollution Control Agency, Library, 520 Lafayette, St. Paul, MN (612-296-7719)

New York: U.S. EPA Region 2 Library, Room 402, 26 Federal Plaza, New York, NY 10278 (212-264-2881); U.S. EPA Public Information Office, Carborundum Center, Suite 530, 345 Third Street, Niagara Falls, NY 14303 (716-285-8842); New York State Department of Environmental Conservation (NYSDEC), Room 310, 50 Wolf Road, Albany, NY 12333 (518-457-7463); NYSDEC, Region 6, 7th Floor, State Office Building, 317 Washington Street, Watertown, NY 13602 (315-785-2513); NYSDEC, Region 7, 615 Erie Boulevard West, Syracuse, NY 13204 (315-426-7400); NYSDEC, Region 8, 6274 East Avon-Lima Road, Avon, NY 14414 (716-226-2466); NYSDEC, Region 9, 270 Michigan Avenue, Buffalo, NY 14203 (716-851-7070)

Ohio: Ohio Environmental Protection Agency Library—Central District Office, 1800 Watermark Road, Columbus, OH 43215 (614-644-3024); U.S. EPA Eastern District Office, 25809 Central Ridge Road, Westlake, OH 44145 (216-522-7260)

Pennsylvania: Pennsylvania Department of Environmental Resources, 230 Chestnut Street, Meadville, PA 16335 (814-332-6945); U.S. EPA Region 3 Library, 8th Floor, 841 Chestnut Building, Philadelphia, PA 19107-4431 (215-597-7904)

Wisconsin: Water Resources Center, University of Wisconsin-Madison, 2nd Floor, 1975 Willow Drive, Madison, WI (608-262-3069)

EPA is also making a number of documents available in electronic format at no incremental cost to users of the Internet. These documents include the contents of this Federal Register document, the SID, many documents listed below, and other supporting materials.

The documents listed below are also available for a fee upon written request or telephone call to the National Technical Information Center (NTIS), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161 (telephone 800-553-6847 or 703-487-4650). Alternatively, copies may be obtained for a fee upon written request or telephone call to the Educational Resources Information Center/Clearinghouse for Science, Mathematics, and Environmental Education (ERIC/CSMEE), 1200 Chambers Road, Room 310, Columbus, OH 43212 (614-292-6717). When ordering, please include the NTIS or ERIC/CSMEE accession number.

A. Final Water Quality Guidance for the Great Lakes System: Supplementary Information Document (SID). NTIS Number: PB95187266. ERIC Number: D046.

B. Great Lakes Water Quality Initiative Criteria Document for the Protection of Aquatic Life in Ambient Water. NTIS Number: PB95187282. ERIC Number: D048.

C. Great Lakes Water Quality Initiative Technical Support Document for the Procedure to Determine Bioaccumulation Factors. NTIS Number: PB95187290. ERIC Number: D049.

D. Great Lakes Water Quality Initiative Criteria Document for the Protection of Human Health. NTIS Number: PB95187308. ERIC Number: D050.

E. Great Lakes Water Quality Initiative Technical Support Document for Human Health Criteria and Values. NTIS Number: PB95187316. ERIC Number: D051.

F. Great Lakes Water Quality Initiative Criteria Document for the Protection of Wildlife: DDT; Mercury; 2,3,7,8-TCDD; PCBs. NTIS Number: PB95187324. ERIC Number: D052.

G. Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria. NTIS Number: PB95187332. ERIC Number: D053.

H. Assessment of Compliance Costs Resulting from Implementation of the Final Great Lakes Water Quality Guidance. NTIS Number: PB95187340. ERIC Number: D054.

I. Regulatory Impact Analysis of the Final Great Lakes Water Quality Guidance. NTIS Number: PB95187357. ERIC Number: D055.

List of Subjects

40 CFR Part 9
Reporting and recordkeeping requirements.

40 CFR Part 122
Administrative practice and procedure, Confidential business information, Great Lakes, Hazardous substances, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 123
Administrative practice and procedure, Confidential business information, Great Lakes, Hazardous substances, Indians-lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 131
Great Lakes, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 132
Administrative practice and procedure, Great Lakes, Indians-lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Dated: March 13, 1995.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40, chapter I, parts 9, 122, 123, and 131 are amended, and part 132 is added as follows:

***15386 PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT**
1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 et seq., 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 et seq., 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 et seq., 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.
40 CFR § 9.1

2. Section 9.1 is amended as follows:

a. By adding in numerical order the entry “122.44(r)” under the heading “EPA Administered Permit Programs: The National Pollutant Discharge Elimination System”.

b. By revising the entries under the heading “State Permit Requirements”;

c. By adding in numerical order the entries “131.1” and “131.5” and by revising the entries “131.20”, “131.21” and “131.22” under the heading “Water Quality Standards Regulations”; and

d. By adding in numerical order a new heading and new entries for “Water Quality Guidance for the Great Lakes System” to read as follows:

40 CFR § 9.1

§9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
EPA Administered Permit Programs: The National Pollutant Discharge Elimination System	
* * * * *	
122.44(r)	2040-0180
* * * * *	
State Permit Requirements	
123.21-123.24	2040-0057, 2040-0170
123.25	2040-0004, 2040-0110, 2040-0170, 2040-0180
123.26-123.29	2040-0057, 2040-0170
123.43	2040-0057, 2040-0170
123.44	2040-0057, 2040-0170, 2040-0180

123.45	2040-0057, 2040-0170
123.62	2040-0057, 2040-0170, 2040-0180
123.63	2040-0057, 2040-0170, 2040-0180
123.64	2040-0057, 2040-0170

Water Quality Standards Regulation

131.1	2040-0180
131.5	2040-0180

* * * * *

131.20	2040-0049
131.21	2040-0049, 2040-0180
131.22	2040-0049

* * * * *

Water Quality Guidance for the Great Lakes System

132.1	2040-0180
132.2	2040-0180
132.3	2040-0180
132.4	2040-0180
132.5	2040-0180
Appendix A	2040-0180
Appendix B	2040-0180
Appendix C	2040-0180
Appendix D	2040-0180

Appendix E	2040-0180
Appendix F	2040-0180

* * * * *

PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

3. The authority citation for part 122 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1251 et seq.

40 CFR § 122.44

4. Section 122.44 is amended by adding a new paragraph (r) to read as follows:

40 CFR § 122.44

§122.44 Establishing limitations, standards, and other permit conditions (applicable to State NPDES programs, see §123.25).

* * * * *

(r) Great Lakes. When a permit is issued to a facility that discharges into the Great Lakes System (as defined in 40 CFR 132.2), conditions promulgated by the State, Tribe, or EPA pursuant to 40 CFR part 132.

PART 123—STATE PROGRAM REQUIREMENTS

5. The authority citation for part 123 continues to read as follows:

Authority: Clean Water Act, 33 U.S.C. 1251 et seq.

40 CFR § 123.25

6. Section 123.25 is amended by removing “and” at the end of paragraph (a)(36), removing the period at the end of paragraph (a)(37) and adding “; and” in its place, and adding a new paragraph (a)(38) to read as follows:

40 CFR § 123.25

§123.25 Requirements for permitting.

(a) * * *

(38) For a Great Lakes State or Tribe (as defined in 40 CFR 132.2), 40 CFR part 132 (NPDES permitting implementation procedures only).

* * * * *40 CFR § 123.44

7. Section 123.44 is amended by adding a new paragraph (c)(9) to read as follows:

40 CFR § 123.44

§123.44 EPA review of and objections to State permits.

* * * * *

(c) * * *

(9) For a permit issued by a Great Lakes State or Tribe (as defined in 40 CFR 132.2), the permit does not satisfy the conditions promulgated by the State, Tribe, or EPA pursuant to 40 CFR part 132.

* * * * *40 CFR § 123.62

8. Section 123.62 is amended by adding a new paragraph (f) to read as follows:

40 CFR § 123.62

§123.62 Procedures for revision of State programs.

* * * * *

(f) Revision of a State program by a Great Lakes State or Tribe (as defined in 40 CFR 132.2) to conform to section 118 of the CWA and 40 CFR part 132 shall be accomplished pursuant to 40 CFR part 132.

40 CFR § 123.63

9. Section 123.63 is amended by adding a new paragraph (a)(6) and adding and reserving paragraph (b) to read as follows:

40 CFR § 123.63

§123.63 Criteria for withdrawal of State programs.

(a) * * *

(6) Where a Great Lakes State or Tribe (as defined in 40 CFR 132.2) fails to adequately incorporate the NPDES permitting implementation procedures promulgated by the State, Tribe, or EPA pursuant to 40 CFR part 132 into individual permits.

(b) [Reserved]

PART 131—WATER QUALITY STANDARDS

10. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 et seq.

40 CFR § 131.1

11. Section 131.1 is revised to read as follows:

40 CFR § 131.1

§131.1 Scope.

40 CFR § 132.2

This part describes the requirements and procedures for developing, reviewing, revising, and approving water quality standards by the States as authorized by section 303(c) of the Clean Water Act. Additional specific procedures for developing, reviewing, revising, and approving water quality standards for Great Lakes States or Great Lakes Tribes (as defined in 40 CFR 132.2) to conform to section 118 of the ***15387** Clean Water Act and 40 CFR part 132, are provided in 40 CFR part 132.

40 CFR § 131.5

12. Section 131.5 is amended by revising paragraph (a)(5), by redesignating paragraph (b) as paragraph (c), and by adding a new paragraph (b) to read as follows:

40 CFR § 131.5

§131.5 EPA Authority.

(a) * * *

(5) Whether the State submission meets the requirements included in §131.6 of this part and, for Great Lakes States or Great Lakes Tribes (as defined in 40 CFR 132.2) to conform to section 118 of the Act, the requirements of 40 CFR part 132.

(b) If EPA determines that the State's or Tribe's water quality standards are consistent with the factors listed in paragraphs (a)(1) through (a)(5) of this section, EPA approves the standards. EPA must disapprove the State's or Tribe's water quality standards and promulgate Federal standards under section 303(c)(4), and for Great Lakes States or Great Lakes Tribes under section 118(c)(2)(C) of the Act, if State or Tribal adopted standards are not consistent with the factors listed in paragraphs (a)(1) through (a)(5) of this section. EPA may also promulgate a new or revised standard when necessary to meet the requirements of the Act.

* * * * *40 CFR § 131.21

13. Section 131.21 is amended by revising paragraph (b) to read as follows:

40 CFR § 131.21

§131.21 EPA review and approval of water quality standards.

* * * * *

(b) The Regional Administrator's approval or disapproval of a State water quality standard shall be based on the requirements of the Act as described in §§131.5 and 131.6, and, with respect to Great Lakes States or Tribes (as defined in 40 CFR 132.2), 40 CFR part 132.

* * * * *

14. Part 132 is added as follows:

PART 132—WATER QUALITY GUIDANCE FOR THE GREAT LAKES SYSTEM

Sec.

132.1 Scope, purpose, and availability of documents.

132.2 Definitions.

132.3 Adoption of criteria.

132.4 State adoption and application of methodologies, policies and procedures.

132.5 Procedures for adoption and EPA review.

132.6 Application of part 132 requirements in Great Lakes States and Tribes. [Reserved]

Tables to Part 132

Appendix A to Part 132—Great Lakes Water Quality Initiative Methodologies for Development of Aquatic Life Criteria and Values

Appendix B to Part 132—Great Lakes Water Quality Initiative Methodology for Development of Bioaccumulation Factors

Appendix C to Part 132—Great Lakes Water Quality Initiative Methodology for Development of Human Health Criteria and Values

Appendix D to Part 132—Great Lakes Water Quality Initiative Methodology for the Development of Wildlife Criteria

Appendix E to Part 132—Great Lakes Water Quality Initiative Antidegradation Policy

Appendix F to Part 132—Great Lakes Water Quality Initiative Implementation Procedures

Authority: 33 U.S.C. 1251 et seq.

40 CFR § 132.1

§132.1 Scope, purpose, and availability of documents.

(a) This part constitutes the Water Quality Guidance for the Great Lakes System (Guidance) required by section 118(c)(2) of the Clean Water Act (33 U.S.C. 1251 et seq.) as amended by the Great Lakes Critical Programs Act of 1990 (Pub. L. 101-596, 104 Stat. 3000 et seq.). The Guidance in this part identifies minimum water quality standards, antidegradation policies, and implementation procedures for the Great Lakes System to protect human health, aquatic life, and wildlife.

(b) The U.S. Environmental Protection Agency, Great Lakes States, and Great Lakes Tribes will use the Guidance in this part to evaluate the water quality programs of the States and Tribes to assure that they are protective of water quality. State and Tribal programs do not need to be identical to the Guidance in this part, but must contain provisions that are consistent with (as protective as) the Guidance in this part. The scientific, policy and legal basis for EPA's development of each section of the final Guidance in this part is set forth in the preamble, Supplementary Information Document, Technical Support Documents,

and other supporting documents in the public docket. EPA will follow the guidance set out in these documents in reviewing the State and Tribal water quality programs in the Great Lakes for consistency with this part.

(c) The Great Lakes States and Tribes must adopt provisions consistent with the Guidance in this part applicable to waters in the Great Lakes System or be subject to EPA promulgation of its terms pursuant to this part.

(d) EPA understands that the science of risk assessment is rapidly improving. Therefore, to ensure that the scientific basis for the methodologies in appendices A through D are always current and peer reviewed, EPA will review the methodologies and revise them, as appropriate, every 3 years.

(e) Certain documents referenced in the appendixes to this part with a designation of NTIS and/or ERIC are available for a fee upon request to the National Technical Information Center (NTIS), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161. Alternatively, copies may be obtained for a fee upon request to the Educational Resources Information Center/Clearinghouse for Science, Mathematics, and Environmental Education (ERIC/CSMEE), 1200 Chambers Road, Room 310, Columbus, Ohio 43212. When ordering, please include the NTIS or ERIC/CSMEE accession number.
40 CFR § 132.2

§132.2 Definitions.
The following definitions apply in this part. Terms not defined in this section have the meaning given by the Clean Water Act and EPA implementing regulations.

Acute-chronic ratio (ACR) is a standard measure of the acute toxicity of a material divided by an appropriate measure of the chronic toxicity of the same material under comparable conditions.

Acute toxicity is concurrent and delayed adverse effect(s) that results from an acute exposure and occurs within any short observation period which begins when the exposure begins, may extend beyond the exposure period, and usually does not constitute a substantial portion of the life span of the organism.

Adverse effect is any deleterious effect to organisms due to exposure to a substance. This includes effects which are or may become debilitating, harmful or toxic to the normal functions of the organism, but does not include non-harmful effects such as tissue discoloration alone or the induction of enzymes involved in the metabolism of the substance.

Bioaccumulation is the net accumulation of a substance by an organism as a result of uptake from all environmental sources.

Bioaccumulation factor (BAF) is the ratio (in L/kg) of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where both the organism and its food are exposed and the ratio does not change substantially over time.

Bioaccumulative chemical of concern (BCC) is any chemical that has the potential to cause adverse effects which, upon entering the surface waters, by itself or as its toxic transformation ***15388** product, accumulates in aquatic organisms by a human health bioaccumulation factor greater than 1000, after considering metabolism and other physicochemical properties that might enhance or inhibit bioaccumulation, in accordance with the methodology in appendix B of this part. Chemicals with half-lives of less than eight weeks in the water column, sediment, and biota are not BCCs. The minimum BAF information needed to define an organic chemical as a BCC is either a field-measured BAF or a BAF derived using the BSAF methodology. The minimum BAF information needed to define an inorganic chemical, including an organometal, as a BCC is either a field-measured BAF or a laboratory-measured BCF. BCCs include, but are not limited to, the pollutants identified as BCCs in section A of Table 6 of this part.

Bioconcentration is the net accumulation of a substance by an aquatic organism as a result of uptake directly from the ambient water through gill membranes or other external body surfaces.

Bioconcentration factor (BCF) is the ratio (in L/kg) of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through the water only and the ratio does not change substantially over time.

Biota-sediment accumulation factor (BSAF) is the ratio (in kg of organic carbon/kg of lipid) of a substance's lipid-normalized concentration in tissue of an aquatic organism to its organic carbon-normalized concentration in surface sediment, in situations where the ratio does not change substantially over time, both the organism and its food are exposed, and the surface sediment is representative of average surface sediment in the vicinity of the organism.

Carcinogen is a substance which causes an increased incidence of benign or malignant neoplasms, or substantially decreases the time to develop neoplasms, in animals or humans. The classification of carcinogens is discussed in section II.A of appendix C to part 132.

Chronic toxicity is concurrent and delayed adverse effect(s) that occurs only as a result of a chronic exposure.

Connecting channels of the Great Lakes are the Saint Mary's River, Saint Clair River, Detroit River, Niagara River, and Saint Lawrence River to the Canadian Border.

Criterion continuous concentration (CCC) is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed indefinitely without resulting in an unacceptable effect.

Criterion maximum concentration (CMC) is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed briefly without resulting in an unacceptable effect.

EC50 is a statistically or graphically estimated concentration that is expected to cause one or more specified effects in 50 percent of a group of organisms under specified conditions.

Endangered or threatened species are those species that are listed as endangered or threatened under section 4 of the Endangered Species Act.

Existing Great Lakes discharger is any building, structure, facility, or installation from which there is or may be a “discharge of pollutants” (as defined in 40 CFR 122.2) to the Great Lakes System, that is not a new Great Lakes discharger.

Federal Indian reservation, Indian reservation, or reservation means all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and including rights-of-way running through the reservation.

Final acute value (FAV) is (a) a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable acute toxicity tests have been conducted on the material) have higher GMAVs, or (b) the SMAV of an important and/or critical species, if the SMAV is lower than the calculated estimate.

Final chronic value (FCV) is (a) a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable chronic toxicity tests have been conducted on the material) have higher GMCVs, (b) the quotient of an FAV divided by an appropriate acute-chronic ratio, or (c) the SMCV of an important and/or critical species, if the SMCV is lower than the calculated estimate or the quotient, whichever is applicable.

Final plant value (FPV) is the lowest plant value that was obtained with an important aquatic plant species in an acceptable toxicity test for which the concentrations of the test material were measured and the adverse effect was biologically important.

Genus mean acute value (GMAV) is the geometric mean of the SMAVs for the genus.

Genus mean chronic value (GMCV) is the geometric mean of the SMCVs for the genus.

Great Lakes means Lake Ontario, Lake Erie, Lake Huron (including Lake St. Clair), Lake Michigan, and Lake Superior; and the connecting channels (Saint Mary's River, Saint Clair River, Detroit River, Niagara River, and Saint Lawrence River to the Canadian Border).

Great Lakes States and Great Lakes Tribes, or Great Lakes States and Tribes means the States of Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin, and any Indian Tribe as defined in this part which is located in whole or in part within the drainage basin of the Great Lakes, and for which EPA has approved water quality standards under section 303 of the Clean Water Act or which EPA has authorized to administer an NPDES program under section 402 of the Clean Water Act.

Great Lakes System means all the streams, rivers, lakes and other bodies of water within the drainage basin of the Great Lakes within the United States.

Human cancer criterion (HCC) is a Human Cancer Value (HCV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C of this part.

Human cancer value (HCV) is the maximum ambient water concentration of a substance at which a lifetime of exposure from either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities, will represent a plausible upper-bound risk of contracting cancer of one in 100,000 using the exposure assumptions specified in the Methodologies for the Development of Human Health Criteria and Values in appendix C of this part.

Human noncancer criterion (HNC) is a Human Noncancer Value (HNV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C of this part.

Human noncancer value (HNV) is the maximum ambient water concentration of a substance at which adverse noncancer effects are not likely to occur in the human population from lifetime exposure via either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities using the Methodologies for the Development of Human Health Criteria and Values in appendix C of this part.

Indian Tribe or Tribe means any Indian Tribe, band, group, or community recognized by the Secretary of the Interior and exercising governmental authority over a Federal Indian reservation.

LC50 is a statistically or graphically estimated concentration that is expected ***15389** to be lethal to 50 percent of a group of organisms under specified conditions.

Load allocation (LA) is the portion of a receiving water's loading capacity that is attributed either to one of its existing or future nonpoint sources or to natural background sources, as more fully defined at 40 CFR 130.2(g). Nonpoint sources include: in-place contaminants, direct wet and dry deposition, groundwater inflow, and overland runoff.

Loading capacity is the greatest amount of loading that a water can receive without violating water quality standards.

Lowest observed adverse effect level (LOAEL) is the lowest tested dose or concentration of a substance which resulted in an observed adverse effect in exposed test organisms when all higher doses or concentrations resulted in the same or more severe effects.

Method detection level is the minimum concentration of an analyte (substance) that can be measured and reported with a 99 percent confidence that the analyte concentration is greater than zero as determined by the procedure set forth in appendix B of 40 CFR part 136.

Minimum Level (ML) is the concentration at which the entire analytical system must give a recognizable signal and acceptable calibration point. The ML is the concentration in a sample that is equivalent to the concentration of the lowest calibration standard analyzed by a specific analytical procedure, assuming that all the method-specified sample weights, volumes and processing steps have been followed.

New Great Lakes discharger is any building, structure, facility, or installation from which there is or may be a “discharge of pollutants” (as defined in 40 CFR 122.2) to the Great Lakes System, the construction of which commenced after March 23, 1997.

No observed adverse effect level (NOAEL) is the highest tested dose or concentration of a substance which resulted in no observed adverse effect in exposed test organisms where higher doses or concentrations resulted in an adverse effect.

No observed effect concentration (NOEC) is the highest concentration of toxicant to which organisms are exposed in a full life-cycle or partial life-cycle (short-term) test, that causes no observable adverse effects on the test organisms (i.e., the highest concentration of toxicant in which the values for the observed responses are not statistically significantly different from the controls).

Open waters of the Great Lakes (OWGLs) means all of the waters within Lake Erie, Lake Huron (including Lake St. Clair), Lake Michigan, Lake Ontario, and Lake Superior lakeward from a line drawn across the mouth of tributaries to the Lakes, including all waters enclosed by constructed breakwaters, but not including the connecting channels.

Quantification level is a measurement of the concentration of a contaminant obtained by using a specified laboratory procedure calibrated at a specified concentration above the method detection level. It is considered the lowest concentration at which a particular contaminant can be quantitatively measured using a specified laboratory procedure for monitoring of the contaminant.

Quantitative structure activity relationship (QSAR) or structure activity relationship (SAR) is a mathematical relationship between a property (activity) of a chemical and a number of descriptors of the chemical. These descriptors are chemical or physical characteristics obtained experimentally or predicted from the structure of the chemical.

Risk associated dose (RAD) is a dose of a known or presumed carcinogenic substance in (mg/kg)/day which, over a lifetime of exposure, is estimated to be associated with a plausible upper bound incremental cancer risk equal to one in 100,000.

Species mean acute value (SMAV) is the geometric mean of the results of all acceptable flow-through acute toxicity tests (for which the concentrations of the test material were measured) with the most sensitive tested life stage of the species. For a species for which no such result is available for the most sensitive tested life stage, the SMAV is the geometric mean of the results of all acceptable acute toxicity tests with the most sensitive tested life stage.

Species mean chronic value (SMCV) is the geometric mean of the results of all acceptable life-cycle and partial life-cycle toxicity tests with the species; for a species of fish for which no such result is available, the SMCV is the geometric mean of all acceptable early life-stage tests.

Stream design flow is the stream flow that represents critical conditions, upstream from the source, for protection of aquatic life, human health, or wildlife.

Threshold effect is an effect of a substance for which there is a theoretical or empirically established dose or concentration below which the effect does not occur.

Tier I criteria are numeric values derived by use of the Tier I methodologies in appendixes A, C and D of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part, that either have been adopted as numeric criteria into a water quality standard or are used to implement narrative water quality criteria.

Tier II values are numeric values derived by use of the Tier II methodologies in appendixes A and C of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part, that are used to implement narrative water quality criteria.

Total maximum daily load (TMDL) is the sum of the individual wasteload allocations for point sources and load allocations for nonpoint sources and natural background, as more fully defined at 40 CFR 130.2(i). A TMDL sets and allocates the maximum amount of a pollutant that may be introduced into a water body and still assure attainment and maintenance of water quality standards.

Tributaries of the Great Lakes System means all waters of the Great Lakes System that are not open waters of the Great Lakes, or connecting channels.

Uncertainty factor (UF) is one of several numeric factors used in operationally deriving criteria from experimental data to account for the quality or quantity of the available data.

Uptake is acquisition of a substance from the environment by an organism as a result of any active or passive process.

Wasteload allocation (WLA) is the portion of a receiving water's loading capacity that is allocated to one of its existing or future point sources of pollution, as more fully defined at 40 CFR 130.2(h). In the absence of a TMDL approved by EPA pursuant to 40 CFR 130.7 or an assessment and remediation plan developed and approved in accordance with procedure 3.A of appendix F of this part, a WLA is the allocation for an individual point source, that ensures that the level of water quality to be achieved by the point source is derived from and complies with all applicable water quality standards.

Wet weather point source means any discernible, confined and discrete conveyance from which pollutants are, or may be, discharged as the result of a wet weather event. Discharges from wet weather point sources shall include only: discharges of storm water from a municipal separate storm sewer as defined at 40 CFR 122.26(b)(8); storm water discharge associated with industrial activity as defined at 40 CFR 122.26(b)(14); discharges of storm water and sanitary wastewaters (domestic, ***15390** commercial, and industrial) from a combined sewer overflow; or any other stormwater discharge for which a permit is required under section 402(p) of the Clean Water Act. A storm water discharge associated with industrial activity which is mixed with process wastewater shall not be considered a wet weather point source.

40 CFR § 132.3

§132.3 Adoption of criteria.

The Great Lakes States and Tribes shall adopt numeric water quality criteria for the purposes of section 303(c) of the Clean Water Act applicable to waters of the Great Lakes System in accordance with §132.4(d) that are consistent with:

(a) The acute water quality criteria for protection of aquatic life in Table 1 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part;

(b) The chronic water quality criteria for protection of aquatic life in Table 2 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part;

(c) The water quality criteria for protection of human health in Table 3 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part; and

(d) The water quality criteria for protection of wildlife in Table 4 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part.

40 CFR § 132.4

§132.4 State adoption and application of methodologies, policies and procedures.

(a) The Great Lakes States and Tribes shall adopt requirements applicable to waters of the Great Lakes System for the purposes of sections 118, 301, 303, and 402 of the Clean Water Act that are consistent with:

(1) The definitions in §132.2;

(2) The Methodologies for Development of Aquatic Life Criteria and Values in appendix A of this part;

(3) The Methodology for Development of Bioaccumulation Factors in appendix B of this part;

(4) The Methodologies for Development of Human Health Criteria and Values in appendix C of this part;

(5) The Methodology for Development of Wildlife Criteria in appendix D of this part;

(6) The Antidegradation Policy in appendix E of this part; and

(7) The Implementation Procedures in appendix F of this part.

(b) Except as provided in paragraphs (g), (h), and (i) of this section, the Great Lakes States and Tribes shall use methodologies consistent with the methodologies designated as Tier I methodologies in appendixes A, C, and D of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part when adopting or revising numeric water quality criteria for the purposes of section 303(c) of the Clean Water Act for the Great Lakes System.

(c) Except as provided in paragraphs (g), (h), and (i) of this section, the Great Lakes States and Tribes shall use methodologies and procedures consistent with the methodologies designated as Tier I methodologies in appendixes A, C, and D of this part, the Tier II methodologies in appendixes A and C of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part to develop numeric criteria and values when implementing narrative water quality criteria adopted for purposes of section 303(c) of the Clean Water Act.

(d) The water quality criteria and values adopted or developed pursuant to paragraphs (a) through (c) of this section shall apply as follows:

(1) The acute water quality criteria and values for the protection of aquatic life, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(2) The chronic water quality criteria and values for the protection of aquatic life, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(3) The water quality criteria and values for protection of human health, or site-specific modifications thereof, shall apply as follows:

(i) Criteria and values derived as HCV-Drinking and HNV-Drinking shall apply to the Open Waters of the Great Lakes, all connecting channels of the Great Lakes, and all other waters of the Great Lakes System that have been designated as public water supplies by any State or Tribe in accordance with 40 CFR 131.10.

(ii) Criteria and values derived as HCV-Nondrinking and HNV-Nondrinking shall apply to all waters of the Great Lakes System other than those in paragraph (d)(3)(i) of this section.

(4) Criteria for protection of wildlife, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(e) The Great Lakes States and Tribes shall apply implementation procedures consistent with the procedures in appendix F of this part for all applicable purposes under the Clean Water Act, including developing total maximum daily loads for the purposes of section 303(d) and water quality-based effluent limits for the purposes of section 402, in establishing controls on the discharge of any pollutant to the Great Lakes System by any point source with the following exceptions:

(1) The Great Lakes States and Tribes are not required to apply these implementation procedures in establishing controls on the discharge of any pollutant by a wet weather point source. Any adopted implementation procedures shall conform with all applicable Federal, State and Tribal requirements.

(2) The Great Lakes States and Tribes may, but are not required to, apply procedures consistent with procedures 1, 2, 3, 4, 5, 7, 8, and 9 of appendix F of this part in establishing controls on the discharge of any pollutant set forth in Table 5 of this part. Any procedures applied in lieu of these implementation procedures shall conform with all applicable Federal, State, and Tribal requirements.

(f) The Great Lakes States and Tribes shall apply an antidegradation policy consistent with the policy in appendix E for all applicable purposes under the Clean Water Act, including 40 CFR 131.12.

(g) For pollutants listed in Table 5 of this part, the Great Lakes States and Tribes shall:

(1) Apply any methodologies and procedures acceptable under 40 CFR part 131 when developing water quality criteria or implementing narrative criteria; and

(2) Apply the implementation procedures in appendix F of this part or alternative procedures consistent with all applicable Federal, State, and Tribal laws.

(h) For any pollutant other than those in Table 5 of this part for which the State or Tribe demonstrates that a methodology or procedure in this part is not scientifically defensible, the Great Lakes States and Tribes shall:

(1) Apply an alternative methodology or procedure acceptable under 40 CFR part 131 when developing water quality criteria; or

(2) Apply an alternative implementation procedure that is consistent with all applicable Federal, State, and Tribal laws.

(i) Nothing in this part shall prohibit the Great Lakes States and Tribes from adopting numeric water quality criteria, narrative criteria, or water quality values that are more stringent than criteria or values specified in §132.3 or that would be derived from application of the methodologies set forth in appendixes A, B, C, and D of this part, or to adopt antidegradation standards and implementation procedures more ***15391** stringent than those set forth in appendixes E and F of this part.
40 CFR § 132.5

§132.5 Procedures for adoption and EPA review.

(a) Except as provided in paragraph (c) of this section, the Great Lakes States and Tribes shall adopt and submit for EPA review and approval the criteria, methodologies, policies, and procedures developed pursuant to this part no later than September 23, 1996.

(b) The following elements must be included in each submission to EPA for review:

(1) The criteria, methodologies, policies, and procedures developed pursuant to this part;

(2) Certification by the Attorney General or other appropriate legal authority pursuant to 40 CFR 123.62 and 40 CFR 131.6(e) as appropriate;

(3) All other information required for submission of National Pollutant Discharge Elimination System (NPDES) program modifications under 40 CFR 123.62; and

(4) General information which will aid EPA in determining whether the criteria, methodologies, policies and procedures are consistent with the requirements of the Clean Water Act and this part, as well as information on general policies which may affect their application and implementation.

(c) The Regional Administrator may extend the deadline for the submission required in paragraph (a) of this section if the Regional Administrator believes that the submission will be consistent with the requirements of this part and can be reviewed and approved pursuant to this section no later than March 23, 1997.

(d) If a Great Lakes State or Tribe makes no submission pursuant to this part to EPA for review, the requirements of this part shall apply to discharges to waters of the Great Lakes System located within the State or Federal Indian reservation upon EPA's publication of a final rule indicating the effective date of the part 132 requirements in the identified jurisdictions.

(e) If a Great Lakes State or Tribe submits criteria, methodologies, policies, and procedures pursuant to this part to EPA for review that contain substantial modifications of the State or Tribal NPDES program, EPA shall issue public notice and provide a minimum of 30 days for public comment on such modifications. The public notice shall conform with the requirements of 40 CFR 123.62.

(f) After review of State or Tribal submissions under this section, and following the public comment period in subparagraph (e) of this section, if any, EPA shall either:

(1) Publish notice of approval of the submission in the Federal Register within 90 days of such submission; or

(2) Notify the State or Tribe within 90 days of such submission that EPA has determined that all or part of the submission is inconsistent with the requirements of the Clean Water Act or this part and identify any necessary changes to obtain EPA approval. If the State or Tribe fails to adopt such changes within 90 days after the notification, EPA shall publish a notice in the Federal Register identifying the approved and disapproved elements of the submission and a final rule in the Federal Register identifying the provisions of part 132 that shall apply to discharges within the State or Federal Indian reservation.

(g) EPA's approval or disapproval of a State or Tribal submission shall be based on the requirements of this part and of the Clean Water Act. EPA's determination whether the criteria, methodologies, policies, and procedures in a State or Tribal submission are consistent with the requirements of this part will be based on whether:

(1) For pollutants listed in Tables 1, 2, 3, and 4 of this part. The Great Lakes State or Tribe has adopted numeric water quality criteria as protective as each of the numeric criteria in Tables 1, 2, 3, and 4 of this part, taking into account any site-specific criteria modifications in accordance with procedure 1 of appendix F of this part;

(2) For pollutants other than those listed in Tables 1, 2, 3, 4, and 5 of this part. The Great Lakes State or Tribe demonstrates that either:

(i) It has adopted numeric criteria in its water quality standards that were derived, or are as protective as or more protective than could be derived, using the methodologies in appendixes A, B, C, and D of this part, and the site-specific criteria modification procedures in accordance with procedure 1 of appendix F of this part; or

(ii) It has adopted a procedure by which water quality-based effluent limits and total maximum daily loads are developed using the more protective of:

(A) Numeric criteria adopted by the State into State water quality standards and approved by EPA prior to March 23, 1997; or

(B) Water quality criteria and values derived pursuant to §132.4(c); and

(3) For methodologies, policies, and procedures. The Great Lakes State or Tribe has adopted methodologies, policies, and procedures as protective as the corresponding methodology, policy, or procedure in §132.4. The Great Lakes State or Tribe may adopt provisions that are more protective than those contained in this part. Adoption of a more protective element in one provision may be used to offset a less protective element in the same provision as long as the adopted provision is as protective as the corresponding provision in this part; adoption of a more protective element in one provision, however, is not justification for adoption of a less protective element in another provision of this part.

(h) A submission by a Great Lakes State or Tribe will need to include any provisions that EPA determines, based on EPA's authorities under the Clean Water Act and the results of consultation under section 7 of the Endangered Species Act, are necessary to ensure that water quality is not likely to jeopardize the continued existence of any endangered or threatened species listed under section 4 of the Endangered Species Act or result in the destruction or adverse modification of such species' critical habitat.

(i) EPA's approval of the elements of a State's or Tribe's submission will constitute approval under section 118 of the Clean Water Act, approval of the submitted water quality standards pursuant to section 303 of the Clean Water Act, and approval of the submitted modifications to the State's or Tribe's NPDES program pursuant to section 402 of the Clean Water Act.
40 CFR § 132.6

§132.6 Application of part 132 requirements in Great Lakes States and Tribes. [Reserved]

Tables to Part 132

Table 1.—Acute Water Quality Criteria for Protection of Aquatic Life in Ambient Water
EPA recommends that metals criteria be expressed as dissolved concentrations (see appendix A, I.A.4 for more information regarding metals criteria).

(a)

Table 1.—Acute Water Quality Criteria for Protection of Aquatic Life in Ambient Water

Chemical	CMC (MUg/L)	Conversion factor (CF)
Arsenic (III)	[a,b] 339.8	1.000

Chromium (VI)	[a,b] 16.02		0.982
Cyanide	[c] 22	n/a	
Dieldrin	[d] 0.24	n/a	
Endrin	[d] 0.086	n/a	
Lindane	[d] 0.95	n/a	
Mercury (II)	[a,b] 1.694		0.85
Parathion	[d] 0.065	n/a	
Selenium	[a,b] 19.34		0.922

***15392** (b)

Chemical	m_A	b_A	Conversion factor (CF)
Cadmium [a,b]	1.128	3.6867	0.85
Chromium (III) [a,b]	0.819	+3.7256	0.316
Copper [a,b]	0.9422	1.700	0.960
Nickel [a,b]	0.846	+2.255	0.998
Pentachlorophenol [c]	1.005	4.869	n/a
Zinc [a,b]	0.8473	+0.884	0.978

Table 2.—Chronic Water Quality Criteria for Protection of Aquatic Life in Ambient Water
EPA recommends that metals criteria be expressed as dissolved concentrations (see appendix A, I.A.4 for more information regarding metals criteria).

(a)

Table 2.—Chronic Water Quality Criteria for Protection of Aquatic Life in Ambient Water

Chemical	CCC (MUg/L)	Conversion factor (CF)
Arsenic (III)	[a,b] 147.9	1.000
Chromium (VI)	[a,b] 10.98	0.962

Cyanide	[c] 5.2	n/a	
Dieldrin	[d] 0.056	n/a	
Endrin	[d] 0.036	n/a	
Mercury (II)	[a,b] 0.9081		0.85
Parathion	[d] 0.013	n/a	
Selenium	[a,b] 5		0.922

(b)

Chemical	m_c	b_c	Conversion factor (CF)
Cadmium [a,b]	0.7852	2.715	0.850
Chromium (III) [a,b]	0.819	+0.6848	0.860
Copper [a,b]	0.8545	1.702	0.960
Nickel [a,b]	0.846	+0.0584	0.997
Pentachlorophenol [c]	1.005	5.134	n/a
Zinc [a,b]	0.8473	+0.884	0.986

Table 3.—Water Quality Criteria for Protection of Human Health

Chemical	HNV (MUg/L)		HCV (MUg/L)	
	Drinking	Nondrinking	Drinking	Nondrinking
Benzene	1.9E1	5.1E2	1.2E1	3.1E2
Chlordane	1.4E-3	1.4E-3	2.5E-4	2.5E-4
Chlorobenzene	4.7E2	3.2E3		
Cyanides	6.0E2	4.8E4		
DDT	2.0E-3	2.0E-3	1.5E-4	1.5E-4
Dieldrin	4.1E-4	4.1E-4	6.5E-6	6.5E-6
2,4-Dimethylphenol	4.5E2	8.7E3		
2,4-Dinitrophenol	5.5E1	2.8E3		

Hexachlorobenzene	4.6E-2	4.6E-2	4.5E-4	4.5E-4	
Hexachloroethane	6.0	7.6	5.3	6.7	
Lindane	4.7E-1	5.0E-1			
Mercury [1]	1.8E-3	1.8E-3			
Methylene chloride	1.6E3	9.0E4	4.7E1	2.6E3	
PCBs (class)	.....		3.9E-6	3.9E-6	
2,3,7,8-TCDD	6.7E-8	6.7E-8	8.6E-9	8.6E-9	
Toluene	5.6E3	5.1E4			
Toxaphene	.....		6.8E-5	6.8E-5	
Trichloroethylene	.....		2.9E1	3.7E2	

Table 4.—Water Quality Criteria for Protection of Wildlife

Chemical	Criteria (MUg/L)
DDT and metabolites	1.1E-5
Mercury (including methylmercury)	1.3E-3
PCBs (class)	7.4E-5
2,3,7,8-TCDD	3.1E-9

***15393** Table 5.—Pollutants Subject to Federal, State, and Tribal Requirements
Alkalinity

Ammonia

Bacteria

Biochemical oxygen demand (BOD)

Chlorine

Color

Dissolved oxygen

Dissolved solids

pH

Phosphorus

Salinity

Temperature

Total and suspended solids

Turbidity

Table 6.—Pollutants of Initial Focus in the Great Lakes Water Quality Initiative
A. Pollutants that are bioaccumulative chemicals of concern (BCCs):

Chlordane

4,4#-DDD; p,p#-DDD; 4,4#-TDE; p,p#-TDE

4,4#-DDE; p,p#-DDE

4,4#-DDT; p,p#-DDT

Dieldrin

Hexachlorobenzene

Hexachlorobutadiene; hexachloro-1, 3-butadiene

Hexachlorocyclohexanes; BHCs

alpha-Hexachlorocyclohexane; alpha-BHC

beta-Hexachlorocyclohexane; beta-BHC

delta-Hexachlorocyclohexane; delta-BHC

Lindane; gamma-hexachlorocyclohexane; gamma-BHC

Mercury

Mirex

Octachlorostyrene

PCBs; polychlorinated biphenyls

Pentachlorobenzene

Photomirex

2,3,7,8-TCDD; dioxin

1,2,3,4-Tetrachlorobenzene

1,2,4,5-Tetrachlorobenzene Toxaphene

B. Pollutants that are not bioaccumulative chemicals of concern:

Acenaphthene

Acenaphthylene

Acrolein; 2-propenal

Acrylonitrile

Aldrin

Aluminum

Anthracene

Antimony

Arsenic

Asbestos

1,2-Benzanthracene; benz[a]anthracene

Benzene

Benzidine

Benzo[a]pyrene; 3,4-benzopyrene

3,4-Benzofluoranthene; benzo[b]fluoranthene

11,12-Benzofluoranthene; benzo[k]fluoranthene

1,12-Benzoperylene; benzo[ghi]perylene

Beryllium

Bis(2-chloroethoxy) methane

Bis(2-chloroethyl) ether

Bis(2-chloroisopropyl) ether

Bromoform; tribomomethane

4-Bromophenyl phenyl ether

Butyl benzyl phthalate

Cadmium

Carbon tetrachloride; tetrachloromethane

Chlorobenzene

p-Chloro-m-cresol; 4-chloro-3-methylphenol

Chlorodibromomethane

Chlorethane

2-Chloroethyl vinyl ether

Chloroform; trichloromethane

2-Chloronaphthalene

2-Chlorophenol

4-Chlorophenyl phenyl ether

Chlorpyrifos

Chromium

Chrysene

Copper

Cyanide

2,4-D; 2,4-Dichlorophenoxyacetic acid

DEHP; di(2-ethylhexyl) phthalate

Diazinon

1,2:5,6-Dibenzanthracene; dibenz[a,h]anthracene

Dibutyl phthalate; di-n-butyl phthalate

1,2-Dichlorobenzene

1,3-Dichlorobenzene

1,4-Dichlorobenzene

3,3#-Dichlorobenzidine

Dichlorobromomethane; bromodichloromethane

1,1-Dichloroethane

1,2-Dichloroethane

1,1-Dichloroethylene; vinylidene chloride

1,2-trans-Dichloroethylene

2,4-Dichlorophenol

1,2-Dichloropropane

1,3-Dichloropropene; 1,3-dichloropropylene

Diethyl phthalate

2,4-Dimethylphenol; 2,4-xylenol

Dimethyl phthalate

4,6-Dinitro-o-cresol; 2-methyl-4,6-dinitrophenol

2,4-Dinitrophenol

2,4-Dinitrotoluene

2,6-Dinitrotoluene

Dioctyl phthalate; di-n-octyl phthalate

1,2-Diphenylhydrazine

Endosulfan; thiodan

alpha-Endosulfan

beta-Endosulfan

Endosulfan sulfate

Endrin

Endrin aldehyde

Ethylbenzene

Fluoranthene

Fluorene; 9H-fluorene

Fluoride

Guthion

Heptachlor

Heptachlor epoxide

Hexachlorocyclopentadiene

Hexachloroethane

Indeno[1,2,3-cd]pyrene; 2,3-o-phenylene pyrene

Isophorone

Lead

Malathion

Methoxychlor

Methyl bromide; bromomethane

Methyl chloride; chloromethane

Methylene chloride; dichloromethane

Napthalene

Nickel

Nitrobenzene

2-Nitrophenol

4-Nitrophenol

N-Nitrosodimethylamine

N-Nitrosodiphenylamine

N-Nitrosodipropylamine; N-nitrosodi-n-propylamine

Parathion

Pentachlorophenol

Phenanthrene

Phenol

Iron

Pyrene

Selenium

Silver

1,1,2,2-Tetrachloroethane

Tetrachloroethylene

Thallium

Toluene; methylbenzene

1,2,4-Trichlorobenzene

1,1,1-Trichloroethane

1,1,2-Trichloroethane

Trichloroethylene; trichloroethene

2,4,6-Trichlorophenol

Vinyl chloride; chloroethylene; chloroethene

Zinc

Appendix A to part 132—Great Lakes Water Quality Initiative Methodologies for Developments of Aquatic Life Criteria and Values

Methodology for Deriving Aquatic Life Criteria: Tier I

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this appendix.

15394** ***I. Definitions

A. Material of Concern. When defining the material of concern the following should be considered:

1. Each separate chemical that does not ionize substantially in most natural bodies of water should usually be considered a separate material, except possibly for structurally similar organic compounds that only exist in large quantities as commercial mixtures of the various compounds and apparently have similar biological, chemical, physical, and toxicological properties.

2. For chemicals that ionize substantially in most natural bodies of water (e.g., some phenols and organic acids, some salts of phenols and organic acids, and most inorganic salts and coordination complexes of metals and metalloid), all forms that would be in chemical equilibrium should usually be considered one material. Each different oxidation state of a metal and each different non-ionizable covalently bonded organometallic compound should usually be considered a separate material.

3. The definition of the material of concern should include an operational analytical component. Identification of a material simply as “sodium,” for example, implies “total sodium,” but leaves room for doubt. If “total” is meant, it must be explicitly stated. Even “total” has different operational definitions, some of which do not necessarily measure “all that is there” in all samples. Thus, it is also necessary to reference or describe the analytical method that is intended. The selection of the operational analytical component should take into account the analytical and environmental chemistry of the material and various practical considerations, such as labor and equipment requirements, and whether the method would require measurement in the field or would allow measurement after samples are transported to a laboratory.

a. The primary requirements of the operational analytical component are that it be appropriate for use on samples of receiving water, that it be compatible with the available toxicity and bioaccumulation data without making extrapolations that are too hypothetical, and that it rarely result in underprotection or overprotection of aquatic organisms and their uses. Toxicity is the property of a material, or combination of materials, to adversely affect organisms.

b. Because an ideal analytical measurement will rarely be available, an appropriate compromise measurement will usually have to be used. This compromise measurement must fit with the general approach that if an ambient concentration is lower than the criterion, unacceptable effects will probably not occur, i.e., the compromise measure must not err on the side of underprotection when measurements are made on a surface water. What is an appropriate measurement in one situation might not be appropriate for another. For example, because the chemical and physical properties of an effluent are usually quite different from those of the receiving water, an analytical method that is appropriate for analyzing an effluent might not be appropriate for expressing a criterion, and vice versa. A criterion should be based on an appropriate analytical measurement, but the criterion is not rendered useless if an ideal measurement either is not available or is not feasible.

Note: The analytical chemistry of the material might have to be taken into account when defining the material or when judging the acceptability of some toxicity tests, but a criterion must not be based on the sensitivity of an analytical method. When aquatic organisms are more sensitive than routine analytical methods, the proper solution is to develop better analytical methods.

4. It is now the policy of EPA that the use of dissolved metal to set and measure compliance with water quality standards is the recommended approach, because dissolved metal more closely approximates the bioavailable fraction of metal in the water column that does total recoverable metal. One reason is that a primary mechanism for water column toxicity is adsorption at the gill surface which requires metals to be in the dissolved form. Reasons for the consideration of total recoverable metals criteria include risk management considerations not covered by evaluation of water column toxicity. A risk manager may consider sediments and food chain effects and may decide to take a conservative approach for metals, considering that metals are very persistent chemicals. This approach could include the use of total recoverable metal in water quality standards. A range of different risk management decisions can be justified. EPA recommends that State water quality standards be based on dissolved metal. EPA will also approve a State risk management decision to adopt standards based on total recoverable metal, if those standards are otherwise approvable under this program.

B. Acute Toxicity. Concurrent and delayed adverse effect(s) that results from an acute exposure and occurs within any short observation period which begins when the exposure begins, may extend beyond the exposure period, and usually does not constitute a substantial portion of the life span of the organism. (Concurrent toxicity is an adverse effect to an organism that results from, and occurs during, its exposure to one or more test materials.) Exposure constitutes contact with a chemical or physical agent. Acute exposure, however, is exposure of an organism for any short period which usually does not constitute a substantial portion of its life span.

C. Chronic Toxicity. Concurrent and delayed adverse effect(s) that occurs only as a result of a chronic exposure. Chronic exposure is exposure of an organism for any long period or for a substantial portion of its life span.

II. Collection of Data

A. Collect all data available on the material concerning toxicity to aquatic animals and plants.

B. All data that are used should be available in typed, dated, and signed hard copy (e.g., publication, manuscript, letter, memorandum, etc.) with enough supporting information to indicate that acceptable test procedures were used and that the results are reliable. In some cases, it might be appropriate to obtain written information from the investigator, if possible. Information that is not available for distribution shall not be used.

C. Questionable data, whether published or unpublished, must not be used. For example, data must be rejected if they are from tests that did not contain a control treatment, tests in which too many organisms in the control treatment died or showed signs of stress or disease, and tests in which distilled or deionized water was used as the dilution water without the addition of appropriate salts.

D. Data on technical grade materials may be used if appropriate, but data on formulated mixtures and emulsifiable concentrates of the material must not be used.

E. For some highly volatile, hydrolyzable, or degradable materials, it might be appropriate to use only results of flow-through tests in which the concentrations of test material in test solutions were measured using acceptable analytical methods. A flow-through test is a test with aquatic organisms in which test solutions flow into constant-volume test chambers either intermittently (e.g., every few minutes) or continuously, with the excess flowing out.

F. Data must be rejected if obtained using:

1. Brine shrimp, because they usually only occur naturally in water with salinity greater than 35 g/kg.

2. Species that do not have reproducing wild populations in North America.

3. Organisms that were previously exposed to substantial concentrations of the test material or other contaminants.

4. Saltwater species except for use in deriving acute-chronic ratios. An ACR is a standard measure of the acute toxicity of a material divided by an appropriate measure of the chronic toxicity of the same material under comparable conditions.

G. Questionable data, data on formulated mixtures and emulsifiable concentrates, and data obtained with species non-resident to North America or previously exposed organisms may be used to provide auxiliary information but must not be used in the derivation of criteria.

III. Required Data

A. Certain data should be available to help ensure that each of the major kinds of possible adverse effects receives adequate consideration. An adverse effect is a change in an organism that is harmful to the organism. Exposure means contact with a chemical or physical agent. Results of acute and chronic toxicity tests with representative species of aquatic animals are necessary so that data available for tested species can be considered a useful indication of the sensitivities of appropriate untested species. Fewer data concerning toxicity to aquatic plants are usually available because procedures for conducting tests with plants and interpreting the results of such tests are not as well developed.

B. To derive a Great Lakes Tier I criterion for aquatic organisms and their uses, the following must be available:

1. Results of acceptable acute (or chronic) tests (see section IV or VI of this appendix) with at least one species of freshwater animal in at least eight different families such that all of the following are included:

***15395** a. The family Salmonidae in the class Osteichthyes;

b. One other family (preferably a commercially or recreationally important, warmwater species) in the class Osteichthyes (e.g., bluegill, channel catfish);

c. A third family in the phylum Chordata (e.g., fish, amphibian);

d. A planktonic crustacean (e.g., a cladoceran, copepod);

e. A benthic crustacean (e.g., ostracod, isopod, amphipod, crayfish);

f. An insect (e.g., mayfly, dragonfly, damselfly, stonefly, caddisfly, mosquito, midge);

g. A family in a phylum other than Arthropoda or Chordata (e.g., Rotifera, Annelida, Mollusca);

h. A family in any order of insect or any phylum not already represented.

2. Acute-chronic ratios (see section VI of this appendix) with at least one species of aquatic animal in at least three different families provided that of the three species:

a. At least one is a fish;

b. At least one is an invertebrate; and

c. At least one species is an acutely sensitive freshwater species (the other two may be saltwater species).

3. Results of at least one acceptable test with a freshwater algae or vascular plant is desirable but not required for criterion derivation (see section VIII of this appendix). If plants are among the aquatic organisms most sensitive to the material, results of a test with a plant in another phylum (division) should also be available.

C. If all required data are available, a numerical criterion can usually be derived except in special cases. For example, derivation of a chronic criterion might not be possible if the available ACRs vary by more than a factor of ten with no apparent pattern. Also, if a criterion is to be related to a water quality characteristic (see sections V and VII of this appendix), more data will be required.

D. Confidence in a criterion usually increases as the amount of available pertinent information increases. Thus, additional data are usually desirable.

IV. Final Acute Value

A. Appropriate measures of the acute (short-term) toxicity of the material to a variety of species of aquatic animals are used to calculate the Final Acute Value (FAV). The calculated Final Acute Value is a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable acute toxicity tests have been conducted on the material) have higher Genus Mean Acute Values (GMAVs). An acute test is a comparative study in which organisms, that are subjected to different treatments, are observed for a short period usually not constituting a substantial portion of their life span. However, in some cases, the Species Mean Acute Value (SMAV) of a commercially or recreationally important species of the Great Lakes System is lower than the calculated FAV, then the SMAV replaces the calculated FAV in order to provide protection for that important species.

B. Acute toxicity tests shall be conducted using acceptable procedures. For good examples of acceptable procedures see American Society for Testing and Materials (ASTM) Standard E 729, Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians.

C. Except for results with saltwater annelids and mysids, results of acute tests during which the test organisms were fed should not be used, unless data indicate that the food did not affect the toxicity of the test material. (Note: If the minimum acute-chronic ratio data requirements (as described in section III.B.2 of this appendix) are not met with freshwater data alone, saltwater data may be used.)

D. Results of acute tests conducted in unusual dilution water, e.g., dilution water in which total organic carbon or particulate matter exceeded five mg/L, should not be used, unless a relationship is developed between acute toxicity and organic carbon or particulate matter, or unless data show that organic carbon or particulate matter, etc., do not affect toxicity.

E. Acute values must be based upon endpoints which reflect the total severe adverse impact of the test material on the organisms used in the test. Therefore, only the following kinds of data on acute toxicity to aquatic animals shall be used:

1. Tests with daphnids and other cladocerans must be started with organisms less than 24 hours old and tests with midges must be started with second or third instar larvae. It is preferred that the results should be the 48-hour EC50 based on the total percentage of organisms killed and immobilized. If such an EC50 is not available for a test, the 48-hour LC50 should be used in place of the desired 48-hour EC50. An EC50 or LC50 of longer than 48 hours can be used as long as the animals were not fed and the control animals were acceptable at the end of the test. An EC50 is a statistically or graphically estimated concentration that is expected to cause one or more specified effects in 50% of a group of organisms under specified conditions. An LC50 is a statistically or graphically estimated concentration that is expected to be lethal to 50% of a group of organisms under specified conditions.

2. It is preferred that the results of a test with embryos and larvae of barnacles, bivalve molluscs (clams, mussels, oysters and scallops), sea urchins, lobsters, crabs, shrimp and abalones be the 96-hour EC50 based on the percentage of organisms with incompletely developed shells plus the percentage of organisms killed. If such an EC50 is not available from a test, of the values that are available from the test, the lowest of the following should be used in place of the desired 96-hour EC50: 48- to 96-hour EC50s based on percentage of organisms with incompletely developed shells plus percentage of organisms killed, 48- to 96-hour EC50s based upon percentage of organisms with incompletely developed shells, and 48-hour to 96-hour LC50s. (Note: If the minimum acute-chronic ratio data requirements (as described in section III.B.2 of this appendix) are not met with freshwater data alone, saltwater data may be used.)

3. It is preferred that the result of tests with all other aquatic animal species and older life stages of barnacles, bivalve molluscs (clams, mussels, oysters and scallops), sea urchins, lobsters, crabs, shrimp and abalones be the 96-hour EC50 based on percentage of organisms exhibiting loss of equilibrium plus percentage of organisms immobilized plus percentage of organisms killed. If such an EC50 is not available from a test, of the values that are available from a test the lower of the following should

be used in place of the desired 96-hour EC50: the 96-hour EC50 based on percentage of organisms exhibiting loss of equilibrium plus percentage of organisms immobilized and the 96-hour LC50.

4. Tests whose results take into account the number of young produced, such as most tests with protozoans, are not considered acute tests, even if the duration was 96 hours or less.

5. If the tests were conducted properly, acute values reported as “greater than” values and those which are above the solubility of the test material should be used, because rejection of such acute values would bias the Final Acute Value by eliminating acute values for resistant species.

F. If the acute toxicity of the material to aquatic animals has been shown to be related to a water quality characteristic such as hardness or particulate matter for freshwater animals, refer to section V of this appendix.

G. The agreement of the data within and between species must be considered. Acute values that appear to be questionable in comparison with other acute and chronic data for the same species and for other species in the same genus must not be used. For example, if the acute values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values would be appropriate, absent countervailing circumstances.

H. If the available data indicate that one or more life stages are at least a factor of two more resistant than one or more other life stages of the same species, the data for the more resistant life stages must not be used in the calculation of the SMAV because a species cannot be considered protected from acute toxicity if all of the life stages are not protected.

I. For each species for which at least one acute value is available, the SMAV shall be calculated as the geometric mean of the results of all acceptable flow-through acute toxicity tests in which the concentrations of test material were measured with the most sensitive tested life stage of the species. For a species for which no such result is available, the SMAV shall be calculated as the geometric mean of all acceptable acute toxicity tests with the most sensitive tested life stage, i.e., results of flow-through tests in which the concentrations were not measured and results of static and renewal tests based on initial concentrations (nominal concentrations are acceptable for most test materials if measured concentrations are not available) of test material. A renewal test is a test with aquatic organisms in which either the test solution in a test chamber is removed and replaced at least once during the test or the test organisms are transferred into a new test solution of the same composition at least once during the test. A static test is a test with aquatic organisms in which the solution ***15396** and organisms that are in a test chamber at the beginning of the test remain in the chamber until the end of the test, except for removal of dead test organisms.

Note 1: Data reported by original investigators must not be rounded off. Results of all intermediate calculations must not be rounded off to fewer than four significant digits.

Note 2: The geometric mean of N numbers is the Nth root of the product of the N numbers. Alternatively, the geometric mean can be calculated by adding the logarithms of the N numbers, dividing the sum by N, and taking the antilog of the quotient. The geometric mean of two numbers is the square root of the product of the two numbers, and the geometric mean of one number is that number. Either natural (base e) or common (base 10) logarithms can be used to calculate geometric means as long as they are used consistently within each set of data, i.e., the antilog used must match the logarithms used.

Note 3: Geometric means, rather than arithmetic means, are used here because the distributions of sensitivities of individual organisms in toxicity tests on most materials and the distributions of sensitivities of species within a genus are more likely to be lognormal than normal. Similarly, geometric means are used for ACRs because quotients are likely to be closer to lognormal than normal distributions. In addition, division of the geometric mean of a set of numerators by the geometric mean of the set of denominators will result in the geometric mean of the set of corresponding quotients.

J. For each genus for which one or more SMAVs are available, the GMAV shall be calculated as the geometric mean of the SMAVs available for the genus.

K. Order the GMAVs from high to low.

L. Assign ranks, R, to the GMAVs from "1" for the lowest to "N" for the highest. If two or more GMAVs are identical, assign them successive ranks.

M. Calculate the cumulative probability, P, for each GMAV as R/(N+1).

N. Select the four GMAVs which have cumulative probabilities closest to 0.05 (if there are fewer than 59 GMAVs, these will always be the four lowest GMAVs).

O. Using the four selected GMAVs, and Ps, calculate

Note: Natural logarithms (logarithms to base e, denoted as ln) are used herein merely because they are easier to use on some hand calculators and computers than common (base 10) logarithms. Consistent use of either will produce the same result.

P. If for a commercially or recreationally important species of the Great Lakes System the geometric mean of the acute values from flow-through tests in which the concentrations of test material were measured is lower than the calculated Final Acute Value (FAV), then that geometric mean must be used as the FAV instead of the calculated FAV.

Q. See section VI of this appendix.

V. Final Acute Equation

A. When enough data are available to show that acute toxicity to two or more species is similarly related to a water quality characteristic, the relationship shall be taken into account as described in sections V.B through V.G of this appendix or using analysis of covariance. The two methods are equivalent and produce identical results. The manual method described below provides an understanding of this application of covariance analysis, but computerized versions of covariance analysis are much more convenient for analyzing large data sets. If two or more factors affect toxicity, multiple regression analysis shall be used.

B. For each species for which comparable acute toxicity values are available at two or more different values of the water quality characteristic, perform a least squares regression of the acute toxicity values on the corresponding values of the water quality characteristic to obtain the slope and its 95 percent confidence limits for each species.

Note: Because the best documented relationship is that between hardness and acute toxicity of metals in fresh water and a log-log relationship fits these data, geometric means and natural logarithms of both toxicity and water quality are used in the rest of this section. For relationships based on other water quality characteristics, such as Ph, temperature, no transformation or a different transformation might fit the data better, and appropriate changes will be necessary throughout this section.

C. Decide whether the data for each species are relevant, taking into account the range and number of the tested values of the water quality characteristic and the degree of agreement within and between species. For example, a slope based on six data points might be of limited value if it is based only on data for a very narrow range of values of the water quality characteristic. A slope based on only two data points, however, might be useful if it is consistent with other information and if the two points cover a broad enough range of the water quality characteristic. In addition, acute values that appear to be questionable in comparison with other acute and chronic data available for the same species and for other species in the same genus should not be used. For example, if after adjustment for the water quality characteristic, the acute values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values would be appropriate, absent countervailing justification. If useful slopes are not available for at least one fish and one invertebrate or if the available slopes are too dissimilar or if too

few data are available to adequately define the relationship between acute toxicity and the water quality characteristic, return to section IV.G of this appendix, using the results of tests conducted under conditions and in waters similar to those commonly used for toxicity tests with the species.

D. For each species, calculate the geometric mean of the available acute values and then divide each of the acute values for the species by the geometric mean for the species. This normalizes the acute values so that the geometric mean of the normalized values for each species individually and for any combination of species is 1.0.

E. Similarly normalize the values of the water quality characteristic for each species individually using the same procedure as above.

F. Individually for each species perform a least squares regression of the normalized ***15397** acute values of the water quality characteristic. The resulting slopes and 95 percent confidence limits will be identical to those obtained in section V.B. of this appendix. If, however, the data are actually plotted, the line of best fit for each individual species will go through the point 1,1 in the center of the graph.

G. Treat all of the normalized data as if they were all for the same species and perform a least squares regression of all of the normalized acute values on the corresponding normalized values of the water quality characteristic to obtain the pooled acute slope, V, and its 95 percent confidence limits. If all of the normalized data are actually plotted, the line of best fit will go through the point 1,1 in the center of the graph.

H. For each species calculate the geometric mean, W, of the acute toxicity values and the geometric mean, X, of the values of the water quality characteristic. (These were calculated in sections V.D and V.E of this appendix).

I. For each species, calculate the logarithm, Y, of the SMAV at a selected value, Z, of the water quality characteristic using the equation:

Y=ln WV(ln Xln Z)
J. For each species calculate the SMAV at X using the equation:

$SMAV=e^{Y}$
Note: Alternatively, the SMAVs at Z can be obtained by skipping step H above, using the equations in steps I and J to adjust each acute value individually to Z, and then calculating the geometric mean of the adjusted values for each species individually. This alternative procedure allows an examination of the range of the adjusted acute values for each species.

K. Obtain the FAV at Z by using the procedure described in sections IV.J through IV.O of this appendix.

L. If, for a commercially or recreationally important species of the Great Lakes System the geometric mean of the acute values at Z from flow-through tests in which the concentrations of the test material were measured is lower than the FAV at Z, then the geometric mean must be used as the FAV instead of the FAV.

M. The Final Acute Equation is written as:

$FAV=e^{(V[\ln(\text{water quality characteristic})]+AV[\ln Z])}$,
where:

V=pooled acute slope, and A=ln(FAV at Z).
Because V, A, and Z are known, the FAV can be calculated for any selected value of the water quality characteristic.

VI. Final Chronic Value

A. Depending on the data that are available concerning chronic toxicity to aquatic animals, the Final Chronic Value (FCV) can be calculated in the same manner as the FAV or by dividing the FAV by the Final Acute-Chronic Ratio (FACR). In some cases, it might not be possible to calculate a FCV. The FCV is (a) a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable chronic toxicity tests have been conducted on the material) have higher GMCVs, or (b) the quotient of an FAV divided by an appropriate ACR, or (c) the SMCV of an important and/or critical species, if the SMCV is lower than the calculated estimate or the quotient, whichever is applicable.

Note: As the name implies, the ACR is a way of relating acute and chronic toxicities.

B. Chronic values shall be based on results of flow-through (except renewal is acceptable for daphnids) chronic tests in which the concentrations of test material in the test solutions were properly measured at appropriate times during the test. A chronic test is a comparative study in which organisms, that are subjected to different treatments, are observed for a long period or a substantial portion of their life span.

C. Results of chronic tests in which survival, growth, or reproduction in the control treatment was unacceptably low shall not be used. The limits of acceptability will depend on the species.

D. Results of chronic tests conducted in unusual dilution water, e.g., dilution water in which total organic carbon or particulate matter exceeded five mg/L, should not be used, unless a relationship is developed between chronic toxicity and organic carbon or particulate matter, or unless data show that organic carbon, particulate matter, etc., do not affect toxicity.

E. Chronic values must be based on endpoints and lengths of exposure appropriate to the species. Therefore, only results of the following kinds of chronic toxicity tests shall be used:

1. Life-cycle toxicity tests consisting of exposures of each of two or more groups of individuals of a species to a different concentration of the test material throughout a life cycle. To ensure that all life stages and life processes are exposed, tests with fish should begin with embryos or newly hatched young less than 48 hours old, continue through maturation and reproduction, and should end not less than 24 days (90 days for salmonids) after the hatching of the next generation. Tests with daphnids should begin with young less than 24 hours old and last for not less than 21 days, and for ceriodaphnids not less than seven days. For good examples of acceptable procedures see American Society for Testing and Materials (ASTM) Standard E 1193 Guide for conducting renewal life-cycle toxicity tests with Daphnia magna and ASTM Standard E 1295 Guide for conducting three-brood, renewal toxicity tests with Ceriodaphnia dubia. Tests with mysids should begin with young less than 24 hours old and continue until seven days past the median time of first brood release in the controls. For fish, data should be obtained and analyzed on survival and growth of adults and young, maturation of males and females, eggs spawned per female, embryo viability (salmonids only), and hatchability. For daphnids, data should be obtained and analyzed on survival and young per female. For mysids, data should be obtained and analyzed on survival, growth, and young per female.

2. Partial life-cycle toxicity tests consist of exposures of each of two more groups of individuals of a species of fish to a different concentration of the test material through most portions of a life cycle. Partial life-cycle tests are allowed with fish species that require more than a year to reach sexual maturity, so that all major life stages can be exposed to the test material in less than 15 months. A life-cycle test is a comparative study in which organisms, that are subjected to different treatments, are observed at least from a life stage in one generation to the same life-stage in the next generation. Exposure to the test material should begin with immature juveniles at least two months prior to active gonad development, continue through maturation and reproduction, and end not less than 24 days (90 days for salmonids) after the hatching of the next generation. Data should be obtained and

analyzed on survival and growth of adults and young, maturation of males and females, eggs spawned per female, embryo viability (salmonids only), and hatchability.

3. Early life-stage toxicity tests consisting of 28- to 32-day (60 days post hatch for salmonids) exposures of the early life stages of a species of fish from shortly after fertilization through embryonic, larval, and early juvenile development. Data should be obtained and analyzed on survival and growth.

Note: Results of an early life-stage test are used as predictions of results of life-cycle and partial life-cycle tests with the same species. Therefore, when results of a life-cycle or partial life-cycle test are available, results of an early life-stage test with the same species should not be used. Also, results of early life-stage tests in which the incidence of mortalities or abnormalities increased substantially near the end of the test shall not be used because the results of such tests are possibly not good predictions of comparable life-cycle or partial life-cycle tests.

F. A chronic value may be obtained by calculating the geometric mean of the lower and upper chronic limits from a chronic test or by analyzing chronic data using regression analysis.

1. A lower chronic limit is the highest tested concentration:

a. In an acceptable chronic test;

b. Which did not cause an unacceptable amount of adverse effect on any of the specified biological measurements; and

c. Below which no tested concentration caused an unacceptable effect.

2. An upper chronic limit is the lowest tested concentration:

a. In an acceptable chronic test;

b. Which did cause an unacceptable amount of adverse effect on one or more of the specified biological measurements; and,

c. Above which all tested concentrations also caused such an effect.

Note: Because various authors have used a variety of terms and definitions to interpret and report results of chronic tests, reported results should be reviewed carefully. The amount of effect that is considered unacceptable is often based on a statistical hypothesis test, but might also be defined in terms of a specified percent reduction from the controls. A small percent reduction (e.g., three percent) might be considered acceptable even if it is statistically significantly different from the control, whereas a large percent reduction (e.g., 30 percent) might be considered unacceptable even if it is not statistically significant.

G. If the chronic toxicity of the material to aquatic animals has been shown to be related ***15398** to a water quality characteristic such as hardness or particulate matter for freshwater animals, refer to section VII of this appendix.

H. If chronic values are available for species in eight families as described in section III.B.1 of this appendix, a SMCV shall be calculated for each species for which at least one chronic value is available by calculating the geometric mean of the results of all acceptable life-cycle and partial life-cycle toxicity tests with the species; for a species of fish for which no such result is available, the SMCV is the geometric mean of all acceptable early life-stage tests. Appropriate GMCVs shall also be calculated. A GMCV is the geometric mean of the SMCVs for the genus. The FCV shall be obtained using the procedure described in sections IV.J through IV.O of this appendix, substituting SMCV and GMCV for SMAV and GMAV respectively. See section VI.M of this appendix.

Note: Section VI.I through VI.L are for use when chronic values are not available for species in eight taxonomic families as described in section III.B.1 of this appendix.

I. For each chronic value for which at least one corresponding appropriate acute value is available, calculate an ACR, using for the numerator the geometric mean of the results of all acceptable flow-through (except static is acceptable for daphnids and midges) acute tests in the same dilution water in which the concentrations are measured. For fish, the acute test(s) should be conducted with juveniles. The acute test(s) should be part of the same study as the chronic test. If acute tests were not conducted as part of the same study, but were conducted as part of a different study in the same laboratory and dilution water, then they may be used. If no such acute tests are available, results of acute tests conducted in the same dilution water in a different laboratory may be used. If no such acute tests are available, an ACR shall not be calculated.

J. For each species, calculate the SMACR as the geometric mean of all ACRs available for that species. If the minimum ACR data requirements (as described in section III.B.2 of this appendix) are not met with freshwater data alone, saltwater data may be used along with the freshwater data.

K. For some materials, the ACR seems to be the same for all species, but for other materials the ratio seems to increase or decrease as the SMAV increases. Thus the FACR can be obtained in three ways, depending on the data available:

1. If the species mean ACR seems to increase or decrease as the SMAVs increase, the FACR shall be calculated as the geometric mean of the ACRs for species whose SMAVs are close to the FAV.

2. If no major trend is apparent and the ACRs for all species are within a factor of ten, the FACR shall be calculated as the geometric mean of all of the SMACRs.

3. If the most appropriate SMACRs are less than 2.0, and especially if they are less than 1.0, acclimation has probably occurred during the chronic test. In this situation, because continuous exposure and acclimation cannot be assured to provide adequate protection in field situations, the FACR should be assumed to be two, so that the FCV is equal to the Criterion Maximum Concentration (CMC). (See section X.B of this appendix.)

If the available SMACRs do not fit one of these cases, a FACR may not be obtained and a Tier I FCV probably cannot be calculated.

L. Calculate the FCV by dividing the FAV by the FACR.

FCV=FAV+FACR

If there is a Final Acute Equation rather than a FAV, see also section V of this appendix.
M. If the SMCV of a commercially or recreationally important species of the Great Lakes System is lower than the calculated FCV, then that SMCV must be used as the FCV instead of the calculated FCV.

N. See section VIII of this appendix.

VII. Final Chronic Equation

A. A Final Chronic Equation can be derived in two ways. The procedure described in section VII.A of this appendix will result in the chronic slope being the same as the acute slope. The procedure described in sections VII.B through N of this appendix will usually result in the chronic slope being different from the acute slope.

1. If ACRs are available for enough species at enough values of the water quality characteristic to indicate that the ACR appears to be the same for all species and appears to be independent of the water quality characteristic, calculate the FACR as the geometric mean of the available SMACRs.

2. Calculate the FCV at the selected value Z of the water quality characteristic by dividing the FAV at Z (see section V.M of this appendix) by the FACR.

3. Use V=pooled acute slope (see section V.M of this appendix), and

L=pooled chronic slope.

4. See section VII.M of this appendix.

B. When enough data are available to show that chronic toxicity to at least one species is related to a water quality characteristic, the relationship should be taken into account as described in sections C through G below or using analysis of covariance. The two methods are equivalent and produce identical results. The manual method described below provides an understanding of this application of covariance analysis, but computerized versions of covariance analysis are much more convenient for analyzing large data sets. If two or more factors affect toxicity, multiple regression analysis shall be used.

C. For each species for which comparable chronic toxicity values are available at two or more different values of the water quality characteristic, perform a least squares regression of the chronic toxicity values on the corresponding values of the water quality characteristic to obtain the slope and its 95 percent confidence limits for each species.

Note: Because the best documented relationship is that between hardness and acute toxicity of metals in fresh water and a log-log relationship fits these data, geometric means and natural logarithms of both toxicity and water quality are used in the rest of this section. For relationships based on other water quality characteristics, such as Ph, temperature, no transformation or a different transformation might fit the data better, and appropriate changes will be necessary throughout this section. It is probably preferable, but not necessary, to use the same transformation that was used with the acute values in section V of this appendix.

D. Decide whether the data for each species are relevant, taking into account the range and number of the tested values of the water quality characteristic and the degree of agreement within and between species. For example, a slope based on six data points might be of limited value if it is based only on data for a very narrow range of values of the water quality characteristic. A slope based on only two data points, however, might be more useful if it is consistent with other information and if the two points cover a broad range of the water quality characteristic. In addition, chronic values that appear to be questionable in comparison with other acute and chronic data available for the same species and for other species in the same genus in most cases should not be used. For example, if after adjustment for the water quality characteristic, the chronic values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values is, in most cases, absent countervailing circumstances, appropriate. If a useful chronic slope is not available for at least one species or if the available slopes are too dissimilar or if too few data are available to adequately define the relationship between chronic toxicity and the water quality characteristic, it might be appropriate to assume that the chronic slope is the same as the acute slope, which is equivalent to assuming that the ACR is independent of the water quality characteristic. Alternatively, return to section VI.H of this appendix, using the results of tests conducted under conditions and in waters similar to those commonly used for toxicity tests with the species.

E. Individually for each species, calculate the geometric mean of the available chronic values and then divide each chronic value for a species by the mean for the species. This normalizes the chronic values so that the geometric mean of the normalized values for each species individually, and for any combination of species, is 1.0.

F. Similarly, normalize the values of the water quality characteristic for each species individually.

G. Individually for each species, perform a least squares regression of the normalized chronic toxicity values on the corresponding normalized values of the water quality characteristic. The resulting slopes and the 95 percent confidence limits will be identical to those obtained in section VII.B of this appendix. Now, however, if the data are actually plotted, the line of best fit for each individual species will go through the point 1,1 in the center of the graph.

H. Treat all of the normalized data as if they were all the same species and perform a least squares regression of all of the normalized chronic values on the corresponding normalized values of the water quality characteristic to obtain the pooled chronic slope, L, and its 95 percent confidence limits.

If all normalized data are actually plotted, the line of best fit will go through the point 1,1 in the center of the graph.

***15399** I. For each species, calculate the geometric mean, M, of the toxicity values and the geometric mean, P, of the values of the water quality characteristic. (These are calculated in sections VII.E and F of this appendix.)

J. For each species, calculate the logarithm, Q, of the SMCV at a selected value, Z, of the water quality characteristic using the equation:

Q=ln M—L(ln Pln Z)
Note: Although it is not necessary, it is recommended that the same value of the water quality characteristic be used here as was used in section V of this appendix.

K. For each species, calculate a SMCV at Z using the equation:

$SMCV=e^{Q}$
Note: Alternatively, the SMCV at Z can be obtained by skipping section VII.J of this appendix, using the equations in sections VII.J and K of this appendix to adjust each chronic value individually to Z, and then calculating the geometric means of the adjusted values for each species individually. This alternative procedure allows an examination of the range of the adjusted chronic values for each species.

L. Obtain the FCV at Z by using the procedure described in sections IV.J through O of this appendix.

M. If the SMCV at Z of a commercially or recreationally important species of the Great Lakes System is lower than the calculated FCV at Z, then that SMCV shall be used as the FCV at Z instead of the calculated FCV.

N. The Final Chronic Equation is written as:

$FCV=e^{(L[\ln(\text{water quality characteristic})]+\ln SL[\ln Z])}$

Where:

L=pooled chronic slope and S = FCV at Z.
Because L, S, and Z are known, the FCV can be calculated for any selected value of the water quality characteristic.

VIII. Final Plant Value

A. A Final Plant Value (FPV) is the lowest plant value that was obtained with an important aquatic plant species in an acceptable toxicity test for which the concentrations of the test material were measured and the adverse effect was biologically important. Appropriate measures of the toxicity of the material to aquatic plants are used to compare the relative sensitivities of aquatic plants and animals. Although procedures for conducting and interpreting the results of toxicity tests with plants are not well-developed, results of tests with plants usually indicate that criteria which adequately protect aquatic animals and their uses will, in most cases, also protect aquatic plants and their uses.

B. A plant value is the result of a 96-hour test conducted with an alga or a chronic test conducted with an aquatic vascular plant.

Note: A test of the toxicity of a metal to a plant shall not be used if the medium contained an excessive amount of a complexing agent, such as EDTA, that might affect the toxicity of the metal. Concentrations of EDTA above 200 mg/L should be considered excessive.

C. The FPV shall be obtained by selecting the lowest result from a test with an important aquatic plant species in which the concentrations of test material are measured and the endpoint is biologically important.

IX. Other Data

Pertinent information that could not be used in earlier sections might be available concerning adverse effects on aquatic organisms. The most important of these are data on cumulative and delayed toxicity, reduction in survival, growth, or reproduction, or any other adverse effect that has been shown to be biologically important. Delayed toxicity is an adverse effect to an organism that results from, and occurs after the end of, its exposure to one or more test materials. Especially important are data for species for which no other data are available. Data from behavioral, biochemical, physiological, microcosm, and field studies might also be available. Data might be available from tests conducted in unusual dilution water (see sections IV.D and VI.D of this appendix), from chronic tests in which the concentrations were not measured (see section VI.B of this appendix), from tests with previously exposed organisms (see section II.F.3 of this appendix), and from tests on formulated mixtures or emulsifiable concentrates (see section II.D of this appendix). Such data might affect a criterion if the data were obtained with an important species, the test concentrations were measured, and the endpoint was biologically important.

X. Criterion

A. A criterion consists of two concentrations: the CMC and the Criterion Continuous Concentration (CCC).

B. The CMC is equal to one-half the FAV. The CMC is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed briefly without resulting in an unacceptable effect.

C. The CCC is equal to the lowest of the FCV or the FPV (if available) unless other data (see section IX of this appendix) show that a lower value should be used. The CCC is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed indefinitely without resulting in an unacceptable effect. If toxicity is related to a water quality characteristic, the CCC is obtained from the Final Chronic Equation or FPV (if available) that results in the lowest concentrations in the usual range of the water quality characteristic, unless other data (see section IX) show that a lower value should be used.

D. Round both the CMC and the CCC to two significant digits.

E. The criterion is stated as:

The procedures described in the Tier I methodology indicate that, except possibly where a commercially or recreationally important species is very sensitive, aquatic organisms should not be affected unacceptably if the four-day average concentration

of (1) does not exceed (2) mg/L more than once every three years on the average and if the one-hour average concentration does not exceed (3) mg/L more than once every three years on the average.

Where:

(1) = insert name of material

(2) = insert the CCC

(3) = insert the CMC

If the CMC averaging period of one hour or the CCC averaging period of four days is inappropriate for the pollutant, or if the once-in-three-year allowable excursion frequency is inappropriate for the pollutant or for the sites to which a criterion is applied, then the State may specify alternative averaging periods or frequencies. The choice of an alternative averaging period or frequency shall be justified by a scientifically defensible analysis demonstrating that the alternative values will protect the aquatic life uses of the water. Appropriate laboratory data and/or well-designed field biological surveys shall be submitted to EPA as justification for differing averaging periods and/or frequencies of exceedance.

XI. Final Review

A. The derivation of the criterion should be carefully reviewed by rechecking each step of the Guidance in this part. Items that should be especially checked are:

1. If unpublished data are used, are they well documented?

2. Are all required data available?

3. Is the range of acute values for any species greater than a factor of 10?

4. Is the range of SMAVs for any genus greater than a factor of 10?

5. Is there more than a factor of 10 difference between the four lowest GMAVs?

6. Are any of the lowest GMAVs questionable?

7. Is the FAV reasonable in comparison with the SMAVs and GMAVs?

8. For any commercially or recreationally important species of the Great Lakes System, is the geometric mean of the acute values from flow-through tests in which the concentrations of test material were measured lower than the FAV?

9. Are any of the chronic values used questionable?

10. Are any chronic values available for acutely sensitive species?

11. Is the range of acute-chronic ratios greater than a factor of 10?

12. Is the FCV reasonable in comparison with the available acute and chronic data?

13. Is the measured or predicted chronic value for any commercially or recreationally important species of the Great Lakes System below the FCV?

14. Are any of the other data important?

15. Do any data look like they might be outliers?

16. Are there any deviations from the Guidance in this part? Are they acceptable?

B. On the basis of all available pertinent laboratory and field information, determine if the criterion is consistent with sound scientific evidence. If it is not, another criterion, either higher or lower, shall be derived consistent with the Guidance in this part.

Methodology for Deriving Aquatic Life Values: Tier II

15400** ***XII. Secondary Acute Value

If all eight minimum data requirements for calculating an FAV using Tier I are not met, a Secondary Acute Value (SAV) for the waters of the Great Lakes System shall be calculated for a chemical as follows:

To calculate a SAV, the lowest GMAV in the database is divided by the Secondary Acute Factor (SAF) (Table A-1 of this appendix) corresponding to the number of satisfied minimum data requirements listed in the Tier I methodology (section III.B.1 of this appendix). (Requirements for definitions, data collection and data review, contained in sections I, II, and IV shall be applied to calculation of a SAV.) If all eight minimum data requirements are satisfied, a Tier I criterion calculation may be possible. In order to calculate a SAV, the database must contain, at a minimum, a genus mean acute value (GMAV) for one of the following three genera in the family Daphnidae—Ceriodaphnia sp., Daphnia sp., or Simocephalus sp.

If appropriate, the SAV shall be made a function of a water quality characteristic in a manner similar to that described in Tier I.

XIII. Secondary Acute-Chronic Ratio

If three or more experimentally determined ACRs, meeting the data collection and review requirements of Section VI of this appendix, are available for the chemical, determine the FACR using the procedure described in Section VI. If fewer than three acceptable experimentally determined ACRs are available, use enough assumed ACRs of 18 so that the total number of ACRs equals three. Calculate the Secondary Acute-Chronic Ratio (SACR) as the geometric mean of the three ACRs. Thus, if no experimentally determined ACRs are available, the SACR is 18.

XIV. Secondary Chronic Value

Calculate the Secondary Chronic Value (SCV) using one of the following:

If appropriate, the SCV will be made a function of a water quality characteristic in a manner similar to that described in Tier I.

XV. Commercially or Recreationally Important Species

If for a commercially or recreationally important species of the Great Lakes System the geometric mean of the acute values or chronic values from flow-through tests in which the concentrations of the test materials were measured is lower than the calculated SAV or SCV, then that geometric mean must be used as the SAV or SCV instead of the calculated SAV or SCV.

XVI. Tier II Value

A. A Tier II value shall consist of two concentrations: the Secondary Maximum Concentration (SMC) and the Secondary Continuous Concentration (SCC).

B. The SMC is equal to one-half of the SAV.

C. The SCC is equal to the lowest of the SCV or the Final Plant Value, if available, unless other data (see section IX of this appendix) show that a lower value should be used.

If toxicity is related to a water quality characteristic, the SCC is obtained from the Secondary Chronic Equation or FPV, if available, that results in the lowest concentrations in the usual range of the water quality characteristic, unless other data (See section IX of this appendix) show that a lower value should be used.

D. Round both the SMC and the SCC to two significant digits.

E. The Tier II value is stated as:

The procedures described in the Tier II methodology indicate that, except possibly where a locally important species is very sensitive, aquatic organisms should not be affected unacceptably if the four-day average concentration of (1) does not exceed (2) mg/L more than once every three years on the average and if the one-hour average concentration does not exceed (3) mg/L more than once every three years on the average.

Where:

(1) = insert name of material

(2) = insert the SCC

(3) = insert the SMC
As discussed above, States and Tribes have the discretion to specify alternative averaging periods or frequencies (see section X.E. of this appendix).

XVII. Appropriate Modifications
On the basis of all available pertinent laboratory and field information, determine if the Tier II value is consistent with sound scientific evidence. If it is not, another value, either higher or lower, shall be derived consistent with the Guidance in this part.

Table A-1.— Secondary Acute Factors

Number of minimum data requirements satisfied	Adjustment factor
1	21.9
2	13.0
3	8.0
4	7.0
5	6.1
6	5.2
7	4.3

Appendix B to Part 132—Great Lakes Water Quality Initiative

Methodology for Deriving Bioaccumulation Factors

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this appendix.

I. Introduction

A. The purpose of this methodology is to describe procedures for deriving bioaccumulation factors (BAFs) to be used in the calculation of Great Lakes Water Quality Guidance (Guidance) human health Tier I criteria and Tier II values and wildlife Tier I criteria. A subset of the human health BAFs are also used to identify the chemicals that are considered bioaccumulative chemicals of concern (BCCs).

B. Bioaccumulation reflects uptake of a substance by aquatic organisms exposed to the substance through all routes (i.e., ambient water and food), as would occur in nature. Bioconcentration reflects uptake of a substance by aquatic organisms exposed to the substance only through the ambient water. Both BAFs and bioconcentration factors (BCFs) are proportionality constants that describe the relationship between the concentration of a substance in aquatic organisms and its concentration in the ambient water. For the Guidance in this part, BAFs, rather than BCFs, are used to calculate Tier I criteria for human health and wildlife and Tier II values for human health because they better account for the total exposure of aquatic organisms to chemicals.

C. For organic chemicals, baseline BAFs can be derived using four methods. Measured baseline BAFs are derived from field-measured BAFs; predicted baseline BAFs are derived using biota-sediment accumulation factors (BSAFs) or are derived by multiplying a laboratory-measured or predicted BCF by a food-chain multiplier (FCM). The lipid content of the aquatic organisms is used to account for partitioning of organic chemicals within organisms so that data from different ***15401** tissues and species can be integrated. In addition, the baseline BAF is based on the concentration of freely dissolved organic chemicals in the ambient water to facilitate extrapolation from one water to another.

D. For inorganic chemicals, baseline BAFs can be derived using two of the four methods. Baseline BAFs are derived using either field-measured BAFs or by multiplying laboratory-measured BCFs by a FCM. For inorganic chemicals, BAFs are assumed to equal BCFs (i.e., the FCM is 1.0), unless chemical-specific biomagnification data support using a FCM other than 1.0.

E. Because both humans and wildlife consume fish from both trophic levels 3 and 4, two baseline BAFs are needed to calculate either a human health criterion or value or a wildlife criterion for a chemical. When appropriate, ingestion through consumption of invertebrates, plants, mammals, and birds in the diet of wildlife species to be protected may be taken into account.

II. Definitions

Baseline BAF. For organic chemicals, a BAF that is based on the concentration of freely dissolved chemical in the ambient water and takes into account the partitioning of the chemical within the organism; for inorganic chemicals, a BAF that is based on the wet weight of the tissue.

Baseline BCF. For organic chemicals, a BCF that is based on the concentration of freely dissolved chemical in the ambient water and takes into account the partitioning of the chemical within the organism; for inorganic chemicals, a BCF that is based on the wet weight of the tissue.

Bioaccumulation. The net accumulation of a substance by an organism as a result of uptake from all environmental sources.

Bioaccumulation factor (BAF). The ratio (in L/kg) of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where both the organism and its food are exposed to and the ratio does not change substantially over time.

Bioconcentration. The net accumulation of a substance by an aquatic organism as a result of uptake directly from the ambient water through gill membranes or other external body surfaces.

Bioconcentration factor (BCF). The ratio (in L/kg) of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through the water only and the ratio does not change substantially over time.

Biota-sediment accumulation factor (BSAF). The ratio (in kg of organic carbon/kg of lipid) of a substance's lipid-normalized concentration in tissue of an aquatic organism to its organic carbon-normalized concentration in surface sediment, in situations where the ratio does not change substantially over time, both the organism and its food are exposed, and the surface sediment is representative of average surface sediment in the vicinity of the organism.

Depuration. The loss of a substance from an organism as a result of any active or passive process.

Food-chain multiplier (FCM). The ratio of a BAF to an appropriate BCF.

Octanol-water partition coefficient (K_{OW}). The ration of the concentration of a substance in the n-octanol phase to its concentration in the aqueous phase in an equilibrated two-phase octanol-water system. For log K_{OW}, the log of the octanol-water partition coefficient is a base 10 logarithm.

Uptake. Acquisition of a substance from the environment by an organism as a result of any active or passive process.

III. Review and Selection of Data

A. Data Sources. Measured BAFs, BSAFs and BCFs are assembled from available sources including the following:

1. EPA Ambient Water Quality Criteria documents issued after January 1, 1980.

2. Published scientific literature.

3. Reports issued by EPA or other reliable sources.

4. Unpublished data.

One useful source of references is the Aquatic Toxicity Information Retrieval (AQUIRE) database.

B. Field-Measured BAFs. The following procedural and quality assurance requirements shall be met for field-measured BAFs:

1. The field studies used shall be limited to those conducted in the Great Lakes System with fish at or near the top of the aquatic food chain (i.e., in trophic levels 3 and/or 4).

2. The trophic level of the fish species shall be determined.

3. The site of the field study should not be so unique that the BAF cannot be extrapolated to other locations where the criteria and values will apply.

4. For organic chemicals, the percent lipid shall be either measured or reliably estimated for the tissue used in the determination of the BAF.

5. The concentration of the chemical in the water shall be measured in a way that can be related to particulate organic carbon (POC) and/or dissolved organic carbon (DOC) and should be relatively constant during the steady-state time period.

6. For organic chemicals with log K_{ow} greater than four, the concentrations of POC and DOC in the ambient water shall be either measured or reliably estimated.

7. For inorganic and organic chemicals, BAFs shall be used only if they are expressed on a wet weight basis; BAFs reported on a dry weight basis cannot be converted to wet weight unless a conversion factor is measured or reliably estimated for the tissue used in the determination of the BAF.

C. Field-Measured BSAFs. The following procedural and quality assurance requirements shall be met for field-measured BSAFs:

1. The field studies used shall be limited to those conducted in the Great Lakes System with fish at or near the top of the aquatic food chain (i.e., in trophic levels 3 and/or 4).

2. Samples of surface sediments (0-1 cm is ideal) shall be from locations in which there is net deposition of fine sediment and is representative of average surface sediment in the vicinity of the organism.

3. The K_{ow}s used shall be acceptable quality as described in section III.F below.

4. The site of the field study should not be so unique that the resulting BAF cannot be extrapolated to other locations where the criteria and values will apply.

5. The tropic level of the fish species shall be determined.

6. The percent lipid shall be either measured or reliably estimated for the tissue used in the determination of the BAF.

D. Laboratory-Measured BCFs. The following procedural and quality assurance requirements shall be met for laboratory-measured BCFs:

1. The test organism shall not be diseased, unhealthy, or adversely affected by the concentration of the chemical.

2. The total concentration of the chemical in the water shall be measured and should be relatively constant during the steady-state time period.

3. The organisms shall be exposed to the chemical using a flow-through or renewal procedure.

4. For organic chemicals, the percent lipid shall be either measured or reliably estimated for the tissue used in the determination of the BCF.

5. For organic chemicals with log K_{ow} greater than four, the concentrations of POC and DOC in the test solution shall be either measured or reliably estimated.

6. Laboratory-measured BCFs should be determined using fish species, but BCFs determined with molluscs and other invertebrates may be used with caution. For example, because invertebrates metabolize some chemicals less efficiently than vertebrates, a baseline BCF determined for such a chemical using invertebrates is expected to be higher than a comparable baseline BCF determined using fish.

7. If laboratory-measured BCFs increase or decrease as the concentration of the chemical increases in the test solutions in a bioconcentration test, the BCF measured at the lowest test concentration that is above concentrations existing in the control water shall be used (i.e., a BCF should be calculated from a control treatment). The concentrations of an inorganic chemical in a bioconcentration test should be greater than normal background levels and greater than levels required for normal nutrition of the test species if the chemical is a micronutrient, but below levels that adversely affect the species. Bioaccummulation of an inorganic chemical might be overestimated if concentrations are at or below normal background levels due to, for example, nutritional requirements of the test organisms.

8. For inorganic and organic chemicals, BCFs shall be used only if they are expressed on a wet weight basis. BCFs reported on a dry weight basis cannot be converted to wet weight unless a conversion factor is measured or reliably estimated for the tissue used in the determination of the BAF.

9. BCFs for organic chemicals may be based on measurement or radioactivity only when the BCF is intended to include metabolites or when there is confidence that there is no interference due to metabolites.

10. The calculation of the BCF must appropriately address growth dilution.

11. Other aspects of the methodology used should be similar to those described by ASTM (1990).

***15402** E. Predicted BCFs. The following procedural and quality assurance requirements shall be met for predicted BCFs:

1. The K_{ow} used shall be of acceptable quality as described in section III.F below.

2. The predicted baseline BCF shall be calculated using the equation: predicted baseline BCF = K_{ow}

where:

K_{ow} = octanol-water partition coefficient.

F. Octanol-Water Partition Coefficient (K_{ow}). 1. The value of K_{ow} used for an organic chemical shall be determined by giving priority to the experimental and computational techniques used as follows:

Log K_{ow} < 4:

Priority	Technique
1	Slow-stir.
1	Generator-column.
1	Shake-flask.
2	Reverse-phase liquid chromatography on C18 chromatography packing with extrapolation to zero percent solvent.
3	Reverse-phase liquid chromatography on C18 chromatography packing without extrapolation to zero percent solvent.
4	Calculated by the CLOGP program.

Log K_{ow} > 4:

Priority	Technique
1	Slow Stir.
1	Generator-column.
2	Reverse-phase liquid chromatography on C18 chromatography packing with extrapolation to zero percent solvent.
3	Reverse-phase liquid chromatography on C18 chromatography packing without extrapolation to zero percent solvent.
4	Shake-flask.
5	Calculated by the CLOGP program.

2. The CLOGP program is a computer program available from Pomona College. A value of K_{ow} that seems to be different from the others should be considered an outlier and not used. The value of K_{ow} used for an organic chemical shall be the geometric mean of the available K_{ow}s with highest priority or can be calculated from the arithmetic mean of the available log K_{ow} with the highest priority. Because it is an intermediate value in the derivation of a BAF, the value used for the K_{ow} of a chemical should not be rounded to fewer than three significant digits and a value for log K_{ow} should not be rounded to fewer than three significant digits after the decimal point.

G. This methodology provides overall guidance for the derivation of BAFs, but it cannot cover all the decisions that must be made in the review and selection of acceptable data. Professional judgment is required throughout the process. A degree of uncertainty is associated with the determination of any BAF, BSAF, BCF or K_{ow}. The amount of uncertainty in a baseline BAF depends on both the quality of data available and the method used to derive the BAF.

H. Hereinafter in this methodology, the terms BAF, BSAF, BCF and K_{ow} refer to ones that are consistent with the procedural and quality assurance requirements given above.

IV. Four Methods for Deriving Baseline BAFs

Baseline BAFs shall be derived using the following four methods, which are listed from most preferred to least preferred:

A. A measured baseline BAF for an organic or inorganic chemical derived from a field study of acceptable quality.

B. A predicted baseline BAF for an organic chemical derived using field-measured BSAFs of acceptable quality.

C. A predicted baseline BAF for an organic or inorganic chemical derived from a BCF measured in a laboratory study of acceptable quality and a FCM.

D. A predicted baseline BAF for an organic chemical derived from a K_{ow} of acceptable quality and a FCM.

For comparative purposes, baseline BAFs should be derived for each chemical by as many of the four methods as available data allow.

V. Calculation of Baseline BAFs for Organic Chemicals

A. Lipid Normalization. 1. It is assumed that BAFs and BCFs for organic chemicals can be extrapolated on the basis of percent lipid from one tissue to another and from one aquatic species to another in most cases.

2. Because BAFs and BCFs for organic chemicals are related to the percent lipid, it does not make any difference whether the tissue sample is whole body or edible portion, but both the BAF (or BCF) and the percent lipid must be determined for the same tissue. The percent lipid of the tissue should be measured during the BAF or BCF study, but in some cases it can be reliably estimated from measurements on tissue from other organisms. If percent lipid is not reported for the test organisms in the original study, it may be obtained from the author; or, in the case of a laboratory study, lipid data for the same or a comparable laboratory population of test organisms that were used in the original study may be used.

3. The lipid-normalized concentration, C_l, of a chemical in tissue is defined using the following equation:

Where:

C_B=concentration of the organic chemical in the tissue of aquatic biota (either whole organism or specified tissue) (MUg/g).

f_l=fraction of the tissue that is lipid.

B. Bioavailability. By definition, baseline BAFs and BCFs for organic chemicals, whether measured or predicted are based on the concentration of the chemical that is freely dissolved in the ambient water in order to account for bioavailability. For the purposes of this Guidance in this part, the relationship between the total concentration of the chemical in the water (i.e., that which is freely dissolved plus that which is sorbed to particulate organic carbon or to dissolved organic carbon) to the freely dissolved concentration of the chemical in the ambient water shall be calculated using the following equation:

Where:

C^{fd}_w=freely dissolved concentration of the organic chemical in the ambient water;

C^{t}_w=total concentration of the organic chemical in the ambient water;

f_{fd}=fraction of the total chemical in the ambient water that is freely dissolved.

The fraction of the total chemical in the ambient water that is freely dissolved, f_{fd}, shall be calculated using the following equation:

Where:

DOC=concentration of dissolved organic carbon, kg of dissolved organic carbon/L of water.

K_{OW}=octanol-water partition coefficient of the chemical.

POC=concentration of particulate organic carbon, kg of particulate organic carbon/L of water.

C. Food-Chain Multiplier. In the absence of a field-measured BAF or a predicted BAF derived from a BSAF, a FCM shall be used to calculate the baseline BAF for trophic levels 3 and 4 from a laboratory-measured or predicted BCF. For an organic chemical, the FCM used shall be derived from Table B-1 using the chemical's log K_{OW} and linear interpolation. A FCM greater than 1.0 applies to most organic chemicals with a log K_{OW} of four or more. The trophic level used shall take into account the age or size of the fish species consumed by the human, avian or mammalian predator because, for some species of fish, the young are in trophic level 3 whereas the adults are in trophic level 4.

D. Calculation of a Baseline BAF from a Field-Measured BAF. A baseline BAF shall be calculated from a field-measured BAF of acceptable quality using the following equation:

***15403** Where:

BAF^{t}_{T}=BAF based on total concentration in tissue and water.

f_l=fraction of the tissue that is lipid.

f_{fd}=fraction of the total chemical that is freely dissolved in the ambient water.

The trophic level to which the baseline BAF applies is the same as the trophic level of the organisms used in the determination of the field-measured BAF. For each trophic level, a species mean measured baseline BAF shall be calculated as the geometric mean if more than one measured baseline BAF is available for a given species. For each trophic level, the geometric mean of the species mean measured baseline BAFs shall be calculated. If a baseline BAF based on a measured BAF is available for either trophic level 3 or 4, but not both, a measured baseline BAF for the other trophic level shall be calculated using the ratio of the FCMs that are obtained by linear interpolation from Table B-1 for the chemical.
E. Calculation of a Baseline BAF from a Field-Measured BSAF. 1. A baseline BAF for organic chemical “i” shall be calculated from a field-measured BSAF of acceptable quality using the following equation:

Where:

$(BSAF)_i$=BSAF for chemical “i”.

$(BSAF)_r$=BSAF for the reference chemical “r”.

$(K_{OW})_i$=octanol-water partition coefficient for chemical “i”.

$(K_{OW})_r$=octanol-water partition coefficient for the reference chemical “r”.
2. A BSAF shall be calculated using the following equation:

Where:

C_t=the lipid-normalized concentration of the chemical in tissue.

C_{SOC}=the organic carbon-normalized concentration of the chemical in sediment.
3. The organic carbon-normalized concentration of a chemical in sediment, C_{SOC}, shall be calculated using the following equation:

Where:

C_S=concentration of chemical in sediment (mg/g sediment).

f_{OC}=fraction of the sediment that is organic carbon.
4. Predicting BAFs from BSAFs requires data from a steady-state (or near steady-state) condition between sediment and ambient water for both a reference chemical “r” with a field-measured BAF_l^{fd} and other chemicals “n=i” for which BSAFs are to be determined.

5. The trophic level to which the baseline BAF applies is the same as the trophic level of the organisms used in the determination of the BSAF. For each trophic level, a species mean baseline BAF shall be calculated as the geometric mean if more than one baseline BAF is predicted from BSAFs for a given species. For each trophic level, the geometric mean of the species mean baseline BAFs derived using BSAFs shall be calculated.

6. If a baseline BAF based on a measured BSAF is available for either trophic level 3 or 4, but not both, a baseline BAF for the other trophic level shall be calculated using the ratio of the FCMs that are obtained by linear interpolation from Table B-1 for the chemical.

F. Calculation of a Baseline BAF from a Laboratory-Measured BCF. A baseline BAF for trophic level 3 and a baseline BAF for trophic level 4 shall be calculated from a laboratory-measured BCF of acceptable quality and a FCM using the following equation:

Where:

$BCF^{t}T$=BCF based on total concentration in tissue and water.

fl=fraction of the tissue that is lipid.

f_{fd}=fraction of the total chemical in the test water that is freely dissolved.

FCM=the food-chain multiplier obtained from Table B-1 by linear interpolation for trophic level 3 or 4, as necessary.

For each trophic level, a species mean baseline BAF shall be calculated as the geometric mean if more than one baseline BAF is predicted from laboratory-measured BCFs for a given species. For each trophic level, the geometric mean of the species mean baseline BAFs based on laboratory-measured BCFs shall be calculated.

G. Calculation of a Baseline BAF from an Octanol-Water Partition Coefficient. A baseline BAF for trophic level 3 and a baseline BAF for trophic level 4 shall be calculated from a K_{OW} of acceptable quality and a FCM using the following equation:

Baseline BAF=(FCM) (predicted baseline BCF)=(FCM) (K_{OW})

Where:

FCM=the food-chain multiplier obtained from Table B-1 by linear interpolation for trophic level 3 or 4, as necessary.

K_{OW}=octanol-water partition coefficient.

VI. Human Health and Wildlife BAFs for Organic Chemicals

A. To calculate human health and wildlife BAFs for an organic chemical, the K_{OW} of the ***15404** y15404[chemical shall be used with a POC concentration of 0.00000004 kg/L and a DOC concentration of 0.000002 kg/L to yield the fraction freely dissolved:

B. The human health BAFs for an organic chemical shall be calculated using the following equations:

For trophic level 3:

For trophic level 4:

Where:
0.0182 and 0.0310 are the standardized fraction lipid values for trophic levels 3 and 4, respectively, that are used to derive human health criteria and values for the GLI.

C. The wildlife BAFs for an organic chemical shall be calculated using the following equations:

For trophic level 3:

For trophic level 4:

Where:
0.0646 and 0.1031 are the standardized fraction lipid values for trophic levels 3 and 4, respectively, that are used to derive wildlife criteria for the GLI.

VII. Human Health and Wildlife BAFs for Inorganic Chemicals

A. For inorganic chemicals, the baseline BAFs for trophic levels 3 and 4 are both assumed to equal the BCF determined for the chemical with fish, i.e., the FCM is assumed to be 1 for both trophic levels 3 and 4. However, a FCM greater than 1 might be applicable to some metals, such as mercury, if, for example, an organometallic form of the metal biomagnifies.

B. BAFs for Human Health Criteria and Values.

1. Measured BAFs and BCFs used to determine human health BAFs for inorganic chemicals shall be based on edible tissue (e.g., muscle) of freshwater fish unless it is demonstrated that whole-body BAFs or BCFs are similar to edible-tissue BAFs or BCFs. BCFs and BAFs based on measurements of aquatic plants and invertebrates should not be used in the derivation of human health criteria and values.

2. If one or more field-measured baseline BAFs for an inorganic chemical are available from studies conducted in the Great Lakes System with the muscle of fish:

a. For each trophic level, a species mean measured baseline BAF shall be calculated as the geometric mean if more than one measured BAF is available for a given species; and

b. For each trophic level, the geometric mean of the species mean measured baseline BAFs shall be used as the human health BAF for that chemical.

3. If an acceptable measured baseline BAF is not available for an inorganic chemical and one or more acceptable edible-portion laboratory-measured BCFs are available for the chemical, a predicted baseline BAF shall be calculated by multiplying the geometric mean of the BCFs times a FCM. The FCM will be 1.0 unless chemical-specific biomagnification data support using a multiplier other than 1.0. The predicted baseline BAF shall be used as the human health BAF for that chemical.

C. BAFs for Wildlife Criteria.

1. Measured BAFs and BCFs used to determine wildlife BAFs for inorganic chemicals shall be based on whole-body freshwater fish and invertebrate data unless it is demonstrated that edible-tissue BAFs or BCFs are similar to whole-body BAFs or BCFs.

***15405** 2. If one or more field-measured baseline BAFs for an inorganic chemical are available from studies conducted in the Great Lakes System with whole body of fish or invertebrates:

2. For each trophic level, a species mean measured baseline BAF shall be calculated as the geometric mean if more than one measured BAF is available for a given species.

b. For each trophic level, the geometric mean of the species mean measured baseline BAFs shall be used as the wildlife BAF for that chemical.

3. If an acceptable measured baseline BAF is not available for an inorganic chemical and one or more acceptable whole-body laboratory-measured BCFs are available for the chemical, a predicted baseline BAF shall be calculated by multiplying the geometric mean of the BCFs times a FCM. The FCM will be 1.0 unless chemical-specific biomagnification data support using a multiplier other than 1.0. The predicted baseline BAF shall be used as the wildlife BAF for that chemical.

VIII. Final Review

For both organic and inorganic chemicals, human health and wildlife BAFs for both trophic levels shall be reviewed for consistency with all available data concerning the bioaccumulation, bioconcentration, and metabolism of the chemical. For example, information concerning octanol-water partitioning, molecular size, or other physicochemical properties that might enhance or inhibit bioaccumulation should be considered for organic chemicals. BAFs derived in accordance with this methodology should be modified if changes are justified by available data.

IX. Literature Cited

ASTM. 1990. Standard Practice for Conducting Bioconcentration Tests with Fishes and Saltwater Bivalve Molluscs. Standard E 1022. American Society for Testing and Materials, Philadelphia, PA.

Table B-1.—Food-Chain Multipliers for Trophic Levels 2, 3 & 4

Log K_{ow}	Trophic level 2	Trophic [1] level 3	Trophic level 4
2.0	1.000	1.005	1.000
2.5	1.000	1.010	1.002
3.0	1.000	1.028	1.007
3.1	1.000	1.034	1.007
3.2	1.000	1.042	1.009
3.3	1.000	1.053	1.012
3.4	1.000	1.067	1.014
3.5	1.000	1.083	1.019
3.6	1.000	1.103	1.023
3.7	1.000	1.128	1.033
3.8	1.000	1.161	1.042
3.9	1.000	1.202	1.054

4.0	1.000	1.253	1.072
4.1	1.000	1.315	1.096
4.2	1.000	1.380	1.130
4.3	1.000	1.491	1.178
4.4	1.000	1.614	1.242
4.5	1.000	1.766	1.334
4.6	1.000	1.950	1.459
4.7	1.000	2.175	1.633
4.8	1.000	2.452	1.871
4.9	1.000	2.780	2.193
5.0	1.000	3.181	2.612
5.1	1.000	3.643	3.162
5.2	1.000	4.188	3.873
5.3	1.000	4.803	4.742
5.4	1.000	5.502	5.821
5.5	1.000	6.266	7.079
5.6	1.000	7.096	8.551
5.7	1.000	7.962	10.209
5.8	1.000	8.841	12.050
5.9	1.000	9.716	13.964
6.0	1.000	10.556	15.996
6.1	1.000	11.337	17.783
6.2	1.000	12.064	19.907
6.3	1.000	12.691	21.677
6.4	1.000	13.228	23.281
6.5	1.000	13.662	24.604
6.6	1.000	13.980	25.645
6.7	1.000	14.223	26.363
6.8	1.000	14.355	26.669

6.9	1.000	14.388		26.669
7.0	1.000	14.305		26.242
7.1	1.000	14.142		25.468
7.2	1.000	13.852		24.322
7.3	1.000	13.474		22.856
7.4	1.000	12.987		21.038
7.5	1.000	12.517		18.967
7.6	1.000	11.708		16.749
7.7	1.000	10.914		14.388
7.8	1.000	10.069		12.050
7.9	1.000	9.162		9.840
8.0	1.000	8.222		7.798
8.1	1.000	7.278	6.012	
8.2	1.000	6.361		4.519
8.3	1.000	5.489		3.311
8.4	1.000	4.683		2.371
8.5	1.000	3.949		1.663
8.6	1.000	3.296		1.146
8.7	1.000	2.732		0.778
8.8	1.000	2.246		0.521
8.9	1.000	1.837		0.345
9.0	1.000	1.493		0.226

***15406 Appendix C to Part 132—Great Lakes Water Quality Initiative Methodologies for Development of Human Health Criteria and Values**

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this appendix.

I. Introduction

Great Lakes States and Tribes shall adopt provisions consistent with this appendix C to ensure protection of human health.

A. Goal. The goal of the human health criteria for the Great Lakes System is the protection of humans from unacceptable exposure to toxicants via consumption of contaminated fish and drinking water and from ingesting water as a result of participation in water-oriented recreational activities.

B. Definitions.

Acceptable daily exposure (ADE). An estimate of the maximum daily dose of a substance which is not expected to result in adverse noncancer effects to the general human population, including sensitive subgroups.

Adverse effect. Any deleterious effect to organisms due to exposure to a substance. This includes effects which are or may become debilitating, harmful or toxic to the normal functions of the organism, but does not include non-harmful effects such as tissue discoloration alone or the induction of enzymes involved in the metabolism of the substance.

Carcinogen. A substance which causes an increased incidence of benign or malignant neoplasms, or substantially decreases the time to develop neoplasms, in animals or humans. The classification of carcinogens is discussed in section II.A of appendix C to part 132.

Human cancer criterion (HCC). A Human Cancer Value (HCV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C.

Human cancer value (HCV). The maximum ambient water concentration of a substance at which a lifetime of exposure from either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities, will represent a plausible upper-bound risk of contracting cancer of one in 100,000 using the exposure assumptions specified in the Methodologies for the Development of Human Health Criteria and Values in appendix C of this part.

Human noncancer criterion (HNC). A Human Noncancer Value (HNV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C of this part.

Human noncancer value (HNV). The maximum ambient water concentration of a substance at which adverse noncancer effects are not likely to occur in the human population from lifetime exposure via either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities using the Methodologies for the Development of Human Health criteria and Values in appendix C of this part.

Linearized multi-stage model. A conservative mathematical model for cancer risk assessment. This model fits linear dose-response curves to low doses. It is consistent with a no-threshold model of carcinogenesis, i.e., exposure to even a very small amount of the substance is assumed to produce a finite increased risk of cancer.

Lowest observed adverse effect level (LOAEL). The lowest tested dose or concentration of a substance which resulted in an observed adverse effect in exposed test organisms when all higher doses or concentrations resulted in the same or more severe effects.

No observed adverse effect level (NOAEL). The highest tested dose or concentration of a substance which resulted in no observed adverse effect in exposed test organisms where higher doses or concentrations resulted in an adverse effect.

Quantitative structure activity relationship (OSAR) or structure activity relationship (SAR). A mathematical relationship between a property (activity) of a chemical and a number of descriptors of the chemical. These descriptors are chemical or physical characteristics obtained experimentally or predicted from the structure of the chemical.

Relative source contribution (RSC). The factor (percentage) used in calculating an HNV or HNC to account for all sources of exposure to a contaminant. The RSC reflects the percent of total exposure which can be attributed to surface water through water intake and fish consumption.

Risk associated dose (RAD). A dose of a known or presumed carcinogenic substance in (mg/kg/day) which, over a lifetime of exposure, is estimated to be associated with a plausible upper bound incremental cancer risk equal to one in 100,000.

Slope factor. Also known as q_1*, slope factor is the incremental rate of cancer development calculated through use of a linearized multistage model or other appropriate model. It is expressed in (mg/kg/day) of exposure to the chemical in question.

Threshold effect. An effect of a substance for which there is a theoretical or empirically established dose or concentration below which the effect does not occur.

Uncertainty factor (UF). One of several numeric factors used in operationally deriving criteria from experimental data to account for the quality or quantity of the available data.

C. Level of Protection. The criteria developed shall provide a level of protection likely to be without appreciable risk of carcinogenic and/or noncarcinogenic effects. Criteria are a function of the level of designated risk or no adverse effect estimation, selection of data and exposure assumptions. Ambient criteria for single carcinogens shall not be set at a level representing a lifetime upper-bound incremental risk greater than one in 100,000 of developing cancer using the hazard assessment techniques and exposure assumptions described herein. Criteria affording protection from noncarcinogenic effects shall be established at levels that, taking into account uncertainties, are considered likely to be without an appreciable risk of adverse human health effects (i.e., acute, subchronic and chronic toxicity including reproductive and developmental effects) during a lifetime of exposure, using the risk assessment techniques and exposure assumptions described herein.

D. Two-tiered Classification. Chemical concentration levels in surface water protective of human health shall be derived based on either a Tier I or Tier II classification. The two Tiers are primarily distinguished by the amount of toxicity data available for deriving the concentration levels and the quantity and quality of data on bioaccumulation.

II. Minimum Data Requirements

The best available toxicity data on the adverse health effects of a chemical and the best data on bioaccumulation factors shall be used when developing human health Tier I criteria or Tier II values. The best available toxicity data shall include data from well ***15407** -conducted epidemiologic and/or animal studies which provide, in the case of carcinogens, an adequate weight of evidence of potential human carcinogenicity and, in the case of noncarcinogens, a dose-response relationship involving critical effects biologically relevant to humans. Such information should be obtained from the EPA Integrated Risk Information System (IRIS) database, the scientific literature, and other informational databases, studies and/or reports containing adverse health effects data of adequate quality for use in this procedure. Strong consideration shall be given to the most currently available guidance provided by IRIS in deriving criteria or values, supplemented with any recent data not incorporated into IRIS. When deviations from IRIS are anticipated or considered necessary, it is strongly recommended that such actions be communicated to the EPA Reference Dose (RfD) and/or the Cancer Risk Assessment Verification Endeavor (CRAVE) workgroup immediately. The best available bioaccumulation data shall include data from field studies and well-conducted laboratory studies.

A. Carcinogens. Tier I criteria and Tier II values shall be derived using the methodologies described in section III.A of this appendix when there is adequate evidence of potential human carcinogenic effects for a chemical. It is strongly recommended that the EPA classification system for chemical carcinogens, which is described in the 1986 EPA Guidelines for Carcinogenic Risk Assessment (U.S. EPA, 1986), or future modifications thereto, be used in determining whether adequate evidence of potential carcinogenic effects exists. Carcinogens are classified, depending on the weight of evidence, as either human carcinogens, probable human carcinogens, or possible human carcinogens. The human evidence is considered inadequate and therefore the chemical cannot be classified as a human carcinogen, if one of two conditions exists: (a) there are few pertinent data, or (b) the available studies, while showing evidence of association, do not exclude chance, bias, or confounding and therefore a casual interpretation is not credible. The animal evidence is considered inadequate, and therefore the chemical cannot

be classified as a probable or possible human carcinogen, when, because of major qualitative or quantitative limitations, the evidence cannot be interpreted as showing either the presence or absence of a carcinogenic effect.

Chemicals are described as “human carcinogens” when there is sufficient evidence from epidemiological studies to support a causal association between exposure to the chemicals and cancer. Chemicals described as “probable human carcinogens” include chemicals for which the weight of evidence of human carcinogenicity based on epidemiological studies is limited. Limited human evidence is that which indicates that a causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding, cannot adequately be excluded. Probable human carcinogens are also agents for which there is sufficient evidence from animal studies and for which there is inadequate evidence or no data from epidemiologic studies. Sufficient animal evidence is data which indicates that there is an increased incidence of malignant tumors or combined malignant and benign tumors: (a) in multiple species or strains; (b) in multiple experiments (e.g., with different routes of administration or using different dose levels); or (c) to an unusual degree in a single experiment with regard to high incidence, unusual site or type of tumor, or early age at onset. Additional evidence may be provided by data on dose-response effects, as well as information from short-term tests (such as mutagenicity/genotoxicity tests which help determine whether the chemical interacts directly with DNA) or on chemical structure, metabolism or mode of action.

“Possible human carcinogens” are chemicals with limited evidence of carcinogenicity in animals in the absence of human data. Limited animal evidence is defined as data which suggests a carcinogenic effect but are limited because: (a) The studies involve a single species, strain, or experiment and do not meet criteria for sufficient evidence (see preceding paragraph); or (b) the experiments are restricted by inadequate dosage levels, inadequate duration of exposure to the agent, inadequate period of follow-up, poor survival, too few animals, or inadequate reporting; or (c) the studies indicate an increase in the incidence of benign tumors only. More specifically, this group can include a wide variety of evidence, e.g., (a) a malignant tumor response in a single well-conducted experiment that does not meet conditions for sufficient evidence, (b) tumor response of marginal statistical significance in studies having inadequate design or reporting, (c) benign but not malignant tumors with an agent showing no response in a variety of short-term tests for mutagenicity, and (d) response of marginal statistical significance in a tissue known to have a high or variable background rate.

1. Tier I: Weight of evidence of potential human carcinogenic effects sufficient to derive a Tier I HCC shall generally include human carcinogens, probable human carcinogens and can include, on a case-by-case basis, possible human carcinogens if studies have been well-conducted albeit based on limited evidence, when compared to studies used in classifying human and probable human carcinogens. The decision to use data on a possible human carcinogen for deriving Tier I criteria shall be a case-by-case determination. In determining whether to derive a Tier I HCC, additional evidence that shall be considered includes but is not limited to available information on mode of action, such as mutagenicity/genotoxicity (determinations of whether the chemical interacts directly with DNA), structure activity, and metabolism.

2. Tier II: Weight of evidence of possible human carcinogenic effects sufficient to derive a Tier II human cancer value shall include those possible human carcinogens for which there are at a minimum, data sufficient for quantitative risk assessment, but for which data are inadequate for Tier I criterion development due to a tumor response of marginal statistical significance or inability to derive a strong dose-response relationship. In determining whether to derive Tier II human cancer values, additional evidence that shall be considered includes but is not limited to available information on mode of action such as mutagenicity/ genotoxicity (determinations of whether the chemical interacts directly with DNA), structure activity and metabolism. As with the use of data on possible human carcinogens in developing Tier I criteria, the decision to use data on possible human carcinogens to derive Tier II values shall be made on a case-by-case basis.

B. Noncarcinogens. All available toxicity data shall be evaluated considering the full range of possible health effects of a chemical, i.e., acute/subacute, chronic/subchronic and reproductive/developmental effects, in order to best describe the dose-response relationship of the chemical, and to calculate human noncancer criteria and values which will protect against the most sensitive endpoint(s) of toxicity. Although it is desirable to have an extensive database which considers a wide range of possible adverse effects, this type of data exists for a very limited number of chemicals. For many others, there is a range in quality

and quantity of data available. To assure minimum reliability of criteria and values, it is necessary to establish a minimum database with which to develop Tier I criteria or Tier II values. The following represent the minimum data sets necessary for this procedure.

1. Tier I: The minimum data set sufficient to derive a Tier I human HNC shall include at least one well-conducted epidemiologic study or animal study. A well-conducted epidemiologic study for a Tier I HNC must quantify exposure level(s) and demonstrate positive association between exposure to a chemical and adverse effect(s) in humans. A well-conducted study in animals must demonstrate a dose response relationship involving one or more critical effect(s) biologically relevant to humans. (For example, study results from an animal whose pharmacokinetics and toxicokinetics match those of a human would be considered most biologically relevant.) Ideally, the duration of a study should span multiple generations of exposed test species or at least a major portion of the lifespan of one generation. This type of data is currently very limited. By the use of uncertainty adjustments, shorter term studies (such as 90-day subchronic studies) with evaluation of more limited effect(s) may be used to extrapolate to longer exposures or to account for a variety of adverse effects. For Tier I criteria developed pursuant to this procedure, such a limited study must be conducted for at least 90 days in rodents or 10 percent of the lifespan of other appropriate test species and demonstrate a no observable adverse effect level (NOAEL). Chronic studies of one year or longer in rodents or 50 percent of the lifespan or greater in other appropriate test species that demonstrate a lowest observable adverse effect level (LOAEL) may be sufficient for use in Tier I criterion derivation if the effects observed at the LOAEL were relatively mild and reversible as compared to ***15408** effects at higher doses. This does not preclude the use of a LOAEL from a study (of chronic duration) with only one or two doses if the effects observed appear minimal when compared to effect levels observed at higher doses in other studies.

2. Tier II: When the minimum data for deriving Tier I criteria are not available to meet the Tier I data requirements, a more limited database may be considered for deriving Tier II values. As with Tier I criteria, all available data shall be considered and ideally should address a range of adverse health effects with exposure over a substantial portion of the lifespan (or multiple generations) of the test species. When such data are lacking it may be necessary to rely on less extensive data in order to establish a Tier II value. With the use of appropriate uncertainty factors to account for a less extensive database, the minimum data sufficient to derive a Tier II value shall include a NOAEL from at least one well-conducted short-term repeated dose study. This study shall be of at least 28 days duration, in animals demonstrating a dose-response, and involving effects biologically relevant to humans. Data from studies of longer duration (greater than 28 days) and LOAELs from such studies (greater than 28 days) may be more appropriate in some cases for derivation of Tier II values. Use of a LOAEL should be based on consideration of the following information: severity of effect, quality of the study and duration of the study.

C. Bioaccumulation factors (BAFs).

1. Tier I for Carcinogens and Noncarcinogens: To be considered a Tier I cancer or noncancer human health criterion, along with satisfying the minimum toxicity data requirements of sections II.A.1 and II.B.1 of this appendix, a chemical must have the following minimum bioaccumulation data. For all organic chemicals either: (a) a field-measured BAF; (b) a BAF derived using the BSAF methodology; or (c) a chemical with a BAF less than 125 regardless of how the BAF was derived. For all inorganic chemicals, including organometals such as mercury, either: (a) a field-measured BAF or (b) a laboratory-measured BCF.

2. Tier II for Carcinogens and Noncarcinogens: A chemical is considered a Tier II cancer or noncancer human health value if it does not meet either the minimum toxicity data requirements of sections II.A.1 and II.B.1 of this appendix or the minimum bioaccumulation data requirements of section II.C.1 of this appendix.

III. Principles for Development of Tier I Criteria or Tier II Values

The fundamental components of the procedure to calculate Tier I criteria or Tier II values are the same. However, certain of the aspects of the procedure designed to account for short-duration studies or other limitations in data are more likely to be relevant in deriving Tier II values than Tier I criteria.

A. Carcinogens.

1. A non-threshold mechanism of carcinogenesis shall be assumed unless biological data adequately demonstrate the existence of a threshold on a chemical-specific basis.

2. All appropriate human epidemiologic data and animal cancer bioassay data shall be considered. Data specific to an environmentally appropriate route of exposure shall be used. Oral exposure should be used preferentially over dermal and inhalation since, in most cases, the exposure routes of greatest concern are fish consumption and drinking water/incidental ingestion. The risk associated dose shall be set at a level corresponding to an incremental cancer risk of one in 100,000. If acceptable human epidemiologic data are available for a chemical, it shall be used to derive the risk associated dose. If acceptable human epidemiologic data are not available, the risk associated dose shall be derived from available animal bioassay data. Data from a species that is considered most biologically relevant to humans (i.e., responds most like humans) is preferred where all other considerations regarding quality of data are equal. In the absence of data to distinguish the most relevant species, data from the most sensitive species tested, i.e., the species showing a carcinogenic effect at the lowest administered dose, shall generally be used.

3. When animal bioassay data are used and a non-threshold mechanism of carcinogenicity is assumed, the data are fitted to a linearized multistage computer model (e.g., Global '86 or equivalent model). Global '86 is the linearized multistage model, derived by Howe, Crump and Van Landingham (1986), which EPA uses to determine cancer potencies. The upper-bound 95 percent confidence limit on risk (or, the lower 95 percent confidence limit on dose) at the one in 100,000 risk level shall be used to calculate a risk associated dose (RAD). Other models, including modifications or variations of the linear multistage model which are more appropriate to the available data may be used where scientifically justified.

4. If the duration of the study is significantly less than the natural lifespan of the test animal, the slope may be adjusted on a case-by-case basis to compensate for latent tumors which were not expressed (e.g., U.S. EPA, 1980) In the absence of alternative approaches which compensate for study durations significantly less than lifetime, the permitting authority may use the process described in the 1980 National Guidelines (see 45 FR 79352).

5. A species scaling factor shall be used to account for differences between test species and humans. It shall be assumed that milligrams per surface area per day is an equivalent dose between species (U.S. EPA, 1986). All doses presented in mg/kg bodyweight will be converted to an equivalent surface area dose by raising the mg/kg dose to the 2/3 power. However, if adequate pharmacokinetic and metabolism studies are available, these data may be factored into the adjustment for species differences on a case-by-case basis.

6. Additional data selection and adjustment decisions must also be made in the process of quantifying risk. Consideration must be given to tumor selection for modeling, e.g., pooling estimates for multiple tumor types and identifying and combining benign and malignant tumors. All doses shall be adjusted to give an average daily dose over the study duration. Adjustments in the rate of tumor response must be made for early mortality in test species. The goodness-of-fit of the model to the data must also be assessed.

7. When a linear, non-threshold dose response relationship is assumed, the RAD shall be calculated using the following equation:

Where:

RAD=risk associated dose in milligrams of toxicant per kilogram body weight per day (mg/kg/day).

0.00001 (110^{5})=incremental risk of developing cancer equal to one in 100,000.

q_1*=slope factor $(mg/kg/day)^{1}$.

8. If human epidemiologic data and/or other biological data (animal) indicate that a chemical causes cancer via a threshold mechanism, the risk associated dose may, on a case-by-case basis, be calculated using a method which assumes a threshold mechanism is operative.

B. Noncarcinogens.

1. Noncarcinogens shall generally be assumed to have a threshold dose or concentration below which no adverse effects should be observed. Therefore, the Tier I criterion or Tier II value is the maximum water concentration of a substance at or below which a lifetime exposure from drinking the water, consuming fish caught in the water, and ingesting water as a result of participating in water-related recreation activities is likely to be without appreciable risk of deleterious effects.

For some noncarcinogens, there may not be a threshold dose below which no adverse effects should be observed. Chemicals acting as genotoxic teratogens and germline mutagens are thought to possibly produce reproductive and/or developmental effects via a genetically linked mechanism which may have no threshold. Other chemicals also may not demonstrate a threshold. Criteria for these types of chemicals will be established on a case-by-case basis using appropriate assumptions reflecting the likelihood that no threshold exists.

2. All appropriate human and animal toxicologic data shall be reviewed and evaluated. To the maximum extent possible, data most specific to the environmentally relevant route of exposure shall be used. Oral exposure data should be used preferentially over dermal and inhalation since, in most cases, the exposure routes of greatest concern are fish consumption and drinking water/incidental ingestion. When acceptable human data are not available (e.g., well-conducted epidemiologic studies), animal data from species most biologically relevant to humans shall be used. In the absence of data to distinguish the most relevant species, data from the most sensitive animal species tested, i.e., the species showing a toxic effect at the lowest administered dose (given a relevant route of exposure), should generally be used.

***15409** 3. Minimum data requirements are specified in section II.B of this appendix. The experimental exposure level representing the highest level tested at which no adverse effects were demonstrated (NOAEL) from studies satisfying the provisions of section II.B of this appendix shall be used for criteria calculations. In the absence of a NOAEL, the LOAEL from studies satisfying the provisions of section II.B of this appendix may be used if it is based on relatively mild and reversible effects.

4. Uncertainty factors shall be used to account for the uncertainties in predicting acceptable dose levels for the general human population based upon experimental animal data or limited human data.

a. An uncertainty factor of 10 shall generally be used when extrapolating from valid experimental results from studies on prolonged exposure to average healthy humans. This 10-fold factor is used to protect sensitive members of the human population.

b. An uncertainty factor of 100 shall generally be used when extrapolating from valid results of long-term studies on experimental animals when results of studies of human exposure are not available or are inadequate. In comparison to a, above, this represents an additional 10-fold uncertainty factor in extrapolating data from the average animal to the average human.

c. An uncertainty factor of up to 1000 shall generally be used when extrapolating from animal studies for which the exposure duration is less than chronic, but greater than subchronic (e.g., 90 days or more in length), or when other significant deficiencies in study quality are present, and when useful long-term human data are not available. In comparison to b, above, this represents an additional UF of up to 10-fold for less than chronic, but greater than subchronic, studies.

d. An UF of up to 3000 shall generally be used when extrapolating from animal studies for which the exposure duration is less than subchronic (e.g., 28 days). In comparison to b above, this represents an additional UF of up to 30-fold for less than

subchronic studies (e.g., 28-day). The level of additional uncertainty applied for less than chronic exposures depends on the duration of the study used relative to the lifetime of the experimental animal.

e. An additional UF of between one and ten may be used when deriving a criterion from a LOAEL. This UF accounts for the lack of an identifiable NOAEL. The level of additional uncertainty applied may depend upon the severity and the incidence of the observed adverse effect.

f. An additional UF of between one and ten may be applied when there are limited effects data or incomplete sub-acute or chronic toxicity data (e.g., reproductive/developmental data). The level of quality and quantity of the experimental data available as well as structure-activity relationships may be used to determine the factor selected.

g. When deriving an UF in developing a Tier I criterion or Tier II value, the total uncertainty, as calculated following the guidance of sections 4.a through f, cited above, shall not exceed 10,000 for Tier I criteria and 30,000 for Tier II values.

5. All study results shall be converted, as necessary, to the standard unit for acceptable daily exposure of milligrams of toxicant per kilogram of body weight per day (mg/kg/day). Doses shall be adjusted for continuous exposure (i.e., seven days/week, 24 hours/day, etc.).

C. Criteria and Value Derivation.

1. Standard Exposure Assumptions. The following represent the standard exposure assumptions used to calculate Tier I criteria and Tier II values for carcinogens and noncarcinogens. Higher levels of exposure may be assumed by States and Tribes pursuant to Clean Water Act (CWA) section 510, or where appropriate in deriving site-specific criteria pursuant to procedure 1 in appendix F to part 132.

BW = body weight of an average human (BW = 70kg).

WC_d = per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies = two liters/day.

—or—

WC_r = per capita incidental daily water ingestion for surface waters not used as human drinking water sources = 0.01 liters/day.

FC = per capita daily consumption of regionally caught freshwater fish = 0.015kg/day (0.0036 kg/day for trophic level 3 and 0.0114 kg/day for trophic level 4).

BAF = bioaccumulation factor for trophic level 3 and trophic level 4, as derived using the BAF methodology in appendix B to part 132.

2. Carcinogens. The Tier I human cancer criteria or Tier II values shall be calculated as follows:

Where:

HCV=Human Cancer Value in milligrams per liter (mg/L).

RAD=Risk associated dose in milligrams toxicant per kilogram body weight per day (mg/kg/day) that is associated with a lifetime incremental cancer risk equal to one in 100,000.

BW=weight of an average human (BW=70 kg).

WC_d=per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies=two liters/day.

or

WC_r=per capita incidental daily water ingestion for surface waters not used as human drinking water sources=0.01 liters/day.

FC_{TL3}=mean consumption of trophic level 3 of regionally caught freshwater fish=0.0036 kg/day.

FC_{TL4}=mean consumption of trophic level 4 of regionally caught freshwater fish=0.0114 kg/day.

BAF^{HH}_{TL3}=bioaccumulation factor for trophic level 3 fish, as derived using the BAF methodology in appendix B to part 132.

BAF^{HH}_{TL4}=bioaccumulation factor for trophic level 4 fish, as derived using the BAF methodology in appendix B to part 132.
3. Noncarcinogens. The Tier I human noncancer criteria or Tier II values shall be calculated as follows:

Where:

HNV=Human noncancer value in milligrams per liter (mg/L).

ADE=Acceptable daily exposure in milligrams toxicant per kilogram body weight per day (mg/kg/day).

RSC=Relative source contribution factor of 0.8. An RSC derived from actual exposure data may be developed using the methodology outlined by the 1980 National Guidelines (see 45 FR 79354).

BW=weight of an average human (BW=70 kg).

WC_d=per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies=two liters/day.

or

WC_r=per capita incidental daily water ingestion for surface waters not used as human drinking water sources=0.01 liters/day.

***15410** FC_{TL3}=mean consumption of trophic level 3 fish by regional sport fishers of regionally caught freshwater fish=0.0036 kg/day.

FC_{TL4}=mean consumption of trophic level 4 fish by regional sport fishers of regionally caught freshwater fish=0.0114 kg/day.

BAF^{HH}_{TL3}=human health bioaccumulation factor for edible portion of trophic level 3 fish, as derived using the BAF methodology in appendix B to part 132.

BAF^{HH}_{TL4}=human health bioaccumulation factor for edible portion of trophic level 4 fish, as derived using the BAF methodology in appendix B to part 132.

IV. References

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Appendix D to Part 132—Great Lakes Water Quality Initiative Methodology for the Development of Wildlife Criteria

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this appendix.

I. Introduction

A. A Great Lakes Water Quality Wildlife Criterion (GLWC) is the concentration of a substance which is likely to, if not exceeded, protect avian and mammalian wildlife populations inhabiting the Great Lakes basin from adverse effects resulting from the ingestion of water and aquatic prey taken from surface waters of the Great Lakes System. These criteria are based on existing toxicological studies of the substance of concern and quantitative information about the exposure of wildlife species to the substance (i.e., food and water consumption rates). Since toxicological and exposure data for individual wildlife species are limited, a GLWC is derived using a methodology similar to that used to derive noncancer human health criteria (Barnes and Dourson, 1988; NAS, 1977; NAS, 1980; U.S. EPA, 1980). Separate avian and mammalian values are developed using taxonomic class-specific toxicity data and exposure data for five representative Great Lakes basin wildlife species. The wildlife species selected are representative of avian and mammalian species resident in the Great Lakes basin which are likely to experience the highest exposures to bioaccumulative contaminants through the aquatic food web; they are the bald eagle, herring gull, belted kingfisher, mink, and river otter.

B. This appendix establishes a methodology which is required when developing Tier I wildlife criteria for bioaccumulative chemicals of concern (BCCs). The use of the equation provided in the methodology is encouraged, but not required, for the development of Tier I criteria or Tier II values for pollutants other than those identified in Table 6-A for which Tier I criteria or Tier II values are determined to be necessary for the protection of wildlife in the Great Lakes basin. A discussion of the methodology for deriving Tier II values can be found in the Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria (Wildlife TSD).

C. In the event that this methodology is used to develop criteria for pollutants other than BCCs, or in the event that the Tier II methodology described in the Wildlife TSD is used to derive Tier II values, the methodology for deriving bioaccumulation factors under appendix B to part 132 must be used in either derivation. For chemicals which do not biomagnify to the extent of BCCs, it may be appropriate to select different representative species which are better examples of species with the highest exposures for the given chemical. The equation presented in this methodology, however, is still encouraged. In addition, procedure 1 of appendix F of this part describes the procedures for calculating site-specific wildlife criteria.

D. The term “wildlife value” (WV) is used to denote the value for each representative species which results from using the equation presented below, the value obtained from averaging species values within a class, or any value derived from application of the site-specific procedure provided in procedure 1 of appendix F of this part. The WVs calculated for the representative species are used to calculate taxonomic class-specific WVs. The WV is the concentration of a substance which, if not exceeded, should better protect the taxon in question.

E. “Tier I wildlife criterion,” or “Tier I criterion” is used to denote the number derived from data meeting the Tier I minimum database requirements, and which will be protective of the two classes of wildlife. It is synonymous with the term “GLWC,” and the two are used interchangeably.

II. Calculation of Wildlife Values for Tier I Criteria

Table 4 of Part 132 and Table D-1 of this appendix contain criteria calculated by EPA using the methodology provided below.

A. Equation for Avian and Mammalian Wildlife Values. Tier I wildlife values for the pollutants designated BCCs pursuant to part 132 are to be calculated using the equation presented below.

Where:

WV=Wildlife Value in milligrams of substance per liter (mg/L).

TD=Test Dose (TD) in milligrams of substance per kilograms per day (mg/kg-d) for the test species. This shall be either a NOAEL or a LOAEL.

UF_A=Uncertainty Factor (UF) for extrapolating toxicity data across species (unitless). A species-specific UF shall be selected and applied to each representative species, consistent with the equation.

UF_S=UF for extrapolating from subchronic to chronic exposures (unitless).

UF_L=UF for LOAEL to NOAEL extrapolations (unitless).

Wt=Average weight in kilograms (kg) for the representative species.

W=Average daily volume of water consumed in liters per day (L/d) by the representative species.

F_{TLi}=Average daily amount of food consumed from trophic level i in kilograms per day (kg/d) by the representative species.

BAF^{WL}_{TLi}=Bioaccumulation factor (BAF) for wildlife food in trophic level i in liters per kilogram (L/kg), developed using the BAF methodology in appendix B to part 132, Methodology for Development of Bioaccumulation Factors. For consumption of piscivorous birds by other birds (e.g., herring gull by eagles), the BAF is derived by multiplying the trophic level 3 BAF for fish by a biomagnification factor to account for the biomagnification from fish to the consumed birds.

B. Identification of Representative Species for Protection. For bioaccumulative chemicals, piscivorous species are identified as the focus of concern for wildlife criteria development in the Great Lakes. An analysis of known or estimated exposure components for avian and mammalian wildlife species is presented in the Wildlife TSD. This analysis identifies three avian species (eagle, kingfisher and herring gull) and two mammalian species (mink and otter) as representative species for protection. The TD obtained from toxicity data for each taxonomic class is used to calculate WVs for each of the five representative species.

C. Calculation of Avian and Mammalian Wildlife Values and GLWC Derivation. The avian WV is the geometric mean of the WVs calculated for the three representative avian species. The mammalian WV is the geometric mean of the WVs calculated for the two representative mammalian species. The lower of the mammalian and avian WVs must be selected as the GLWC.

III. Parameters of the Effect Component of the Wildlife Criteria Methodology

A. Definitions. The following definitions provide additional specificity and guidance in the evaluation of toxicity data and the application of this methodology.

Acceptable endpoints. For the purpose of wildlife criteria derivation, acceptable subchronic and chronic endpoints are those which affect reproductive or developmental success, organismal viability or growth, or any other endpoint which is, or is directly related to, parameters that influence population dynamics.

***15411** Chronic effect. An adverse effect that is measured by assessing an acceptable endpoint, and results from continual exposure over several generations, or at least over a significant part of the test species' projected life span or life stage.

Lowest-observed-adverse-effect-level (LOAEL). The lowest tested dose or concentration of a substance which resulted in an observed adverse effect in exposed test organisms when all higher doses or concentrations resulted in the same or more severe effects.

No-observed-adverse-effect-level (NOAEL). The highest tested dose or concentration of a substance which resulted in no observed adverse effect in exposed test organisms where higher doses or concentrations resulted in an adverse effect.

Subchronic effect. An adverse effect, measured by assessing an acceptable endpoint, resulting from continual exposure for a period of time less than that deemed necessary for a chronic test.

B. Minimum Toxicity Database for Tier I Criteria Development. A TD value is required for criterion calculation. To derive a Tier I criterion for wildlife, the data set shall provide enough data to generate a subchronic or chronic dose-response curve for any given substance for both mammalian and avian species. In reviewing the toxicity data available which meet the minimum data requirements for each taxonomic class, the following order of preference shall be applied to select the appropriate TD to be used for calculation of individual WVs. Data from peer-reviewed field studies of wildlife species take precedence over other types of studies, where such studies are of adequate quality. An acceptable field study must be of subchronic or chronic duration, provide a defensible, chemical-specific dose-response curve in which cause and effect are clearly established, and assess acceptable endpoints as defined in this document. When acceptable wildlife field studies are not available, or determined to be of inadequate quality, the needed toxicity information may come from peer-reviewed laboratory studies. When laboratory studies are used, preference shall be given to laboratory studies with wildlife species over traditional laboratory animals to reduce uncertainties in making interspecies extrapolations. All available laboratory data and field studies shall be reviewed to corroborate the final GLWC, to assess the reasonableness of the toxicity value used, and to assess the appropriateness of any UFs which are applied. When evaluating the studies from which a test dose is derived in general, the following requirements must be met:

1. The mammalian data must come from at least one well-conducted study of 90 days or greater designed to observe subchronic or chronic effects as defined in this document.

2. The avian data must come from at least one well-conducted study of 70 days or greater designed to observe subchronic or chronic effects as defined in this document.

3. In reviewing the studies from which a TD is derived for use in calculating a WV, studies involving exposure routes other than oral may be considered only when an equivalent oral daily dose can be estimated and technically justified because the criteria calculations are based on an oral route of exposure.

4. In assessing the studies which meet the minimum data requirements, preference should be given to studies which assess effects on developmental or reproductive endpoints because, in general, these are more important endpoints in ensuring that a population's productivity is maintained. The Wildlife TSD provides additional discussion on the selection of an appropriate toxicity study.

C. Selection of TD Data. In selecting data to be used in the derivation of WVs, the evaluation of acceptable endpoints, as defined in Section III.A of this appendix, will be the primary selection criterion. All data not part of the selected subset may be used to assess the reasonableness of the toxicity value and the appropriateness of the Ufs which are applied.

1. If more than one TD value is available within a taxonomic class, based on different endpoints of toxicity, that TD, which is likely to reflect best potential impacts to wildlife populations through resultant changes in mortality or fecundity rates, shall be used for the calculation of WVs.

2. If more than one TD is available within a taxonomic class, based on the same endpoint of toxicity, the TD from the most sensitive species shall be used.

3. If more than one TD based on the same endpoint of toxicity is available for a given species, the TD for that species shall be calculated using the geometric mean of those TDs.

D. Exposure Assumptions in the Determination of the TD. 1. In those cases in which a TD is available in units other than milligrams of substance per kilograms per day (mg/kg/d), the following procedures shall be used to convert the TD to the appropriate units prior to calculating a WV.

2. If the TD is given in milligrams of toxicant per liter of water consumed by the test animals (mg/L), the TD shall be multiplied by the daily average volume of water consumed by the test animals in liters per day (L/d) and divided by the average weight of the test animals in kilograms (kg).

3. If the TD is given in milligrams of toxicant per kilogram of food consumed by the test animals (mg/kg), the TD shall be multiplied by the average amount of food in kilograms consumed daily by the test animals (kg/d) and divided by the average weight of the test animals in kilograms (kg).

E. Drinking and Feeding Rates. 1. When drinking and feeding rates and body weight are needed to express the TD in milligrams of substance per kilograms per day (mg/kg/d), they are obtained from the study from which the TD was derived. If not already determined, body weight, and drinking and feeding rates are to be converted to a wet weight basis.

2. If the study does not provide the needed values, the values shall be determined from appropriate scientific literature. For studies done with domestic laboratory animals, either the Registry of Toxic Effects of Chemical Substances (National Institute for Occupational Safety and Health, the latest edition, Cincinnati, OH), or Recommendations for and Documentation of Biological Values for Use in Risk Assessment (U.S. EPA, 1988) should be consulted. When these references do not contain exposure information for the species used in a given study, either the allometric equations from Calder and Braun (1983) and Nagy (1987), which are presented below, or the exposure estimation methods presented in Chapter 4 of the Wildlife Exposure Factors Handbook (U.S. EPA, 1993), should be applied to approximate the needed feeding or drinking rates. Additional discussion and recommendations are provided in the Wildlife TSD. The choice of the methods described above is at the discretion of the State or Tribe.

3. For mammalian species, the general allometric equations are:

a. $F = 0.0687 (Wt)^{0.82}$

Where:

F = Feeding rate of mammalian species in kilograms per day (kg/d) dry weight.

Wt = Average weight in kilograms (kg) of the test animals.

b. $W = 0.099 (Wt)^{0.90}$

Where:

W = Drinking rate of mammalian species in liters per day (L/d).

Wt = Average weight in kilograms (kg) of the test animals.
4. For avian species, the general allometric equations are:

a. $F = 0.0582 (Wt)^{0.65}$

Where:

F = Feeding rate of avian species in kilograms per day (kg/d) dry weight.

Wt = Average weight in kilograms (kg) of the test animals.
b. $W = 0.059 (Wt)^{0.67}$

Where:

W = Drinking rate of avian species in liters per day (L/d).

Wt = Average weight in kilograms (kg) of the test animals.
F. LOAEL to NOAEL Extrapolations (UF_L). In those cases in which a NOAEL is unavailable as the TD and a LOAEL is available, the LOAEL may be used to estimate the NOAEL. If used, the LOAEL shall be divided by an UF to estimate a NOAEL for use in deriving WVs. The value of the UF shall not be less than one and should not exceed 10, depending on the dose-response curve and any other available data, and is represented by UF_L in the equation expressed in Section II.A of this appendix. Guidance for selecting an appropriate UF_L, based on a review of available wildlife toxicity data, is available in the Wildlife TSD.

G. Subchronic to Chronic Extrapolations (US_S). In instances where only subchronic data are available, the TD may be derived from subchronic data. In such cases, the TD shall be divided by an UF to extrapolate from subchronic to chronic levels. The value of the UF shall not be less than one and should not exceed 10, and is represented by UF_S in the equation expressed in Section II.A of this appendix. This factor is to be used when assessing highly bioaccumulative substances where toxicokinetic considerations suggest that a bioassay of limited length ***15412** underestimates chronic effects. Guidance for selecting an appropriate UF_S, based on a review of available wildlife toxicity data, is available in the Wildlife TSD.

H. Interspecies Extrapolations (UF_A). 1. The selection of the UF_A shall be based on the available toxicological data and on available data concerning the physicochemical, toxicokinetic, and toxicodynamic properties of the substance in question and the amount and quality of available data. This value is an UF that is intended to account for differences in toxicological sensitivity among species. Guidance for selecting an appropriate UF_A, based on a review of available wildlife toxicity data, is available in the Wildlife TSD. Additional discussion of an interspecies UF located in appendix A to the Great Lakes Water Quality Initiative Technical Support Document for Human Health Criteria may be useful in determining the appropriate value for UF_A.

2. For the derivation of Tier I criteria, a UF_A shall not be less than one and should not exceed 100, and shall be applied to each of the five representative species, based on existing data and best professional judgment. The value of UF_A may differ for each of the representative species.

3. For Tier I wildlife criteria, the UF_A shall be used only for extrapolating toxicity data across species within a taxonomic class, except as provided below. The Tier I UF_A is not intended for interclass extrapolations because of the poorly defined comparative toxicokinetic and toxicodynamic parameters between mammals and birds. However, an interclass extrapolation

employing a UF_A may be used for a given chemical if it can be supported by a validated biologically-based dose-response model or by an analysis of interclass toxicological data, considering acceptable endpoints, for a chemical analog that acts under the same mode of toxic action.

IV. Parameters of the Exposure Component of the Wildlife Criteria Methodology

A. Drinking and Feeding Rates of Representative Species. The body weights (Wt), feeding rates (F_{Tli}), drinking rates (W), and trophic level dietary composition (as food ingestion rate and percent in diet) for each of the five representative species are presented in Table D-2 of this appendix. Guidance on incorporating the non-aquatic portion of the bald eagle and mink diets in the criteria calculations is available in the Wildlife TSD.

B. BAFs. The Methodology for Development of Bioaccumulation Factors is presented in appendix B to part 132. Trophic level 3 and 4 BAFs are used to derive Wvs because these are the trophic levels at which the representative species feed.

V. References

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D. National Academy of Sciences. 1977. Chemical Contaminants: Safety and Risk Assessment, in Drinking Water and Health, Volume 1. National Academy Press.

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H. U.S. EPA. 1988. Recommendations for, and documentation of, biological values for use in risk assessment. NTIS-PB88-179874.

I. U.S. EPA. 1993. Wildlife Exposure Factors Handbook, Volumes I and II. EPA/600/R-93/187a and b.

Tables to Appendix D to Part 132

Table D-1.—Tier I Great Lakes Wildlife Criteria

Substance	Criterion (MUg/L)

DDT & Metabolites	1.1E-5
Mercury	1.3E-3
PCBs (total)	7.4E-5
2,3,7,8-TCDD	3.1E-9

Table D-2.—Exposure Parameters for the Five Representative Species Identified for Protection

Species (units)	Adult body weight (kg)	Water ingestion rate (L/day)	Food ingestion rate of prey in each trophic level (kg/day)	Trophic level of prey (percent of diet)
Mink	0.80	0.081	TL3: 0.159; Other: 0.0177	TL3: 90; Other: 10.
Otter	7.4	0.600	TL3: 0.977; TL4: 0.244	TL3: 80; TL4: 20.
Kingfisher	0.15	0.017	TL3: 0.0672	TL3: 100.
Herring gull	1.1	0.063	TL3: 0.192; TL4: 0.0480	Fish: 90—TL3: 80; TL4: 20.
	.....	.....	Other: 0.0267	Other: 10.
Bald eagle	4.6	0.160	TL3: 0.371; TL4: 0.0929	Fish: 92—TL3: 80; TL4: 20.
	.....	.....	PB: 00283; Other: 0.0121	Birds: 8—PB: 70; non-aquatic: 30.

Appendix E to Part 132—Great Lakes Water Quality Initiative Antidegradation Policy

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) appendix E to part 132.

The State or Tribe shall adopt an antidegradation standard applicable to all waters of the Great Lakes System and identify the methods for implementing such a standard. Consistent with 40 CFR 131.12, an acceptable antidegradation standard and implementation procedure are required elements of a State's or Tribe's water quality standards program. Consistent with 40 CFR 131.6, a complete water quality standards submission needs to include both an antidegradation standard and antidegradation implementation procedures. At a minimum, States and Tribes shall adopt provisions in their antidegradation standard and implementation methods consistent with sections I, II, III and IV of this appendix, applicable to pollutants identified as bioaccumulative chemicals of concern (BCCs).

I. Antidegradation Standard

This antidegradation standard shall be applicable to any action or activity by any source, point or nonpoint, of pollutants that is anticipated to result in an increased loading of BCCs to surface waters of the Great Lakes System and for which independent regulatory authority exists requiring compliance with water quality standards. Pursuant to this standard:

A. Existing instream water uses, as defined pursuant to 40 CFR 131, and the level of water quality necessary to protect existing uses shall be maintained and protected. Where designated uses of the waterbody are impaired, there shall be no lowering of the water quality with respect to the pollutant or pollutants which are causing the impairment;

B. Where, for any parameter, the quality of the waters exceed levels necessary to support the propagation of fish, shellfish, and wildlife and recreation in and on the waters, that water shall be considered high quality for that parameter consistent

with the definition of high quality water found at section II.A of this appendix and that quality ***15413** shall be maintained and protected unless the State or Tribe finds, after full satisfaction of intergovernmental coordination and public participation provisions of the State's or Tribe's continuing planning process, that allowing lower water quality is necessary to accommodate important economic or social development in the area in which the waters are located. In allowing such degradation, the State or Tribe shall assure water quality adequate to protect existing uses fully. Further, the State or Tribe shall assure that there shall be achieved the highest statutory and regulatory requirements for all new and existing point sources and all cost-effective and reasonable best management practices for nonpoint source control. The State or Tribe shall utilize the Antidegradation Implementation Procedures adopted pursuant to the requirements of this regulation in determining if any lowering of water quality will be allowed;

C. Where high quality waters constitute an outstanding national resource, such as waters of national and State parks and wildlife refuges and waters of exceptional recreational or ecological significance, that water quality shall be maintained and protected; and

D. In those cases where the potential lowering of water quality is associated with a thermal discharge, the decision to allow such degradation shall be consistent with section 316 of the Clean Water Act (CWA).

II. Antidegradation Implementation Procedures

A. Definitions.

Control Document. Any authorization issued by a State, Tribal or Federal agency to any source of pollutants to waters under its jurisdiction that specifies conditions under which the source is allowed to operate.

High quality waters. High quality waters are water bodies in which, on a parameter by parameter basis, the quality of the waters exceeds levels necessary to support propagation of fish, shellfish, and wildlife and recreation in and on the water.

Lake Superior Basin—Outstanding International Resource Waters. Those waters designated as such by a Tribe or State consistent with the September 1991 Bi-National Program to Restore and Protect the Lake Superior Basin. The purpose of such designations shall be to ensure that any new or increased discharges of Lake Superior bioaccumulative substances of immediate concern are subject to best technology in process and treatment requirements.

Lake Superior Basin—Outstanding National Resource Waters. Those waters designated as such by a Tribe or State consistent with the September 1991 Bi-National Program to Restore and Protect the Lake Superior Basin. The purpose of such designations shall be to prohibit new or increased discharges of Lake Superior bioaccumulative substances of immediate concern from point sources in these areas.

Lake Superior bioaccumulative substances of immediate concern. A list of substances identified in the September 1991 Bi-National Program to Restore and Protect the Lake Superior Basin. They include: 2, 3, 7, 8-TCDD; octachlorostyrene; hexachlorobenzene; chlordane; DDT, DDE, and other metabolites; toxaphene; PCBs; and mercury. Other chemicals may be added to the list following States' or Tribes' assessments of environmental effects and impacts and after public review and comment.

Outstanding National Resource Waters. Those waters designated as such by a Tribe or State. The State or Tribal designation shall describe the quality of such waters to serve as the benchmark of the water quality that shall be maintained and protected. Waters that may be considered for designation as Outstanding National Resource Waters include, but are not limited to, water bodies that are recognized as:

Important because of protection through official action, such as Federal or State law, Presidential or secretarial action, international treaty, or interstate compact;

Having exceptional recreational significance;

Having exceptional ecological significance;

Having other special environmental, recreational, or ecological attributes; or waters whose designation as Outstanding National Resource Waters is reasonably necessary for the protection of other waters so designated.

Significant Lowering of Water Quality. A significant lowering of water quality occurs when there is a new or increased loading of any BCC from any regulated existing or new facility, either point source or nonpoint source for which there is a control document or reviewable action, as a result of any activity including, but not limited to:

(1) Construction of a new regulated facility or modification of an existing regulated facility such that a new or modified control document is required;

(2) Modification of an existing regulated facility operating under a current control document such that the production capacity of the facility is increased;

(3) Addition of a new source of untreated or pretreated effluent containing or expected to contain any BCC to an existing wastewater treatment works, whether public or private;

(4) A request for an increased limit in an applicable control document;

(5) Other deliberate activities that, based on the information available, could be reasonably expected to result in an increased loading of any BCC to any waters of the Great Lakes System.

b. Notwithstanding the above, changes in loadings of any BCC within the existing capacity and processes, and that are covered by the existing applicable control document, are not subject to an antidegradation review. These changes include, but are not limited to:

(1) Normal operational variability;

(2) Changes in intake water pollutants;

(3) Increasing the production hours of the facility, (e.g., adding a second shift); or

(4) Increasing the rate of production.

C. Also, excluded from an antidegradation review are new effluent limits based on improved monitoring data or new water quality criteria or values that are not a result of changes in pollutant loading.

B. For all waters, the Director shall ensure that the level of water quality necessary to protect existing uses is maintained. In order to achieve this requirement, and consistent with 40 CFR 131.10, water quality standards use designations must include all existing uses. Controls shall be established as necessary on point and nonpoint sources of pollutants to ensure that the criteria applicable to the designated use are achieved in the water and that any designated use of a downstream water is protected. Where water quality does not support the designated uses of a waterbody or ambient pollutant concentrations exceed water quality criteria applicable to that waterbody, the Director shall not allow a lowering of water quality for the pollutant or pollutants preventing the attainment of such uses or exceeding such criteria.

C. For Outstanding National Resource Waters:

1. The Director shall ensure, through the application of appropriate controls on pollutant sources, that water quality is maintained and protected.

2. Exception. A short-term, temporary (i.e., weeks or months) lowering of water quality may be permitted by the Director.

D. For high quality waters, the Director shall ensure that no action resulting in a lowering of water quality occurs unless an antidegradation demonstration has been completed pursuant to section III of this appendix and the information thus provided is determined by the Director pursuant to section IV of this appendix to adequately support the lowering of water quality.

1. The Director shall establish conditions in the control document applicable to the regulated facility that prohibit the regulated facility from undertaking any deliberate action, such that there would be an increase in the rate of mass loading of any BCC, unless an antidegradation demonstration is provided to the Director and approved pursuant to section IV of this appendix prior to commencement of the action. Imposition of limits due to improved monitoring data or new water quality criteria or values, or changes in loadings of any BCC within the existing capacity and processes, and that are covered by the existing applicable control document, are not subject to an antidegradation review.

2. For BCCs known or believed to be present in a discharge, from a point or nonpoint source, a monitoring requirement shall be included in the control document. The control document shall also include a provision requiring the source to notify the Director or any increased loadings. Upon notification, the Director shall require actions as necessary to reduce or eliminate the increased loading.

3. Fact Sheets prepared pursuant to 40 CFR 124.8 and 124.56 shall reflect any conditions developed under sections II.D.1 or II.D.2 of this appendix and included in a permit.

E. Special Provisions for Lake Superior.The following conditions apply in addition to those specified in section II.B through II.C of this appendix for waters of Lake Superior so designated.

1. A State or Tribe may designate certain specified areas of the Lake Superior Basin as Lake Superior Basin—Outstanding National Resource Waters for the purpose of prohibiting the new or increased discharge of Lake Superior bioaccumulative substances of immediate concern from point sources in these areas.

2. States and Tribes may designate all waters of the Lake Superior Basin as Outstanding International Resource Waters for the purpose of restricting the increased discharge of ***15414** Lake Superior bioaccumulative substances of immediate concern from point sources consistent with the requirements of sections III.C and IV.B of this appendix.

F. Exemptions. Except as the Director may determine on a case-by-case basis that the application of these procedures is required to adequately protect water quality, or as the affected waterbody is an Outstanding National Resource Water as defined in section II.A of this appendix, the procedures in this part do not apply to:

1. Short-term, temporary (i.e., weeks or months) lowering of water quality;

2. Bypasses that are not prohibited at 40 CFR 122.41(m); and

3. Response actions pursuant to the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), as amended, or similar Federal, State or Tribal authorities, undertaken to alleviate a release into the environment of hazardous substances, pollutants or contaminants which may pose an imminent and substantial danger to public health or welfare.

III. Antidegradation Demonstration

Any entity seeking to lower water quality in a high quality water or create a new or increased discharge of Lake Superior bioaccumulative substances of immediate concern in a Lake Superior Outstanding International Resource Water must first, as required by sections II.D or II.E.2 of this appendix, submit an antidegradation demonstration for consideration by the Director. States and Tribes should tailor the level of detail and documentation in antidegradation reviews, to the specific circumstances encountered. The antidegradation demonstration shall include the following:

A. Pollution Prevention Alternatives Analysis. Identify any cost-effective pollution prevention alternatives and techniques that are available to the entity, that would eliminate or significantly reduce the extent to which the increased loading results in a lowering of water quality.

B. Alternative or Enhanced Treatment Analysis. Identify alternative or enhanced treatment techniques that are available to the entity that would eliminate the lowering of water quality and their costs relative to the cost of treatment necessary to achieve applicable effluent limitations.

C. Lake Superior. If the States or Tribes designate the waters of Lake Superior as Outstanding International Resource Waters pursuant to section II.E.2 of this appendix, then any entity proposing a new or increased discharge of any Lake Superior bioaccumulative substance of immediate concern to the Lake Superior Basin shall identify the best technology in process and treatment to eliminate or reduce the extent of the lowering of water quality. In this case, the requirements in section III.B of this appendix do not apply.

D. Important Social or Economic Development Analysis. Identify the social or economic development and the benefits to the area in which the waters are located that will be foregone if the lowering of water quality is not allowed.

E. Special Provision for Remedial Actions. Entities proposing remedial actions pursuant to the CERCLA, as amended, corrective actions pursuant to the Resource Conservation and Recovery Act, as amended, or similar actions pursuant to other Federal or State environmental statutes may submit information to the Director that demonstrates that the action utilizes the most cost effective pollution prevention and treatment techniques available, and minimizes the necessary lowering of water quality, in lieu of the information required by sections III.B through III.D of this appendix.

IV. Antidegradation Decision

A. Once the Director determines that the information provided by the entity proposing to increase loadings is administratively complete, the Director shall use that information to determine whether or not the lowering of water quality is necessary, and, if it is necessary, whether or not the lowering of water quality will support important social and economic development in the area. If the proposed lowering of water quality is either not necessary, or will not support important social and economic development, the Director shall deny the request to lower water quality. If the lowering of water quality is necessary, and will support important social and economic development, the Director may allow all or part of the proposed lowering to occur as necessary to accommodate the important social and economic development. In no event may the decision reached under this section allow water quality to be lowered below the minimum level required to fully support existing and designated uses. The decision of the Director shall be subject to the public participation requirements of 40 CFR 25.

B. If States designate the waters of Lake Superior as Outstanding International Resource Waters pursuant to section II.E.2 of this appendix, any entity requesting to lower water quality in the Lake Superior Basin as a result of the new or increased discharge of any Lake Superior bioaccumulative substance of immediate concern shall be required to install and utilize the best technology in process and treatment as identified by the Director.

Appendix F to Part 132—Great Lakes Water Quality Initiative Implementation Procedures

Procedure 1: Site-specific Modifications to Criteria and Values

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure.

A. Requirements for Site-specific Modifications to Criteria and Values. Criteria and values may be modified on a site-specific basis to reflect local environmental conditions as restricted by the following provisions. Any such modifications must be protective of designated uses and aquatic life, wildlife or human health and be submitted to EPA for approval. In addition, any site-specific modifications that result in less stringent criteria must be based on a sound scientific rationale and shall not be likely to jeopardize the continued existence of endangered or threatened species listed or proposed under section 4 of the Endangered Species Act (ESA) or result in the destruction or adverse modification of such species' critical habitat. More stringent modifications shall be developed to protect endangered or threatened species listed or proposed under section 4 of the ESA, where such modifications are necessary to ensure that water quality is not likely to jeopardize the continued existence of such species or result in the destruction or adverse modification of such species' critical habitat. More stringent modifications may also be developed to protect candidate (C1) species being considered by the U.S. Fish and Wildlife Service (FWS) for listing under section 4 of the ESA, where such modifications are necessary to protect such species.

1. Aquatic Life.

a. Aquatic life criteria or values may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under Clean Water Act (CWA) section 510.

Guidance on developing site-specific criteria in these instances is provided in Chapter 3 of the U.S. EPA Water Quality Standards Handbook, Second Edition—Revised (1994).

b. Less stringent site-specific modifications to chronic or acute aquatic life criteria or values may be developed when:

i. The local water quality characteristics such as Ph, hardness, temperature, color, etc., alter the biological availability or toxicity of a pollutant; or

ii. The sensitivity of the aquatic organisms species that “occur at the site” differs from the species actually tested in developing the criteria. The phrase “occur at the site” includes the species, genera, families, orders, classes, and phyla that: are usually present at the site; are present at the site only seasonally due to migration; are present intermittently because they periodically return to or extend their ranges into the site; were present at the site in the past, are not currently present at the site due to degraded conditions, and are expected to return to the site when conditions improve; are present in nearby bodies of water, are not currently present at the site due to degraded conditions, and are expected to be present at the site when conditions improve. The taxa that “occur at the site” cannot be determined merely by sampling downstream and/or upstream of the site at one point in time. “Occur at the site” does not include taxa that were once present at the site but cannot exist at the site now due to permanent physical alteration of the habitat at the site resulting, for example, from dams, etc.

c. Less stringent modifications also may be developed to acute and chronic aquatic life criteria or values to reflect local physical and hydrological conditions.

Guidance on developing site-specific criteria is provided in Chapter 3 of the U.S. EPA Water Quality Standards Handbook, Second Edition—Revised (1994).

***15415** d. Any modifications to protect threatened or endangered aquatic species required by procedure 1.A of this appendix may be accomplished using either of the two following procedures:

i. If the Species Mean Acute Value (SMAV) for a listed or proposed species, or for a surrogate of such species, is lower than the calculated Final Acute Value (FAV), such lower SMAV may be used instead of the calculated FAV in developing site-specific modified criteria; or,

ii. The site-specific criteria may be calculated using the recalculation procedure for site-specific modifications described in Chapter 3 of the U.S. EPA Water Quality Standards Handbook, Second Edition—Revised (1994).

2. Wildlife.

a. Wildlife water quality criteria may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under CWA section 510.

b. Less stringent site-specific modifications to wildlife water quality criteria may be developed when a site-specific bioaccumulation factor (BAF) is derived which is lower than the system-wide BAF derived under appendix B of this part. The modification must consider both the mobility of prey organisms and wildlife populations in defining the site for which criteria are developed. In addition, there must be a showing that:

i. Any increased uptake of the toxicant by prey species utilizing the site will not cause adverse effects in wildlife populations; and

ii. Wildlife populations utilizing the site or downstream waters will continue to be fully protected.

c. Any modification to protect endangered or threatened wildlife species required by procedure 1.A of this appendix must consider both the mobility of prey organisms and wildlife populations in defining the site for which criteria are developed, and may be accomplished by using the following recommended method.

i. The methodology presented in appendix D to part 132 is used, substituting appropriate species-specific toxicological, epidemiological, or exposure information, including changes to the BAF;

ii. An interspecies uncertainty factor of 1 should be used where epidemiological data are available for the species in question. If necessary, species-specific exposure parameters can be derived as presented in Appendix D of this part;

iii. An intraspecies uncertainty factor (to account for protection of individuals within a wildlife population) should be applied in the denominator of the effect part of the wildlife equation in appendix D of this part in a manner consistent with the other uncertainty factors described in appendix D of this part; and

iv. The resulting wildlife value for the species in question should be compared to the two class-specific wildlife values which were previously calculated, and the lowest of the three shall be selected as the site-specific modification.

Note: Further discussion on the use of this methodology may be found in the Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria.

3. BAFs.

a. BAFs may be modified on a site-specific basis to larger values, pursuant to the authority reserved to the States and Tribes under CWA section 510, where reliable data show that local bioaccumulation is greater than the system-wide value.

b. BAFs may be modified on a site-specific basis to lower values, where scientifically defensible, if:

i. The fraction of the total chemical that is freely dissolved in the ambient water is different than that used to derive the system-wide BAFs (i.e., the concentrations of particulate organic carbon and the dissolved organic carbon are different than those used to derive the system-wide BAFs);

ii. Input parameters of the Gobas model, such as the structure of the aquatic food web and the disequilibrium constant, are different at the site than those used to derive the system-wide BAFs;

iii. The percent lipid of aquatic organisms that are consumed and occur at the site is different than that used to derive the system-wide BAFs; or

iv. Site-specific field-measured BAFs or biota-sediment accumulation factor (BSAFs) are determined.

If site-specific BAFs are derived, they shall be derived using the methodology in appendix B of this part.

c. Any more stringent modifications to protect threatened or endangered species required by procedure 1.A of this appendix shall be derived using procedures set forth in the methodology in appendix B of this part.

4. Human Health.

a. Human health criteria or values may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under CWA section 510. Human health criteria or values shall be modified on a site-specific basis to provide additional protection appropriate for highly exposed subpopulations.

b. Less stringent site-specific modifications to human health criteria or values may be developed when:

i. local fish consumption rates are lower than the rate used in deriving human health criteria or values under appendix C of this part; and/or

ii. a site-specific BAF is derived which is lower than that used in deriving human health criteria or values under appendix C of this part.

B. Notification Requirements. When a State proposes a site-specific modification to a criterion or value as allowed in section 4.A above, the State should notify the other Great Lakes States of such a proposal and, for less stringent criteria, supply appropriate justification.

C. References.

U.S. EPA. 1984. Water Quality Standards Handbook—Revised. Chapter 3 and Appendices. U.S. Environmental Protection Agency, Office of Water Resource Center (RC-4100), 401 M Street, SW., Washington, DC 20960.

Procedure 2: Variances from Water Quality Standards for Point Sources

The Great Lakes States or Tribes may adopt water quality standards (WQS) variance procedures and may grant WQS variances for point sources pursuant to such procedures. Variance procedures shall be consistent with (as protective as) the provisions in this procedure.

A. Applicability. A State or Tribe may grant a variance to a WQS which is the basis of a water quality-based effluent limitation included in a National Pollutant Discharge Elimination System (NPDES) permit. A WQS variance applies only to the permittee requesting the variance and only to the pollutant or pollutants specified in the variance. A variance does not affect, or require the State or Tribe to modify, the corresponding water quality standard for the waterbody as a whole.

1. This provision shall not apply to new Great Lakes dischargers or recommencing dischargers.

2. A variance to a water quality standard shall not be granted that would likely jeopardize the continued existence of any endangered or threatened species listed under Section 4 of the Endangered Species Act (ESA) or result in the destruction or adverse modification of such species' critical habitat.

3. A WQS variance shall not be granted if standards will be attained by implementing effluent limits required under sections 301(b) and 306 of the Clean Water Act (CWA) and by the permittee implementing cost-effective and reasonable best management practices for nonpoint source control.

B. Maximum Timeframe for Variances. A WQS variance shall not exceed five years or the term of the NPDES permit, whichever is less. A State or Tribe shall review, and modify as necessary, WQS variances as part of each water quality standards review pursuant to section 303(c) of the CWA.

C. Conditions to Grant a Variance. A variance may be granted if:

1. The permittee demonstrates to the State or Tribe that attaining the WQS is not feasible because:

a. Naturally occurring pollutant concentrations prevent the attainment of the WQS;

b. Natural, ephemeral, intermittent or low flow conditions or water levels prevent the attainment of the WQS, unless these conditions may be compensated for by the discharge of sufficient volume of effluent to enable WQS to be met without violating State or Tribal water conservation requirements;

c. Human-caused conditions or sources of pollution prevent the attainment of the WQS and cannot be remedied, or would cause more environmental damage to correct than to leave in place;

d. Dams, diversions or other types of hydrologic modifications preclude the attainment of the WQS, and it is not feasible to restore the waterbody to its original condition or to operate such modification in a way that would result in the attainment of the WQS;

e. Physical conditions related to the natural features of the waterbody, such as the lack of a proper substrate cover, flow, depth, pools, riffles, and the like, unrelated to chemical water quality, preclude attainment of WQS; or

***15416** f. Controls more stringent than those required by sections 301(b) and 306 of the CWA would result in substantial and widespread economic and social impact.

2. In addition to the requirements of C.1, above, the permittee shall also:

a. Show that the variance requested conforms to the requirements of the State's or Tribe's antidegradation procedures; and

b. Characterize the extent of any increased risk to human health and the environment associated with granting the variance compared with compliance with WQS absent the variance, such that the State or Tribe is able to conclude that any such increased risk is consistent with the protection of the public health, safety and welfare.

D. Submittal of Variance Application. The permittee shall submit an application for a variance to the regulatory authority issuing the permit. The application shall include:

1. All relevant information demonstrating that attaining the WQS is not feasible based on one or more of the conditions in section C.1 of this procedure; and,

2. All relevant information demonstrating compliance with the conditions in section C.2 of this procedure.

E. Public Notice of Preliminary Decision. Upon receipt of a complete application for a variance, and upon making a preliminary decision regarding the variance, the State or Tribe shall public notice the request and preliminary decision for public comment pursuant to the regulatory authority's Administrative Procedures Act and shall notify the other Great Lakes States and Tribes of the preliminary decision. This public notice requirement may be satisfied by including the supporting information for the variance and the preliminary decision in the public notice of a draft NPDES permit.

F. Final Decision on Variance Request. The State or Tribe shall issue a final decision on the variance request within 90 days of the expiration of the public comment period required in section E of this procedure. If all or part of the variance is approved by the State or Tribe, the decision shall include all permit conditions needed to implement those parts of the variance so approved. Such permit conditions shall, at a minimum, require:

1. Compliance with an initial effluent limitation which, at the time the variance is granted, represents the level currently achievable by the permittee, and which is no less stringent than that achieved under the previous permit;

2. That reasonable progress be made toward attaining the water quality standards for the waterbody as a whole through appropriate conditions;

3. When the duration of a variance is shorter than the duration of a permit, compliance with an effluent limitation sufficient to meet the underlying water quality standard, upon the expiration of said variance; and

4. A provision that allows the permitting authority to reopen and modify the permit based on any State or Tribal triennial water quality standards revisions to the variance.

The State shall deny a variance request if the permittee fails to make the demonstrations required under section C of this procedure.

G. Incorporating Variance into Permit. The State or Tribe shall establish and incorporate into the permittee's NPDES permit all conditions needed to implement the variance as determined in section F of this procedure.

H. Renewal of Variance. A variance may be renewed, subject to the requirements of sections A through G of this procedure. As part of any renewal application, the permittee shall again demonstrate that attaining WQS is not feasible based on the requirements of section C of this procedure. The permittee's application shall also contain information concerning its compliance with the conditions incorporated into its permit as part of the original variance pursuant to sections F and G of this procedure. Renewal of a variance may be denied if the permittee did not comply with the conditions of the original variance.

I. EPA Approval. All variances and supporting information shall be submitted by the State or Tribe to the appropriate EPA regional office and shall include:

1. Relevant permittee applications pursuant to section D of this procedure;

2. Public comments and records of any public hearings pursuant to section E of this procedure;

3. The final decision pursuant to section F of this procedure; and,

4. NPDES permits issued pursuant to section G of this procedure.

5. Items required by sections I.1 through I.3. of this procedure shall be submitted by the State within 30 days of the date of the final variance decision. The item required by section I.4 of this procedure shall be submitted in accordance with the State or Tribe Memorandum of Agreement with the Regional Administrator pursuant to 40 CFR 123.24.
40 CFR § 123.4440 CFR § 131.21
6. EPA shall review the State or Tribe submittal for compliance with the CWA pursuant to 40 CFR 123.44, and 40 CFR 131.21.

J. State WQS Revisions. All variances shall be appended to the State or Tribe WQS rules.

Procedure 3: Total Maximum Daily Loads, Wasteload Allocations for Point Sources, Load Allocations for Nonpoint Sources, Wasteload Allocations in the Absence of a TMDL, and Preliminary Wasteload Allocations for Purposes of Determining the Need for Water Quality Based Effluent Limits

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure 3 for the purpose of developing Total Maximum Daily Loads (TMDLs), Wasteload Allocations (WLAs) in the Absence of TMDLs, and Preliminary Wasteload Allocations for Purposes of Determining the Need for Water Quality Based Effluent Limits (WQBELs), except as specifically provided.

A. Where a State or Tribe develops an assessment and remediation plan that the State or Tribe certifies meets the requirements of sections B through F of this procedure and public participation requirements applicable to TMDLs, and that has been approved by EPA as meeting those requirements under 40 CFR 130.6, the assessment and remediation plan may be used in lieu of a TMDL for purposes of appendix F to part 132. Assessment and remediation plans under this procedure may include, but are not limited to, Lakewide Management Plans, Remedial Action Plans, and State Water Quality Management Plans. Also, any part of an assessment and remediation plan that also satisfies one or more requirements under Clean Water Act (CWA) section 303(d) or implementing regulations may be incorporated by reference into a TMDL as appropriate. Assessment and remediation plans under this section should be tailored to the level of detail and magnitude for the watershed and pollutant being assessed.

B. General Conditions of Application. Except as provided in §132.4, the following are conditions applicable to establishing TMDLs for all pollutants and pollutant parameters in the Great Lakes System, with the exception of whole effluent toxicity, unless otherwise provided in procedure 6 of appendix F. Where specified, these conditions also apply to wasteload allocations (WLAs) calculated in the absence of TMDLs and to preliminary WLAs for purposes of determining the needs for WQBELs under procedure 5 of appendix F.

1. TMDLs Required. TMDLs shall, at a minimum, be established in accordance with the listing and priority setting process established in section 303(d) of the CWA and at 40 CFR 130.7. Where water quality standards cannot be attained immediately, TMDLs must reflect reasonable assurances that water quality standards will be attained in a reasonable period of time. Some TMDLs may be based on attaining water quality standards over a period of time, with specific controls on individual sources being implemented in stages. Determining the reasonable period of time in which water quality standards will be met is a case-specific determination considering a number of factors including, but not limited to: receiving water characteristics; persistence, behavior and ubiquity of pollutants of concern; type of remediation activities necessary; available regulatory and non-regulatory controls; and individual State or Tribal requirements for attainment of water quality standards.

2. Attainment of Water Quality Standards. A TMDL must ensure attainment of applicable water quality standards, including all numeric and narrative criteria, Tier I criteria, and Tier II values for each pollutant or pollutants for which a TMDL is established.

3. TMDL Allocations.

a. TMDLs shall include WLAs for point sources and load allocations (LAs) for nonpoint sources, including natural background, such that the sum of these allocations is not greater than the loading capacity of the water for the pollutant(s) addressed by the TMDL, minus the sum of a specified margin of safety (MOS) and any capacity reserved for future growth.

b. Nonpoint source LAs shall be based on:

i. Existing pollutant loadings if changes in loadings are not reasonably anticipated to occur;

ii. Increases in pollutant loadings that are reasonably anticipated to occur;

***15417** iii. Anticipated decreases in pollutant loadings if such decreased loadings are technically feasible and are reasonably anticipated to occur within a reasonable time period as a result of implementation of best management practices or other load reduction measures. In determining whether anticipated decreases in pollutant loadings are technically feasible and can reasonably be expected to occur within a reasonable period of time, technical and institutional factors shall be considered. These decisions are case-specific and should reflect the particular TMDL under consideration.

c. WLAs. The portion of the loading capacity not assigned to nonpoint sources including background, or to an MOS, or reserved for future growth is allocated to point sources. Upon reissuance, NPDES permits for these point sources must include effluent limitations consistent with WLAs in EPA-approved or EPA-established TMDLs.

d. Monitoring. For LAs established on the basis of subsection b.iii above, monitoring data shall be collected and analyzed in order to validate the TMDL's assumptions, to varify anticipated load reductions, to evaluate the effectiveness of controls being used to implement the TMDL, and to revise the WLAs and LAs as necessary to ensure that water quality standards will be achieved within the time-period established in the TMDL.

4. WLA Values. If separate EPA-approved or EPA-established TMDLs are prepared for different segments of the same watershed, and the separate TMDLs each include WLAs for the same pollutant for one or more of the same point sources, then WQBELs for that pollutant for the point source(s) shall be consistent with the most stringent of those WLAs in order to ensure attainment of all applicable water quality standards.

5. Margin of Safety (MOS). Each TMDL shall include a MOS sufficient to account for technical uncertainties in establishing the TMDL and shall describe the manner in which the MOS is determined and incorporated into the TMDL. The MOS may be provided by leaving a portion of the loading capacity unallocated or by using conservative modeling assumptions to establish WLAs and LAs. If a portion of the loading capacity is left unallocated to provide a MOS, the amount left unallocated shall be described. If conservative modeling assumptions are relied on to provide a MOS, the specific assumptions providing the MOS shall be identified.

6. More Stringent Requirements. States and Tribes may exercise authority reserved to them under section 510 of the CWA to develop more stringent TMDLs (including WLAs and LAs) than are required herein, provided that all LAs in such TMDLs reflect actual nonpoint source loads or those loads that can reasonably be expected to occur within a reasonable time-period as a result of implementing nonpoint source controls.

7. Accumulation in Sediments. TMDLs shall reflect, where appropriate and where sufficient data are available, contributions to the water column from sediments inside and outside of any applicable mixing zones. TMDLs shall be sufficiently stringent so as to prevent accumulation of the pollutant of concern in sediments to levels injurious to designated or existing uses, human health, wildlife and aquatic life.

8. Wet Weather Events. Notwithstanding the exception provided for the establishment of controls on wet weather point sources in §132.4(e)(1), TMDLs shall reflect, where appropriate and where sufficient data are available, discharges resulting from wet

weather events. This procedure does not provide specific procedures for considering discharges resulting from wet weather events. However, some of the provisions of procedure 3 may be deemed appropriate for considering wet weather events on a case-by-case basis.

9. Background Concentration of Pollutants. The representative background concentration of pollutants shall be established in accordance with this subsection to develop TMDLs, WLAs calculated in the absence of a TMDL, or preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F. Background loadings may be accounted for in a TMDL through an allocation to a single “background” category or through individual allocations to the various background sources.

a. Definition of Background. “Background” represents all loadings that: (1) flow from upstream waters into the specified watershed, waterbody or waterbody segment for which a TMDL, WLA in the absence of a TMDL or preliminary WLA for the purpose of determining the need for a WQBEL is being developed; (2) enter the specified watershed, waterbody or waterbody segment through atmospheric deposition or sediment release or resuspension; or (3) occur within the watershed, waterbody or waterbody segment as a result of chemical reactions.

b. Data considerations. When determining what available data are acceptable for use in calculating background, the State or Tribe should use best professional judgment, including consideration of the sampling location and the reliability of the data through comparison to reported analytical detection levels and quantification levels. When data in more than one of the data sets or categories described in section B.9.c.i through B.9.c.iii below exist, best professional judgment should be used to select the one data set that most accurately reflects or estimates background concentrations. Pollutant degradation and transport information may be considered when utilizing pollutant loading data.

c. Calculation requirements. Except as provided below, the representative background concentration for a pollutant in the specified watershed, waterbody or waterbody segment shall be established on a case-by-case basis as the geometric mean of:

i. Acceptable available water column data; or

ii. Water column concentrations estimated through use of acceptable available caged or resident fish tissue data; or

iii. Water column concentrations estimated through use of acceptable available or projected pollutant loading data.

d. Detection considerations.

i. Commonly accepted statistical techniques shall be used to evaluate data sets consisting of values both above and below the detection level.

ii. When all of the acceptable available data in a data set or category, such as water column, caged or resident fish tissue or pollutant loading data, are below the level of detection for a pollutant, then all the data for that pollutant in that data set shall be assumed to be zero.

10. Effluent Flow. If WLAs are expressed as concentrations of pollutants, the TMDL shall also indicate the point source effluent flows assumed in the analyses. Mass loading limitations established in NPDES permits must be consistent with both the WLA and assumed effluent flows used in establishing the TMDL.

11. Reserved Allocations. TMDLs may include reserved allocations of loading capacity to accommodate future growth and additional sources. Where such reserved allocations are not included in a TMDL, any increased loadings of the pollutant for which the TMDL was developed that are due to a new or expanded discharge shall not be allowed unless the TMDL is revised in accordance with these proceudres to include an allocation for the new or expanded discharge.

C. Mixing Zones for Bioaccumulative Chemicals of Concern (BCCs). The following requirements shall be applied in establishing TMDLs, WLAs in the absence of TMDLs, and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F, for BCCs:

1. Beginning on March 23, 1997, there shall be no mixing available for new discharges of BCCs to the Great Lakes System. WLAs established through TMDLs, WLAs in the absence of TMDLs, and preliminary WLAs for purposes of determining the need for WQBELs for new discharges of BCCs shall be set equal to the most stringent applicable water quality criteria or values for the BCCs in question.

2. For purposes of section C of procedure 3 of appendix F, new discharges are defined as: (1) discharges from new Great Lakes dischargers; or (2) new or expanded discharges from an existing Great Lakes discharger. All other discharges of BCCs are defined as existing discharges.

3. Up until March 23, 2007, mixing zones for BCCs may be allowed for existing discharges to the Great Lakes System pursuant to the procedures specified in sections D and E of this procedure.

4. Except as provided in sections C.5 and C.6 of this procedure, permits issued on or after March 23, 1997 shall not authorize mixing zones for existing discharges of BCCs to the Great Lakes System after March 23, 2007. After March 23, 2007, WLAs established through TMDLs, WLAs established in the absence of TMDLs and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F for existing dischrges of BCCs to the Great Lakes System shall be set equal to the most stringent applicable water quality criteria or values for the BCCs in question.

5. Exception for Water Conservation. States and Tribes may grant mixing zones for any existing discharge of BCCs to the Great Lakes ***15418** System beyond the dates specified in sections C.3 and C.4 of this procedure, where it can be demonstrated, on a case-by-case basis, that failure to grant a mixing zone would preclude water conservation measures that would lead to overall load reductions in BCCs, even though higher concentrations of BCCs occur in the effluent. Such mixing zones must also be consistent with sections D and E of this procedure.

6. Exception for Technical and Economic Considerations. States and Tribes may grant mixing zones beyond the dates specified in sections C.3 and C.4 of this procedure for any existing discharges of a BCC to the Great Lakes System upon the request of a discharger subject to the limited circumstances specified in sections C.6.a through C.6.d below. Such mixing zones shall also be consistent with sections D and E of this procedure.

a. The permitting authority must determine that:

i. The discharger is in compliance with and will continue to implement all applicable technology-based treatment and pretreatment requirements of CWA sections 301, 302, 304, 306, 307, 401, and 402, and is in compliance with its existing NPDES water quality-based effluent limitations, including those based on a mixing zone; and

ii. The discharger has reduced and will continue to reduce the loading of the BCC for which a mixing zone is requested to the maximum extent possible.

b. In making the determination in section C.6.a above, the State or Tribal authority should consider:

i. The availability and feasibility, including cost effectiveness, of additional controls or pollution prevention measures for reducing and ultimately eliminating BCCs for that discharger, including those used by similar dischargers;

ii. Whether the discharger or affected communities will suffer unreasonable economic effects if the mixing zone is eliminated;

iii. The extent to which the discharger will implement an ambient monitoring plan to ensure compliance with water quality criteria at the edge of any authorized mixing zone or to ensure consistency with any applicable TMDL or such other strategy consistent with section A of this procedure; and,

iv. Other information the State or Tribe deems appropriate.

c. Any exceptions to the mixing zone elimination provision for existing discharges of BCCs granted pursuant to this section shall:

i. Not result in any less stringent limitations than those existing March 23, 1997;

ii. Not likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat;

iii. Be limited to one permit term unless the permitting authority makes a new determination in accordance with this section for each successive permit application in which a mixing zone for the BCC(s) is sought;

iv. Reflect all information relevant to the size of the mixing zone considered by the State or Tribe under subsection b above;

v. Protect all designated and existing uses of the receiving water;

vi. Meet all applicable aquatic life, wildlife and human health criteria and values at the edge of the mixing zone and, as appropriate, within the mixing zone or be consistent with any appropriate TMDL or such other strategy consistent with section A of this procedure;

vii. Ensure the discharger has developed and conducted a pollutant minimization program for the BCC(s) if required to do so under regulations adopted consistent with procedure 8 of appendix F; and

viii. Ensure that alternative means for reducing BCCs elsewhere in the watershed are evaluated.

d. For each draft NPDES permit that would allow a mixing zone for one or more BCCs after March 23, 2007, the fact sheet or statement of basis for the draft permit, required to be made available through public notice under 40 CFR 124.6(e), shall:

i. Specify the mixing provisions used in calculating the permit limits; and

ii. Identify each BCC for which a mixing zone is proposed.

D. Deriving TMDLs, WLAs, and LAs for Point and Nonpoint Sources: WLAs in the Absence of a TMDL; and Preliminary WLAs for Purposes of Determining the Need for WQBELs for OWGL. This section addresses conditions for deriving TMDLs for Open Waters of the Great Lakes (OWGL), inland lakes and other waters of the Great Lakes System with no appreciable flow relative to their volumes. State and Tribal procedures to derive TMDLs under this section must be consistent with (as protective as) the general conditions in section B of this procedure, CWA section 303(d), existing regulations (40 CFR 130.7), section C of this procedure, and sections D.1. through D.4 below. State and Tribal procedures to derive WLAs calculated in the absence of a TMDL and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F must be consistent with sections B.9, C.1, C3 through C.6, and D. 1 through D.4 of this procedure.

1. Individual point source WLAs and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F shall assume no greater dilution than one part effluent to 10 parts receiving water for implementation of numeric

and narrative chronic criteria and values (including, but not limited to human cancer criteria, human cancer values, human noncancer values, human noncancer criteria, wildlife criteria, and chronic aquatic life criteria and values) unless an alternative mixing zone is demonstrated as appropriate in a mixing zone demonstration conducted pursuant to section F of this procedure. In no case shall a mixing zone be granted that exceeds the area where discharge-induced mixing occurs.

2. Appropriate mixing zone assumptions to be used in calculating load allocations for nonpoint sources shall be determined, consistent with applicable State or Tribal requirements, on a case-by-case basis.

3. WLAs and preliminary WLAs based on acute aquatic life criteria or values shall not exceed the Final Acute Value (FAV), unless a mixing zone demonstration is conducted and approved pursuant to section F of this procedure. If mixing zones from two or more proximate sources interact or overlap, the combined effect must be evaluated to ensure that applicable criteria and values will be met in the area where acute mixing zones overlap.

4. In no case shall a mixing zone be granted that would likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat.

E. Deriving TMDLs, WLAs, and LAs for Point and Nonpoint Sources; WLAs in the Absence of a TMDL; and Preliminary WLAs for the Purposes of Determining the Need for WQBELs for Great Lakes Systems Tributaries and Connecting Channels. This section describes conditions for deriving TMDLs for tributaries and connecting channels of the Great Lakes System that exhibit appreciable flows relative to their volumes. State and Tribal procedures to derive TMDLs must be consistent with the general conditions listed in section B of this procedure, section C of this procedure, existing TMDL regulations (40 CFR 130.7) and specific conditions E.1 through E.5. State and Tribal procedures to derive WLAs calculated in the absence of a TMDL, and preliminary WLAs for purposes of determining reasonable potential under procedure 5 of this appendix for discharges to tributaries and connecting channels must be consistent with sections B.9, C.1, C.3 through C.6, and E.1 through E.5 of this procedure.

1. Stream Design. These design flows must be used unless data exist to demonstrate that an alternative stream design flow is appropriate for stream-specific and pollutant-specific conditions. For purposes of calculating a TMDL, WLAs in the absence of a TMDL, or preliminary WLAs for the purposes of determining reasonable potential under procedure 5 of this appendix, using a steady-state model, the stream design flows shall be:

a. The 7-day, 10-year stream design flow (7Q10), or the 4-day, 3-year biologically-based stream design flow for chronic aquatic life criteria or values;

b. The 1-day, 10-year stream design flow (1Q10), for acute aquatic life criteria or values;

c. The harmonic mean flow for human health criteria or values;

d. The 90-day, 10-year flow (90Q10) for wildlife criteria.

e. TMDLs, WLAs in the absence of TMDLs, and preliminary WLAs for the purpose of determining the need for WQBELs calculated using dynamic modelling do not need to incorporate the stream design flows specified in sections E.1.a through E.1.d of this procedure.

2. Loading Capacity. The loading capacity is the greatest amount of loading that a water can receive without violating water quality standards. The loading capacity is initially calculated at the farthest downstream location in the watershed drainage basin. The maximum allowable loading consistent with the attainment of each applicable numeric ***15419** criterion or value for a given pollutant is determined by multiplying the applicable criterion or value by the flow at the farthest downstream location in the tributary basin at the design flow condition described above. This loading is then compared to the loadings at

sites within the basin to assure that applicable numeric criteria or values for a given pollutant are not exceeded at all applicable sites. The lowest load is then selected as the loading capacity.

3. Polluant Degradation. TMDLs, WLAs in the absence of a TMDL and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F shall be based on the assumption that a pollutant does not degrade. However, the regulatory authority may take into account degradation of the pollutant if each of the following conditions are met.

a. Scientifically valid field studies or other relevant information demonstrate that degradation of the pollutant is expected to occur under the full range of environmental conditions expected to be encountered;

b. Scientifically valid field studies or other relevant information address other factors that affect the level of pollutants in the water column including, but not limited to, resuspension of sediments, chemical speciation, and biological and chemical transformation.

4. Acute Aquatic Life Criteria and Values. WLAs and LAs established in a TMDL, WLAs in the absence of a TMDL, and preliminary WLAs for the purpose of determining the need for WQBELs based on acute aquatic life criteria or values shall not exceed the FAV, unless a mixing zone demonstration is completed and approved pursuant to section F of this procedure. If mixing zones from two or more proximate sources interact or overlap, the combined effect must be evaluated to ensure that applicable criteria and values will be met in the area where any applicable acute mixing zones overlap. This acute WLA review shall include, but not be limited to, consideration of:

a. The expected dilution under all effluent flow and concentration conditions at stream design flow;

b. Maintenance of a zone of passage for aquatic organisms; and

c. Protection of critical aquatic habitat.

In no case shall a permitting authority grant a mixing zone that would likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat.

5. Chronic Mixing Zones. WLAs and LAs established in a TMDL, WLAs in the absence of a TMDL, and preliminary WLAs for the purposes of determining the need for WQBELs for protection of aquatic life, wildlife and human health from chronic effects shall be calculated using a dilution fraction no greater than 25 percent of the stream design flow unless a mixing zone demonstration pursuant to section F of this procedure is conducted and approved. A demonstration for a larger mixing zone may be provided, if approved and implemented in accordance with section F of this procedure. In no case shall a permitting authority grant a mixing zone that would likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat.

F. Mixing Zone Demonstration Requirements.

1. For purposes of establishing a mixing zone other than as specified in sections D and E above, a mixing zone demonstration must:

a. Describe the amount of dilution occurring at the boundaries of the proposed mixing zone and the size, shape, and location of the area of mixing, including the manner in which diffusion and dispersion occur;

b. For sources discharging to the open waters of the Great Lakes (OWGLs), define the location at which discharge-induced mixing ceases;

c. Document the substrate character and geomorphology within the mixing zone;

d. Show that the mixing zone does not interfere with or block passage of fish or aquatic life;

e. Show that the mixing zone will be allowed only to the extent that the level of the pollutant permitted in the waterbody would not likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat;

f. Show that the mixing zone does not extend to drinking water intakes;

g. Show that the mixing zone would not otherwise interfere with the designated or existing uses of the receiving water or downstream waters;

h. Document background water quality concentrations;

i. Show that the mixing zone does not promote undesirable aquatic life or result in a dominance of nuisance species; and

j. Provide that by allowing additional mixing/dilution:

i. Substances will not settle to form objectionable deposits;

ii. Floating debris, oil, scum, and other matter in concentrations that form nuisances will not be produced; and

iii. Objectionable color, odor, taste or turbidity will not be produced.

2. In addition, the mixing zone demonstration shall address the following factors:

a. Whether or not adjacent mixing zones overlap;

b. Whether organisms would be attracted to the area of mixing as a result of the effluent character; and

c. Whether the habitat supports endemic or naturally occurring species.

3. The mixing zone demonstration must be submitted to EPA for approval. Following approval of a mixing zone demonstration consistent with sections F.1 and F.2, adjustment to the dilution ratio specified in section D.1 of this procedure shall be limited to the dilution available in the area where discharger-induced mixing occurs.

4. The mixing zone demonstration shall be based on the assumption that a pollutant does not degrade within the proposed mixing zone, unless:

a. Scientifically valid field studies or other relevant information demonstrate that degradation of the pollutant is expected to occur under the full range of environmental conditions expected to be encountered; and

b. Scientifically valid field studies or other relevant information address other factors that affect the level of pollutants in the water column including, but not limited to, resuspension of sediments, chemical speciation, and biological and chemical transformation.

Procedure 4: Additivity

The Great Lakes States and Tribes shall adopt additivity provisions consistent with (as protective as) this procedure.

A. The Great Lakes States and Tribes shall adopt provisions to protect human health from the potential adverse additive effects from both the noncarcinogenic and carcinogenic components of chemical mixtures in effluents. For the chlorinated dibenzo-p-dioxins (CDDs) and chlorinated dibenzofurans (CDFs) listed in Table 1, potential adverse additive effects in effluents shall be accounted for in accordance with section B of this procedure.

B. Toxicity Equivalency Factors (TEFs)/Bioaccumulation Equivalency Factors (BEFs).

1. The TEFs in Table 1 and BEFs in Table 2 shall be used when calculating a 2,3,7,8-TCDD toxicity equivalence concentration in effluent to be used when implementing both human health noncancer and cancer criteria. The chemical concentration of each CDDs and CDFs in effluent shall be converted to a 2,3,7,8-TCDD toxicity equivalence concentration in effluent by (a) multiplying the chemical concentration of each CDDs and CDFs in the effluent by the appropriate TEF in Table 1 below, (b) multiplying each product from step (a) by the BEF for each CDDs and CDFs in Table 2 below, and (c) adding all final products from step (b). The equation for calculating the 2,3,7,8-TCDD toxicity equivalence concentration in effluent is:

where:

$(TEC)_{tcdd}$=2,3,7,8-TCDD toxicity equivalence concentration in effluent

$(C)_x$=concentration of total chemical x in effluent

$(TEF)_x$=TCDD toxicity equivalency factor for x

$(BEF)_x$=TCDD bioaccumulation equivalency factor for x

2. The 2,3,7,8-TCDD toxicity equivalence concentration in effluent shall be used when developing waste load allocations under procedure 3, preliminary waste load allocations for purposes of determining reasonable potential under procedure 5, and for purposes of establishing effluent quality limits under procedure 5.

Table 1.—Toxicity Equivalency Factors for CDDs and CDFs

Congener	TEF
2,3,7,8-TCDD	1.0
1,2,3,7,8-PeCDD	0.5
1,2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.01
OCDD	0.001
2,3,7,8-TCDF	0.1
1,2,3,7,8-PeCDF	0.05
2,3,4,7,8-PeCDF	0.5

1,2,3,4,7,8-HxCDF	0.1
1,2,3,6,7,8-HxCDF	0.1
2,3,4,6,7,8-HxCDF	0.1
1,2,3,7,8,9-HxCDF	0.1
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.01
OCDF	0.001

Table 2.—Bioaccumulation Equivalency Factors for CDDs and CDFs

Congener	BEF
2,3,7,8-TCDD	1.0
1,2,3,7,8-PeCDD	0.9
1,2,3,4,7,8-HxCDD	0.3
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.05
OCDD	0.01
2,3,7,8-TCDF	0.8
1,2,3,7,8-PeCDF	0.2
2,3,4,7,8-PeCDF	1.6
1,2,3,4,7,8-HxCDF	0.08
1,2,3,6,7,8-HxCDF	0.2
2,3,4,6,7,8-HxCDF	0.7
1,2,3,7,8,9-HxCDF	0.6
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.4
OCDF	0.02

***15420 Procedure 5: Reasonable Potential To Exceed Water Quality Standards**

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure. If a permitting authority determines that a pollutant is or may be discharged into the Great Lakes System at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any Tier I criterion or Tier II value, the permitting authority shall incorporate a water quality-based effluent limitation (WQBEL) in an NPDES permit for the discharge of that pollutant. When facility-specific effluent monitoring data are available, the permitting authority shall make this determination by developing preliminary effluent limitations (PEL) and comparing those effluent limitations to the projected effluent quality (PEQ) of the discharge in accordance with the following procedures. In all cases, the permitting authority shall use any valid, relevant, representative information that indicates a reasonable potential to exceed any Tier I criterion or Tier II value.

A. Developing Preliminary Effluent Limitations on the Discharge of a Pollutant From a Point Source.

1. The permitting authority shall develop preliminary wasteload allocations (WLAs) for the discharge of the pollutant from the point source to protect human health, wildlife, acute aquatic life, and chronic aquatic life, based upon any existing Tier I criteria. Where there is no Tier I criterion nor sufficient data to calculate a Tier I criterion, the permitting authority shall calculate a Tier II value for such pollutant for the protection of human health, and aquatic life and the preliminary WLAs shall be based upon such values. Where there is insufficient data to calculate a Tier II value, the permitting authority shall apply the procedure set forth in section C of this procedure to determine whether data must be generated to calculate a Tier II value.

2. The following provisions in procedure 3 of appendix F shall be used as the basis for determining preliminary WLAs in accordance with section 1 of this procedure: procedure 3.B.9, Background Concentrations of Pollutants; procedure 3.C, Mixing Zones for Bioaccumulative Chemicals of Concern (BCCs), procedures 3.C.1, and 3.C.3 through 3.C.6; procedure 3.D, Deriving TMDLs for Discharges to Lakes (when the receiving water is an open water of the Great Lakes (OWGL), an inland lake or other water of the Great Lakes System with no appreciable flow relative to its volume); procedure 3.E, Deriving TMDLs, WLAs and Preliminary WLAs, and load allocations (LAs) for Discharges to Great Lakes System Tributaries (when the receiving water is a tributary or connecting channel of the Great Lakes that exhibits appreciable flow relative to its volume); and procedure 3.F, Mixing Zone Demonstration Requirements.

3. The permitting authority shall develop PELs consistent with the preliminary WLAs developed pursuant to sections A.1 and A.2 of this procedure, and in accordance with existing State or Tribal procedures for converting WLAs into WQBELs. At a minimum:

a. The PELs based upon criteria and values for the protection of human health and wildlife shall be expressed as monthly limitations;

b. The PELs based upon criteria and values for the protection of aquatic life from chronic effects shall be expressed as either monthly limitations or weekly limitations; and

c. The PELs based upon the criteria and values for the protection of aquatic life from acute effects shall be expressed as daily limitations.

B. Determining Reasonable Potential Using Effluent Pollutant Concentration Data.

If representative, facility-specific effluent monitoring data samples are available for a pollutant discharged from a point source to the waters of the Great Lakes System, the permitting authority shall apply the following procedures:

1. The permitting authority shall specify the PEQ as the 95 percent confidence level of the 95th percentile based on a log-normal distribution of the effluent concentration; or the maximum observed effluent concentration, whichever is greater. In calculating the PEQ, the permitting authority shall identify the number of effluent samples and the coefficient of variation of the effluent data, obtain the appropriate multiplying factor from Table 1 of procedure 6 of appendix F, and multiply the maximum effluent

concentration by that factor. The coefficient of variation of the effluent data shall be calculated as the ratio of the standard deviation of the effluent data divided by the arithmetic average of the effluent data, except that where there are fewer than ten effluent concentration data points the coefficient of variation shall be specified as 0.6. If the PEQ exceeds any of the PELs developed in accordance with section A.3 of this procedure, the permitting authority shall establish a WQBEL in a NPDES permit for such pollutant.

2. In lieu of following the procedures under section B.1 of this procedure, the permitting authority may apply procedures consistent with the following:

a. The permitting authority shall specify the PEQ as the 95th percentile of the distribution of the projected population of daily values of the facility-specific effluent monitoring data projected using a scientifically defensible statistical method that accounts for and captures the long-term daily variability of the effluent quality, accounts for limitations associated with sparse data sets and, unless otherwise shown by the effluent data set, assumes a lognormal distribution of the facility-specific effluent data. If the PEQ exceeds the PEL based on the criteria and values for the protection of aquatic life from acute effects developed in accordance with section A.3 of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant;

b. The permitting authority shall calculate the PEQ as the 95th percentile of the distribution of the projected population of monthly averages of the facility-specific effluent monitoring data using a scientifically defensible statistical method that accounts for and captures the long-term variability of the monthly average effluent quality, accounts for limitations associated with sparse data sets and, unless otherwise shown by the effluent data set, assumes a lognormal distribution of the facility-specific effluent data. If the PEQ exceeds the PEL based on criteria and values for the protection of aquatic life from chronic effects, human health or wildlife developed in accordance with section A.3 of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant; and

c. The permitting authority shall calculate the PEQ as the 95th percentile of the distribution of the projected population of weekly averages of the facility-specific effluent monitoring data using a scientifically defensible statistical method that accounts for and captures the long-term variability of the weekly average effluent quality, accounts for limitations associated with sparse data sets and, unless otherwise shown by the effluent data set, assumes a lognormal distribution of the facility-specific effluent data. If the PEQ exceeds the PEL based on criteria and values to protect aquatic life from chronic effects developed in accordance with section A.3 of this procedure, the permitting ***15421** authority shall establish a WQBEL in an NPDES permit for such pollutant.

C. Developing Necessary Data to Calculate Tier II Values Where Such Data Does Not Currently Exist.
40 CFR § 122.44
1. Except as provided in sections C.2, C.4, or D of this procedure, for each pollutant listed in Table 6 of part 132 that a permittee reports as known or believed to be present in its effluent, and for which pollutant data sufficient to calculate Tier II values for non-cancer human health, acute aquatic life and chronic aquatic life do not exist, the permitting authority shall take the following actions:

a. The permitting authority shall use all available, relevant information, including Quantitative Structure Activity Relationship information and other relevant toxicity information, to estimate ambient screening values for such pollutant which will protect humans from health effects other than cancer, and aquatic life from acute and chronic effects.

b. Using the procedures specified in sections A.1 and A.2 of this procedure, the permitting authority shall develop preliminary WLAs for the discharge of the pollutant from the point source to protect human health, acute aquatic life, and chronic aquatic life, based upon the estimated ambient screening values.

c. The permitting authority shall develop PELs in accordance with section A.3 of this procedure, which are consistent with the preliminary WLAs developed in accordance with section C.1.b of this procedure.

d. The permitting authority shall compare the PEQ developed according to the procedures set forth in section B of this procedure to the PELs developed in accordance with section C.1.c of this procedure. If the PEQ exceeds any of the PELs, the permitting authority shall generate or require the permittee to generate the data necessary to derive Tier II values for noncancer human health, acute aquatic life and chronic aquatic life.

e. The data generated in accordance with section C.1.d of this procedure shall be used in calculating Tier II values as required under section A.1 of this procedure. The calculated Tier II value shall be used in calculating the preliminary WLA and PEL under section A of this procedure, for purposes of determining whether a WQBEL must be included in the permit. If the permitting authority finds that the PEQ exceeds the calculated PEL, a WQBEL for the pollutant or a permit limit on an indicator parameter consistent with 40 CFR 122.44(d)(1)(vi)(C) must be included in the permit.

2. With the exception of bioaccumulative chemicals of concern (BCCs), a permitting authority is not required to apply the procedures set forth in section C.1 of this procedure or include WQBELs to protect aquatic life for any pollutant listed in Table 6 of part 132 discharged by an existing point source into the Great Lakes System, if:

a. There is insufficient data to calculate a Tier I criterion or Tier II value for aquatic life for such pollutant;

b. The permittee has demonstrated through a biological assessment that there are no acute or chronic effects on aquatic life in the receiving water; and

c. The permittee has demonstrated in accordance with procedure 6 of this appendix that the whole effluent does not exhibit acute or chronic toxicity.

3. Nothing in sections C.1 or C.2 of this procedure shall preclude or deny the right of a permitting authority to:

a. Determine, in the absence of the data necessary to derive a Tier II value, that the discharge of the pollutant will cause, have the reasonable potential to cause, or contribute to an excursion above a narrative criterion for water quality; and

b. Incorporate a WQBEL for the pollutant into an NPDES permit.

4. If the permitting authority develops a WQBEL consistent with section C.3 of this procedure, and the permitting authority demonstrates that the WQBEL developed under section C.3 of this procedure is at least as stringent as a WQBEL that would have been based upon the Tier II value or values for that pollutant, the permitting authority shall not be obligated to generate or require the permittee to generate the data necessary to derive a Tier II value or values for that pollutant.

D. Consideration of Intake Pollutants in Determining Reasonable Potential.
40 CFR § 122.44
1. General.

a. Any procedures adopted by a State or Tribe for considering intake pollutants in water quality-based permitting shall be consistent with this section and section E.

b. The determinations under this section and section E shall be made on a pollutant-by-pollutant, outfall-by-outfall, basis.

c. This section and section E apply only in the absence of a TMDL applicable to the discharge prepared by the State or Tribe and approved by EPA, or prepared by EPA pursuant to 40 CFR 130.7(d), or in the absence of an assessment and remediation

plan submitted and approved in accordance with procedure 3.A. of appendix F. This section and section E do not alter the permitting authority's obligation under 40 CFR 122.44(d)(vii)(B) to develop effluent limitations consistent with the assumptions and requirements of any available WLA for the discharge, which is part of a TMDL prepared by the State or Tribe and approved by EPA pursuant to 40 CFR 130.7, or prepared by EPA pursuant to 40 CFR 130.7(d).

2. Definition of Same Body of Water.

a. This definition applies to this section and section E of this procedure.

b. An intake pollutant is considered to be from the same body of water as the discharge if the permitting authority finds that the intake pollutant would have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee. This finding may be deemed established if:

i. The background concentration of the pollutant in the receiving water (excluding any amount of the pollutant in the facility's discharge) is similar to that in the intake water;

ii. There is a direct hydrological connection between the intake and discharge points; and

iii. Water quality characteristics (e.g., temperature, Ph, hardness) are similar in the intake and receiving waters.

c. The permitting authority may also consider other site-specific factors relevant to the transport and fate of the pollutant to make the finding in a particular case that a pollutant would or would not have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee.

d. An intake pollutant from groundwater may be considered to be from the same body of water if the permitting authority determines that the pollutant would have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee, except that such a pollutant is not from the same body of water if the groundwater contains the pollutant partially or entirely due to human activity, such as industrial, commercial, or municipal operations, disposed actions, or treatment processes.

e. An intake pollutant is the amount of a pollutant that is present in waters of the United States (including groundwater as provided in section D.2.d of this procedure) at the time it is withdrawn from such waters by the discharger or other facility (e.g., public water supply) supplying the discharger with intake water.

3. Reasonable Potential Determination.

a. The permitting authority may use the procedure described in this section of procedure 5 in lieu of procedures 5.A through C provided the conditions specified below are met.

b. The permitting authority may determine that there is no reasonable potential for the discharge of an identified intake pollutant or pollutant parameter to cause or contribute to an excursion above a narrative or numeric water quality criterion within an applicable water quality standard where a discharger demonstrates to the satisfaction of the permitting authority (based upon information provided in the permit application or other information deemed necessary by the permitting authority) that:

i. The facility withdraws 100 percent of the intake water containing the pollutant from the same body of water into which the discharge is made;

ii. The facility does not contribute any additional mass of the identified intake pollutant to its wastewater;

iii. The facility does not alter the identified intake pollutant chemically or physically in a manner that would cause adverse water quality impacts to occur that would not occur if the pollutants were left in-stream;

iv. The facility does not increase the identified intake pollutant concentration, as defined by the permitting authority, at the edge of the mixing zone, or at the point of discharge if a mixing zone is not allowed, as compared to the pollutant concentration in the intake water, unless the increased concentration does not cause or contribute to an excursion above an applicable water quality standard; and

v. The timing and location of the discharge would not cause adverse water quality impacts to occur that would not occur if the identified intake pollutant were left in-stream.

c. Upon a finding under section D.3.b of this procedure that a pollutant in the ***15422** discharge does not cause, have the reasonable potential to cause, or contribute to an excursion above an applicable water quality standard, the permitting authority is not required to include a WQBEL for the identified intake pollutant in the facility's permit, provided:

i. The NPDES permit fact sheet or statement of basis includes a specific determination that there is no reasonable potential for the discharge of an identified intake pollutant to cause or contribute to an excursion above an applicable narrative or numeric water quality criterion and references appropriate supporting documentation included in the administrative record;

ii. The permit requires all influent, effluent, and ambient monitoring necessary to demonstrate that the conditions in section D.3.b of this procedure are maintained during the permit term; and

iii. The permit contains a reopener clause authorizing modification or revocation and reissuance of the permit if new information indicates changes in the conditions in section D.3.b of this procedure.

d. Absent a finding under section D.3.b of this procedure that a pollutant in the discharge does not cause, have the reasonable potential to cause, or contribute to an excursion above an applicable water quality standard, the permitting authority shall use the procedures under sections 5.A through C of this procedure to determine whether a discharge causes, has the reasonable potential to cause, or contribute to an excursion above an applicable narrative or numeric water quality criterion.

E. Consideration of Intake Pollutants in Establishing WQBELs.

1. General. This section applies only when the concentration of the pollutant of concern upstream of the discharge (as determined using the provisions in procedure 3.B.9 of appendix F) exceeds the most stringent applicable water quality criterion for that pollutant.

2. The requirements of sections D.1-D.2 of this procedure shall also apply to this section.

3. Intake Pollutants from the Same Body of Water.

a. In cases where a facility meets the conditions in sections D.3.b.i and D.3.b.iii through D.3.b.v of this procedure, the permitting authority may establish effluent limitations allowing the facility to discharge a mass and concentration of the pollutant that are no greater than the mass and concentration of the pollutant identified in the facility's intake water (“no net addition limitations”). The permit shall specify how compliance with mass and concentration limitations shall be assessed. No permit may authorize “no net addition limitations” which are effective after March 23, 2007. After that date, WQBELs shall be established in accordance with procedure 5.F.2 of appendix F.

b. Where proper operation and maintenance of a facility's treatment system results in removal of a pollutant, the permitting authority may establish limitations that reflect the lower mass and/or concentration of the pollutant achieved by such treatment, taking into account the feasibility of establishing such limits.

c. For pollutants contained in intake water provided by a water system, the concentration of the intake pollutant shall be determined at the point where the raw water supply is removed from the same body of water, except that it shall be the point where the water enters the water supplier's distribution system where the water treatment system removes any of the identified pollutants from the raw water supply. Mass shall be determined by multiplying the concentration of the pollutant determined in accordance with this paragraph by the volume of the facility's intake flow received from the water system.

4. Intake Pollutants from a Different Body of Water. Where the pollutant in a facility's discharge originates from a water of the United States that is not the same body of water as the receiving water (as determined in accordance with section D.2 of this procedure), WQBELs shall be established based upon the most stringent applicable water quality criterion for that pollutant.

5. Multiple Sources of Intake Pollutants. Where a facility discharges intake pollutants that originate in part from the same body of water, and in part from a different body of water, the permitting authority may apply the procedures of sections E.3 and E.4 of this procedure to derive an effluent limitation reflecting the flow-weighted average of each source of the pollutant, provided that adequate monitoring to determine compliance can be established and is included in the permit.

F. Other Applicable Conditions.

1. In addition to the above procedures, effluent limitations shall be established to comply with all other applicable State, Tribal and Federal laws and regulations, including technology-based requirements and antidegradation policies.

2. Once the permitting authority has determined in accordance with this procedure that a WQBEL must be included in an NPDES permit, the permitting authority shall:

a. Rely upon the WLA established for the point source either as part of any TMDL prepared under procedure 3 of this appendix and approved by EPA pursuant to 40 CFR 130.7, or as part of an assessment and remediation plan developed and approved in accordance with procedure 3.A of this appendix, or, in the absence of such TMDL or plan, calculate WLAs for the protection of acute and chronic aquatic life, wildlife and human health consistent with the provisions referenced in section A.1 of this procedure for developing preliminary wasteload allocations, and

b. Develop effluent limitations consistent with these WLAs in accordance with existing State or Tribal procedures for converting WLAs into WQBELs.

3. When determining whether WQBELs are necessary, information from chemical-specific, whole effluent toxicity and biological assessments shall be considered independently.

4. If the geometric mean of a pollutant in fish tissue samples collected from a waterbody exceeds the tissue basis of a Tier I criterion or Tier II value, after consideration of the variability of the pollutant's bioconcentration and bioaccumulation in fish, each facility that discharges detectable levels of such pollutant to that water has the reasonable potential to cause or contribute to an excursion above a Tier I criteria or a Tier II value and the permitting authority shall establish a WQBEL for such pollutant in the NPDES permit for such facility.

Procedure 6: Whole Effluent Toxicity Requirements

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) procedure 6 of appendix F of part 132.

The following definitions apply to this part:

Acute toxic unit (TU_a). $100/LC_{50}$ where the LC_{50} is expressed as a percent effluent in the test medium of an acute whole effluent toxicity (WET) test that is statistically or graphically estimated to be lethal to 50 percent of the test organisms.

Chronic toxic unit (TU_c). 100/NOEC or $100/IC_{25}$, where the NOEC and IC_{25} are expressed as a percent effluent in the test medium.

Inhibition concentration 25 (IC_{25}). the toxicant concentration that would cause a 25 percent reduction in a non-quantal biological measurement for the test population. For example, the IC_{25} is the concentration of toxicant that would cause a 25 percent reduction in mean young per female or in growth for the test population.

No observed effect concentration (NOEC). The highest concentration of toxicant to which organisms are exposed in a full life-cycle or partial life-cycle (short-term) test, that causes no observable adverse effects on the test organisms (i.e., the highest concentration of toxicant in which the values for the observed responses are not statistically significantly different from the controls).

A. Whole Effluent Toxicity Requirements. The Great Lakes States and Tribes shall adopt whole effluent toxicity provisions consistent with the following:

1. A numeric acute WET criterion of 0.3 acute toxic units (TU_a) measured pursuant to test methods in 40 CFR part 136, or a numeric interpretation of a narrative criterion establishing that 0.3 TU_a measured pursuant to test methods in 40 CFR part 136 is necessary to protect aquatic life from acute effects of WET. At the discretion of the permitting authority, the foregoing requirement shall not apply in an acute mixing zone that is sized in accordance with EPA-approved State and Tribal methods.

2. A numeric chronic WET criterion of one chronic toxicity unit (TU_c) measured pursuant to test methods in 40 CFR part 136, or a numeric interpretation of a narrative criterion establishing that one TU_c measured pursuant to test methods in 40 CFR part 136 is necessary to protect aquatic life from the chronic effects of WET. At the discretion of the permitting authority, the foregoing requirements shall not apply within a chronic mixing zone consistent with: (a) procedures 3.D.1 and 3.D.4, for discharges to the open of the Great Lakes (OWGL), inland ***15423** lakes and other waters of the Great Lakes System with no appreciable flow relative to their volume, or (b) procedure 3.E.5 for discharges to tributaries and connecting channels of the Great Lakes System.

B. WET Test Methods. All WET tests performed to implement or ascertain compliance with this procedure shall be performed in accordance with methods established in 40 CFR part 136.

C. Permit Conditions.

40 CFR § 122.44

1. Where a permitting authority determines pursuant to section D of this procedure that the WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards, the permitting authority:

a. Shall (except as provided in section C.1.e of this procedure) establish a water quality-based effluent limitation (WQBEL) or WQBELs for WET consistent with section C.1.b of this procedure;

b. Shall calculate WQBELs pursuant to section C.1.a. of this procedure to ensure attainment of the State's or Tribe's chronic WET criteria under receiving water flow conditions described in procedures 3.E.1.a (or where applicable, with procedure 3.E.1.e) for Great Lakes System tributaries and connecting channels, and with mixing zones no larger than allowed pursuant to section A.2. of this procedure. Shall calculate WQBELs to ensure attainment of the State's or Tribe's acute WET criteria under receiving water flow conditions described in procedure 3.E.1.b (or where applicable, with procedure 3.E.1.e) for Great Lakes System

tributaries and connecting channels, with an allowance for mixing zones no greater than specified pursuant to section A.1 of this procedure.

c. May specify in the NPDES permit the conditions under which a permittee would be required to perform a toxicity reduction evaluation.

d. May allow with respect to any WQBEL established pursuant to section C.1.a of this procedure an appropriate schedule of compliance consistent with procedure 9 of appendix F; and

e. May decide on a case-by-case basis that a WQBEL for WET is not necessary if the State's or Tribe's water quality standards do not contain a numeric criterion for WET, and the permitting authority demonstrates in accordance with 40 CFR 122.44(d)(1)(v) that chemical-specific effluent limits are sufficient to ensure compliance with applicable criteria.

2. Where a permitting authority lacks sufficient information to determine pursuant to section D of this procedure whether the WET of an effluent is or may be discharged at levels that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards, then the permitting authority should consider including in the NPDES permit appropriate conditions to require generation of additional data and to control toxicity if found, such as:

a. WET testing requirements to generate the data needed to adequately characterize the toxicity of the effluent to aquatic life;

b. Language requiring a permit reopener clause to establish WET limits if any toxicity testing data required pursuant to section C.2.a of this procedure indicate that the WET of an effluent is or may be discharged at levels that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards.
40 CFR § 122.44
3. Where sufficient data are available for a permitting authority to determine pursuant to section D of this procedure that the WET of an effluent neither is nor may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards, the permitting authority may include conditions and limitations described in section C.2 of this procedure at its discretion.

D. Reasonable Potential Determinations. The permitting authority shall take into account the factors described in 40 CFR 122.44(d)(1)(ii) and, where representative facility-specific WET effluent data are available, apply the following requirements in determining whether the WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards.

1. The permitting authority shall characterize the toxicity of the discharge by:

a. Either averaging or using the maximum of acute toxicity values collected within the same day for each species to represent one daily value. The maximum of all daily values for the most sensitive species tested is used for reasonable potential determinations;

b. Either averaging or using the maximum of chronic toxicity values collected within the same calendar month for each species to represent one monthly value. The maximum of such values, for the most sensitive species tested, is used for reasonable potential determinations:

c. Estimating the toxicity values for the missing endpoint using a default acute-chronic ratio (ACR) of 10, when data exist for either acute WET or chronic WET, but not for both endpoints.

2. The WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric acute WET criterion or numeric interpretation of a narrative criterion within a State's or Tribe's water quality standards, when effluent-specific information demonstrates that:

(TU_a effluent) (B) (effluent flow/(Qad+effluent flow))>AC

Where TU_a effluent is the maximum measured acute toxicity of 100 percent effluent determined pursuant to section D.1.a. of this procedure, B is the multiplying factor taken from Table F6-1 of this procedure to convert the highest measured effluent toxicity value to the estimated 95th percentile toxicity value for the discharge, effluent flow is the same effluent flow used to calculate the preliminary wasteload allocations (WLAs) for individual pollutants to meet the acute criteria and values for those pollutants, AC is the numeric acute WET criterion or numeric interpretation of a narrative criterion established pursuant to section A.1 of this procedure and expressed in TU_a, and Qad is the amount of the receiving water available for dilution calculated using: (i) the specified design flow(s) for tributaries and connecting channels in section C.1.b of this procedure, or where appropriate procedure 3.E.1.e of appendix F, and using EPA-approved State and Tribal procedures for establishing acute mixing zones in tributaries and connecting channels, or (ii) the EPA-approved State and Tribal procedures for establishing acute mixing zones in OWGLs. Where there are less than 10 individual WET tests, the multiplying factor taken from Table F6-1 of this procedure shall be based on a coefficient of variation (CV) or 0.6. Where there are 10 or more individual WET tests, the multiplying factor taken from Table F6-1 shall be based on a CV calculated as the standard deviation of the acute toxicity values found in the WET tests divided by the arithmetic mean of those toxicity values.

3. The WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric chronic WET criterion or numeric interpretation of a narrative criterion within a State's or Tribe's water quality standards, when effluent-specific information demonstrates that:

(TU_c effluent) (B) (effluent flow/Qad+effluent flow))>CC

Where TU_c effluent is the maximum measured chronic toxicity value of 100 percent effluent determined in accordance with section D.1.b. of this procedure, B is the multiplying factor taken from Table F6-1 of this procedure, effluent flow is the same effluent flow used to calculate the preliminary WLAs for individual pollutants to meet the chronic criteria and values for those pollutants, CC is the numeric chronic WET criterion or numeric interpretation of a narrative criterion established pursuant to section A.2 of this procedure and expressed in TU_c, and Qad is the amount of the receiving water available for dilution calculated using: (i) the design flow(s) for tributaries and connecting channels specified in procedure 3.E.1.a of appendix F, and where appropriate procedure 3.E.1.e of appendix F, and in accordance with the provisions of procedure 3.E.5 for chronic mixing zones, or (ii) procedures 3.D.1 and 3.D.4 for discharges to the OWGLs. Where there are less than 10 individual WET tests, the multiplying factor taken from Table F6-1 of this procedure shall be based on a CV of 0.6. Where there are 10 more individual WET tests, the multiplying factor taken from Table F6-1 of this procedure shall be based on a CV calculated as the standard deviation of the WET tests divided by the arithmetic mean of the WET tests.

Table F6-1.— Reasonable Potential Multiplying Factors: 95% Confidence Level and 95% Probability Basis

Number of Samples	Coefficient of variation																			
0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.9	2.0		
1	1.4	1.9	2.6	3.6	4.7	6.2	8.0	10.1	12.6	15.5	18.7	22.3	26.4	30.8	35.6	40.7	46.2	52.1	58.4	64.9
2	1.3	1.6	2.0	2.5	3.1	3.8	4.6	5.4	6.4	7.4	8.5	9.7	10.9	12.2	13.6	15.0	16.4	17.9	19.5	21.1

3	1.2	1.5	1.8	2.1	2.5	3.0	3.5	4.0	4.6	5.2	5.8	6.5	7.2	7.9	8.6	9.3	10.0	10.8	11.5	12.3
4	1.2	1.4	1.7	1.9	2.2	2.6	2.9	3.3	3.7	4.2	4.6	5.0	5.5	6.0	6.4	6.9	7.4	7.8	8.3	8.8
5	1.2	1.4	1.6	1.8	2.1	2.3	2.6	2.9	3.2	3.6	3.9	4.2	4.5	4.9	5.2	5.6	5.9	6.2	6.6	6.9
6	1.1	1.3	1.5	1.7	1.9	2.1	2.4	2.6	2.9	3.1	3.4	3.7	3.9	4.2	4.5	4.7	5.0	5.2	5.5	5.7
7	1.1	1.3	1.4	1.6	1.8	2.0	2.2	2.4	2.6	2.8	3.1	3.3	3.5	3.7	3.9	4.1	4.3	4.5	4.7	4.9
8	1.1	1.3	1.4	1.6	1.7	1.9	2.1	2.3	2.4	2.6	2.8	3.0	3.2	3.3	3.5	3.7	3.9	4.0	4.2	4.3
9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1	3.2	3.4	3.5	3.6	3.8	3.9
10	1.1	1.2	1.3	1.5	1.6	1.7	1.9	2.0	2.2	2.3	2.4	2.6	2.7	2.8	3.0	3.1	3.2	3.3	3.4	3.6
11	1.1	1.2	1.3	1.4	1.6	1.7	1.8	1.9	2.1	2.2	2.3	2.4	2.5	2.7	2.8	2.9	3.0	3.1	3.2	3.3
12	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	3.0	3.0
13	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.5	2.6	2.7	2.8	2.9
14	1.1	1.2	1.3	1.4	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.3	2.4	2.5	2.6	2.6	2.7
15	1.1	1.2	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.8	1.9	2.0	2.1	2.2	2.2	2.3	2.4	2.4	2.5	2.5
16	1.1	1.1	1.2	1.3	1.4	1.5	1.6	1.6	1.7	1.8	1.9	1.9	2.0	2.1	2.1	2.2	2.3	2.3	2.4	2.4
17	1.1	1.1	1.2	1.3	1.4	1.4	1.5	1.6	1.7	1.7	1.8	1.9	1.9	2.0	2.0	2.1	2.2	2.2	2.3	2.3
18	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.6	1.6	1.7	1.7	1.8	1.9	1.9	2.0	2.0	2.1	2.1	2.2	2.2
19	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.5	1.6	1.6	1.7	1.8	1.8	1.9	1.9	2.0	2.0	2.0	2.1	2.1
20	1.1	1.1	1.2	1.2	1.3	1.4	1.4	1.5	1.5	1.6	1.6	1.7	1.7	1.8	1.8	1.9	1.9	2.0	2.0	2.0
30	1.0	1.1	1.1	1.1	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5
40	1.0	1.0	1.1	1.1	1.1	1.1	1.1	1.1	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.3	1.3
50	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
60	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
70	1.0	1.0	1.0	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
80	1.0	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8
90	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
100	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.7	0.7	0.7

***15424 Procedure 7: Loading Limits**

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure.

Whenever a water quality-based effluent limitation (WQBEL) is developed, the WQBEL shall be expressed as both a concentration value and a corresponding mass loading rate.

A. Both mass and concentration limits shall be based on the same permit averaging periods such as daily, weekly, or monthly averages, or in other appropriate permit averaging periods.

B. The mass loading rates shall be calculated using effluent flow rates that are consistent with those used in establishing the WQBELs expressed in concentration.

Procedure 8: Water Quality-based Effluent Limitations Below the Quantification Level

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure.

When a water quality-based effluent limitation (WQBEL) for a pollutant is calculated to be less than the quantification level:

A. Permit Limits. The permitting authority shall designate as the limit in the NPDES permit the WQBEL exactly as calculated.

B. Analytical Method and Quantification Level.

1. The permitting authority shall specify in the permit the most sensitive, applicable, analytical method, specified in or approved under 40 CFR part 136, or other appropriate method if one is not available under 40 CFR part 136, to be used to monitor for the presence and amount in an effluent of the pollutant for which the WQBEL is established; and shall specify in accordance with section B.2 of this procedure, the quantification level that can be achieved by use of the specified analytical method.

2. The quantification level shall be the minimum level (ML) specified in or approved under 40 CFR part 136 for the method for that pollutant. If no such ML exists, or if the method is not specified or approved under 40 CFR part 136, the quantification level shall be the lowest quantifiable level practicable. The permitting authority may specify a higher quantification level if the permittee demonstrates that a higher quantification level is appropriate because of effluent-specific matrix interference.

3. The permit shall state that, for the purpose of compliance assessment, the analytical method specified in the permit shall be used to monitor the amount of pollutant in an effluent down to the quantification level, provided that the analyst has complied with the specified quality assurance/quality control procedures in the relevant method.

4. The permitting authority shall use applicable State and Tribal procedures to average and account for monitoring data. The permitting authority may specify in the permit the value to be used to interpret sample values below the quantification level.

C. Special Conditions. The permit shall contain a reopener clause authorizing modification or revocation and reissuance of the permit if new information generated as a result of special conditions included in the permit indicates that presence of the pollutant in the discharge at levels above the WQBEL. Special conditions that may be included in the permit include, but are not limited to, fish tissue sampling, whole effluent toxicity (WET) tests, limits and/or monitoring requirements on internal waste streams, and monitoring for surrogate parameters. Data generated as a result of special conditions can be used to reopen the permit to establish more stringent effluent limits or conditions, if necessary.

D. Pollutant Minimization Program. The permitting authority shall include a condition in the permit requiring the permittee to develop and conduct a pollutant minimization program for each pollutant with a WQBEL below the quantification level. The goal of the pollutant minimization program shall be to reduce all potential sources of the pollutant to maintain the effluent at or below the WQBEL. In addition, States and Tribes may consider cost-effectiveness when establishing the requirements of a PMP. The pollutant minimization program shall include, but is not limited to, the following:

1. An annual review and semi-annual monitoring of potential sources of the pollutant, which may include fish tissue monitoring and other bio-uptake sampling;

2. Quarterly monitoring for the pollutant in the influent to the wastewater treatment system;

3. Submittal of a control strategy designed to proceed toward the goal of maintaining all sources of the pollutant to the wastewater collection system below the WQBEL;

4. When the sources of the pollutant are discovered, appropriate cost-effective control ***15425** measures shall be implemented, consistent with the control strategy; and

5. An annual status report that shall be sent to the permitting authority including:

a. All minimization program monitoring results for the previous year;

b. A list of potential sources of the pollutant; and

c. A summary of all action taken to reduce or eliminate the identified sources of the pollutant.
40 CFR § 122.44
6. Any information generated as a result of procedure 8.D can be used to support a request for subsequent permit modifications, including revisions to (e.g., more or less frequent monitoring), or removal of the requirements of procedure 8.D, consistent with 40 CFR 122.44, 122.62 and 122.63.

Procedure 9: Compliance Schedules
The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) procedure 9 of appendix F of part 132.

A. Limitations for New Great Lakes Dischargers. When a permit issued on or after March 23, 1997 to a new Great Lakes discharger (defined in Part 132.2) contains a water quality-based effluent limitation (WQBEL), the permittee shall comply with such a limitation upon the commencement of the discharge.

B. Limitations for Existing Great Lakes Dischargers.

1. Any existing permit that is reissued or modified on or after March 23, 1997 to contain a new or more restrictive WQBEL may allow a reasonable period of time, up to five years from the date of permit issuance or modification, for the permittee to comply with that limit, provided that the Tier I criterion or whole effluent toxicity (WET) criterion was adopted (or, in the case of a narrative criterion, Tier II value, or Tier I criterion derived pursuant to the methodology in appendix A of part 132, was newly derived) after July 1, 1977.

2. When the compliance schedule established under paragraph 1 goes beyond the term of the permit, an interim permit limit effective upon the expiration date shall be included in the permit and addressed in the permit's fact sheet or statement of basis. The administrative record for the permit shall reflect the final limit and its compliance date.

3. If a permit establishes a schedule of compliance under paragraph 1 which exceeds one year from the date of permit issuance or modification, the schedule shall set forth interim requirements and dates for their achievement. The time between such interim dates may not exceed one year. If the time necessary for completion of any interim requirement is more than one year and is not readily divisible into stages for completion, the permit shall require, at a minimum, specified dates for annual submission of progress reports on the status of any interim requirements.

C. Delayed Effectiveness of Tier II Limitations for Existing Great Lakes Discharges.

1. Whenever a limit (calculated in accordance with Procedure 3) based upon a Tier II value is included in a reissued or modified permit for an existing Great Lakes discharger, the permit may provide a reasonable period of time, up to two years, in which to provide additional studies necessary to develop a Tier I criterion or to modify the Tier II value. In such cases, the permit shall require compliance with the Tier II limitation within a reasonable period of time, no later than five years after permit issuance or modification, and contain a reopener clause.

2. The reopener clause shall authorize permit modifications if specified studies have been completed by the permittee or provided by a third-party during the time allowed to conduct the specified studies, and the permittee or a third-party demonstrates, through such studies, that a revised limit is appropriate. Such a revised limit shall be incorporated through a permit modification and a reasonable time period, up to five years, shall be allowed for compliance. If incorporated prior to the compliance date of the original Tier II limitation, any such revised limit shall not be considered less-stringent for purposes of the anti-backsliding provisions of section 402(o) of the Clean Water Act.

3. If the specified studies have been completed and do not demonstrate that a revised limit is appropriate, the permitting authority may provide a reasonable additional period of time, not to exceed five years with which to achieve compliance with the original effluent limitation.

4. Where a permit is modified to include new or more stringent limitations, on a date within five years of the permit expiration date, such compliance schedules may extend beyond the term of a permit consistent with section B.2 of this procedure.

5. If future studies (other than those conducted under paragraphs 1, 2, or 3 above) result in a Tier II value being changed to a less stringent Tier II value or Tier I criterion, after the effective date of a Tier II-based limit, the existing Tier II-based limit may be revised to be less stringent if:

(a) It complies with sections 402(o) (2) and (3) of the CWA; or,

(b) In non-attainment waters, where the existing Tier II limit was based on procedure 3, the cumulative effect of revised effluent limitation based on procedure 3 of this appendix will assure compliance with water quality standards; or,

(c) In attained waters, the revised effluent limitation complies with the State or Tribes' antidegradation policy and procedures.

[FR Doc. 95-6671 Filed 3-22-95; 8:45 am]

BILLING CODE 6560-50-P

Footnotes

tr a CMC=CMC.

d $^{tr\ d}$b CMC=(CMC) CF. The CMC shall be rounded to two significant digits.

c CMC should be considered free cyanide as CN.

t d CMC=CMC.

Notes:

The term “n/a” means not applicable.

CMC is Criterion Maximum Concentration.

tr FNCMC is the CMC expressed as total recoverable.

d FNCMC is the CMC expressed as a dissolved concentration.

t FNCMC is the CMC expressed as a total concentration.

tr $_{AA}$a CMC=exp { m [ln (hardness)]+b}.

d [tr d]b CMC=(CMC) CF. The CMC shall be rounded to two significant digits.

t [AA t]c CMC=exp m { [pH]+b}. The CMC shall be rounded to two significant digits.

Notes:

The term “exp” represents the base e exponential function.

The term “n/a” means not applicable.

CMC is Criterion Maximum Concentration.

tr FNCMC is the CMC expressed as total recoverable.

d FNCMC is the CMC expressed as a dissolved concentration.

t FNCMC is the CMC expressed as a total concentration.

tr a CCC=CCC.

d [tr d]b CCC=(CCC) CF. The CCC shall be rounded to two significant digits.

c CCC should be considered free cyanide as CN.

t d CCC=CCC.

Notes:

The term “n/a” means not applicable.

CCC is Criterion Continuous Concentration.

tr FNCCC is the CCC expressed as total recoverable.

d FNCCC is the CCC expressed as a dissolved concentration.

t FNCCC is the CCC expressed as a total concentration.

tr [cc]a CCC=exp {m[ln (hardness)]+b}.

[d tr d]b CCC=(CCC) (CF). The CCC shall be rounded to two significant digits.

t [AA t]c CMC=exp {m[pH]+b}. The CMC shall be rounded to two significant digits.

Notes:

The term “exp” represents the base e exponential function.

The term “n/a” means not applicable.

CCC is Criterion Continuous Concentration.

tr FNCCC is the CCC expressed as total recoverable.

d FNCCC is the CCC expressed as a dissolved concentration.

t FNCCC is the CCC expressed as a total concentration.

1 Includes methylmercury.

1 The FCMs for trophic level 3 are the geometric mean of the FCMs for sculpin and alewife.

Note: TL3=trophic level three fish; TL4=trophic level four fish; PB =piscivorous birds; Other=non-aquatic birds and mammals.

End of Document

ENVIRONMENTAL PROTECTION AGENCY

[FRL 1623-3]

Water Quality Criteria Documents; Availability

AGENCY: Environmental Protection Agency.

ACTION: Notice of Water Quality Criteria Documents.

SUMMARY: EPA announces the availability and provides summaries of water quality criteria documents for 64 toxic pollutants or pollutant categories. These criteria are published pursuant to section 304(a)(1) of the Clean Water Act.

AVAILABILITY OF DOCUMENTS: Summaries of both aquatic-based and health-based criteria from the documents are published below. Copies of the complete documents for individual pollutants may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, (703-487-4650). A list of the NTIS publication order numbers for all 64 criteria documents is published below. These documents are also available for public inspection and copying during normal business hours at: Public Information Reference Unit, U.S. Environmental Protection Agency, Room 2404 (rear), 401 M St., S.W., Washington, D.C. 20460. As provided in 40 CFR Part 2, a reasonable fee may be charged for copying services. Copies of these documents are also available for review in the EPA Regional Office libraries.

Copies of the documents are not available from the EPA office listed below. Requests sent to that office will be forwarded to NTIS or returned to the sender.

1. Acenaphthene, PB81-117269.
2. Acrolein, PB81-117277.
3. Acrylonitrile, PB81-117285.
4. Aldrin/Dieldrin, PB81-117301.
5. Antimony, PB81-117319.
6. Arsenic, PB81-117327.
7. Asbestos, PB81-117335.
8. Benzene, PB81-117293.
9. Benzidine, PB81-117343.
10. Beryllium, PB81-117350.
11. Cadmium, PB81-117368.
12. Carbon Tetrachloride, PB81-117376.
13. Chlordane, PB81-117384.
14. Chlorinated benzenes, PB81-117392.
15. Chlorinated ethanes, PB81-117400.
16. Chloroalkyl ethers, PB81-117418.
17. Chlorinated naphthalene, PB81-117426.
18. Chlorinated phenols, PB81-117434.
19. Chloroform, PB81-117442.
20. 2-chlorophenol, PB81-117459.
21. Chromium, PB81-117467.
22. Copper, PB81-117475.
23. Cyanides, PB81-117483.
24. DDT, PB81-117491.
25. Dichlorobenzenes, PB81-117509.
26. Dichlorobenzidine, PB81-117517.
27. Dichloroethylenes, PB81-117525.
28. 2,4-dichlorophenol, PB81-117533.
29. Dichloropropanes/propenes, PB81-117541.
30. 2,4-dimethylphenol, PB81-117558.
31. Dinitrotoluene, PB81-117566.
32. Diphenylhydrazine, PB81-117731.
33. Endosulfan, PB81-117574.
34. Endrin, PB81-117582.
35. Ethylbenzene, PB81-117590.
36. Fluoranthene, PB81-117608.
37. Haloethers, PB81-117616.
38. Halomethanes, PB81-117624.
39. Heptachlor, PB81-117632.
40. Hexachlorobutadiene, PB81-117640.
41. Hexachlorocyclohexane, PB81-117657.
42. Hexachlorocyclopentadiene, PB81-117665.
43. Isophorone, PB81-117673.
44. Lead, PB81-117681.
45. Mercury, PB81-117699.
46. Naphthalene, PB81-117707.
47. Nickel, PB81-117715.
48. Nitrobenzene, PB81-117723.
49. Nitrophenols, PB81-117749.
50. Nitrosamines, PB81-117756.
51. Pentachlorophenol, PB81-117764.
52. Phenol, PB81-117772.
53. Phthalate esters, PB81-117780.
54. Polychlorinated biphenyls (PCBs), PB81-117798.
55. Polynuclear aromatic hydrocarbons, PB81-117806.
56. Selenium, PB81-117814.
57. Silver, PB81-117822.
58. Tetrachloroethylene, PB81-117830.
59. Thallium, PB81-117848.
60. Toluene, PB81-117855.
61. Toxaphene, PB81-117863.
62. Trichloroethylene, PB81-117871.
63. Vinyl chloride, PB81-117889.
64. Zinc, PB81-117897.

FOR FURTHER INFORMATION CONTACT: Dr. Frank Gostomski, Criteria and Standards Division (WH-585), United States Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, (202) 245-3042.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to section 304(a)(1) of the Clean Water Act, 33 U.S.C. 1314(a)(1), EPA is required to periodically review and publish criteria for water quality accurately reflecting the latest scientific knowledge:

(A) on the kind and extent of all identifiable effects on health and welfare including, but not limited to, plankton, fish, shellfish, wildlife, plant life, shorelines, beaches, esthetics, and recreation which may be expected from the presence of pollutants in any body of water, including groundwater, (B) on the concentration and dispersal of pollutants, or their byproducts, through biological, physical, and chemical processes, and (C) on the effects of pollutants on biological community diversity, productivity, and stability, including information on the factors affecting rates of eutrophication and rates of organic and inorganic sedimentation for varying types of receiving waters.

EPA is today announcing the availability of criteria documents for 64 of the 65 pollutants designated as toxic under section 307(a)(1) of the Act. The document on TCDD (Dioxin) will be published within the next month after review of recent studies. Criteria for the section 307(a)(1) toxic pollutants being published today will replace the criteria for those same pollutants found in the EPA publication, *Quality Criteria for Water*, (the "Red Book.") Criteria for all other pollutants and water constituents found in the "Red Book" remain valid. The criteria published today have been derived using revised methodologies for determining pollutant concentrations that will, when not exceeded, reasonably protect human health and aquatic life. Draft criteria documents were made available for public comment (44 FR 15926, March 15, 1979, 44 FR 43660, July 25, 1979, 44 FR 56628, October 1, 1979). These final criteria have been derived after consideration of all comments received.

These criteria documents are also issued in satisfaction of the Settlement Agreement in *Natural Resources Defense Council, et al.* v. *Train*, 8 E.R.C. 2120 (1976), modified, 12 E.R.C. 1833 (D.D.C. 1979). Pursuant to paragraph 11 of that agreement, EPA is required to publish criteria documents for the 65 pollutants which Congress, in the 1977 amendments to the Act, designated as toxic under section 307(a)(1). These documents contain recommended maximum permissible pollutant concentrations consistent with the protection of aquatic organisms, human health, and some recreational activities. Although paragraph 11 imposes certain obligations on the Agency, it does not create additional authority.

The Development of Water Quality Criteria

Section 304(a)(1) criteria contain two essential types of information: (1) discussions of available scientific data on the effects of pollutants on public health and welfare, aquatic life and recreation, and (2) quantitative concentrations or qualitative assessments of the pollutants in water which will generally ensure water

section 304(a)(1) criteria codified in the "Red Book." Presumptive applicability meant that a State had to adopt a criterion for a particular water quality parameter at least as stringent as the recommendation in the Red Book unless the State was able to justify a less stringent criterion based on: natural background conditions, more recent scientific evidence, or local, site-specific information. EPA is rescinding the policy of presumptive applicability because it has proven to be too inflexible in actual practice.

Although the section 304(a)(1) criteria represent a reasonable estimate of pollutant concentrations consistent with the maintenance of designated water uses, States may appropriately modify these values to reflect local conditions. In certain circumstances, the criteria may not accurately reflect the toxicity of a pollutant because of the effect of local water quality characteristics or varying sensitivities of local populations. For example, in some cases, ecosystem adaptation may enable a viable, balanced aquatic population to exist in waters with high natural background levels of certain pollutants. Similarly, certain compounds may be more or less toxic in some waters because of differences in alkalinity, temperature, hardness, and other factors.

Methods for adjusting the section 304(a)(1) criteria to reflect these local differences are discussed below.

Relationship of Section 304(a)(1) Criteria to Designated Water Uses:

The criteria published today can be used to support the designated uses which are generally found in State standards. The following section discusses the relationship between the criteria and individual use classifications. Where a water body is designated for more than one use, criteria necessary to protect the most sensitive use should be applied.

1. *Recreation:* Recreational uses of water include such activities as swimming, wading, boating and fishing. Although insufficient data exist on the effects of toxic pollutants resulting from exposure through such primary contact as swimming, section 304(a)(1) criteria based on human health effects may be used to support this designated use where fishing is included in the State definition of "recreation." In this situation only the portion of the criterion based on fish consumption should be used.

2. *Protection and Propagation of Fish and Other Aquatic Life:* The section 304(a)(1) criteria based on toxicity to aquatic life may be used directly to support this designated use.

3. *Agricultural and Industrial Uses:* The section 304(a)(1) criteria were not specifically developed to reflect the impact of pollutants on agricultural and industrial uses. However, the criteria developed for human health and aquatic life are sufficiently stringent to protect these other uses. States may establish criteria specifically designed to protect these uses.

4. *Public Water Supply:* The drinking water exposure component of the human health effects criteria can apply directly to this use classification or may be appropriately modified depending upon whether the specific water supply system falls within the auspices of the Safe Drinking Water Act's (SDWA) regulatory control, and the type and level of treatment imposed upon the supply before delivery to the consumer. The SDWA controls the presence of toxic pollutants in finished ("end-of-tap") drinking water. A brief description of relevant sections of this Act is necessary to explain how the SDWA will work in conjunction with section 304(a)(1) criteria in protecting human health from the effects of toxics due to consumption of water.

Pursuant to section 1412 of the SDWA, EPA has promulgated "National Interim Primary Drinking Water Standards" for certain organic and inorganic substances. These standards establish "maximum contaminant levels" ("MCLs") which specify the maximum permissible level of a contaminant in water which may be delivered to a user of a public water system now defined as serving a minimum of 25 people. MCLs are established based on consideration of a range of factors including not only the health effects of the contaminants but also technological and economic feasibility of the contaminants' removal from the supply. EPA is required to establish revised primary drinking water regulations based on the effects of a contaminant on human health, and include treatment capability, monitoring availability, and costs. Under Section 1401(1)(D)(i) of the SDWA, EPA is also allowed to establish the minimum quality criteria for water which may be taken into a public water supply system.

Section 304(a)(1) criteria provide estimates of pollutant concentrations protective of human health, but do not consider treatment technology, costs and other feasibility factors. The section 304(a)(1) criteria also include fish bioaccumulation and consumption factors in addition to direct human drinking water intake. These numbers were not developed to serve as "end of tap" drinking water standards, and they have no regulatory significance under the SDWA. Drinking water standards are established based on considerations, including technological and economic feasibility, not relevant to section 304(a)(1) criteria. Section 304(a)(1) criteria may be analogous to the recommended maximum contaminant levels (RMCLs) under section 1412(b)(1)(B) of the SDWA in which, based upon a report from the National Academy of Sciences, the Administrator should set target levels for contaminants in drinking water at which "no known or anticipated adverse effects occur and which allows an adequate margin of safety". RMCLs do not take treatment, cost, and other feasibility factors into consideration. Section 304(a)(1) criteria are, in concept, related to the health-based goals specified in the RMCLs. Specific mandates of the SDWA such as the consideration of multi-media exposure, as well as different methods for setting maximum contaminant levels under the two Acts, may result in differences between the two numbers.

MCLs of the SDWA, where they exist, control toxic chemicals in finished drinking water. However, because of variations in treatment and the fact that only a relatively small number of MCLs have been developed, ambient water criteria may be used by the States as a supplement to SDWA regulations. States will have the option of applying MCLs, section 304(a)(1) human health effects criteria, modified section 304(a)(1) criteria or controls more stringent than these three to protect against the effects of toxic pollutants by ingestion from drinking water.

For untreated drinking water supplies, States may control toxics in the ambient water through either use of MCLs (if they exist for the pollutants of concern), section 304(a)(1) human health effects criteria, or a more strigent contaminant level than the former two options.

For treated drinking water supplies serving less than 25 people, States may choose toxics control through application of MCLs (if they exist for the pollutants of concern and are attainable by the type of treatment) in the finished drinking water. States also have the options to control toxics in the ambient water by choosing section 304(a)(1) criteria, adjusted section 304(a)(1) criteria resulting from the reduction of the direct drinking water exposure component in the criteria calculation to the extent that the treatment procedure reduces the level of pollutants, or a more stringent contaminant level than the former three options.

For treated drinking water supplies serving 25 people or greater, States *must* control toxics down to levels at least as stringent as MCLs (where they exist for

probably some untested species, will have sensitivities below the maximum value or the 24-hour average under some conditions and would be adversely affected if the highest allowable pollutant concentrations and the worst conditions existed for a long time. In actual practice, such a situation is not likely to occur and thus the aquatic community as a whole will normally be protected if the criteria are not exceeded. In any aquatic community there is a wide range of individual species sensitivities to the effects of toxic pollutants. A criterion adequate to protect the most susceptible life stage of the most sensitive species would in many cases be more stringent than necessary to protect the overall aquatic community.

The aquatic life criteria specify both maximum and 24-hour average values. The combination of the two values is designed to provide adequate protection of aquatic life and its uses from acute and chronic toxicity and bioconcentration without being as restrictive as a one-number criterion would have to be to provide the same amount of protection. A time period of 24 hours was chosen in order to ensure that concentrations not reach harmful levels for unacceptably long periods. Averaging for longer periods, such as a week or a month for example, could permit high concentrations to persist long enough to produce significant adverse effects. A 24-hour period was chosen instead of a slightly longer or shorter period in recognition of daily fluctuations in waste discharges and of the influence of daily cycles of sunlight and darkness and temperature on both pollutants and aquatic organisms.

The maximum value, which is derived from acute toxicity data, prevents significant risk of adverse impact to organisms exposed to concentrations above the 24-hour average. Merely specifying the average value over a specified time period is insufficient because concentrations of chemicals higher than the average value can kill or cause irreparable damage in short periods. Furthermore, for some chemicals the effect of intermittent high exposures is cumulative. It is therefore necessary to place an upper limit on pollutant concentrations to which aquatic organisms might be exposed. The two-number criterion is intended to describe the highest average ambient water concentration which will produce a water quality generally suited to the maintenance of aquatic life while restricting the extent and duration of the excursions over that average to levels which will not cause harm. The only way to assure the same degree of protection with a one-number criterion would be to use the 24-hour average as a concentration that is not to be exceeded at any time in any place.

Since some substances may be more toxic in freshwater than in saltwater, or vice versa, provision is made for deriving separate water quality criteria for freshwater and for saltwater for each substance. However, for some substances sufficient data may not be available to derive one or both of these criteria using the Guidelines.

Specific aquatic life criteria have not been developed for all of the 65 toxic pollutants. In those cases where there were insufficient data to allow the derivation of a criterion, narrative descriptions of apparent threshold levels for acute and/or chronic effects based on the available data are presented. These descriptions are intended to convey a sense of the degree of toxicity of the pollutant in the absence of a criterion recommendation.

Summary of the Aquatic Life Guidelines

The Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and its Uses were developed to describe an objective, internally consistent, and appropriate way of ensuring that water quality criteria for aquatic life would provide, on the average, a reasonable amount of protection without an unreasonable amount of overprotection or underprotection. The resulting criteria are not intended to provide 100 percent protection of all species and all uses of aquatic life all of the time, but they are intended to protect most species in a balanced, healthy aquatic community. The Guidelines are published as Appendix B of this Notice. Responses to public comments on these Guidelines are attached as Appendix D.

Minimum data requirements are identified in four areas: acute toxicity to animals (eight data points), chronic toxicity to animals (three data points), toxicity to plants, and residues. Guidance is also given for discarding poor quality data.

Data on acute toxicity are needed for a variety of fish and invertebrate species and are used to derive a Final Acute Value. By taking into account the number and relative sensitivities of the tested species, the Final Acute Value is designed to protect most, but not necessarily all, of the tested and untested species.

Data on chronic toxicity to animals can be used to derive a Final Chronic Value by two different means. If chronic values are available for a specified number and array of species, a final chronic value can be calculated directly. If not, an acute-chronic ratio is derived and then used with the Final Acute Value to obtain the Final Chronic Value.

The Final Plant Value is obtained by selecting the lowest plant toxicity value based on measured concentrations.

The Final Residue Value is intended to protect wildlife which consume aquatic organisms and the marketability of aquatic organisms. Protection of the marketability of aquatic organisms is, in actuality, protection of a use of that water body ("commercial fishery"). Two kinds of data are necessary to calculate the Final Residue Value: a bioconcentration factor (BCF) and a maximum permissible tissue concentration, which can be an FDA action level or can be the result of a chronic wildlife feeding study. For lipid soluble pollutants, the BCF is normalized for percent lipids and then the Final Residue Value is calculated by dividing the maximum permissible tissue concentration by the normalized BCF and by an appropriate percent lipid value. BCFs are normalized for percent lipids since the BCF measured for any individual aquatic species is generally proportional to the percent lipids in that species.

If sufficient data are available to demonstrate that one or more of the final values should be related to a water quality characteristic, such as salinity, hardness, or suspended solids, the final value(s) are expressed as a function of that characteristic.

After the four final values (Final Acute Value, Final Chronic Value, Final Plant Value, and Final Residue Value) have been obtained, the criterion is established with the Final Acute Value becoming the maximum value and the lowest of the other three values becoming the 24-hour average value. All of the data used to calculate the four final values and any additional pertinent information are then reviewed to determine if the criterion is reasonable. If sound scientific evidence indicates that the criterion should be raised or lowered, appropriate changes are made as necessary.

The present Guidelines have been revised from the earlier published versions (43 FR 21506, May 18, 1978; 43 FR 29028, July 5, 1978; 44 FR 15926, March 15, 1979). Details have been added in many places and the concept of a minimum data base has been incorporated. In addition, three adjustment factors and the species sensitivity factor have been deleted. These modifications were the result of the Agency's analysis of public comments and comments received from the Science Advisory Board on earlier

human epidemiology studies using the following basic exposure assumptions: a 70-kilogram male person (*Report of the Task Group on Reference Man*, International Commission for Radiation Protection, November 23, 1957) as the exposed individual; the average daily consumption of freshwater and estuarine fish and shellfish products equal to 6.5 grams/day; and the average ingestion of two liters/day of water (*Drinking Water and Health*, National Academy of Sciences, National Research Council, 1977). Criteria based on these assumptions are estimated to be protective of an adult male who experiences average exposure conditions.

Two basic methods were used to formulate health criteria, depending on whether the prominent adverse effect was cancer or other toxic manifestations. The following sections detail these methods.

Carcinogens

Extrapolation of cancer responses from high to low doses and subsequent risk estimation from animal data is performed using a linearized multi-stage model. This procedure is flexible enough to fit all monotonically-increasing dose response data, since it incorporates several adjustable parameters. The multi-stage model is a linear non-threshold model as was the "one-hit" model originally used in the proposed criteria documents. The linearized multi-stage model and its characteristics are described fully in Appendix C. The linear non-threshold concept has been endorsed by the four agencies in the Interagency Regulatory Liaison Group and is less likely to underestimate risk at the low doses typical of environmental exposure than other models that could be used. Because of the uncertainties associated with dose response, animal-to-human extrapolation and other unknown factors, because of the use of average exposure assumptions, and because of the serious public health consequences that could result if risk were underestimated, EPA believes that it is prudent to use conservative methods to estimate risk in the water quality criteria program. The linearized multistage model is more systematic and invokes fewer arbitrary assumptions than the "one-hit" procedure previously used.

It should be noted that extrapolation models provide estimates of risk since a variety of assumptions are built into any model. Models using widely different assumptions may produce estimates ranging over several orders of magnitude. Since there is at present no way to demonstrate the scientific validity of any model, the use of risk extrapolation models is a subject of debate in the scientific community. However, risk extrapolation is generally recognized as the only tool available at this time for estimating the magnitude of health hazards associated with non-threshold toxicants and has been endorsed by numerous Federal agencies and scientific organizations, including EPA's Carcinogen Assessment Group, the National Academy of Sciences, and the Interagency Regulatory Liaison Group as a useful means of assessing the risks of exposure to various carcinogenic pollutants.

Non-Carcinogens

Health criteria based on toxic effects of pollutants other than carcinogenicity are estimates of concentrations which are not expected to produce adverse effects in humans. They are based upon Acceptable Daily Intake (ADI) levels and are generally derived using no-observed-adverse-effect-level (NOAEL) data from animal studies although human data are used wherever available. The ADI is calculated using safety factors to account for uncertainties inherent in extrapolation from animal to man. In accordance with the National Research Council recommendations (*Drinking Water and Health*, National Academy of Sciences, National Research Council, 1977), safety factors of 10, 100, or 1,000 are used depending on the quality and quantity of data. In some instances extrapolations are made from inhalation studies or limits to approximate a human response from ingestion using the Stokinger-Woodward model (Journal of American Water Works Association, 1958). Calculations of criteria from ADIs are made using the standard exposure assumptions (2 liters of water, 6.5 grams of edible aquatic products, and an average body weight of 70 kg).

Dated: October 24, 1980.

Douglas M. Costle,

Administrator.

Appendix A—Summary of Water Quality Criteria

Acenaphthene

Freshwater Aquatic Life

The available data for acenaphthene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 1,700 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of acenaphthene to sensitive freshwater aquatic animals but toxicity to freshwater algae occur at concentrations as low as 520 μg/l.

Saltwater Aquatic Life

The available data for acenaphthene indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 970 and 710 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. Toxicity to algae occurs at concentrations as low as 500 μg/l.

Human Health

Sufficient data is not available for acenaphthene to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 20 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Acrolein

Freshwater Aquatic Life

The available data for acrolein indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 68 and 21 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for acrolein indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 55 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of acrolein to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of acrolein ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 320 μg/l.

For the protection of human health from the toxic properties of acrolein ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 780 μg/l.

Acrylonitrile

Freshwater Aquatic Life

The available data for acrylonitrile indicate that acute toxicity to freshwater aquatic life occurs at concentrations as

estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 22 ng/l, 2.2 ng/l, and .22 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 175 ng/l, 17.5 ng/l, and 1.75 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Asbestos

Freshwater Aquatic Life

No freshwater organisms have been tested with any asbestiform mineral and no statement can be made concerning acute or chronic toxicity.

Saltwater Aquatic Life

No saltwater organisms have been tested with any asbestiform mineral and no statement can be made concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of asbestos through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 300,000 fibers/1,30,000 fibers/1, and 3,000 fibers/1, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Benzene

Freshwater Aquatic Life

The available data for benzene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 5,300 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of benzene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for benzene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 5,100 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of benzene to sensitive saltwater aquatic life, but adverse effects occur at concentrations as low as 700 μg/l with a fish species exposed for 168 days.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of benzene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 6.6 μg/l, .66 μg/l, and .066 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 400 μg/l, 40.0 μg/l, and 4.0 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Benzidine

Freshwater Aquatic Life

The available data for benzidine indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 2,500 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of benzidine to sensitive freshwater aquatic life.

Saltwater Aquatic Life

No saltwater organisms have been tested with benzidine and no statement can be made concerning acute and chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of benzidine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 1.2 ng/1, .12 ng/1, and .01 ng/1, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 5.3 ng/1, .53 ng/1, and .05 ng/1, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Beryllium

Freshwater Aquatic Life

The available data for beryllium indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 130 and 5.3 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. Hardness has a substantial effect on acute toxicity.

Salt water Aquatic Life

The limited saltwater data base available for beryllium does not permit any statement concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of beryllium through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 37 ng/l, 3.7 ng/l, and .37 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 641 ng/l, 64.1 ng/l, and 6.41 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Cadmium

Freshwater Aquatic Life

For total recoverable cadmium the criterion (in μg/l) to protect freshwater aquatic life as derived using the Guidelines is the numerical value given

this time due to the insufficiency in the available data for trichlorobenzene.

For comparison purposes, two approaches were used to derive criterion levels for monochlorobenzene. Based on available toxicity data, for the protection of public health, the derived level is 488 μg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 20 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no demonstrated relationship to potential adverse human health effects.

Chlorinated Ethanes

Freshwater Aquatic Life

The available freshwater data for chlorinated ethanes indicate that toxicity increases greatly with increasing chlorination, and that acute toxicity occurs at concentrations as low as 118,000 μg/l for 1,2-dichloroethane, 18,000 μg/l for two trichloroethanes, 9,320 μg/l for two tetrachloroethanes, 7,240 μg/l for pentachloroethane, and 980 μg/l for hexachloroethane. Chronic toxicity occurs at concentrations as low as 20,000 μg/l for 1,2-dichloroethane, 3400 μg/l for 1,1,2-trichloroethane, 2,400 μg/l for 1,1,2,2,-tetrachloroethane, 1,100 μg/l for pentachloroethane, and 540 μg/l for hexachloroethane. Acute and chronic toxicity would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available saltwater data for chlorinated ethanes indicate that toxicity increases greatly with increasing chlorination and that acute toxicity to fish and invertebrate species occurs at concentrations as low as 113,000 μg/l for 1,2-dichloroethane, 31,200 μg/l for 1,1,1-trichloroethane, 9,020 μg/l for 1,1,2,2-tetrachloroethane, 390 μg/l for pentachloroethane, and 940 μg/l for hexachloroethane. Chronic toxicity occurs at concentrations as low as 201 μg/l for pentachloroethane. Acute and chronic toxicity would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,2-dichloroethane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 9.4 μg/l, .94 μg/l, and .094 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 2,430 μg/l, 243 μg/l, and 24.3 μg/l respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the protection of human health from the toxic properties of 1,1,1-trichloroethane ingested through water and contaminated aquatic organism, the ambient water criterion is determined to be 18.4 mg/l.

For the protection of human health from the toxic properties of 1,1,1,-trichloroethane ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 1.03 g/l.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,1,2-trichloroethane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 6.0 μg/l, .6 μg/l, and .06 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 418 μg/l, 41.8 μg/l, and 4.18 μg/l respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,1,2,2-tetrachloroethane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 1.7 μg/l, .17 μg/l, and .017 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 107 μg/l, 10.7 μg/l, and 1.07 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of hexachloroethane through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 19 μg/l, 1.9 μg/l, and .19 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 87.4 μg/l, 8.74 μg/l, and .87 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for monochloroethane.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for 1,1,-dichloroethane.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for 1,1,1,2-tetrachloroethane.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for pentachloroethane.

Chlorinated Naphthalenes

Freshwater Aquatic Life

The available data for chlorinated naphthalenes indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 1,600 μg/l and would occur at lower concentrations among species that are

recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 3-methyl-4-chlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 3000 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Sufficient data is not available for 3-methyl-6-chlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 20 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Chloroalkyl Ethers

Freshwater Aquatic Life

The available data for chloroalkyl ethers indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 238,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of chloroalkyl ethers to sensitive freshwater aquatic life.

Saltwater Aquatic Life

No saltwater organisms have been tested with any chloroalkyl ether and no statement can be made concerning acute and chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of bis-(chloromethyl)-ether through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .038 ng/l, .0038 ng/l, and .00038 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 18.4 ng/l, 1.84 ng/l, and .184 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of bis (2-chloroethyl) ether through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .3 μg/l, .03 μg/l, and .003 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 13.6 μg/l, 1.36 μg/l, and .136 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the protection of human health from the toxic properties of bis (2-chloroisopropyl) ether ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 34.7 μg/l.

For the protection of human health from the toxic properties of bis (2-chloroisopropyl) ether ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 4.36 mg/l.

Chloroform

Freshwater Aquatic Life

The available data for choloroform indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 28,900 μg/l, and would occur at lower concentrations among species that are more sensitive than the three tested species. Twenty-seven-day LC50 values indicate that chronic toxicity occurs at concentrations as low as 1,240 μg/l, and could occur at lower concentrations among species or other life stages that are more sensitive than the earliest life cycle stage of the rainbow trout.

Saltwater Aquatic Life

The data base for saltwater species is limited to one test and no statement can be made concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of chloroform through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 1.90 μg/l, .19 μg/l, and .019 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 157 μg/l, 15.7 μg/l, and 1.57 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

2-Chlorophenol

Freshwater Aquatic Life

The availabe data for 2-chlorophenol indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 4,380 μg/l and would occur at lower concentrations among species that are more sensitive that those tested. No definitive data are available concerning the chronic toxicity of 2-chlorophenol to sensitive freshwater aquatic life but flavor impairment occurs in one species of fish at concentrations as low as 2,000 μg/l.

Saltwater Aquatic Life

No saltwater organisms have been tested with 2-chlorophenol and no statement can be made concerning acute and chronic toxicity.

Human Health

Sufficient data is not available for 2-chlorophenol to derive a level which would protect against the potential toxicity of this compound. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 0.1 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criteria have limitations and have no

chronic toxicity of TDE to sensitive saltwater aquatic life.

DDE

The available data for DDE indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 14 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of DDE to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of DDT through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .24 ng/l, .024 ng/l, and .0024 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are .24 ng/l, .024 ng/l, and .0024 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment of an "acceptable" risk level.

Dichlorobenzenes

Freshwater Aquatic Life

The available data for dichlorobenzenes indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 1,120 and 763 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for dichlorobenzenes indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 1,970 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of dichlorobenzenes to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of dichlorobenzenes (all isomers) ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 400 μg/l.

For the protection of human health from the toxic properties of dichlorobenzenes (all isomers) ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 2.6 mg/l.

Dichlorobenzidines

Freshwater Aquatic Life

The data base available for dichlorobenzidines and freshwater organisms is limited to one test on bioconcentration of 3,3'-dichlorobenzidine and no statement can be made concerning acute or chronic toxicity.

Saltwater Aquatic Life

No saltwater organisms have been tested with any dichlorobenzidine and no statement can be made concerning acute or chronic toxicity.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of dichlorobenzidine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero base on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .103 μg/l, .0103 μg/l, and .00103 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are .204 μg/l, .0204 μg/l, and .00204 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Dichloroethylenes

Freshwater Aquatic Life

The available data for dichloroethylenes indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 11,600 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of dichlorethylenes to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for dichlorethylenes indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 224,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity dichloroethylenes to sensitive saltwater aquatic life.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of 1,1-dichloroethylene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are .33 μg/l, .033 μg/l, and .0033 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 18.5 μg/l, 1.85 μg/l, and .185 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficency in the available data for 1,2-dichloroethylene.

2,4-Dichlorophenol

Freshwater Aquatic Life

The available data for 2,4-dichlorophenol indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 2,020 and 365 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive that those tested. Mortality to early life stages of one species of fish occurs at concentrations as low as 70 μg/l.

Saltwater Aquatic Life

Only one test has been conducted with saltwater organisms on 2,4-dichlorophenol and no statement can be made concerning acute or chronic toxicity.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for 2,4-dichlorophenol.

epresent an Agency judgment on an "acceptable" risk level.

Endosulfan

Freshwater Aquatic Life

For endosulfan the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.056 μg/l as a 24-hour average and the concentration should not exceed 0.22 μg/l at any time.

Saltwater Aquatic Life

For endosulfan the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.0087 μg/l as a 24-hour average and the concentration should not exceed 0.034 μg/l at any time.

Human Health

For the protection of human health from the toxic properties of endosulfan ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 74 μg/l.

For the protection of human health from the toxic properties of endosulfan ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 159 μg/l.

Endrin

Freshwater Aquatic Life

For endrin the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.0023 μg/l as a 24-hour average and the concentration should not exceed 0.18 μg/l at any time.

Saltwater Aquatic Life

For endrin the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.0023 μg/l as a 24-hour average and the concentration should not exceed 0.037 μg/l at any time.

Human Health

The ambient water quality criterion for endrin is recommended to be identical to the existing drinking water standard which is 1 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Ethylbenzene

Freshwater Aquatic Life

The available data for ethylbenzene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 32,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No definitive data are available concerning the chronic toxicity of ethylbenzene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for ethylbenzene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 430 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of ethylbenzene to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of ethylbenzene ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 1.4 mg/l.

For the protection of human health from the toxic properties of ethylbenzene ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 3.28 mg/l.

Fluoranthene

Freshwater Aquatic Life

The available data for fluoranthene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 3980 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of fluoranthene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for fluoranthene indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 40 and 16 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the protection of human health from the toxic properties of fluoranthene ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 42 μg/l.

For the protection of human health from the toxic properties of fluoranthene ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 54 μg/l.

Haloethers

Freshwater Aquatic Life

The available data for haloethers indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 360 and 122 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

No saltwater organisms have been tested with any haloether and no statement can be made concerning acute or chronic toxicity.

Human Health

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for haloethers.

Halomethanes

Freshwater Aquatic Life

The available data for halomethanes indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 11,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of halomethanes to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for halomethanes indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 12,000 and 6,400 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. A decrease in algal cell numbers occurs at concentrations as low as 11,500 μg/l.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of chloromethane, bromomethane, dichloromethane, bromodichloromethane, tribromomethane, dichlorodifluoromethane, trichlorofluoromethane, or combinations of these chemicals through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are

represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of tech-HCH through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 123 ng/l, 12.3 ng/l, and 1.23 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 414 ng/l, 41.4 ng/l, and 4.14 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of gamma-HCH through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentrations should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 186 ng/l, 18.6 ng/l, and 1.86 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 625 ng/l, 62.5 ng/l, 6.25 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for delta-HCH.

Using the present guidelines, a satisfactory criterion cannot be derived at this time due to the insufficiency in the available data for epsilon-HCH.

Hexachlorocyclopentadiene

Freshwater Aquatic Life

The available data for hexachlorocyclopentadiene indicate that acute and chronic toxicity to freshwater aquatic life occurs at concentrations as low as 7.0 and 5.2 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data to hexachlorocyclopentadiene indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 7.0 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of hexachlorocyclopentadiene to sensitive saltwater aquatic life.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for hexachlorocyclopentadiene. Based on available toxicity data, for the protection of public health, the derived level is 206 μg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 1.0 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Isophorone

Freshwater Aquatic Life

The available data for isophorone indicate that acute toxicity to freshwater aquatic life ocurs at concentrations as low as 117,000 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of isophorone to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for isophorone indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 12,900 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of isophorone to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of isophorone ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 5.2 mg/l.

For the protection of human health from the toxic properties of isophorone ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 520 mg/l.

Lead

Freshwater Aquatic Life

For total recoverable lead the criterion (in μg/l) to protect freshwater aquatic life as derived using the Guidelines is the numerical value given by e(2.35[ln(hardness)]-9.48) as a 24-hour average and the concentration (in μg/l) should not exceed the numerical value given by e(1.22[ln(hardness)]-0.47) at any time. For example, at hardnesses of 50, 100, and 200 mg/l as $CaCO_3$ the criteria are 0.75, 3.8, and 20 μg/l, respectively, as 24-hour averages, and the concentrations should not exceed 74, 170, and 400 μg/l, respectively, at any time.

Saltwater Aquatic Life

The available data for total recoverable lead indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 668 and 25 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

The ambient water quality criterion for lead is recommended to be identical to the existing drinking water standard which is 50 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective to human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Mercury

Freshwater Aquatic Life

For total recoverable mercury the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.00057 μg/l as a 24-hour average and the concentration should not exceed 0.0017 μg/l at any time.

Saltwater Aquatic Life

For total recoverable mercury the criterion to protect saltwater aquatic life as derived using the Guidelines is 0.025 μg/l as a 24-hour average and the concentration should not exceed 3.7 μg/l at any time.

Human Health

For the protection of human health from the toxic properties of mercury

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of n-nitrosodimethylamine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 14 ng/l, 1.4 ng/l, and .14 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 160,000 ng/l, 16,000 ng/l, and 1,600 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure of n-nitrosodiethylamine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 8 ng/l, 0.8 ng/l, and 0.08 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 12,400 ng/l, 1,240 ng/l, and 124 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure in n-nitrosodi-n-butylamine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 64 ng/l 6.4 ng/l and .064 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 5,868 ng/l, 587 ng/l, and 58.7 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure in n-nitrosodiphenylamine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 49,000 ng/l 4,900 ng/l and 490 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 161,000 ng/l, 16,100 ng/l, and 1,610 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

For the maximum protection of human health from the potential carcinogenic effects due to exposure in n-nitrosopyrrolidine through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk, over the lifetimes are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 160 ng/l 16.0 ng/l and 1.60 ng/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 919,000 ng/l, 91,900 ng/l, and 9,190 ng/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Pentachlorophenol

Freshwater Aquatic Life

The available data for pentachlorophenol indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 55 and 3.2 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for pentachlorophenol indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 53 and 34 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for pentachlorophenol. Based on available toxicity data, for the protection of public health, the derived level is 1.01 mg/l. Using available organoleptic data, for controlling undesirable taste and odor quality of ambient water, the estimated level is 30 μg/l. It should be recognized that organoleptic data as a basis for establishing a water quality criterion have limitations and have no demonstrated relationship to potential adverse human health effects.

Phenol

Freshwater Aquatic Life

The available data for phenol indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 10,200 and 2,560 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for phenol indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 5,800 ug/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of phenol to sensitive saltwater aquatic life.

Human Health

For comparison purposes, two approaches were used to derive criterion levels for phenol. Based on available toxicity data, for the protection of public health, the derived level is 3.5 mg/l. Using available organoleptic data, for controlling

than those tested. No data are available concerning the chronic toxicity of inorganic selenate to sensitive freshwater aquatic life.

Saltwater Aquatic Life

For total recoverable inorganic selenite the criterion to protect saltwater aquatic life as derived using the Guidelines is 54 μg/l as a 24-hour average and the concentration should not exceed 410 μg/l at any time.

No data are available concerning the toxicity of inorganic selenate to saltwater aquatic life.

Human Health

The ambient water quality criterion for selenium is recommended to be identical to the existing drinking water standard which is 10 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Silver

Freshwater Aquatic Life

For freshwater aquatic life the concentration (in μg/l) of total recoverable silver should not exceed the numerical value given by "e[1.72(ln (hardness)-6.52)]" at any time. For example, at hardnesses of 50, 100, 200 mg/l as $CaCO_3$ the concentration of total recoverable silver should not exceed 1.2, 4.1, and 13 μg/l, respectively, at any time. The available data indicate that chronic toxicity to freshwater aquatic life may occur at concentrations as low as 0.12 μg/l.

Saltwater Aquatic Life

For saltwater aquatic life the concentration of total recoverable silver should not exceed 2.3 μg/l at any time. No data are available concerning the chronic toxicity of silver to sensitive saltwater aquatic life.

Human Health

The ambient water quality criterion for silver is recommended to be identical to the existing drinking water standard which is 50 μg/l. Analysis of the toxic effects data resulted in a calculated level which is protective of human health against the ingestion of contaminated water and contaminated aquatic organisms. The calculated value is comparable to the present standard. For this reason a selective criterion based on exposure solely from consumption of 6.5 grams of aquatic organisms was not derived.

Tetrachloroethylene

Freshwater Aquatic Life

The available data for tetrachloroethylene indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 5,280 and 840 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Saltwater Aquatic Life

The available data for tetrachloroethylene indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations low as 10,200 and 450 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the maximum protection of human health from the potential carcinogenic effects due to exposure of tetrachloroethylene through ingestion of contaminated water and contaminated aquatic organisms, the ambient water concentration should be zero based on the non-threshold assumption for this chemical. However, zero level may not be attainable at the present time. Therefore, the levels which may result in incremental increase of cancer risk over the lifetime are estimated at 10^{-5}, 10^{-6}, and 10^{-7}. The corresponding criteria are 8 μg/l, .8 μg/l, and .08 μg/l, respectively. If the above estimates are made for consumption of aquatic organisms only, excluding consumption of water, the levels are 88.5 μg/l, 8.85 μg/l, and .88 μg/l, respectively. Other concentrations representing different risk levels may be calculated by use of the Guidelines. The risk estimate range is presented for information purposes and does not represent an Agency judgment on an "acceptable" risk level.

Thallium

Freshwater Aquatic Life

The available data for thallium indicate that acute and chronic toxicity to freshwater aquatic life occur at concentrations as low as 1,400 and 40 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested. Toxicity to one species of fish occurs at concentrations as low as 20 μg/l after 2,600 hours of exposure.

Saltwater Aquatic Life

The available data for thallium indicate that acute toxicity to saltwater aquatic life occurs at concentrations as low as 2,130 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of thallium to sensitive saltwater aquatic life.

Human Health

For the protection of human health from the toxic properties of thallium ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 13 μg/l.

For the protection of human health from the toxic properties of thallium ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 48 μg/l.

Toluene

Freshwater Aquatic Life

The available data for toluene indicate that acute toxicity to freshwater aquatic life occurs at concentrations as low as 17,500 μg/l and would occur at lower concentrations among species that are more sensitive than those tested. No data are available concerning the chronic toxicity of toluene to sensitive freshwater aquatic life.

Saltwater Aquatic Life

The available data for toluene indicate that acute and chronic toxicity to saltwater aquatic life occur at concentrations as low as 6,300 and 5,000 μg/l, respectively, and would occur at lower concentrations among species that are more sensitive than those tested.

Human Health

For the protection of human health from the toxic properties of toluene ingested through water and contaminated aquatic organisms, the ambient water criterion is determined to be 14.3 mg/l.

For the protection of human health from the toxic properties of toluene ingested through contaminated aquatic organisms alone, the ambient water criterion is determined to be 424 mg/l.

Toxaphene

Freshwater Aquatic Life

For toxaphene the criterion to protect freshwater aquatic life as derived using the Guidelines is 0.013 μg/l as a 24-hour average and the concentration should not exceed 1.6 μg/l at any time.

Saltwater Aquatic Life

For saltwater aquatic life the concentration of toxaphene should not exceed 0.070 μg/l at any time. No data

necessarily all of the species all of the time. Aquatic communities can tolerate some stress and occasional adverse effects on a few species, and so total protection of all of the species all of the time is not necessary. Rather, the Guidelines attempt to provide a reasonable and adequate amount of protection with only a small possibility of considerable overprotection or underprotection. Within these constraints, it seems appropriate to err on the side of overprotection.

The numerical aquatic life criteria derived using the Guidelines are expressed as two numbers, rather than the traditional one number, so that the criteria can more accurately reflect toxicological and practical realities. The combination of both a maximum value and a 24-hour average value is designed to provide adequate protection of aquatic life and its uses from acute and chronic toxicity to animals, toxicity to plants and bioconcentration by aquatic organisms without being as restrictive as a one-number criterion would have to be to provide the same amout of protection. The only way to assure the same degree of protection with a one-number criterion would be to use the 24-hour average as a concentration that is not to be exceeded at any time in any place.

The two-number criterion is intended to identify an average pollutant concentration which will produce a water qualtiy generally suited to the maintenance of aquatic life and its uses while restricting the extent and duration of excursions over the average so that the total exposure will not cause unacceptable adverse effects. Merely specifying an average value over a time period is insufficient, unless the period of time is rather short, because of concentration higher than the average value can kill or cause substantial damage in short periods. Furthermore, for some substances the effect of intermittent high exposures is cumulative. It is therefore necessary to place an upper limit on pollutant concentrations to which aquatic organisms might be exposed, especially when the maximum value is not much higher than the average value. For some substances the maximum may be so much higher than the 24-hour average that in any real-world situation the maximum will never be reached if the 24-hour average is achieved. In such cases the 24-hour average will be limiting and the maximum will have no practical significance, except to indicate that elevated concentrations are acceptable as long as the 24-hour average is achieved.

These Guidelines have been developed on the assumption that the results of laboratory tests are generally useful for predicting what will happen in field situations. The resulting criteria are meant to apply to most bodies of water in the United States, except for the Great Salt Lake. All aquatic organisms and their common uses are meant to be considered, but not necessarily protected, if relevant data are available, with at least one specific exception. This exception is the accumulation of residues of organic compounds in the siscowet subspecies of lake trout which occurs in Lake Superior and contains up to 67% fat in the fillets (Thurston, C.E., 1962, Physical Characteristics and Chemical Composition of Two Subspecies of Lake Trout, J. Fish. Res. Bd. Canada 19:39–44). Neither siscowet nor organisms in the Great Salt Lake are intentionally protected by these Guidelines because both may be too atypical.

With appropriate modifications these Guidelines can be used to derive criteria for any specified geographical area, body of water (such as the Great Salt Lake), or group of similar bodies of water. Thus with appropriate modifications the Guidelines can be used to derive national, state, or local criteria if adequate information is available concerning the effects of the substance of concern on appropriate species and their uses. However, the basic concepts described in the Guidelines should be modified only when sound scientific evidence indicates that a criterion produced using the Guidelines would probably significantly overprotect or underprotect the presence or uses of aquatic life.

Criteria produced by these Guidelines are not enforceable numbers. They may be used in developing enforceable numbers, such as water quality standards and effluent standards. However, the development of standards may take into account additional factors such as social, legal, economic, and hydrological considerations, the environmental and analytical chemistry of the substance, the extrapolation from laboratory data to field situations, and the relationship between the species for which data are available and the species which are to be protected.

Because fresh water and salt water (including both estuarine and marine waters) have basically different chemical compositions and because freshwater and saltwater species rarely inhabit the same water simultaneously, separate criteria should be derived for these two kinds of waters. However, for some substances sufficient data may not be available to allow derivation of one or both of these criteria using the Guidelines.

These Guidelines are meant to be used after a decision is made that a criterion is needed for a substance. The Guidelines do not address the rationale for making that decision. If the potential for adverse effects on aquatic life and its uses are part of the basis for deciding whether or not a criterion is needed for a substance, these Guidelines may be helpful in the collection and interpretation of relevant data.

I. Define the Substance for Which the Criterion Is To Be Derived

A. Each separate chemical which would not ionize significantly in most natural bodies of water should usually be considered a separate substance, except possibly for structurally similar organic compounds that only differ in the number and location of atoms of a specific halogen, and only exist in large quantities as commercial mixtures of the various compounds, and apparently have similar chemical, biological, and toxicological properties.

B. For chemicals, which would ionize significantly in most natural bodies of water, such as inorganic salts, organic acids and phenols, all forms that would be in chemical equilibrium should usually be considered one substance. For metals, each different valence and each different covalently bonded organometallic compound should usually be considered a separate substance.

C. The definition of the substance may also need to take into account the analytical chemistry and fate of the substance.

II. Collect and Review Available Data

A. Collect all available data on the substance concerning (1) toxicity to, and bioaccumulation by, aquatic animals and plants, (2) FDA action levels, and (3) chronic feeding studies with wildlife.

B. Discard all data that are not available in hard copy (publication, manuscript, letter, memorandum, etc.) with enough supporting information to indicate that acceptable test procedures were used and that the results are reliable. Do not assume that all published data are acceptable.

C. Discard questionable data. For example, discard data from tests for which no control treatment existed, in which too many organisms in the control treatment died or showed signs of stress or disease, or in which distilled or deionized water was used as the dilution water for aquatic organisms. Discard data on formulated mixtures and emulsifiable concentrates of the

xposure to toxicant or for whom the cute adverse effect of the exposure cannot be adequately measured. Such freshwater and saltwater animals include air-breathing molluscs, unionid clams, operculate snails, and bivalve molluscs, except for some species that cannot "close up" and thus prevent exposure to toxicant, such as the bay scallop (*Argopecten irradians*).

F. For the use of LC50 or EC50 values for durations shorter and longer than those listed above, see Section X.

G. If the acute toxicity of the substance to aquatic animals has been shown to be related to a water quality characteristic such as hardness for freshwater organisms or salinity for saltwater organisms, a Final Acute Equation should be derived based on that water quality characteristic. Go to Section V.

H. If the acute toxicity of the substance has not been adequately shown to be related to a water quality characteristic, for each species for which at least one acute value is available, calculate the geometric mean of the results of all flow-through tests in which the toxicant concentrations were measured. For a species for which no such result is available, calculate the geometric mean of all available acute values, i.e., results of flow-through tests in which the toxicant concentrations were not measured and results of static and renewal tests based on initial total toxicant concentrations.

Note.—The geometric mean of N numbers is obtained by taking the N^{th} root of the product of N numbers. Alternatively, the geometric mean can be calculated by adding the logarithms of the N numbers, dividing the sum by N, and taking the antilog of the quotient. The geometric mean of two numbers can also be calculated as the square root of the product of the two numbers. The geometric mean of one number is that number. Either natural (base e) or common (base 10) logarithms can be used to calculate geometric means as long as they are used consistently within each set of data, i.e., the antilog used must match the logarithm used.

I. Count the number=N of species for which a species mean acute value is available.

J. Order the species mean acute values from low to high. Take the common logarithms of the N values (log mean values).

K. The intervals (cell widths) for the lower cumulative proportion calculations are 0.11 common log units apart, starting from the lowest log value. The value of 0.11 is an estimate of average precision and was calculated from replicate species acute values.

L. Starting with the lowest log mean value, separate the N values into intervals (or cells) calculated in Step IV. K.

M. Calculate cumulative proportions for each non-empty interval by summing the number of values in the present and all lower intervals and dividing by N. These calculations only need to be done for the first three non-empty intervals (or cells).

N. Calculate the arithmetic mean of the log mean values for each of the three intervals.

O. Using the two interval mean acute values and cumulative proportions closest to 0.05, linearly extrapolate or interpolate to the 0.05 log concentration. The Final Acute Value is the antilog of the 0.05 concentration.

In other words, where

Prop(1) and conc(1) are the cumulative proportion and mean log value for the lowest non-empty interval.

Prop(2) and conc(2) are the cumulative proportion and mean log value for the second lowest non-empty interval.

A=Slope of the cumulative proportions

B=The 0.05 log value

Then:

$A=[0.05-Prop(1)]/[Prop(2)-Prop(1)]$

$B=conc(1)+A\,[conc(2)-conc(1)]$

Final Acute Value $=10^B$

P. If for an important species, such as a recreationally or commercially important species, the geometric mean of the acute values from flow-through tests in which the toxicant concentrations were measured is lower than the Final Acute Value, then that geometric mean should be used as the Final Acute Value.

Q. Go to Section VI.

V. Final Acute Equation

A. When enough data are available to show that acute toxicity to two or more species is similarly affected by a water quality characteristic, this effect can be taken into account as described below. Pooled regression analysis should produce similar results, although data available for individual species would be weighted differently.

B. For each species for which comparable acute toxicity values are available at two or more different values of a water quality characteristic which apparently affects toxicity, perform a least squares regression of the natural logarithms of the acute toxicity values on the natural logarithms of the values of the water quality characteristic. [Natural logarithms [logarithms to the base e, denoted as ln] are used herein merely because they are easier to use on some hand calculators and computers than common logarithms [logarithms to the base 10]. Consistent use of either will produce the same result.] No transformation or a different transformation may be used if it fits the data better, but appropriate changes will be necessary throughout this section.

C. Determine whether or not each acute slope is meaningful, taking into account the range and number of values of the water quality characteristic tested. For example, a slope based on four data points may be of limited value if it is based only on data for a narrow range of values of the water quality characteristic. On the other hand, a slope based on only two data points may be meaningful if it is consistent with other information and if the two points cover a broad enough range of the water quality characteristic. If meaningful slopes are not available for at least two species or if the available slopes are not similar, return to Section IV. H., using the results of tests conducted under conditions and in water similar to those commonly used for toxicity tests with the species.

D. Calculate the mean acute slope (V) as the arithmetic average of all the meaningful acute slopes for individual species.

E. For each species calculate the geometric mean (W) of the acute toxicity values and the geometric mean (X) of the related values of the water quality characteristic.

F. For each species calculate the logarithmic intercept (Y) using the equation: $Y=\ln W-V(\ln X)$.

G. For each species calculate the species mean acute intercept as the antilog of Y.

H. Obtain the Final Acute Intercept by using the procedure described in Section IV. I–O, except insert "Intercept" for "Value".

I. If for an important species, such as a recreationally or commercially important species, the intercept calculated only from results of flow-through tests in which the toxicant concentrations were measured is lower than the Final Acute Intercept, then that intercept should be used as the Final Acute Intercept.

J. The Final Acute Equation is written as $e^{(V[\ln(\text{water quality characteristic})]+\ln Z)}$, where V=mean acute slope and Z=Final Acute Intercept.

VI. Final Chronic Value

A. The Final Chronic Value can be calculated in the same manner as the Final Acute Value or by dividing the Final Acute Value by the Final Acute-Chronic Ratio, depending on the data available. In some cases it will not be possible to calculate a Final Chronic Value.

B. Use only the results of flow-through (except renewal is acceptable for

meaningful chronic slope is not available for at least one species, return to Section VI. H.

C. Calculate the mean chronic slope (L) as the arithmetic average of all the meaningful chronic slopes for individual species.

D. For each species calculate the geometric mean (M) of the toxicity values and the geometric mean (P) of the related values of the water quality characteristic.

E. For each species calculate the logarithmic intercept (Q) using the equation: $Q = \ln M - L(\ln P)$.

F. For each species calculate a species mean chronic intercept as the antilog of Q.

G. Obtain the Final Chronic Intercept by using the procedure described in Section IV. I–O, except insert "Intercept" for "Value".

H. If the species mean chronic intercept of an important species, such as a commercially or recreationally important species, is lower than the Final Chronic Intercept, then that species mean chronic intercept should be used as the Final Chronic Intercept.

I. The Final Chronic Equation is written as $e^{(L[\ln(\text{Water quality characteristic})]+\ln R)}$, where L = mean chronic slope and R = Final Chronic Intercept.

VIII. Final Plant Value

A. Appropriate measures of the toxicity of the substance to aquatic plants are used to compare the relative sensitivities of aquatic plants and animals.

B. A value is a concentration which decreased growth (as measured by dry weight, chlorophyll, etc.) in a 96-hr or longer test with an alga or in a chronic test with an aquatic vascular plant.

C. Obtain the Final Plant Value by selecting the lowest plant value from a test in which the toxicant concentrations were measured.

IX. Final Residue Value

A. The Final Residue Value is derived in order to (1) prevent commercially or recreationally important aquatic organisms from exceeding relevant FDA action levels and (2) protect wildlife, including fishes and birds, that eat aquatic organisms from demonstrated adverse effects. A residue value is calculated by dividing a maximum permissible tissue concentration by an appropriate bioconcentration factor (BCF), where the BCF is the quotient of the concentration of a substance in all or part of an aquatic organism divided by the concentration in water to which the organism has been exposed. A maximum permissible tissue concentration is either (1) an action level from the FDA Administrative Guidelines Manual for fish oil or for the edible portion of fish or shellfish, or (2) a maximum acceptable dietary intake based on observations on survival, growth or reproduction in a chronic wildlife feeding study. If no maximum permissible tissue concentration is available, go to Section X because no Final Residue Value can be derived.

B. 1. A BCF determined in a laboratory test should be used only if it was calculated based on measured concentrations of the substance in the test solution and was based on an exposure that continued until either steady-state or 28-days was reached. Steady-state is reached when the BCF does not change significantly over a period of time, such as two days or 16 percent of the length of the exposure, whichever is longer. If a steady-state BCF is not available for a species, the available BCF for the longest exposure over 28 days should be used for that species.

2. A BCF from a field exposure should be used only when it is known that the concentration of the substance was reasonably constant for a long enough period of time over the range of territory inhabited by the organisms.

3. If BCF values from field exposures are consistently lower or higher than those from laboratory exposures, then only those values from field exposures should be used if possible.

4. A BCF should be calculated based on the concentration of the substance and its metabolites, which are structurally similar and are not much more soluble in water than the parent compound, in appropriate tissue and should be corrected for the concentration in the organisms at the beginning of the test.

5. A BCF value obtained from a laboratory or field exposure that caused an observable adverse effect on the test organism may be used only if it is similar to that obtained with unaffected organisms at lower concentrations in the same test.

6. Whenever a BCF is determined for a lipid-soluble substance, the percent lipids should also be determined in the tissue for which the BCF was calculated.

C. A BCF calculated using dry tissue weights must be converted to a wet tissue weight basis by multiplying the dry weight BCF value by 0.1 for plankton and by 0.2 for individual species of fishes and invertebrates.

Note.—The values of 0.2 and 0.1 were derived from data published in:

McDiffett, W. F., 1970. Ecology 51:975–988.
Brocksen, R. W., et al. 1968. J. Wildlife Management 32:52–75.
Cummins, K. W., et al. 1973. Ecology 54: 336–345.
Pesticide Analytical Manual, Volume I. Food and Drug Administration, 1969.
Love, R. M., 1957. In The Physiology of Fishes, Vol. I, M. E. Brown, ed. Academic Press, New York. p. 411.
Ruttner, F., 1963. Fundamentals of Limnology. 3rd ed. Trans. by D. G. Frey and F. E. J. Fry. Univ. of Toronto Press, Toronto.

Some additional values can be found in:

Sculthorpe, C. D., 1967. The Biology of Aquatic Vascular Plants. Arnold Publishing Ltd., London.

D. If enough pertinent data exist, several residue values can be calculated by dividing maximum permissible tissue concentrations by appropriate BCF values.

1. For each available maximum acceptable dietary intake derived from a chronic feeding study with wildlife, including birds and aquatic organisms, the appropriate BCF is based on the whole body of aquatic species which constitute or represent a major portion of the diet of the tested wildlife species.

2. For an FDA action level, the appropriate BCF is the highest geometric mean species BCF for the edible portion (muscle for decapods, muscle with or without skin for fishes, adductor muscle for scallops and total living tissue for other bivalve molluscs) of a consumed species. The highest species BCF is used because FDA action levels are applied on a species-by-species basis.

E. For lipid-soluble substances, it may be possible to calculate additional residue values. Because steady-state BCF values for a lipid-soluble chemical seem to be proportional to percent lipids from one tissue to another and from one species to another, extrapolations can be made from tested tissues or species to untested tissues or species on the basis of percent lipids.

1. For each BCF for which the percent lipids is known for the same tissue for which the BCF was measured, the BCF should be normalized to a one percent lipid basis by dividing the BCF by the percent lipids. This adjustment to a one percent lipid basis makes all the measured BCF values comparable regardless of the species or tissue for which the BCF was measured.

2. Calculate the geometric mean normalized BCF. Data for both saltwater and freshwater species can be used to determine the mean normalized BCF, because the normalized BCF seems to be about the same for both kinds of organisms.

3. Residue values can then be calculated by dividing the maximum permissible tissue concentrations by the mean normalized BCF and by a percent lipids value appropriate to the maximum permissible tissue concentration, *i.e.*,

riteria for carcinogens are presented as a range of pollutant concentrations associated with corresponding incremental risks.

For compounds which do not manifest any apparent carcinogenic effect, the threshold assumption is used in deriving a criterion. This assumption is based on the premise that a physiological reserve capacity exists within the organism which is thought to be depleted before clinical disease ensues. Alternatively, it may be assumed that the rate of damage will be insignificant over the life span of the organism. Thus, ambient water quality criteria are derived for non-carcinogenic chemicals, and presumably result in no observable-adverse-effect levels (NOAELs) in the exposed human population.

In some instances, criteria are based on organoleptic characteristics, i.e., thresholds for taste or odor. Such criteria are established when insufficient information is available on toxicologic effects or when the estimate of the level of the pollutant in ambient water based on organoleptic effects is lower than the level calculated from toxicologic data. It should be recognized that criteria based solely on organoleptic effects do not necessarily represent approximations of acceptable risk levels for human health.

Several ambient water quality criteria documents deal with classes of compounds which include chemicals exhibiting varying degrees of structural similarity. Because prediction of biological effects based solely on structural parameters is difficult, the derivation of compound-specific criteria is preferable to a class criterion. A compound-specific criterion is defined as a level derived from data on each individual subject compound that does not represent a significant risk to the public. For some chemical classes, however, a compound-specific criterion cannot be derived for each member of a class. In such instances, it is sometimes justifiable to derive a class criterion in which available data on one member of a class may be used to estimate criteria for other chemicals of the class because a sufficient data base is not available for those compounds.

For some chemicals and chemical classes, the data base was judged to be insufficient for the derivation of a criterion. In those cases, deficiencies in the available information are detailed.

III. Approach

The human health effects chapters attempt to summarize all information on the individual chemicals or classes of chemicals which might be useful in the risk assessment process to develop water quality criteria. Although primary emphasis is placed on identifying epidemiologic and toxicologic data, these assessments typically contain discussions on four topics: existing levels of human exposure, pharmacokinetics, toxic effects, and criterion formulation.

For all documents, an attempt is made to include the known relevant information. Review articles and reports are often used in the process of data evaluation and synthesis. Scientific judgment is exercised in the review and evaluation of the data in each document and in the identification of the adverse effects against which protective criteria are sought. In addition, each of these documents is reviewed by a peer committee of scientists familiar with the specific compound(s). These work groups evaluate the quality of the available data, the completeness of the data summary, and the validity of the derived criterion.

In the analysis and organization of the data, an attempt is made to be consistent with respect to the format and the application of acceptable scientific principles. Evaluation procedures used in the hazard assessment process follow the principles outlined by the National Academy of Sciences in *Drinking Water and Health* (1977) and the guidelines of the Carcinogen Assessment Group of the U.S. EPA.

A. Exposure

The exposure section of the health effects chapters reviews known information on current levels of human exposure to the individual pollutant from all sources. Much of the data was obtained from monitoring studies of air, water, food, soil, and human or animal tissue residues. The major purpose of this section is to provide background information on the contribution of water exposure relative to all other sources. Consequently, the exposure section includes subsections reviewing different routes of exposure including water and food ingestion, inhalation, and dermal contact.

Information on exposure can be valuable in developing and assessing a water quality criterion. In these documents exposure from consumption of contaminated water and contaminated fish and shellfish products is used in criterion formulation. Data for all modes of exposure are useful in relating total intake to the expected contribution from contaminated water, fish, and shellfish. In addition, information for all routes of exposure, not limited to drinking water and fish and shellfish ingestion, can be used to justify or assess the feasibility of the formulation of criteria for ambient water.

The use of fish consumption as an exposure factor requires the quantitation of pollutant residues in the edible portions of the ingested species. Accordingly, bioconcentration factors (BCFs) are used to relate pollutant residues in aquatic organisms to the pollutant concentration in the ambient waters in which they reside.

To estimate the average per capita intake of a pollutant due to consumption of contaminated fish and shellfish the results of a diet survey were analyzed to calculate the average consumption of freshwater and estuarine fish and shellfish (U.S. EPA, 1980). A species is considered to be a consumed freshwater or estuarine fish and shellfish species if at some stage in its life cycle, it is harvested from fresh or estuarine water for human consumption in significant quantities (Stephan, 1980).

Three different procedures are used to estimate the weighted average BCF depending upon the lipid solubility of the chemical and the availability of bioconcentration data.

For lipid-soluble compounds, the average BCF is calculated from the weighted average percent lipids in the edible portions of consumed freshwater and estuarine fish and shellfish which was calculated from data on consumption of each species and its corresponding percent lipids to be 3.0 percent (Stephan, 1980). Because the steady-state BCFs for lipid-soluble compounds are proportional to percent lipids, bioconcentration factors for fish and shellfish can be adjusted to the average percent lipids for aquatic organisms consumed by Americans. For many lipid-soluble pollutants, there exists at least one BCF for which the percent lipid value was measured for the tissues for which the BCF is determined.

With 3.0 percent as the weighted average percent lipids for freshwater and estuarine fish and shellfish in the average diet, a BCF, and a corresponding percent lipid value, the weighted average bioconcentration factor can be calculated.

Example:

Weighted average percent lipids for average diet = 3.0 percent

Measured BCF of 17 for trichloroethylene with bluegills at 4.8 percent lipids

Weighted average BCF for average diet equals

$$17 \times \frac{3.0\%}{4.8\%} = 10.6$$

significance, is not available for most of the compounds under study. Consequently, most NOAELs derived from chronic studies are based either on gross toxic effects or on effects directly related to functional impairment or defined pathological lesions.

For compounds on which adequate chronic toxicity studies are not available, studies on acute and subacute toxicity assume greater significance. Acute toxicity studies usually involve single exposures at lethal or near lethal doses. Subacute studies often involve exposures exceeding 10 percent of the life span of the test organism, e.g., 90 days for the rat with an average life span of 30 months. Such studies are useful in establishing the nature of the compound's toxic effects and other parameters of compound toxicity, such as target organ effects, metabolic behavior, physiological/biochemical effects, and patterns of retention and tissue distribution. The utility of acute and subacute studies in deriving environmentally meaningful NOELs is uncertain, although McNamara (1976) has developed application factors for such derivations.

In some cases where adequate data are not available from studies utilizing oral routes of administration, no-effect levels for oral exposures may be estimated from dermal or inhalation studies. Such estimates involve approximations of the total dose administered based on assumptions about breathing rates and/or magnitude of absorption.

D. Criterion Rationale

This section reviews existing standards for the chemical(s), summarizes data on current levels of human exposure, attempts to identify special groups at risk, and defines the basis for the recommended criterion.

Information on existing standards is included primarily for comparison with the proposed water quality criteria. Some of the present standards, such as those recommended by the Occupational Safety and Health Administration (OSHA) or the American Conference of Governmental Industrial Hygienists (ACGIH), are based on toxicologic data but are intended as acceptable levels for occupational rather than environmental exposure. Other levels, such as those recommended by the National Academy of Sciences in *Drinking Water and Health* (1977) or in the U.S. EPA Interim Primary Drinking Water Standards, are more closely related to proposed water quality criteria. Emphasis is placed on detailing the basis for the existing standards wherever possible.

Summaries of current levels of human exposure, presented in this section, specifically address the suitability of the data to derive water quality criteria. The identification of special groups at risk, either because of geographical or occupational differences in exposure or biological differences in susceptibility to the compound(s), focuses on the impact that these groups should have on the development of water quality criteria.

The basis for the recommended criteria section summarizes and qualifies all of the data used in developing the criteria.

IV. Guidelines for Criteria Derivation

The derivation of water quality criteria from laboratory animal toxicity data is essentially a two-step procedure. First, a total daily intake for humans must be estimated which establishes either a defined level of risk for non-threshold effects or a no-effect level for threshold effects. Secondly, assumptions must be made about the contribution of contaminated water and the consumption of fish/shellfish to the total daily intake of the chemical. These estimates are then used to establish the tolerable daily intake and consequently the water quality criterion.

A. Non-Threshold Effects

After the decision has been made that a compound has the potential for causing cancers in humans and that data exist which permit the derivation of a criterion, the water concentration which is estimated to cause a lifetime carcinogenic risk of 10^{-5} is determined. The lifetime carcinogenicity risk is the probability that a person would get cancer sometime in his or her life assuming continuous exposure to the compound. The water concentration is calculated by using the low-dose extrapolation procedure proposed by Crump (1980). This procedure is an improvement on the multistage low dose extrapolation procedure by Crump, et al. (1977).

The data used for quantitative estimates are of two types: (1) lifetime animal studies, and (2) human studies where excess cancer risk has been associated with exposure to the agent. In animal studies it is assumed, unless evidence exists to the contrary, that if a carcinogenic response occurs at the dose levels used in the study, then proportionately lower responses will also occur at all lower doses, with an incidence determined by the extrapolation model discussed below.

1. Choice of Model.

There is no really solid scientific basis for any mathematical extrapolation model which relates carcinogen exposure to cancer risks at the extremely low levels of concentration that must be dealt with in evaluating the environmental hazards. For practical reasons, such low levels of risk cannot be measured directly either using animal experiments or epidemiologic studies. We must, therefore, depend on our current understanding of the mechanisms of carcinogenesis for guidance as to which risk model to use. At the present time, the dominant view of the carcinogenic process involves the concept that most agents which cause cancer also cause irreversible damage to DNA. This position is reflected by the fact that a very large proportion of agents which cause cancer are also mutagenic. There is reason to expect that the quantal type of biological response that is characteristic of mutagenesis is associated with a linear non-threshold dose-response relationship. Indeed, there is substantial evidence from mutagenesis studies with both ionizing radiation and with a wide variety of chemicals that this type of dose-response model is the appropriate one to use. This is particularly true at the lower end of the dose-response curve; at higher doses, there can be an upward curvature, probably reflecting the effects of multistage processes on the mutagenic response. The linear non-threshold dose-response relationship is also consistent with the relatively few epidemiological studies of cancer responses to specific agents that contain enough information to make the evaluation possible (e.g., radiation-induced leukemia, breast and thyroid cancer, skin cancer induced by arsenic in drinking water, and liver cancer induced by aflatoxin in the diet). There is also some evidence from animal experiments that is consistent with the linear non-threshold hypothesis (e.g., liver tumors induced in mice by 2-acetylaminofluorene in the large scale ED_{01} study at the National Center of Toxicological Research, and the initiation stage of the two-stage carcinogenesis model in the rat liver and the mouse skin).

Because it has the best, albeit limited, scientific basis of any of the current mathematical extrapolation models, the linear non-threshold model has been adopted as the primary basis for risk extrapolation to low levels of the dose-response relationship. The risk assessments made with this model should be regarded as conservative, representing the most plausible upper limit for the risk; i.e., the true risk is not likely to be higher than the estimate, but it could be smaller.

where ppm is parts per million of the carcinogenic agent in the diet, F is the weight of the food consumed per day in kgms, and r is the absorption fraction.

In the absence of any data to the contrary, r is assumed to be one. For a uniform diet the weight of the food consumed is proportional to the calories required, which, in turn, is proportional to the surface area or the ⅔rds power of the weight, so that: $m \alpha ppm \times W^{2/3} \times r$ or

$$\frac{m}{rW^{2/3}} \alpha ppm$$

As a result, ppm in the diet is often assumed to be an equivalent exposure between species. However, we feel that this is not justified since the calories/kg of food is significantly different in the diet of man vs. laboratory animals, primarily due to moisture content differences. Instead, we use an empirically derived food factor, f=F/W, which is the fraction of a species body weight that is consumed per day as food. We use the rates given below.

Species	W	f
Man	70	0.028
Rat	0.35	0.05
Mice	0.03	0.13

Thus, when the exposure is given as a certain dietary concentration in ppm, the exposure in $mg/W^{2/3}$ is

$$\frac{m}{r \times W^{2/3}} = \frac{ppm \times F}{W^{2/3}} =$$

$$\frac{ppm \times fxW}{W^{2/3}} = ppm \times f \times W^{1/3}$$

When exposure is given in terms of mg/kg/day=m/Wr=s the conversion is simply:

$$\frac{m}{rW^{2/3}} = s \times W^{1/3}$$

When exposure is via inhalation, the calculation of dose can be considered for two cases where (1) the carcinogenic agent is either a completely water-soluble gas or an aerosol and is absorbed proportionally to the amount of air breathed in, and (2) where the carcinogen is a poorly water-soluble gas which reaches an equilibrium between the air breathed and the body compartments. After equilibrium is reached, the rate of absorption of these agents is expected to be proportional to metabolic rate, which in turn is proportional to the rate of oxygen consumption, which in turn is a function of surface area.

Case 1

Agents that are in the form of particulate matter or virtually completely absorbed gases such as SO_x can reasonably be expected to be absorbed proportional to the breathing rate. In this case the exposure in mg/day may be expressed as: $m=I \times v \times r$ where I is inhalation rate per day in m^3, v is mg/m^3 of the agent in air, and r is the absorption fraction.

The inhalation rates, I, for various species can be calculated from the observation (FASEB, 1974) that 25 gm mice breathe 34.5 liters/day and 113 gm rats breathe 105 liters/day. For mice and rats of other weights, W, (expressed in kg), the surface area proportionality can be used to determine breathing rates (in m^3/day) as follows:

For mice, $I=0.0345\ (W/0.025)^{2/3} m^3$/day

For rats, $I=0.105\ (W/0.113)^{2/3} m^3$/day

For humans, the values of 20 m^3/day [a] is adopted as a standard breathing rate (ICRP, 1977).

The equivalent exposure in $mg/W^{2/3}$ for these agents can be derived from the air intake data in a way analogous to the food intake data. The empirical factors for the air intake per kg per day, i=I/W based upon the previously stated relationships, are as tabulated below:

Species	W	i=I/W
Man	70	0.29
Rat	0.35	0.64
Mice	0.03	1.3

Therefore, for particulates or completely absorbed gases, the equivalent exposure in $mg/W^{2/3}$ is:

$$\frac{m}{W^{2/3}} = \frac{Ivr}{W^{2/3}} = \frac{iWvr}{W^{2/3}} = iW^{1/3}\,vr$$

In the absence of empirical data or a sound theoretical argument to the contrary, the fraction absorbed, r, is assumed to be the same for all species.

Case 2

The dose in mg/day of partially soluble vapors is proportional to the O_2 consumption which in turn is proportional to $W^{2/3}$ and to the solubility of gas in body fluids, which can be expressed as an absorption coefficient r for the gas. Therefore, when expressing the O_2 consumption as $O_2=k\,W^{2/3}$, where k is a constant independent of species, it follows that $m=k\,W^{2/3} \times v \times r$ or

$$d = \frac{m}{W^{2/3}} = kvr$$

As with Case 1, in the absence of experimental information or a sound theoretical argument to the contrary, the absorption fraction, r, is assumed to be the same for all species. Therefore, for these substances a certain concentration in ppm or μ/m^3 in experimental animals is equivalent to the same concentration in humans. This is supported by the observation that the minimum alveolar concentration, necessary to produce a given "stage" of anesthesia, is similar in man and animals (Dripps, et al. 1977). When the animals were exposed via the oral route and human exposure is via inhalation or vice-versa, the assumption is made, unless there is pharmacokinetic evidence to the contrary, that absorption is equal by either exposure route.

e. If the duration of experiment (L_e) is less than the natural life span of the test animal (L), the slope q_1^*, or more generally the exponent g(d), is increased by multiplying a factor $(L/L_e)^3$. We assume that if the average dose, d, is continued, the age specific rate of cancer will continue to increase as a constant function of the background rate. The age specific rates for humans increase at least by the 2nd power of the age and often by a considerably higher power, as demonstrated by Doll (1971). Thus, we would expect the cumulative tumor rate to increase by at least the 3rd power of age. Using this fact, we assume that the slope q_1^*, or more generally, the exponent g(d), would also increase by at least the 3rd power of age. As a result, if the slope q_1^* [or g(d)] is calculated at age L_e, we would expect that if the experiment had been continued for the full life span, L, at the given average exposure, the slope q_1^* [or g(d)] would have been increased by at least $(L/L_e)^3$.

This adjustment is conceptually consistent to the proportional hazard model proposed by Cox (1972) and the time-to-tumor model considered by Crump, et al. (1977) where the probability of cancer at age t and dose d is given by $P(d,t)=1-\exp[-f(t) \times g(d)]$

4. Calculation of Carcinogenic Potency Based on Human Data. If human epidemiology studies and sufficiently valid exposure information are available for the compound, they are always used in some way. If they show a carcinogenic effect, the data are analyzed to give an estimate of the linear dependence of cancer rates on lifetime average dose, which is equivalent to the factor q_1^*. If they show

[a] From "Recommendation of the International Commission on Radiological Protection," page 9, the average breathing rate is 10^7 cm^3 per 8-hour work day and 2×10^7 cm^3 in 24 hours.

"ndication of carcinogenicity" is interpreted as the absence of carcinogenicity data from animal experimental studies or human epidemiology. Available short-term carcinogenicity screening tests are reported in the criteria documents, but they are not used either for derivation of numerical criteria nor to rule out the uncertainty factor approach.

Because of the high degree of judgment involved in the selection of a safety factor, the criterion derivation section of each document should provide a detailed discussion and justification for both the selection of the safety factor and the data to which it is applied. This discussion should reflect a critical review of the available data base. Factors to be considered include number of animals, species, and parameters tested; quality of controls; dose levels; route; and dosing schedules. An effort should be made to differentiate between results which constitute a toxicologically sufficient data base and data which may be spurious in nature.

2. Use of Acceptable Daily Intake (ADI). For carcinogens, the assumption of low dose linearity precludes the necessity for defining total exposure in the estimation of increased incremental risk. For non-carcinogens, ADIs and criteria derived therefrom are calculated from total exposure data that include contributions from the diet and air. The equation used to derive the criterion (C) is: $C=ADI-(DT+IN)/[2\ l+(0.0065\ kg \times R)]$ where 2 l is assumed daily water consumption, 0.0065 kg is assumed daily fish consumption, R is bioconcentration factor in units of l/kg, DT is estimated non-fish dietary intake, and IN is estimated daily intake by inhalation.

If estimates of IN and DT cannot be provided from experimental data, an assumption must be made concerning total exposure. It is recognized that either the inability to estimate DT and IN due to lack of data or the wide variability in DT and IN in different states may add an additional element of uncertainty to the criterion formulation process. In terms of scientific validity, the accurate estimate of the Acceptable Daily Intake is the major factor in satisfactory derivation of water quality criteria.

3. Use of Threshold Limit Values or Animal Inhalation Studies. Threshold Limit Values (TLVs) are established by the American Conference of Governmental and Industrial Hygienists (ACGIH) and represent 8-hour time-weighted average concentrations in air that are intended to protect workers from various adverse health effects over a normal working lifetime. Similar values are set by NIOSH (criteria) and OSHA (standards) for 10- and 8-hour exposures, respectively. To the extent that these values are based on sound toxicologic assessments and have been protective in the work environment, they provide useful information for deriving or evaluating water quality criteria. However, each TLV must be carefully examined to determine if the basis of the TLV contains data which can be used directly to derive a water quality criterion using the uncertainty factor approach. In addition, the history of each TLV must be examined to assess the extent to which it has assured worker safety. In each case, the types of effects against which TLVs are designed to protect are examined in terms of their relevance to exposure from water. It must be demonstrated that the chemical is not a localized irritant and that there is no significant effect at the site of entry irrespective of the routes of exposure (i.e., oral or inhalation).

If the TLV or similar value is recommended as the basis of the criterion, consideration of the above points is explicitly stated in the criterion derivation section of the document. Particular emphasis is placed on the quality of the TLV relative to the available toxicity data that normally is given priority over TLVs or similar established values. If the TLV can be justified as the basis for the cirterion, then the problems associated with the estimation of acceptable oral doses from inhalation data must be addressed.

Estimating equivalencies of dose-response relationships from one route of exposure to another introduces an additional element of uncertainty in the derivation of criteria. Consequently, whenever possible, ambient water quality criteria should be based on data involving oral exposures. if oral data are insufficient, data from other routes of exposure may be useful in the criterion derivation process.

Inhalation data, including TLVs or similar values, are the most common alternatives to oral data. Estimates of equivalent doses can be based upon: (1) available pharmacokinetic data for oral and inhalation routes, (2) measurements of absorption efficiency from ingested or inhaled chemicals, or (3) comparative excretion data when the associated metabolic pathways are equivalent to those following oral ingestion or inhalation. Given that sufficient pharmacokinetic data are available, the use of accepted pharmacokinetic models provides the most satisfactory approach for dose conversions. However, if available pharmacokinetic data are marginal or of questionable quality, pharmacokinetic modeling is inappropriate.

The Stokinger and Woodward (1958) approach, or similar models based on assumptions of breathing rate and absorption efficiency, represents possible alternatives when data are not sufficient to justify pharmacokinetic modeling. Such alternative approaches, however, provide less satisfactory approximations because they are not based on pharmacokinetic data. Consequently, in using the Stokinger and Woodward or related models, the uncertainties inherent in each of the assumptions and the basis of each assumption must be clearly stated in the derivation of the criterion.

The use of data pertaining to other routes of exposure to derive water quality criteria may also be considered. As with inhalation data, an attempt is made to use accepted toxicologic and pharmacokinetic principles to estimate equivalent oral doses. If simplifying assumptions are used, their bases and limitations must be clearly specified.

Because of the uncertainties involved in extrapolating from one route of exposure to another and the consequent limitations that this may place on the derived criterion, the decision to disallow such extrapolation and recommend no criterion is highly judgmental and must be made on a case-by-case basis. A decision for or against criteria derivation must balance the quantity and quality of the available data against a perceived risk to the human population.

If the Stokinger and Woodward (1958) approach is used to calculate an ADI from a TLV, the general equation is:

$ADI=TLV\times BR\times DE\times d\times A_A/(A_O\times SF)$

where:

ADI = Acceptable daily intake in mg
TLV = Concentration in air in mg/m³
DE = Duration of exposure in hours per day
d = 5 days/7 days
A_A = Efficiency of absorption from air
A_O = Efficiency of absorption from oral exposure
SF = Safety factor following guidelines given above
BR = Amount of air breathed per day; assume 10 m³

For deriving an ADI from animal toxicity data, the equation is:

$ADI=C_A\times D_E\times d\times A_A\times BR\times 70\ kg/(BW_A\times A_O\times SF)$

where:

ADI = Acceptable daily intake in mg
C_A = Concentration in air in mg/m³
D_E = Duration of exposure in hours per day
d = Number of days exposed/number of days observed
A_A = Efficiency of absorption from air
BR = Volume of air breathed per day in m³
70 kg = Assumed human body weight
BW_A = Body weight of experimental animals in kg

limitations of the proposed criterion as well as the type of data needed to generate a compound-specific criterion.

A class criterion should be abandoned when there is sufficient data availabe to derive a compound-specific criterion which protects against the biological effect of primary concern; e.g., the availability of a good subchronic study would not necessarily result in the abandonment of a class criterion based on potential carcinogenicity.

The inability to derive a valid class criterion does not, and should not, preclude regulation of a compound or group of compounds based on concern for potential human health effects. The failure to recommend a criterion is simply a statement that the degree of concern cannot be quantified based on the available data and risk assessment methodology.

E. Essential Elements

Some chemicals, particularly certain metals, are essential to biological organisms at low levels but may be toxic and/ or carcinogenic at high levels. Because of potential toxic effects, it is legitimate to establish criteria for such essential elements. However, criteria must consider essentiality and cannot be established at levels which would result in deficiency of the element in the human population.

Elements are accepted as essential if listed by NAS Food and Nutrition Board or a comparably qualified panel. Elements not yet determined to be essential but for which supportive data on essentiality exists need to be further reviewed by such a panel.

To modify the toxicity and carcinogenicity based criteria, essentiality must be quantified either as a "recommended daily allowance" (RDA) or "minimum daily requirement" (MDR). These levels are then compared to estimated daily doses associated with the adverse effect of primary concern. The difference between the RDA or MDR and the daily doses causing a specified risk level for carcinogens or ADIs for non-carcinogens defines the spread of daily doses from which the criterion may be derived. Because errors are inherent in defining both essential and maximum tolerable levels, the criterion is derived from dose levels near the center of such a dose range. The decision to use either the MDR or RDA is guided by the spread of the doses and the quality of the essentiality and toxicity estimates.

The modification of criteria by consideration of essentiality must take into account all routes of exposure. If water is a significant source of the MDR or RDA, the criterion must allow for attainment of essential intake. Conversely, even when essentiality may be attained from nonwater sources, standard criteria derivation methods may be adjusted if the derived criterion represents a small fraction of the ADI or MDR. On a case-by-case basis, the modification in the use of the guidelines may include the use of different safety factors for non-carcinogens or other modifications which can be explicitly justified.

F. Use of Existing Standards

For some chemicals for which criteria are to be established, drinking water standards already exist. These standards represent not only a critical assessment of literature, but also a body of human experience since their promulgation. Therefore, it is valid to accept the existing standard unless there is compelling evidence to the contrary. This decision should be made after considering the existing standards vs. new scientific evidence which has accumulated since the standards have been established. There are several instances where the peer review process recommended usage of the present drinking water standards.

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EPA attempted to clearly and concisely deal with all issues which might significantly affect the resulting criteria without going into extreme detail on every potential problem. Because numerous judgments must be made, a reasonable amount of experience in aquatic toxicology will be necessary for a person to utilize the Guidelines effectively.

7. Comment—The Guidelines are too complex.

Response—Deriving a water quality criterion is a complex exercise because several different kinds of data and a wide variety of organisms need to be considered. In addition, because data have been generated using various procedures, numerous individual decisions need to be made and the Guidelines attempt to provide guidance concerning decisions that seem to need to be made frequently. The Guidelines are more complex than initially envisioned to help insure that criteria for different pollutants are derived in a reasonably comparable manner. Although the process of deriving a water quality criterion for aquatic life is complex, the Guidelines help organize the process into logical components and steps.

8. Comment—The Guidelines should be more flexible.

Response—The Guidelines are meant to provide guidance and at the same time allow reasonable flexibility. They have been used with quite a variety of pollutants for which the requirements of the minimum data base are satisfied, and they seem to be reasonably appropriate in all cases because the experiences with these substances were a major part of the basis for the Guidelines. If sound scientific evidence indicates that a particular aspect of the Guidelines is not appropriate for a specific substance, then some other more appropriate procedure should be used. However, the Guidelines should not be changed based on individual whim or personal preference.

9. Comment—The Guidelines should take into account synergism and antagonism by a wide variety of factors and the effect of the pollutant on important ecological relationships.

Response—Very little practically useful information is available on these factors in connection with the effects of pollutants on aquatic organisms. Synergism and antagonism are possible between numerous combination of two or more pollutants, and some data indicate that such interactions are not only species specific, but also vary with the ratios and absolute concentrations of the pollutants and the life stage of the species. Pollutants may affect the structure and function of aquatic ecosystems separate from their effects on individual species, but practical applications of such ideas seem very tenuous at this time. Little information is available concerning such effects, and the significance of the available data is questionable. An obviously important ecological relationship is the dependence of higher organisms on lower organisns for food. Even here, the existence of numerous lower species and their adaptability reduces the importance of any individual food species.

10. Comment—The Guidelines should take into account all identifiable effects—beneficial as well as harmful.

Response—Few tests have been conducted to identify beneficial effects of individual pollutants on aquatic organisms. However, beneficial effects are sometimes observed in chronic toxicity tests at concentrations below those that cause adverse effects. Usually in such cases the organisms in low concentrations of the pollutant are longer or heavier or reproduce more that do the controls. Even if such effects are statistically significant, they are not judged as adverse or harmful. On the other hand, a beneficial effect on one species may ultimately be to the detriment of a community if a balance between species is disturbed. Also, a concentration that benefits one species may harm a more sensitive species.

11. Comment—The Guidelines should take into account analytical methodology.

Response—The Guidelines do take into account analytical methodology in the definition of the substance, when necessary, but not in deriving the numerical value of the criterion. Concentrations which cannot be routinely measured accurately can often be measured accurately by nonroutine methods and, more importantly, do sometimes adversely affect aquatic organisms. When aquatic organisms are more sensitive than routine analytical methods, the proper solution is to develop better analytical methods, not to underprotect aquatic life. One use of criteria should be to identify needs in analytical chemistry.

12. Comment—The Guidelines should take into account (a) production and usage patterns, (b) chemical, physical and biological factors pertaining to degradation and fate of pollutants, including properties such as solubility in water, decay rate, persistence, and transformation pathways, and (c) whether or not a criterion is needed for the substance.

Response—Items included in (a) and (b) may be important in deciding whether a criterion is needed for a substance, but the Guidelines are intended to be used after the decision has been made that a criterion is needed. EPA is presently developing principles that can be used to decide whether or not a criterion is needed for a substance and items such as those listed above are probably some of the factors that should be considered when deciding whether or not a criterion is needed. If the toxicity of the chemical is used to evaluate the need for a criterion, the Guidelines may be useful in the collection and interpretation of the available toxicity data.

13. Comment—The Guidelines should take into account costs to states and industries, technological feasibility, and such characteristics of bodies of water as assimilative capacity, dispersal, dissipative factors, dilution, hydrology, mixing zones, and sediment.

Response—Factors such as these should be considered in developing standards, but not in deriving criteria. EPA is presently developing an implementation policy which will describe which of the above factors and which characteristics of the pollutant should be used, and how they should be used, in developing standards.

14. Comment—The Guidelines are not appropriate for establishing a concentration which may be present in an effluent.

Response—The Guidelines are for deriving water quality criteria, not effluent standards nor mixing zone standards nor water quality standards. Water quality criteria will probably be one factor taken into account in the development of water quality standards and toxicity-based effluent standards, but not technology-based effluent standards. EPA is presently developing policies concerning proper use of water quality criteria in various regulatory activities.

15. Comment—The derivation of criteria should be fundamentally a scientific exercise and should not employ subjective judgments.

Response—No exercise which involves the use and interpretation of data can avoid subjective judgment. Indeed, even the generation of scientific data requires subjective judgment, such as how many test organisms to use, what temperature to use, etc. One may decide to accept the recommendations of experts, but this is usually still a subjective decision. In statistics the subjective decisions are made on the basis of probability statements but the final decisions are still subjective judgments. Although the development of the Guidelines and the derivation of criteria cannot avoid subjective

variables that need to be taken into account. The major advantage of field studies is that conditions are natural (i.e., conditions are not controlled), but this is also the major problem with field studies. With uncontrolled conditions, numerous variables must be taken into account, because any individual variable or combination of variables may affect the results or indeed may be the cause of the results. Therefore, field studies on natural populations usually must last over several seasons and possibly over more than one year to be reasonably sure that proposed cause-and-effect relationships are real.

Another problem with field studies that are based on statistically significant differences is the power of the test. Because natural biological, spacial, and temporal variability is often rather great, a large number of samples is usually required to detect even a moderate change. A field study which purports to show that no change occurred is of no value if the power of the test calculated from the experimental design and observed variability was not high enough.

Because field studies are high cost-high risk ventures, well-designed laboratory tests are usually much more cost-effective for obtaining data on (1) the toxicity of substances to a variety of species and (2) the effect of various water quality characteristics on toxicity. Laboratory tests have been shown to generally be useful predictors of what happens in a field situation, and so it makes little sense to conduct high risk, high cost field studies rather than laboratory tests. Even definitive field studies rarely provide enough information to allow extrapolation of results to other situations, so field studies are more useful in reviewing criteria than in deriving criteria.

22. Comment—Field verification of laboratory tests and of the Guidelines are needed.

Response—Field verification of laboratory tests and of the Guidelines are certainly desirable and provide information that cannot be obtained in a laboratory. Field verification studies do not need to be as risky or as costly as studies on the effects of a pollutant on natural populations because verification studies can be designed (1) as a side-by-side comparison of the results of laboratory tests and field tests or (2) based on existing results of laboratory tests.

23. Comment—EPA should allow criteria to be derived using on-site acute toxicity tests and an application factor.

Response—This approach is usually suggested for developing effluent standards but may be just as applicable to deriving water quality criteria under certain conditions. This approach cannot be used with pollutants whose most sensitive adverse effect is due to residues. Also, it can only be used when the application factor has already been acceptably determined. Finally, acute tests must be determined with either an appropriate range of species or with an appropriate sensitive species. The implementation policy presently being developed by EPA will probably allow the use of appropriate on-site toxicity tests in the development of site-specific criteria and standards.

24. Comment—It is not clear what level of protection is intended.

Response—EPA feels that it is not possible to specify a minimum level of protection that is necessary to "protect aquatic life" or even to protect a particular species for such reasons as:

a. There are so many untested species.

b. Little practically useful information is available concerning synergism, antagonism, ecological relationships, and avoidance.

c. The effect of factors such as temperature on toxicity seems to be species-specific for at least some substances.

d. Information is not available concerning what amount of any effect would be ecologically significant and whether the amount is species-specific.

One possible conclusion is that to protect aquatic life, all species must be adequately protected. A possible extension of this would be that all criteria should be zero because any amount of any pollutant may affect some aquatic organism. Indeed, the assimilative capacity of body of water largely depends on the ability of aquatic life to "process" pollutants and to some extent, any organism which "processes" a pollutant is in some way affected by it.

The apparent level of protection is different for each kind of effect (acute toxicity to animals, chronic toxicity to animals, toxicity to plants, and bioaccumulation) because of the quality and quantity of the available information. An attempt was made to take into account such things as the importance of the effect, the quality of the available data, and the probable ecological relevance of the test methods. Thus it was felt that with regards to toxicity to animals it was probably not necessary to protect all of the species all of the time, but it certainly seems appropriate to protect most of the species most of the time and to protect important species.

On the other hand, the data base on toxicity to aquatic plants is usually very small and a variety of tests and endpoints have been used, especially with algae. Also, little information is available concerning the ecological relevance of the results of any toxicity test with algae in a concentrated test medium, especially because so many species of algae exist in each body of water.

The results of bioconcentration tests with organic chemicals, but not with inorganic chemicals, can apparently be extrapolated reasonably well based on percent lipids from one aquatic animal species to another, at least within commercially and recreationally important species. In addition, the limits on acceptable concentrations in tissue are reasonably well defined in some cases.

These kinds of considerations merely illustrate the complexity of the problem and the necessity for making decisions about each kind of effect individually. In addition, it is important to distinguish between the apparent level of protection provided by the Guidelines and the actual level of protection which will result in a field situation from the use of the implementation policy.

No attempt was made to develop Guidelines which would achieve a predetermined numerical level of protection. For each effect much desirable information is not available, and so it would be misleading to imply a level of sophistication that is not currently possible. EPA believes that the present state-of-the-art in aquatic toxicology does allow some useful conclusions about the ability of a substance to adversely affect aquatic organisms and their uses whenever the requirements of the minimum data base are satisfied, with the full realization that the resulting criterion may be somewhat overprotective or underprotective.

In almost all cases more data would be desirable and so an attempt to reach the "golden mean" will sometimes result incriteria being to high and sometimes too low. One alternative is to derive no criteria until all desirable data are available; this is unacceptable because it will almost always result in no criteria and no protection. The other alternative is to apply safety or uncertainty factors that are inversely proportional to the adequacy of the data base. In the long run this approach would encourage the generation of useful data where it was most needed, but in the short run would require many significant subjective decisions beyond the current state-of-the-art.

25. Comment—The Guidelines should not base criteria on "worst case" assumptions.

is likely to be closer to a lognormal distribution than a normal distribution. Thus the geometric mean, rather than the arithemetic mean, of the upper and lower chronic limits is used.

32. Comment—There should not be any criteria which apply to all bodies of water. Criteria should be specific for individual states, regions, other geographic areas, or bodies of water.

Response—The Guidelines are designed to provide guidance in the collection and interpretation of data concerning the effects of pollutants on aquatic life and its uses. The uses of the resulting criteria will be described by EPA in various regulations. If desired, the Guidelines can be appropriately modified and used to derive a criterion specific to one or more bodies of water or geographic areas if an appropriate data base is available. The critical literature reviews on which the criteria are based will be available for use in the derivation of local, state, or regional criteria. The latitude allowed for deriving local, state, or regional criteria and standards will be determined by the implementation policy presently being developed by EPA.

33. Comment—The Guidelines should result in criteria that are specific for individual species or groups of species (e.g., warmwater and coldwater).

Response—If the necessary data were available, criteria could be derived for any particular species or group of species. It was impractical for EPA to derive criteria for many such groups, but a relatively simple division is freshwater and saltwater organisms because these two groups rarely coexist. Most other possible general divisions of species are faced with the problem that species coexist in various combinations unless the groups are very narrow. In addition, toxicity data are rarely available for very many individual species and so data for representative species must be used, unless appropriate new data are generated. Also, the available data sometimes show wide differences within families so extrapolations from one species to another are often tenuous. Because of these problems, deriving criteria for individual species or groups of species was deemed impractical.

34. Comment—A criterion should be one number, not two.

Response—The two-number criterion is an acknowledgement that aquatic organisms can tolerate short exposures to concentrations that are higher than those they can tolerate continuously. In a two-number criterion, the higher number can assure that short-term fluctuations above the average are not too high, whereas the lower number can assure that the long-term average is not too high. A one-number criterion could be derived by using the existing 24-hour average as an instantaneous maximum. This would certainly provide additional protection, but would provide unnecessary overprotection in most cases. Because a one-number criterion would be more of an approximation than a two-number criterion, one-number criteria would be too high or too low more often and to a greater degree than two-number criteria.

35. Comment—The criteria should not specify sampling schemes.

Response—Criteria should state numerical concentration limits in terms of exposure durations because, everything else being constant, the amount of adverse effect depends on both the concentration of the pollutant and the duration of exposure. Criteria in the Green Book, Blue Book, and Red Book were usually stated as single numbers with no duration expressly stated. The implication was that the criteria were never to be exceeded at any time. Each criterion was apparently and instantaneous maximum. In practice, however, standards derived from these criteria were usually enforced on the basis of 24-hour composite samples. To avoid any ambiguity, the Guidelines specify that a criterion should be explicitly stated in terms of two time frames: an instantaneous maximum and a 24-hour average. However, this is not a specification for a sampling scheme. Standards developed from such a criterion should probably specify a sampling scheme for compliance monitoring, but it would not necessarily be in terms of point measurements and 24-hour averages.

Any sampling scheme used to determine whether or not an ambient concentration exceeds a water quality criterion or a comparable water quality standard should take into account such things as the ratio of the instantaneous maximum and the 24-hour average and the retention time of the body of water because these will primarily determine which portion of the criterion is most limiting in any specific situation. The sampling scheme should probably also take into account the cost of the analyses and results of any past analyses.

36. Comment—The criteria should be stated in terms of time frames longer that an instantaneous maximum and a 24-hour average.

Response—These two time frames were chosen because they would allow the derivation of a criterion which would be less restrictive than, but just as protective as, the previous one-number criterion. These two specific time frames were chosen because they match two kinds of samples that are commonly collected: grab samples and 24-hour composite samples. These specific time frames could probably be changed somewhat without much practical effect, but EPA saw no particular advantage to anyone to introducing novel time periods. For example, for all practical purposes in most situations a 10-minutes average is probably about the same as an instantaneous maximum.

Large increases in the time frames, however, would not provide the same amount of protection. If the instantaneous maximum were changed to a 24- or 96-hour average, and the 24-hour average were changed to a 7- or 30-day average with no change in the numerical limits, the amount of protection afforded aquatic life would fall to an unacceptable level. The longer the time span for the average, the higher the instantaneous concentration could be for short periods of time within that span. Although most chronic tests last for 28-days or longer, some chronic effects may be caused by short exposures of sensitive life stages. If the acute-chronic ratio is small, fluctuations in the instantaneous concentration may even cause acute toxicity, especially for cumulative pollutants, because for some substances the 24-, 48-, and 96-hour acute values do not differ too much.

37. Comment—A two-number criterion will be difficult to enforce.

Response—Criteria are not enforceable. Standards are enforceable. When standards to protect aquatic life are developed, they may or may not be in the same format as the criteria for aquatic life. Few standards are adequately enforced because of the high cost of continuous monitoring. The real value of many criteria and standards is in the design of waste treatment facilities; a two-number criterion should be a better basis for design than a one-number criterion.

38. Comment—The criteria should be expressed to one significant figure, not two.

Response—EPA acknowledges that there is much variability in some of the data and that the range of sensitivites is often great. When the requirements of the minimum data base are satisfied and the data agree reasonably well, two significant figures are not unreasonable. Rounding off to one significant figure could arbitrarily raise or lower the criterion by up to forty percent with no apparent consistent benefits to dischargers, regulators, or aquatic life.

39. Comment—The Guidelines should only use data for species that ought to be protected.

damage than elevated concentrations of a pollutant that produces a wide range of species sensitivities.

49. Comment—The distinction between ionizable and unionizable compounds is not very good because some chemicals ionize and reach chemical equilibrium very slowly and others very rapidly.

Response—Most chemicals can readily be classified into one of three groups:

A. Chemicals that ionize, including hydrolyze, at least 90% and reach 90% of equilibrium in less than 8 hours in most surface waters.

B. Chemicals that ionize, including hydrolyze, less than 10% in 30 days in most surface waters.

C. Chemicals that do not fit into either one of the above categories.

For the purpose of the Guidelines, chemicals in the A group should be considered ionizable, chemicals in the B group should be considered non-ionizable, and chemicals in the C group should be classified on a case-by-case basis. Although the distinction between ionizable and unionizable may not be perfect, it is very useful for most chemicals.

50. Comment—Each individual organic compound should be considered separately.

Response—The vast majority of organic chemicals will be considered separately according to the Guidelines except for structurally similar organic compounds that meet all three specifications given in the Guidelines, such as polychlorinated biphenyls and toxaphene.

51. Comment—In-stream water quality criteria are meaningless for substances that are highly insoluble.

Response—The concentration of some substances in sediment may be important separate from the concentration of the substance in the ambient water and for these compounds a sediment quality criterion may be necessary. Generally such compounds can also cause adverse effects if the concentration in the ambient water is too high even if the concentration in the sediment is low. Thus for such compounds both kinds of criteria may be necessary rather than just one or the other.

52. Comment—If a substance is not dissolved, it is not biologically or toxicologically available.

Response—Although this may usually be true, it certainly does not apply to elemental mercury which can be oxidized and methylated to form a very toxic compound. Some organic acids and phenols and hydroxide and carbonate salts of metals have solubilities which differ substantially from one body of water to another.

53. Comment—Criteria for metals should not be for total metal.

Response—Criteria for metals will generally not be based on total metal. Most will be based on total recoverable metal because forms of metals that are not measured in the total recoverable procedure probably are not, and will not become, toxic. A major problem is that some people use a procedure for total recoverable, but report the results as total, metal. In many situations the two results are about the same, but in some cases the results are quite different.

54. Comment—The Guidelines should give more guidance for distinguishing between acceptable and unacceptable data.

Response—The Guidelines contain as much detail on this subject as EPA believes is currently feasible. Items such as the maximum acceptable control mortality and minimum number of test organisms are based on what many aquatic toxicologists generally feel are acceptable, as expressed in published methods. No data should be used in the derivation of a criteria until their quality and acceptability had been reviewed by a competent person. Competent people will occasionally disagree, but that is a fundamental property of subjective decisions.

55. Comment—Only published data should be used.

Response—Peer review is one of many concepts that is better in theory than in practice. Some poor quality data are published and some high quality data are rejected. In addition, publication is not a particularly rapid process. Whether or not data are used should depend on the applicability and quality of the data, not on whether they have been published. Data that are not published should be made readily available if they are used to derive water quality criteria.

56. Comment—All static test are unacceptable

Response—In general, high quality flow-through acute tests are preferable to high quality static acute tests, but static tests are by no means unacceptable. Few data are available to show whether static tests consistently produce acute values lower or higher or different than flow-through tests. Whereas degradation, violatilization, and buildup of metabolic products are more likely to be a problem in static tests, operator and mechanical errors are more likely in flow-through tests. Static acute tests are certainly not unacceptable for most pollutants, but static chronic tests generally are unacceptable because of changes in the toxicant concentrations and the quality of the dilution water during the test.

57. Comment—Data obtained using test organisms that were previously exposed to the pollutant should be used.

Response—Comparisons of results obtained with unexposed and previously exposed organisms should indicate whether or not acclimation has occurred. Generally, data obtained with acclimated organisms should not be used in deriving criteria because acclimated organisms are the exception rather than the norm. Rarely, if ever, can acclimation be depended on to protect organisms in a field situation because concentrations often fluctuate and motile organisms do not stay in one location very long. Data obtained with acclimated organisms may be acceptable for use in deriving some site-specific criteria.

58. Comment—Foreign species should be used to expand the data base.

Response—Foreign species may be representative of indigenous species, but some of them are quite unusual. Data obtained with foreign species may give good indications of indigenous speceis that should be used in tests on some pollutants and may identify some potential problems that should be investigated.

59. Comment—If data for brine shrimp are not used, the criteria should not apply to saline waters.

Response—Data obtained using brine shrimp are not used because these organisms are atypical. Although they may not be usually sensitive or insensitive to various pollutants, the species found in North America and used for testing only survive in the Great Salt Lake and in salt ponds near San Francisco Bay. These two habitats are unlike any others in the United States. If criteria were to be derived specifically for the Great Salt Lake or for salt ponds, then data for brine shrimp should be used.

60. Comment—Structure-activity relationships should not be used unless proven.

Response—No provision is made in the Guidelines for the use of structure-activity relationships. Such relationships may soon be well enough understood that they can be used in deriving water quality criteria.

61. Comment—A criterion should not be derived for a pollutant until data are available for a broad range of commercially, recreationally, and ecologically important species. Each species should be acutely and chronically tested under a variety of conditions in a number of different waters.

useful, but such a test cannot be used with just two points and does not take into account such things as the comparability of the data, the quality of the test, and the range of the independent variable. A relationship based on six points may not be as significant as it seems if five of the points are tightly grouped.

71. Comment—The Guidelines should not combine 96-hr LC50 values and 48-hr EC50 values.

Response—Both LC50 values and EC50 values are used to measure acute toxicity of a substance to aquatic organisms. In general, an EC50 can be based on a wide variety of effects, but the Guidelines specify that the only effects to be used for deriving criteria are incomplete shell development, immobilization, and loss of equilibrium. All of these are certainly drastic effects. In a field situation these effects probably often lead to death. Just as the endpoint may be specific for the species, so may be the length of the test. The generally accepted length of an acute test with daphnids is 48 hours, whereas for most species of fish, it is 96 hours. Thus the Guidelines use both 48-hr EC50 values and 96-hr LC50 values because they are the widely accepted durations and endpoints used to measure acute toxicity to specific species.

72. Comment—Shell deposition tests are chronic tests and should not be equated with lethality tests.

Response—"Acute" implies "short" not "death". Many acute toxicity tests do use death for the effect, but many also use non-lethal effects. The shell deposition test is one of many non-lethal acute tests and is generally accepted as a short test compared to the average life span of oysters.

73. Comment—Adjustment factors should not be used to adjust for the length of the test, the technique, and unmeasured concentrations.

Response—All three kinds of adjustment factors have been deleted from the Guidelines. The factor for the length of the test was found to be unnecessary because most tests had been conducted for the standard times usually specified for the individual species. Thus the Guidelines now specify that only data from tests conducted for the time specified for the species should be used to calculate the Final Acute Value.

EPA has found that on the average flow-through acute tests give results slightly lower than do static tests, but the relationship does not seem to be too consistent and may vary from species to species for some pollutants. In addition, on the average results based on measured concerntrations do not seem to be much different from those based on unmeasured concentrations.

However, the results of flow-through tests based on measured concentrations are generally accepted as being better measures of acute toxicity than the results of flow-through tests based on unmeasured concentrations or the results of any static or renewal tests.Therefore, whenever the results of flow-through acute tests in which the concentrations were measured are available, the results of all other kinds of acute tests with that species and pollutant are not used in the calculation of the species mean acute value.

74. Comment—Species sensitivity factors should be pollutant-specific; and average factor should not be calculated for a variety of substances.

Response—EPA agrees. The requirement for acute values for at least eight different species was developed in part to allow for a reasonably good calculation of a mean acute value and a species sensitivity factor for each individual pollutant. A better way of using the acute values for the individual species has been developed, but no extrapolations are made from one pollutant to another.

75. Comment—The distribution of species mean acute values for a pollutant will be truncated if the species cannot be killed or affected by concentrations above solubility.

Response—Some species are so resistant to some pollutants that they cannot be killed or affected in acute tests even by concentrations which are much above solubility. Such "greater than" values cannot be used in the calculation of means and variances for pollutants. When the "greater than" values are for insensitive species and are at or above solubility, the values can be used in the calculation of the Final Acute Value by adjusting the cumulative proportions for all the speices with quantitative values. The shape of the curve at the high end cannot be determined, but the Final Acute Value is more dependent on the species mean acute values and the cumulative probabilities at the low end.

76. Comment—Early life-stage tests with fish should be used interchangeably with life-cycle and partial life-cycle tests with fish.

Response—EPA agrees that early life-stage tests with fish generally give about the same results as comparable life-cycle and partial life-cycle tests. However, because the shorter test is merely a predictor of the longer tests, whenever both kinds of results are available, the results of life-cycle and partial life-cycle tests should be used instead of the results of early life-stage tests.

77. Comment—Appropriate measures of chronic toxicity and appropriate lengths of exposure should be defined.

Response—The descriptions of appropriate chronic tests have been clarified.

78. Comment—The factor of 0.44 should not be used.

Response—It is not now used.

79. Comment—The Final Chronic Value should not be lower than the lowest measured species chronic value, even if chronic data are not available for sensitive species.

Response—Aquatic ecosystems cannot be protected from chronic toxicity by protecting only the insensitive species from chronic toxicity. In the past both arbitrary and experimentally determined application factors have been used to relate acute and chronic toxicity. For a variety of reasons the Guidelines do not use an application factor, but instead use the acute-chronic ratio, which is similar to the inverse of an application factor. Thus the acute-chronic ratio should normally be greater than one. The acute-chronic ratio is to be used with invertebrates as well as fish and is to be an experimentally determined value for each individual pollutant. The acute-chronic ratio should also avoid the confusion as to whether a large application factor is one that is close to unity or one that has a denominator that is much larger than the numerator. The acute-chronic ratio is calculated by dividing the appropriate measure of acute toxicity for the species (as specified in the Guidelines) by the appropriate measure of chronic toxicity for the same species (as specified in the Guidelines).

Some people have confused application factors and safety factors and use of the term "acute-chronic ratio" should help avoid this problem. Acute-chronic ratios are a way of estimating the chronic sensitivity of a species for which no chronic toxicity data are available. Safety factors would provide an extra margin of safety beyond the sensitivity of the species. Safety or uncertainty factors are intended to reduce the possibility of underprotection, whereas acute-chronic ratios are intended to estimate the actual chronic sensitivity of the species to the pollutant. This estimate is just as likely to be too high as it is to be too low. A mean acute-chronic ratio will in fact be too high for half the species and too low for the other half.

When three or more acute-chronic ratios have been determined for a pollutant with both fish and

79 FR 27303-01
NOTICES
ENVIRONMENTAL PROTECTION AGENCY
[EPA-HQ-OW-2014-0135; FRL—9910-81-OW]

Updated National Recommended Water Quality Criteria for the Protection of Human Health

Tuesday, May 13, 2014

AGENCY: Environmental Protection Agency (EPA).

***27303** ACTION: Notice of Availability.

SUMMARY: EPA is announcing the availability of draft updated national recommended water quality criteria for the protection of human health for the purpose of obtaining public comments. EPA has updated its national recommended water quality criteria for human health for ninety-four chemical pollutants to reflect the latest scientific information and current EPA policies. This draft update is based on EPA's current methodology for deriving human health criteria as described in “Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)” and does not establish new policy. EPA's recommended water quality criteria provide technical information for States and authorized Tribes to establish water quality standards under the Clean Water Act to protect human health.

DATES: The public comment period begins on May 13, 2014 and ends on July 14, 2014. Technical comments should be submitted to the public EPA docket by July 14, 2014.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OW-2014-0135, by one of the following methods:

• www.regulations.gov: Follow the on-line instructions for submitting comments.

• Mail: Water Docket, Environmental Protection Agency, 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Attention Docket ID No. EPA-HQ-OW-2014-0135.

• Hand Delivery: Water Docket, EPA Docket Center, EPA WJC West Building Room 3334, 1301 Constitution Ave. NW., Washington, DC, 20004, Attention Docket EPA-HQ-OW-2014-0135. Deliveries to the docket are accepted only during their normal hours of operation: 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. For access to docket materials, call (202) 566-2426, to schedule an appointment.

• Email: ow-docket@epa.gov; Attention Docket No. EPA-HQ-OW-2014-0135. To ensure that EPA can properly respond to comments, commenters should cite the section(s) or chemical(s) in draft updates to which each comment refers. Commenters should use a separate paragraph for each issue discussed, and must submit any references cited in their comments. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment. Electronic files should avoid any form of encryption and should be free of any defects or viruses.

Instructions: Direct your comments to Docket ID No. EPA-HQ-OW-2014-0135. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov. The www.regulations.gov Web site is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through www.regulations.gov your email address will be automatically

captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the Water Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426.

FOR FURTHER INFORMATION CONTACT: Heidi Bethel at U.S. EPA, Office of Water, Health and Ecological Criteria Division (Mail Code 4304T), 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone: (202) 566-2054; or email: bethel.heidi@epa.gov.

SUPPLEMENTARY INFORMATION:

I. What should I consider as I prepare my comments for EPA?

In preparation for submitting comments for EPA on this action, please review the draft chemical-specific support documents EPA is publishing (1) in the public docket for this action under Docket ID No. EPA-HQ-OW-2014-0135, or (2) on EPA's Web site http://water.epa.gov/scitech/swguidance/standards/criteria/current/hhdraft.cfm. Provide EPA with comments regarding scientific views related to the draft updated national recommended water quality criteria for protecting human health. Include any recommended references for data or other scientific information to be considered by EPA.

II. What are recommended water quality criteria?

EPA's recommended water quality criteria are scientifically derived numeric values that protect aquatic life or human health from the deleterious effects of pollutants in ambient water.

***27304** Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish and, from time to time, revise, criteria for protection of water quality and human health that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Section 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water.

EPA's recommended Section 304(a) criteria provide technical information to States and authorized Tribes in adopting water quality standards that ultimately provide a basis for assessing water body health and controlling discharges or releases of pollutants. Under the CWA and its implementing regulations, States and authorized Tribes are to adopt water quality criteria to protect designated uses (e.g., public water supply, aquatic life, recreational use, or industrial use). EPA's recommended water quality criteria do not substitute for the CWA or regulations, nor are they regulations themselves. Thus, EPA's recommended criteria do not impose legally binding requirements. States and authorized Tribes have the discretion to adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.

III. What are the updated criteria?

Today, EPA is publishing draft updated national recommended water quality criteria for the protection of human health for ninety-four chemical pollutants. These revisions are based on EPA's current methodology for deriving human health criteria

(See: Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000), EPA-822-B-00-004, October 2000). The methodology describes EPA's current approach for deriving national recommended water quality criteria for the protection of human health.

The revision of these criteria represents a systematic update of EPA's national recommended 304(a) criteria. EPA has previously described its process for publishing revised criteria [see National Recommended Water Quality Criteria—Correction (64 FR 19781; or EPA 822-Z-99-001) or the Federal Register Notice for EPA's 2000 Methodology (65 FR 66444)]. EPA is announcing the availability of the updated human health criteria in today's Notice in order to solicit scientific views. EPA has updated the draft human health criteria using information sources and models that have previously undergone external peer review. A fact sheet and a summary of updated input parameters (e.g., cancer slope factor, reference dose, and bioaccumulation factors) used to derive the updated criteria was prepared to assist reviewers. EPA has also developed chemical-specific support documents for each of the ninety-four chemical pollutants. The support documents detail the latest scientific information supporting the updated draft human health criteria, particularly the updated toxicity and exposure input values. All of these documents are available in the docket (EPA-HQ-OW-2014-0135) and on EPA's Web site http://water.epa.gov/scitech/swguidance/standards/criteria/current/hhdraft.cfm.

IV. What is the relationship between the draft national recommended water quality criteria and your state or tribal water quality standards?

As part of the water quality standards triennial review process defined in section 303(c)(1) of the CWA, the States and authorized Tribes are responsible for maintaining and revising water quality standards. Water quality standards consist of designated uses, water quality criteria to protect those uses, a policy for antidegradation, and may include general policies for application and implementation. Section 303(c)(1) requires States and authorized Tribes to review and modify, if appropriate, their water quality standards at least once every three years.

States and authorized Tribes must adopt water quality criteria that protect designated uses. Protective criteria are based on a sound scientific rationale and contain sufficient parameters or constituents to protect the designated uses. Criteria may be expressed in either narrative or numeric form. States and authorized Tribes have four options when adopting water quality criteria for which EPA has published section 304(a) criteria. They can:

(1) Establish numerical values based on recommended section 304(a) criteria;

(2) Adopt section 304(a) criteria modified to reflect site specific conditions;

(3) Adopt criteria derived using other scientifically defensible methods; or

(4) Establish narrative criteria where numeric criteria cannot be determined (40 CFR 131.11).

EPA believes that it is important for States and authorized Tribes to consider any new or updated 304(a) criteria as part of their triennial review to ensure that state or tribal water quality standards reflect current science and protect applicable designated uses. These updated criteria recommendations may change based on scientific views shared in response to this notice, but once final they would supersede EPA's previous recommendations.

Consistent with 40 CFR 131.21, new or revised water quality criteria adopted into law or regulation by States and authorized Tribes on or after May 30, 2000 are in effect for CWA purposes only after EPA approval.

Dated: April 29, 2014.

Nancy K. Stoner,

Acting Assistant Administrator, Office of Water.

[FR Doc. 2014-10963 Filed 5-12-14; 8:45 am]

BILLING CODE 6560-50-P

United States Environmental Protection Agency

Office of Water
4304T

EPA-820-F-14-003
May 2014

Human Health Ambient Water Quality Criteria: Draft 2014 Update

Summary

EPA is announcing in the Federal Register the availability of draft updated ambient water quality criteria for the protection of human health for the purpose of obtaining public comments. EPA has updated its national recommended water quality criteria for human health for 94 chemical pollutants to reflect the latest scientific information and EPA policies. EPA will accept written scientific views from the public on the draft updated human health criteria for 60 days. Once finalized, EPA water quality criteria provide recommendations to states and tribes authorized to establish water quality standards under the Clean Water Act.

Background

Ambient water quality criteria developed by EPA under the Clean Water Act represent specific levels of chemicals or conditions in a water body that are not expected to cause adverse effects to human health. EPA is required to develop and publish water quality criteria that reflect the latest scientific knowledge. These criteria are not rules, nor do they automatically become part of a state's water quality standards. States may adopt the criteria that EPA publishes, modify EPA's criteria to reflect site-specific conditions, or adopt different criteria based on other scientifically-defensible methods. EPA must, however, approve any new water quality standards adopted by a state before they can be used for Clean Water Act purposes.

In this 2014 update, EPA has revised 94 of the existing human health criteria to reflect the latest scientific information, including updated exposure factors (body weight, drinking water intake, fish consumption rate), bioaccumulation factors, and toxicity factors (reference dose, cancer slope factor). The criteria have also been updated to follow the current EPA methodology for deriving human health criteria (2000). Specific updates are described in detail below.

Due to outstanding technical issues, including new toxicity factors and bioaccumulation factors, EPA is *not* updating criteria for the following chemical pollutants at this time: antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium (III or VI), copper, manganese, methylmercury, nickel, nitrates, nitrosamines, N-nitrosodibutylamine, N-nitrosodiethylamine, N-nitrosopyrrolidine, N-nitrosodimethylamine, N-nitrosodi-n-propylamine, N-nitrosodiphenylamine, polychlorinated biphenyls (PCBs), selenium, thallium, zinc, or 2,3,7,8-TCDD (dioxin).

Updated Exposure Assumptions

Body Weight

EPA has updated the default body weight assumption for human health criteria to 80 kilograms based on National Health and Nutrition Examination Survey (NHANES) data from 1999 to 2006. This represents the mean body weight for adults ages 21 and older. EPA's previously recommended body weight assumption was 70 kilograms, which was based on the mean body weight of adults from the NHANES III database (1988-1994).

Drinking Water

EPA has updated the default drinking water intake rate assumption to 3 liters per day based on NHANES data from 2003 to 2006 for all sources of water at the 90th percentile for adults ages 21 and older. This value is based on consumer-only estimates of direct and indirect water ingestion. EPA previously recommended a default drinking water intake rate of 2 liters per day, which represented the 86th percentile for adults surveyed in the US Department of Agriculture's 1994-1996 Continuing Survey of Food Intake by Individuals (CSFII) analysis and the 88th percentile of adults in the National Cancer Institute study of the 1977-1978 Nationwide Food Consumption Survey.

Fish Consumption

EPA has updated the default fish consumption rate to 22 grams per day. This rate represents the 90th percentile consumption rate of freshwater and estuarine fish for the U.S. adult population 21 years of age and older, based on NHANES data from 2003 to 2010 (USEPA 2014). EPA's previously recommend rate of 17.5 grams per day was based on the 90th percentile consumption rate of freshwater and estuarine fish for the U.S. adult population and was derived from 1994-1996 CSFII data.

As described in EPA's human health criteria methodology (USEPA 2000), the level of fish intake in highly exposed populations varies by geographical location. Therefore, EPA suggests a four preference hierarchy for states and authorized tribes that encourages use of the best local, state, or regional data available to derive fish consumption rates. EPA recommends that states and authorized tribes consider developing criteria to protect highly exposed population groups and use local or regional data over the default values as more representative of their target population group(s). The four preference hierarchy is: (1) use of local data; (2) use of data reflecting similar geography/ population groups; (3) use of data from national surveys; and (4) use of EPA's default intake rates.

Bioaccumulation Factors

EPA's national recommended water quality criteria for the protection of human health have been updated using bioaccumulation factors rather than bioconcentration factors, as recommended in EPA's human health criteria methodology (USEPA 2000). Unlike bioconcentration factors, bioaccumulation factors account for more exposure pathways than direct water contact. As a result, the updated criteria will better represent exposures to pollutants that affect human health. In order to account for the variation in bioaccumulation that is due to trophic position of the organism, EPA's human health criteria methodology (USEPA 2000) recommends that bioaccumulation factors be determined and applied to three trophic levels of fish. EPA used a peer-reviewed model called Estimation Program Interface Suite (EPI Suite) to develop bioaccumulation factors for each trophic level of fish.

Updated Health Risk Factors

EPA has updated the health risk factors using the most current toxicity information. EPA's Integrated Risk Information System (IRIS) is the primary recommended source for reference dose and cancer slope factor information. For some pollutants, more recent assessments may be found using other resources provided by EPA's Office of Water, EPA's Office of Pesticide Programs, and international or state agencies.

Relative Source Contribution

EPA has updated the human health criteria to reflect the recommended default relative source contribution (RSC) of 20 percent, as recommended in EPA's human health criteria methodology (USEPA 2000). The RSC component of the human health criteria calculation for non-carcinogens designates a percentage of the reference dose that accounts for exposures from water and fish (freshwater and estuarine), when there are other possible exposure routes. Other such routes include, but are not limited to, exposure to a particular pollutant from marine fish consumption, non-fish food consumption, dermal exposure, and respiratory exposure. For pollutants exhibiting threshold effects, the use of an RSC ensures that an individual's total exposure from all sources of a pollutant does not exceed that threshold level.

In accordance with EPA's human health criteria methodology (USEPA 2000), an alternative RSC may be used to derive human health criteria when there are sufficient data available to support a scientifically defensible alternative value.

For More Information

Contact: Heidi Bethel by telephone at (202) 566-2054, by email at bethel.heidi@epa.gov, or by mail at U.S. EPA, Health and Ecological Criteria Division (4304T), 1200 Pennsylvania Ave., N.W., Washington, D.C. 20460.
To access the Federal Register notice, the draft updated criteria, and supporting documents visit: http://water.epa.gov/scitech/swguidance/standards/criteria/health/.

References

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USEPA (U.S. Environmental Protection Agency). 2012. Estimation Programs Interface Suite™ for Microsoft® Windows, v 4.10. United States Environmental Protection Agency, Washington, DC, USA.

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60 FR 15366-01
RULES and REGULATIONS
ENVIRONMENTAL PROTECTION AGENCY
40 CFR Parts 9, 122, 123, 131, and 132
[FRL-5173-7]
RIN 2040-AC08

Final Water Quality Guidance for the Great Lakes System

Thursday, March 23, 1995

***15366** AGENCY: U.S. Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: EPA is publishing Final Water Quality Guidance for the Great Lakes System. Great Lakes States and Tribes will use the water quality criteria, methodologies, policies, and procedures in the Guidance to establish consistent, enforceable, long-term protection for fish and shellfish in the Great Lakes and their tributaries, as well as for the people and wildlife who consume them.

The Guidance was initially developed by the Great Lakes States, EPA, and other Federal agencies in open dialogue with citizens, local governments, and industries in the Great Lakes ecosystem. It will affect all types of pollutants, but will target especially the types of long-lasting pollutants that accumulate in the food web of large lakes.

The Guidance consists of water quality criteria for 29 pollutants to protect aquatic life, wildlife, and human health, and detailed methodologies to develop criteria for additional pollutants; implementation procedures to develop more consistent, enforceable water quality-based effluent limits in discharge permits, as well as total maximum daily loads of pollutants that can be allowed to reach the Lakes and their tributaries from all sources; and antidegradation policies and procedures.

Under the Clean Water Act, the States of Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin must adopt provisions into their water quality standards and NPDES permit programs within two years (by March 23, 1997) that are consistent with the Guidance, or EPA will promulgate the provisions for them. The Guidance for the Great Lakes System will help establish consistent, enforceable, long-term protection from all types of pollutants, but will place short-term emphasis on the types of long-lasting pollutants that accumulate in the food web and pose a threat to the Great Lakes System. The Guidance includes minimum water quality criteria, antidegradation policies, and implementation procedures that provide a coordinated ecosystem approach for addressing existing and possible pollutant problems and improves consistency in water quality standards and permitting procedures in the Great Lakes System. In addition, the Guidance provisions help establish consistent goals or minimum requirements for Remedial Action Plans (RAPs) and Lakewide Management Plans (LaMPs) that are critical to the success of international multi-media efforts to protect and restore the Great Lakes ecosystem.

EFFECTIVE DATE: April 24, 1995.

ADDRESSES: The public docket for this rulemaking, including applicable Federal Register documents, public comments in response to these documents, the Final Water Quality Guidance for the Great Lakes System, Response to Comments Document, other major supporting documents, and the index to the docket are available for inspection and copying at U.S. EPA Region 5, 77 West Jackson Blvd., Chicago, IL 60604 by appointment only. Appointments may be made by calling Wendy Schumacher (telephone 312-886-0142).

Information concerning the Great Lakes Initiative (GLI) Clearinghouse is available from Ken Fenner, Water Quality Branch Chief, (WQS-16J), U.S. EPA Region 5, 77 W. Jackson Blvd., Chicago, IL 60604 (312-353-2079).

Copies of the Information Collection Request for the Guidance are available by writing or calling Sandy Farmer, Information Policy Branch, EPA, 401 M St., S.W. (Mail Code 2136), Washington, DC 20460 (202-260-2740).

Selected documents supporting the Guidance are also available for viewing by the public at locations listed in section XI of the preamble.

Selected documents supporting the Guidance are available by mail upon request for a fee. Selected documents are also available in electronic format at no incremental cost to users of the Internet. See section XI of the preamble for additional information.

FOR FURTHER INFORMATION CONTACT: Kenneth A. Fenner, Water Quality Branch Chief (WQS-16J), U.S. EPA Region 5, 77 W. Jackson Blvd., Chicago, IL 60604 (312-353-2079).

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I. Introduction

Section 118(c)(2) of the Clean Water Act (CWA) (Pub. L. 92-500 as amended by the Great Lakes Critical Programs Act of 1990 (CPA), Pub. L. 101-596, November 16, 1990) required EPA to publish proposed and final water quality guidance on minimum water quality standards, antidegradation policies, and implementation procedures for the Great Lakes System. In response to these requirements, EPA published the Proposed Water Quality Guidance for the Great Lakes System (proposed Guidance) in the Federal Register on April 16, 1993 (58 FR 20802). EPA also published four subsequent documents in the Federal Register identifying corrections and requesting comments on additional related materials (April 16, 1993, 58 FR 21046; August 9, 1993, 58 FR 42266; September 13, 1993, 58 FR 47845; and August 30, 1994, 59 FR 44678). EPA received over 26,500 pages of comments, data, and information from over 6,000 commenters in response to ***15367** these documents and from meetings with members of the public.

After reviewing and analyzing the information in the proposal and these comments, EPA has developed the Final Water Quality Guidance for the Great Lakes System (final Guidance), published in this document and codified in 40 CFR part 132, which includes six appendixes of detailed methodologies, policies, and procedures. This preamble describes the background and purpose of the final Guidance, and briefly summarizes the major provisions. Detailed discussion of EPA's reasons for issuing the final Guidance, analysis of comments and issues, description of specific changes made to the proposed Guidance, and further description of the final Guidance, are provided in “Final Water Quality Guidance for the Great Lakes System: Supplementary Information Document” (SID), (EPA, 1995, 820-B-95-001) and in additional technical and supporting documents which are available in the docket for this rulemaking. Copies of the SID and other supporting documents are also available from EPA in electronic format, or in printed form for a fee upon request; see section XI of this preamble.

II. Background

The Great Lakes are one of the outstanding natural resources of the world. They have played a vital role in the history and development of the United States and Canada, and have physical, chemical, and biological characteristics that make them a unique ecosystem. The Great Lakes themselves—Lakes Superior, Huron, Michigan, Erie and Ontario and their connecting channels—plus all of the streams, rivers, lakes and other bodies of water that are within the drainage basin of the Lakes collectively comprise the Great Lakes System.

The System spans over 750 miles across eight States—New York, Pennsylvania, Ohio, Michigan, Indiana, Illinois, Wisconsin and Minnesota—and the Province of Ontario. The Lakes contain approximately 18 percent of the world's and 95 percent of the United States' fresh surface water supply. The Great Lakes are a source of drinking water and energy, and are used for recreational, transportation, agricultural and industrial purposes by the more than 46 million Americans and Canadians who inhabit the Great Lakes region, including 29 Native American tribes. Over 1,000 industries and millions of jobs are dependent upon water from the Great Lakes. The Great Lakes System also supports hundreds of species of aquatic life, wildlife and plants along more than 4,500 miles of coastline which boast six National Parks and Lakeshores, six National Forests, seven National Wildlife Refuges, and hundreds of State parks, forests and sanctuaries.

Because of their unique features, the Great Lakes are viewed as important to the residents of the region, and to the Nation as a whole. The natural resources of the region have contributed to the development of its economy. The Lakes' natural beauty and aquatic resources form the basis for heavy recreational activity. The Great Lakes Basin Ecosystem—the interacting components of air, land, water and living organisms, including humans, that live within the Great Lakes drainage basin—is a remarkably diverse and unique ecosystem important in the global ecology.

In the past few decades, the presence of environmental contaminants in the Great Lakes has been of significant concern. In spite of the fact that the Great Lakes contain 5,500 cubic miles of water that cover a total surface area of 94,000 square miles, they have proved to be sensitive to the effects of pollutants that accumulate in them. The internal responses and processes that operate in the Great Lakes because of their depth and long hydraulic residence times cause pollutants to recycle between biota, sediments and the water column.

The first major basin-wide environmental problem in the Great Lakes emerged in the late 1960s, when increased nutrients had dramatically stimulated the growth of green plants and algae, reduced dissolved oxygen levels, and accelerated the process of eutrophication. As oxygen levels continued to drop, certain species of insects and fish were displaced from affected areas of the Great Lakes Basin Ecosystem. Environmental managers determined that a lakewide approach was necessary to adequately control accelerated eutrophication. From the late 1960s through the late 1970s, United States and Canadian regulatory agencies agreed on measures to limit the loadings of phosphorus, including effluent limits on all major municipal sewage treatment facilities, limitations on the phosphorus content in household detergents, and reductions in nonpoint source runoff loadings. As a result of all of these efforts, open lake phosphorus concentrations have declined, and phosphorus loadings from municipal sewage treatment facilities have been reduced by an estimated 80 to 90 percent. These reductions have resulted in dramatic improvements in nearshore water quality and measurable improvements in open lake conditions.

More recently, scientists and public leaders have reached a general consensus that the presence of environmentally persistent, bioaccumulative contaminants is a serious environmental threat to the Great Lakes Basin Ecosystem. Beginning in 1963, adverse environmental impacts in the form of poor reproductive success and high levels of the pesticide DDT were observed in herring gulls in Lake Michigan. Through ongoing research, scientists have detected 362 contaminants in the Great Lakes System. Of these, approximately one third have toxicological data showing that they can have acute or chronic toxic effects on aquatic life, wildlife and/or human health. Chemicals that have been found to bioaccumulate at levels of concern in the Great Lakes include, but are not limited to, polychlorinated biphenyls (PCBs), mercury, DDT, dioxin, chlordane, and mirex. The main route of exposure to these chemicals for humans is through the consumption of Great Lakes fish.

Potential adverse human health effects by these pollutants resulting from the consumption of fish include both the increased risk of cancer and the potential for systemic or noncancer risks such as kidney damage. EPA has calculated health risks to populations in the Great Lakes basin from consumption of contaminated fish based on exposure to eight bioaccumulative pollutants: chlordane, DDT, dieldrin, hexachlorobenzene, mercury, PCBs, 2,3,7,8-TCDD, and toxaphene. These chemicals were chosen based on their potential to cause adverse human health effects (i.e., cancer or disease) and the availability of information on fish tissue contaminant concentrations from the Great Lakes.

Based on these data, EPA estimates that the lifetime cancer risks for Native Americans in the Great Lakes System due to ingestion of contaminated fish at current concentrations range from $1.8\ 10^{-3}$ (Lake Superior) (1.8 in one thousand) to $3.7\ 10^{-2}$ (Lake Michigan) (3.7 in 100). Estimated risks to low income minority sport anglers range from $2.5\ 10^{-3}$ (2.5 in one thousand) (Lake Superior) to $1.2\ 10^{-2}$ (1.2 in 100) (Lake Michigan). Estimated risks for other sport anglers range from $9.7\ 10^{-4}$ (9.7 in ten thousand) (Lake Superior) to $4.5\ 10^{-3}$ (4.5 in one thousand) (Lake Michigan). (See section I.B.2.a of the SID.) In comparison, EPA has long maintained that $1\ 10^{-4}$ (one in ten thousand) to $1\ 10^{-6}$ (one in 1 million) is an appropriate range of risk to protect human health.

***15368** EPA also estimates a high potential risk of systemic (noncancer) injury to populations in the Great Lakes basin due to ingestion of fish contaminated with these pollutants at current concentrations. The systemic adverse health effects associated with the assessed contaminants are described in section I.B of the SID.

Although the Great Lakes States and EPA have moved forward to deal with these problems, control of persistent, bioaccumulative pollutants proved to be more complex and difficult than dealing with nutrients. As a result, inconsistencies began to be apparent in the ways various States developed and implemented controls for the pollutants. By the mid-1980s, such inconsistencies became of increasing concern to EPA and State environmental managers.

EPA began the Great Lakes Water Quality Initiative (“Initiative”) in cooperation with the Great Lakes States to establish a consistent level of environmental protection for the Great Lakes ecosystem, particularly in the area of State water quality standards and the National Pollutant Discharge Elimination System (NPDES) programs. In the spring of 1989, the Council of Great Lakes Governors unanimously agreed to participate in the Initiative with EPA, because the Initiative supported the principles and goals of the Great Lakes Toxic Substances Control Agreement (Governors' Agreement). Signed in 1986 by the Governors of all eight Great Lakes States, the Governors' Agreement affirmed the Governors' intention to manage and protect the resources of the Great Lakes basin through the joint pursuit of unified and cooperative principles, policies and programs enacted and adhered to by each Great Lakes State.

The Initiative provided a forum for a regional dialogue to establish minimum requirements that would reduce disparities between State water quality controls in the Great Lakes basin. The scope of the Initiative included development of proposed Great Lakes water quality guidance—Great Lakes-specific water quality criteria and methodologies to protect aquatic life, wildlife and human health, procedures to implement water quality criteria, and an antidegradation policy.

Three committees were formed to oversee the Initiative. A Steering Committee (composed of directors of water programs from the Great Lakes States' environmental agencies and EPA's National and Regional Offices) discussed policy, scientific, and technical issues, directed the work of the Technical Work Group and ratified final proposals. The Technical Work Group (consisting of technical staff from the Great Lakes States' environmental agencies, EPA, the U.S. Fish and Wildlife Service, and the National Park Service) prepared proposals on elements of the Guidance for consideration by the Steering Committee. The Public Participation Group (consisting of representatives from environmental groups, municipalities, industry and academia) observed the deliberations of the other two committees, advised them of the public's concerns, and kept its various constituencies apprised of ongoing activities and issues. These three groups were collectively known as the Initiative Committees. From the start, one goal of the Initiative Committees was to develop the Guidance elements in an open public forum, drawing upon the extensive expertise and interest of individuals and groups within the Great Lakes community.

The Initiative efforts were well underway when Congress amended section 118 of the CWA in 1990 through the CPA. The general purpose of these amendments was to improve the effectiveness of EPA's existing programs in the Great Lakes by identifying key treaty provisions agreed to by the United States and Canada in the Great Lakes Water Quality Agreement (GLWQA), imposing statutory deadlines for the implementation of these key activities, and increasing Federal resources for program operations in the Great Lakes System.

Section 118(c)(2) requires EPA to publish proposed and final water quality guidance for the Great Lakes System. This Guidance must conform with the objectives and provisions of the GLWQA (a binational agreement establishing common water quality objectives for the Great Lakes) and be no less restrictive than provisions of the CWA and National water quality criteria and guidance. The Guidance must specify minimum requirements for the waters in the Great Lakes System in three areas: (1) water quality standards (including numerical limits on pollutants in ambient Great Lakes waters to protect human health, aquatic life and wildlife); (2) antidegradation policies; and (3) implementation procedures.

The Great Lakes States must adopt water quality standards, antidegradation policies and implementation procedures for waters within the Great Lakes System which are consistent with the final Guidance within two years of EPA's publication. In the absence of such action, EPA is required to promulgate any necessary requirements within that two-year period. In addition, when an Indian Tribe is authorized to administer the NPDES or water quality standards program in the Great Lakes basin, it will also need to adopt provisions consistent with the final Guidance into their water programs.

On December 6, 1991, the Initiative Steering Committee unanimously recommended that EPA publish the draft Guidance ratified by that group in the Federal Register for public review and comment. The agreement that the draft Great Lakes Guidance was ready for public notice did not represent an endorsement by every State of all of the specific proposals. Rather, all parties agreed on the importance of proceeding to publish the draft Great Lakes Guidance in order to further solicit public comment. State Steering Committee members indicated their intent to develop and submit specific comments on the proposed Guidance during the public comment period. EPA worked to convert the agreements reached in principle by the Steering Committee into a formal package suitable for publication in the Federal Register as proposed Guidance. EPA generally used the draft proposal ratified by the Steering Committee as the basis for preparing the Federal Register proposal package. Modifications were necessary, however, to reflect statutory and regulatory requirements and EPA policy considerations, to propose procedures for State and Tribal adoption of the final Guidance, to provide suitable discussion of various alternative options, and to accommodate necessary format changes. Where modifications were made, the preamble to the proposal described both the modification and the original Steering Committee-approved guidelines, and invited public comment on both. All elements approved by the Steering Committee were either incorporated in the proposed rule or discussed in the preamble to the proposal.

III. Purpose of the Guidance

The final Guidance represents a milestone in the 30 years of effort described above on the part of the Great Lakes stakeholders to define and apply innovative, comprehensive environmental programs in protecting and restoring the Great Lakes. In particular, this publication of the final Guidance culminates six years of intensive, cooperative effort that included participation by the eight Great Lakes States, the environmental community, academia, industry, municipalities and EPA Regional and National offices.

***15369** The final Guidance will help establish consistent, enforceable, long-term protection with respect to all types of pollutants, but will place short-term emphasis on the types of long-lasting pollutants that accumulate in the food web and pose a threat to the Great Lakes System. The final Guidance will establish goals and minimum requirements that will further the next phase of Great Lakes programs, including the Great Lakes Toxic Reduction Effort's integrated, multi-media ecosystem approach.

EPA and State development of the Guidance—from drafting through proposal and now final publication—was guided by several general principles that are discussed below.

A. Use the Best Available Science to Protect Human Health, Aquatic Life, and Wildlife

EPA and the Initiative Committees have been committed throughout the Initiative to using the best available science to develop programs to protect the Great Lakes System. In the 1986 Governors' Agreement, the Governors of the Great Lakes States recognized that the problem of persistent toxic substances was the foremost environmental issue confronting the Great Lakes. They also recognized that the regulation of toxic contaminants was scientifically complex because the pollutants are numerous, their pathways into the Lakes are varied, and their effects on the environment, aquatic life and human health are not completely understood. Based on the importance of the Great Lakes Basin Ecosystem and the documented adverse effects from toxic contamination, however, the Governors directed their environmental administrators to jointly develop an agreement and procedure for coordinating the control of toxic releases and achieving greater uniformity of regulations governing such releases within the Great Lakes basin.

As discussed further above, the Initiative was subsequently created to begin work on these goals. EPA and the Great Lakes States, with input from interested parties in the basin, began collecting and analyzing data, comparing regulatory requirements and technical guidance in their various jurisdictions, and drafting specific methodologies and procedures to control the discharge of toxic contaminants. The provisions of the final Guidance were based in large part on these prior efforts of the Initiative Committees, and incorporate the best available science to protect human health, wildlife and aquatic life in the Great Lakes System. For example, the final Guidance includes new criteria and a methodology developed by the Initiative Committees to specifically protect wildlife; incorporates recent data on the bioavailability of metals into the aquatic life criteria and methodologies; incorporates Great Lakes-specific data on fish consumption rates and fish lipid contents into the human health criteria; and provides a methodology to determine the bioaccumulation properties of individual pollutants. Additionally, EPA understands that the science of risk assessment is rapidly improving. Therefore, in order to ensure that the scientific basis for the criteria methodologies is always current and peer reviewed, EPA will review the methodologies and revise them as appropriate every three years.

B. Recognize the Unique Nature of the Great Lakes Basin Ecosystem

The final Guidance also reflects the unique nature of the Great Lakes Basin Ecosystem by establishing special provisions for chemicals of concern. EPA and the Great Lakes States believe it is reasonable and appropriate to establish special provisions for the chemicals of most concern because of the physical, chemical and biological characteristics of the Great Lakes System, and the documented environmental harm to the ecosystem from the past and continuing presence of these types of pollutants. The Initiative Committees devoted considerable effort to identifying the chemicals of most concern to the Great Lakes System —persistent, bioaccumulative pollutants termed “bioaccumulative chemicals of concern (BCCs)”—and developing the most appropriate criteria, methodologies, policies, and procedures to address them. The special provisions for BCCs, initially developed by the Initiative Committees and incorporated into the final Guidance, include antidegradation procedures, to ensure that future problems are minimized; general phase-out and elimination of mixing zones for BCCs, except in limited circumstances, to reduce their overall loadings to the Lakes; more extensive data generation requirements to ensure that they are not under-regulated for lack of data; and development of water quality criteria that will protect wildlife that feed on aquatic prey.

The final Guidance is designed not only to begin to address existing problems, but also to prevent emerging and potential problems posed by additional chemicals in the future which may damage the overall health of the Great Lakes. The experience with such pollutants as DDT and PCBs indicates that it takes many decades to overcome the damage to the ecosystem caused by even short-term discharges, and that prevention would have been dramatically less costly than clean-up. Issuance of the final Guidance alone will not solve the existing long-term problems in the Great Lakes System from these contaminants. Full implementation of provisions consistent with the final Guidance will, however, provide a coordinated ecosystem approach for addressing possible pollutant problems before they produce adverse and long-lasting basin-wide impacts, rather than waiting to see what the future impacts of the pollutants might be before acting to control them. The comprehensive approach used in the development of the final Guidance provides regulatory authorities with both remedial and preventive ways of gauging the actions and potential effects of chemical stressors upon the Great Lakes Basin Ecosystem. The methodologies, policies and procedures contained in the final Guidance provide mechanisms for appropriately addressing both pollutants that have been or may in the future be documented as chemicals of concern.

C. Promote Consistency in Standards and Implementation Procedures While Allowing Appropriate Flexibility to States and Tribes

Promoting consistency in standards and implementation procedures while providing for appropriate State flexibility was the third principle in State and EPA development of the final Guidance. The underlying rationale for the Governors' Agreement, the Initiative, and the requirements set forth in the CPA was a recognition of the need to promote consistency through adoption of minimum water quality standards, antidegradation policies, and implementation procedures by Great Lakes States and Tribes to protect human health, aquatic life and wildlife. Although provisions in the CWA provide for the adoption of and periodic revisions to State water quality criteria, such provisions do not necessarily ensure that water quality criteria of adjoining States are consistent within a shared water body. For example, ambient water quality criteria in place in six of the eight Great Lakes States to protect aquatic life from acute effects range from 1.79 MUg/L to 15.0 MUg/L for cadmium, and from 0.21 MUg/L to 1.33 MUg/L for dieldrin. Other examples of variations in acute aquatic life criteria include nickel, which ranges from 290.30 MUg/L to 852.669 MUg/L; lindane, ***15370** with a range of no criteria in place to 1.32 MUg/L; and mercury, ranging from 0.5 MUg/L to 2.4 MUg/L. Similar ranges and disparities exist for chronic aquatic life criteria, and for water quality criteria to protect human health.

Disparities also exist among State procedures to translate water quality criteria into individual discharge permits. Wide variations exist, for example, in procedures for the granting of mixing zones, interpretation of background levels of pollutants, consideration of pollutants present in intake waters, controls for pollutants present in concentrations below the level of detection, and determination of appropriate levels for pollutants discharged in mixtures with other pollutants. Additionally, when addressing the accumulation of chemicals by fish that will be consumed by humans and wildlife, some States consider accumulation through multiple steps in the food chain (bioaccumulation) while others consider only the single step of concentration from the water column (bioconcentration). Further disparities exist in different translator methodologies in deriving numeric values for implementing narrative water quality criteria; different assumptions when calculating total maximum daily loads (TMDLs) and wasteload allocations (WLAs), including different assumptions about background concentrations, mixing zones, receiving water flows, or environmental fate; and different practices in deciding what pollutants need to be regulated in a discharge, what effect detection limits have on compliance determinations, and how to develop whole effluent toxicity limitations.

These inconsistencies in State standards and implementation procedures have resulted in the disparate regulation of point source discharges. In the Governors' Agreement, the Governors recognized that the water resources of the basin transcend political boundaries and committed to taking steps to manage the Great Lakes as an integrated ecosystem. The Great Lakes States, as participants in the Initiative Committees, recommended provisions, based on their extensive experience in administering State water programs and knowledge of the significant differences in these programs within the basin, that were ultimately included in the proposed Guidance. The final Guidance incorporates the work begun by the Initiative Committees to identify these disparities and improve consistency in water quality standards and permit procedures in the Great Lakes System.

Although improved consistency in State water programs is a primary goal of the final Guidance, it is also necessary to provide appropriate flexibility to States and Tribes in the development and implementation of water programs. In overseeing States' implementation of the CWA, EPA has found that reasonable flexibility is not only necessary to accommodate site-specific situations and unforeseen circumstances, but is also appropriate to enable innovation and progress as new approaches and information become available. Many commenters, including the Great Lakes States, urged EPA to evaluate the appropriate level of flexibility provided to States and Tribes in the proposed Guidance provisions. EPA reviewed all sections of the proposed Guidance and all comments received to determine the appropriate level of flexibility needed to address these concerns while still providing a minimum level of consistency between the State and Tribal programs. Based on this review, the final Guidance provides flexibility for State and Tribal adoption and implementation of provisions consistent with the final Guidance in many areas, including the following:

—Antidegradation: Great Lakes States and Tribes may develop their own approaches for implementing the prohibition against deliberate actions of dischargers that increase the mass loading of BCCs without an approved antidegradation demonstration. Furthermore, States and Tribes have flexibility in adopting antidegradation provisions regarding non-BCCs.

—TMDLs: Great Lakes States and Tribes may use assessment and remediation plans for the purposes of appendix F to part 132 if the State or Tribe certifies that the assessment and remediation plan meets certain TMDL-related provisions in the final Guidance and public participation requirements applicable to TMDLs, and if EPA approves such plan. Thus, States have the flexibility in many cases to use LAMPs, RAPs and State Water Quality Management Plans in lieu of TMDLs.

—Intake Credits: Great Lakes States and Tribes may consider the presence of intake water pollutants in establishing water quality-based effluent limits (WQBELs) in accordance with procedure 5 of appendix F.

—Site-Specific Modifications: Great Lakes States and Tribes may adopt either more or less stringent modifications to human health, wildlife, and aquatic life criteria and bioaccumulation factors (BAFs) based on site-specific circumstances specified in procedure 1 of appendix F. All criteria, however, must be sufficient not to cause jeopardy to threatened or endangered species listed or proposed to be listed under the Federal Endangered Species Act.

—Variances: Great Lakes States and Tribes may grant variances from water quality standards based on the factors identified in procedure 2 of appendix F.

—Compliance Schedules: Great Lakes States and Tribes may allow existing Great Lakes dischargers additional time to comply with permit limits in order to collect data to derive new or revised Tier I criteria and Tier II values in accordance with procedure 9 of appendix F.

—Mixing Zones: Great Lakes States and Tribes may authorize mixing zones for existing discharges of BCCs after the 10-year phase-out period in accordance with procedure 3.B of appendix F, if the permitting authority determines, among other things, that the discharger has reduced its discharge of the BCC for which a mixing zone is sought to the maximum extent possible. Water conservation efforts that result in overall reductions of BCCs are also allowed even if they result in higher effluent concentrations.

—Scientific Defensibility Exclusion: Great Lakes States and Tribes may apply alternate procedures consistent with Federal, State, and Tribal requirements upon demonstration that a provision in the final Guidance would not be scientifically defensible if applied to a particular pollutant in one or more sites. This provision is in §132.4(h) of the final Guidance.

—Reduced Detail: In many instances, EPA has revised the proposed Guidance to reduce the amount of detail in the provisions without sacrificing the objectives of the provisions. Examples of such revisions include simplification of procedures for developing TMDLs in procedure 3 of appendix F, and simplification of procedures for determining reasonable potential to exceed water quality standards in procedure 5.B of appendix F.

—Other Provisions: Flexibility is also present in provisions for the exercise of best professional judgment by the Great Lakes States and Tribes when implementing many individual provisions in the final Guidance including: determining the appropriate uncertainty factors in the human health and wildlife criteria methodologies; selection of data sets for establishing water quality criteria; identifying reasonable and prudent ***15371** measures in antidegradation provisions; and specifying appropriate margins of safety when developing TMDLs. In all cases, of course, State and Tribal provisions would need to be scientifically defensible and consistent with all applicable regulatory requirements.

D. Establish Equitable Strategies to Control Pollution Sources

Many commenters argued that the proposed Guidance unfairly focused on point source discharges. They asserted that nonpoint sources or diffuse sources of pollution, such as air emissions, are responsible for most of the loadings of some pollutants of concern in the Great Lakes, that increased regulation of point sources will be inequitable and expensive, and that the final Guidance will not result in any environmental improvement given the large, continuing contribution of toxic pollutants by nonpoint sources.

EPA recognizes that regulation of point source discharges alone cannot address all existing or future environmental problems from toxic pollutants in the Great Lakes. In addition to discharges from point sources, toxic pollutants are also contributed to the Great Lakes from industrial and municipal emissions to the air, resuspension of pollutants from contaminated sediments, urban and agricultural runoff, hazardous waste and Superfund sites, and spills. Restoration and maintenance of a healthy ecosystem will require significant efforts in all of these areas. EPA, Canada and the Great Lakes States and Tribes are currently implementing or developing many voluntary and regulatory programs to address these and other nonpoint sources of environmental contaminants in the Great Lakes.

Additionally, EPA intends to use the scientific data developed in the final Guidance and new or revised water quality criteria subsequently adopted by Great Lakes States and Tribes in evaluating and determining appropriate levels of control in other environmental programs. For example, EPA's future biennial reports under section 112(m) of the Clean Air Act will consider the extent to which air discharges cause or contribute to exceedances of water quality criteria in assessing whether additional air emission standards or control measures are necessary to prevent serious adverse effects. Similarly, once provisions consistent with the final Guidance are adopted by the Great Lakes States or Tribes, they will serve as applicable or relevant and appropriate requirements (ARARs) for on-site responses under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). EPA will also consider the data and criteria developed for the final Guidance, including the information on BCCs, in developing or evaluating LaMPs and RAPs under section 118 of the CWA and Article VI, Annex 2 of the GLWQA; determination of corrective action requirements under sections 3004(u), 3008(h), or 7003 of the Solid Waste Disposal Act; new or existing chemical reviews under the Toxic Substances Control Act (TSCA); pesticide reviews under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and reporting requirements for toxic releases under the Emergency Planning and Community Right-to-Know Act (EPCRA).

The final Guidance also includes provisions to address the contribution of pollutants by nonpoint sources. First, the water quality criteria to protect human health, wildlife and aquatic life, and the antidegradation provisions apply to the waters in the Great Lakes System regardless of whether discharges to the water are from point or nonpoint sources. Accordingly, any regulatory programs for nonpoint sources that require compliance with water quality standards would also be subject to the criteria and antidegradation provisions of the final Guidance once they are adopted into State or Tribal standards.

Second, several elements of the final Guidance would, after State, Tribal or Federal promulgation, require or allow permitting authorities to consider the presence of pollutants in ambient waters—including pollutants from nonpoint source dischargers—in establishing WQBELs for point sources. For example, permit authorities may consider the presence of other point or nonpoint source discharges when evaluating whether to grant a variance from water quality criteria. Additionally, the provisions for TMDLs address nonpoint sources by specifying that the loading capacity of a receiving water that does not meet water quality standards for a particular pollutant be allocated, where appropriate, among nonpoint as well as point sources of the pollutant, including, at a minimum, a margin of safety to account for technical uncertainties in establishing the TMDL.

The development of TMDLs is the preferred mechanism for addressing equitable division of the loading capacities of these nonattained waters. Because TMDLs have not been completed for most nonattained waters, however, the final Guidance promotes the development of TMDLs through a phased approach, where appropriate, and provides for short-term regulatory relief to point source dischargers in the absence of TMDLs through intake credits, variances, and other water quality permitting procedures.

EPA received numerous comments on the problem posed in controlling mercury in particular. Many commenters stated that since the primary source of mercury is now atmospheric deposition, point sources contribute only a minor portion of the total loading of mercury to the Great Lakes System and further restriction of point source discharges would have no apparent effect in improving water quality. Although EPA believes that there is sufficient flexibility in the Guidance to handle the unique problems posed by mercury (e.g., water quality variances, phased TMDLs, intake credits), EPA is committed to developing a mercury permitting strategy to provide a holistic, comprehensive approach for dealing with this pollutant. EPA will publish this strategy no later than two years following publication of this Guidance.

There are also many ongoing voluntary and regulatory activities that address nonpoint sources of toxic pollutants to the Great Lakes System, including activities taken under the Clean Air Act Amendments of 1990 (CAAA), the CWA, and State regulatory and voluntary programs. Some of these activities are summarized in the preamble to the proposed Guidance (58 FR 20826-32) and section I.D of the SID.

In addition to the many ongoing activities, EPA and the Great Lakes States, Tribes, and other federal agencies are pursuing a multi-media program to prevent and to further reduce toxic loadings from all sources of pollution to the Great Lakes System, with an emphasis on nonpoint sources. This second phase of the Great Lakes Water Quality Initiative, called the Great Lakes Toxic Reduction Effort (GLTRE), will build on the open, participative public dialogue established during the development of the final Guidance. Through the GLTRE, the Federal, State, and Tribal agencies intend to coordinate and enhance the effectiveness of ongoing actions and existing tools to prevent and reduce nonpoint source and wet-weather point source contributions of toxic pollutants in the Great Lakes System. A special emphasis will be placed on BCCs identified in the final Guidance.

A partial list of ongoing actions that are being or could be focused on BCCs includes: implementation of the CAAA to reduce atmospheric deposition of toxics; Resource Conservation and Recovery Act and CERCLA remedial actions to reduce loadings of toxics from ***15372** hazardous waste sites; increased focus (through the GLTRE) on toxic pollutants emanating from combined sewer overflows and stormwater outfalls; application in the Great Lakes basin of the National Contaminated Sediment Management Strategy; implementation of spill prevention planning practices to minimize this potential source of loadings to the Great Lakes; improved reporting of toxic pollutants under the Toxic Release Inventory; public education on the dangers of mercury and other BCCs; pesticide registration and re-registration processes; development of a "mass balance" model for fate and transport of pollutants in the Great Lakes; and, development of a "virtual elimination strategy." These programs will prevent and further reduce mass loadings of pollutants and facilitate equitable division of the costs of any necessary control measures between point and nonpoint sources.

In addition to the GLTRE, which is basin-wide in scope, a primary vehicle for coordinating Federal and State programs at the local level for meeting water quality standards and restoring beneficial uses for the open waters of the Great Lakes are LaMPS. LaMPs will define media specific program actions to further reduce loadings of toxic substances, assess whether these programs will ensure restoration and attainment of water quality standards and designated beneficial uses, and recommend any media-specific program enhancements as necessary. Additionally, LaMPs will be periodically updated and revised to assess progress in implementing media-specific programs, assess the reductions in toxic loadings to the Great Lakes System through these programs, incorporate advances in the understanding of the System based on new data and information, and recommend specific adjustments to media programs as appropriate.

E. Promote Pollution Prevention Practices

The final Guidance also promotes pollution prevention practices consistent with EPA's National Pollution Prevention Strategy and the Pollution Prevention Action Plan for the Great Lakes. The Pollution Prevention Act of 1990 declares as National policy that reducing the sources of pollution is the preferred approach to environmental protection. When source reductions are not possible, however, recycling, treating and properly disposing of pollutants in an environmentally safe manner complete the hierarchy of management options designed to prevent pollution from entering the environment.

Consistent with the goals of the Pollution Prevention Act, EPA developed the Great Lakes Pollution Prevention Action Plan (April, 1991). The Great Lakes Pollution Prevention Action Plan highlights how EPA, in partnership with the States, will incorporate pollution prevention into actions designed to reduce the use and release of toxic substances in the Great Lakes basin.

The final Guidance builds upon these two components of the Great Lakes program by promoting the development of pollution prevention analysis and activities in the level of detection, mixing zone, and antidegradation sections of the final Guidance. Also, the decision to provide special provisions for BCCs implements EPA's commitment to pollution prevention by reducing the discharge of these pollutants in the future. This preventive step not only makes good environmental management sense, but is appropriate based on the documented adverse effects that the past and present discharge of these pollutants has produced in the Great Lakes basin.

F. Provide Accurate Assessment of Costs and Benefits

In developing the final Guidance, EPA identified and carefully evaluated the anticipated costs and benefits from implementation of the major provisions. EPA received many comments on the draft cost and benefit studies conducted as part of the proposed Regulatory Impact Analysis (RIA) required by Executive Order 12291, and its successor, Executive Order 12866. Based upon consideration of those comments and further analysis, EPA has revised the RIA. The results of this analysis are summarized in section V of this preamble.

IV. Summary of the Final Guidance

The final Guidance will establish minimum water quality standards, antidegradation policies, and implementation procedures for the waters of the Great Lakes System in the States of Illinois, Indiana, Michigan, Minnesota, New York, Pennsylvania, Ohio and Wisconsin, including waters within the jurisdiction of Indian Tribes. Specifically, the final Guidance specifies numeric criteria for selected pollutants to protect aquatic life, wildlife and human health within the Great Lakes System and provides methodologies to derive numeric criteria for additional pollutants discharged to these waters. The final Guidance also contains minimum procedures to translate the proposed ambient water quality criteria into enforceable controls on discharges of pollutants, and a final antidegradation policy.

The provisions of the final Guidance are not enforceable requirements until adopted by States or Tribes, or promulgated by EPA for a particular State or Tribe. The Great Lakes States and Tribes must adopt water quality standards, antidegradation policies, and implementation procedures for waters within the Great Lakes System consistent with the (as protective as) final Guidance or be subject to EPA promulgation. Great Lakes Tribes include any Tribe within the Great Lakes basin for which EPA has approved water quality standards under section 303 or has authorized to administer a NPDES program under section 402 of the CWA. No Indian Tribe has been authorized to administer these water programs in the Great Lakes basin as of this time. If a Great Lakes State fails to adopt provisions consistent with the final Guidance within two years of this publication in the Federal Register (that is, by March 23, 1997), EPA will publish a final rule at the end of that time period identifying the provisions of the final Guidance that will apply to waters and discharges within that jurisdiction. Additionally, when an Indian Tribe is authorized to administer the NPDES or water quality standards program in the Great Lakes basin, it will also need to adopt provisions consistent with the final Guidance into their water programs.

The following sections provide a brief summary of the provisions of the final Guidance. A more complete discussion of the final Guidance, including EPA's analysis of major comments, issues, and a description of specific changes made to the proposed Guidance, are contained in the SID.

The parenthetical note at the beginning of each section provides references to the primary provisions in the final Guidance being discussed in the section, and to discussions in the SID. The final Guidance is codified as 40 CFR 132, including appendixes A through F. Note that appendix F consists of procedures 1 through 9. For ease of reference, sections in appendix F may be referred to by appending the section designation to the procedure number. For example, section A.1 of procedure 1 may be referred to as procedure 1.A.1 of appendix F.

15373** ***A. Water Quality Criteria and Methodologies

1. Protection of Aquatic Life
(§§132.3(a), 132.3(b), 132.4(a)(2); Tables 1 and 2 to part 132; appendix A to part 132; section III, SID)

The final Guidance contains numeric criteria to protect aquatic life for 15 pollutants, and a two-tiered methodology to derive criteria (Tier I) or values (Tier II) for additional pollutants discharged to the Great Lakes System. Aquatic life criteria are derived to establish ambient concentrations for pollutants, which, if not exceeded in the Great Lakes System, will protect fish, invertebrates, and other aquatic life from adverse effects due to that pollutant. The final Guidance includes both acute and chronic criteria to protect aquatic life from acute and chronic exposures to pollutants.

Tier I aquatic life criteria for each chemical are based on laboratory toxicity data for a variety of aquatic species (e.g., fish and invertebrates) which are representative of species in the freshwater aquatic environment as a whole. The Guidance also includes a Tier II methodology to be used in the absence of the full set of data needed to meet Tier I data requirements. For pollutants for which Tier I criteria have not been adopted into State or Tribal water quality standards, States must use methodologies consistent with either the Tier I or Tier II methodologies, depending on the data available, in conjunction with whole effluent toxicity requirements in the final Guidance (see section IV.B.5 of this preamble), to implement their existing narrative water quality criteria that prohibit toxic pollutants in toxic amounts in all waters. The Great Lakes States and Tribes are not required to use the Tier II methodology to adopt numeric criteria into their water quality standards.

Use of the two-tiered final Guidance methodologies in these situations will enable regulatory authorities to translate narrative criteria to derive TMDLs and individual NPDES permit limits on a more uniform basis. EPA and the States determined that there is a need to regulate pollutants more consistently in the Great Lakes System when faced with limited numbers of criteria. Many of the Great Lakes States are already employing procedures similar to the approach in the final Guidance to implement narrative criteria. EPA determined the Tier II approach improves upon existing mechanisms by utilizing all available data.

The two-tiered methodology allows the application of the final Guidance to all pollutants, except those listed in Table 5 of part 132 (see section IV.E of this preamble). The Tier I aquatic life methodology includes data requirements very similar to those used in current guidelines for developing National water quality criteria guidance under section 304(a) of the CWA. For example, both require that acceptable toxicity data for aquatic species in at least eight different families representing differing habitats and taxonomic groups must exist before a Tier I numeric criterion can be derived. The Tier II aquatic life methodology is used to derive Tier II values which can be calculated with fewer toxicity data than Tier I. Tier II values can, in certain instances, be based on toxicity data from a single taxonomic family, provided the data are acceptable. The Tier II methodology generally produces more stringent values than the Tier I methodology, to reflect greater uncertainty in the absence of additional toxicity data. As more data become available, the derived Tier II values tend to become less conservative. That is, they more closely approximate Tier I numeric criteria. EPA and the States believe it is desirable to continue to supplement toxicity data to ultimately derive Tier I numeric criteria.

One difference from the existing National water quality criteria guidelines is that the final Guidance methodology for aquatic life deletes the provision in the National guidelines to use a Final Residue Value (FRV) in deriving a criterion. The FRV is intended to prevent concentrations of pollutants in commercially or recreationally important aquatic species from affecting the marketability of those species or affecting wildlife that consume them by preventing the exceedance of applicable Food

and Drug Administration action levels and concentrations that affect wildlife. The final Guidance provides specific, separate methodologies to protect wildlife and human health (discussed below) which EPA believes will provide more accurate and appropriate levels of protection than the FRVs.

For pollutants without Tier I criteria but with enough data to derive Tier II values for aquatic life, the proposal would have required permittees to meet permit limits based on both Tier II values and whole effluent toxicity (WET) testing. In response to comments, the final Guidance clarifies that States and Tribes may adopt provisions allowing use of indicator parameter limits consistent with 40 CFR 122.44(d)(1)(vi)(C). When deriving limits to meet narrative criteria, States and Tribes have the option of using an indicator parameter limit, including use of a WET limit under appropriate conditions, in lieu of a Tier II-based limit. If use of an indicator parameter is allowed, the State or Tribe must ensure that the indicator parameter will attain the "applicable water quality standard" (as described in 40 CFR 122.44(d)(1)(vi)(C). The "applicable water quality standard" in this instance would be the State's or Tribe's narrative water quality standard that protects aquatic life.

Finally, the aquatic criteria for metals in the proposed Guidance were expressed as total recoverable concentrations. The final Guidance expresses the criteria for metals in dissolved form because the dissolved metal more closely approximates the bioavailable fraction of metal in the water column than does the total recoverable metal. The dissolved criteria are obtained by multiplying the chronic and/or acute criterion by appropriate conversion factors in Table 1 or 2. This is consistent with many comments on the issue and with the policy on metals detailed in "Office of Water Policy and Technical Guidance on Interpretation and Implementation of Aquatic Life Metals Criteria" (October 1, 1993). A document describing the methodology to convert total recoverable metals criteria to dissolved metals criteria was published in the Federal Register on August 30, 1994 (59 FR 44678). If a State or Tribe fails to adopt approvable aquatic life criteria for metals, EPA will promulgate criteria expressed as dissolved concentrations.

EPA Region 5, in cooperation with EPA Regions 2 and 3 and Headquarters offices, and the Great Lakes States and Tribes, will establish a Great Lakes Initiative (GLI) Clearinghouse to assist States and Tribes in developing numeric Tier I water quality criteria for aquatic life, human health and wildlife and Tier II water quality values for aquatic life and human health. As additional toxicological data and exposure data become available or additional Tier I numeric criteria and Tier II values are calculated by EPA, States, or Tribes, Region 5 will ensure that this information is disseminated to the Great Lakes States and Tribes. EPA believes operation of the GLI Clearinghouse will help ensure consistency during implementation of the final Guidance.

2. Protection of Human Health
(§§132.3(c), 132.4(a)(4); Table 3 to part 132; appendix C to part 132; section V of the SID)

The final Guidance contains numeric human health criteria for 18 pollutants, and includes Tier I and Tier II methodologies to derive cancer and ***15374** non-cancer human health criteria for additional pollutants. The proposed Guidance contained numeric criteria for 20 pollutants, but two pollutants were deleted because they do not meet the more restrictive minimum data requirements for BAFs used in the final Guidance.

Tier I human health criteria are derived to establish ambient concentrations of chemicals which, if not exceeded in the Great Lakes System, will protect individuals from adverse health impacts from that chemical due to consumption of aquatic organisms and water, including incidental water consumption related to recreational activities in the Great Lakes System. For each chemical, chronic criteria are derived to reflect long-term consumption of food and water from the Great Lakes System. Tier II values are intended to provide a conservative, interim level of protection in the establishment of a permit limit, and are distinguished from the Tier I approach by the amount and quality of data used for derivation.

The final Guidance differs from current National water quality criteria guidelines when calculating the assumed human exposure through consumption of aquatic organisms. The final Guidance uses BAFs predicted from biota-sediment accumulation factors (BSAFs) in addition to field-measured BAFs, and uses a food chain multiplier (FCM) to account for biomagnification when using measured or predicted bioconcentration factors (BCFs). BAFs are discussed further in section IV.A.4. of this preamble.

Human health water quality criteria for carcinogens are typically expressed in concentrations associated with a plausible upper bound of increased risk of developing cancer. In practice, the level of cancer risk generally accepted by EPA and the States typically ranges between 10^{4} (one in one thousand) and 10^{6} (one in one million). In contrast, as discussed in section II above, the cancer risk from ingestion of contaminated fish at current concentrations in the Great Lakes System are as high as 1.2 10^{2} (1.2 in 100). The proposed and final Guidance establishes 10^{5} (one in one hundred thousand) as the risk level used for deriving criteria and values for individual carcinogens. This is within the range historically used in EPA actions, and approved for State actions, designed to protect human health. The majority of the Great Lakes States use 10^{5} as a baseline risk level in establishing their water quality standards.

The methodology is designed to protect humans who drink water or consume fish from the Great Lakes System. The portion of the methodology addressing fish consumption includes a factor describing how much fish humans consume per day. The final Guidance includes a Great Lakes-specific fish consumption rate of 15 grams per day, based upon several fish consumption surveys from the Great Lakes, including a recent study by West et al. that was discussed in a Federal Register document on August 30, 1994 (59 FR 44678). This rate differs from the 6.5 grams per day rate which is used in the National water quality criteria guidelines as a National average consumption value. The 15 grams per day represents the mean consumption rate of regional fish caught and consumed by the Great Lakes sport fishing population.

Commenters argued that a 15 gram per day assumption in the methodology would not adequately protect populations that consume greater than this amount (e.g., low-income minority anglers and Native Americans), and that such an approach therefore would be inconsistent with Executive Order 12898 regarding environmental justice (February 16, 1994, 59 FR 7629). EPA believes that the human health criteria methodology, including the fish consumption rate, will provide adequate health protection for the public, including more highly exposed sub-populations. In carrying out regulatory actions under a variety of statutory authorities, including the CWA, EPA has generally viewed an upper bound incremental cancer risk in the range of 10^{4} to 10^{6} as adequately protective of public health. As discussed above, the human health criteria methodology is based on a risk level of 10^{5}. Therefore, if fish are contaminated at the level permitted by criteria derived under the final Guidance, individuals eating up to 10 times (i.e., 150 grams per day) the assumed fish consumption rate would still be protected at the 10^{4} risk level. Available data indicate that, even among low-income minorities who as a group consume more fish than the population on average, the overwhelming majority (approximately 95 percent) consume less than 150 grams per day. The final Guidance requires, moreover, that States and Tribes modify the human health criteria on a site-specific basis to provide additional protection appropriate for highly exposed sub-populations. Thus, where a State or Tribe finds that a population of high-end consumers would not be adequately protected by criteria derived using the 15 gram per day assumption (e.g., where the risk was greater than 10^{4}), the State or Tribe would be required to modify the criteria to provide appropriate additional protection. The final Guidance also requires States and Tribes to adopt provisions to protect human health from the potential adverse effects of mixtures of pollutants in effluents, specifically including mixtures of carcinogens. Understood in the larger context of the human health methodology and the final Guidance as a whole, therefore, EPA believes that the 15 gram per day fish consumption rate provides adequate health protection for the public, including highly exposed populations, and that the final Guidance is therefore consistent with Executive Order 12898.

In developing bioaccumulation factors, the proposed Guidance used a 5.0 percent lipid value for fish consumed by humans, based on Great Lakes-specific data. The current National methodology uses a 3.0 percent lipid value. The final Guidance uses a 3.10 percent lipid value for trophic level 4 fish and 1.82 for trophic level 3 fish. These percent lipid values are based on an analysis of the West et al. study cited above and data from State fish contaminant monitoring programs.

The final Guidance contains specific technical guidelines concerning the range of uncertainty factors that may be applied by the State and Tribal agencies on the basis of their best professional judgment. The final Guidance places a cap of 30,000 on the combined product of uncertainty factors that may be applied in the derivation of non-cancer Tier II values and a combined

uncertainty factor of 10,000 for Tier I criteria. The likely maximum combined uncertainty factor for Tier I criteria in most cases is 3,000. The SID discusses further the use of the uncertainty factors in the derivation of human health criteria and values.

The proposed Guidance used an 80 percent relative source contribution (RSC) from surface water pathways for BCCs, and a 100 percent RSC for all other pollutants, in deriving noncancer criteria. The RSC concept is applied in the National drinking water regulations and is intended to account, at least in part, for exposures from other sources for those bioaccumulative pollutants for which surface water pathways are likely to be major contributors to human exposure. The final Guidance uses the more protective 80 percent RSC for all pollutants in deriving noncancer criteria. This change was made because of concern that for non-BCCs as well as ***15375** BCCs, there may be other sources of exposures for noncarcinogens.

3. Protection of Wildlife

(§§132.3(d), 132.4(a)(5); Table 4 to part 132; appendix D to part 132; section VI of the SID)

The final Guidance contains numeric criteria to protect wildlife for four pollutants and a methodology to derive Tier I criteria for additional BCCs. Wildlife criteria are derived to establish ambient concentrations of chemicals which, if not exceeded, will protect mammals and birds from adverse impacts from that chemical due to consumption of food and/or water from the Great Lakes System.

These are EPA's first water quality criteria specifically for the protection of wildlife. The methodology is based largely on the noncancer human health paradigm. It focuses, however, on endpoints related to reproduction and population survival rather than the survival of individual members of a species. The methodology incorporates pollutant-specific effect data for a variety of mammals and birds and species-specific exposure parameters for two mammals and three birds representative of mammals and birds resident in the Great Lakes basin which are likely to experience significant exposure to bioaccumulative contaminants through the aquatic food web.

In the proposal, EPA included a two-tiered approach similar to that for aquatic life and human health. In response to comments, the final Guidance requires States and Tribes to adopt provisions consistent with only the Tier I wildlife methodology, and only to apply this methodology for BCCs (see section IV.A.4 below). The TSD provides discretionary guidelines for the use of Tier I and Tier II methodologies for other pollutants. The wildlife methodology was limited to the BCCs because these are the chemicals of greatest concern to the higher trophic level wildlife species feeding from the aquatic food web in the Great Lakes basin. This decision is consistent with comments made by the EPA Science Advisory Board (SAB) who agreed that the initial focus for wildlife criteria development should be on persistent, bioaccumulative organic contaminants (USEPA, 1994, EPA-SAB-EPEC-ADV-94-001).

Numerous commenters were concerned that the mercury criterion for wildlife was not scientifically appropriate. After review of all comments and a reevaluation of all the data, the mercury criterion for wildlife has been increased from 180 pg/L to 1300 pg/L. EPA believes the 1300 pg/L is protective of wildlife in the Great Lakes System.

In developing bioaccumulation factors, the proposed Guidance used a 7.9 percent lipid value for fish consumed by wildlife. The final Guidance uses a 10.31 percent lipid value for trophic level 4 fish and 6.46 for trophic level 3 fish. These percent lipid values are based on the actual prey species consumed by the representative wildlife species specified in the methodology, and are used to estimate the BAFs for the trophic levels which those species consume. The percent lipid is based on the preferential consumption patterns of wildlife and cross-referenced with fish weight and size and appropriate percent lipid. This approach is a more accurate reflection of the lipid content of the fish consumed by wildlife species than the approach used in the proposal.

4. Bioaccumulation Methodology

(§132.4(a)(3); appendix B to part 132; section IV of the SID)

The proposed Guidance incorporated BAFs in the derivation of criteria and values to protect human health and wildlife. Bioaccumulation refers to the uptake and retention of a substance by an aquatic organism from its surrounding medium and from food. For certain chemicals, uptake through the aquatic food chain is the most important route of exposure for wildlife and humans. The wildlife criteria and the human health criteria and values incorporate appropriate BAFs in order to more accurately account for the total exposure to a chemical. Current EPA guidelines for the derivation of human health water quality criteria use BCFs, which measure only uptake from water, when field-measured BAFs are not available. EPA believes, however, that the BAF is a better predictor of the concentration of a chemical within fish tissues in the Great Lakes System because it includes consideration of the uptake of contaminants from all routes of exposure.

The proposed Guidance included a hierarchy of three methods for deriving BAFs for non-polar organic chemicals: field-measured BAFs; predicted BAFs derived by multiplying a laboratory-measured BCF by a food-chain multiplier; and BAFs predicted by multiplying a BCF calculated from the log K_{ow} by a food-chain multiplier. For inorganic chemicals, the proposal would have required either a field-measured BAF or laboratory-measured BCF. On August 30, 1994, EPA published a document in the Federal Register (59 FR 44678) requesting comments on revising the hierarchy of methods for deriving BAFs for organic chemicals, and issues pertaining to the model used to assist in predicting BAFs when a field-measured BAF is not available. Based on the comments received, the final Guidance modifies the proposed hierarchy by adding a predicted BAF based on a BSAF as the second method in the hierarchy. BSAFs may be used for predicting BAFs from concentrations of chemicals in surface sediments. In addition, the final Guidance uses a model to assist in predicting BAFs that includes both benthic and pelagic food chains thereby incorporating exposures of organisms to chemicals from both the sediment and the water column. The model used in the proposal only included the pelagic food chain, and therefore, did not account for exposure to aquatic organisms from sediment.

The proposed Guidance used the total concentration of a chemical in the ambient water when deriving BAFs for organic chemicals. In the preamble to the proposed Guidance and in the Federal Register document cited above, EPA requested comments on deriving BAFs in terms of the freely dissolved concentration of the chemical in the ambient water. Based on comments received from the proposal and the document, the final Guidance uses the freely dissolved concentration of a chemical instead of the total concentration in the derivation of BAFs for organic chemicals. Use of the freely dissolved concentration will improve the accuracy of extrapolations between water bodies.

Finally, as discussed in section II of this preamble, bioaccumulation of persistent pollutants is a serious environmental threat to the Great Lakes Basin Ecosystem. Because of these concerns, the proposed Guidance would have required that pollutants with human health BAFs greater than 1000 receive increased attention and more stringent controls within the Great Lakes System. These pollutants are termed BCCs. EPA identified 28 BCCs in the proposed Guidance. The additional controls for BCCs are specified in certain of the implementation procedures and the antidegradation procedures, and are discussed further in the SID. The final Guidance continues to include increased attention on and more stringent controls for BCCs within the Great Lakes System. The final Guidance identifies 22 BCCs that are targeted for special controls instead of the 28 in the proposed Guidance. Six BCCs were deleted from the proposed list because of concern that the methods used to estimate the BAFs may not ***15376** account for the metabolism or degradation of the pollutants in the environment. States and Tribes may identify more BCCs as additional BAF data become available. The final Guidance designates as BCCs only those chemicals with human health BAFs greater than 1000 that were derived from either a field-measured BAF or a predicted BAF based on a field-measured BSAF (for non-metals) or from a field-measured BAF or a laboratory-measured BCF (for metals). Field-measured BAFs and BSAFs, unlike BAFs based only on laboratory analyses or calculations, account for the effects of metabolism.

B. Implementation Procedures

(§§132.4(a)(7), 132.4(e); appendix F to part 132; section VIII of the SID)
This section of the preamble discusses nine specific procedures contained in the final Guidance for implementing water quality standards and developing NPDES permits to attain the standards.

1. Site-Specific Modifications

(Procedure 1 of appendix F to part 132; section VIII.A of the SID)
The proposed Guidance would have allowed States and Tribes to adopt site-specific modifications to water quality criteria and values under certain circumstances. States and Tribes could modify aquatic life criteria to be either more stringent or less stringent when local water quality characteristics altered the biological availability or toxicity of a pollutant, or where local species' sensitivities differed from tested species. Less stringent modifications to chronic aquatic life criteria could also be made to reflect local physical and hydrological conditions. States and Tribes could also modify BAFs and human health and wildlife criteria to be more stringent, but not less stringent than the final Guidance.

The final Guidance retains most of the above provisions, but in addition allows less stringent modifications to acute aquatic life criteria and values to reflect local physical and hydrological conditions, less stringent modifications to BAFs in developing human health and wildlife criteria, and the use of fish consumption rates lower than 15 grams per day if justified. The final Guidance also specifies that site-specific modifications must be made to prevent water quality that would cause jeopardy to endangered or threatened species that are listed or proposed under the ESA, and prohibits any less-stringent site-specific modifications that would cause such jeopardy. Other issues related to the ESA are discussed in section IX of this preamble.

2. Variances from Water Quality Standards for Point Sources

(Procedure 2 of appendix F to part 132; section VIII.B of the SID)
The final Guidance allows Great Lakes States and Tribes to adopt variances from water quality standards, applicable to individual existing Great Lakes dischargers for up to five years, where specified conditions exist. For example, a variance may be granted when compliance with a criterion would result in substantial and widespread social and economic impacts or where certain stream conditions prevent the attainment of the criterion. No significant changes were made in this section from the proposed Guidance.

3. TMDLs and Mixing Zones

(Procedure 3 of appendix F to part 132; section VIII.C of the SID)
Section 303(d) of the CWA and implementing regulations at 40 CFR 130.7 require the establishment of TMDLs for waters not attaining water quality standards after implementation of existing or planned pollution controls. The TMDL quantifies the maximum allowable loading of a pollutant to a water body and allocates the loading capacity to contributing point and nonpoint sources (including natural background) such that water quality standards for that pollutant will be attained. A TMDL must incorporate a margin of safety (MOS) that accounts for uncertainty about the relationship between pollutant loads and water quality. TMDLs may involve single point sources or multiple sources (e.g., point sources and nonpoint sources) and may be established for geographic areas that range in size from large watersheds to relatively small water body segments.

The proposal attempted to develop a single, consistent approach for developing TMDLs to be used by all States and Tribes in the Great Lakes System. Current practice in the eight Great Lakes States includes distinct technical procedures and program approaches that differ in scale, emphasis, scope and level of detail. Two options for TMDL development were proposed. One, Option A, focused on first evaluating the basin as a whole and then conducting individual site-by-site adjustments as necessary to ensure attainment of water quality standards at each location in the basin. The other, Option B, focused on evaluating limits needed for individual point sources with supplemental emphasis on basin-wide considerations as necessary. Both approaches are consistent with the CWA, but result in different methodologies for TMDL development.

Both options proposed that within 10 years of the effective date of the final Guidance (i.e., two five-year NPDES permit terms), mixing zones would be prohibited for BCCs for existing point source discharges to the Great Lakes System. Further, both proposed that mixing zones be denied for new point source discharges of BCCs as of the effective date of the final Guidance.

Both options also specified procedures for determining background levels of pollutants present in ambient waters. In addition, the proposal would have tightened the relationship between TMDL development and NPDES permit issuance by providing that TMDLs be established for each pollutant causing an impairment in a water body prior to the issuance or reissuance of any NPDES permits for that pollutant.

The final Guidance merges both Options A and B into one single set of minimum regulatory requirements for TMDL development. In general, the final TMDL procedures are less detailed than the proposal, and offer more flexibility for States and Tribes in establishing TMDLs. The final TMDL procedures contain elements from both Options A and B that were deemed critical for a minimum level of consistency among the Great Lakes States and Tribes. These critical elements include: mixing zone specifications, design flows, and procedures for determining background concentrations.

The final Guidance also includes a prohibition on mixing zones for BCCs after 12 years in most circumstances. Maintaining these restrictions on the availability of mixing zones is consistent with both the Steering Committee's policy views and the bi-national GLWQA goal of virtual elimination of persistent, bioaccumulative toxics. Because of the unique nature of the Great Lakes ecosystem, documented ecological impacts, and the need for consistency, EPA believes that the general prohibition on mixing zones for BCCs is reasonable and appropriate. However, a new exception is allowed if a facility with an existing BCC discharge can demonstrate that it is reducing that discharge to the maximum extent feasible (considering technical and economic factors) but cannot meet WQBELs for that discharge without a mixing zone. EPA, in conjunction with stakeholders within the Great Lakes Basin, will develop guidance for use by ***15377** States and Tribes in exercising the exception provision with special focus on the technical and economic feasibility criteria. This guidance will also consider the notice, public hearing, monitoring and pollution prevention demonstration elements of the exception criteria.

The final Guidance also retains many of the proposed provisions for calculating background concentrations used in TMDLs and WLAs established in the absence of TMDLs. The procedure addressing data points below the level of detection, however, has been modified so that it no longer specifies the use of default values (i.e., half of the level of detection).

The final TMDL procedures do not require that TMDLs be established for point sources prior to the issuance/reissuance of NPDES permits. The final Guidance defers to the existing National program for determining when a TMDL is required. Lastly, the final Guidance allows assessment and remediation plans that are approved by EPA under 40 CFR 130.6 to be used in lieu of a TMDL for purposes of appendix F as long as they meet the general conditions of a TMDL as outlined by procedure 3 of appendix F, and the public participation requirements applicable to TMDLs.

4. Additivity

(Procedure 4 of appendix F to part 132; section VIII.D of the SID)
EPA has traditionally developed numeric water quality criteria on a single pollutant basis. While some potential environmental hazards involve significant exposure to only a single compound, most instances of contamination in surface waters involve mixtures of two or more pollutants. The individual pollutants in such mixtures can act or interact in various ways which may affect the magnitude and nature of risks or effects on human health, aquatic life and wildlife. WET tests are available to generally address interactive effects of mixtures on aquatic organisms. EPA's 1986 “Guidelines for the Health Risk Assessment of Chemical Mixtures” set forth principles and procedures for human health risk assessment of chemical mixtures. There are currently no technical guidelines on how to assess effects on wildlife from chemical mixtures.

The preamble for the proposed Guidance discussed several possible approaches to address additive effects from multiple pollutants. Proposed regulatory language was provided for two specific options, each with separate provisions related to aquatic life, wildlife and human health. One approach was developed by the Initiative Committees, modified to delete the application of toxicity equivalency factors (TEFs) for PCBs to wildlife. The other approach was developed by EPA. Neither approach addressed the possible toxicologic interactions between pollutants in a mixture (e.g., synergism or antagonism) because of the limited data available on these interactive effects. In the absence of contrary data, both approaches recommended that the risk

to human health from individual carcinogens in a mixture be considered additive, and that a 10^{-5} risk level be adopted as a cap for the cancer risk associated with mixtures. Both approaches also proposed using TEFs to assess the risk to humans and wildlife from certain chemical classes. The TEF approach converts the concentration of individual components in a mixture of chemicals to an "equivalent" concentration expressed in terms of a reference chemical. Both approaches used the 17 TEFs for dioxins and furans identified in the 1989 EPA document, "Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-Dioxins and -Dibenzofurans," and the 1989 update.

The final Guidance includes a general requirement for States and Tribes to adopt an additivity provision consistent with procedure 4 of appendix F to protect human health from the potential additive adverse effects from both the noncarcinogenic and carcinogenic components of chemical mixtures in effluents. The final Guidance also requires the use of the 17 TEFs included in the proposed Guidance to protect human health from the potential additive adverse effects in effluents.

5. Determining the Need for WQBELs (Reasonable Potential)

(Procedure 5 of appendix F to part 132; section VIII.E of the SID)
EPA's existing regulations require NPDES permits to include WQBELs to control all pollutants or pollutant parameters which the permitting authority determines are or may be discharged at a level which will cause, have the reasonable potential to cause or contribute to an excursion of any applicable water quality standard. If the permitting authority determines that a discharge has the reasonable potential to cause or contribute to an excursion of an applicable numeric water quality criterion, it must include a WQBEL for the individual pollutant in the permit. In the absence of an adopted numeric water quality criterion for an individual pollutant, the permitting authority must derive appropriate WQBELs from the State or Tribal narrative water quality criterion by either calculating a numeric criterion for the pollutant; applying EPA's water quality criteria developed under section 304(a) of the CWA, supplemented with other information where necessary; or establishing effluent limitations on an indicator pollutant. See 40 CFR 122.44(d)(1).

The final Guidance implements these National requirements by specifying procedures for determining whether a discharge has the reasonable potential to cause or contribute to an exceedance of Tier I criteria or Tier II values based on facility-specific effluent data. The final Guidance also specifies procedures for determining whether permitting authorities must generate or require permittees to generate data sufficient to calculate Tier II values when specified pollutants of concern in the Great Lakes System are known or suspected of being discharged, but neither Tier I criteria nor Tier II values have been derived due to a lack of toxicological data. EPA believes that the data necessary to calculate Tier II values for aquatic life, wildlife and human health currently exists for most of the specified pollutants of concern.

The final Guidance maintains all the basic requirements from the proposed procedure. Some minor changes are that the procedure no longer includes a special provision for effluent dominated streams, and the procedure allows a broader range of statistical approaches to be used when evaluating effluent data, which provides added simplicity and flexibility to States and Tribes.

Another change from the proposal is the relationship in the final Guidance between the reasonable potential and TMDL procedures. Numerous commenters pointed out that the proposed Guidance indicated that TMDLs would be required for any water receiving effluent from a discharger found to exhibit reasonable potential. Given the fact that there are many waterbodies in the Great Lakes basin for which TMDLs have not been developed, and the obvious need for permitting to proceed in the interim until TMDLs are completed, the final Guidance provides that the permitting authority can establish waste load allocations and WQBELs in the absence of a TMDL or an assessment and remediation plan developed and approved in accordance with procedure 3.A of appendix F. A more detailed discussion of the assessment and remediation plan and its relationship to a TMDL can be found in section VIII.C.2 of the SID. Procedures for establishing such WLAs are therefore addressed in the final Guidance.

***15378 6. Intake Pollutants**

(Procedures 5.D and 5.E of appendix F to part 132; section VIII.E of the SID)
The proposed Guidance allowed a permitting authority to determine that the return of an identified intake water pollutant to the same body of water under specified circumstances does not cause, have the reasonable potential to cause, or contribute to an excursion above water quality standards, and therefore, that a WQBEL would not be required for that pollutant. Under the proposal, this "pass through" of intake water pollutants would be allowed if the facility returns the intake water containing the pollutant of concern to the same waterbody; does not contribute additional mass of pollutant; does not increase the concentration of the intake water pollutant; and does not discharge at a time or location, or alter the pollutant in a manner which would cause adverse impacts to occur that would not occur if the pollutant were left in-stream.

EPA received numerous comments on the proposal. Some commenters argued that the proposed provision was too narrow because relief would not be available if the facility added any amount of the pollutant to the discharge, even where the facility was not contributing any additional mass or concentration to the waterbody than was contained in the intake water. After consideration of public comments, EPA decided to expand the intake pollutant provisions to include not only a reasonable potential procedure like the one contained in the proposal, but also a provision that allows the permitting authority to take into account the presence of pollutants in intake water in deriving WQBELs. Specifically, the final Guidance authorizes the permitting authority to establish limits based on a principle of "no net addition" (i.e., the limit would allow the mass and concentration of the pollutant in the discharge up to the mass and concentration of the pollutant in the intake water). This provision would be available where the facility's discharge is to the same body of water as the intake water, and could be applied for up to 12 years after publication of the final Guidance. After that time, if a TMDL or comparable plan that meets the requirements of procedure 3 of appendix F has not been completed, the facility's WQBEL must be established in accordance with the "baseline" provisions in procedure 5.F.2 of appendix F. This time limit provides a period of relief for dischargers that are not causing increased impacts on the waterbody by virtue of their discharge that would not have occurred had the pollutant remained in-stream, while maintaining the incentive for development of a comprehensive assessment and remediation plan for achieving attainment of water quality standards, which EPA believes is a critical element of the final Guidance for addressing pollutants for which a large contributor to non-attainment is nonpoint source pollution.

The final Guidance allows States and Tribes to address intake pollutants in a manner consistent with assessment and remediation plans that have been developed through mechanisms other than TMDLs in order to provide flexibility where such plans comprehensively address the point and non-point sources of non-attainment in a waterbody and the means for attaining compliance with standards.

EPA believes that 12 years provides sufficient time for States to develop and complete the water quality assessments that would serve as the basis for establishing effluent limits (including "no net addition" limits, where appropriate) under procedure 3.A of appendix F. However, EPA also recognizes that unforeseen events could delay State completion of these assessments, and therefore will, at 7 years following promulgation, in consultation with the States, evaluate the progress of the assessments. If this evaluation shows that completion of the assessments may not be accomplished by the 12 year date, EPA will revisit these provisions, and consider proposing extensions if appropriate.

Under the final Guidance, the permitting authority can permit the discharge of intake pollutants to a different body of water that is in non-attainment provided limitations require the discharge to meet a WQBEL for the pollutant equal to the pollutant's water quality criterion. Because inter-waterbody transfers of pollutants introduce pollutants to the receiving water that would not be present in that waterbody in the absence of the facility's discharge, EPA does not believe that relief for such pollutants comparable to the "no net addition" approach would be appropriate. However, to address the concern raised by commenters about facilities with multiple sources of intake water, the permitting authority may use a flow-weighted combination of these approaches when the facility has co-mingled sources of intake water from the same and different bodies of water.

EPA maintains that the preferred approach to deal with non-attainment waters, particularly when multiple sources contribute a pollutant for which the receiving water exceeds the applicable criterion, is development of a TMDL or comparable assessment and remediation plan. The above “no net addition” permitting approach provides additional flexibility in situations where a TMDL or comparable plan has not yet been developed. Other existing relief mechanisms include variances to water quality standards, removal of non-existing uses, and site-specific criteria.

7. WET

(Procedure 6 of appendix F to part 132; section VIII.F of the SID)
Existing EPA regulations define WET as “the aggregate toxic effect of an effluent measured directly by a toxicity test.” These regulations require WET limits to be included in permits in most circumstances in which the WET of a discharge has the reasonable potential to cause or contribute to an in-stream excursion above either a State's numeric criteria for toxicity or narrative criteria for water quality (40 CFR 122.2, 122.44(d)(1)). The regulations allow States and Tribes the flexibility to control for WET with either numeric or narrative criteria. Current technical guidelines recommend that no discharge should exceed 0.3 acute toxic units (TUa = 100/LC50) at the edge of an acute mixing zone and 1.0 chronic toxic units (TUc = 100/NOEC, the No Observed Effect Concentration) at the edge of a chronic mixing zone.

The proposed Guidance would have continued to allow States and Tribes the flexibility to choose to control WET with either numeric or narrative criteria, but specified that no discharge could exceed 1.0 TU_a at the point of discharge (i.e., no acute mixing zones) and 1.0 TU_c at the edge of a chronic mixing zone (with some exceptions). In addition, the proposal contained minimum requirements for appropriate test methods to measure WET and for permit conditions, and procedures for determining whether or not limits for WET are necessary.

The final Guidance differs principally from the proposal in requiring States and Tribes to adopt 0.3 TU_a and 1.0 TU_c either as numeric criteria or as an equivalent numeric interpretation of narrative criteria. The final Guidance also allows the use of acute mixing zones for the application of the acute criterion. This approach will promote consistency among States and Tribes in controlling WET, while still permitting considerable flexibility regarding implementation measures, consistent with current National policies and guidelines.

***15379 8. Loading Limits**

(Procedure 9 of appendix F to part 132; section VIII.G of the SID)
The final Guidance provides that WQBELs be expressed in terms of both concentration and mass loading rate, except for those pollutants that cannot appropriately be expressed in terms of mass. These provisions clarify the application of existing Federal regulations at 40 CFR 122.45(f), and are consistent with current EPA guidance which requires the inclusion of any limits determined necessary based on best professional judgment to meet water quality standards, including, where appropriate, mass loading rate limits. They are also consistent with the antidegradation policy for the Great Lakes System in appendix E of the final Guidance.

9. Levels of Quantification

(Procedure 8 of appendix F to part 132; section VIII.H of the SID)
Many of the pollutants of concern in the Great Lakes System cause unacceptable toxic effects at very low concentrations. This results in instances where WQBELs are below levels of reliable quantification. When this occurs, the permitting authority may not be able to determine whether the pollutant concentration is above or below the WQBEL. The final Guidance requires adoption of pollutant minimization programs (PMPs) for such permits to increase the likelihood that the concentration of the pollutant is as close to the effluent limit as possible. The PMP is an ongoing, iterative process that requires, among other things,

internal wastestream monitoring and submission of status reports. The use of PMPs for facilities with pollutants below the level of quantification is consistent with existing EPA guidance.

Unlike the proposal, however, the final Guidance eliminates additional minimum requirements for BCCs. For example, the final Guidance recommends but does not require bio-uptake studies that had been proposed to assess impacts to the receiving water and evaluate the effectiveness of the PMP.

10. Compliance Schedules

(Procedure 9 of appendix F to part 132; section VIII.I of the SID)
The final Guidance includes a procedure that allows Great Lakes States and Tribes to include schedules of compliance in permits for existing Great Lakes dischargers for effluent limitations based on new water quality criteria and certain other requirements. Generally, compliance schedules may provide for up to five years to comply with the effluent limitation in question and may, in specified cases, allow the compliance schedule to go beyond the term of the permit. Existing Great Lakes dischargers are those whose construction commenced before March 23, 1997. Thus the term, existing Great Lakes discharges, covers expanding dischargers who were ineligible for compliance schedules under the proposal. The final Guidance also provides the opportunity for States and Tribes to allow dischargers additional time to comply with effluent limitations based on Tier II values while conducting studies to justify modifications of those limitations.

C. Antidegradation Provisions

(§132.4(a)(6); appendix E to part 132; section VII of the SID)
EPA's existing regulations, at 40 CFR 131.6, establish an antidegradation policy as one of the minimum requirements of an acceptable water quality standards submittal. Section 131.12 describes the required elements of an antidegradation policy. These are: protection of water quality necessary to maintain existing uses, protection of high quality waters (those where water quality exceeds levels necessary to support propagation of fish, shellfish, and wildlife and recreation in and on the waters) and protection of water quality in those water bodies identified as outstanding National resources.

The proposed Guidance provided detailed procedures for implementing antidegradation that were not part of the existing regulations. The detailed implementation procedures were intended to result in greater consistency in how antidegradation was applied throughout the Great Lakes System. The proposed Guidance specified, among other things, how high quality waters should be identified, what activities should and should not require review under antidegradation, and the information necessary to support a request to lower water quality and the procedures to be followed by a Tribe or State in making a decision whether or not to allow a lowering of water quality.

The final Guidance maintains the overall structure of the proposed Guidance while allowing Tribes and States greater flexibility in how antidegradation is implemented. As in the proposal, the final Guidance is composed of an antidegradation standard, antidegradation implementation procedures, antidegradation demonstration and antidegradation decision. However, many of the detailed requirements found in the proposed Guidance appear in the SID accompanying the final Guidance as nonbinding guidelines, including provisions specific to non-BCCs.

Key elements of the proposed Guidance that are retained in the final Guidance for BCCs include: identification of high quality waters on a pollutant-by-pollutant basis; requirements for States and Tribes to adopt an antidegradation standard consistent with the final Guidance for BCCs; minimum requirements for conducting an antidegradation review of any activity expected to result in a significant lowering of water quality due to BCCs, minimum requirements for notifying permitting authorities of increases in discharges of BCCs; and, minimum requirements for an antidegradation demonstration consisting of a pollution prevention analysis, an alternative treatment analysis and a showing that the significant lowering of water quality will allow for important social and economic development. Significant changes from the proposed Guidance include: encouraging, but not

requiring, States and Tribes to adopt provisions consistent with the antidegradation standard and implementation procedures for non-BCCs; replacement of numeric existing effluent quality-based (EEQ) limits as a means of implementing antidegradation for BCCs with a narrative description of the types of activities that will trigger an antidegradation review; and greater flexibility in the implementation, demonstration and decision components. A detailed discussion of the basis for each of the changes is provided in Section VII the SID.

D. Regulatory Requirements

(Part 132; Tables 5 and 6 to part 132; section II of the SID)
The Great Lakes States must adopt water quality standards, anti-degradation policies, and implementation procedures for waters within the Great Lakes System which are consistent with the final Guidance within two years of this publication. If a Great Lakes State fails to adopt such standards, policies, and procedures, section 118(c)(2)(C) of the CWA requires EPA to promulgate them not later than the end of that two-year period. Additionally, when an Indian Tribe is authorized to administer the NPDES or water quality standards program in the Great Lakes basin, it will also need to adopt provisions consistent with the final Guidance into its water program.

Part 132 establishes requirements and procedures to implement section 118(c)(2)(C). Sections 132.3 and 132.4 ***15380** require Great Lakes States and Tribes to adopt criteria, methodologies, policies, and procedures consistent with the criteria, methodologies, policies, and procedures contained in part 132—that is, the definitions in §132.2, the numeric criteria in Tables 1 through 4, the criteria development methodologies in appendixes A through D, the antidegradation policy in appendix E, and the implementation procedures in appendix F. Section 132.5 specifies the procedures for States and Tribes to make their submissions to EPA, and for EPA to approve or disapprove the submissions. The section specifies that in reviewing submissions, EPA will consider provisions of State and Tribal submissions to be "consistent with" the final Guidance if each provision is as protective as the corresponding provision of the final Guidance. If a State or Tribe fails to make a submission, or if provisions of the submission are not consistent with the final Guidance, §132.5 provides that EPA will publish a final rule in the Federal Register identifying the final Guidance provisions that will apply to discharges within the particular State or Federal Indian Reservation.

Section 132.4 specifies that water quality criteria adopted by States and Tribes consistent with the final Guidance will apply to all waters of the Great Lakes System, regardless of designated uses of the waters in most cases, with some variations in human health criteria depending on whether the waters are designated for drinking water use. Section 132.4 also contains certain exceptions in applying the final Guidance methodologies and procedures. First, States and Tribes do not have to adopt and apply the final Guidance methodologies and procedures for the 14 pollutants listed in Table 5 of part 132. EPA believes that some or all of the methodologies and procedures are not scientifically appropriate for these pollutants. Second, if a State or Tribe demonstrates that the final Guidance methodologies or procedures are not scientifically defensible for a particular pollutant, the State or Tribe may use alternate methodologies or procedures so long as they meet all applicable Federal, State, and Tribal laws. Third, §132.4 specifies that for wet-weather point sources, States and Tribes generally do not have to adopt and apply the final Guidance implementation procedures. The exception is the TMDL general condition for wet weather events. Fourth, pursuant to section 510 of the CWA, part 132 specifies that nothing in the final Guidance prohibits States or Tribes from adopting provisions more stringent than the final Guidance.

As discussed further in section IX of this preamble, §132.4 also provides that State and Tribal submissions will need to include any provisions that EPA determines, based on EPA's authorities under the CWA and the results of consultation with the U.S. Fish and Wildlife Service (FWS) under section 7 of the ESA, are necessary to ensure that water quality is not likely to cause jeopardy to any endangered or threatened species listed under the ESA.

Part 132 extends the requirements of section 118(c)(2)(C) to Indian Tribes within the Great Lakes basin for which EPA has approved water quality standards under section 303 of the CWA or which EPA has authorized to administer an NPDES program under section 402 of the CWA. EPA believes that inclusion of Great Lakes Tribes in this way is necessary and appropriate to be

consistent with section 518 of the CWA. The reasons for EPA's proposal are discussed further in the preamble to the proposed Guidance (58 FR 20834), and section II.D.3 of the SID. As a practical matter, no Great Lakes Tribes currently have approved water quality standards or authorized NPDES programs, so the submission requirements of part 132 do not apply to any Great Lakes Tribes. Tribes that are approved or authorized in the future, however, will need to adopt provisions consistent with the final Guidance in their water programs.

V. Costs, Cost-Effectiveness and Benefits

(Section IX of the SID)
Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether the regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a "significant regulatory action" because it raises novel policy issues arising out of the development of a comprehensive ecosystem-based approach for a large geographic area involving several States, Tribal governments, local governments, and a large number of regulated dischargers. This approach, including the Great Lakes Water Quality Initiative which developed the core concepts of the final Guidance, is a unique and precedential approach to the implementation of environmental programs. As such, this action was submitted to OMB for review pursuant to Executive Order 12866. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

The following is a summary of major elements of the "Regulatory Impact Analysis of the Final Great Lakes Water Quality Guidance" (RIA) (EPA 820-B-95-011) that has been prepared in compliance with Executive Order 12866. Further discussion is included in section IX of the SID, and in the full RIA, which is available in the docket for this rulemaking.

The provisions of the final Guidance are not enforceable requirements until adopted by States or Tribes, or promulgated by EPA for a particular State or Tribe. Therefore, this publication of the final Guidance does not have an immediate effect on dischargers. Until actions are taken to promulgate and implement these provisions (or equally protective provisions consistent with the final Guidance), there will be no economic effect on any dischargers. For the purposes of the RIA, EPA's analysis of costs and benefits assumes that either State or EPA promulgations occur consistent with the final Guidance within the next two years.

Under the CWA, costs cannot be a basis for adopting water quality criteria that will not be protective of designated uses. If a range of scientifically defensible criteria that are protective can be identified, however, costs may be considered in selecting a particular criterion within that range. Costs may also be relevant under the antidegradation standard as applied to high quality waters.

EPA has assessed compliance costs for facilities that could be affected by provisions adopted by States or Tribes consistent with the final Guidance. EPA has also assessed basin-wide risk reduction benefits to sport anglers and Native American subsistence

anglers in the basin, and benefits for three case study sites in the Great Lakes System. ***15381** The methodology used in each assessment and the results of these assessments are discussed below.

EPA solicited public comment and supporting data on the RIA methodology used to estimate both costs and benefits for implementation of the proposed Guidance. EPA evaluated these comments and supporting data as well as comments provided by OMB and revised the RIA methodology prior to performing these assessments for the final Guidance.

A. Costs

Based on the information provided by each State and a review of the permit files, EPA identified about 3,800 direct dischargers that could be affected by State or Tribal adoption or subsequent EPA promulgation, if necessary, of requirements consistent with the final Guidance. Of these, about 590 are major dischargers and the remaining 3,210 are minor dischargers. Of the 590 majors, about 275 are industrial facilities and 315 are publicly owned treatment works (POTWs). Out of these dischargers, EPA used a stratified random sampling procedure to select 59 facilities (50 major and nine minor) that it considered representative of all types and sizes of facilities in the basin.

EPA divided the major facilities into nine industrial categories and a category for POTWs. The nine industrial categories are: mining, food and food products, pulp and paper, inorganic chemical manufacturing, organic chemical manufacturing/petroleum refining, metals manufacturing, electroplating/metal fabrication, steam electric power plants, and miscellaneous facilities.

For each major and minor facility in the sample, EPA estimated incremental costs to comply with subsequently promulgated provisions consistent with the final Guidance, using a baseline of compliance with the requirements of section 303(c)(2)(B) of the CWA. Using a decision matrix, costs were developed for two different scenarios—a “low-end” cost scenario and a “high-end” cost scenario—to account for the range of regulatory flexibility available to States and Tribes when adopting and implementing provisions consistent with the final Guidance. In addition, the decision matrix specified assumptions used for selection of control options in the cost analysis such as optimization of existing treatment processes and operations, in-plant pollutant minimization and prevention, and “end of pipe” effluent treatment.

The annualized costs for direct and indirect dischargers to implement the final Guidance are estimated to be between $60 million (low end) and $380 million (high end) (first quarter 1994 dollars). EPA believes the costs for implementing the final Guidance, which balance pollution prevention, “end-of-pipe” treatment and regulatory flexibility, will approach the low end of the cost range. Costs are unlikely to reach the high end of the cost range because State and Tribal authorities are likely to choose implementation options that provide some degree of relief to point source dischargers, especially because in many cases the nonpoint source contributions will be significant. Furthermore, cost estimates for both scenarios, but especially for the high-end scenario, may be overstated because in cases where the final Guidance provides States and Tribes flexibility in selecting less costly approaches when implementing provisions consistent with the final Guidance, the most costly approach was used to estimate the costs. This approach was used to reduce uncertainty in the cost analysis for the final Guidance.

Under the low-end cost scenario, major industrial facilities and POTWs would account for about 65 percent of the costs, indirect dischargers about 33 percent, and minor dischargers about two percent. Among the major dischargers three categories would account for most of the costs—POTWs (39 percent), pulp and paper (14 percent), and miscellaneous (eight percent). The average per plant costs for different industry categories range from zero to $168,000. The two highest average cost categories are pulp and paper ($151,000) and miscellaneous ($168,000). Although major POTWs make up a large portion of the total cost, the average cost per plant under the low-end scenario is not among the highest at $75,000 per facility. About half of the low-end costs are associated with pollution prevention activities, and about half are for capital and operating costs for wastewater treatment.

For the high-end cost scenario, direct dischargers account for 98 percent of the total estimated cost, and indirect dischargers account for two percent. This shift in proportion of costs between direct and indirect dischargers and between the low and the high estimates are due to the assumption that more direct dischargers will need to use end-of-pipe treatment under the high-end

scenario. In addition, it was assumed that a smaller proportion of indirect dischargers (10 percent) would be impacted under the high-end scenario, since municipalities are adding end-of-pipe treatment which should reduce the need for source controls (i.e., reduce the need for increased pretreatment program efforts) by indirect discharges. Less than 10 percent of the high-end costs are associated with pollution prevention activities, and over 90 percent are for capital and operating costs for wastewater treatment.

Under the high-end scenario for the direct dischargers, municipal major dischargers are expected to incur just under 70 percent of total costs, and industrial major dischargers account for 29 percent of total costs. Minor direct dischargers are estimated to incur less than one percent of the total costs. The two major industrial categories with the largest total annualized cost are the pulp and paper (23 percent of total) and miscellaneous (three percent) categories. The food and food products and metal finishing categories are estimated to incur less than 1 percent of the total annualized cost.

Under the high-end scenario, the average annual cost per major municipal facility is just over $822,000 per facility. Average annualized costs for industrial majors vary widely across categories, with the highest average cost estimated for pulp and paper ($1,583,000 per plant) and miscellaneous ($433,700 per plant) categories. Regardless of the scenario, the average costs for minor facilities are negligible at an estimated $500 per facility.

The costs described above account for the costs of eliminating mixing zones for BCCs except in narrow circumstances, costs related to implementation of Tier II values, and specific calculated costs related to intake credits. The cost assessment also projects the potential cost savings across the different scenarios that facilities may realize if States or Tribes use existing regulatory relief mechanisms to modify or eliminate the need for a WQBEL for an identified pollutant (e.g., variances, TMDLs, site-specific modifications to criteria, and changes in designated uses).

In addition to the cost estimates described above, EPA estimated the cost to comply with requirements consistent with the antidegradation provisions of the final Guidance. This potential future cost is expressed as a “lost opportunity” cost for facilities impacted by the antidegradation requirements. This cost could result in the addition of about $22 million each year.

B. Cost-Effectiveness

EPA estimated the cost-effectiveness of the final Guidance in terms of the cost of reducing the loadings of toxic pollutants from point sources. The cost-effectiveness (cost per pound removed) is derived by dividing the annualized costs of implementing the final ***15382** Guidance by the toxicity-weighted pounds (pound-equivalents) of pollutants removed. Pound-equivalents are calculated by multiplying pounds of each pollutant removed by the toxic weight (based on the toxicity of copper) for that pollutant.

It is estimated that implementation of provisions consistent with the final Guidance would be responsible for the reduction of about six to eight million toxic pounds per year, or 16 to 22 percent of the toxic-weighted baseline for the low- and high-end scenarios, respectively. The cost-effectiveness of the scenarios, over the baseline, is quite good, ranging from $10 to $50 per pound-equivalent.

Approximately 80 percent of the pollutant load reduction from implementation of the final Guidance, regardless of the scenario, is attributable to reducing BCCs as a result of PMPs and end-of-pipe treatment. The largest pollutant load reductions occur for chlordane, dieldrin, heptachlor, lead, and pentachlorobenzene.

In a separate analysis, EPA also investigated the cost-effectiveness of regulating point and nonpoint sources of mercury and PCBs, two contaminants associated with fish advisories in the Great Lakes basin. Although data and resource constraints limited the findings from these analyses, the preliminary results indicate that point sources may factor cost-effectively into pollutant reduction scenarios. For both contaminants, the cost-effectiveness of point and nonpoint source controls are likely to be highly site-specific.

C. Benefits

The benefits analysis is intended to provide insight into both the types and potential magnitude of the economic benefits expected to arise as a result of implementation of provisions adopted by States and Tribes consistent with the final Guidance. To the extent feasible, empirical estimates of the potential magnitude of the benefits are developed and then compared to the estimated costs of implementing provisions adopted by States and Tribes consistent with the final Guidance.

The benefits analysis is based on a case study approach, using benefits transfer applied to three case studies. The case study approach was used because it is more amenable to meaningful benefit-cost analyses than are studies of larger aggregate areas. Although the results obtained for a case study site may not apply uniformly to the entire Great Lakes basin, the case study approach does provide a pragmatic and realistic perspective of how implementation of the final Guidance can generate benefits, the types of benefits anticipated, and how these benefits compare to costs.

The case studies include: (1) the lower Fox River drainage, including Green Bay, located on Lake Michigan in northeastern Wisconsin; (2) the Saginaw River and Saginaw Bay, located on Lake Huron in northeastern Michigan; and (3) the Black River, located on Lake Erie in north-central Ohio. The case studies were selected from a list of candidate sites (i.e., designated Areas of Concern (AOCs) in the Great Lakes basin) on the basis of data availability and the relevance of the water quality problems to the final Guidance (i.e., areas in which problems were more likely to be associated with on-going point source discharges rather than historic loadings from Superfund sites and other sources). Geographic diversity was also considered in selecting the sites so that the analyses might better promote a broad perspective of the final Guidance's benefits and costs.

For each of the three case studies, EPA estimated future toxics-oriented water quality benefits, and then attributed a percentage of these benefits to implementation of the final Guidance. The attribution of benefits was based only on the estimated reduction in loadings from point sources at the case study sites and information on the relative contribution of point sources to total loadings in the basin. EPA did not attempt to calculate the longer-term benefits to human health, wildlife, and aquatic life once the final Guidance provisions are fully implemented by nonpoint sources as well as point sources and the minimum protection levels are attained in the ambient water.

In the Fox River and Green Bay case study, total annual undiscounted benefits attributable to the final Guidance range from $0.3 million to $8.5 million (first quarter 1994 dollars). Human health benefits account for between 29 percent and 72 percent of the estimated benefits, recreational fishing accounts for between eight percent and 45 percent, and nonuse/ecologic benefits account for between nine percent and 23 percent. Municipal and industrial dischargers in this case study are estimated to incur annualized costs of about $3.6 million.

In the Saginaw River/Bay case study, total annual undiscounted benefits range from $0.2 million to $7.7 million. Recreational fishing benefits account for between 36 percent and 60 percent of the estimated benefits, non-use benefits account for between 18 percent and 30 percent, and human health benefits account for between eight percent and 36 percent. Total annualized costs to municipal and industrial dischargers are estimated to be about $2.6 million.

In the Black River case study, total annual undiscounted benefits range from $0.4 million to $1.5 million. Recreational fishing benefits account for between 48 percent and 63 percent of the estimated benefits, and nonuse benefits account for between 32 percent and 44 percent. Total annualized costs to municipal and industrial dischargers are estimated to be $2.1 million.

An inherent limitation of the case study approach is the inability to extrapolate from a limited set of river-based sites to the Great Lakes basin as a whole. Accordingly, extrapolation of the case study results to the Great Lakes basin is not recommended. However, as noted above, the three case studies were selected on the basis of data availability, the relative importance of point source discharges to the watersheds' problems, and an attempt to portray spatial diversity throughout the Great Lakes basin. Thus, there is no reason to conclude that the selected sites are not reflective of the basin, even though benefits (and costs) tend to be highly site-specific. In addition, the benefits extend from the case study rivers into the larger, open-water environment of the Great Lakes.

The representativeness of the case study sites was assessed by comparing the percentage of total benefits estimated to accrue in the case study areas to the percentage of basin-wide costs incurred by the case study sites. Benefits-related measures (such as population, recreational angling days, and nonconsumptive recreation days) were used in place of total benefits for this analysis because there is no estimate of benefits for the entire Great Lakes basin. The three case studies combine to account for nearly 14 percent of the total cost of the final Guidance, nearly 17 percent of the loadings reductions, and from four percent to 10 percent of the benefits proxies (i.e., basin-wide population, recreational angling, nonconsumptive recreation, and commercial fishery harvest). Thus, the three case studies may represent a reasonably proportionate share of costs and benefits.

In addition to the case study analyses, a basin-wide risk assessment was conducted for Great Lakes anglers. EPA collected data and information on the consumption of Great Lakes basin fish to estimate baseline risk levels and reductions in risks due to implementation of the final Guidance for two populations at risk: Great Lakes sport anglers (including minority and ***15383** low-income anglers) and Native Americans engaged in subsistence fishing in the basin. For sport anglers, EPA estimated that the projected reduction in loadings from point sources based on controls consistent with the final Guidance would result in a reduction of annual excess lifetime cancer cases (potential cancer cases assuming a 70-year lifetime exposure period) of 2.2 to 4.1 for low-income minorities in lakeshore counties; 0.4 to 0.8 for other minorities in lakeshore counties; and 21.9 to 41.9 for all other sport anglers. For Native American subsistence anglers, EPA estimated that reductions from point source loadings attributable to the final Guidance would result in a reduction of excess lifetime cancer cases of between 0.1 and 0.3 using a low fish ingestion scenario and 0.5 to 1.1 using a high fish ingestion scenario. Note that these estimates do not include the long-term benefits (including reduced cancer cases) that will result once the final Guidance provisions are fully implemented and the minimum protection levels are attained in the ambient water.

In total, using the most conservative consumption scenario for Native Americans, these reductions represent between 0.35 and 0.67 excess cancer cases per year, and potential basin-wide benefits of the final Guidance for this one benefits category of between $0.7 million and $6.7 million per year, based on the estimated value of a statistical life of between $2.0 million and $10.0 million. Comparison to case study results, which were based on a more comprehensive sample of facilities within case study areas than was possible for the entire basin, indicates these values likely underestimate the potential risk reduction benefits of the final Guidance at the basin level. For example, if the average percentage load reduction for PCBs for the three case studies is used to reflect reductions in PCBs for the basin, the reduction in excess cancer cases increases to between three and six cases per year, and potential benefits increase to between $6.6 and $60 million per year.

The reduction in pollutant loadings for PCBs was likely understated in the basin-wide analysis because the analysis did not count pollutant load reduction benefits when the current State-based permit limit and the final Guidance-based permit limit were both below the pollutant analytical method detection limit (MDL). Only three sample facilities in the population of 59 sample facilities used to project basin-wide costs and human health benefits had State-based permit limits for PCBs. Since the current State-based permit limit and the final Guidance-based permit limit were below the MDL in all three facilities, “zero” reduction in PCB loadings for the basin was estimated. This, of course, is an artifact of the methodology and the size of the sample population selected for the analysis, and would not occur, as demonstrated in the case study analysis, if a larger sample population had been used.

VI. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), EPA generally is required to conduct a final regulatory flexibility analysis (FRFA) describing the impact of the regulatory action on small entities as part of the final rulemaking. However, under section 605(b) of the RFA, if EPA certifies that the rule will not have a significant economic impact on a substantial number of small entities, EPA is not required to prepare a FRFA.

Implementation of the final Guidance is dependent upon future promulgation of provisions consistent with it by State or Tribal agencies or, if necessary, EPA. Until actions are taken to promulgate and implement these provisions, or equally protective provisions consistent with the final Guidance, there will be no economic effect of this rule on any entities, large or small. For

that reason, and pursuant to Section 605(b) of the RFA, EPA is certifying that this rule itself will not have a significant economic impact on a substantial number of small entities.

Although EPA is certifying that this rule will not have a significant economic impact on a substantial number of small entities, and therefore is not required to prepare a FRFA, it is nevertheless including for public information in the RIA a discussion of the possible economic effects to small entities that could result from State or Tribal adoption of provisions consistent with the final Guidance or subsequent EPA promulgation, if necessary. As discussed above, small facilities are projected to incur costs of only approximately $500 per facility to comply with subsequently promulgated requirements that are consistent with the final Guidance. Accordingly, EPA believes there will be no significant economic impact on a substantial number of small entities as a result of State or Tribal implementation of the final Guidance.

VII. Enhancing the Intergovernmental Partnership Under Executive Order 12875

In compliance with Executive Order 12875 (58 FR 58093, October 28, 1993), EPA has involved State, Tribal, and local governments in the development of the final Guidance.

As described in section II above, the core elements of the final Guidance were developed by the Great Lakes States, EPA, and other Federal agencies in open dialogue with citizens, local governments, and industries in the Great Lakes ecosystem over a five-year period through the Initiative. The Initiative process marks the first time that EPA has developed a major rulemaking effort in the water program through a regional public forum. The Initiative process is described further in the preamble to the proposed Guidance (58 FR 20820-23) and section II of this preamble.

In addition to the participation by State and local governments in the initial development of the proposed Guidance and in the public comment process, several activities have been carried out since the publication of the proposed Guidance. These include:

(1) On April 26, 1994, EPA held a public meeting to solicit additional information from interested parties on the proposed Guidance. As part of EPA's outreach efforts to State, Tribal and local governments, a special invitation was sent inviting elected officials and other State, Tribal and local representatives to participate in the public meeting. EPA specifically welcomed Tribal and local officials and opened the floor to them to hear and discuss their specific concerns and views on the final Guidance.

(2) A series of meetings and teleconferences were held with Great Lakes States in early 1994 to discuss their comments on several issues, including development of water quality criteria, State adoption requirements, WET, BAFs, additivity, compliance schedules, anti-backsliding, nonpoint sources, and international concerns.

(3) In October, 1994, EPA met with each individual State in the Great Lakes basin to discuss the nature, form, and scope of the proposed Guidance, and State concerns with implementation of the provisions under consideration. The following issues were discussed at each of the meetings: intake credits, antidegradation and EEQ, wildlife criteria, excluded pollutants (e.g., ammonia and chlorine), elimination of mixing zones, site-specific modifications, fish consumption, appropriate degrees of flexibility for implementation (e.g., guidance vs. regulation), and implementation procedures.

(4) In 1994 and 1995, EPA met with representatives of the National Wildlife Federation to discuss EPA's activities in developing the final Guidance in ***15384** accordance with the terms of a consent decree governing the schedule for development of the final Guidance.

(5) In 1994, EPA also met with elected officials and other representatives from several local communities in the Great Lakes basin to discuss issues regarding the economic impact of the proposed Guidance on local communities and POTWs. Issues discussed include cost impacts associated with implementing water quality criteria, methodologies, and implementation procedures; dealing with pollution from nonpoint sources; public outreach to control pollutants such as mercury instead of costly end-of-pipe treatment; and applicability of provisions in the final Guidance to the National water quality program.

(6) EPA held an additional 18 consultations with the regulated community throughout 1994. Such meetings allowed representatives of dischargers to share additional data, which has been placed in the docket for this rulemaking, and concerns about a range of issues, including cost concerns, that the dischargers expect to arise in implementation of the final Guidance.

(7) In 1994, EPA met with State representatives to conduct initial planning for implementation of the GLI Clearinghouse. All Great Lakes States agreed to participate in this effort, which will involve the sharing of toxicological and other data to assist in the development of additional water quality criteria and values.

The results of the above efforts have assisted in the development of the final Guidance through broad communication with a full range of interested parties, sharing of additional information, and incorporation of features to improve the implementation of the final Guidance.

EPA has estimated the total annual State government burden to implement the final Guidance as approximately 5,886 hours, resulting in a State government cost of $175,992 annually. Such burden and costs were estimated based upon the burden and costs associated with developing water quality criteria, review of antidegradation policy demonstrations, review of approvable control strategies and BCC monitoring data, and review of variance requests. The total annual local government burden is estimated to be 42,296 hours with an associated cost of $2,008,624. All of the burden and costs to local governments are associated with being a regulated entity as an operator of a POTW.

VIII. Paperwork Reduction Act

The information collection requirements in this final Guidance have been approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., and have been assigned OMB control number 2040-0180. EPA has prepared an Information Collection Request (ICR) document (ICR No. 1639.02). A copy of ICR 1639.02 may be obtained by writing to Ms. Sandy Farmer, Information Policy Branch, EPA 2136, Washington, D.C. 20460, or by calling (202) 260-2740.

The annual public reporting and record keeping burden for this regulation is estimated to be 128,787 hours for the affected 3,795 permittees, or an average of 34 hours. This includes the total annual burden to local governments as POTW operators, estimated to be 45,296 hours. The total annual burden to State governments is estimated to be 5,886 hours. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

In this rulemaking EPA is also amending the table of currently approved ICR control numbers issued by OMB for various regulations into 40 CFR 9.1. This amendment updates the table to accurately display those information requirements promulgated under the CWA. The affected regulations are codified at 40 CFR parts 122, 123, 131, and 132. EPA will continue to present OMB control numbers in a consolidated table format. The table will be codified in 40 CFR part 9 of EPA's regulations and in each 40 CFR volume containing EPA regulations. The table lists the section numbers with reporting and recordkeeping requirements, and the current OMB control numbers. This display of the OMB control numbers and their subsequent codification in the CFR satisfies the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.) and OMB's implementing regulations at 5 CFR part 1320.

The ICR for this rulemaking was previously subject to public notice and comment prior to OMB approval. As a result, EPA finds that there is “good cause” under section 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(B)) to amend this table without prior notice and comment. Due to the technical nature of the table, further notice and comment would be unnecessary.

IX. Endangered Species Act

Pursuant to section 7(a)(2) of the ESA, EPA consulted with the FWS concerning EPA's publication of the final Guidance. EPA and the FWS have now completed both informal and formal consultation conducted over a two-year period.

As a result of the consultation, as well as an analysis of comments, EPA modified several provisions of the final Guidance. The procedure for site-specific modifications provides that Great Lakes States and Tribes must make site-specific modifications to criteria and values where necessary to ensure the resulting water quality does not cause jeopardy to listed or proposed species. Similarly, the antidegradation policy and implementation procedures restrict certain actions States and Tribes may take to allow lowering of water quality in high quality waters, or to adopt variances or mixing zones. Additionally, the regulatory requirements were modified to require Great Lakes States and Tribes to include in their part 132 submissions any provisions that EPA determines, based on EPA's authorities under the CWA and the results of consultation under section 7 of the ESA, are necessary to ensure that water quality is not likely to cause jeopardy to listed species. EPA and the FWS also agreed on how further consultations will be conducted as the final Guidance is implemented. The two agencies also agreed that EPA will undertake a review of water quality standards and implementation of those standards for ammonia and chlorine in the Great Lakes basin as part of EPA's responsibilities under section 303(c) of the CWA.

During the consultation, two issues were identified that required formal consultation, as defined in 40 CFR part 402. These issues were: the absence of toxicological data concerning effects of contaminants on three species of freshwater mussels in the Great Lakes basin, and the adequacy of the wildlife criteria methodology to protect three endangered or threatened wildlife species in the basin. On February 21, 1995, the FWS provided EPA with a written Biological Opinion (Opinion) on these issues. The Opinion is available in the docket for this rulemaking. On both issues, the FWS concluded that the water quality resulting from implementation of the final Guidance will not cause jeopardy to the listed species. To minimize the amount or extent of any incidental take that might ***15385** occur, the FWS consulted closely with EPA to develop a coordinated approach. The final Opinion specified reasonable and prudent measures that the FWS considers necessary or appropriate to minimize such impact. EPA has agreed to implement the measures, and the FWS and EPA will continue to work cooperatively during the implementation.

X. Judicial Review of Provisions Not Amended

In some situations, EPA has renumbered or included other editorial changes to regulations that have been promulgated in past rulemakings. Additionally, to provide for ease in reading changes to existing regulations, EPA has in some cases repeated entire sections, including portions not changed. The promulgation of this final rule, however, does not provide another opportunity to seek judicial review on the substance of the existing regulations.

XI. Supporting Documents

All documents that are referenced in this preamble are available for inspection and photocopying in the docket for this rulemaking at the address listed at the beginning of this preamble. A reasonable fee will be charged for photocopies.

Selected documents supporting the final Guidance are also available for viewing by the public at locations listed below:

Illinois: Illinois State Library, 300 South 2nd Street, Springfield, IL 62701 (217-785-5600)

Indiana: Indiana Department of Environmental Management, Office of Water Management, 100 North Senate Street, Indianapolis, IN 46204 (317-232-8671)

Michigan: Library of Michigan, Government Documents Service, 717 West Allegan, Lansing, MI 48909 (517-373-1300); Detroit Public Library, Sociology and Economics Department, 5201 Woodward Avenue, Detroit, MI 48902 (313-833-1440)

Minnesota: Minnesota Pollution Control Agency, Library, 520 Lafayette, St. Paul, MN (612-296-7719)

New York: U.S. EPA Region 2 Library, Room 402, 26 Federal Plaza, New York, NY 10278 (212-264-2881); U.S. EPA Public Information Office, Carborundum Center, Suite 530, 345 Third Street, Niagara Falls, NY 14303 (716-285-8842); New York State Department of Environmental Conservation (NYSDEC), Room 310, 50 Wolf Road, Albany, NY 12333 (518-457-7463); NYSDEC, Region 6, 7th Floor, State Office Building, 317 Washington Street, Watertown, NY 13602 (315-785-2513); NYSDEC, Region 7, 615 Erie Boulevard West, Syracuse, NY 13204 (315-426-7400); NYSDEC, Region 8, 6274 East Avon-Lima Road, Avon, NY 14414 (716-226-2466); NYSDEC, Region 9, 270 Michigan Avenue, Buffalo, NY 14203 (716-851-7070)

Ohio: Ohio Environmental Protection Agency Library—Central District Office, 1800 Watermark Road, Columbus, OH 43215 (614-644-3024); U.S. EPA Eastern District Office, 25809 Central Ridge Road, Westlake, OH 44145 (216-522-7260)

Pennsylvania: Pennsylvania Department of Environmental Resources, 230 Chestnut Street, Meadville, PA 16335 (814-332-6945); U.S. EPA Region 3 Library, 8th Floor, 841 Chestnut Building, Philadelphia, PA 19107-4431 (215-597-7904)

Wisconsin: Water Resources Center, University of Wisconsin-Madison, 2nd Floor, 1975 Willow Drive, Madison, WI (608-262-3069)

EPA is also making a number of documents available in electronic format at no incremental cost to users of the Internet. These documents include the contents of this Federal Register document, the SID, many documents listed below, and other supporting materials.

The documents listed below are also available for a fee upon written request or telephone call to the National Technical Information Center (NTIS), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161 (telephone 800-553-6847 or 703-487-4650). Alternatively, copies may be obtained for a fee upon written request or telephone call to the Educational Resources Information Center/Clearinghouse for Science, Mathematics, and Environmental Education (ERIC/CSMEE), 1200 Chambers Road, Room 310, Columbus, OH 43212 (614-292-6717). When ordering, please include the NTIS or ERIC/CSMEE accession number.

A. Final Water Quality Guidance for the Great Lakes System: Supplementary Information Document (SID). NTIS Number: PB95187266. ERIC Number: D046.

B. Great Lakes Water Quality Initiative Criteria Document for the Protection of Aquatic Life in Ambient Water. NTIS Number: PB95187282. ERIC Number: D048.

C. Great Lakes Water Quality Initiative Technical Support Document for the Procedure to Determine Bioaccumulation Factors. NTIS Number: PB95187290. ERIC Number: D049.

D. Great Lakes Water Quality Initiative Criteria Document for the Protection of Human Health. NTIS Number: PB95187308. ERIC Number: D050.

E. Great Lakes Water Quality Initiative Technical Support Document for Human Health Criteria and Values. NTIS Number: PB95187316. ERIC Number: D051.

F. Great Lakes Water Quality Initiative Criteria Document for the Protection of Wildlife: DDT; Mercury; 2,3,7,8-TCDD; PCBs. NTIS Number: PB95187324. ERIC Number: D052.

G. Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria. NTIS Number: PB95187332. ERIC Number: D053.

H. Assessment of Compliance Costs Resulting from Implementation of the Final Great Lakes Water Quality Guidance. NTIS Number: PB95187340. ERIC Number: D054.

I. Regulatory Impact Analysis of the Final Great Lakes Water Quality Guidance. NTIS Number: PB95187357. ERIC Number: D055.

List of Subjects

40 CFR Part 9
Reporting and recordkeeping requirements.

40 CFR Part 122
Administrative practice and procedure, Confidential business information, Great Lakes, Hazardous substances, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 123
Administrative practice and procedure, Confidential business information, Great Lakes, Hazardous substances, Indians-lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 131
Great Lakes, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 132
Administrative practice and procedure, Great Lakes, Indians-lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Dated: March 13, 1995.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40, chapter I, parts 9, 122, 123, and 131 are amended, and part 132 is added as follows:

***15386 PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT**
1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 et seq., 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 et seq., 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 et seq., 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.
40 CFR § 9.1

2. Section 9.1 is amended as follows:

a. By adding in numerical order the entry “122.44(r)” under the heading “EPA Administered Permit Programs: The National Pollutant Discharge Elimination System”.

b. By revising the entries under the heading “State Permit Requirements”;

c. By adding in numerical order the entries “131.1” and “131.5” and by revising the entries “131.20”, “131.21” and “131.22” under the heading “Water Quality Standards Regulations”; and

d. By adding in numerical order a new heading and new entries for “Water Quality Guidance for the Great Lakes System” to read as follows:

40 CFR § 9.1

§9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
EPA Administered Permit Programs: The National Pollutant Discharge Elimination System	
* * * * *	
122.44(r)	2040-0180
* * * * *	
State Permit Requirements	
123.21-123.24	2040-0057, 2040-0170
123.25	2040-0004, 2040-0110, 2040-0170, 2040-0180
123.26-123.29	2040-0057, 2040-0170
123.43	2040-0057, 2040-0170
123.44	2040-0057, 2040-0170, 2040-0180

123.45	2040-0057, 2040-0170
123.62	2040-0057, 2040-0170, 2040-0180
123.63	2040-0057, 2040-0170, 2040-0180
123.64	2040-0057, 2040-0170

Water Quality Standards Regulation

131.1	2040-0180
131.5	2040-0180

* * * * *

131.20	2040-0049
131.21	2040-0049, 2040-0180
131.22	2040-0049

* * * * *

Water Quality Guidance for the Great Lakes System

132.1	2040-0180
132.2	2040-0180
132.3	2040-0180
132.4	2040-0180
132.5	2040-0180
Appendix A	2040-0180
Appendix B	2040-0180
Appendix C	2040-0180
Appendix D	2040-0180

Appendix E	2040-0180
Appendix F	2040-0180

* * * * *

PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

3. The authority citation for part 122 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1251 et seq.

40 CFR § 122.44

4. Section 122.44 is amended by adding a new paragraph (r) to read as follows:

40 CFR § 122.44

§122.44 Establishing limitations, standards, and other permit conditions (applicable to State NPDES programs, see §123.25).

* * * * *

(r) Great Lakes. When a permit is issued to a facility that discharges into the Great Lakes System (as defined in 40 CFR 132.2), conditions promulgated by the State, Tribe, or EPA pursuant to 40 CFR part 132.

PART 123—STATE PROGRAM REQUIREMENTS

5. The authority citation for part 123 continues to read as follows:

Authority: Clean Water Act, 33 U.S.C. 1251 et seq.

40 CFR § 123.25

6. Section 123.25 is amended by removing “and” at the end of paragraph (a)(36), removing the period at the end of paragraph (a)(37) and adding “; and” in its place, and adding a new paragraph (a)(38) to read as follows:

40 CFR § 123.25

§123.25 Requirements for permitting.

(a) * * *

(38) For a Great Lakes State or Tribe (as defined in 40 CFR 132.2), 40 CFR part 132 (NPDES permitting implementation procedures only).

* * * * *40 CFR § 123.44

7. Section 123.44 is amended by adding a new paragraph (c)(9) to read as follows:

40 CFR § 123.44

§123.44 EPA review of and objections to State permits.

* * * * *

(c) * * *

(9) For a permit issued by a Great Lakes State or Tribe (as defined in 40 CFR 132.2), the permit does not satisfy the conditions promulgated by the State, Tribe, or EPA pursuant to 40 CFR part 132.

* * * * *40 CFR § 123.62

8. Section 123.62 is amended by adding a new paragraph (f) to read as follows:

40 CFR § 123.62

§123.62 Procedures for revision of State programs.

* * * * *

(f) Revision of a State program by a Great Lakes State or Tribe (as defined in 40 CFR 132.2) to conform to section 118 of the CWA and 40 CFR part 132 shall be accomplished pursuant to 40 CFR part 132.

40 CFR § 123.63

9. Section 123.63 is amended by adding a new paragraph (a)(6) and adding and reserving paragraph (b) to read as follows:

40 CFR § 123.63

§123.63 Criteria for withdrawal of State programs.

(a) * * *

(6) Where a Great Lakes State or Tribe (as defined in 40 CFR 132.2) fails to adequately incorporate the NPDES permitting implementation procedures promulgated by the State, Tribe, or EPA pursuant to 40 CFR part 132 into individual permits.

(b) [Reserved]

PART 131—WATER QUALITY STANDARDS

10. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 et seq.

40 CFR § 131.1

11. Section 131.1 is revised to read as follows:

40 CFR § 131.1

§131.1 Scope.

40 CFR § 132.2

This part describes the requirements and procedures for developing, reviewing, revising, and approving water quality standards by the States as authorized by section 303(c) of the Clean Water Act. Additional specific procedures for developing, reviewing, revising, and approving water quality standards for Great Lakes States or Great Lakes Tribes (as defined in 40 CFR 132.2) to conform to section 118 of the ***15387** Clean Water Act and 40 CFR part 132, are provided in 40 CFR part 132.

40 CFR § 131.5

12. Section 131.5 is amended by revising paragraph (a)(5), by redesignating paragraph (b) as paragraph (c), and by adding a new paragraph (b) to read as follows:

40 CFR § 131.5

§131.5 EPA Authority.

(a) * * *

(5) Whether the State submission meets the requirements included in §131.6 of this part and, for Great Lakes States or Great Lakes Tribes (as defined in 40 CFR 132.2) to conform to section 118 of the Act, the requirements of 40 CFR part 132.

(b) If EPA determines that the State's or Tribe's water quality standards are consistent with the factors listed in paragraphs (a)(1) through (a)(5) of this section, EPA approves the standards. EPA must disapprove the State's or Tribe's water quality standards and promulgate Federal standards under section 303(c)(4), and for Great Lakes States or Great Lakes Tribes under section 118(c)(2)(C) of the Act, if State or Tribal adopted standards are not consistent with the factors listed in paragraphs (a)(1) through (a)(5) of this section. EPA may also promulgate a new or revised standard when necessary to meet the requirements of the Act.

* * * * *40 CFR § 131.21

13. Section 131.21 is amended by revising paragraph (b) to read as follows:

40 CFR § 131.21

§131.21 EPA review and approval of water quality standards.

* * * * *

(b) The Regional Administrator's approval or disapproval of a State water quality standard shall be based on the requirements of the Act as described in §§131.5 and 131.6, and, with respect to Great Lakes States or Tribes (as defined in 40 CFR 132.2), 40 CFR part 132.

* * * * *

14. Part 132 is added as follows:

PART 132—WATER QUALITY GUIDANCE FOR THE GREAT LAKES SYSTEM

Sec.

132.1 Scope, purpose, and availability of documents.

132.2 Definitions.

132.3 Adoption of criteria.

132.4 State adoption and application of methodologies, policies and procedures.

132.5 Procedures for adoption and EPA review.

132.6 Application of part 132 requirements in Great Lakes States and Tribes. [Reserved]

Tables to Part 132

Appendix A to Part 132—Great Lakes Water Quality Initiative Methodologies for Development of Aquatic Life Criteria and Values

Appendix B to Part 132—Great Lakes Water Quality Initiative Methodology for Development of Bioaccumulation Factors

Appendix C to Part 132—Great Lakes Water Quality Initiative Methodology for Development of Human Health Criteria and Values

Appendix D to Part 132—Great Lakes Water Quality Initiative Methodology for the Development of Wildlife Criteria

Appendix E to Part 132—Great Lakes Water Quality Initiative Antidegradation Policy

Appendix F to Part 132—Great Lakes Water Quality Initiative Implementation Procedures

Authority: 33 U.S.C. 1251 et seq.

40 CFR § 132.1

§132.1 Scope, purpose, and availability of documents.

(a) This part constitutes the Water Quality Guidance for the Great Lakes System (Guidance) required by section 118(c)(2) of the Clean Water Act (33 U.S.C. 1251 et seq.) as amended by the Great Lakes Critical Programs Act of 1990 (Pub. L. 101-596, 104 Stat. 3000 et seq.). The Guidance in this part identifies minimum water quality standards, antidegradation policies, and implementation procedures for the Great Lakes System to protect human health, aquatic life, and wildlife.

(b) The U.S. Environmental Protection Agency, Great Lakes States, and Great Lakes Tribes will use the Guidance in this part to evaluate the water quality programs of the States and Tribes to assure that they are protective of water quality. State and Tribal programs do not need to be identical to the Guidance in this part, but must contain provisions that are consistent with (as protective as) the Guidance in this part. The scientific, policy and legal basis for EPA's development of each section of the final Guidance in this part is set forth in the preamble, Supplementary Information Document, Technical Support Documents,

and other supporting documents in the public docket. EPA will follow the guidance set out in these documents in reviewing the State and Tribal water quality programs in the Great Lakes for consistency with this part.

(c) The Great Lakes States and Tribes must adopt provisions consistent with the Guidance in this part applicable to waters in the Great Lakes System or be subject to EPA promulgation of its terms pursuant to this part.

(d) EPA understands that the science of risk assessment is rapidly improving. Therefore, to ensure that the scientific basis for the methodologies in appendices A through D are always current and peer reviewed, EPA will review the methodologies and revise them, as appropriate, every 3 years.

(e) Certain documents referenced in the appendixes to this part with a designation of NTIS and/or ERIC are available for a fee upon request to the National Technical Information Center (NTIS), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161. Alternatively, copies may be obtained for a fee upon request to the Educational Resources Information Center/Clearinghouse for Science, Mathematics, and Environmental Education (ERIC/CSMEE), 1200 Chambers Road, Room 310, Columbus, Ohio 43212. When ordering, please include the NTIS or ERIC/CSMEE accession number.
40 CFR § 132.2

§132.2 Definitions.
The following definitions apply in this part. Terms not defined in this section have the meaning given by the Clean Water Act and EPA implementing regulations.

Acute-chronic ratio (ACR) is a standard measure of the acute toxicity of a material divided by an appropriate measure of the chronic toxicity of the same material under comparable conditions.

Acute toxicity is concurrent and delayed adverse effect(s) that results from an acute exposure and occurs within any short observation period which begins when the exposure begins, may extend beyond the exposure period, and usually does not constitute a substantial portion of the life span of the organism.

Adverse effect is any deleterious effect to organisms due to exposure to a substance. This includes effects which are or may become debilitating, harmful or toxic to the normal functions of the organism, but does not include non-harmful effects such as tissue discoloration alone or the induction of enzymes involved in the metabolism of the substance.

Bioaccumulation is the net accumulation of a substance by an organism as a result of uptake from all environmental sources.

Bioaccumulation factor (BAF) is the ratio (in L/kg) of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where both the organism and its food are exposed and the ratio does not change substantially over time.

Bioaccumulative chemical of concern (BCC) is any chemical that has the potential to cause adverse effects which, upon entering the surface waters, by itself or as its toxic transformation ***15388** product, accumulates in aquatic organisms by a human health bioaccumulation factor greater than 1000, after considering metabolism and other physicochemical properties that might enhance or inhibit bioaccumulation, in accordance with the methodology in appendix B of this part. Chemicals with half-lives of less than eight weeks in the water column, sediment, and biota are not BCCs. The minimum BAF information needed to define an organic chemical as a BCC is either a field-measured BAF or a BAF derived using the BSAF methodology. The minimum BAF information needed to define an inorganic chemical, including an organometal, as a BCC is either a field-measured BAF or a laboratory-measured BCF. BCCs include, but are not limited to, the pollutants identified as BCCs in section A of Table 6 of this part.

Bioconcentration is the net accumulation of a substance by an aquatic organism as a result of uptake directly from the ambient water through gill membranes or other external body surfaces.

Bioconcentration factor (BCF) is the ratio (in L/kg) of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through the water only and the ratio does not change substantially over time.

Biota-sediment accumulation factor (BSAF) is the ratio (in kg of organic carbon/kg of lipid) of a substance's lipid-normalized concentration in tissue of an aquatic organism to its organic carbon-normalized concentration in surface sediment, in situations where the ratio does not change substantially over time, both the organism and its food are exposed, and the surface sediment is representative of average surface sediment in the vicinity of the organism.

Carcinogen is a substance which causes an increased incidence of benign or malignant neoplasms, or substantially decreases the time to develop neoplasms, in animals or humans. The classification of carcinogens is discussed in section II.A of appendix C to part 132.

Chronic toxicity is concurrent and delayed adverse effect(s) that occurs only as a result of a chronic exposure.

Connecting channels of the Great Lakes are the Saint Mary's River, Saint Clair River, Detroit River, Niagara River, and Saint Lawrence River to the Canadian Border.

Criterion continuous concentration (CCC) is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed indefinitely without resulting in an unacceptable effect.

Criterion maximum concentration (CMC) is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed briefly without resulting in an unacceptable effect.

EC50 is a statistically or graphically estimated concentration that is expected to cause one or more specified effects in 50 percent of a group of organisms under specified conditions.

Endangered or threatened species are those species that are listed as endangered or threatened under section 4 of the Endangered Species Act.

Existing Great Lakes discharger is any building, structure, facility, or installation from which there is or may be a “discharge of pollutants” (as defined in 40 CFR 122.2) to the Great Lakes System, that is not a new Great Lakes discharger.

Federal Indian reservation, Indian reservation, or reservation means all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and including rights-of-way running through the reservation.

Final acute value (FAV) is (a) a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable acute toxicity tests have been conducted on the material) have higher GMAVs, or (b) the SMAV of an important and/or critical species, if the SMAV is lower than the calculated estimate.

Final chronic value (FCV) is (a) a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable chronic toxicity tests have been conducted on the material) have higher GMCVs, (b) the quotient of an FAV divided by an appropriate acute-chronic ratio, or (c) the SMCV of an important and/or critical species, if the SMCV is lower than the calculated estimate or the quotient, whichever is applicable.

Final plant value (FPV) is the lowest plant value that was obtained with an important aquatic plant species in an acceptable toxicity test for which the concentrations of the test material were measured and the adverse effect was biologically important.

Genus mean acute value (GMAV) is the geometric mean of the SMAVs for the genus.

Genus mean chronic value (GMCV) is the geometric mean of the SMCVs for the genus.

Great Lakes means Lake Ontario, Lake Erie, Lake Huron (including Lake St. Clair), Lake Michigan, and Lake Superior; and the connecting channels (Saint Mary's River, Saint Clair River, Detroit River, Niagara River, and Saint Lawrence River to the Canadian Border).

Great Lakes States and Great Lakes Tribes, or Great Lakes States and Tribes means the States of Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin, and any Indian Tribe as defined in this part which is located in whole or in part within the drainage basin of the Great Lakes, and for which EPA has approved water quality standards under section 303 of the Clean Water Act or which EPA has authorized to administer an NPDES program under section 402 of the Clean Water Act.

Great Lakes System means all the streams, rivers, lakes and other bodies of water within the drainage basin of the Great Lakes within the United States.

Human cancer criterion (HCC) is a Human Cancer Value (HCV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C of this part.

Human cancer value (HCV) is the maximum ambient water concentration of a substance at which a lifetime of exposure from either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities, will represent a plausible upper-bound risk of contracting cancer of one in 100,000 using the exposure assumptions specified in the Methodologies for the Development of Human Health Criteria and Values in appendix C of this part.

Human noncancer criterion (HNC) is a Human Noncancer Value (HNV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C of this part.

Human noncancer value (HNV) is the maximum ambient water concentration of a substance at which adverse noncancer effects are not likely to occur in the human population from lifetime exposure via either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities using the Methodologies for the Development of Human Health Criteria and Values in appendix C of this part.

Indian Tribe or Tribe means any Indian Tribe, band, group, or community recognized by the Secretary of the Interior and exercising governmental authority over a Federal Indian reservation.

LC50 is a statistically or graphically estimated concentration that is expected ***15389** to be lethal to 50 percent of a group of organisms under specified conditions.

Load allocation (LA) is the portion of a receiving water's loading capacity that is attributed either to one of its existing or future nonpoint sources or to natural background sources, as more fully defined at 40 CFR 130.2(g). Nonpoint sources include: in-place contaminants, direct wet and dry deposition, groundwater inflow, and overland runoff.

Loading capacity is the greatest amount of loading that a water can receive without violating water quality standards.

Lowest observed adverse effect level (LOAEL) is the lowest tested dose or concentration of a substance which resulted in an observed adverse effect in exposed test organisms when all higher doses or concentrations resulted in the same or more severe effects.

Method detection level is the minimum concentration of an analyte (substance) that can be measured and reported with a 99 percent confidence that the analyte concentration is greater than zero as determined by the procedure set forth in appendix B of 40 CFR part 136.

Minimum Level (ML) is the concentration at which the entire analytical system must give a recognizable signal and acceptable calibration point. The ML is the concentration in a sample that is equivalent to the concentration of the lowest calibration standard analyzed by a specific analytical procedure, assuming that all the method-specified sample weights, volumes and processing steps have been followed.

New Great Lakes discharger is any building, structure, facility, or installation from which there is or may be a “discharge of pollutants” (as defined in 40 CFR 122.2) to the Great Lakes System, the construction of which commenced after March 23, 1997.

No observed adverse effect level (NOAEL) is the highest tested dose or concentration of a substance which resulted in no observed adverse effect in exposed test organisms where higher doses or concentrations resulted in an adverse effect.

No observed effect concentration (NOEC) is the highest concentration of toxicant to which organisms are exposed in a full life-cycle or partial life-cycle (short-term) test, that causes no observable adverse effects on the test organisms (i.e., the highest concentration of toxicant in which the values for the observed responses are not statistically significantly different from the controls).

Open waters of the Great Lakes (OWGLs) means all of the waters within Lake Erie, Lake Huron (including Lake St. Clair), Lake Michigan, Lake Ontario, and Lake Superior lakeward from a line drawn across the mouth of tributaries to the Lakes, including all waters enclosed by constructed breakwaters, but not including the connecting channels.

Quantification level is a measurement of the concentration of a contaminant obtained by using a specified laboratory procedure calibrated at a specified concentration above the method detection level. It is considered the lowest concentration at which a particular contaminant can be quantitatively measured using a specified laboratory procedure for monitoring of the contaminant.

Quantitative structure activity relationship (QSAR) or structure activity relationship (SAR) is a mathematical relationship between a property (activity) of a chemical and a number of descriptors of the chemical. These descriptors are chemical or physical characteristics obtained experimentally or predicted from the structure of the chemical.

Risk associated dose (RAD) is a dose of a known or presumed carcinogenic substance in (mg/kg)/day which, over a lifetime of exposure, is estimated to be associated with a plausible upper bound incremental cancer risk equal to one in 100,000.

Species mean acute value (SMAV) is the geometric mean of the results of all acceptable flow-through acute toxicity tests (for which the concentrations of the test material were measured) with the most sensitive tested life stage of the species. For a species for which no such result is available for the most sensitive tested life stage, the SMAV is the geometric mean of the results of all acceptable acute toxicity tests with the most sensitive tested life stage.

Species mean chronic value (SMCV) is the geometric mean of the results of all acceptable life-cycle and partial life-cycle toxicity tests with the species; for a species of fish for which no such result is available, the SMCV is the geometric mean of all acceptable early life-stage tests.

Stream design flow is the stream flow that represents critical conditions, upstream from the source, for protection of aquatic life, human health, or wildlife.

Threshold effect is an effect of a substance for which there is a theoretical or empirically established dose or concentration below which the effect does not occur.

Tier I criteria are numeric values derived by use of the Tier I methodologies in appendixes A, C and D of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part, that either have been adopted as numeric criteria into a water quality standard or are used to implement narrative water quality criteria.

Tier II values are numeric values derived by use of the Tier II methodologies in appendixes A and C of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part, that are used to implement narrative water quality criteria.

Total maximum daily load (TMDL) is the sum of the individual wasteload allocations for point sources and load allocations for nonpoint sources and natural background, as more fully defined at 40 CFR 130.2(i). A TMDL sets and allocates the maximum amount of a pollutant that may be introduced into a water body and still assure attainment and maintenance of water quality standards.

Tributaries of the Great Lakes System means all waters of the Great Lakes System that are not open waters of the Great Lakes, or connecting channels.

Uncertainty factor (UF) is one of several numeric factors used in operationally deriving criteria from experimental data to account for the quality or quantity of the available data.

Uptake is acquisition of a substance from the environment by an organism as a result of any active or passive process.

Wasteload allocation (WLA) is the portion of a receiving water's loading capacity that is allocated to one of its existing or future point sources of pollution, as more fully defined at 40 CFR 130.2(h). In the absence of a TMDL approved by EPA pursuant to 40 CFR 130.7 or an assessment and remediation plan developed and approved in accordance with procedure 3.A of appendix F of this part, a WLA is the allocation for an individual point source, that ensures that the level of water quality to be achieved by the point source is derived from and complies with all applicable water quality standards.

Wet weather point source means any discernible, confined and discrete conveyance from which pollutants are, or may be, discharged as the result of a wet weather event. Discharges from wet weather point sources shall include only: discharges of storm water from a municipal separate storm sewer as defined at 40 CFR 122.26(b)(8); storm water discharge associated with industrial activity as defined at 40 CFR 122.26(b)(14); discharges of storm water and sanitary wastewaters (domestic, ***15390** commercial, and industrial) from a combined sewer overflow; or any other stormwater discharge for which a permit is required under section 402(p) of the Clean Water Act. A storm water discharge associated with industrial activity which is mixed with process wastewater shall not be considered a wet weather point source.

40 CFR § 132.3

§132.3 Adoption of criteria.

The Great Lakes States and Tribes shall adopt numeric water quality criteria for the purposes of section 303(c) of the Clean Water Act applicable to waters of the Great Lakes System in accordance with §132.4(d) that are consistent with:

(a) The acute water quality criteria for protection of aquatic life in Table 1 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part;

(b) The chronic water quality criteria for protection of aquatic life in Table 2 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part;

(c) The water quality criteria for protection of human health in Table 3 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part; and

(d) The water quality criteria for protection of wildlife in Table 4 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part.

40 CFR § 132.4

§132.4 State adoption and application of methodologies, policies and procedures.

(a) The Great Lakes States and Tribes shall adopt requirements applicable to waters of the Great Lakes System for the purposes of sections 118, 301, 303, and 402 of the Clean Water Act that are consistent with:

(1) The definitions in §132.2;

(2) The Methodologies for Development of Aquatic Life Criteria and Values in appendix A of this part;

(3) The Methodology for Development of Bioaccumulation Factors in appendix B of this part;

(4) The Methodologies for Development of Human Health Criteria and Values in appendix C of this part;

(5) The Methodology for Development of Wildlife Criteria in appendix D of this part;

(6) The Antidegradation Policy in appendix E of this part; and

(7) The Implementation Procedures in appendix F of this part.

(b) Except as provided in paragraphs (g), (h), and (i) of this section, the Great Lakes States and Tribes shall use methodologies consistent with the methodologies designated as Tier I methodologies in appendixes A, C, and D of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part when adopting or revising numeric water quality criteria for the purposes of section 303(c) of the Clean Water Act for the Great Lakes System.

(c) Except as provided in paragraphs (g), (h), and (i) of this section, the Great Lakes States and Tribes shall use methodologies and procedures consistent with the methodologies designated as Tier I methodologies in appendixes A, C, and D of this part, the Tier II methodologies in appendixes A and C of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part to develop numeric criteria and values when implementing narrative water quality criteria adopted for purposes of section 303(c) of the Clean Water Act.

(d) The water quality criteria and values adopted or developed pursuant to paragraphs (a) through (c) of this section shall apply as follows:

(1) The acute water quality criteria and values for the protection of aquatic life, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(2) The chronic water quality criteria and values for the protection of aquatic life, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(3) The water quality criteria and values for protection of human health, or site-specific modifications thereof, shall apply as follows:

(i) Criteria and values derived as HCV-Drinking and HNV-Drinking shall apply to the Open Waters of the Great Lakes, all connecting channels of the Great Lakes, and all other waters of the Great Lakes System that have been designated as public water supplies by any State or Tribe in accordance with 40 CFR 131.10.

(ii) Criteria and values derived as HCV-Nondrinking and HNV-Nondrinking shall apply to all waters of the Great Lakes System other than those in paragraph (d)(3)(i) of this section.

(4) Criteria for protection of wildlife, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(e) The Great Lakes States and Tribes shall apply implementation procedures consistent with the procedures in appendix F of this part for all applicable purposes under the Clean Water Act, including developing total maximum daily loads for the purposes of section 303(d) and water quality-based effluent limits for the purposes of section 402, in establishing controls on the discharge of any pollutant to the Great Lakes System by any point source with the following exceptions:

(1) The Great Lakes States and Tribes are not required to apply these implementation procedures in establishing controls on the discharge of any pollutant by a wet weather point source. Any adopted implementation procedures shall conform with all applicable Federal, State and Tribal requirements.

(2) The Great Lakes States and Tribes may, but are not required to, apply procedures consistent with procedures 1, 2, 3, 4, 5, 7, 8, and 9 of appendix F of this part in establishing controls on the discharge of any pollutant set forth in Table 5 of this part. Any procedures applied in lieu of these implementation procedures shall conform with all applicable Federal, State, and Tribal requirements.

(f) The Great Lakes States and Tribes shall apply an antidegradation policy consistent with the policy in appendix E for all applicable purposes under the Clean Water Act, including 40 CFR 131.12.

(g) For pollutants listed in Table 5 of this part, the Great Lakes States and Tribes shall:

(1) Apply any methodologies and procedures acceptable under 40 CFR part 131 when developing water quality criteria or implementing narrative criteria; and

(2) Apply the implementation procedures in appendix F of this part or alternative procedures consistent with all applicable Federal, State, and Tribal laws.

(h) For any pollutant other than those in Table 5 of this part for which the State or Tribe demonstrates that a methodology or procedure in this part is not scientifically defensible, the Great Lakes States and Tribes shall:

(1) Apply an alternative methodology or procedure acceptable under 40 CFR part 131 when developing water quality criteria; or

(2) Apply an alternative implementation procedure that is consistent with all applicable Federal, State, and Tribal laws.

(i) Nothing in this part shall prohibit the Great Lakes States and Tribes from adopting numeric water quality criteria, narrative criteria, or water quality values that are more stringent than criteria or values specified in §132.3 or that would be derived from application of the methodologies set forth in appendixes A, B, C, and D of this part, or to adopt antidegradation standards and implementation procedures more ***15391** stringent than those set forth in appendixes E and F of this part.
40 CFR § 132.5

§132.5 Procedures for adoption and EPA review.

(a) Except as provided in paragraph (c) of this section, the Great Lakes States and Tribes shall adopt and submit for EPA review and approval the criteria, methodologies, policies, and procedures developed pursuant to this part no later than September 23, 1996.

(b) The following elements must be included in each submission to EPA for review:

(1) The criteria, methodologies, policies, and procedures developed pursuant to this part;

(2) Certification by the Attorney General or other appropriate legal authority pursuant to 40 CFR 123.62 and 40 CFR 131.6(e) as appropriate;

(3) All other information required for submission of National Pollutant Discharge Elimination System (NPDES) program modifications under 40 CFR 123.62; and

(4) General information which will aid EPA in determining whether the criteria, methodologies, policies and procedures are consistent with the requirements of the Clean Water Act and this part, as well as information on general policies which may affect their application and implementation.

(c) The Regional Administrator may extend the deadline for the submission required in paragraph (a) of this section if the Regional Administrator believes that the submission will be consistent with the requirements of this part and can be reviewed and approved pursuant to this section no later than March 23, 1997.

(d) If a Great Lakes State or Tribe makes no submission pursuant to this part to EPA for review, the requirements of this part shall apply to discharges to waters of the Great Lakes System located within the State or Federal Indian reservation upon EPA's publication of a final rule indicating the effective date of the part 132 requirements in the identified jurisdictions.

(e) If a Great Lakes State or Tribe submits criteria, methodologies, policies, and procedures pursuant to this part to EPA for review that contain substantial modifications of the State or Tribal NPDES program, EPA shall issue public notice and provide a minimum of 30 days for public comment on such modifications. The public notice shall conform with the requirements of 40 CFR 123.62.

(f) After review of State or Tribal submissions under this section, and following the public comment period in subparagraph (e) of this section, if any, EPA shall either:

(1) Publish notice of approval of the submission in the Federal Register within 90 days of such submission; or

(2) Notify the State or Tribe within 90 days of such submission that EPA has determined that all or part of the submission is inconsistent with the requirements of the Clean Water Act or this part and identify any necessary changes to obtain EPA approval. If the State or Tribe fails to adopt such changes within 90 days after the notification, EPA shall publish a notice in the Federal Register identifying the approved and disapproved elements of the submission and a final rule in the Federal Register identifying the provisions of part 132 that shall apply to discharges within the State or Federal Indian reservation.

(g) EPA's approval or disapproval of a State or Tribal submission shall be based on the requirements of this part and of the Clean Water Act. EPA's determination whether the criteria, methodologies, policies, and procedures in a State or Tribal submission are consistent with the requirements of this part will be based on whether:

(1) For pollutants listed in Tables 1, 2, 3, and 4 of this part. The Great Lakes State or Tribe has adopted numeric water quality criteria as protective as each of the numeric criteria in Tables 1, 2, 3, and 4 of this part, taking into account any site-specific criteria modifications in accordance with procedure 1 of appendix F of this part;

(2) For pollutants other than those listed in Tables 1, 2, 3, 4, and 5 of this part. The Great Lakes State or Tribe demonstrates that either:

(i) It has adopted numeric criteria in its water quality standards that were derived, or are as protective as or more protective than could be derived, using the methodologies in appendixes A, B, C, and D of this part, and the site-specific criteria modification procedures in accordance with procedure 1 of appendix F of this part; or

(ii) It has adopted a procedure by which water quality-based effluent limits and total maximum daily loads are developed using the more protective of:

(A) Numeric criteria adopted by the State into State water quality standards and approved by EPA prior to March 23, 1997; or

(B) Water quality criteria and values derived pursuant to §132.4(c); and

(3) For methodologies, policies, and procedures. The Great Lakes State or Tribe has adopted methodologies, policies, and procedures as protective as the corresponding methodology, policy, or procedure in §132.4. The Great Lakes State or Tribe may adopt provisions that are more protective than those contained in this part. Adoption of a more protective element in one provision may be used to offset a less protective element in the same provision as long as the adopted provision is as protective as the corresponding provision in this part; adoption of a more protective element in one provision, however, is not justification for adoption of a less protective element in another provision of this part.

(h) A submission by a Great Lakes State or Tribe will need to include any provisions that EPA determines, based on EPA's authorities under the Clean Water Act and the results of consultation under section 7 of the Endangered Species Act, are necessary to ensure that water quality is not likely to jeopardize the continued existence of any endangered or threatened species listed under section 4 of the Endangered Species Act or result in the destruction or adverse modification of such species' critical habitat.

(i) EPA's approval of the elements of a State's or Tribe's submission will constitute approval under section 118 of the Clean Water Act, approval of the submitted water quality standards pursuant to section 303 of the Clean Water Act, and approval of the submitted modifications to the State's or Tribe's NPDES program pursuant to section 402 of the Clean Water Act.
40 CFR § 132.6

§132.6 Application of part 132 requirements in Great Lakes States and Tribes. [Reserved]

Tables to Part 132

Table 1.—Acute Water Quality Criteria for Protection of Aquatic Life in Ambient Water
EPA recommends that metals criteria be expressed as dissolved concentrations (see appendix A, I.A.4 for more information regarding metals criteria).

(a)

Table 1.—Acute Water Quality Criteria for Protection of Aquatic Life in Ambient Water

Chemical	CMC	Conversion factor (CF)
	(MUg/L)	
Arsenic (III)	[a,b] 339.8	1.000

Chromium (VI)	[a,b] 16.02		0.982
Cyanide	[c] 22	n/a	
Dieldrin	[d] 0.24	n/a	
Endrin	[d] 0.086	n/a	
Lindane	[d] 0.95	n/a	
Mercury (II)	[a,b] 1.694		0.85
Parathion	[d] 0.065	n/a	
Selenium	[a,b] 19.34		0.922

***15392** (b)

Chemical	m_A	b_A	Conversion factor (CF)
Cadmium [a,b]	1.128	3.6867	0.85
Chromium (III) [a,b]	0.819	+3.7256	0.316
Copper [a,b]	0.9422	1.700	0.960
Nickel [a,b]	0.846	+2.255	0.998
Pentachlorophenol [c]	1.005	4.869	n/a
Zinc [a,b]	0.8473	+0.884	0.978

Table 2.—Chronic Water Quality Criteria for Protection of Aquatic Life in Ambient Water
EPA recommends that metals criteria be expressed as dissolved concentrations (see appendix A, I.A.4 for more information regarding metals criteria).

(a)

Table 2.—Chronic Water Quality Criteria for Protection of Aquatic Life in Ambient Water

Chemical	CCC (MUg/L)	Conversion factor (CF)
Arsenic (III)	[a,b] 147.9	1.000
Chromium (VI)	[a,b] 10.98	0.962

Cyanide	[c] 5.2	n/a	
Dieldrin	[d] 0.056	n/a	
Endrin	[d] 0.036	n/a	
Mercury (II)	[a,b] 0.9081		0.85
Parathion	[d] 0.013	n/a	
Selenium	[a,b] 5		0.922

(b)

Chemical	m_c	b_c	Conversion factor (CF)
Cadmium [a,b]	0.7852	2.715	0.850
Chromium (III) [a,b]	0.819	+0.6848	0.860
Copper [a,b]	0.8545	1.702	0.960
Nickel [a,b]	0.846	+0.0584	0.997
Pentachlorophenol [c]	1.005	5.134	n/a
Zinc [a,b]	0.8473	+0.884	0.986

Table 3.—Water Quality Criteria for Protection of Human Health

Chemical	HNV (MUg/L)		HCV (MUg/L)	
	Drinking	Nondrinking	Drinking	Nondrinking
Benzene	1.9E1	5.1E2	1.2E1	3.1E2
Chlordane	1.4E-3	1.4E-3	2.5E-4	2.5E-4
Chlorobenzene	4.7E2	3.2E3		
Cyanides	6.0E2	4.8E4		
DDT	2.0E-3	2.0E-3	1.5E-4	1.5E-4
Dieldrin	4.1E-4	4.1E-4	6.5E-6	6.5E-6
2,4-Dimethylphenol	4.5E2	8.7E3		
2,4-Dinitrophenol	5.5E1	2.8E3		

Hexachlorobenzene	4.6E-2	4.6E-2	4.5E-4	4.5E-4	
Hexachloroethane	6.0	7.6	5.3	6.7	
Lindane	4.7E-1	5.0E-1			
Mercury [1]	1.8E-3	1.8E-3			
Methylene chloride	1.6E3	9.0E4	4.7E1	2.6E3	
PCBs (class)	.....		3.9E-6	3.9E-6	
2,3,7,8-TCDD	6.7E-8	6.7E-8	8.6E-9	8.6E-9	
Toluene	5.6E3	5.1E4			
Toxaphene	.....		6.8E-5	6.8E-5	
Trichloroethylene	.....		2.9E1	3.7E2	

Table 4.—Water Quality Criteria for Protection of Wildlife

Chemical	Criteria (MUg/L)
DDT and metabolites	1.1E-5
Mercury (including methylmercury)	1.3E-3
PCBs (class)	7.4E-5
2,3,7,8-TCDD	3.1E-9

***15393** Table 5.—Pollutants Subject to Federal, State, and Tribal Requirements
Alkalinity

Ammonia

Bacteria

Biochemical oxygen demand (BOD)

Chlorine

Color

Dissolved oxygen

Dissolved solids

pH

Phosphorus

Salinity

Temperature

Total and suspended solids

Turbidity

Table 6.—Pollutants of Initial Focus in the Great Lakes Water Quality Initiative
A. Pollutants that are bioaccumulative chemicals of concern (BCCs):

Chlordane

4,4#-DDD; p,p#-DDD; 4,4#-TDE; p,p#-TDE

4,4#-DDE; p,p#-DDE

4,4#-DDT; p,p#-DDT

Dieldrin

Hexachlorobenzene

Hexachlorobutadiene; hexachloro-1, 3-butadiene

Hexachlorocyclohexanes; BHCs

alpha-Hexachlorocyclohexane; alpha-BHC

beta-Hexachlorocyclohexane; beta-BHC

delta-Hexachlorocyclohexane; delta-BHC

Lindane; gamma-hexachlorocyclohexane; gamma-BHC

Mercury

Mirex

Octachlorostyrene

PCBs; polychlorinated biphenyls

Pentachlorobenzene

Photomirex

2,3,7,8-TCDD; dioxin

1,2,3,4-Tetrachlorobenzene

1,2,4,5-Tetrachlorobenzene Toxaphene

B. Pollutants that are not bioaccumulative chemicals of concern:

Acenaphthene

Acenaphthylene

Acrolein; 2-propenal

Acrylonitrile

Aldrin

Aluminum

Anthracene

Antimony

Arsenic

Asbestos

1,2-Benzanthracene; benz[a]anthracene

Benzene

Benzidine

Benzo[a]pyrene; 3,4-benzopyrene

3,4-Benzofluoranthene; benzo[b]fluoranthene

11,12-Benzofluoranthene; benzo[k]fluoranthene

1,12-Benzoperylene; benzo[ghi]perylene

Beryllium

Bis(2-chloroethoxy) methane

Bis(2-chloroethyl) ether

Bis(2-chloroisopropyl) ether

Bromoform; tribomomethane

4-Bromophenyl phenyl ether

Butyl benzyl phthalate

Cadmium

Carbon tetrachloride; tetrachloromethane

Chlorobenzene

p-Chloro-m-cresol; 4-chloro-3-methylphenol

Chlorodibromomethane

Chlorethane

2-Chloroethyl vinyl ether

Chloroform; trichloromethane

2-Chloronaphthalene

2-Chlorophenol

4-Chlorophenyl phenyl ether

Chlorpyrifos

Chromium

Chrysene

Copper

Cyanide

2,4-D; 2,4-Dichlorophenoxyacetic acid

DEHP; di(2-ethylhexyl) phthalate

Diazinon

1,2:5,6-Dibenzanthracene; dibenz[a,h]anthracene

Dibutyl phthalate; di-n-butyl phthalate

1,2-Dichlorobenzene

1,3-Dichlorobenzene

1,4-Dichlorobenzene

3,3#-Dichlorobenzidine

Dichlorobromomethane; bromodichloromethane

1,1-Dichloroethane

1,2-Dichloroethane

1,1-Dichloroethylene; vinylidene chloride

1,2-trans-Dichloroethylene

2,4-Dichlorophenol

1,2-Dichloropropane

1,3-Dichloropropene; 1,3-dichloropropylene

Diethyl phthalate

2,4-Dimethylphenol; 2,4-xylenol

Dimethyl phthalate

4,6-Dinitro-o-cresol; 2-methyl-4,6-dinitrophenol

2,4-Dinitrophenol

2,4-Dinitrotoluene

2,6-Dinitrotoluene

Dioctyl phthalate; di-n-octyl phthalate

1,2-Diphenylhydrazine

Endosulfan; thiodan

alpha-Endosulfan

beta-Endosulfan

Endosulfan sulfate

Endrin

Endrin aldehyde

Ethylbenzene

Fluoranthene

Fluorene; 9H-fluorene

Fluoride

Guthion

Heptachlor

Heptachlor epoxide

Hexachlorocyclopentadiene

Hexachloroethane

Indeno[1,2,3-cd]pyrene; 2,3-o-phenylene pyrene

Isophorone

Lead

Malathion

Methoxychlor

Methyl bromide; bromomethane

Methyl chloride; chloromethane

Methylene chloride; dichloromethane

Napthalene

Nickel

Nitrobenzene

2-Nitrophenol

4-Nitrophenol

N-Nitrosodimethylamine

N-Nitrosodiphenylamine

N-Nitrosodipropylamine; N-nitrosodi-n-propylamine

Parathion

Pentachlorophenol

Phenanthrene

Phenol

Iron

Pyrene

Selenium

Silver

1,1,2,2-Tetrachloroethane

Tetrachloroethylene

Thallium

Toluene; methylbenzene

1,2,4-Trichlorobenzene

1,1,1-Trichloroethane

1,1,2-Trichloroethane

Trichloroethylene; trichloroethene

2,4,6-Trichlorophenol

Vinyl chloride; chloroethylene; chloroethene

Zinc

Appendix A to part 132—Great Lakes Water Quality Initiative Methodologies for Developments of Aquatic Life Criteria and Values

Methodology for Deriving Aquatic Life Criteria: Tier I

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this appendix.

15394** ***I. Definitions

A. Material of Concern. When defining the material of concern the following should be considered:

1. Each separate chemical that does not ionize substantially in most natural bodies of water should usually be considered a separate material, except possibly for structurally similar organic compounds that only exist in large quantities as commercial mixtures of the various compounds and apparently have similar biological, chemical, physical, and toxicological properties.

2. For chemicals that ionize substantially in most natural bodies of water (e.g., some phenols and organic acids, some salts of phenols and organic acids, and most inorganic salts and coordination complexes of metals and metalloid), all forms that would be in chemical equilibrium should usually be considered one material. Each different oxidation state of a metal and each different non-ionizable covalently bonded organometallic compound should usually be considered a separate material.

3. The definition of the material of concern should include an operational analytical component. Identification of a material simply as “sodium,” for example, implies “total sodium,” but leaves room for doubt. If “total” is meant, it must be explicitly stated. Even “total” has different operational definitions, some of which do not necessarily measure “all that is there” in all samples. Thus, it is also necessary to reference or describe the analytical method that is intended. The selection of the operational analytical component should take into account the analytical and environmental chemistry of the material and various practical considerations, such as labor and equipment requirements, and whether the method would require measurement in the field or would allow measurement after samples are transported to a laboratory.

a. The primary requirements of the operational analytical component are that it be appropriate for use on samples of receiving water, that it be compatible with the available toxicity and bioaccumulation data without making extrapolations that are too hypothetical, and that it rarely result in underprotection or overprotection of aquatic organisms and their uses. Toxicity is the property of a material, or combination of materials, to adversely affect organisms.

b. Because an ideal analytical measurement will rarely be available, an appropriate compromise measurement will usually have to be used. This compromise measurement must fit with the general approach that if an ambient concentration is lower than the criterion, unacceptable effects will probably not occur, i.e., the compromise measure must not err on the side of underprotection when measurements are made on a surface water. What is an appropriate measurement in one situation might not be appropriate for another. For example, because the chemical and physical properties of an effluent are usually quite different from those of the receiving water, an analytical method that is appropriate for analyzing an effluent might not be appropriate for expressing a criterion, and vice versa. A criterion should be based on an appropriate analytical measurement, but the criterion is not rendered useless if an ideal measurement either is not available or is not feasible.

Note: The analytical chemistry of the material might have to be taken into account when defining the material or when judging the acceptability of some toxicity tests, but a criterion must not be based on the sensitivity of an analytical method. When aquatic organisms are more sensitive than routine analytical methods, the proper solution is to develop better analytical methods.

4. It is now the policy of EPA that the use of dissolved metal to set and measure compliance with water quality standards is the recommended approach, because dissolved metal more closely approximates the bioavailable fraction of metal in the water column that does total recoverable metal. One reason is that a primary mechanism for water column toxicity is adsorption at the gill surface which requires metals to be in the dissolved form. Reasons for the consideration of total recoverable metals criteria include risk management considerations not covered by evaluation of water column toxicity. A risk manager may consider sediments and food chain effects and may decide to take a conservative approach for metals, considering that metals are very persistent chemicals. This approach could include the use of total recoverable metal in water quality standards. A range of different risk management decisions can be justified. EPA recommends that State water quality standards be based on dissolved metal. EPA will also approve a State risk management decision to adopt standards based on total recoverable metal, if those standards are otherwise approvable under this program.

B. Acute Toxicity. Concurrent and delayed adverse effect(s) that results from an acute exposure and occurs within any short observation period which begins when the exposure begins, may extend beyond the exposure period, and usually does not constitute a substantial portion of the life span of the organism. (Concurrent toxicity is an adverse effect to an organism that results from, and occurs during, its exposure to one or more test materials.) Exposure constitutes contact with a chemical or physical agent. Acute exposure, however, is exposure of an organism for any short period which usually does not constitute a substantial portion of its life span.

C. Chronic Toxicity. Concurrent and delayed adverse effect(s) that occurs only as a result of a chronic exposure. Chronic exposure is exposure of an organism for any long period or for a substantial portion of its life span.

II. Collection of Data

A. Collect all data available on the material concerning toxicity to aquatic animals and plants.

B. All data that are used should be available in typed, dated, and signed hard copy (e.g., publication, manuscript, letter, memorandum, etc.) with enough supporting information to indicate that acceptable test procedures were used and that the results are reliable. In some cases, it might be appropriate to obtain written information from the investigator, if possible. Information that is not available for distribution shall not be used.

C. Questionable data, whether published or unpublished, must not be used. For example, data must be rejected if they are from tests that did not contain a control treatment, tests in which too many organisms in the control treatment died or showed signs of stress or disease, and tests in which distilled or deionized water was used as the dilution water without the addition of appropriate salts.

D. Data on technical grade materials may be used if appropriate, but data on formulated mixtures and emulsifiable concentrates of the material must not be used.

E. For some highly volatile, hydrolyzable, or degradable materials, it might be appropriate to use only results of flow-through tests in which the concentrations of test material in test solutions were measured using acceptable analytical methods. A flow-through test is a test with aquatic organisms in which test solutions flow into constant-volume test chambers either intermittently (e.g., every few minutes) or continuously, with the excess flowing out.

F. Data must be rejected if obtained using:

1. Brine shrimp, because they usually only occur naturally in water with salinity greater than 35 g/kg.

2. Species that do not have reproducing wild populations in North America.

3. Organisms that were previously exposed to substantial concentrations of the test material or other contaminants.

4. Saltwater species except for use in deriving acute-chronic ratios. An ACR is a standard measure of the acute toxicity of a material divided by an appropriate measure of the chronic toxicity of the same material under comparable conditions.

G. Questionable data, data on formulated mixtures and emulsifiable concentrates, and data obtained with species non-resident to North America or previously exposed organisms may be used to provide auxiliary information but must not be used in the derivation of criteria.

III. Required Data

A. Certain data should be available to help ensure that each of the major kinds of possible adverse effects receives adequate consideration. An adverse effect is a change in an organism that is harmful to the organism. Exposure means contact with a chemical or physical agent. Results of acute and chronic toxicity tests with representative species of aquatic animals are necessary so that data available for tested species can be considered a useful indication of the sensitivities of appropriate untested species. Fewer data concerning toxicity to aquatic plants are usually available because procedures for conducting tests with plants and interpreting the results of such tests are not as well developed.

B. To derive a Great Lakes Tier I criterion for aquatic organisms and their uses, the following must be available:

1. Results of acceptable acute (or chronic) tests (see section IV or VI of this appendix) with at least one species of freshwater animal in at least eight different families such that all of the following are included:

***15395** a. The family Salmonidae in the class Osteichthyes;

b. One other family (preferably a commercially or recreationally important, warmwater species) in the class Osteichthyes (e.g., bluegill, channel catfish);

c. A third family in the phylum Chordata (e.g., fish, amphibian);

d. A planktonic crustacean (e.g., a cladoceran, copepod);

e. A benthic crustacean (e.g., ostracod, isopod, amphipod, crayfish);

f. An insect (e.g., mayfly, dragonfly, damselfly, stonefly, caddisfly, mosquito, midge);

g. A family in a phylum other than Arthropoda or Chordata (e.g., Rotifera, Annelida, Mollusca);

h. A family in any order of insect or any phylum not already represented.

2. Acute-chronic ratios (see section VI of this appendix) with at least one species of aquatic animal in at least three different families provided that of the three species:

a. At least one is a fish;

b. At least one is an invertebrate; and

c. At least one species is an acutely sensitive freshwater species (the other two may be saltwater species).

3. Results of at least one acceptable test with a freshwater algae or vascular plant is desirable but not required for criterion derivation (see section VIII of this appendix). If plants are among the aquatic organisms most sensitive to the material, results of a test with a plant in another phylum (division) should also be available.

C. If all required data are available, a numerical criterion can usually be derived except in special cases. For example, derivation of a chronic criterion might not be possible if the available ACRs vary by more than a factor of ten with no apparent pattern. Also, if a criterion is to be related to a water quality characteristic (see sections V and VII of this appendix), more data will be required.

D. Confidence in a criterion usually increases as the amount of available pertinent information increases. Thus, additional data are usually desirable.

IV. Final Acute Value

A. Appropriate measures of the acute (short-term) toxicity of the material to a variety of species of aquatic animals are used to calculate the Final Acute Value (FAV). The calculated Final Acute Value is a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable acute toxicity tests have been conducted on the material) have higher Genus Mean Acute Values (GMAVs). An acute test is a comparative study in which organisms, that are subjected to different treatments, are observed for a short period usually not constituting a substantial portion of their life span. However, in some cases, the Species Mean Acute Value (SMAV) of a commercially or recreationally important species of the Great Lakes System is lower than the calculated FAV, then the SMAV replaces the calculated FAV in order to provide protection for that important species.

B. Acute toxicity tests shall be conducted using acceptable procedures. For good examples of acceptable procedures see American Society for Testing and Materials (ASTM) Standard E 729, Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians.

C. Except for results with saltwater annelids and mysids, results of acute tests during which the test organisms were fed should not be used, unless data indicate that the food did not affect the toxicity of the test material. (Note: If the minimum acute-chronic ratio data requirements (as described in section III.B.2 of this appendix) are not met with freshwater data alone, saltwater data may be used.)

D. Results of acute tests conducted in unusual dilution water, e.g., dilution water in which total organic carbon or particulate matter exceeded five mg/L, should not be used, unless a relationship is developed between acute toxicity and organic carbon or particulate matter, or unless data show that organic carbon or particulate matter, etc., do not affect toxicity.

E. Acute values must be based upon endpoints which reflect the total severe adverse impact of the test material on the organisms used in the test. Therefore, only the following kinds of data on acute toxicity to aquatic animals shall be used:

1. Tests with daphnids and other cladocerans must be started with organisms less than 24 hours old and tests with midges must be started with second or third instar larvae. It is preferred that the results should be the 48-hour EC50 based on the total percentage of organisms killed and immobilized. If such an EC50 is not available for a test, the 48-hour LC50 should be used in place of the desired 48-hour EC50. An EC50 or LC50 of longer than 48 hours can be used as long as the animals were not fed and the control animals were acceptable at the end of the test. An EC50 is a statistically or graphically estimated concentration that is expected to cause one or more specified effects in 50% of a group of organisms under specified conditions. An LC50 is a statistically or graphically estimated concentration that is expected to be lethal to 50% of a group of organisms under specified conditions.

2. It is preferred that the results of a test with embryos and larvae of barnacles, bivalve molluscs (clams, mussels, oysters and scallops), sea urchins, lobsters, crabs, shrimp and abalones be the 96-hour EC50 based on the percentage of organisms with incompletely developed shells plus the percentage of organisms killed. If such an EC50 is not available from a test, of the values that are available from the test, the lowest of the following should be used in place of the desired 96-hour EC50: 48- to 96-hour EC50s based on percentage of organisms with incompletely developed shells plus percentage of organisms killed, 48- to 96-hour EC50s based upon percentage of organisms with incompletely developed shells, and 48-hour to 96-hour LC50s. (Note: If the minimum acute-chronic ratio data requirements (as described in section III.B.2 of this appendix) are not met with freshwater data alone, saltwater data may be used.)

3. It is preferred that the result of tests with all other aquatic animal species and older life stages of barnacles, bivalve molluscs (clams, mussels, oysters and scallops), sea urchins, lobsters, crabs, shrimp and abalones be the 96-hour EC50 based on percentage of organisms exhibiting loss of equilibrium plus percentage of organisms immobilized plus percentage of organisms killed. If such an EC50 is not available from a test, of the values that are available from a test the lower of the following should

be used in place of the desired 96-hour EC50: the 96-hour EC50 based on percentage of organisms exhibiting loss of equilibrium plus percentage of organisms immobilized and the 96-hour LC50.

4. Tests whose results take into account the number of young produced, such as most tests with protozoans, are not considered acute tests, even if the duration was 96 hours or less.

5. If the tests were conducted properly, acute values reported as “greater than” values and those which are above the solubility of the test material should be used, because rejection of such acute values would bias the Final Acute Value by eliminating acute values for resistant species.

F. If the acute toxicity of the material to aquatic animals has been shown to be related to a water quality characteristic such as hardness or particulate matter for freshwater animals, refer to section V of this appendix.

G. The agreement of the data within and between species must be considered. Acute values that appear to be questionable in comparison with other acute and chronic data for the same species and for other species in the same genus must not be used. For example, if the acute values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values would be appropriate, absent countervailing circumstances.

H. If the available data indicate that one or more life stages are at least a factor of two more resistant than one or more other life stages of the same species, the data for the more resistant life stages must not be used in the calculation of the SMAV because a species cannot be considered protected from acute toxicity if all of the life stages are not protected.

I. For each species for which at least one acute value is available, the SMAV shall be calculated as the geometric mean of the results of all acceptable flow-through acute toxicity tests in which the concentrations of test material were measured with the most sensitive tested life stage of the species. For a species for which no such result is available, the SMAV shall be calculated as the geometric mean of all acceptable acute toxicity tests with the most sensitive tested life stage, i.e., results of flow-through tests in which the concentrations were not measured and results of static and renewal tests based on initial concentrations (nominal concentrations are acceptable for most test materials if measured concentrations are not available) of test material. A renewal test is a test with aquatic organisms in which either the test solution in a test chamber is removed and replaced at least once during the test or the test organisms are transferred into a new test solution of the same composition at least once during the test. A static test is a test with aquatic organisms in which the solution ***15396** and organisms that are in a test chamber at the beginning of the test remain in the chamber until the end of the test, except for removal of dead test organisms.

Note 1: Data reported by original investigators must not be rounded off. Results of all intermediate calculations must not be rounded off to fewer than four significant digits.

Note 2: The geometric mean of N numbers is the Nth root of the product of the N numbers. Alternatively, the geometric mean can be calculated by adding the logarithms of the N numbers, dividing the sum by N, and taking the antilog of the quotient. The geometric mean of two numbers is the square root of the product of the two numbers, and the geometric mean of one number is that number. Either natural (base e) or common (base 10) logarithms can be used to calculate geometric means as long as they are used consistently within each set of data, i.e., the antilog used must match the logarithms used.

Note 3: Geometric means, rather than arithmetic means, are used here because the distributions of sensitivities of individual organisms in toxicity tests on most materials and the distributions of sensitivities of species within a genus are more likely to be lognormal than normal. Similarly, geometric means are used for ACRs because quotients are likely to be closer to lognormal than normal distributions. In addition, division of the geometric mean of a set of numerators by the geometric mean of the set of denominators will result in the geometric mean of the set of corresponding quotients.

J. For each genus for which one or more SMAVs are available, the GMAV shall be calculated as the geometric mean of the SMAVs available for the genus.

K. Order the GMAVs from high to low.

L. Assign ranks, R, to the GMAVs from "1" for the lowest to "N" for the highest. If two or more GMAVs are identical, assign them successive ranks.

M. Calculate the cumulative probability, P, for each GMAV as R/(N+1).

N. Select the four GMAVs which have cumulative probabilities closest to 0.05 (if there are fewer than 59 GMAVs, these will always be the four lowest GMAVs).

O. Using the four selected GMAVs, and Ps, calculate

Note: Natural logarithms (logarithms to base e, denoted as ln) are used herein merely because they are easier to use on some hand calculators and computers than common (base 10) logarithms. Consistent use of either will produce the same result.

P. If for a commercially or recreationally important species of the Great Lakes System the geometric mean of the acute values from flow-through tests in which the concentrations of test material were measured is lower than the calculated Final Acute Value (FAV), then that geometric mean must be used as the FAV instead of the calculated FAV.

Q. See section VI of this appendix.

V. Final Acute Equation

A. When enough data are available to show that acute toxicity to two or more species is similarly related to a water quality characteristic, the relationship shall be taken into account as described in sections V.B through V.G of this appendix or using analysis of covariance. The two methods are equivalent and produce identical results. The manual method described below provides an understanding of this application of covariance analysis, but computerized versions of covariance analysis are much more convenient for analyzing large data sets. If two or more factors affect toxicity, multiple regression analysis shall be used.

B. For each species for which comparable acute toxicity values are available at two or more different values of the water quality characteristic, perform a least squares regression of the acute toxicity values on the corresponding values of the water quality characteristic to obtain the slope and its 95 percent confidence limits for each species.

Note: Because the best documented relationship is that between hardness and acute toxicity of metals in fresh water and a log-log relationship fits these data, geometric means and natural logarithms of both toxicity and water quality are used in the rest of this section. For relationships based on other water quality characteristics, such as Ph, temperature, no transformation or a different transformation might fit the data better, and appropriate changes will be necessary throughout this section.

C. Decide whether the data for each species are relevant, taking into account the range and number of the tested values of the water quality characteristic and the degree of agreement within and between species. For example, a slope based on six data points might be of limited value if it is based only on data for a very narrow range of values of the water quality characteristic. A slope based on only two data points, however, might be useful if it is consistent with other information and if the two points cover a broad enough range of the water quality characteristic. In addition, acute values that appear to be questionable in comparison with other acute and chronic data available for the same species and for other species in the same genus should not be used. For example, if after adjustment for the water quality characteristic, the acute values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values would be appropriate, absent countervailing justification. If useful slopes are not available for at least one fish and one invertebrate or if the available slopes are too dissimilar or if too

few data are available to adequately define the relationship between acute toxicity and the water quality characteristic, return to section IV.G of this appendix, using the results of tests conducted under conditions and in waters similar to those commonly used for toxicity tests with the species.

D. For each species, calculate the geometric mean of the available acute values and then divide each of the acute values for the species by the geometric mean for the species. This normalizes the acute values so that the geometric mean of the normalized values for each species individually and for any combination of species is 1.0.

E. Similarly normalize the values of the water quality characteristic for each species individually using the same procedure as above.

F. Individually for each species perform a least squares regression of the normalized ***15397** acute values of the water quality characteristic. The resulting slopes and 95 percent confidence limits will be identical to those obtained in section V.B. of this appendix. If, however, the data are actually plotted, the line of best fit for each individual species will go through the point 1,1 in the center of the graph.

G. Treat all of the normalized data as if they were all for the same species and perform a least squares regression of all of the normalized acute values on the corresponding normalized values of the water quality characteristic to obtain the pooled acute slope, V, and its 95 percent confidence limits. If all of the normalized data are actually plotted, the line of best fit will go through the point 1,1 in the center of the graph.

H. For each species calculate the geometric mean, W, of the acute toxicity values and the geometric mean, X, of the values of the water quality characteristic. (These were calculated in sections V.D and V.E of this appendix).

I. For each species, calculate the logarithm, Y, of the SMAV at a selected value, Z, of the water quality characteristic using the equation:

Y=ln WV(ln Xln Z)
J. For each species calculate the SMAV at X using the equation:

$SMAV=e^{Y}$
Note: Alternatively, the SMAVs at Z can be obtained by skipping step H above, using the equations in steps I and J to adjust each acute value individually to Z, and then calculating the geometric mean of the adjusted values for each species individually. This alternative procedure allows an examination of the range of the adjusted acute values for each species.

K. Obtain the FAV at Z by using the procedure described in sections IV.J through IV.O of this appendix.

L. If, for a commercially or recreationally important species of the Great Lakes System the geometric mean of the acute values at Z from flow-through tests in which the concentrations of the test material were measured is lower than the FAV at Z, then the geometric mean must be used as the FAV instead of the FAV.

M. The Final Acute Equation is written as:

$FAV=e^{(V[\ln(\text{water quality characteristic})]+AV[\ln Z])}$,
where:

V=pooled acute slope, and A=ln(FAV at Z).
Because V, A, and Z are known, the FAV can be calculated for any selected value of the water quality characteristic.

VI. Final Chronic Value

A. Depending on the data that are available concerning chronic toxicity to aquatic animals, the Final Chronic Value (FCV) can be calculated in the same manner as the FAV or by dividing the FAV by the Final Acute-Chronic Ratio (FACR). In some cases, it might not be possible to calculate a FCV. The FCV is (a) a calculated estimate of the concentration of a test material such that 95 percent of the genera (with which acceptable chronic toxicity tests have been conducted on the material) have higher GMCVs, or (b) the quotient of an FAV divided by an appropriate ACR, or (c) the SMCV of an important and/or critical species, if the SMCV is lower than the calculated estimate or the quotient, whichever is applicable.

Note: As the name implies, the ACR is a way of relating acute and chronic toxicities.

B. Chronic values shall be based on results of flow-through (except renewal is acceptable for daphnids) chronic tests in which the concentrations of test material in the test solutions were properly measured at appropriate times during the test. A chronic test is a comparative study in which organisms, that are subjected to different treatments, are observed for a long period or a substantial portion of their life span.

C. Results of chronic tests in which survival, growth, or reproduction in the control treatment was unacceptably low shall not be used. The limits of acceptability will depend on the species.

D. Results of chronic tests conducted in unusual dilution water, e.g., dilution water in which total organic carbon or particulate matter exceeded five mg/L, should not be used, unless a relationship is developed between chronic toxicity and organic carbon or particulate matter, or unless data show that organic carbon, particulate matter, etc., do not affect toxicity.

E. Chronic values must be based on endpoints and lengths of exposure appropriate to the species. Therefore, only results of the following kinds of chronic toxicity tests shall be used:

1. Life-cycle toxicity tests consisting of exposures of each of two or more groups of individuals of a species to a different concentration of the test material throughout a life cycle. To ensure that all life stages and life processes are exposed, tests with fish should begin with embryos or newly hatched young less than 48 hours old, continue through maturation and reproduction, and should end not less than 24 days (90 days for salmonids) after the hatching of the next generation. Tests with daphnids should begin with young less than 24 hours old and last for not less than 21 days, and for ceriodaphnids not less than seven days. For good examples of acceptable procedures see American Society for Testing and Materials (ASTM) Standard E 1193 Guide for conducting renewal life-cycle toxicity tests with Daphnia magna and ASTM Standard E 1295 Guide for conducting three-brood, renewal toxicity tests with Ceriodaphnia dubia. Tests with mysids should begin with young less than 24 hours old and continue until seven days past the median time of first brood release in the controls. For fish, data should be obtained and analyzed on survival and growth of adults and young, maturation of males and females, eggs spawned per female, embryo viability (salmonids only), and hatchability. For daphnids, data should be obtained and analyzed on survival and young per female. For mysids, data should be obtained and analyzed on survival, growth, and young per female.

2. Partial life-cycle toxicity tests consist of exposures of each of two more groups of individuals of a species of fish to a different concentration of the test material through most portions of a life cycle. Partial life-cycle tests are allowed with fish species that require more than a year to reach sexual maturity, so that all major life stages can be exposed to the test material in less than 15 months. A life-cycle test is a comparative study in which organisms, that are subjected to different treatments, are observed at least from a life stage in one generation to the same life-stage in the next generation. Exposure to the test material should begin with immature juveniles at least two months prior to active gonad development, continue through maturation and reproduction, and end not less than 24 days (90 days for salmonids) after the hatching of the next generation. Data should be obtained and

analyzed on survival and growth of adults and young, maturation of males and females, eggs spawned per female, embryo viability (salmonids only), and hatchability.

3. Early life-stage toxicity tests consisting of 28- to 32-day (60 days post hatch for salmonids) exposures of the early life stages of a species of fish from shortly after fertilization through embryonic, larval, and early juvenile development. Data should be obtained and analyzed on survival and growth.

Note: Results of an early life-stage test are used as predictions of results of life-cycle and partial life-cycle tests with the same species. Therefore, when results of a life-cycle or partial life-cycle test are available, results of an early life-stage test with the same species should not be used. Also, results of early life-stage tests in which the incidence of mortalities or abnormalities increased substantially near the end of the test shall not be used because the results of such tests are possibly not good predictions of comparable life-cycle or partial life-cycle tests.

F. A chronic value may be obtained by calculating the geometric mean of the lower and upper chronic limits from a chronic test or by analyzing chronic data using regression analysis.

1. A lower chronic limit is the highest tested concentration:

a. In an acceptable chronic test;

b. Which did not cause an unacceptable amount of adverse effect on any of the specified biological measurements; and

c. Below which no tested concentration caused an unacceptable effect.

2. An upper chronic limit is the lowest tested concentration:

a. In an acceptable chronic test;

b. Which did cause an unacceptable amount of adverse effect on one or more of the specified biological measurements; and,

c. Above which all tested concentrations also caused such an effect.

Note: Because various authors have used a variety of terms and definitions to interpret and report results of chronic tests, reported results should be reviewed carefully. The amount of effect that is considered unacceptable is often based on a statistical hypothesis test, but might also be defined in terms of a specified percent reduction from the controls. A small percent reduction (e.g., three percent) might be considered acceptable even if it is statistically significantly different from the control, whereas a large percent reduction (e.g., 30 percent) might be considered unacceptable even if it is not statistically significant.

G. If the chronic toxicity of the material to aquatic animals has been shown to be related ***15398** to a water quality characteristic such as hardness or particulate matter for freshwater animals, refer to section VII of this appendix.

H. If chronic values are available for species in eight families as described in section III.B.1 of this appendix, a SMCV shall be calculated for each species for which at least one chronic value is available by calculating the geometric mean of the results of all acceptable life-cycle and partial life-cycle toxicity tests with the species; for a species of fish for which no such result is available, the SMCV is the geometric mean of all acceptable early life-stage tests. Appropriate GMCVs shall also be calculated. A GMCV is the geometric mean of the SMCVs for the genus. The FCV shall be obtained using the procedure described in sections IV.J through IV.O of this appendix, substituting SMCV and GMCV for SMAV and GMAV respectively. See section VI.M of this appendix.

Note: Section VI.I through VI.L are for use when chronic values are not available for species in eight taxonomic families as described in section III.B.1 of this appendix.

I. For each chronic value for which at least one corresponding appropriate acute value is available, calculate an ACR, using for the numerator the geometric mean of the results of all acceptable flow-through (except static is acceptable for daphnids and midges) acute tests in the same dilution water in which the concentrations are measured. For fish, the acute test(s) should be conducted with juveniles. The acute test(s) should be part of the same study as the chronic test. If acute tests were not conducted as part of the same study, but were conducted as part of a different study in the same laboratory and dilution water, then they may be used. If no such acute tests are available, results of acute tests conducted in the same dilution water in a different laboratory may be used. If no such acute tests are available, an ACR shall not be calculated.

J. For each species, calculate the SMACR as the geometric mean of all ACRs available for that species. If the minimum ACR data requirements (as described in section III.B.2 of this appendix) are not met with freshwater data alone, saltwater data may be used along with the freshwater data.

K. For some materials, the ACR seems to be the same for all species, but for other materials the ratio seems to increase or decrease as the SMAV increases. Thus the FACR can be obtained in three ways, depending on the data available:

1. If the species mean ACR seems to increase or decrease as the SMAVs increase, the FACR shall be calculated as the geometric mean of the ACRs for species whose SMAVs are close to the FAV.

2. If no major trend is apparent and the ACRs for all species are within a factor of ten, the FACR shall be calculated as the geometric mean of all of the SMACRs.

3. If the most appropriate SMACRs are less than 2.0, and especially if they are less than 1.0, acclimation has probably occurred during the chronic test. In this situation, because continuous exposure and acclimation cannot be assured to provide adequate protection in field situations, the FACR should be assumed to be two, so that the FCV is equal to the Criterion Maximum Concentration (CMC). (See section X.B of this appendix.)

If the available SMACRs do not fit one of these cases, a FACR may not be obtained and a Tier I FCV probably cannot be calculated.

L. Calculate the FCV by dividing the FAV by the FACR.

FCV=FAV+FACR

If there is a Final Acute Equation rather than a FAV, see also section V of this appendix.
M. If the SMCV of a commercially or recreationally important species of the Great Lakes System is lower than the calculated FCV, then that SMCV must be used as the FCV instead of the calculated FCV.

N. See section VIII of this appendix.

VII. Final Chronic Equation

A. A Final Chronic Equation can be derived in two ways. The procedure described in section VII.A of this appendix will result in the chronic slope being the same as the acute slope. The procedure described in sections VII.B through N of this appendix will usually result in the chronic slope being different from the acute slope.

1. If ACRs are available for enough species at enough values of the water quality characteristic to indicate that the ACR appears to be the same for all species and appears to be independent of the water quality characteristic, calculate the FACR as the geometric mean of the available SMACRs.

2. Calculate the FCV at the selected value Z of the water quality characteristic by dividing the FAV at Z (see section V.M of this appendix) by the FACR.

3. Use V=pooled acute slope (see section V.M of this appendix), and

L=pooled chronic slope.

4. See section VII.M of this appendix.

B. When enough data are available to show that chronic toxicity to at least one species is related to a water quality characteristic, the relationship should be taken into account as described in sections C through G below or using analysis of covariance. The two methods are equivalent and produce identical results. The manual method described below provides an understanding of this application of covariance analysis, but computerized versions of covariance analysis are much more convenient for analyzing large data sets. If two or more factors affect toxicity, multiple regression analysis shall be used.

C. For each species for which comparable chronic toxicity values are available at two or more different values of the water quality characteristic, perform a least squares regression of the chronic toxicity values on the corresponding values of the water quality characteristic to obtain the slope and its 95 percent confidence limits for each species.

Note: Because the best documented relationship is that between hardness and acute toxicity of metals in fresh water and a log-log relationship fits these data, geometric means and natural logarithms of both toxicity and water quality are used in the rest of this section. For relationships based on other water quality characteristics, such as Ph, temperature, no transformation or a different transformation might fit the data better, and appropriate changes will be necessary throughout this section. It is probably preferable, but not necessary, to use the same transformation that was used with the acute values in section V of this appendix.

D. Decide whether the data for each species are relevant, taking into account the range and number of the tested values of the water quality characteristic and the degree of agreement within and between species. For example, a slope based on six data points might be of limited value if it is based only on data for a very narrow range of values of the water quality characteristic. A slope based on only two data points, however, might be more useful if it is consistent with other information and if the two points cover a broad range of the water quality characteristic. In addition, chronic values that appear to be questionable in comparison with other acute and chronic data available for the same species and for other species in the same genus in most cases should not be used. For example, if after adjustment for the water quality characteristic, the chronic values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values is, in most cases, absent countervailing circumstances, appropriate. If a useful chronic slope is not available for at least one species or if the available slopes are too dissimilar or if too few data are available to adequately define the relationship between chronic toxicity and the water quality characteristic, it might be appropriate to assume that the chronic slope is the same as the acute slope, which is equivalent to assuming that the ACR is independent of the water quality characteristic. Alternatively, return to section VI.H of this appendix, using the results of tests conducted under conditions and in waters similar to those commonly used for toxicity tests with the species.

E. Individually for each species, calculate the geometric mean of the available chronic values and then divide each chronic value for a species by the mean for the species. This normalizes the chronic values so that the geometric mean of the normalized values for each species individually, and for any combination of species, is 1.0.

F. Similarly, normalize the values of the water quality characteristic for each species individually.

G. Individually for each species, perform a least squares regression of the normalized chronic toxicity values on the corresponding normalized values of the water quality characteristic. The resulting slopes and the 95 percent confidence limits will be identical to those obtained in section VII.B of this appendix. Now, however, if the data are actually plotted, the line of best fit for each individual species will go through the point 1,1 in the center of the graph.

H. Treat all of the normalized data as if they were all the same species and perform a least squares regression of all of the normalized chronic values on the corresponding normalized values of the water quality characteristic to obtain the pooled chronic slope, L, and its 95 percent confidence limits.

If all normalized data are actually plotted, the line of best fit will go through the point 1,1 in the center of the graph.

***15399** I. For each species, calculate the geometric mean, M, of the toxicity values and the geometric mean, P, of the values of the water quality characteristic. (These are calculated in sections VII.E and F of this appendix.)

J. For each species, calculate the logarithm, Q, of the SMCV at a selected value, Z, of the water quality characteristic using the equation:

$$Q=\ln M—L(\ln P\ln Z)$$

Note: Although it is not necessary, it is recommended that the same value of the water quality characteristic be used here as was used in section V of this appendix.

K. For each species, calculate a SMCV at Z using the equation:

$$SMCV=e^{Q}$$

Note: Alternatively, the SMCV at Z can be obtained by skipping section VII.J of this appendix, using the equations in sections VII.J and K of this appendix to adjust each chronic value individually to Z, and then calculating the geometric means of the adjusted values for each species individually. This alternative procedure allows an examination of the range of the adjusted chronic values for each species.

L. Obtain the FCV at Z by using the procedure described in sections IV.J through O of this appendix.

M. If the SMCV at Z of a commercially or recreationally important species of the Great Lakes System is lower than the calculated FCV at Z, then that SMCV shall be used as the FCV at Z instead of the calculated FCV.

N. The Final Chronic Equation is written as:

$$FCV=e^{(L[\ln(\text{water quality characteristic})]+\ln SL[\ln Z])}$$

Where:

L=pooled chronic slope and S = FCV at Z.
Because L, S, and Z are known, the FCV can be calculated for any selected value of the water quality characteristic.

VIII. Final Plant Value

A. A Final Plant Value (FPV) is the lowest plant value that was obtained with an important aquatic plant species in an acceptable toxicity test for which the concentrations of the test material were measured and the adverse effect was biologically important. Appropriate measures of the toxicity of the material to aquatic plants are used to compare the relative sensitivities of aquatic plants and animals. Although procedures for conducting and interpreting the results of toxicity tests with plants are not well-developed, results of tests with plants usually indicate that criteria which adequately protect aquatic animals and their uses will, in most cases, also protect aquatic plants and their uses.

B. A plant value is the result of a 96-hour test conducted with an alga or a chronic test conducted with an aquatic vascular plant.

Note: A test of the toxicity of a metal to a plant shall not be used if the medium contained an excessive amount of a complexing agent, such as EDTA, that might affect the toxicity of the metal. Concentrations of EDTA above 200 mg/L should be considered excessive.

C. The FPV shall be obtained by selecting the lowest result from a test with an important aquatic plant species in which the concentrations of test material are measured and the endpoint is biologically important.

IX. Other Data

Pertinent information that could not be used in earlier sections might be available concerning adverse effects on aquatic organisms. The most important of these are data on cumulative and delayed toxicity, reduction in survival, growth, or reproduction, or any other adverse effect that has been shown to be biologically important. Delayed toxicity is an adverse effect to an organism that results from, and occurs after the end of, its exposure to one or more test materials. Especially important are data for species for which no other data are available. Data from behavioral, biochemical, physiological, microcosm, and field studies might also be available. Data might be available from tests conducted in unusual dilution water (see sections IV.D and VI.D of this appendix), from chronic tests in which the concentrations were not measured (see section VI.B of this appendix), from tests with previously exposed organisms (see section II.F.3 of this appendix), and from tests on formulated mixtures or emulsifiable concentrates (see section II.D of this appendix). Such data might affect a criterion if the data were obtained with an important species, the test concentrations were measured, and the endpoint was biologically important.

X. Criterion

A. A criterion consists of two concentrations: the CMC and the Criterion Continuous Concentration (CCC).

B. The CMC is equal to one-half the FAV. The CMC is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed briefly without resulting in an unacceptable effect.

C. The CCC is equal to the lowest of the FCV or the FPV (if available) unless other data (see section IX of this appendix) show that a lower value should be used. The CCC is an estimate of the highest concentration of a material in the water column to which an aquatic community can be exposed indefinitely without resulting in an unacceptable effect. If toxicity is related to a water quality characteristic, the CCC is obtained from the Final Chronic Equation or FPV (if available) that results in the lowest concentrations in the usual range of the water quality characteristic, unless other data (see section IX) show that a lower value should be used.

D. Round both the CMC and the CCC to two significant digits.

E. The criterion is stated as:

The procedures described in the Tier I methodology indicate that, except possibly where a commercially or recreationally important species is very sensitive, aquatic organisms should not be affected unacceptably if the four-day average concentration

of (1) does not exceed (2) mg/L more than once every three years on the average and if the one-hour average concentration does not exceed (3) mg/L more than once every three years on the average.

Where:

(1) = insert name of material

(2) = insert the CCC

(3) = insert the CMC

If the CMC averaging period of one hour or the CCC averaging period of four days is inappropriate for the pollutant, or if the once-in-three-year allowable excursion frequency is inappropriate for the pollutant or for the sites to which a criterion is applied, then the State may specify alternative averaging periods or frequencies. The choice of an alternative averaging period or frequency shall be justified by a scientifically defensible analysis demonstrating that the alternative values will protect the aquatic life uses of the water. Appropriate laboratory data and/or well-designed field biological surveys shall be submitted to EPA as justification for differing averaging periods and/or frequencies of exceedance.

XI. Final Review

A. The derivation of the criterion should be carefully reviewed by rechecking each step of the Guidance in this part. Items that should be especially checked are:

1. If unpublished data are used, are they well documented?

2. Are all required data available?

3. Is the range of acute values for any species greater than a factor of 10?

4. Is the range of SMAVs for any genus greater than a factor of 10?

5. Is there more than a factor of 10 difference between the four lowest GMAVs?

6. Are any of the lowest GMAVs questionable?

7. Is the FAV reasonable in comparison with the SMAVs and GMAVs?

8. For any commercially or recreationally important species of the Great Lakes System, is the geometric mean of the acute values from flow-through tests in which the concentrations of test material were measured lower than the FAV?

9. Are any of the chronic values used questionable?

10. Are any chronic values available for acutely sensitive species?

11. Is the range of acute-chronic ratios greater than a factor of 10?

12. Is the FCV reasonable in comparison with the available acute and chronic data?

13. Is the measured or predicted chronic value for any commercially or recreationally important species of the Great Lakes System below the FCV?

14. Are any of the other data important?

15. Do any data look like they might be outliers?

16. Are there any deviations from the Guidance in this part? Are they acceptable?

B. On the basis of all available pertinent laboratory and field information, determine if the criterion is consistent with sound scientific evidence. If it is not, another criterion, either higher or lower, shall be derived consistent with the Guidance in this part.

Methodology for Deriving Aquatic Life Values: Tier II

15400** ***XII. Secondary Acute Value

If all eight minimum data requirements for calculating an FAV using Tier I are not met, a Secondary Acute Value (SAV) for the waters of the Great Lakes System shall be calculated for a chemical as follows:

To calculate a SAV, the lowest GMAV in the database is divided by the Secondary Acute Factor (SAF) (Table A-1 of this appendix) corresponding to the number of satisfied minimum data requirements listed in the Tier I methodology (section III.B.1 of this appendix). (Requirements for definitions, data collection and data review, contained in sections I, II, and IV shall be applied to calculation of a SAV.) If all eight minimum data requirements are satisfied, a Tier I criterion calculation may be possible. In order to calculate a SAV, the database must contain, at a minimum, a genus mean acute value (GMAV) for one of the following three genera in the family Daphnidae—Ceriodaphnia sp., Daphnia sp., or Simocephalus sp.

If appropriate, the SAV shall be made a function of a water quality characteristic in a manner similar to that described in Tier I.

XIII. Secondary Acute-Chronic Ratio

If three or more experimentally determined ACRs, meeting the data collection and review requirements of Section VI of this appendix, are available for the chemical, determine the FACR using the procedure described in Section VI. If fewer than three acceptable experimentally determined ACRs are available, use enough assumed ACRs of 18 so that the total number of ACRs equals three. Calculate the Secondary Acute-Chronic Ratio (SACR) as the geometric mean of the three ACRs. Thus, if no experimentally determined ACRs are available, the SACR is 18.

XIV. Secondary Chronic Value

Calculate the Secondary Chronic Value (SCV) using one of the following:

If appropriate, the SCV will be made a function of a water quality characteristic in a manner similar to that described in Tier I.

XV. Commercially or Recreationally Important Species

If for a commercially or recreationally important species of the Great Lakes System the geometric mean of the acute values or chronic values from flow-through tests in which the concentrations of the test materials were measured is lower than the calculated SAV or SCV, then that geometric mean must be used as the SAV or SCV instead of the calculated SAV or SCV.

XVI. Tier II Value

A. A Tier II value shall consist of two concentrations: the Secondary Maximum Concentration (SMC) and the Secondary Continuous Concentration (SCC).

B. The SMC is equal to one-half of the SAV.

C. The SCC is equal to the lowest of the SCV or the Final Plant Value, if available, unless other data (see section IX of this appendix) show that a lower value should be used.

If toxicity is related to a water quality characteristic, the SCC is obtained from the Secondary Chronic Equation or FPV, if available, that results in the lowest concentrations in the usual range of the water quality characteristic, unless other data (See section IX of this appendix) show that a lower value should be used.

D. Round both the SMC and the SCC to two significant digits.

E. The Tier II value is stated as:

The procedures described in the Tier II methodology indicate that, except possibly where a locally important species is very sensitive, aquatic organisms should not be affected unacceptably if the four-day average concentration of (1) does not exceed (2) mg/L more than once every three years on the average and if the one-hour average concentration does not exceed (3) mg/L more than once every three years on the average.

Where:

(1) = insert name of material

(2) = insert the SCC

(3) = insert the SMC
As discussed above, States and Tribes have the discretion to specify alternative averaging periods or frequencies (see section X.E. of this appendix).

XVII. Appropriate Modifications
On the basis of all available pertinent laboratory and field information, determine if the Tier II value is consistent with sound scientific evidence. If it is not, another value, either higher or lower, shall be derived consistent with the Guidance in this part.

Table A-1.— Secondary Acute Factors

Number of minimum data requirements satisfied	Adjustment factor
1	21.9
2	13.0
3	8.0
4	7.0
5	6.1
6	5.2
7	4.3

Appendix B to Part 132—Great Lakes Water Quality Initiative

Methodology for Deriving Bioaccumulation Factors

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this appendix.

I. Introduction

A. The purpose of this methodology is to describe procedures for deriving bioaccumulation factors (BAFs) to be used in the calculation of Great Lakes Water Quality Guidance (Guidance) human health Tier I criteria and Tier II values and wildlife Tier I criteria. A subset of the human health BAFs are also used to identify the chemicals that are considered bioaccumulative chemicals of concern (BCCs).

B. Bioaccumulation reflects uptake of a substance by aquatic organisms exposed to the substance through all routes (i.e., ambient water and food), as would occur in nature. Bioconcentration reflects uptake of a substance by aquatic organisms exposed to the substance only through the ambient water. Both BAFs and bioconcentration factors (BCFs) are proportionality constants that describe the relationship between the concentration of a substance in aquatic organisms and its concentration in the ambient water. For the Guidance in this part, BAFs, rather than BCFs, are used to calculate Tier I criteria for human health and wildlife and Tier II values for human health because they better account for the total exposure of aquatic organisms to chemicals.

C. For organic chemicals, baseline BAFs can be derived using four methods. Measured baseline BAFs are derived from field-measured BAFs; predicted baseline BAFs are derived using biota-sediment accumulation factors (BSAFs) or are derived by multiplying a laboratory-measured or predicted BCF by a food-chain multiplier (FCM). The lipid content of the aquatic organisms is used to account for partitioning of organic chemicals within organisms so that data from different ***15401** tissues and species can be integrated. In addition, the baseline BAF is based on the concentration of freely dissolved organic chemicals in the ambient water to facilitate extrapolation from one water to another.

D. For inorganic chemicals, baseline BAFs can be derived using two of the four methods. Baseline BAFs are derived using either field-measured BAFs or by multiplying laboratory-measured BCFs by a FCM. For inorganic chemicals, BAFs are assumed to equal BCFs (i.e., the FCM is 1.0), unless chemical-specific biomagnification data support using a FCM other than 1.0.

E. Because both humans and wildlife consume fish from both trophic levels 3 and 4, two baseline BAFs are needed to calculate either a human health criterion or value or a wildlife criterion for a chemical. When appropriate, ingestion through consumption of invertebrates, plants, mammals, and birds in the diet of wildlife species to be protected may be taken into account.

II. Definitions

Baseline BAF. For organic chemicals, a BAF that is based on the concentration of freely dissolved chemical in the ambient water and takes into account the partitioning of the chemical within the organism; for inorganic chemicals, a BAF that is based on the wet weight of the tissue.

Baseline BCF. For organic chemicals, a BCF that is based on the concentration of freely dissolved chemical in the ambient water and takes into account the partitioning of the chemical within the organism; for inorganic chemicals, a BCF that is based on the wet weight of the tissue.

Bioaccumulation. The net accumulation of a substance by an organism as a result of uptake from all environmental sources.

Bioaccumulation factor (BAF). The ratio (in L/kg) of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where both the organism and its food are exposed to and the ratio does not change substantially over time.

Bioconcentration. The net accumulation of a substance by an aquatic organism as a result of uptake directly from the ambient water through gill membranes or other external body surfaces.

Bioconcentration factor (BCF). The ratio (in L/kg) of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through the water only and the ratio does not change substantially over time.

Biota-sediment accumulation factor (BSAF). The ratio (in kg of organic carbon/kg of lipid) of a substance's lipid-normalized concentration in tissue of an aquatic organism to its organic carbon-normalized concentration in surface sediment, in situations where the ratio does not change substantially over time, both the organism and its food are exposed, and the surface sediment is representative of average surface sediment in the vicinity of the organism.

Depuration. The loss of a substance from an organism as a result of any active or passive process.

Food-chain multiplier (FCM). The ratio of a BAF to an appropriate BCF.

Octanol-water partition coefficient (K_{OW}). The ration of the concentration of a substance in the n-octanol phase to its concentration in the aqueous phase in an equilibrated two-phase octanol-water system. For log K_{OW}, the log of the octanol-water partition coefficient is a base 10 logarithm.

Uptake. Acquisition of a substance from the environment by an organism as a result of any active or passive process.

III. Review and Selection of Data

A. Data Sources. Measured BAFs, BSAFs and BCFs are assembled from available sources including the following:

1. EPA Ambient Water Quality Criteria documents issued after January 1, 1980.

2. Published scientific literature.

3. Reports issued by EPA or other reliable sources.

4. Unpublished data.

One useful source of references is the Aquatic Toxicity Information Retrieval (AQUIRE) database.

B. Field-Measured BAFs. The following procedural and quality assurance requirements shall be met for field-measured BAFs:

1. The field studies used shall be limited to those conducted in the Great Lakes System with fish at or near the top of the aquatic food chain (i.e., in trophic levels 3 and/or 4).

2. The trophic level of the fish species shall be determined.

3. The site of the field study should not be so unique that the BAF cannot be extrapolated to other locations where the criteria and values will apply.

4. For organic chemicals, the percent lipid shall be either measured or reliably estimated for the tissue used in the determination of the BAF.

5. The concentration of the chemical in the water shall be measured in a way that can be related to particulate organic carbon (POC) and/or dissolved organic carbon (DOC) and should be relatively constant during the steady-state time period.

6. For organic chemicals with log K_{ow} greater than four, the concentrations of POC and DOC in the ambient water shall be either measured or reliably estimated.

7. For inorganic and organic chemicals, BAFs shall be used only if they are expressed on a wet weight basis; BAFs reported on a dry weight basis cannot be converted to wet weight unless a conversion factor is measured or reliably estimated for the tissue used in the determination of the BAF.

C. Field-Measured BSAFs. The following procedural and quality assurance requirements shall be met for field-measured BSAFs:

1. The field studies used shall be limited to those conducted in the Great Lakes System with fish at or near the top of the aquatic food chain (i.e., in trophic levels 3 and/or 4).

2. Samples of surface sediments (0-1 cm is ideal) shall be from locations in which there is net deposition of fine sediment and is representative of average surface sediment in the vicinity of the organism.

3. The K_{ow}s used shall be acceptable quality as described in section III.F below.

4. The site of the field study should not be so unique that the resulting BAF cannot be extrapolated to other locations where the criteria and values will apply.

5. The tropic level of the fish species shall be determined.

6. The percent lipid shall be either measured or reliably estimated for the tissue used in the determination of the BAF.

D. Laboratory-Measured BCFs. The following procedural and quality assurance requirements shall be met for laboratory-measured BCFs:

1. The test organism shall not be diseased, unhealthy, or adversely affected by the concentration of the chemical.

2. The total concentration of the chemical in the water shall be measured and should be relatively constant during the steady-state time period.

3. The organisms shall be exposed to the chemical using a flow-through or renewal procedure.

4. For organic chemicals, the percent lipid shall be either measured or reliably estimated for the tissue used in the determination of the BCF.

5. For organic chemicals with log K_{ow} greater than four, the concentrations of POC and DOC in the test solution shall be either measured or reliably estimated.

6. Laboratory-measured BCFs should be determined using fish species, but BCFs determined with molluscs and other invertebrates may be used with caution. For example, because invertebrates metabolize some chemicals less efficiently than vertebrates, a baseline BCF determined for such a chemical using invertebrates is expected to be higher than a comparable baseline BCF determined using fish.

7. If laboratory-measured BCFs increase or decrease as the concentration of the chemical increases in the test solutions in a bioconcentration test, the BCF measured at the lowest test concentration that is above concentrations existing in the control water shall be used (i.e., a BCF should be calculated from a control treatment). The concentrations of an inorganic chemical in a bioconcentration test should be greater than normal background levels and greater than levels required for normal nutrition of the test species if the chemical is a micronutrient, but below levels that adversely affect the species. Bioaccummulation of an inorganic chemical might be overestimated if concentrations are at or below normal background levels due to, for example, nutritional requirements of the test organisms.

8. For inorganic and organic chemicals, BCFs shall be used only if they are expressed on a wet weight basis. BCFs reported on a dry weight basis cannot be converted to wet weight unless a conversion factor is measured or reliably estimated for the tissue used in the determination of the BAF.

9. BCFs for organic chemicals may be based on measurement or radioactivity only when the BCF is intended to include metabolites or when there is confidence that there is no interference due to metabolites.

10. The calculation of the BCF must appropriately address growth dilution.

11. Other aspects of the methodology used should be similar to those described by ASTM (1990).

***15402** E. Predicted BCFs. The following procedural and quality assurance requirements shall be met for predicted BCFs:

1. The K_{ow} used shall be of acceptable quality as described in section III.F below.

2. The predicted baseline BCF shall be calculated using the equation: predicted baseline BCF = K_{ow}

where:

K_{ow} = octanol-water partition coefficient.

F. Octanol-Water Partition Coefficient (K_{ow}). 1. The value of K_{ow} used for an organic chemical shall be determined by giving priority to the experimental and computational techniques used as follows:

Log K_{ow} < 4:

Priority	Technique
1	Slow-stir.
1	Generator-column.
1	Shake-flask.
2	Reverse-phase liquid chromatography on C18 chromatography packing with extrapolation to zero percent solvent.
3	Reverse-phase liquid chromatography on C18 chromatography packing without extrapolation to zero percent solvent.
4	Calculated by the CLOGP program.

Log K_{ow} > 4:

Priority	Technique
1	Slow Stir.
1	Generator-column.
2	Reverse-phase liquid chromatography on C18 chromatography packing with extrapolation to zero percent solvent.
3	Reverse-phase liquid chromatography on C18 chromatography packing without extrapolation to zero percent solvent.
4	Shake-flask.
5	Calculated by the CLOGP program.

2. The CLOGP program is a computer program available from Pomona College. A value of K_{ow} that seems to be different from the others should be considered an outlier and not used. The value of K_{ow} used for an organic chemical shall be the geometric mean of the available K_{ow}s with highest priority or can be calculated from the arithmetic mean of the available log K_{ow} with the highest priority. Because it is an intermediate value in the derivation of a BAF, the value used for the K_{ow} of a chemical should not be rounded to fewer than three significant digits and a value for log K_{ow} should not be rounded to fewer than three significant digits after the decimal point.

G. This methodology provides overall guidance for the derivation of BAFs, but it cannot cover all the decisions that must be made in the review and selection of acceptable data. Professional judgment is required throughout the process. A degree of uncertainty is associated with the determination of any BAF, BSAF, BCF or K_{ow}. The amount of uncertainty in a baseline BAF depends on both the quality of data available and the method used to derive the BAF.

H. Hereinafter in this methodology, the terms BAF, BSAF, BCF and K_{ow} refer to ones that are consistent with the procedural and quality assurance requirements given above.

IV. Four Methods for Deriving Baseline BAFs

Baseline BAFs shall be derived using the following four methods, which are listed from most preferred to least preferred:

A. A measured baseline BAF for an organic or inorganic chemical derived from a field study of acceptable quality.

B. A predicted baseline BAF for an organic chemical derived using field-measured BSAFs of acceptable quality.

C. A predicted baseline BAF for an organic or inorganic chemical derived from a BCF measured in a laboratory study of acceptable quality and a FCM.

D. A predicted baseline BAF for an organic chemical derived from a K_{ow} of acceptable quality and a FCM.

For comparative purposes, baseline BAFs should be derived for each chemical by as many of the four methods as available data allow.

V. Calculation of Baseline BAFs for Organic Chemicals

A. Lipid Normalization. 1. It is assumed that BAFs and BCFs for organic chemicals can be extrapolated on the basis of percent lipid from one tissue to another and from one aquatic species to another in most cases.

2. Because BAFs and BCFs for organic chemicals are related to the percent lipid, it does not make any difference whether the tissue sample is whole body or edible portion, but both the BAF (or BCF) and the percent lipid must be determined for the same tissue. The percent lipid of the tissue should be measured during the BAF or BCF study, but in some cases it can be reliably estimated from measurements on tissue from other organisms. If percent lipid is not reported for the test organisms in the original study, it may be obtained from the author; or, in the case of a laboratory study, lipid data for the same or a comparable laboratory population of test organisms that were used in the original study may be used.

3. The lipid-normalized concentration, C_l, of a chemical in tissue is defined using the following equation:

Where:

C_B=concentration of the organic chemical in the tissue of aquatic biota (either whole organism or specified tissue) (MUg/g).

f_l=fraction of the tissue that is lipid.

B. Bioavailability. By definition, baseline BAFs and BCFs for organic chemicals, whether measured or predicted are based on the concentration of the chemical that is freely dissolved in the ambient water in order to account for bioavailability. For the purposes of this Guidance in this part, the relationship between the total concentration of the chemical in the water (i.e., that which is freely dissolved plus that which is sorbed to particulate organic carbon or to dissolved organic carbon) to the freely dissolved concentration of the chemical in the ambient water shall be calculated using the following equation:

Where:

C^{fd}_w=freely dissolved concentration of the organic chemical in the ambient water;

C^{t}_w=total concentration of the organic chemical in the ambient water;

f_{fd}=fraction of the total chemical in the ambient water that is freely dissolved.

The fraction of the total chemical in the ambient water that is freely dissolved, f_{fd}, shall be calculated using the following equation:

Where:

DOC=concentration of dissolved organic carbon, kg of dissolved organic carbon/L of water.

K_{OW}=octanol-water partition coefficient of the chemical.

POC=concentration of particulate organic carbon, kg of particulate organic carbon/L of water.

C. Food-Chain Multiplier. In the absence of a field-measured BAF or a predicted BAF derived from a BSAF, a FCM shall be used to calculate the baseline BAF for trophic levels 3 and 4 from a laboratory-measured or predicted BCF. For an organic chemical, the FCM used shall be derived from Table B-1 using the chemical's log K_{OW} and linear interpolation. A FCM greater than 1.0 applies to most organic chemicals with a log K_{OW} of four or more. The trophic level used shall take into account the age or size of the fish species consumed by the human, avian or mammalian predator because, for some species of fish, the young are in trophic level 3 whereas the adults are in trophic level 4.

D. Calculation of a Baseline BAF from a Field-Measured BAF. A baseline BAF shall be calculated from a field-measured BAF of acceptable quality using the following equation:

***15403** Where:

BAF^{t}_{T}=BAF based on total concentration in tissue and water.

f_l=fraction of the tissue that is lipid.

f_{fd}=fraction of the total chemical that is freely dissolved in the ambient water.

The trophic level to which the baseline BAF applies is the same as the trophic level of the organisms used in the determination of the field-measured BAF. For each trophic level, a species mean measured baseline BAF shall be calculated as the geometric mean if more than one measured baseline BAF is available for a given species. For each trophic level, the geometric mean of the species mean measured baseline BAFs shall be calculated. If a baseline BAF based on a measured BAF is available for either trophic level 3 or 4, but not both, a measured baseline BAF for the other trophic level shall be calculated using the ratio of the FCMs that are obtained by linear interpolation from Table B-1 for the chemical.
E. Calculation of a Baseline BAF from a Field-Measured BSAF. 1. A baseline BAF for organic chemical “i” shall be calculated from a field-measured BSAF of acceptable quality using the following equation:

Where:

$(BSAF)_i$=BSAF for chemical “i”.

$(BSAF)_r$=BSAF for the reference chemical “r”.

$(K_{OW})_i$=octanol-water partition coefficient for chemical “i”.

$(K_{OW})_r$=octanol-water partition coefficient for the reference chemical “r”.
2. A BSAF shall be calculated using the following equation:

Where:

C_t=the lipid-normalized concentration of the chemical in tissue.

C_{SOC}=the organic carbon-normalized concentration of the chemical in sediment.
3. The organic carbon-normalized concentration of a chemical in sediment, C_{SOC}, shall be calculated using the following equation:

Where:

C_S=concentration of chemical in sediment (mg/g sediment).

f_{OC}=fraction of the sediment that is organic carbon.
4. Predicting BAFs from BSAFs requires data from a steady-state (or near steady-state) condition between sediment and ambient water for both a reference chemical “r” with a field-measured BAF_l^{fd} and other chemicals “n=i” for which BSAFs are to be determined.

5. The trophic level to which the baseline BAF applies is the same as the trophic level of the organisms used in the determination of the BSAF. For each trophic level, a species mean baseline BAF shall be calculated as the geometric mean if more than one baseline BAF is predicted from BSAFs for a given species. For each trophic level, the geometric mean of the species mean baseline BAFs derived using BSAFs shall be calculated.

6. If a baseline BAF based on a measured BSAF is available for either trophic level 3 or 4, but not both, a baseline BAF for the other trophic level shall be calculated using the ratio of the FCMs that are obtained by linear interpolation from Table B-1 for the chemical.

F. Calculation of a Baseline BAF from a Laboratory-Measured BCF. A baseline BAF for trophic level 3 and a baseline BAF for trophic level 4 shall be calculated from a laboratory-measured BCF of acceptable quality and a FCM using the following equation:

Where:

$BCF^{t}T$=BCF based on total concentration in tissue and water.

fl=fraction of the tissue that is lipid.

f_{fd}=fraction of the total chemical in the test water that is freely dissolved.

FCM=the food-chain multiplier obtained from Table B-1 by linear interpolation for trophic level 3 or 4, as necessary.

For each trophic level, a species mean baseline BAF shall be calculated as the geometric mean if more than one baseline BAF is predicted from laboratory-measured BCFs for a given species. For each trophic level, the geometric mean of the species mean baseline BAFs based on laboratory-measured BCFs shall be calculated.

G. Calculation of a Baseline BAF from an Octanol-Water Partition Coefficient. A baseline BAF for trophic level 3 and a baseline BAF for trophic level 4 shall be calculated from a K_{OW} of acceptable quality and a FCM using the following equation:

Baseline BAF=(FCM) (predicted baseline BCF)=(FCM) (K_{OW})

Where:

FCM=the food-chain multiplier obtained from Table B-1 by linear interpolation for trophic level 3 or 4, as necessary.

K_{OW}=octanol-water partition coefficient.

VI. Human Health and Wildlife BAFs for Organic Chemicals

A. To calculate human health and wildlife BAFs for an organic chemical, the K_{OW} of the ***15404** y15404[chemical shall be used with a POC concentration of 0.00000004 kg/L and a DOC concentration of 0.000002 kg/L to yield the fraction freely dissolved:

B. The human health BAFs for an organic chemical shall be calculated using the following equations:

For trophic level 3:

For trophic level 4:

Where:
0.0182 and 0.0310 are the standardized fraction lipid values for trophic levels 3 and 4, respectively, that are used to derive human health criteria and values for the GLI.

C. The wildlife BAFs for an organic chemical shall be calculated using the following equations:

For trophic level 3:

For trophic level 4:

Where:
0.0646 and 0.1031 are the standardized fraction lipid values for trophic levels 3 and 4, respectively, that are used to derive wildlife criteria for the GLI.

VII. Human Health and Wildlife BAFs for Inorganic Chemicals

A. For inorganic chemicals, the baseline BAFs for trophic levels 3 and 4 are both assumed to equal the BCF determined for the chemical with fish, i.e., the FCM is assumed to be 1 for both trophic levels 3 and 4. However, a FCM greater than 1 might be applicable to some metals, such as mercury, if, for example, an organometallic form of the metal biomagnifies.

B. BAFs for Human Health Criteria and Values.

1. Measured BAFs and BCFs used to determine human health BAFs for inorganic chemicals shall be based on edible tissue (e.g., muscle) of freshwater fish unless it is demonstrated that whole-body BAFs or BCFs are similar to edible-tissue BAFs or BCFs. BCFs and BAFs based on measurements of aquatic plants and invertebrates should not be used in the derivation of human health criteria and values.

2. If one or more field-measured baseline BAFs for an inorganic chemical are available from studies conducted in the Great Lakes System with the muscle of fish:

a. For each trophic level, a species mean measured baseline BAF shall be calculated as the geometric mean if more than one measured BAF is available for a given species; and

b. For each trophic level, the geometric mean of the species mean measured baseline BAFs shall be used as the human health BAF for that chemical.

3. If an acceptable measured baseline BAF is not available for an inorganic chemical and one or more acceptable edible-portion laboratory-measured BCFs are available for the chemical, a predicted baseline BAF shall be calculated by multiplying the geometric mean of the BCFs times a FCM. The FCM will be 1.0 unless chemical-specific biomagnification data support using a multiplier other than 1.0. The predicted baseline BAF shall be used as the human health BAF for that chemical.

C. BAFs for Wildlife Criteria.

1. Measured BAFs and BCFs used to determine wildlife BAFs for inorganic chemicals shall be based on whole-body freshwater fish and invertebrate data unless it is demonstrated that edible-tissue BAFs or BCFs are similar to whole-body BAFs or BCFs.

***15405** 2. If one or more field-measured baseline BAFs for an inorganic chemical are available from studies conducted in the Great Lakes System with whole body of fish or invertebrates:

2. For each trophic level, a species mean measured baseline BAF shall be calculated as the geometric mean if more than one measured BAF is available for a given species.

b. For each trophic level, the geometric mean of the species mean measured baseline BAFs shall be used as the wildlife BAF for that chemical.

3. If an acceptable measured baseline BAF is not available for an inorganic chemical and one or more acceptable whole-body laboratory-measured BCFs are available for the chemical, a predicted baseline BAF shall be calculated by multiplying the geometric mean of the BCFs times a FCM. The FCM will be 1.0 unless chemical-specific biomagnification data support using a multiplier other than 1.0. The predicted baseline BAF shall be used as the wildlife BAF for that chemical.

VIII. Final Review

For both organic and inorganic chemicals, human health and wildlife BAFs for both trophic levels shall be reviewed for consistency with all available data concerning the bioaccumulation, bioconcentration, and metabolism of the chemical. For example, information concerning octanol-water partitioning, molecular size, or other physicochemical properties that might enhance or inhibit bioaccumulation should be considered for organic chemicals. BAFs derived in accordance with this methodology should be modified if changes are justified by available data.

IX. Literature Cited

ASTM. 1990. Standard Practice for Conducting Bioconcentration Tests with Fishes and Saltwater Bivalve Molluscs. Standard E 1022. American Society for Testing and Materials, Philadelphia, PA.

Table B-1.—Food-Chain Multipliers for Trophic Levels 2, 3 & 4

Log K_{ow}	Trophic level 2	Trophic [1] level 3	Trophic level 4
2.0	1.000	1.005	1.000
2.5	1.000	1.010	1.002
3.0	1.000	1.028	1.007
3.1	1.000	1.034	1.007
3.2	1.000	1.042	1.009
3.3	1.000	1.053	1.012
3.4	1.000	1.067	1.014
3.5	1.000	1.083	1.019
3.6	1.000	1.103	1.023
3.7	1.000	1.128	1.033
3.8	1.000	1.161	1.042
3.9	1.000	1.202	1.054

4.0	1.000	1.253	1.072
4.1	1.000	1.315	1.096
4.2	1.000	1.380	1.130
4.3	1.000	1.491	1.178
4.4	1.000	1.614	1.242
4.5	1.000	1.766	1.334
4.6	1.000	1.950	1.459
4.7	1.000	2.175	1.633
4.8	1.000	2.452	1.871
4.9	1.000	2.780	2.193
5.0	1.000	3.181	2.612
5.1	1.000	3.643	3.162
5.2	1.000	4.188	3.873
5.3	1.000	4.803	4.742
5.4	1.000	5.502	5.821
5.5	1.000	6.266	7.079
5.6	1.000	7.096	8.551
5.7	1.000	7.962	10.209
5.8	1.000	8.841	12.050
5.9	1.000	9.716	13.964
6.0	1.000	10.556	15.996
6.1	1.000	11.337	17.783
6.2	1.000	12.064	19.907
6.3	1.000	12.691	21.677
6.4	1.000	13.228	23.281
6.5	1.000	13.662	24.604
6.6	1.000	13.980	25.645
6.7	1.000	14.223	26.363
6.8	1.000	14.355	26.669

6.9	1.000	14.388		26.669
7.0	1.000	14.305		26.242
7.1	1.000	14.142		25.468
7.2	1.000	13.852		24.322
7.3	1.000	13.474		22.856
7.4	1.000	12.987		21.038
7.5	1.000	12.517		18.967
7.6	1.000	11.708		16.749
7.7	1.000	10.914		14.388
7.8	1.000	10.069		12.050
7.9	1.000	9.162		9.840
8.0	1.000	8.222		7.798
8.1	1.000	7.278	6.012	
8.2	1.000	6.361		4.519
8.3	1.000	5.489		3.311
8.4	1.000	4.683		2.371
8.5	1.000	3.949		1.663
8.6	1.000	3.296		1.146
8.7	1.000	2.732		0.778
8.8	1.000	2.246		0.521
8.9	1.000	1.837		0.345
9.0	1.000	1.493		0.226

***15406 Appendix C to Part 132—Great Lakes Water Quality Initiative Methodologies for Development of Human Health Criteria and Values**

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this appendix.

I. Introduction

Great Lakes States and Tribes shall adopt provisions consistent with this appendix C to ensure protection of human health.

A. Goal. The goal of the human health criteria for the Great Lakes System is the protection of humans from unacceptable exposure to toxicants via consumption of contaminated fish and drinking water and from ingesting water as a result of participation in water-oriented recreational activities.

B. Definitions.

Acceptable daily exposure (ADE). An estimate of the maximum daily dose of a substance which is not expected to result in adverse noncancer effects to the general human population, including sensitive subgroups.

Adverse effect. Any deleterious effect to organisms due to exposure to a substance. This includes effects which are or may become debilitating, harmful or toxic to the normal functions of the organism, but does not include non-harmful effects such as tissue discoloration alone or the induction of enzymes involved in the metabolism of the substance.

Carcinogen. A substance which causes an increased incidence of benign or malignant neoplasms, or substantially decreases the time to develop neoplasms, in animals or humans. The classification of carcinogens is discussed in section II.A of appendix C to part 132.

Human cancer criterion (HCC). A Human Cancer Value (HCV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C.

Human cancer value (HCV). The maximum ambient water concentration of a substance at which a lifetime of exposure from either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities, will represent a plausible upper-bound risk of contracting cancer of one in 100,000 using the exposure assumptions specified in the Methodologies for the Development of Human Health Criteria and Values in appendix C of this part.

Human noncancer criterion (HNC). A Human Noncancer Value (HNV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C of this part.

Human noncancer value (HNV). The maximum ambient water concentration of a substance at which adverse noncancer effects are not likely to occur in the human population from lifetime exposure via either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities using the Methodologies for the Development of Human Health criteria and Values in appendix C of this part.

Linearized multi-stage model. A conservative mathematical model for cancer risk assessment. This model fits linear dose-response curves to low doses. It is consistent with a no-threshold model of carcinogenesis, i.e., exposure to even a very small amount of the substance is assumed to produce a finite increased risk of cancer.

Lowest observed adverse effect level (LOAEL). The lowest tested dose or concentration of a substance which resulted in an observed adverse effect in exposed test organisms when all higher doses or concentrations resulted in the same or more severe effects.

No observed adverse effect level (NOAEL). The highest tested dose or concentration of a substance which resulted in no observed adverse effect in exposed test organisms where higher doses or concentrations resulted in an adverse effect.

Quantitative structure activity relationship (OSAR) or structure activity relationship (SAR). A mathematical relationship between a property (activity) of a chemical and a number of descriptors of the chemical. These descriptors are chemical or physical characteristics obtained experimentally or predicted from the structure of the chemical.

Relative source contribution (RSC). The factor (percentage) used in calculating an HNV or HNC to account for all sources of exposure to a contaminant. The RSC reflects the percent of total exposure which can be attributed to surface water through water intake and fish consumption.

Risk associated dose (RAD). A dose of a known or presumed carcinogenic substance in (mg/kg/day) which, over a lifetime of exposure, is estimated to be associated with a plausible upper bound incremental cancer risk equal to one in 100,000.

Slope factor. Also known as q_1*, slope factor is the incremental rate of cancer development calculated through use of a linearized multistage model or other appropriate model. It is expressed in (mg/kg/day) of exposure to the chemical in question.

Threshold effect. An effect of a substance for which there is a theoretical or empirically established dose or concentration below which the effect does not occur.

Uncertainty factor (UF). One of several numeric factors used in operationally deriving criteria from experimental data to account for the quality or quantity of the available data.

C. Level of Protection. The criteria developed shall provide a level of protection likely to be without appreciable risk of carcinogenic and/or noncarcinogenic effects. Criteria are a function of the level of designated risk or no adverse effect estimation, selection of data and exposure assumptions. Ambient criteria for single carcinogens shall not be set at a level representing a lifetime upper-bound incremental risk greater than one in 100,000 of developing cancer using the hazard assessment techniques and exposure assumptions described herein. Criteria affording protection from noncarcinogenic effects shall be established at levels that, taking into account uncertainties, are considered likely to be without an appreciable risk of adverse human health effects (i.e., acute, subchronic and chronic toxicity including reproductive and developmental effects) during a lifetime of exposure, using the risk assessment techniques and exposure assumptions described herein.

D. Two-tiered Classification. Chemical concentration levels in surface water protective of human health shall be derived based on either a Tier I or Tier II classification. The two Tiers are primarily distinguished by the amount of toxicity data available for deriving the concentration levels and the quantity and quality of data on bioaccumulation.

II. Minimum Data Requirements

The best available toxicity data on the adverse health effects of a chemical and the best data on bioaccumulation factors shall be used when developing human health Tier I criteria or Tier II values. The best available toxicity data shall include data from well ***15407** -conducted epidemiologic and/or animal studies which provide, in the case of carcinogens, an adequate weight of evidence of potential human carcinogenicity and, in the case of noncarcinogens, a dose-response relationship involving critical effects biologically relevant to humans. Such information should be obtained from the EPA Integrated Risk Information System (IRIS) database, the scientific literature, and other informational databases, studies and/or reports containing adverse health effects data of adequate quality for use in this procedure. Strong consideration shall be given to the most currently available guidance provided by IRIS in deriving criteria or values, supplemented with any recent data not incorporated into IRIS. When deviations from IRIS are anticipated or considered necessary, it is strongly recommended that such actions be communicated to the EPA Reference Dose (RfD) and/or the Cancer Risk Assessment Verification Endeavor (CRAVE) workgroup immediately. The best available bioaccumulation data shall include data from field studies and well-conducted laboratory studies.

A. Carcinogens. Tier I criteria and Tier II values shall be derived using the methodologies described in section III.A of this appendix when there is adequate evidence of potential human carcinogenic effects for a chemical. It is strongly recommended that the EPA classification system for chemical carcinogens, which is described in the 1986 EPA Guidelines for Carcinogenic Risk Assessment (U.S. EPA, 1986), or future modifications thereto, be used in determining whether adequate evidence of potential carcinogenic effects exists. Carcinogens are classified, depending on the weight of evidence, as either human carcinogens, probable human carcinogens, or possible human carcinogens. The human evidence is considered inadequate and therefore the chemical cannot be classified as a human carcinogen, if one of two conditions exists: (a) there are few pertinent data, or (b) the available studies, while showing evidence of association, do not exclude chance, bias, or confounding and therefore a casual interpretation is not credible. The animal evidence is considered inadequate, and therefore the chemical cannot

be classified as a probable or possible human carcinogen, when, because of major qualitative or quantitative limitations, the evidence cannot be interpreted as showing either the presence or absence of a carcinogenic effect.

Chemicals are described as “human carcinogens” when there is sufficient evidence from epidemiological studies to support a causal association between exposure to the chemicals and cancer. Chemicals described as “probable human carcinogens” include chemicals for which the weight of evidence of human carcinogenicity based on epidemiological studies is limited. Limited human evidence is that which indicates that a causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding, cannot adequately be excluded. Probable human carcinogens are also agents for which there is sufficient evidence from animal studies and for which there is inadequate evidence or no data from epidemiologic studies. Sufficient animal evidence is data which indicates that there is an increased incidence of malignant tumors or combined malignant and benign tumors: (a) in multiple species or strains; (b) in multiple experiments (e.g., with different routes of administration or using different dose levels); or (c) to an unusual degree in a single experiment with regard to high incidence, unusual site or type of tumor, or early age at onset. Additional evidence may be provided by data on dose-response effects, as well as information from short-term tests (such as mutagenicity/genotoxicity tests which help determine whether the chemical interacts directly with DNA) or on chemical structure, metabolism or mode of action.

“Possible human carcinogens” are chemicals with limited evidence of carcinogenicity in animals in the absence of human data. Limited animal evidence is defined as data which suggests a carcinogenic effect but are limited because: (a) The studies involve a single species, strain, or experiment and do not meet criteria for sufficient evidence (see preceding paragraph); or (b) the experiments are restricted by inadequate dosage levels, inadequate duration of exposure to the agent, inadequate period of follow-up, poor survival, too few animals, or inadequate reporting; or (c) the studies indicate an increase in the incidence of benign tumors only. More specifically, this group can include a wide variety of evidence, e.g., (a) a malignant tumor response in a single well-conducted experiment that does not meet conditions for sufficient evidence, (b) tumor response of marginal statistical significance in studies having inadequate design or reporting, (c) benign but not malignant tumors with an agent showing no response in a variety of short-term tests for mutagenicity, and (d) response of marginal statistical significance in a tissue known to have a high or variable background rate.

1. Tier I: Weight of evidence of potential human carcinogenic effects sufficient to derive a Tier I HCC shall generally include human carcinogens, probable human carcinogens and can include, on a case-by-case basis, possible human carcinogens if studies have been well-conducted albeit based on limited evidence, when compared to studies used in classifying human and probable human carcinogens. The decision to use data on a possible human carcinogen for deriving Tier I criteria shall be a case-by-case determination. In determining whether to derive a Tier I HCC, additional evidence that shall be considered includes but is not limited to available information on mode of action, such as mutagenicity/genotoxicity (determinations of whether the chemical interacts directly with DNA), structure activity, and metabolism.

2. Tier II: Weight of evidence of possible human carcinogenic effects sufficient to derive a Tier II human cancer value shall include those possible human carcinogens for which there are at a minimum, data sufficient for quantitative risk assessment, but for which data are inadequate for Tier I criterion development due to a tumor response of marginal statistical significance or inability to derive a strong dose-response relationship. In determining whether to derive Tier II human cancer values, additional evidence that shall be considered includes but is not limited to available information on mode of action such as mutagenicity/ genotoxicity (determinations of whether the chemical interacts directly with DNA), structure activity and metabolism. As with the use of data on possible human carcinogens in developing Tier I criteria, the decision to use data on possible human carcinogens to derive Tier II values shall be made on a case-by-case basis.

B. Noncarcinogens. All available toxicity data shall be evaluated considering the full range of possible health effects of a chemical, i.e., acute/subacute, chronic/subchronic and reproductive/developmental effects, in order to best describe the dose-response relationship of the chemical, and to calculate human noncancer criteria and values which will protect against the most sensitive endpoint(s) of toxicity. Although it is desirable to have an extensive database which considers a wide range of possible adverse effects, this type of data exists for a very limited number of chemicals. For many others, there is a range in quality

and quantity of data available. To assure minimum reliability of criteria and values, it is necessary to establish a minimum database with which to develop Tier I criteria or Tier II values. The following represent the minimum data sets necessary for this procedure.

1. Tier I: The minimum data set sufficient to derive a Tier I human HNC shall include at least one well-conducted epidemiologic study or animal study. A well-conducted epidemiologic study for a Tier I HNC must quantify exposure level(s) and demonstrate positive association between exposure to a chemical and adverse effect(s) in humans. A well-conducted study in animals must demonstrate a dose response relationship involving one or more critical effect(s) biologically relevant to humans. (For example, study results from an animal whose pharmacokinetics and toxicokinetics match those of a human would be considered most biologically relevant.) Ideally, the duration of a study should span multiple generations of exposed test species or at least a major portion of the lifespan of one generation. This type of data is currently very limited. By the use of uncertainty adjustments, shorter term studies (such as 90-day subchronic studies) with evaluation of more limited effect(s) may be used to extrapolate to longer exposures or to account for a variety of adverse effects. For Tier I criteria developed pursuant to this procedure, such a limited study must be conducted for at least 90 days in rodents or 10 percent of the lifespan of other appropriate test species and demonstrate a no observable adverse effect level (NOAEL). Chronic studies of one year or longer in rodents or 50 percent of the lifespan or greater in other appropriate test species that demonstrate a lowest observable adverse effect level (LOAEL) may be sufficient for use in Tier I criterion derivation if the effects observed at the LOAEL were relatively mild and reversible as compared to ***15408** effects at higher doses. This does not preclude the use of a LOAEL from a study (of chronic duration) with only one or two doses if the effects observed appear minimal when compared to effect levels observed at higher doses in other studies.

2. Tier II: When the minimum data for deriving Tier I criteria are not available to meet the Tier I data requirements, a more limited database may be considered for deriving Tier II values. As with Tier I criteria, all available data shall be considered and ideally should address a range of adverse health effects with exposure over a substantial portion of the lifespan (or multiple generations) of the test species. When such data are lacking it may be necessary to rely on less extensive data in order to establish a Tier II value. With the use of appropriate uncertainty factors to account for a less extensive database, the minimum data sufficient to derive a Tier II value shall include a NOAEL from at least one well-conducted short-term repeated dose study. This study shall be of at least 28 days duration, in animals demonstrating a dose-response, and involving effects biologically relevant to humans. Data from studies of longer duration (greater than 28 days) and LOAELs from such studies (greater than 28 days) may be more appropriate in some cases for derivation of Tier II values. Use of a LOAEL should be based on consideration of the following information: severity of effect, quality of the study and duration of the study.

C. Bioaccumulation factors (BAFs).

1. Tier I for Carcinogens and Noncarcinogens: To be considered a Tier I cancer or noncancer human health criterion, along with satisfying the minimum toxicity data requirements of sections II.A.1 and II.B.1 of this appendix, a chemical must have the following minimum bioaccumulation data. For all organic chemicals either: (a) a field-measured BAF; (b) a BAF derived using the BSAF methodology; or (c) a chemical with a BAF less than 125 regardless of how the BAF was derived. For all inorganic chemicals, including organometals such as mercury, either: (a) a field-measured BAF or (b) a laboratory-measured BCF.

2. Tier II for Carcinogens and Noncarcinogens: A chemical is considered a Tier II cancer or noncancer human health value if it does not meet either the minimum toxicity data requirements of sections II.A.1 and II.B.1 of this appendix or the minimum bioaccumulation data requirements of section II.C.1 of this appendix.

III. Principles for Development of Tier I Criteria or Tier II Values

The fundamental components of the procedure to calculate Tier I criteria or Tier II values are the same. However, certain of the aspects of the procedure designed to account for short-duration studies or other limitations in data are more likely to be relevant in deriving Tier II values than Tier I criteria.

A. Carcinogens.

1. A non-threshold mechanism of carcinogenesis shall be assumed unless biological data adequately demonstrate the existence of a threshold on a chemical-specific basis.

2. All appropriate human epidemiologic data and animal cancer bioassay data shall be considered. Data specific to an environmentally appropriate route of exposure shall be used. Oral exposure should be used preferentially over dermal and inhalation since, in most cases, the exposure routes of greatest concern are fish consumption and drinking water/incidental ingestion. The risk associated dose shall be set at a level corresponding to an incremental cancer risk of one in 100,000. If acceptable human epidemiologic data are available for a chemical, it shall be used to derive the risk associated dose. If acceptable human epidemiologic data are not available, the risk associated dose shall be derived from available animal bioassay data. Data from a species that is considered most biologically relevant to humans (i.e., responds most like humans) is preferred where all other considerations regarding quality of data are equal. In the absence of data to distinguish the most relevant species, data from the most sensitive species tested, i.e., the species showing a carcinogenic effect at the lowest administered dose, shall generally be used.

3. When animal bioassay data are used and a non-threshold mechanism of carcinogenicity is assumed, the data are fitted to a linearized multistage computer model (e.g., Global '86 or equivalent model). Global '86 is the linearized multistage model, derived by Howe, Crump and Van Landingham (1986), which EPA uses to determine cancer potencies. The upper-bound 95 percent confidence limit on risk (or, the lower 95 percent confidence limit on dose) at the one in 100,000 risk level shall be used to calculate a risk associated dose (RAD). Other models, including modifications or variations of the linear multistage model which are more appropriate to the available data may be used where scientifically justified.

4. If the duration of the study is significantly less than the natural lifespan of the test animal, the slope may be adjusted on a case-by-case basis to compensate for latent tumors which were not expressed (e.g., U.S. EPA, 1980) In the absence of alternative approaches which compensate for study durations significantly less than lifetime, the permitting authority may use the process described in the 1980 National Guidelines (see 45 FR 79352).

5. A species scaling factor shall be used to account for differences between test species and humans. It shall be assumed that milligrams per surface area per day is an equivalent dose between species (U.S. EPA, 1986). All doses presented in mg/kg bodyweight will be converted to an equivalent surface area dose by raising the mg/kg dose to the 2/3 power. However, if adequate pharmacokinetic and metabolism studies are available, these data may be factored into the adjustment for species differences on a case-by-case basis.

6. Additional data selection and adjustment decisions must also be made in the process of quantifying risk. Consideration must be given to tumor selection for modeling, e.g., pooling estimates for multiple tumor types and identifying and combining benign and malignant tumors. All doses shall be adjusted to give an average daily dose over the study duration. Adjustments in the rate of tumor response must be made for early mortality in test species. The goodness-of-fit of the model to the data must also be assessed.

7. When a linear, non-threshold dose response relationship is assumed, the RAD shall be calculated using the following equation:

Where:

RAD=risk associated dose in milligrams of toxicant per kilogram body weight per day (mg/kg/day).

0.00001 (110^{5})=incremental risk of developing cancer equal to one in 100,000.

q_1*=slope factor $(mg/kg/day)^{1}$.

8. If human epidemiologic data and/or other biological data (animal) indicate that a chemical causes cancer via a threshold mechanism, the risk associated dose may, on a case-by-case basis, be calculated using a method which assumes a threshold mechanism is operative.

B. Noncarcinogens.

1. Noncarcinogens shall generally be assumed to have a threshold dose or concentration below which no adverse effects should be observed. Therefore, the Tier I criterion or Tier II value is the maximum water concentration of a substance at or below which a lifetime exposure from drinking the water, consuming fish caught in the water, and ingesting water as a result of participating in water-related recreation activities is likely to be without appreciable risk of deleterious effects.

For some noncarcinogens, there may not be a threshold dose below which no adverse effects should be observed. Chemicals acting as genotoxic teratogens and germline mutagens are thought to possibly produce reproductive and/or developmental effects via a genetically linked mechanism which may have no threshold. Other chemicals also may not demonstrate a threshold. Criteria for these types of chemicals will be established on a case-by-case basis using appropriate assumptions reflecting the likelihood that no threshold exists.

2. All appropriate human and animal toxicologic data shall be reviewed and evaluated. To the maximum extent possible, data most specific to the environmentally relevant route of exposure shall be used. Oral exposure data should be used preferentially over dermal and inhalation since, in most cases, the exposure routes of greatest concern are fish consumption and drinking water/incidental ingestion. When acceptable human data are not available (e.g., well-conducted epidemiologic studies), animal data from species most biologically relevant to humans shall be used. In the absence of data to distinguish the most relevant species, data from the most sensitive animal species tested, i.e., the species showing a toxic effect at the lowest administered dose (given a relevant route of exposure), should generally be used.

***15409** 3. Minimum data requirements are specified in section II.B of this appendix. The experimental exposure level representing the highest level tested at which no adverse effects were demonstrated (NOAEL) from studies satisfying the provisions of section II.B of this appendix shall be used for criteria calculations. In the absence of a NOAEL, the LOAEL from studies satisfying the provisions of section II.B of this appendix may be used if it is based on relatively mild and reversible effects.

4. Uncertainty factors shall be used to account for the uncertainties in predicting acceptable dose levels for the general human population based upon experimental animal data or limited human data.

a. An uncertainty factor of 10 shall generally be used when extrapolating from valid experimental results from studies on prolonged exposure to average healthy humans. This 10-fold factor is used to protect sensitive members of the human population.

b. An uncertainty factor of 100 shall generally be used when extrapolating from valid results of long-term studies on experimental animals when results of studies of human exposure are not available or are inadequate. In comparison to a, above, this represents an additional 10-fold uncertainty factor in extrapolating data from the average animal to the average human.

c. An uncertainty factor of up to 1000 shall generally be used when extrapolating from animal studies for which the exposure duration is less than chronic, but greater than subchronic (e.g., 90 days or more in length), or when other significant deficiencies in study quality are present, and when useful long-term human data are not available. In comparison to b, above, this represents an additional UF of up to 10-fold for less than chronic, but greater than subchronic, studies.

d. An UF of up to 3000 shall generally be used when extrapolating from animal studies for which the exposure duration is less than subchronic (e.g., 28 days). In comparison to b above, this represents an additional UF of up to 30-fold for less than

subchronic studies (e.g., 28-day). The level of additional uncertainty applied for less than chronic exposures depends on the duration of the study used relative to the lifetime of the experimental animal.

e. An additional UF of between one and ten may be used when deriving a criterion from a LOAEL. This UF accounts for the lack of an identifiable NOAEL. The level of additional uncertainty applied may depend upon the severity and the incidence of the observed adverse effect.

f. An additional UF of between one and ten may be applied when there are limited effects data or incomplete sub-acute or chronic toxicity data (e.g., reproductive/developmental data). The level of quality and quantity of the experimental data available as well as structure-activity relationships may be used to determine the factor selected.

g. When deriving an UF in developing a Tier I criterion or Tier II value, the total uncertainty, as calculated following the guidance of sections 4.a through f, cited above, shall not exceed 10,000 for Tier I criteria and 30,000 for Tier II values.

5. All study results shall be converted, as necessary, to the standard unit for acceptable daily exposure of milligrams of toxicant per kilogram of body weight per day (mg/kg/day). Doses shall be adjusted for continuous exposure (i.e., seven days/week, 24 hours/day, etc.).

C. Criteria and Value Derivation.

1. Standard Exposure Assumptions. The following represent the standard exposure assumptions used to calculate Tier I criteria and Tier II values for carcinogens and noncarcinogens. Higher levels of exposure may be assumed by States and Tribes pursuant to Clean Water Act (CWA) section 510, or where appropriate in deriving site-specific criteria pursuant to procedure 1 in appendix F to part 132.

BW = body weight of an average human (BW = 70kg).

WC_d = per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies = two liters/day.

—or—

WC_r = per capita incidental daily water ingestion for surface waters not used as human drinking water sources = 0.01 liters/day.

FC = per capita daily consumption of regionally caught freshwater fish = 0.015kg/day (0.0036 kg/day for trophic level 3 and 0.0114 kg/day for trophic level 4).

BAF = bioaccumulation factor for trophic level 3 and trophic level 4, as derived using the BAF methodology in appendix B to part 132.

2. Carcinogens. The Tier I human cancer criteria or Tier II values shall be calculated as follows:

Where:

HCV=Human Cancer Value in milligrams per liter (mg/L).

RAD=Risk associated dose in milligrams toxicant per kilogram body weight per day (mg/kg/day) that is associated with a lifetime incremental cancer risk equal to one in 100,000.

BW=weight of an average human (BW=70 kg).

WC_d=per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies=two liters/day.

or

WC_r=per capita incidental daily water ingestion for surface waters not used as human drinking water sources=0.01 liters/day.

FC_{TL3}=mean consumption of trophic level 3 of regionally caught freshwater fish=0.0036 kg/day.

FC_{TL4}=mean consumption of trophic level 4 of regionally caught freshwater fish=0.0114 kg/day.

BAF^{HH}_{TL3}=bioaccumulation factor for trophic level 3 fish, as derived using the BAF methodology in appendix B to part 132.

BAF^{HH}_{TL4}=bioaccumulation factor for trophic level 4 fish, as derived using the BAF methodology in appendix B to part 132.
3. Noncarcinogens. The Tier I human noncancer criteria or Tier II values shall be calculated as follows:

Where:

HNV=Human noncancer value in milligrams per liter (mg/L).

ADE=Acceptable daily exposure in milligrams toxicant per kilogram body weight per day (mg/kg/day).

RSC=Relative source contribution factor of 0.8. An RSC derived from actual exposure data may be developed using the methodology outlined by the 1980 National Guidelines (see 45 FR 79354).

BW=weight of an average human (BW=70 kg).

WC_d=per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies=two liters/day.

or

WC_r=per capita incidental daily water ingestion for surface waters not used as human drinking water sources=0.01 liters/day.

***15410** FC_{TL3}=mean consumption of trophic level 3 fish by regional sport fishers of regionally caught freshwater fish=0.0036 kg/day.

FC_{TL4}=mean consumption of trophic level 4 fish by regional sport fishers of regionally caught freshwater fish=0.0114 kg/day.

BAF^{HH}_{TL3}=human health bioaccumulation factor for edible portion of trophic level 3 fish, as derived using the BAF methodology in appendix B to part 132.

BAF^{HH}_{TL4}=human health bioaccumulation factor for edible portion of trophic level 4 fish, as derived using the BAF methodology in appendix B to part 132.

IV. References

A. Howe, R.B., K.S. Crump and C. Van Landingham. 1986. Computer Program to Extrapolate Quantitative Animal Toxicity Data to Low Doses. Prepared for EPA under subcontract #2-251U-2745 to Research Triangle Institute.

B. U.S. Environmental Protection Agency. 1980. Water Quality Criteria Availability, Appendix C Guidelines and Methodology Used in the Preparation of Health Effects Assessment Chapters of the Consent Decree Water Quality Criteria Documents. Available from U.S. Environmental Protection Agency, Office of Water Resource Center (WH-550A), 401 M St., SW., Washington, DC 20460.

C. U.S. Environmental Protection Agency. 1986. Guidelines for Carcinogen Risk Assessment. Available from U.S. Environmental Protection Agency, Office of Water Resource Center (WH-550A), 401 M St., SW., Washington, DC 20460.

Appendix D to Part 132—Great Lakes Water Quality Initiative Methodology for the Development of Wildlife Criteria

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this appendix.

I. Introduction

A. A Great Lakes Water Quality Wildlife Criterion (GLWC) is the concentration of a substance which is likely to, if not exceeded, protect avian and mammalian wildlife populations inhabiting the Great Lakes basin from adverse effects resulting from the ingestion of water and aquatic prey taken from surface waters of the Great Lakes System. These criteria are based on existing toxicological studies of the substance of concern and quantitative information about the exposure of wildlife species to the substance (i.e., food and water consumption rates). Since toxicological and exposure data for individual wildlife species are limited, a GLWC is derived using a methodology similar to that used to derive noncancer human health criteria (Barnes and Dourson, 1988; NAS, 1977; NAS, 1980; U.S. EPA, 1980). Separate avian and mammalian values are developed using taxonomic class-specific toxicity data and exposure data for five representative Great Lakes basin wildlife species. The wildlife species selected are representative of avian and mammalian species resident in the Great Lakes basin which are likely to experience the highest exposures to bioaccumulative contaminants through the aquatic food web; they are the bald eagle, herring gull, belted kingfisher, mink, and river otter.

B. This appendix establishes a methodology which is required when developing Tier I wildlife criteria for bioaccumulative chemicals of concern (BCCs). The use of the equation provided in the methodology is encouraged, but not required, for the development of Tier I criteria or Tier II values for pollutants other than those identified in Table 6-A for which Tier I criteria or Tier II values are determined to be necessary for the protection of wildlife in the Great Lakes basin. A discussion of the methodology for deriving Tier II values can be found in the Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria (Wildlife TSD).

C. In the event that this methodology is used to develop criteria for pollutants other than BCCs, or in the event that the Tier II methodology described in the Wildlife TSD is used to derive Tier II values, the methodology for deriving bioaccumulation factors under appendix B to part 132 must be used in either derivation. For chemicals which do not biomagnify to the extent of BCCs, it may be appropriate to select different representative species which are better examples of species with the highest exposures for the given chemical. The equation presented in this methodology, however, is still encouraged. In addition, procedure 1 of appendix F of this part describes the procedures for calculating site-specific wildlife criteria.

D. The term “wildlife value” (WV) is used to denote the value for each representative species which results from using the equation presented below, the value obtained from averaging species values within a class, or any value derived from application of the site-specific procedure provided in procedure 1 of appendix F of this part. The WVs calculated for the representative species are used to calculate taxonomic class-specific WVs. The WV is the concentration of a substance which, if not exceeded, should better protect the taxon in question.

E. “Tier I wildlife criterion,” or “Tier I criterion” is used to denote the number derived from data meeting the Tier I minimum database requirements, and which will be protective of the two classes of wildlife. It is synonymous with the term “GLWC,” and the two are used interchangeably.

II. Calculation of Wildlife Values for Tier I Criteria

Table 4 of Part 132 and Table D-1 of this appendix contain criteria calculated by EPA using the methodology provided below.

A. Equation for Avian and Mammalian Wildlife Values. Tier I wildlife values for the pollutants designated BCCs pursuant to part 132 are to be calculated using the equation presented below.

Where:

WV=Wildlife Value in milligrams of substance per liter (mg/L).

TD=Test Dose (TD) in milligrams of substance per kilograms per day (mg/kg-d) for the test species. This shall be either a NOAEL or a LOAEL.

UF_A=Uncertainty Factor (UF) for extrapolating toxicity data across species (unitless). A species-specific UF shall be selected and applied to each representative species, consistent with the equation.

UF_S=UF for extrapolating from subchronic to chronic exposures (unitless).

UF_L=UF for LOAEL to NOAEL extrapolations (unitless).

Wt=Average weight in kilograms (kg) for the representative species.

W=Average daily volume of water consumed in liters per day (L/d) by the representative species.

F_{TLi}=Average daily amount of food consumed from trophic level i in kilograms per day (kg/d) by the representative species.

BAF^{WL}_{TLi}=Bioaccumulation factor (BAF) for wildlife food in trophic level i in liters per kilogram (L/kg), developed using the BAF methodology in appendix B to part 132, Methodology for Development of Bioaccumulation Factors. For consumption of piscivorous birds by other birds (e.g., herring gull by eagles), the BAF is derived by multiplying the trophic level 3 BAF for fish by a biomagnification factor to account for the biomagnification from fish to the consumed birds.

B. Identification of Representative Species for Protection. For bioaccumulative chemicals, piscivorous species are identified as the focus of concern for wildlife criteria development in the Great Lakes. An analysis of known or estimated exposure components for avian and mammalian wildlife species is presented in the Wildlife TSD. This analysis identifies three avian species (eagle, kingfisher and herring gull) and two mammalian species (mink and otter) as representative species for protection. The TD obtained from toxicity data for each taxonomic class is used to calculate WVs for each of the five representative species.

C. Calculation of Avian and Mammalian Wildlife Values and GLWC Derivation. The avian WV is the geometric mean of the WVs calculated for the three representative avian species. The mammalian WV is the geometric mean of the WVs calculated for the two representative mammalian species. The lower of the mammalian and avian WVs must be selected as the GLWC.

III. Parameters of the Effect Component of the Wildlife Criteria Methodology

A. Definitions. The following definitions provide additional specificity and guidance in the evaluation of toxicity data and the application of this methodology.

Acceptable endpoints. For the purpose of wildlife criteria derivation, acceptable subchronic and chronic endpoints are those which affect reproductive or developmental success, organismal viability or growth, or any other endpoint which is, or is directly related to, parameters that influence population dynamics.

***15411** Chronic effect. An adverse effect that is measured by assessing an acceptable endpoint, and results from continual exposure over several generations, or at least over a significant part of the test species' projected life span or life stage.

Lowest-observed-adverse-effect-level (LOAEL). The lowest tested dose or concentration of a substance which resulted in an observed adverse effect in exposed test organisms when all higher doses or concentrations resulted in the same or more severe effects.

No-observed-adverse-effect-level (NOAEL). The highest tested dose or concentration of a substance which resulted in no observed adverse effect in exposed test organisms where higher doses or concentrations resulted in an adverse effect.

Subchronic effect. An adverse effect, measured by assessing an acceptable endpoint, resulting from continual exposure for a period of time less than that deemed necessary for a chronic test.

B. Minimum Toxicity Database for Tier I Criteria Development. A TD value is required for criterion calculation. To derive a Tier I criterion for wildlife, the data set shall provide enough data to generate a subchronic or chronic dose-response curve for any given substance for both mammalian and avian species. In reviewing the toxicity data available which meet the minimum data requirements for each taxonomic class, the following order of preference shall be applied to select the appropriate TD to be used for calculation of individual WVs. Data from peer-reviewed field studies of wildlife species take precedence over other types of studies, where such studies are of adequate quality. An acceptable field study must be of subchronic or chronic duration, provide a defensible, chemical-specific dose-response curve in which cause and effect are clearly established, and assess acceptable endpoints as defined in this document. When acceptable wildlife field studies are not available, or determined to be of inadequate quality, the needed toxicity information may come from peer-reviewed laboratory studies. When laboratory studies are used, preference shall be given to laboratory studies with wildlife species over traditional laboratory animals to reduce uncertainties in making interspecies extrapolations. All available laboratory data and field studies shall be reviewed to corroborate the final GLWC, to assess the reasonableness of the toxicity value used, and to assess the appropriateness of any UFs which are applied. When evaluating the studies from which a test dose is derived in general, the following requirements must be met:

1. The mammalian data must come from at least one well-conducted study of 90 days or greater designed to observe subchronic or chronic effects as defined in this document.

2. The avian data must come from at least one well-conducted study of 70 days or greater designed to observe subchronic or chronic effects as defined in this document.

3. In reviewing the studies from which a TD is derived for use in calculating a WV, studies involving exposure routes other than oral may be considered only when an equivalent oral daily dose can be estimated and technically justified because the criteria calculations are based on an oral route of exposure.

4. In assessing the studies which meet the minimum data requirements, preference should be given to studies which assess effects on developmental or reproductive endpoints because, in general, these are more important endpoints in ensuring that a population's productivity is maintained. The Wildlife TSD provides additional discussion on the selection of an appropriate toxicity study.

C. Selection of TD Data. In selecting data to be used in the derivation of WVs, the evaluation of acceptable endpoints, as defined in Section III.A of this appendix, will be the primary selection criterion. All data not part of the selected subset may be used to assess the reasonableness of the toxicity value and the appropriateness of the Ufs which are applied.

1. If more than one TD value is available within a taxonomic class, based on different endpoints of toxicity, that TD, which is likely to reflect best potential impacts to wildlife populations through resultant changes in mortality or fecundity rates, shall be used for the calculation of WVs.

2. If more than one TD is available within a taxonomic class, based on the same endpoint of toxicity, the TD from the most sensitive species shall be used.

3. If more than one TD based on the same endpoint of toxicity is available for a given species, the TD for that species shall be calculated using the geometric mean of those TDs.

D. Exposure Assumptions in the Determination of the TD. 1. In those cases in which a TD is available in units other than milligrams of substance per kilograms per day (mg/kg/d), the following procedures shall be used to convert the TD to the appropriate units prior to calculating a WV.

2. If the TD is given in milligrams of toxicant per liter of water consumed by the test animals (mg/L), the TD shall be multiplied by the daily average volume of water consumed by the test animals in liters per day (L/d) and divided by the average weight of the test animals in kilograms (kg).

3. If the TD is given in milligrams of toxicant per kilogram of food consumed by the test animals (mg/kg), the TD shall be multiplied by the average amount of food in kilograms consumed daily by the test animals (kg/d) and divided by the average weight of the test animals in kilograms (kg).

E. Drinking and Feeding Rates. 1. When drinking and feeding rates and body weight are needed to express the TD in milligrams of substance per kilograms per day (mg/kg/d), they are obtained from the study from which the TD was derived. If not already determined, body weight, and drinking and feeding rates are to be converted to a wet weight basis.

2. If the study does not provide the needed values, the values shall be determined from appropriate scientific literature. For studies done with domestic laboratory animals, either the Registry of Toxic Effects of Chemical Substances (National Institute for Occupational Safety and Health, the latest edition, Cincinnati, OH), or Recommendations for and Documentation of Biological Values for Use in Risk Assessment (U.S. EPA, 1988) should be consulted. When these references do not contain exposure information for the species used in a given study, either the allometric equations from Calder and Braun (1983) and Nagy (1987), which are presented below, or the exposure estimation methods presented in Chapter 4 of the Wildlife Exposure Factors Handbook (U.S. EPA, 1993), should be applied to approximate the needed feeding or drinking rates. Additional discussion and recommendations are provided in the Wildlife TSD. The choice of the methods described above is at the discretion of the State or Tribe.

3. For mammalian species, the general allometric equations are:

a. $F = 0.0687 (Wt)^{0.82}$

Where:

F = Feeding rate of mammalian species in kilograms per day (kg/d) dry weight.

Wt = Average weight in kilograms (kg) of the test animals.

b. $W = 0.099 (Wt)^{0.90}$

Where:

W = Drinking rate of mammalian species in liters per day (L/d).

Wt = Average weight in kilograms (kg) of the test animals.
4. For avian species, the general allometric equations are:

a. $F = 0.0582 (Wt)^{0.65}$

Where:

F = Feeding rate of avian species in kilograms per day (kg/d) dry weight.

Wt = Average weight in kilograms (kg) of the test animals.
b. $W = 0.059 (Wt)^{0.67}$

Where:

W = Drinking rate of avian species in liters per day (L/d).

Wt = Average weight in kilograms (kg) of the test animals.
F. LOAEL to NOAEL Extrapolations (UF_L). In those cases in which a NOAEL is unavailable as the TD and a LOAEL is available, the LOAEL may be used to estimate the NOAEL. If used, the LOAEL shall be divided by an UF to estimate a NOAEL for use in deriving WVs. The value of the UF shall not be less than one and should not exceed 10, depending on the dose-response curve and any other available data, and is represented by UF_L in the equation expressed in Section II.A of this appendix. Guidance for selecting an appropriate UF_L, based on a review of available wildlife toxicity data, is available in the Wildlife TSD.

G. Subchronic to Chronic Extrapolations (US_S). In instances where only subchronic data are available, the TD may be derived from subchronic data. In such cases, the TD shall be divided by an UF to extrapolate from subchronic to chronic levels. The value of the UF shall not be less than one and should not exceed 10, and is represented by UF_S in the equation expressed in Section II.A of this appendix. This factor is to be used when assessing highly bioaccumulative substances where toxicokinetic considerations suggest that a bioassay of limited length ***15412** underestimates chronic effects. Guidance for selecting an appropriate UF_S, based on a review of available wildlife toxicity data, is available in the Wildlife TSD.

H. Interspecies Extrapolations (UF_A). 1. The selection of the UF_A shall be based on the available toxicological data and on available data concerning the physicochemical, toxicokinetic, and toxicodynamic properties of the substance in question and the amount and quality of available data. This value is an UF that is intended to account for differences in toxicological sensitivity among species. Guidance for selecting an appropriate UF_A, based on a review of available wildlife toxicity data, is available in the Wildlife TSD. Additional discussion of an interspecies UF located in appendix A to the Great Lakes Water Quality Initiative Technical Support Document for Human Health Criteria may be useful in determining the appropriate value for UF_A.

2. For the derivation of Tier I criteria, a UF_A shall not be less than one and should not exceed 100, and shall be applied to each of the five representative species, based on existing data and best professional judgment. The value of UF_A may differ for each of the representative species.

3. For Tier I wildlife criteria, the UF_A shall be used only for extrapolating toxicity data across species within a taxonomic class, except as provided below. The Tier I UF_A is not intended for interclass extrapolations because of the poorly defined comparative toxicokinetic and toxicodynamic parameters between mammals and birds. However, an interclass extrapolation

employing a UF_A may be used for a given chemical if it can be supported by a validated biologically-based dose-response model or by an analysis of interclass toxicological data, considering acceptable endpoints, for a chemical analog that acts under the same mode of toxic action.

IV. Parameters of the Exposure Component of the Wildlife Criteria Methodology

A. Drinking and Feeding Rates of Representative Species. The body weights (Wt), feeding rates (F_{Tli}), drinking rates (W), and trophic level dietary composition (as food ingestion rate and percent in diet) for each of the five representative species are presented in Table D-2 of this appendix. Guidance on incorporating the non-aquatic portion of the bald eagle and mink diets in the criteria calculations is available in the Wildlife TSD.

B. BAFs. The Methodology for Development of Bioaccumulation Factors is presented in appendix B to part 132. Trophic level 3 and 4 BAFs are used to derive Wvs because these are the trophic levels at which the representative species feed.

V. References

A. Barnes, D.G. and M. Dourson. 1988. Reference Dose (RfD): Description and Use in Health Risk Assessments. Regul. Toxicol. Pharmacol. 8:471-486.

B. Calder III, W.A. and E.J. Braun. 1983. Scaling of Osmotic Regulation in Mammals and Birds. American Journal of Physiology. 244:601-606.

C. Nagy, K.A. 1987. Field Metabolic Rate and Food Requirement Scaling in Mammals and Birds. Ecological Monographs. 57(2):111-128.

D. National Academy of Sciences. 1977. Chemical Contaminants: Safety and Risk Assessment, in Drinking Water and Health, Volume 1. National Academy Press.

E. National Academy of Sciences. 1980. Problems of Risk Estimation, in Drinking Water and Health, Volume 3. National Academy Press.

F. National Institute for Occupational Safety and Health. Latest edition. Registry of Toxic Effects of Chemical Substances. Division of Standards Development and Technology Transfer. (Available only on microfiche or as an electronic database.)

G. U.S. EPA. 1980. Appendix C. Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Criteria Documents, pp. 79347-79357 in Water Quality Criteria Documents; Availability. Available from U.S. Environmental Protection Agency, Office of Water Resource Center (WH-550A), 401 M St. SW, Washington, DC 20460.

H. U.S. EPA. 1988. Recommendations for, and documentation of, biological values for use in risk assessment. NTIS-PB88-179874.

I. U.S. EPA. 1993. Wildlife Exposure Factors Handbook, Volumes I and II. EPA/600/R-93/187a and b.

Tables to Appendix D to Part 132

Table D-1.—Tier I Great Lakes Wildlife Criteria

Substance	Criterion (MUg/L)

DDT & Metabolites	1.1E-5
Mercury	1.3E-3
PCBs (total)	7.4E-5
2,3,7,8-TCDD	3.1E-9

Table D-2.—Exposure Parameters for the Five Representative Species Identified for Protection

Species (units)	Adult body weight (kg)	Water ingestion rate (L/day)	Food ingestion rate of prey in each trophic level (kg/day)	Trophic level of prey (percent of diet)
Mink	0.80	0.081	TL3: 0.159; Other: 0.0177	TL3: 90; Other: 10.
Otter	7.4	0.600	TL3: 0.977; TL4: 0.244	TL3: 80; TL4: 20.
Kingfisher	0.15	0.017	TL3: 0.0672	TL3: 100.
Herring gull	1.1	0.063	TL3: 0.192; TL4: 0.0480	Fish: 90—TL3: 80; TL4: 20.
	.....	.....	Other: 0.0267	Other: 10.
Bald eagle	4.6	0.160	TL3: 0.371; TL4: 0.0929	Fish: 92—TL3: 80; TL4: 20.
	.....	.....	PB: 00283; Other: 0.0121	Birds: 8—PB: 70; non-aquatic: 30.

Appendix E to Part 132—Great Lakes Water Quality Initiative Antidegradation Policy

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) appendix E to part 132.

The State or Tribe shall adopt an antidegradation standard applicable to all waters of the Great Lakes System and identify the methods for implementing such a standard. Consistent with 40 CFR 131.12, an acceptable antidegradation standard and implementation procedure are required elements of a State's or Tribe's water quality standards program. Consistent with 40 CFR 131.6, a complete water quality standards submission needs to include both an antidegradation standard and antidegradation implementation procedures. At a minimum, States and Tribes shall adopt provisions in their antidegradation standard and implementation methods consistent with sections I, II, III and IV of this appendix, applicable to pollutants identified as bioaccumulative chemicals of concern (BCCs).

I. Antidegradation Standard

This antidegradation standard shall be applicable to any action or activity by any source, point or nonpoint, of pollutants that is anticipated to result in an increased loading of BCCs to surface waters of the Great Lakes System and for which independent regulatory authority exists requiring compliance with water quality standards. Pursuant to this standard:

A. Existing instream water uses, as defined pursuant to 40 CFR 131, and the level of water quality necessary to protect existing uses shall be maintained and protected. Where designated uses of the waterbody are impaired, there shall be no lowering of the water quality with respect to the pollutant or pollutants which are causing the impairment;

B. Where, for any parameter, the quality of the waters exceed levels necessary to support the propagation of fish, shellfish, and wildlife and recreation in and on the waters, that water shall be considered high quality for that parameter consistent

with the definition of high quality water found at section II.A of this appendix and that quality ***15413** shall be maintained and protected unless the State or Tribe finds, after full satisfaction of intergovernmental coordination and public participation provisions of the State's or Tribe's continuing planning process, that allowing lower water quality is necessary to accommodate important economic or social development in the area in which the waters are located. In allowing such degradation, the State or Tribe shall assure water quality adequate to protect existing uses fully. Further, the State or Tribe shall assure that there shall be achieved the highest statutory and regulatory requirements for all new and existing point sources and all cost-effective and reasonable best management practices for nonpoint source control. The State or Tribe shall utilize the Antidegradation Implementation Procedures adopted pursuant to the requirements of this regulation in determining if any lowering of water quality will be allowed;

C. Where high quality waters constitute an outstanding national resource, such as waters of national and State parks and wildlife refuges and waters of exceptional recreational or ecological significance, that water quality shall be maintained and protected; and

D. In those cases where the potential lowering of water quality is associated with a thermal discharge, the decision to allow such degradation shall be consistent with section 316 of the Clean Water Act (CWA).

II. Antidegradation Implementation Procedures

A. Definitions.

Control Document. Any authorization issued by a State, Tribal or Federal agency to any source of pollutants to waters under its jurisdiction that specifies conditions under which the source is allowed to operate.

High quality waters. High quality waters are water bodies in which, on a parameter by parameter basis, the quality of the waters exceeds levels necessary to support propagation of fish, shellfish, and wildlife and recreation in and on the water.

Lake Superior Basin—Outstanding International Resource Waters. Those waters designated as such by a Tribe or State consistent with the September 1991 Bi-National Program to Restore and Protect the Lake Superior Basin. The purpose of such designations shall be to ensure that any new or increased discharges of Lake Superior bioaccumulative substances of immediate concern are subject to best technology in process and treatment requirements.

Lake Superior Basin—Outstanding National Resource Waters. Those waters designated as such by a Tribe or State consistent with the September 1991 Bi-National Program to Restore and Protect the Lake Superior Basin. The purpose of such designations shall be to prohibit new or increased discharges of Lake Superior bioaccumulative substances of immediate concern from point sources in these areas.

Lake Superior bioaccumulative substances of immediate concern. A list of substances identified in the September 1991 Bi-National Program to Restore and Protect the Lake Superior Basin. They include: 2, 3, 7, 8-TCDD; octachlorostyrene; hexachlorobenzene; chlordane; DDT, DDE, and other metabolites; toxaphene; PCBs; and mercury. Other chemicals may be added to the list following States' or Tribes' assessments of environmental effects and impacts and after public review and comment.

Outstanding National Resource Waters. Those waters designated as such by a Tribe or State. The State or Tribal designation shall describe the quality of such waters to serve as the benchmark of the water quality that shall be maintained and protected. Waters that may be considered for designation as Outstanding National Resource Waters include, but are not limited to, water bodies that are recognized as:

Important because of protection through official action, such as Federal or State law, Presidential or secretarial action, international treaty, or interstate compact;

Having exceptional recreational significance;

Having exceptional ecological significance;

Having other special environmental, recreational, or ecological attributes; or waters whose designation as Outstanding National Resource Waters is reasonably necessary for the protection of other waters so designated.

Significant Lowering of Water Quality. A significant lowering of water quality occurs when there is a new or increased loading of any BCC from any regulated existing or new facility, either point source or nonpoint source for which there is a control document or reviewable action, as a result of any activity including, but not limited to:

(1) Construction of a new regulated facility or modification of an existing regulated facility such that a new or modified control document is required;

(2) Modification of an existing regulated facility operating under a current control document such that the production capacity of the facility is increased;

(3) Addition of a new source of untreated or pretreated effluent containing or expected to contain any BCC to an existing wastewater treatment works, whether public or private;

(4) A request for an increased limit in an applicable control document;

(5) Other deliberate activities that, based on the information available, could be reasonably expected to result in an increased loading of any BCC to any waters of the Great Lakes System.

b. Notwithstanding the above, changes in loadings of any BCC within the existing capacity and processes, and that are covered by the existing applicable control document, are not subject to an antidegradation review. These changes include, but are not limited to:

(1) Normal operational variability;

(2) Changes in intake water pollutants;

(3) Increasing the production hours of the facility, (e.g., adding a second shift); or

(4) Increasing the rate of production.

C. Also, excluded from an antidegradation review are new effluent limits based on improved monitoring data or new water quality criteria or values that are not a result of changes in pollutant loading.

B. For all waters, the Director shall ensure that the level of water quality necessary to protect existing uses is maintained. In order to achieve this requirement, and consistent with 40 CFR 131.10, water quality standards use designations must include all existing uses. Controls shall be established as necessary on point and nonpoint sources of pollutants to ensure that the criteria applicable to the designated use are achieved in the water and that any designated use of a downstream water is protected. Where water quality does not support the designated uses of a waterbody or ambient pollutant concentrations exceed water quality criteria applicable to that waterbody, the Director shall not allow a lowering of water quality for the pollutant or pollutants preventing the attainment of such uses or exceeding such criteria.

C. For Outstanding National Resource Waters:

1. The Director shall ensure, through the application of appropriate controls on pollutant sources, that water quality is maintained and protected.

2. Exception. A short-term, temporary (i.e., weeks or months) lowering of water quality may be permitted by the Director.

D. For high quality waters, the Director shall ensure that no action resulting in a lowering of water quality occurs unless an antidegradation demonstration has been completed pursuant to section III of this appendix and the information thus provided is determined by the Director pursuant to section IV of this appendix to adequately support the lowering of water quality.

1. The Director shall establish conditions in the control document applicable to the regulated facility that prohibit the regulated facility from undertaking any deliberate action, such that there would be an increase in the rate of mass loading of any BCC, unless an antidegradation demonstration is provided to the Director and approved pursuant to section IV of this appendix prior to commencement of the action. Imposition of limits due to improved monitoring data or new water quality criteria or values, or changes in loadings of any BCC within the existing capacity and processes, and that are covered by the existing applicable control document, are not subject to an antidegradation review.

2. For BCCs known or believed to be present in a discharge, from a point or nonpoint source, a monitoring requirement shall be included in the control document. The control document shall also include a provision requiring the source to notify the Director or any increased loadings. Upon notification, the Director shall require actions as necessary to reduce or eliminate the increased loading.

3. Fact Sheets prepared pursuant to 40 CFR 124.8 and 124.56 shall reflect any conditions developed under sections II.D.1 or II.D.2 of this appendix and included in a permit.

E. Special Provisions for Lake Superior.The following conditions apply in addition to those specified in section II.B through II.C of this appendix for waters of Lake Superior so designated.

1. A State or Tribe may designate certain specified areas of the Lake Superior Basin as Lake Superior Basin—Outstanding National Resource Waters for the purpose of prohibiting the new or increased discharge of Lake Superior bioaccumulative substances of immediate concern from point sources in these areas.

2. States and Tribes may designate all waters of the Lake Superior Basin as Outstanding International Resource Waters for the purpose of restricting the increased discharge of ***15414** Lake Superior bioaccumulative substances of immediate concern from point sources consistent with the requirements of sections III.C and IV.B of this appendix.

F. Exemptions. Except as the Director may determine on a case-by-case basis that the application of these procedures is required to adequately protect water quality, or as the affected waterbody is an Outstanding National Resource Water as defined in section II.A of this appendix, the procedures in this part do not apply to:

1. Short-term, temporary (i.e., weeks or months) lowering of water quality;

2. Bypasses that are not prohibited at 40 CFR 122.41(m); and

3. Response actions pursuant to the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), as amended, or similar Federal, State or Tribal authorities, undertaken to alleviate a release into the environment of hazardous substances, pollutants or contaminants which may pose an imminent and substantial danger to public health or welfare.

III. Antidegradation Demonstration

Any entity seeking to lower water quality in a high quality water or create a new or increased discharge of Lake Superior bioaccumulative substances of immediate concern in a Lake Superior Outstanding International Resource Water must first, as required by sections II.D or II.E.2 of this appendix, submit an antidegradation demonstration for consideration by the Director. States and Tribes should tailor the level of detail and documentation in antidegradation reviews, to the specific circumstances encountered. The antidegradation demonstration shall include the following:

A. Pollution Prevention Alternatives Analysis. Identify any cost-effective pollution prevention alternatives and techniques that are available to the entity, that would eliminate or significantly reduce the extent to which the increased loading results in a lowering of water quality.

B. Alternative or Enhanced Treatment Analysis. Identify alternative or enhanced treatment techniques that are available to the entity that would eliminate the lowering of water quality and their costs relative to the cost of treatment necessary to achieve applicable effluent limitations.

C. Lake Superior. If the States or Tribes designate the waters of Lake Superior as Outstanding International Resource Waters pursuant to section II.E.2 of this appendix, then any entity proposing a new or increased discharge of any Lake Superior bioaccumulative substance of immediate concern to the Lake Superior Basin shall identify the best technology in process and treatment to eliminate or reduce the extent of the lowering of water quality. In this case, the requirements in section III.B of this appendix do not apply.

D. Important Social or Economic Development Analysis. Identify the social or economic development and the benefits to the area in which the waters are located that will be foregone if the lowering of water quality is not allowed.

E. Special Provision for Remedial Actions. Entities proposing remedial actions pursuant to the CERCLA, as amended, corrective actions pursuant to the Resource Conservation and Recovery Act, as amended, or similar actions pursuant to other Federal or State environmental statutes may submit information to the Director that demonstrates that the action utilizes the most cost effective pollution prevention and treatment techniques available, and minimizes the necessary lowering of water quality, in lieu of the information required by sections III.B through III.D of this appendix.

IV. Antidegradation Decision

A. Once the Director determines that the information provided by the entity proposing to increase loadings is administratively complete, the Director shall use that information to determine whether or not the lowering of water quality is necessary, and, if it is necessary, whether or not the lowering of water quality will support important social and economic development in the area. If the proposed lowering of water quality is either not necessary, or will not support important social and economic development, the Director shall deny the request to lower water quality. If the lowering of water quality is necessary, and will support important social and economic development, the Director may allow all or part of the proposed lowering to occur as necessary to accommodate the important social and economic development. In no event may the decision reached under this section allow water quality to be lowered below the minimum level required to fully support existing and designated uses. The decision of the Director shall be subject to the public participation requirements of 40 CFR 25.

B. If States designate the waters of Lake Superior as Outstanding International Resource Waters pursuant to section II.E.2 of this appendix, any entity requesting to lower water quality in the Lake Superior Basin as a result of the new or increased discharge of any Lake Superior bioaccumulative substance of immediate concern shall be required to install and utilize the best technology in process and treatment as identified by the Director.

Appendix F to Part 132—Great Lakes Water Quality Initiative Implementation Procedures

Procedure 1: Site-specific Modifications to Criteria and Values

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure.

A. Requirements for Site-specific Modifications to Criteria and Values. Criteria and values may be modified on a site-specific basis to reflect local environmental conditions as restricted by the following provisions. Any such modifications must be protective of designated uses and aquatic life, wildlife or human health and be submitted to EPA for approval. In addition, any site-specific modifications that result in less stringent criteria must be based on a sound scientific rationale and shall not be likely to jeopardize the continued existence of endangered or threatened species listed or proposed under section 4 of the Endangered Species Act (ESA) or result in the destruction or adverse modification of such species' critical habitat. More stringent modifications shall be developed to protect endangered or threatened species listed or proposed under section 4 of the ESA, where such modifications are necessary to ensure that water quality is not likely to jeopardize the continued existence of such species or result in the destruction or adverse modification of such species' critical habitat. More stringent modifications may also be developed to protect candidate (C1) species being considered by the U.S. Fish and Wildlife Service (FWS) for listing under section 4 of the ESA, where such modifications are necessary to protect such species.

1. Aquatic Life.

a. Aquatic life criteria or values may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under Clean Water Act (CWA) section 510.

Guidance on developing site-specific criteria in these instances is provided in Chapter 3 of the U.S. EPA Water Quality Standards Handbook, Second Edition—Revised (1994).

b. Less stringent site-specific modifications to chronic or acute aquatic life criteria or values may be developed when:

i. The local water quality characteristics such as Ph, hardness, temperature, color, etc., alter the biological availability or toxicity of a pollutant; or

ii. The sensitivity of the aquatic organisms species that “occur at the site” differs from the species actually tested in developing the criteria. The phrase “occur at the site” includes the species, genera, families, orders, classes, and phyla that: are usually present at the site; are present at the site only seasonally due to migration; are present intermittently because they periodically return to or extend their ranges into the site; were present at the site in the past, are not currently present at the site due to degraded conditions, and are expected to return to the site when conditions improve; are present in nearby bodies of water, are not currently present at the site due to degraded conditions, and are expected to be present at the site when conditions improve. The taxa that “occur at the site” cannot be determined merely by sampling downstream and/or upstream of the site at one point in time. “Occur at the site” does not include taxa that were once present at the site but cannot exist at the site now due to permanent physical alteration of the habitat at the site resulting, for example, from dams, etc.

c. Less stringent modifications also may be developed to acute and chronic aquatic life criteria or values to reflect local physical and hydrological conditions.

Guidance on developing site-specific criteria is provided in Chapter 3 of the U.S. EPA Water Quality Standards Handbook, Second Edition—Revised (1994).

***15415** d. Any modifications to protect threatened or endangered aquatic species required by procedure 1.A of this appendix may be accomplished using either of the two following procedures:

i. If the Species Mean Acute Value (SMAV) for a listed or proposed species, or for a surrogate of such species, is lower than the calculated Final Acute Value (FAV), such lower SMAV may be used instead of the calculated FAV in developing site-specific modified criteria; or,

ii. The site-specific criteria may be calculated using the recalculation procedure for site-specific modifications described in Chapter 3 of the U.S. EPA Water Quality Standards Handbook, Second Edition—Revised (1994).

2. Wildlife.

a. Wildlife water quality criteria may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under CWA section 510.

b. Less stringent site-specific modifications to wildlife water quality criteria may be developed when a site-specific bioaccumulation factor (BAF) is derived which is lower than the system-wide BAF derived under appendix B of this part. The modification must consider both the mobility of prey organisms and wildlife populations in defining the site for which criteria are developed. In addition, there must be a showing that:

i. Any increased uptake of the toxicant by prey species utilizing the site will not cause adverse effects in wildlife populations; and

ii. Wildlife populations utilizing the site or downstream waters will continue to be fully protected.

c. Any modification to protect endangered or threatened wildlife species required by procedure 1.A of this appendix must consider both the mobility of prey organisms and wildlife populations in defining the site for which criteria are developed, and may be accomplished by using the following recommended method.

i. The methodology presented in appendix D to part 132 is used, substituting appropriate species-specific toxicological, epidemiological, or exposure information, including changes to the BAF;

ii. An interspecies uncertainty factor of 1 should be used where epidemiological data are available for the species in question. If necessary, species-specific exposure parameters can be derived as presented in Appendix D of this part;

iii. An intraspecies uncertainty factor (to account for protection of individuals within a wildlife population) should be applied in the denominator of the effect part of the wildlife equation in appendix D of this part in a manner consistent with the other uncertainty factors described in appendix D of this part; and

iv. The resulting wildlife value for the species in question should be compared to the two class-specific wildlife values which were previously calculated, and the lowest of the three shall be selected as the site-specific modification.

Note: Further discussion on the use of this methodology may be found in the Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria.

3. BAFs.

a. BAFs may be modified on a site-specific basis to larger values, pursuant to the authority reserved to the States and Tribes under CWA section 510, where reliable data show that local bioaccumulation is greater than the system-wide value.

b. BAFs may be modified on a site-specific basis to lower values, where scientifically defensible, if:

i. The fraction of the total chemical that is freely dissolved in the ambient water is different than that used to derive the system-wide BAFs (i.e., the concentrations of particulate organic carbon and the dissolved organic carbon are different than those used to derive the system-wide BAFs);

ii. Input parameters of the Gobas model, such as the structure of the aquatic food web and the disequilibrium constant, are different at the site than those used to derive the system-wide BAFs;

iii. The percent lipid of aquatic organisms that are consumed and occur at the site is different than that used to derive the system-wide BAFs; or

iv. Site-specific field-measured BAFs or biota-sediment accumulation factor (BSAFs) are determined.

If site-specific BAFs are derived, they shall be derived using the methodology in appendix B of this part.

c. Any more stringent modifications to protect threatened or endangered species required by procedure 1.A of this appendix shall be derived using procedures set forth in the methodology in appendix B of this part.

4. Human Health.

a. Human health criteria or values may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under CWA section 510. Human health criteria or values shall be modified on a site-specific basis to provide additional protection appropriate for highly exposed subpopulations.

b. Less stringent site-specific modifications to human health criteria or values may be developed when:

i. local fish consumption rates are lower than the rate used in deriving human health criteria or values under appendix C of this part; and/or

ii. a site-specific BAF is derived which is lower than that used in deriving human health criteria or values under appendix C of this part.

B. Notification Requirements. When a State proposes a site-specific modification to a criterion or value as allowed in section 4.A above, the State should notify the other Great Lakes States of such a proposal and, for less stringent criteria, supply appropriate justification.

C. References.

U.S. EPA. 1984. Water Quality Standards Handbook—Revised. Chapter 3 and Appendices. U.S. Environmental Protection Agency, Office of Water Resource Center (RC-4100), 401 M Street, SW., Washington, DC 20960.

Procedure 2: Variances from Water Quality Standards for Point Sources

The Great Lakes States or Tribes may adopt water quality standards (WQS) variance procedures and may grant WQS variances for point sources pursuant to such procedures. Variance procedures shall be consistent with (as protective as) the provisions in this procedure.

A. Applicability. A State or Tribe may grant a variance to a WQS which is the basis of a water quality-based effluent limitation included in a National Pollutant Discharge Elimination System (NPDES) permit. A WQS variance applies only to the permittee requesting the variance and only to the pollutant or pollutants specified in the variance. A variance does not affect, or require the State or Tribe to modify, the corresponding water quality standard for the waterbody as a whole.

1. This provision shall not apply to new Great Lakes dischargers or recommencing dischargers.

2. A variance to a water quality standard shall not be granted that would likely jeopardize the continued existence of any endangered or threatened species listed under Section 4 of the Endangered Species Act (ESA) or result in the destruction or adverse modification of such species' critical habitat.

3. A WQS variance shall not be granted if standards will be attained by implementing effluent limits required under sections 301(b) and 306 of the Clean Water Act (CWA) and by the permittee implementing cost-effective and reasonable best management practices for nonpoint source control.

B. Maximum Timeframe for Variances. A WQS variance shall not exceed five years or the term of the NPDES permit, whichever is less. A State or Tribe shall review, and modify as necessary, WQS variances as part of each water quality standards review pursuant to section 303(c) of the CWA.

C. Conditions to Grant a Variance. A variance may be granted if:

1. The permittee demonstrates to the State or Tribe that attaining the WQS is not feasible because:

a. Naturally occurring pollutant concentrations prevent the attainment of the WQS;

b. Natural, ephemeral, intermittent or low flow conditions or water levels prevent the attainment of the WQS, unless these conditions may be compensated for by the discharge of sufficient volume of effluent to enable WQS to be met without violating State or Tribal water conservation requirements;

c. Human-caused conditions or sources of pollution prevent the attainment of the WQS and cannot be remedied, or would cause more environmental damage to correct than to leave in place;

d. Dams, diversions or other types of hydrologic modifications preclude the attainment of the WQS, and it is not feasible to restore the waterbody to its original condition or to operate such modification in a way that would result in the attainment of the WQS;

e. Physical conditions related to the natural features of the waterbody, such as the lack of a proper substrate cover, flow, depth, pools, riffles, and the like, unrelated to chemical water quality, preclude attainment of WQS; or

***15416** f. Controls more stringent than those required by sections 301(b) and 306 of the CWA would result in substantial and widespread economic and social impact.

2. In addition to the requirements of C.1, above, the permittee shall also:

a. Show that the variance requested conforms to the requirements of the State's or Tribe's antidegradation procedures; and

b. Characterize the extent of any increased risk to human health and the environment associated with granting the variance compared with compliance with WQS absent the variance, such that the State or Tribe is able to conclude that any such increased risk is consistent with the protection of the public health, safety and welfare.

D. Submittal of Variance Application. The permittee shall submit an application for a variance to the regulatory authority issuing the permit. The application shall include:

1. All relevant information demonstrating that attaining the WQS is not feasible based on one or more of the conditions in section C.1 of this procedure; and,

2. All relevant information demonstrating compliance with the conditions in section C.2 of this procedure.

E. Public Notice of Preliminary Decision. Upon receipt of a complete application for a variance, and upon making a preliminary decision regarding the variance, the State or Tribe shall public notice the request and preliminary decision for public comment pursuant to the regulatory authority's Administrative Procedures Act and shall notify the other Great Lakes States and Tribes of the preliminary decision. This public notice requirement may be satisfied by including the supporting information for the variance and the preliminary decision in the public notice of a draft NPDES permit.

F. Final Decision on Variance Request. The State or Tribe shall issue a final decision on the variance request within 90 days of the expiration of the public comment period required in section E of this procedure. If all or part of the variance is approved by the State or Tribe, the decision shall include all permit conditions needed to implement those parts of the variance so approved. Such permit conditions shall, at a minimum, require:

1. Compliance with an initial effluent limitation which, at the time the variance is granted, represents the level currently achievable by the permittee, and which is no less stringent than that achieved under the previous permit;

2. That reasonable progress be made toward attaining the water quality standards for the waterbody as a whole through appropriate conditions;

3. When the duration of a variance is shorter than the duration of a permit, compliance with an effluent limitation sufficient to meet the underlying water quality standard, upon the expiration of said variance; and

4. A provision that allows the permitting authority to reopen and modify the permit based on any State or Tribal triennial water quality standards revisions to the variance.

The State shall deny a variance request if the permittee fails to make the demonstrations required under section C of this procedure.

G. Incorporating Variance into Permit. The State or Tribe shall establish and incorporate into the permittee's NPDES permit all conditions needed to implement the variance as determined in section F of this procedure.

H. Renewal of Variance. A variance may be renewed, subject to the requirements of sections A through G of this procedure. As part of any renewal application, the permittee shall again demonstrate that attaining WQS is not feasible based on the requirements of section C of this procedure. The permittee's application shall also contain information concerning its compliance with the conditions incorporated into its permit as part of the original variance pursuant to sections F and G of this procedure. Renewal of a variance may be denied if the permittee did not comply with the conditions of the original variance.

I. EPA Approval. All variances and supporting information shall be submitted by the State or Tribe to the appropriate EPA regional office and shall include:

1. Relevant permittee applications pursuant to section D of this procedure;

2. Public comments and records of any public hearings pursuant to section E of this procedure;

3. The final decision pursuant to section F of this procedure; and,

4. NPDES permits issued pursuant to section G of this procedure.

5. Items required by sections I.1 through I.3. of this procedure shall be submitted by the State within 30 days of the date of the final variance decision. The item required by section I.4 of this procedure shall be submitted in accordance with the State or Tribe Memorandum of Agreement with the Regional Administrator pursuant to 40 CFR 123.24.
40 CFR § 123.4440 CFR § 131.21
6. EPA shall review the State or Tribe submittal for compliance with the CWA pursuant to 40 CFR 123.44, and 40 CFR 131.21.

J. State WQS Revisions. All variances shall be appended to the State or Tribe WQS rules.

Procedure 3: Total Maximum Daily Loads, Wasteload Allocations for Point Sources, Load Allocations for Nonpoint Sources, Wasteload Allocations in the Absence of a TMDL, and Preliminary Wasteload Allocations for Purposes of Determining the Need for Water Quality Based Effluent Limits

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure 3 for the purpose of developing Total Maximum Daily Loads (TMDLs), Wasteload Allocations (WLAs) in the Absence of TMDLs, and Preliminary Wasteload Allocations for Purposes of Determining the Need for Water Quality Based Effluent Limits (WQBELs), except as specifically provided.

A. Where a State or Tribe develops an assessment and remediation plan that the State or Tribe certifies meets the requirements of sections B through F of this procedure and public participation requirements applicable to TMDLs, and that has been approved by EPA as meeting those requirements under 40 CFR 130.6, the assessment and remediation plan may be used in lieu of a TMDL for purposes of appendix F to part 132. Assessment and remediation plans under this procedure may include, but are not limited to, Lakewide Management Plans, Remedial Action Plans, and State Water Quality Management Plans. Also, any part of an assessment and remediation plan that also satisfies one or more requirements under Clean Water Act (CWA) section 303(d) or implementing regulations may be incorporated by reference into a TMDL as appropriate. Assessment and remediation plans under this section should be tailored to the level of detail and magnitude for the watershed and pollutant being assessed.

B. General Conditions of Application. Except as provided in §132.4, the following are conditions applicable to establishing TMDLs for all pollutants and pollutant parameters in the Great Lakes System, with the exception of whole effluent toxicity, unless otherwise provided in procedure 6 of appendix F. Where specified, these conditions also apply to wasteload allocations (WLAs) calculated in the absence of TMDLs and to preliminary WLAs for purposes of determining the needs for WQBELs under procedure 5 of appendix F.

1. TMDLs Required. TMDLs shall, at a minimum, be established in accordance with the listing and priority setting process established in section 303(d) of the CWA and at 40 CFR 130.7. Where water quality standards cannot be attained immediately, TMDLs must reflect reasonable assurances that water quality standards will be attained in a reasonable period of time. Some TMDLs may be based on attaining water quality standards over a period of time, with specific controls on individual sources being implemented in stages. Determining the reasonable period of time in which water quality standards will be met is a case-specific determination considering a number of factors including, but not limited to: receiving water characteristics; persistence, behavior and ubiquity of pollutants of concern; type of remediation activities necessary; available regulatory and non-regulatory controls; and individual State or Tribal requirements for attainment of water quality standards.

2. Attainment of Water Quality Standards. A TMDL must ensure attainment of applicable water quality standards, including all numeric and narrative criteria, Tier I criteria, and Tier II values for each pollutant or pollutants for which a TMDL is established.

3. TMDL Allocations.

a. TMDLs shall include WLAs for point sources and load allocations (LAs) for nonpoint sources, including natural background, such that the sum of these allocations is not greater than the loading capacity of the water for the pollutant(s) addressed by the TMDL, minus the sum of a specified margin of safety (MOS) and any capacity reserved for future growth.

b. Nonpoint source LAs shall be based on:

i. Existing pollutant loadings if changes in loadings are not reasonably anticipated to occur;

ii. Increases in pollutant loadings that are reasonably anticipated to occur;

***15417** iii. Anticipated decreases in pollutant loadings if such decreased loadings are technically feasible and are reasonably anticipated to occur within a reasonable time period as a result of implementation of best management practices or other load reduction measures. In determining whether anticipated decreases in pollutant loadings are technically feasible and can reasonably be expected to occur within a reasonable period of time, technical and institutional factors shall be considered. These decisions are case-specific and should reflect the particular TMDL under consideration.

c. WLAs. The portion of the loading capacity not assigned to nonpoint sources including background, or to an MOS, or reserved for future growth is allocated to point sources. Upon reissuance, NPDES permits for these point sources must include effluent limitations consistent with WLAs in EPA-approved or EPA-established TMDLs.

d. Monitoring. For LAs established on the basis of subsection b.iii above, monitoring data shall be collected and analyzed in order to validate the TMDL's assumptions, to varify anticipated load reductions, to evaluate the effectiveness of controls being used to implement the TMDL, and to revise the WLAs and LAs as necessary to ensure that water quality standards will be achieved within the time-period established in the TMDL.

4. WLA Values. If separate EPA-approved or EPA-established TMDLs are prepared for different segments of the same watershed, and the separate TMDLs each include WLAs for the same pollutant for one or more of the same point sources, then WQBELs for that pollutant for the point source(s) shall be consistent with the most stringent of those WLAs in order to ensure attainment of all applicable water quality standards.

5. Margin of Safety (MOS). Each TMDL shall include a MOS sufficient to account for technical uncertainties in establishing the TMDL and shall describe the manner in which the MOS is determined and incorporated into the TMDL. The MOS may be provided by leaving a portion of the loading capacity unallocated or by using conservative modeling assumptions to establish WLAs and LAs. If a portion of the loading capacity is left unallocated to provide a MOS, the amount left unallocated shall be described. If conservative modeling assumptions are relied on to provide a MOS, the specific assumptions providing the MOS shall be identified.

6. More Stringent Requirements. States and Tribes may exercise authority reserved to them under section 510 of the CWA to develop more stringent TMDLs (including WLAs and LAs) than are required herein, provided that all LAs in such TMDLs reflect actual nonpoint source loads or those loads that can reasonably be expected to occur within a reasonable time-period as a result of implementing nonpoint source controls.

7. Accumulation in Sediments. TMDLs shall reflect, where appropriate and where sufficient data are available, contributions to the water column from sediments inside and outside of any applicable mixing zones. TMDLs shall be sufficiently stringent so as to prevent accumulation of the pollutant of concern in sediments to levels injurious to designated or existing uses, human health, wildlife and aquatic life.

8. Wet Weather Events. Notwithstanding the exception provided for the establishment of controls on wet weather point sources in §132.4(e)(1), TMDLs shall reflect, where appropriate and where sufficient data are available, discharges resulting from wet

weather events. This procedure does not provide specific procedures for considering discharges resulting from wet weather events. However, some of the provisions of procedure 3 may be deemed appropriate for considering wet weather events on a case-by-case basis.

9. Background Concentration of Pollutants. The representative background concentration of pollutants shall be established in accordance with this subsection to develop TMDLs, WLAs calculated in the absence of a TMDL, or preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F. Background loadings may be accounted for in a TMDL through an allocation to a single “background” category or through individual allocations to the various background sources.

a. Definition of Background. “Background” represents all loadings that: (1) flow from upstream waters into the specified watershed, waterbody or waterbody segment for which a TMDL, WLA in the absence of a TMDL or preliminary WLA for the purpose of determining the need for a WQBEL is being developed; (2) enter the specified watershed, waterbody or waterbody segment through atmospheric deposition or sediment release or resuspension; or (3) occur within the watershed, waterbody or waterbody segment as a result of chemical reactions.

b. Data considerations. When determining what available data are acceptable for use in calculating background, the State or Tribe should use best professional judgment, including consideration of the sampling location and the reliability of the data through comparison to reported analytical detection levels and quantification levels. When data in more than one of the data sets or categories described in section B.9.c.i through B.9.c.iii below exist, best professional judgment should be used to select the one data set that most accurately reflects or estimates background concentrations. Pollutant degradation and transport information may be considered when utilizing pollutant loading data.

c. Calculation requirements. Except as provided below, the representative background concentration for a pollutant in the specified watershed, waterbody or waterbody segment shall be established on a case-by-case basis as the geometric mean of:

i. Acceptable available water column data; or

ii. Water column concentrations estimated through use of acceptable available caged or resident fish tissue data; or

iii. Water column concentrations estimated through use of acceptable available or projected pollutant loading data.

d. Detection considerations.

i. Commonly accepted statistical techniques shall be used to evaluate data sets consisting of values both above and below the detection level.

ii. When all of the acceptable available data in a data set or category, such as water column, caged or resident fish tissue or pollutant loading data, are below the level of detection for a pollutant, then all the data for that pollutant in that data set shall be assumed to be zero.

10. Effluent Flow. If WLAs are expressed as concentrations of pollutants, the TMDL shall also indicate the point source effluent flows assumed in the analyses. Mass loading limitations established in NPDES permits must be consistent with both the WLA and assumed effluent flows used in establishing the TMDL.

11. Reserved Allocations. TMDLs may include reserved allocations of loading capacity to accommodate future growth and additional sources. Where such reserved allocations are not included in a TMDL, any increased loadings of the pollutant for which the TMDL was developed that are due to a new or expanded discharge shall not be allowed unless the TMDL is revised in accordance with these proceudres to include an allocation for the new or expanded discharge.

C. Mixing Zones for Bioaccumulative Chemicals of Concern (BCCs). The following requirements shall be applied in establishing TMDLs, WLAs in the absence of TMDLs, and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F, for BCCs:

1. Beginning on March 23, 1997, there shall be no mixing available for new discharges of BCCs to the Great Lakes System. WLAs established through TMDLs, WLAs in the absence of TMDLs, and preliminary WLAs for purposes of determining the need for WQBELs for new discharges of BCCs shall be set equal to the most stringent applicable water quality criteria or values for the BCCs in question.

2. For purposes of section C of procedure 3 of appendix F, new discharges are defined as: (1) discharges from new Great Lakes dischargers; or (2) new or expanded discharges from an existing Great Lakes discharger. All other discharges of BCCs are defined as existing discharges.

3. Up until March 23, 2007, mixing zones for BCCs may be allowed for existing discharges to the Great Lakes System pursuant to the procedures specified in sections D and E of this procedure.

4. Except as provided in sections C.5 and C.6 of this procedure, permits issued on or after March 23, 1997 shall not authorize mixing zones for existing discharges of BCCs to the Great Lakes System after March 23, 2007. After March 23, 2007, WLAs established through TMDLs, WLAs established in the absence of TMDLs and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F for existing dischrges of BCCs to the Great Lakes System shall be set equal to the most stringent applicable water quality criteria or values for the BCCs in question.

5. Exception for Water Conservation. States and Tribes may grant mixing zones for any existing discharge of BCCs to the Great Lakes ***15418** System beyond the dates specified in sections C.3 and C.4 of this procedure, where it can be demonstrated, on a case-by-case basis, that failure to grant a mixing zone would preclude water conservation measures that would lead to overall load reductions in BCCs, even though higher concentrations of BCCs occur in the effluent. Such mixing zones must also be consistent with sections D and E of this procedure.

6. Exception for Technical and Economic Considerations. States and Tribes may grant mixing zones beyond the dates specified in sections C.3 and C.4 of this procedure for any existing discharges of a BCC to the Great Lakes System upon the request of a discharger subject to the limited circumstances specified in sections C.6.a through C.6.d below. Such mixing zones shall also be consistent with sections D and E of this procedure.

a. The permitting authority must determine that:

i. The discharger is in compliance with and will continue to implement all applicable technology-based treatment and pretreatment requirements of CWA sections 301, 302, 304, 306, 307, 401, and 402, and is in compliance with its existing NPDES water quality-based effluent limitations, including those based on a mixing zone; and

ii. The discharger has reduced and will continue to reduce the loading of the BCC for which a mixing zone is requested to the maximum extent possible.

b. In making the determination in section C.6.a above, the State or Tribal authority should consider:

i. The availability and feasibility, including cost effectiveness, of additional controls or pollution prevention measures for reducing and ultimately eliminating BCCs for that discharger, including those used by similar dischargers;

ii. Whether the discharger or affected communities will suffer unreasonable economic effects if the mixing zone is eliminated;

iii. The extent to which the discharger will implement an ambient monitoring plan to ensure compliance with water quality criteria at the edge of any authorized mixing zone or to ensure consistency with any applicable TMDL or such other strategy consistent with section A of this procedure; and,

iv. Other information the State or Tribe deems appropriate.

c. Any exceptions to the mixing zone elimination provision for existing discharges of BCCs granted pursuant to this section shall:

i. Not result in any less stringent limitations than those existing March 23, 1997;

ii. Not likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat;

iii. Be limited to one permit term unless the permitting authority makes a new determination in accordance with this section for each successive permit application in which a mixing zone for the BCC(s) is sought;

iv. Reflect all information relevant to the size of the mixing zone considered by the State or Tribe under subsection b above;

v. Protect all designated and existing uses of the receiving water;

vi. Meet all applicable aquatic life, wildlife and human health criteria and values at the edge of the mixing zone and, as appropriate, within the mixing zone or be consistent with any appropriate TMDL or such other strategy consistent with section A of this procedure;

vii. Ensure the discharger has developed and conducted a pollutant minimization program for the BCC(s) if required to do so under regulations adopted consistent with procedure 8 of appendix F; and

viii. Ensure that alternative means for reducing BCCs elsewhere in the watershed are evaluated.

d. For each draft NPDES permit that would allow a mixing zone for one or more BCCs after March 23, 2007, the fact sheet or statement of basis for the draft permit, required to be made available through public notice under 40 CFR 124.6(e), shall:

i. Specify the mixing provisions used in calculating the permit limits; and

ii. Identify each BCC for which a mixing zone is proposed.

D. Deriving TMDLs, WLAs, and LAs for Point and Nonpoint Sources: WLAs in the Absence of a TMDL; and Preliminary WLAs for Purposes of Determining the Need for WQBELs for OWGL. This section addresses conditions for deriving TMDLs for Open Waters of the Great Lakes (OWGL), inland lakes and other waters of the Great Lakes System with no appreciable flow relative to their volumes. State and Tribal procedures to derive TMDLs under this section must be consistent with (as protective as) the general conditions in section B of this procedure, CWA section 303(d), existing regulations (40 CFR 130.7), section C of this procedure, and sections D.1. through D.4 below. State and Tribal procedures to derive WLAs calculated in the absence of a TMDL and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F must be consistent with sections B.9, C.1, C3 through C.6, and D. 1 through D.4 of this procedure.

1. Individual point source WLAs and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F shall assume no greater dilution than one part effluent to 10 parts receiving water for implementation of numeric

and narrative chronic criteria and values (including, but not limited to human cancer criteria, human cancer values, human noncancer values, human noncancer criteria, wildlife criteria, and chronic aquatic life criteria and values) unless an alternative mixing zone is demonstrated as appropriate in a mixing zone demonstration conducted pursuant to section F of this procedure. In no case shall a mixing zone be granted that exceeds the area where discharge-induced mixing occurs.

2. Appropriate mixing zone assumptions to be used in calculating load allocations for nonpoint sources shall be determined, consistent with applicable State or Tribal requirements, on a case-by-case basis.

3. WLAs and preliminary WLAs based on acute aquatic life criteria or values shall not exceed the Final Acute Value (FAV), unless a mixing zone demonstration is conducted and approved pursuant to section F of this procedure. If mixing zones from two or more proximate sources interact or overlap, the combined effect must be evaluated to ensure that applicable criteria and values will be met in the area where acute mixing zones overlap.

4. In no case shall a mixing zone be granted that would likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat.

E. Deriving TMDLs, WLAs, and LAs for Point and Nonpoint Sources; WLAs in the Absence of a TMDL; and Preliminary WLAs for the Purposes of Determining the Need for WQBELs for Great Lakes Systems Tributaries and Connecting Channels. This section describes conditions for deriving TMDLs for tributaries and connecting channels of the Great Lakes System that exhibit appreciable flows relative to their volumes. State and Tribal procedures to derive TMDLs must be consistent with the general conditions listed in section B of this procedure, section C of this procedure, existing TMDL regulations (40 CFR 130.7) and specific conditions E.1 through E.5. State and Tribal procedures to derive WLAs calculated in the absence of a TMDL, and preliminary WLAs for purposes of determining reasonable potential under procedure 5 of this appendix for discharges to tributaries and connecting channels must be consistent with sections B.9, C.1, C.3 through C.6, and E.1 through E.5 of this procedure.

1. Stream Design. These design flows must be used unless data exist to demonstrate that an alternative stream design flow is appropriate for stream-specific and pollutant-specific conditions. For purposes of calculating a TMDL, WLAs in the absence of a TMDL, or preliminary WLAs for the purposes of determining reasonable potential under procedure 5 of this appendix, using a steady-state model, the stream design flows shall be:

a. The 7-day, 10-year stream design flow (7Q10), or the 4-day, 3-year biologically-based stream design flow for chronic aquatic life criteria or values;

b. The 1-day, 10-year stream design flow (1Q10), for acute aquatic life criteria or values;

c. The harmonic mean flow for human health criteria or values;

d. The 90-day, 10-year flow (90Q10) for wildlife criteria.

e. TMDLs, WLAs in the absence of TMDLs, and preliminary WLAs for the purpose of determining the need for WQBELs calculated using dynamic modelling do not need to incorporate the stream design flows specified in sections E.1.a through E.1.d of this procedure.

2. Loading Capacity. The loading capacity is the greatest amount of loading that a water can receive without violating water quality standards. The loading capacity is initially calculated at the farthest downstream location in the watershed drainage basin. The maximum allowable loading consistent with the attainment of each applicable numeric ***15419** criterion or value for a given pollutant is determined by multiplying the applicable criterion or value by the flow at the farthest downstream location in the tributary basin at the design flow condition described above. This loading is then compared to the loadings at

sites within the basin to assure that applicable numeric criteria or values for a given pollutant are not exceeded at all applicable sites. The lowest load is then selected as the loading capacity.

3. Polluant Degradation. TMDLs, WLAs in the absence of a TMDL and preliminary WLAs for purposes of determining the need for WQBELs under procedure 5 of appendix F shall be based on the assumption that a pollutant does not degrade. However, the regulatory authority may take into account degradation of the pollutant if each of the following conditions are met.

a. Scientifically valid field studies or other relevant information demonstrate that degradation of the pollutant is expected to occur under the full range of environmental conditions expected to be encountered;

b. Scientifically valid field studies or other relevant information address other factors that affect the level of pollutants in the water column including, but not limited to, resuspension of sediments, chemical speciation, and biological and chemical transformation.

4. Acute Aquatic Life Criteria and Values. WLAs and LAs established in a TMDL, WLAs in the absence of a TMDL, and preliminary WLAs for the purpose of determining the need for WQBELs based on acute aquatic life criteria or values shall not exceed the FAV, unless a mixing zone demonstration is completed and approved pursuant to section F of this procedure. If mixing zones from two or more proximate sources interact or overlap, the combined effect must be evaluated to ensure that applicable criteria and values will be met in the area where any applicable acute mixing zones overlap. This acute WLA review shall include, but not be limited to, consideration of:

a. The expected dilution under all effluent flow and concentration conditions at stream design flow;

b. Maintenance of a zone of passage for aquatic organisms; and

c. Protection of critical aquatic habitat.

In no case shall a permitting authority grant a mixing zone that would likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat.

5. Chronic Mixing Zones. WLAs and LAs established in a TMDL, WLAs in the absence of a TMDL, and preliminary WLAs for the purposes of determining the need for WQBELs for protection of aquatic life, wildlife and human health from chronic effects shall be calculated using a dilution fraction no greater than 25 percent of the stream design flow unless a mixing zone demonstration pursuant to section F of this procedure is conducted and approved. A demonstration for a larger mixing zone may be provided, if approved and implemented in accordance with section F of this procedure. In no case shall a permitting authority grant a mixing zone that would likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat.

F. Mixing Zone Demonstration Requirements.

1. For purposes of establishing a mixing zone other than as specified in sections D and E above, a mixing zone demonstration must:

a. Describe the amount of dilution occurring at the boundaries of the proposed mixing zone and the size, shape, and location of the area of mixing, including the manner in which diffusion and dispersion occur;

b. For sources discharging to the open waters of the Great Lakes (OWGLs), define the location at which discharge-induced mixing ceases;

c. Document the substrate character and geomorphology within the mixing zone;

d. Show that the mixing zone does not interfere with or block passage of fish or aquatic life;

e. Show that the mixing zone will be allowed only to the extent that the level of the pollutant permitted in the waterbody would not likely jeopardize the continued existence of any endangered or threatened species listed under section 4 of the ESA or result in the destruction or adverse modification of such species' critical habitat;

f. Show that the mixing zone does not extend to drinking water intakes;

g. Show that the mixing zone would not otherwise interfere with the designated or existing uses of the receiving water or downstream waters;

h. Document background water quality concentrations;

i. Show that the mixing zone does not promote undesirable aquatic life or result in a dominance of nuisance species; and

j. Provide that by allowing additional mixing/dilution:

i. Substances will not settle to form objectionable deposits;

ii. Floating debris, oil, scum, and other matter in concentrations that form nuisances will not be produced; and

iii. Objectionable color, odor, taste or turbidity will not be produced.

2. In addition, the mixing zone demonstration shall address the following factors:

a. Whether or not adjacent mixing zones overlap;

b. Whether organisms would be attracted to the area of mixing as a result of the effluent character; and

c. Whether the habitat supports endemic or naturally occurring species.

3. The mixing zone demonstration must be submitted to EPA for approval. Following approval of a mixing zone demonstration consistent with sections F.1 and F.2, adjustment to the dilution ratio specified in section D.1 of this procedure shall be limited to the dilution available in the area where discharger-induced mixing occurs.

4. The mixing zone demonstration shall be based on the assumption that a pollutant does not degrade within the proposed mixing zone, unless:

a. Scientifically valid field studies or other relevant information demonstrate that degradation of the pollutant is expected to occur under the full range of environmental conditions expected to be encountered; and

b. Scientifically valid field studies or other relevant information address other factors that affect the level of pollutants in the water column including, but not limited to, resuspension of sediments, chemical speciation, and biological and chemical transformation.

Procedure 4: Additivity

The Great Lakes States and Tribes shall adopt additivity provisions consistent with (as protective as) this procedure.

A. The Great Lakes States and Tribes shall adopt provisions to protect human health from the potential adverse additive effects from both the noncarcinogenic and carcinogenic components of chemical mixtures in effluents. For the chlorinated dibenzo-p-dioxins (CDDs) and chlorinated dibenzofurans (CDFs) listed in Table 1, potential adverse additive effects in effluents shall be accounted for in accordance with section B of this procedure.

B. Toxicity Equivalency Factors (TEFs)/Bioaccumulation Equivalency Factors (BEFs).

1. The TEFs in Table 1 and BEFs in Table 2 shall be used when calculating a 2,3,7,8-TCDD toxicity equivalence concentration in effluent to be used when implementing both human health noncancer and cancer criteria. The chemical concentration of each CDDs and CDFs in effluent shall be converted to a 2,3,7,8-TCDD toxicity equivalence concentration in effluent by (a) multiplying the chemical concentration of each CDDs and CDFs in the effluent by the appropriate TEF in Table 1 below, (b) multiplying each product from step (a) by the BEF for each CDDs and CDFs in Table 2 below, and (c) adding all final products from step (b). The equation for calculating the 2,3,7,8-TCDD toxicity equivalence concentration in effluent is:

where:

$(TEC)_{tcdd}$=2,3,7,8-TCDD toxicity equivalence concentration in effluent

$(C)_x$=concentration of total chemical x in effluent

$(TEF)_x$=TCDD toxicity equivalency factor for x

$(BEF)_x$=TCDD bioaccumulation equivalency factor for x

2. The 2,3,7,8-TCDD toxicity equivalence concentration in effluent shall be used when developing waste load allocations under procedure 3, preliminary waste load allocations for purposes of determining reasonable potential under procedure 5, and for purposes of establishing effluent quality limits under procedure 5.

Table 1.—Toxicity Equivalency Factors for CDDs and CDFs

Congener	TEF
2,3,7,8-TCDD	1.0
1,2,3,7,8-PeCDD	0.5
1,2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.01
OCDD	0.001
2,3,7,8-TCDF	0.1
1,2,3,7,8-PeCDF	0.05
2,3,4,7,8-PeCDF	0.5

1,2,3,4,7,8-HxCDF	0.1
1,2,3,6,7,8-HxCDF	0.1
2,3,4,6,7,8-HxCDF	0.1
1,2,3,7,8,9-HxCDF	0.1
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.01
OCDF	0.001

Table 2.—Bioaccumulation Equivalency Factors for CDDs and CDFs

Congener	BEF
2,3,7,8-TCDD	1.0
1,2,3,7,8-PeCDD	0.9
1,2,3,4,7,8-HxCDD	0.3
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.05
OCDD	0.01
2,3,7,8-TCDF	0.8
1,2,3,7,8-PeCDF	0.2
2,3,4,7,8-PeCDF	1.6
1,2,3,4,7,8-HxCDF	0.08
1,2,3,6,7,8-HxCDF	0.2
2,3,4,6,7,8-HxCDF	0.7
1,2,3,7,8,9-HxCDF	0.6
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.4
OCDF	0.02

***15420 Procedure 5: Reasonable Potential To Exceed Water Quality Standards**

Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure. If a permitting authority determines that a pollutant is or may be discharged into the Great Lakes System at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any Tier I criterion or Tier II value, the permitting authority shall incorporate a water quality-based effluent limitation (WQBEL) in an NPDES permit for the discharge of that pollutant. When facility-specific effluent monitoring data are available, the permitting authority shall make this determination by developing preliminary effluent limitations (PEL) and comparing those effluent limitations to the projected effluent quality (PEQ) of the discharge in accordance with the following procedures. In all cases, the permitting authority shall use any valid, relevant, representative information that indicates a reasonable potential to exceed any Tier I criterion or Tier II value.

A. Developing Preliminary Effluent Limitations on the Discharge of a Pollutant From a Point Source.

1. The permitting authority shall develop preliminary wasteload allocations (WLAs) for the discharge of the pollutant from the point source to protect human health, wildlife, acute aquatic life, and chronic aquatic life, based upon any existing Tier I criteria. Where there is no Tier I criterion nor sufficient data to calculate a Tier I criterion, the permitting authority shall calculate a Tier II value for such pollutant for the protection of human health, and aquatic life and the preliminary WLAs shall be based upon such values. Where there is insufficient data to calculate a Tier II value, the permitting authority shall apply the procedure set forth in section C of this procedure to determine whether data must be generated to calculate a Tier II value.

2. The following provisions in procedure 3 of appendix F shall be used as the basis for determining preliminary WLAs in accordance with section 1 of this procedure: procedure 3.B.9, Background Concentrations of Pollutants; procedure 3.C, Mixing Zones for Bioaccumulative Chemicals of Concern (BCCs), procedures 3.C.1, and 3.C.3 through 3.C.6; procedure 3.D, Deriving TMDLs for Discharges to Lakes (when the receiving water is an open water of the Great Lakes (OWGL), an inland lake or other water of the Great Lakes System with no appreciable flow relative to its volume); procedure 3.E, Deriving TMDLs, WLAs and Preliminary WLAs, and load allocations (LAs) for Discharges to Great Lakes System Tributaries (when the receiving water is a tributary or connecting channel of the Great Lakes that exhibits appreciable flow relative to its volume); and procedure 3.F, Mixing Zone Demonstration Requirements.

3. The permitting authority shall develop PELs consistent with the preliminary WLAs developed pursuant to sections A.1 and A.2 of this procedure, and in accordance with existing State or Tribal procedures for converting WLAs into WQBELs. At a minimum:

a. The PELs based upon criteria and values for the protection of human health and wildlife shall be expressed as monthly limitations;

b. The PELs based upon criteria and values for the protection of aquatic life from chronic effects shall be expressed as either monthly limitations or weekly limitations; and

c. The PELs based upon the criteria and values for the protection of aquatic life from acute effects shall be expressed as daily limitations.

B. Determining Reasonable Potential Using Effluent Pollutant Concentration Data.

If representative, facility-specific effluent monitoring data samples are available for a pollutant discharged from a point source to the waters of the Great Lakes System, the permitting authority shall apply the following procedures:

1. The permitting authority shall specify the PEQ as the 95 percent confidence level of the 95th percentile based on a log-normal distribution of the effluent concentration; or the maximum observed effluent concentration, whichever is greater. In calculating the PEQ, the permitting authority shall identify the number of effluent samples and the coefficient of variation of the effluent data, obtain the appropriate multiplying factor from Table 1 of procedure 6 of appendix F, and multiply the maximum effluent

concentration by that factor. The coefficient of variation of the effluent data shall be calculated as the ratio of the standard deviation of the effluent data divided by the arithmetic average of the effluent data, except that where there are fewer than ten effluent concentration data points the coefficient of variation shall be specified as 0.6. If the PEQ exceeds any of the PELs developed in accordance with section A.3 of this procedure, the permitting authority shall establish a WQBEL in a NPDES permit for such pollutant.

2. In lieu of following the procedures under section B.1 of this procedure, the permitting authority may apply procedures consistent with the following:

a. The permitting authority shall specify the PEQ as the 95th percentile of the distribution of the projected population of daily values of the facility-specific effluent monitoring data projected using a scientifically defensible statistical method that accounts for and captures the long-term daily variability of the effluent quality, accounts for limitations associated with sparse data sets and, unless otherwise shown by the effluent data set, assumes a lognormal distribution of the facility-specific effluent data. If the PEQ exceeds the PEL based on the criteria and values for the protection of aquatic life from acute effects developed in accordance with section A.3 of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant;

b. The permitting authority shall calculate the PEQ as the 95th percentile of the distribution of the projected population of monthly averages of the facility-specific effluent monitoring data using a scientifically defensible statistical method that accounts for and captures the long-term variability of the monthly average effluent quality, accounts for limitations associated with sparse data sets and, unless otherwise shown by the effluent data set, assumes a lognormal distribution of the facility-specific effluent data. If the PEQ exceeds the PEL based on criteria and values for the protection of aquatic life from chronic effects, human health or wildlife developed in accordance with section A.3 of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant; and

c. The permitting authority shall calculate the PEQ as the 95th percentile of the distribution of the projected population of weekly averages of the facility-specific effluent monitoring data using a scientifically defensible statistical method that accounts for and captures the long-term variability of the weekly average effluent quality, accounts for limitations associated with sparse data sets and, unless otherwise shown by the effluent data set, assumes a lognormal distribution of the facility-specific effluent data. If the PEQ exceeds the PEL based on criteria and values to protect aquatic life from chronic effects developed in accordance with section A.3 of this procedure, the permitting ***15421** authority shall establish a WQBEL in an NPDES permit for such pollutant.

C. Developing Necessary Data to Calculate Tier II Values Where Such Data Does Not Currently Exist.
40 CFR § 122.44
1. Except as provided in sections C.2, C.4, or D of this procedure, for each pollutant listed in Table 6 of part 132 that a permittee reports as known or believed to be present in its effluent, and for which pollutant data sufficient to calculate Tier II values for non-cancer human health, acute aquatic life and chronic aquatic life do not exist, the permitting authority shall take the following actions:

a. The permitting authority shall use all available, relevant information, including Quantitative Structure Activity Relationship information and other relevant toxicity information, to estimate ambient screening values for such pollutant which will protect humans from health effects other than cancer, and aquatic life from acute and chronic effects.

b. Using the procedures specified in sections A.1 and A.2 of this procedure, the permitting authority shall develop preliminary WLAs for the discharge of the pollutant from the point source to protect human health, acute aquatic life, and chronic aquatic life, based upon the estimated ambient screening values.

c. The permitting authority shall develop PELs in accordance with section A.3 of this procedure, which are consistent with the preliminary WLAs developed in accordance with section C.1.b of this procedure.

d. The permitting authority shall compare the PEQ developed according to the procedures set forth in section B of this procedure to the PELs developed in accordance with section C.1.c of this procedure. If the PEQ exceeds any of the PELs, the permitting authority shall generate or require the permittee to generate the data necessary to derive Tier II values for noncancer human health, acute aquatic life and chronic aquatic life.

e. The data generated in accordance with section C.1.d of this procedure shall be used in calculating Tier II values as required under section A.1 of this procedure. The calculated Tier II value shall be used in calculating the preliminary WLA and PEL under section A of this procedure, for purposes of determining whether a WQBEL must be included in the permit. If the permitting authority finds that the PEQ exceeds the calculated PEL, a WQBEL for the pollutant or a permit limit on an indicator parameter consistent with 40 CFR 122.44(d)(1)(vi)(C) must be included in the permit.

2. With the exception of bioaccumulative chemicals of concern (BCCs), a permitting authority is not required to apply the procedures set forth in section C.1 of this procedure or include WQBELs to protect aquatic life for any pollutant listed in Table 6 of part 132 discharged by an existing point source into the Great Lakes System, if:

a. There is insufficient data to calculate a Tier I criterion or Tier II value for aquatic life for such pollutant;

b. The permittee has demonstrated through a biological assessment that there are no acute or chronic effects on aquatic life in the receiving water; and

c. The permittee has demonstrated in accordance with procedure 6 of this appendix that the whole effluent does not exhibit acute or chronic toxicity.

3. Nothing in sections C.1 or C.2 of this procedure shall preclude or deny the right of a permitting authority to:

a. Determine, in the absence of the data necessary to derive a Tier II value, that the discharge of the pollutant will cause, have the reasonable potential to cause, or contribute to an excursion above a narrative criterion for water quality; and

b. Incorporate a WQBEL for the pollutant into an NPDES permit.

4. If the permitting authority develops a WQBEL consistent with section C.3 of this procedure, and the permitting authority demonstrates that the WQBEL developed under section C.3 of this procedure is at least as stringent as a WQBEL that would have been based upon the Tier II value or values for that pollutant, the permitting authority shall not be obligated to generate or require the permittee to generate the data necessary to derive a Tier II value or values for that pollutant.

D. Consideration of Intake Pollutants in Determining Reasonable Potential.
40 CFR § 122.44
1. General.

a. Any procedures adopted by a State or Tribe for considering intake pollutants in water quality-based permitting shall be consistent with this section and section E.

b. The determinations under this section and section E shall be made on a pollutant-by-pollutant, outfall-by-outfall, basis.

c. This section and section E apply only in the absence of a TMDL applicable to the discharge prepared by the State or Tribe and approved by EPA, or prepared by EPA pursuant to 40 CFR 130.7(d), or in the absence of an assessment and remediation

plan submitted and approved in accordance with procedure 3.A. of appendix F. This section and section E do not alter the permitting authority's obligation under 40 CFR 122.44(d)(vii)(B) to develop effluent limitations consistent with the assumptions and requirements of any available WLA for the discharge, which is part of a TMDL prepared by the State or Tribe and approved by EPA pursuant to 40 CFR 130.7, or prepared by EPA pursuant to 40 CFR 130.7(d).

2. Definition of Same Body of Water.

a. This definition applies to this section and section E of this procedure.

b. An intake pollutant is considered to be from the same body of water as the discharge if the permitting authority finds that the intake pollutant would have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee. This finding may be deemed established if:

i. The background concentration of the pollutant in the receiving water (excluding any amount of the pollutant in the facility's discharge) is similar to that in the intake water;

ii. There is a direct hydrological connection between the intake and discharge points; and

iii. Water quality characteristics (e.g., temperature, Ph, hardness) are similar in the intake and receiving waters.

c. The permitting authority may also consider other site-specific factors relevant to the transport and fate of the pollutant to make the finding in a particular case that a pollutant would or would not have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee.

d. An intake pollutant from groundwater may be considered to be from the same body of water if the permitting authority determines that the pollutant would have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee, except that such a pollutant is not from the same body of water if the groundwater contains the pollutant partially or entirely due to human activity, such as industrial, commercial, or municipal operations, disposed actions, or treatment processes.

e. An intake pollutant is the amount of a pollutant that is present in waters of the United States (including groundwater as provided in section D.2.d of this procedure) at the time it is withdrawn from such waters by the discharger or other facility (e.g., public water supply) supplying the discharger with intake water.

3. Reasonable Potential Determination.

a. The permitting authority may use the procedure described in this section of procedure 5 in lieu of procedures 5.A through C provided the conditions specified below are met.

b. The permitting authority may determine that there is no reasonable potential for the discharge of an identified intake pollutant or pollutant parameter to cause or contribute to an excursion above a narrative or numeric water quality criterion within an applicable water quality standard where a discharger demonstrates to the satisfaction of the permitting authority (based upon information provided in the permit application or other information deemed necessary by the permitting authority) that:

i. The facility withdraws 100 percent of the intake water containing the pollutant from the same body of water into which the discharge is made;

ii. The facility does not contribute any additional mass of the identified intake pollutant to its wastewater;

iii. The facility does not alter the identified intake pollutant chemically or physically in a manner that would cause adverse water quality impacts to occur that would not occur if the pollutants were left in-stream;

iv. The facility does not increase the identified intake pollutant concentration, as defined by the permitting authority, at the edge of the mixing zone, or at the point of discharge if a mixing zone is not allowed, as compared to the pollutant concentration in the intake water, unless the increased concentration does not cause or contribute to an excursion above an applicable water quality standard; and

v. The timing and location of the discharge would not cause adverse water quality impacts to occur that would not occur if the identified intake pollutant were left in-stream.

c. Upon a finding under section D.3.b of this procedure that a pollutant in the ***15422** discharge does not cause, have the reasonable potential to cause, or contribute to an excursion above an applicable water quality standard, the permitting authority is not required to include a WQBEL for the identified intake pollutant in the facility's permit, provided:

i. The NPDES permit fact sheet or statement of basis includes a specific determination that there is no reasonable potential for the discharge of an identified intake pollutant to cause or contribute to an excursion above an applicable narrative or numeric water quality criterion and references appropriate supporting documentation included in the administrative record;

ii. The permit requires all influent, effluent, and ambient monitoring necessary to demonstrate that the conditions in section D.3.b of this procedure are maintained during the permit term; and

iii. The permit contains a reopener clause authorizing modification or revocation and reissuance of the permit if new information indicates changes in the conditions in section D.3.b of this procedure.

d. Absent a finding under section D.3.b of this procedure that a pollutant in the discharge does not cause, have the reasonable potential to cause, or contribute to an excursion above an applicable water quality standard, the permitting authority shall use the procedures under sections 5.A through C of this procedure to determine whether a discharge causes, has the reasonable potential to cause, or contribute to an excursion above an applicable narrative or numeric water quality criterion.

E. Consideration of Intake Pollutants in Establishing WQBELs.

1. General. This section applies only when the concentration of the pollutant of concern upstream of the discharge (as determined using the provisions in procedure 3.B.9 of appendix F) exceeds the most stringent applicable water quality criterion for that pollutant.

2. The requirements of sections D.1-D.2 of this procedure shall also apply to this section.

3. Intake Pollutants from the Same Body of Water.

a. In cases where a facility meets the conditions in sections D.3.b.i and D.3.b.iii through D.3.b.v of this procedure, the permitting authority may establish effluent limitations allowing the facility to discharge a mass and concentration of the pollutant that are no greater than the mass and concentration of the pollutant identified in the facility's intake water (“no net addition limitations”). The permit shall specify how compliance with mass and concentration limitations shall be assessed. No permit may authorize “no net addition limitations” which are effective after March 23, 2007. After that date, WQBELs shall be established in accordance with procedure 5.F.2 of appendix F.

b. Where proper operation and maintenance of a facility's treatment system results in removal of a pollutant, the permitting authority may establish limitations that reflect the lower mass and/or concentration of the pollutant achieved by such treatment, taking into account the feasibility of establishing such limits.

c. For pollutants contained in intake water provided by a water system, the concentration of the intake pollutant shall be determined at the point where the raw water supply is removed from the same body of water, except that it shall be the point where the water enters the water supplier's distribution system where the water treatment system removes any of the identified pollutants from the raw water supply. Mass shall be determined by multiplying the concentration of the pollutant determined in accordance with this paragraph by the volume of the facility's intake flow received from the water system.

4. Intake Pollutants from a Different Body of Water. Where the pollutant in a facility's discharge originates from a water of the United States that is not the same body of water as the receiving water (as determined in accordance with section D.2 of this procedure), WQBELs shall be established based upon the most stringent applicable water quality criterion for that pollutant.

5. Multiple Sources of Intake Pollutants. Where a facility discharges intake pollutants that originate in part from the same body of water, and in part from a different body of water, the permitting authority may apply the procedures of sections E.3 and E.4 of this procedure to derive an effluent limitation reflecting the flow-weighted average of each source of the pollutant, provided that adequate monitoring to determine compliance can be established and is included in the permit.

F. Other Applicable Conditions.

1. In addition to the above procedures, effluent limitations shall be established to comply with all other applicable State, Tribal and Federal laws and regulations, including technology-based requirements and antidegradation policies.

2. Once the permitting authority has determined in accordance with this procedure that a WQBEL must be included in an NPDES permit, the permitting authority shall:

a. Rely upon the WLA established for the point source either as part of any TMDL prepared under procedure 3 of this appendix and approved by EPA pursuant to 40 CFR 130.7, or as part of an assessment and remediation plan developed and approved in accordance with procedure 3.A of this appendix, or, in the absence of such TMDL or plan, calculate WLAs for the protection of acute and chronic aquatic life, wildlife and human health consistent with the provisions referenced in section A.1 of this procedure for developing preliminary wasteload allocations, and

b. Develop effluent limitations consistent with these WLAs in accordance with existing State or Tribal procedures for converting WLAs into WQBELs.

3. When determining whether WQBELs are necessary, information from chemical-specific, whole effluent toxicity and biological assessments shall be considered independently.

4. If the geometric mean of a pollutant in fish tissue samples collected from a waterbody exceeds the tissue basis of a Tier I criterion or Tier II value, after consideration of the variability of the pollutant's bioconcentration and bioaccumulation in fish, each facility that discharges detectable levels of such pollutant to that water has the reasonable potential to cause or contribute to an excursion above a Tier I criteria or a Tier II value and the permitting authority shall establish a WQBEL for such pollutant in the NPDES permit for such facility.

Procedure 6: Whole Effluent Toxicity Requirements

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) procedure 6 of appendix F of part 132.

The following definitions apply to this part:

Acute toxic unit (TU_a). $100/LC_{50}$ where the LC_{50} is expressed as a percent effluent in the test medium of an acute whole effluent toxicity (WET) test that is statistically or graphically estimated to be lethal to 50 percent of the test organisms.

Chronic toxic unit (TU_c). 100/NOEC or $100/IC_{25}$, where the NOEC and IC_{25} are expressed as a percent effluent in the test medium.

Inhibition concentration 25 (IC_{25}). the toxicant concentration that would cause a 25 percent reduction in a non-quantal biological measurement for the test population. For example, the IC_{25} is the concentration of toxicant that would cause a 25 percent reduction in mean young per female or in growth for the test population.

No observed effect concentration (NOEC). The highest concentration of toxicant to which organisms are exposed in a full life-cycle or partial life-cycle (short-term) test, that causes no observable adverse effects on the test organisms (i.e., the highest concentration of toxicant in which the values for the observed responses are not statistically significantly different from the controls).

A. Whole Effluent Toxicity Requirements. The Great Lakes States and Tribes shall adopt whole effluent toxicity provisions consistent with the following:

1. A numeric acute WET criterion of 0.3 acute toxic units (TU_a) measured pursuant to test methods in 40 CFR part 136, or a numeric interpretation of a narrative criterion establishing that 0.3 TU_a measured pursuant to test methods in 40 CFR part 136 is necessary to protect aquatic life from acute effects of WET. At the discretion of the permitting authority, the foregoing requirement shall not apply in an acute mixing zone that is sized in accordance with EPA-approved State and Tribal methods.

2. A numeric chronic WET criterion of one chronic toxicity unit (TU_c) measured pursuant to test methods in 40 CFR part 136, or a numeric interpretation of a narrative criterion establishing that one TU_c measured pursuant to test methods in 40 CFR part 136 is necessary to protect aquatic life from the chronic effects of WET. At the discretion of the permitting authority, the foregoing requirements shall not apply within a chronic mixing zone consistent with: (a) procedures 3.D.1 and 3.D.4, for discharges to the open of the Great Lakes (OWGL), inland ***15423** lakes and other waters of the Great Lakes System with no appreciable flow relative to their volume, or (b) procedure 3.E.5 for discharges to tributaries and connecting channels of the Great Lakes System.

B. WET Test Methods. All WET tests performed to implement or ascertain compliance with this procedure shall be performed in accordance with methods established in 40 CFR part 136.

C. Permit Conditions.

40 CFR § 122.44

1. Where a permitting authority determines pursuant to section D of this procedure that the WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards, the permitting authority:

a. Shall (except as provided in section C.1.e of this procedure) establish a water quality-based effluent limitation (WQBEL) or WQBELs for WET consistent with section C.1.b of this procedure;

b. Shall calculate WQBELs pursuant to section C.1.a. of this procedure to ensure attainment of the State's or Tribe's chronic WET criteria under receiving water flow conditions described in procedures 3.E.1.a (or where applicable, with procedure 3.E.1.e) for Great Lakes System tributaries and connecting channels, and with mixing zones no larger than allowed pursuant to section A.2. of this procedure. Shall calculate WQBELs to ensure attainment of the State's or Tribe's acute WET criteria under receiving water flow conditions described in procedure 3.E.1.b (or where applicable, with procedure 3.E.1.e) for Great Lakes System

tributaries and connecting channels, with an allowance for mixing zones no greater than specified pursuant to section A.1 of this procedure.

c. May specify in the NPDES permit the conditions under which a permittee would be required to perform a toxicity reduction evaluation.

d. May allow with respect to any WQBEL established pursuant to section C.1.a of this procedure an appropriate schedule of compliance consistent with procedure 9 of appendix F; and

e. May decide on a case-by-case basis that a WQBEL for WET is not necessary if the State's or Tribe's water quality standards do not contain a numeric criterion for WET, and the permitting authority demonstrates in accordance with 40 CFR 122.44(d)(1)(v) that chemical-specific effluent limits are sufficient to ensure compliance with applicable criteria.

2. Where a permitting authority lacks sufficient information to determine pursuant to section D of this procedure whether the WET of an effluent is or may be discharged at levels that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards, then the permitting authority should consider including in the NPDES permit appropriate conditions to require generation of additional data and to control toxicity if found, such as:

a. WET testing requirements to generate the data needed to adequately characterize the toxicity of the effluent to aquatic life;

b. Language requiring a permit reopener clause to establish WET limits if any toxicity testing data required pursuant to section C.2.a of this procedure indicate that the WET of an effluent is or may be discharged at levels that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards.
40 CFR § 122.44
3. Where sufficient data are available for a permitting authority to determine pursuant to section D of this procedure that the WET of an effluent neither is nor may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards, the permitting authority may include conditions and limitations described in section C.2 of this procedure at its discretion.

D. Reasonable Potential Determinations. The permitting authority shall take into account the factors described in 40 CFR 122.44(d)(1)(ii) and, where representative facility-specific WET effluent data are available, apply the following requirements in determining whether the WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric WET criterion or narrative criterion within a State's or Tribe's water quality standards.

1. The permitting authority shall characterize the toxicity of the discharge by:

a. Either averaging or using the maximum of acute toxicity values collected within the same day for each species to represent one daily value. The maximum of all daily values for the most sensitive species tested is used for reasonable potential determinations;

b. Either averaging or using the maximum of chronic toxicity values collected within the same calendar month for each species to represent one monthly value. The maximum of such values, for the most sensitive species tested, is used for reasonable potential determinations:

c. Estimating the toxicity values for the missing endpoint using a default acute-chronic ratio (ACR) of 10, when data exist for either acute WET or chronic WET, but not for both endpoints.

2. The WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric acute WET criterion or numeric interpretation of a narrative criterion within a State's or Tribe's water quality standards, when effluent-specific information demonstrates that:

(TU_a effluent) (B) (effluent flow/(Qad+effluent flow))>AC

Where TU_a effluent is the maximum measured acute toxicity of 100 percent effluent determined pursuant to section D.1.a. of this procedure, B is the multiplying factor taken from Table F6-1 of this procedure to convert the highest measured effluent toxicity value to the estimated 95th percentile toxicity value for the discharge, effluent flow is the same effluent flow used to calculate the preliminary wasteload allocations (WLAs) for individual pollutants to meet the acute criteria and values for those pollutants, AC is the numeric acute WET criterion or numeric interpretation of a narrative criterion established pursuant to section A.1 of this procedure and expressed in TU_a, and Qad is the amount of the receiving water available for dilution calculated using: (i) the specified design flow(s) for tributaries and connecting channels in section C.1.b of this procedure, or where appropriate procedure 3.E.1.e of appendix F, and using EPA-approved State and Tribal procedures for establishing acute mixing zones in tributaries and connecting channels, or (ii) the EPA-approved State and Tribal procedures for establishing acute mixing zones in OWGLs. Where there are less than 10 individual WET tests, the multiplying factor taken from Table F6-1 of this procedure shall be based on a coefficient of variation (CV) or 0.6. Where there are 10 or more individual WET tests, the multiplying factor taken from Table F6-1 shall be based on a CV calculated as the standard deviation of the acute toxicity values found in the WET tests divided by the arithmetic mean of those toxicity values.

3. The WET of an effluent is or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any numeric chronic WET criterion or numeric interpretation of a narrative criterion within a State's or Tribe's water quality standards, when effluent-specific information demonstrates that:

(TU_c effluent) (B) (effluent flow/Qad+effluent flow))>CC

Where TU_c effluent is the maximum measured chronic toxicity value of 100 percent effluent determined in accordance with section D.1.b. of this procedure, B is the multiplying factor taken from Table F6-1 of this procedure, effluent flow is the same effluent flow used to calculate the preliminary WLAs for individual pollutants to meet the chronic criteria and values for those pollutants, CC is the numeric chronic WET criterion or numeric interpretation of a narrative criterion established pursuant to section A.2 of this procedure and expressed in TU_c, and Qad is the amount of the receiving water available for dilution calculated using: (i) the design flow(s) for tributaries and connecting channels specified in procedure 3.E.1.a of appendix F, and where appropriate procedure 3.E.1.e of appendix F, and in accordance with the provisions of procedure 3.E.5 for chronic mixing zones, or (ii) procedures 3.D.1 and 3.D.4 for discharges to the OWGLs. Where there are less than 10 individual WET tests, the multiplying factor taken from Table F6-1 of this procedure shall be based on a CV of 0.6. Where there are 10 more individual WET tests, the multiplying factor taken from Table F6-1 of this procedure shall be based on a CV calculated as the standard deviation of the WET tests divided by the arithmetic mean of the WET tests.

Table F6-1.— Reasonable Potential Multiplying Factors: 95% Confidence Level and 95% Probability Basis

Number of Samples	Coefficient of variation																			
0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.9	2.0		
1	1.4	1.9	2.6	3.6	4.7	6.2	8.0	10.1	12.6	15.5	18.7	22.3	26.4	30.8	35.6	40.7	46.2	52.1	58.4	64.9
2	1.3	1.6	2.0	2.5	3.1	3.8	4.6	5.4	6.4	7.4	8.5	9.7	10.9	12.2	13.6	15.0	16.4	17.9	19.5	21.1

3	1.2	1.5	1.8	2.1	2.5	3.0	3.5	4.0	4.6	5.2	5.8	6.5	7.2	7.9	8.6	9.3	10.0	10.8	11.5	12.3
4	1.2	1.4	1.7	1.9	2.2	2.6	2.9	3.3	3.7	4.2	4.6	5.0	5.5	6.0	6.4	6.9	7.4	7.8	8.3	8.8
5	1.2	1.4	1.6	1.8	2.1	2.3	2.6	2.9	3.2	3.6	3.9	4.2	4.5	4.9	5.2	5.6	5.9	6.2	6.6	6.9
6	1.1	1.3	1.5	1.7	1.9	2.1	2.4	2.6	2.9	3.1	3.4	3.7	3.9	4.2	4.5	4.7	5.0	5.2	5.5	5.7
7	1.1	1.3	1.4	1.6	1.8	2.0	2.2	2.4	2.6	2.8	3.1	3.3	3.5	3.7	3.9	4.1	4.3	4.5	4.7	4.9
8	1.1	1.3	1.4	1.6	1.7	1.9	2.1	2.3	2.4	2.6	2.8	3.0	3.2	3.3	3.5	3.7	3.9	4.0	4.2	4.3
9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1	3.2	3.4	3.5	3.6	3.8	3.9
10	1.1	1.2	1.3	1.5	1.6	1.7	1.9	2.0	2.2	2.3	2.4	2.6	2.7	2.8	3.0	3.1	3.2	3.3	3.4	3.6
11	1.1	1.2	1.3	1.4	1.6	1.7	1.8	1.9	2.1	2.2	2.3	2.4	2.5	2.7	2.8	2.9	3.0	3.1	3.2	3.3
12	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	3.0	3.0
13	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.5	2.6	2.7	2.8	2.9
14	1.1	1.2	1.3	1.4	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.3	2.4	2.5	2.6	2.6	2.7
15	1.1	1.2	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.8	1.9	2.0	2.1	2.2	2.2	2.3	2.4	2.4	2.5	2.5
16	1.1	1.1	1.2	1.3	1.4	1.5	1.6	1.6	1.7	1.8	1.9	1.9	2.0	2.1	2.1	2.2	2.3	2.3	2.4	2.4
17	1.1	1.1	1.2	1.3	1.4	1.4	1.5	1.6	1.7	1.7	1.8	1.9	1.9	2.0	2.0	2.1	2.2	2.2	2.3	2.3
18	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.6	1.6	1.7	1.7	1.8	1.9	1.9	2.0	2.0	2.1	2.1	2.2	2.2
19	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.5	1.6	1.6	1.7	1.8	1.8	1.9	1.9	2.0	2.0	2.0	2.1	2.1
20	1.1	1.1	1.2	1.2	1.3	1.4	1.4	1.5	1.5	1.6	1.6	1.7	1.7	1.8	1.8	1.9	1.9	2.0	2.0	2.0
30	1.0	1.1	1.1	1.1	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.5	1.5
40	1.0	1.0	1.1	1.1	1.1	1.1	1.1	1.1	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.3	1.3
50	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
60	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
70	1.0	1.0	1.0	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
80	1.0	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8
90	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
100	1.0	1.0	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.7	0.7	0.7

***15424 Procedure 7: Loading Limits**

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure.

Whenever a water quality-based effluent limitation (WQBEL) is developed, the WQBEL shall be expressed as both a concentration value and a corresponding mass loading rate.

A. Both mass and concentration limits shall be based on the same permit averaging periods such as daily, weekly, or monthly averages, or in other appropriate permit averaging periods.

B. The mass loading rates shall be calculated using effluent flow rates that are consistent with those used in establishing the WQBELs expressed in concentration.

Procedure 8: Water Quality-based Effluent Limitations Below the Quantification Level

The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) this procedure.

When a water quality-based effluent limitation (WQBEL) for a pollutant is calculated to be less than the quantification level:

A. Permit Limits. The permitting authority shall designate as the limit in the NPDES permit the WQBEL exactly as calculated.

B. Analytical Method and Quantification Level.

1. The permitting authority shall specify in the permit the most sensitive, applicable, analytical method, specified in or approved under 40 CFR part 136, or other appropriate method if one is not available under 40 CFR part 136, to be used to monitor for the presence and amount in an effluent of the pollutant for which the WQBEL is established; and shall specify in accordance with section B.2 of this procedure, the quantification level that can be achieved by use of the specified analytical method.

2. The quantification level shall be the minimum level (ML) specified in or approved under 40 CFR part 136 for the method for that pollutant. If no such ML exists, or if the method is not specified or approved under 40 CFR part 136, the quantification level shall be the lowest quantifiable level practicable. The permitting authority may specify a higher quantification level if the permittee demonstrates that a higher quantification level is appropriate because of effluent-specific matrix interference.

3. The permit shall state that, for the purpose of compliance assessment, the analytical method specified in the permit shall be used to monitor the amount of pollutant in an effluent down to the quantification level, provided that the analyst has complied with the specified quality assurance/quality control procedures in the relevant method.

4. The permitting authority shall use applicable State and Tribal procedures to average and account for monitoring data. The permitting authority may specify in the permit the value to be used to interpret sample values below the quantification level.

C. Special Conditions. The permit shall contain a reopener clause authorizing modification or revocation and reissuance of the permit if new information generated as a result of special conditions included in the permit indicates that presence of the pollutant in the discharge at levels above the WQBEL. Special conditions that may be included in the permit include, but are not limited to, fish tissue sampling, whole effluent toxicity (WET) tests, limits and/or monitoring requirements on internal waste streams, and monitoring for surrogate parameters. Data generated as a result of special conditions can be used to reopen the permit to establish more stringent effluent limits or conditions, if necessary.

D. Pollutant Minimization Program. The permitting authority shall include a condition in the permit requiring the permittee to develop and conduct a pollutant minimization program for each pollutant with a WQBEL below the quantification level. The goal of the pollutant minimization program shall be to reduce all potential sources of the pollutant to maintain the effluent at or below the WQBEL. In addition, States and Tribes may consider cost-effectiveness when establishing the requirements of a PMP. The pollutant minimization program shall include, but is not limited to, the following:

1. An annual review and semi-annual monitoring of potential sources of the pollutant, which may include fish tissue monitoring and other bio-uptake sampling;

2. Quarterly monitoring for the pollutant in the influent to the wastewater treatment system;

3. Submittal of a control strategy designed to proceed toward the goal of maintaining all sources of the pollutant to the wastewater collection system below the WQBEL;

4. When the sources of the pollutant are discovered, appropriate cost-effective control ***15425** measures shall be implemented, consistent with the control strategy; and

5. An annual status report that shall be sent to the permitting authority including:

a. All minimization program monitoring results for the previous year;

b. A list of potential sources of the pollutant; and

c. A summary of all action taken to reduce or eliminate the identified sources of the pollutant.
40 CFR § 122.44
6. Any information generated as a result of procedure 8.D can be used to support a request for subsequent permit modifications, including revisions to (e.g., more or less frequent monitoring), or removal of the requirements of procedure 8.D, consistent with 40 CFR 122.44, 122.62 and 122.63.

Procedure 9: Compliance Schedules
The Great Lakes States and Tribes shall adopt provisions consistent with (as protective as) procedure 9 of appendix F of part 132.

A. Limitations for New Great Lakes Dischargers. When a permit issued on or after March 23, 1997 to a new Great Lakes discharger (defined in Part 132.2) contains a water quality-based effluent limitation (WQBEL), the permittee shall comply with such a limitation upon the commencement of the discharge.

B. Limitations for Existing Great Lakes Dischargers.

1. Any existing permit that is reissued or modified on or after March 23, 1997 to contain a new or more restrictive WQBEL may allow a reasonable period of time, up to five years from the date of permit issuance or modification, for the permittee to comply with that limit, provided that the Tier I criterion or whole effluent toxicity (WET) criterion was adopted (or, in the case of a narrative criterion, Tier II value, or Tier I criterion derived pursuant to the methodology in appendix A of part 132, was newly derived) after July 1, 1977.

2. When the compliance schedule established under paragraph 1 goes beyond the term of the permit, an interim permit limit effective upon the expiration date shall be included in the permit and addressed in the permit's fact sheet or statement of basis. The administrative record for the permit shall reflect the final limit and its compliance date.

3. If a permit establishes a schedule of compliance under paragraph 1 which exceeds one year from the date of permit issuance or modification, the schedule shall set forth interim requirements and dates for their achievement. The time between such interim dates may not exceed one year. If the time necessary for completion of any interim requirement is more than one year and is not readily divisible into stages for completion, the permit shall require, at a minimum, specified dates for annual submission of progress reports on the status of any interim requirements.

C. Delayed Effectiveness of Tier II Limitations for Existing Great Lakes Discharges.

1. Whenever a limit (calculated in accordance with Procedure 3) based upon a Tier II value is included in a reissued or modified permit for an existing Great Lakes discharger, the permit may provide a reasonable period of time, up to two years, in which to provide additional studies necessary to develop a Tier I criterion or to modify the Tier II value. In such cases, the permit shall require compliance with the Tier II limitation within a reasonable period of time, no later than five years after permit issuance or modification, and contain a reopener clause.

2. The reopener clause shall authorize permit modifications if specified studies have been completed by the permittee or provided by a third-party during the time allowed to conduct the specified studies, and the permittee or a third-party demonstrates, through such studies, that a revised limit is appropriate. Such a revised limit shall be incorporated through a permit modification and a reasonable time period, up to five years, shall be allowed for compliance. If incorporated prior to the compliance date of the original Tier II limitation, any such revised limit shall not be considered less-stringent for purposes of the anti-backsliding provisions of section 402(o) of the Clean Water Act.

3. If the specified studies have been completed and do not demonstrate that a revised limit is appropriate, the permitting authority may provide a reasonable additional period of time, not to exceed five years with which to achieve compliance with the original effluent limitation.

4. Where a permit is modified to include new or more stringent limitations, on a date within five years of the permit expiration date, such compliance schedules may extend beyond the term of a permit consistent with section B.2 of this procedure.

5. If future studies (other than those conducted under paragraphs 1, 2, or 3 above) result in a Tier II value being changed to a less stringent Tier II value or Tier I criterion, after the effective date of a Tier II-based limit, the existing Tier II-based limit may be revised to be less stringent if:

(a) It complies with sections 402(o) (2) and (3) of the CWA; or,

(b) In non-attainment waters, where the existing Tier II limit was based on procedure 3, the cumulative effect of revised effluent limitation based on procedure 3 of this appendix will assure compliance with water quality standards; or,

(c) In attained waters, the revised effluent limitation complies with the State or Tribes' antidegradation policy and procedures.

[FR Doc. 95-6671 Filed 3-22-95; 8:45 am]

BILLING CODE 6560-50-P

Footnotes

tr a CMC=CMC.

d $^{tr\ d}$b CMC=(CMC) CF. The CMC shall be rounded to two significant digits.

c CMC should be considered free cyanide as CN.

t d CMC=CMC.

Notes:

The term “n/a” means not applicable.

CMC is Criterion Maximum Concentration.

tr FNCMC is the CMC expressed as total recoverable.

d FNCMC is the CMC expressed as a dissolved concentration.

t FNCMC is the CMC expressed as a total concentration.

tr $_{AA}$a CMC=exp { m [ln (hardness)]+b}.

d [tr d]b CMC=(CMC) CF. The CMC shall be rounded to two significant digits.

t [AA t]c CMC=exp m { [pH]+b}. The CMC shall be rounded to two significant digits.

Notes:

The term “exp” represents the base e exponential function.

The term “n/a” means not applicable.

CMC is Criterion Maximum Concentration.

tr FNCMC is the CMC expressed as total recoverable.

d FNCMC is the CMC expressed as a dissolved concentration.

t FNCMC is the CMC expressed as a total concentration.

tr a CCC=CCC.

d [tr d]b CCC=(CCC) CF. The CCC shall be rounded to two significant digits.

c CCC should be considered free cyanide as CN.

t d CCC=CCC.

Notes:

The term “n/a” means not applicable.

CCC is Criterion Continuous Concentration.

tr FNCCC is the CCC expressed as total recoverable.

d FNCCC is the CCC expressed as a dissolved concentration.

t FNCCC is the CCC expressed as a total concentration.

tr [cc]a CCC=exp {m[ln (hardness)]+b}.

[d tr d]b CCC=(CCC) (CF). The CCC shall be rounded to two significant digits.

t [AA t]c CMC=exp {m[pH]+b}. The CMC shall be rounded to two significant digits.

Notes:

The term “exp” represents the base e exponential function.

The term “n/a” means not applicable.

CCC is Criterion Continuous Concentration.

tr FNCCC is the CCC expressed as total recoverable.

d FNCCC is the CCC expressed as a dissolved concentration.

t FNCCC is the CCC expressed as a total concentration.

1 Includes methylmercury.

1 The FCMs for trophic level 3 are the geometric mean of the FCMs for sculpin and alewife.

Note: TL3=trophic level three fish; TL4=trophic level four fish; PB =piscivorous birds; Other=non-aquatic birds and mammals.

End of Document

U.S. ENVIRONMENTAL PROTECTION AGENCY – REGION 10

Technical Support Document

for Action on the State of Oregon's New and Revised Human Health Water Quality Criteria for Toxics and Associated Implementation Provisions Submitted July 12 and 21, 2011

October 17, 2011

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TECHNICAL SUPPORT DOCUMENT

For Action on the State of Oregon's New and Revised Human Health Water Quality Criteria for Toxics and Associated Implementation Provisions Submitted July 12 and 21, 2011

I. INTRODUCTION

In consideration of current information relative to fish consumption in Oregon, the Oregon Department of Environmental Quality (ODEQ) proposed revisions to Oregon's water quality standards (WQS) located in Chapter 340, Division 41 of Oregon's Administrative Rules (OAR 340-041). ODEQ proposed new and revised human health water quality criteria for toxics and associated implementation provisions on December 21, 2010. ODEQ provided a formal public comment period on the proposed revisions and held nine public hearings. The public comment period extended from December 21, 2010 through March 21, 2011. 1,075 written comments were received and responded to by ODEQ. Revisions were adopted by the Oregon Environmental Quality Commission (EQC or Commission) on June 16, 2011, and filed with Oregon Secretary of State on July 13, 2011. Oregon's submittal included a letter dated July 20, 2011, from Larry Knudsen, Assistant Attorney General, certifying that the revisions were adopted in accordance with Oregon State law. In accordance with Section 303(c) of the Clean Water Act (CWA) ODEQ submitted these revisions to EPA for review and approval on July 21, 2011.

ODEQ revised their human health criteria for iron and manganese in a separate submittal dated January 18, 2011, which EPA approved on June 9, 2011. ODEQ also revised the human health criteria for arsenic in a separate submittal dated July 12, 2011, which EPA is now approving as part of this action. ODEQ accepted public comments on these revisions from August 25 to September 30, 2010, and held public hearings in Portland and Pendleton. ODEQ also conducted further public comment on the proposed rule, including revised proposed numeric criteria from February 1 to February 23, 2011. These revisions were adopted by the EQC on April 21, 2011 and became effective under State law upon filing with the Oregon Secretary of State on June 30, 2011. ODEQ submitted the revisions to the human health criteria for arsenic to EPA for review and approval on July 12, 2011. Oregon's submittal included a letter dated July 11, 2011, from Larry Knudsen, Assistant Attorney General, certifying that the revisions were adopted in accordance with Oregon State law.

The June 16, 2011 rule package adopted by the EQC included revisions to the States' Total Maximum Daily Load (TMDL) and National Pollutant Discharge Elimination System (NPDES) permitting regulations found in OAR 340-042 and 045. These are revisions to Oregon's implementation rules and are not water quality standards. Accordingly, Oregon did not include

them in the materials submitted for review under Section 303(c) of the CWA and EPA does not address them in today's action.

Revisions addressed in today's decision can be divided into the general categories described below.

1. ***New and revised human health criteria for carcinogens and non-carcinogens at OAR 340-041-0033.***
   ODEQ adopted new and revised human health criteria for 104 toxic pollutants (48 non-carcinogens and 56 carcinogens) based on a fish consumption rate of 175 grams per day. The criteria for these toxic pollutants are consistent with EPA's 304(a) recommended criteria values[1] and were derived using the methodology presented in EPA's 2000 *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*[2] and EPA's 2001 Methylmercury guidance.[3] The new and revised human health criteria for toxic pollutants are contained in Table 40.

   Additional revisions related to the human health criteria include:

   - The removal of 13 pollutants consistent with EPA's removal of 304(a) recommended criteria values for these same pollutants. Most of these recommended criteria were withdrawn since EPA developed individual criteria for the most toxic of chemicals in the family of chemicals represented by those 13 pollutants.
   - Several new, revised and withdrawn footnotes to the criteria in order to provide clarification.
   - Revisions to the water quality standards provision at OAR 340-041-0033 which revise regulatory citations and table numbers referencing the human health and aquatic life criteria tables.

2. ***Revised arsenic human health criteria.***
   ODEQ adopted revised human health criteria for arsenic and submitted the revised criteria separately to EPA on July 12, 2011.

3. ***New implementation provision entitled "Site-specific background pollutant criteria" at OAR 340-041-0033(6).***
   ODEQ adopted a new provision that allows it to develop a site-specific criteria for a portion of a waterbody in the vicinity of an NPDES permitted discharge in limited instances. The criteria is only applicable for criteria addressing carcinogenic effects on

[1] EPA. 2009. *EPA National Recommended Water Quality Criteria.* U.S. Environmental Protection Agency Office of Water. Office of Science and Technology. Available at: http://water.epa.gov/scitech/swguidance/standards/current/upload/nrwqc-2009.pdf
[2] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, EPA-822-B-00-004. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf
[3] EPA. 2001. *Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 823-R-01-001. Available at: http://www.epa.gov/waterscience/criteria/methylmercury/document.html

human health and for pollutants that are taken into a facility through their intake water and discharged to the same waterbody at an equal or lower mass. The instream criterion concentration is limited to three percent above the ambient condition and may not exceed a 10^{-4} risk level as calculated using the same input variables as used to calculate the criteria in Table 40.

4. ***Revised variance provision at OAR 340-041-0059.***
   ODEQ has removed the variance authorizing procedure found at OAR 340-041-0061(2) and replaced it with a new procedure at OAR 340-041-0059. ODEQ's objective for these revisions was to ensure that variances and their accompanying pollutant reduction plans continue to ensure progress toward meeting standards, to streamline the administration process, and to require pollutant reduction plans with specific milestones that will result in water quality improvement, and add general clarification to the rule. All variances adopted under this provision require EPA approval.

5. ***A correction to a cross-reference in the bacteria provision found at OAR 340-041-0009(10).***
   ODEQ adopted a revision to correct the cross-reference in this provision to reflect rule numbering revisions in OAR 340-041-0061.

6. ***Revised rules explaining how the mechanisms for forestry and agricultural nonpoint sources work to meet water quality standards and the total maximum daily load (TMDL) load at OAR 340-041-0007(5) and OAR 340-041-0061(9)(a)(E), (10), and (11).***
   ODEQ adopted revisions to clarify how nonpoint sources will be addressed in TMDLs and how ODEQ will interact with the Departments of Forestry and Agriculture to ensure needed programs are in place to address these sources of pollution.

II. ORGANIZATION OF DOCUMENT

This document is organized in the following manner. Part III of this document contains background on ODEQ's process to adopt new and revised human health criteria and information regarding the July 12 and 21, 2011 submittals.

Part IV contains the basis for EPA's decisions under section 303(c) of the Clean Water Act (CWA) and implementing regulations found in the Code of Federal Regulations (CFR) at 40 CFR § 131.11 to approve Oregon's new and revised human health criteria. This section includes information regarding EPA's review of Oregon's human health criteria revisions which specifically evaluates the applicability of the human health criteria to Oregon's waters along with the methodology and input variables used by Oregon for their non-carcinogenic and carcinogenic criteria. This includes an evaluation of Oregon's revised fish consumption rate of 175 grams per day used to derive the State's new and revised human health criteria. Separate subsections include the EPA's action on Oregon's new methylmercury human health criteria and revised human health criteria for arsenic. Finally, this section outlines EPA's review and action on new, revised and withdrawn footnotes, withdrawn human health criteria which were replaced by more specific criteria and the Table 40 summary language.

Part V of this document contains EPA's review and action on revisions to Oregon's narrative statement at OAR 340-041-0033.

Parts VI and VII of the document contain EPA's review and approval of two implementation procedures included in the July 21, 2011 submittal – the background pollutant criteria and the revised variance provision.

Part VIII of this document includes EPA's review and action on a minor editorial change to Oregon's bacteria provision to correct a cross-referencing error.

Part IX discusses the revised rules regarding implementation of criteria by forestry and agricultural nonpoint sources. These provisions are not WQS under the CWA and therefore EPA is taking no action on them.

III. BACKGROUND

In 1999, ODEQ initiated a Water Quality Standards Review (triennial review) to update Oregon's criteria for toxic pollutants which were based on the 1986 EPA Gold Book[4] and that were contained in OAR 340-041-0033 and Table 20 of Oregon's water quality standards. This review was completed in 2003. During this review, ODEQ made significant revisions to both their aquatic life and human health criteria based on the updated EPA methodologies and science for deriving aquatic life and human health criteria that had occurred since the Gold Book had been published. The Commission adopted these new and revised water quality standards on May 20, 2004. Upon adoption, ODEQ submitted these criteria changes along with revisions to the narrative toxics provision to EPA on July 8, 2004.

One goal of Oregon's 1999-2003 WQS review was to update its human health criteria for toxic pollutants in order to reflect the latest scientific information and EPA's most recent national CWA § 304(a) human health criteria recommendations.[5] In 2000, EPA published a revised methodology for deriving § 304(a) human health criteria recommendations titled *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (hereinafter referred to as the "2000 Methodology").[6] In separate updates published in 2002 and 2003[7,8] along with 2009,[9] EPA updated the § 304(a) human health criteria recommendations to reflect this new methodology and to consider updated toxicological information in EPA's Integrated Risk Information System (IRIS).[10]

The new and revised human health criteria adopted by Oregon in 2004 were based on EPA's recommendations provided in these documents. The human health criteria were derived using a fish consumption rate of 17.5 grams per day (about 0.6 ounces per day or three 6-ounce meals per month), which represents the 90th percentile of consumption among consumers and non-consumers of fish nationwide. This is the national default fish consumption rate recommended

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[4] EPA. 1986. *Quality Criteria for Water* ("Gold Book"). U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 440/5-86-001. Available at: http://www.epa.gov/waterscience/criteria/library/goldbook.pdf

[5] ODEQ. 2003. *Toxic Compounds Criteria: 1999-2003 Water Quality Standards Review Issue Paper*. Oregon Department of Environmental Quality, Portland, Oregon. Available at: http://www.deq.state.or.us/about/eqc/agendas/attachments/may2004/5.20.04.ItemB.AttchH.pdf

[6] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

[7] EPA. 2002. *Revision of National Recommended Water Quality Criteria*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. *Federal Register*, Volume: 67, Issue: 249, Page: 79091 (67 FR 79091), December 27, 2002. Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2002/December/Day-27/w32770.htm

[8] EPA. 2003. *National Recommended Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. *Federal Register*, Volume: 68, Issue: 250, Page: 75507 (68 FR 75507), December 31, 2003. Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2003/December/Day-31/w32211.htm

[9] EPA. 2009. *EPA National Recommended Water Quality Criteria.* U.S. Environmental Protection Agency Office of Water. Office of Science and Technology. Available at: http://water.epa.gov/scitech/swguidance/standards/current/upload/nrwqc-2009.pdf

[10] EPA. *Integrated Risk Information System (IRIS).* U.S. Environmental Protection Agency, Office of Water, Washington, D.C. Available at: www.epa.gov/iris

by EPA in the 2000 Methodology for use when local, regional or other data is not available. During the public process Oregon received comment regarding concerns that the fish consumption rate used in the criteria may not accurately represent Oregonian's consumption patterns. Following review of these comments ODEQ recommended, and in 2004 the Commission adopted, criteria derived using a fish consumption rate of 17.5 grams per day. However, in recognition of this expressed public concern, the Commission requested that ODEQ seek resources to conduct a fish consumption rate study in Oregon.

Following Oregon's 2004 adoption of these criteria, the Confederated Tribes of the Umatilla Indian Reservation (Umatilla Tribe) and other tribal governments raised objections to EPA, stating that the criteria did not protect tribal members who eat higher amounts of fish and for whom fish consumption is a critical part of their cultural tradition and religion. In response, EPA evaluated the protectiveness of the criteria in light of local and regional fish consumption data and initiated discussions with Oregon regarding this issue. Local data was available from a study conducted by the Columbia River Inter-Tribal Fish Commission (CRITFC)[11] (hereinafter referred to as the "CRITFC Study"), which included surveys of four Columbia River Tribes, two of whom reside in Oregon, the Confederated Tribes of the Umatilla Indian Reservation (CTUIR or Umatilla Tribe) and the Confederated Tribes of the Warms Springs Reservation. In addition, several regional fish consumption studies were also available.

Oregon was not able to obtain funding for a study of Oregon fish consumption rates specific to Oregon but did agree to review available literature and data in collaboration with EPA and the Umatilla Tribe. In the fall of 2006, ODEQ launched the fish consumption rate review project involving seven public workshops and two workgroups. The workgroups were charged with providing ODEQ with information relative to the available science and the potential implementation and fiscal concerns that may be associated with criteria based on a higher fish consumption rate. The Human Health Focus Group (HHFG), made up of public health professionals and toxicologists, reviewed the available data on fish consumption patterns in the Pacific Northwest and elsewhere. The group wrote a report[12] summarizing the science and made recommendations about the quality and appropriate use of the available information. ODEQ considered the HHFG's analysis and the other information obtained during this project to select a fish consumption rate they felt appropriate for use in developing criteria for Oregon's waters.

Oregon addressed several issues during the process of determining an appropriate fish consumption rate for Oregon. These included:

- Which studies should be considered when developing a fish consumption rate for Oregon?
- Should the criteria be based on a fish consumption rate that includes Oregonians who

[11] Columbia River Inter-Tribal Fish Commission (CRITFC). October 1994. *A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin.* Technical Report 94.3. Available at: http://www.critfc.org/tech/94-3report.pdf

[12] ODEQ. June 2008. *Human Health Focus Group Report. Oregon Fish and Shellfish Consumption Rate Project.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/HHFGFinalReportJune2008.pdf

eat large amounts of fish and shellfish for cultural, economic, health or other reasons, or a fish consumption rate reflective of Oregon's total (general) population, including people who do not eat fish or eat it rarely?

- What proportion or percentile of the population(s) should be protected by the criteria? (Within any group, whether Native-Americans, Asian-Americans, commercial fishermen or the general population, there will be some individuals who eat more than any chosen rate and some who eat less than that rate.)
- How should the consumption of salmon (an anadromous fish) and/or marine fish be considered when determining the rate to be used for freshwaters?
- Should the same rate be used for all waters of Oregon or should multiple rates be considered based on known consumption patterns?

Following review of all the information obtained during the fish consumption rate review project, ODEQ determined that a fish consumption rate of 175 grams per day was a reasonable and protective fish consumption rate to use when driving the human health criteria applicable to Oregon's surface waters. A fish consumption rate of 175 grams per day equals approximately 6.2 ounces per day (or approximately 23 8-oz fish or shellfish meals per month). This rate represents the 95th percentile value from the CRITFC study and is within the range of the 90th percentile values from various studies from the Northwest assembled by the HHFG.[13] ODEQ found the 175 grams per day rate to be consistent with the HHFG recommendation to use 90th or 95th percentile values to represent the proportion of the population the criteria should be designed to protect. ODEQ also found the rate to be consistent with HHFG recommendations to use a fish consumption rate that represents fish consumers only, rather than a rate derived from the overall population including both consumers and non-consumers of fish, and to include salmon and other marine species in the rate. Finally, ODEQ recommended that the rate be applied statewide.[14]

On October 23, 2008, ODEQ presented the EQC with a recommendation to revise Oregon's toxics criteria for human health using a FCR of 175 grams per day.[15] The Commission agreed with this recommendation and directed ODEQ to:

1. Revise Oregon's toxics criteria for human health based on a fish consumption rate of 175 grams per person per day;

[13] EPA. June 1, 2010. Technical Support Document for Action on the State of Oregon's New and Revised Human Health Water Quality Criteria for Toxics and Revisions to Narrative Toxics Provisions Submitted on July 8, 2004. U.S. Environmental Protection Agency. See Appendix A for a summary of the studies considered by Oregon. Available at: http://www.epa.gov/region10/pdf/water/oregon-hhwqc-tsd_june2010.pdf

[14] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. pages 8-10. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf

[15] ODEQ. October 6, 2008. *Memo from Dick Pederson, Director ODEQ, to the Environmental Quality Commission. Agenda Item G, Action Item: Oregon's Fish Consumption Rate – For Use in Setting Water Quality Standards for Toxic Pollutants October 23, 2008 EQC Meeting.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/about/eqc/agendas/attachments/2008oct/ItemG.pdf

2. Propose rule language that will allow ODEQ to implement the standards in National Pollutant Discharge Elimination System (NPDES) permits and other Clean Water Act programs in an environmentally meaningful and cost-effective manner;
3. Propose rule language or develop other implementation strategies to reduce the adverse impacts of toxic substances in Oregon's waters that are the result of non-point source (not via a pipe) discharges or other sources not subject to section 402 of the Clean Water Act;
4. Develop a proposed rule and implementation methods that carefully consider the costs and benefits of the fish consumption rate and the data and scientific analysis already compiled or that is developed as part of the rulemaking proceeding.

Pursuant to this directive, ODEQ established a Rulemaking Workgroup in December 2008. The purpose of this group was to provide input and feedback to ODEQ as it developed its proposed rulemaking to revise human health criteria using the revised fish consumption rate and to address potential issues associated with implementing the revised criteria. The workgroup met on a monthly basis from December 2008 until October 2010. In addition, to address the third element of the EQC directive, ODEQ formed other workgroups to address the reduction of toxic pollution from sources not regulated by NPDES permits and to assist in the development of a comprehensive, cross media toxics reduction strategy.[16]

On December 21, 2010, ODEQ issued a proposed rule for public comment that included new and revised human health criteria for toxic pollutants, a revision to their variance rule, a new background pollutant provision and several proposed additions and revisions to rules relating to the implementation of the NPDES program and nonpoint source programs. As detailed in Section I, ODEQ revised the proposed rule in response to comments received, presented it to the Commission for adoption on June 16, 2011, and submitted it to EPA on July 21, 2011.

On June 1, 2010, consistent with a Consent Decree entered in the U.S. District Court in the District of Oregon,[17] EPA acted on the revised human health criteria which Oregon had submitted to EPA on July 8, 2004. As part of this action, EPA disapproved all of Oregon's new and revised human health criteria that were derived using a fish consumption rate of 17.5 grams per day as well as three footnotes associated with those criteria and footnote K insofar as it applies to the "organism only" human health criterion for manganese. EPA found that these human health criteria, derived using a fish consumption rate of 17.5 grams per day, were not protective of Oregon's designated use of fishing consistent with the Commission's October 2008 directive. In the June 1, 2010 letter to ODEQ, EPA stated that it "believe[d] that Oregon's adoption of human health criteria consistent with the Commission's Directive to develop criteria using a fish consumption rate of 175 grams per day statewide would be adequate to address EPA's disapproval of the new and revised human health criteria as well as [3 of the 4] footnotes."[18] As part of the 2010 action, EPA approved the human health criteria for asbestos

[16] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. pages 8-9. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf
[17] *Northwest Environmental Advocates v. U.S. EPA,* No. 06-479-HA (D. Or. 2006).
[18] EPA. June 1, 2010. Letter from Michael A. Bussell, Director, Office of Water and Watersheds, EPA Region 10 to Neil Mullane, Administrator, Water Quality Division, ODEQ, *Re: EPA's Action on New and Revised Human Health Water Quality Criteria for Toxics and Revisions to Narrative Toxics Provisions in Oregon's Water Quality*

and copper since those criteria value were not derived based on a fish consumption rate, footnote K as it applies to the "water + organism criteria for iron and manganese, the withdrawal of eight human health criteria, and revisions to the narrative toxic provisions at OAR 340-041-0033(1) and (2).

A. *ODEQ'S JULY 12 AND JULY 21, 2011 SUBMITTALS*

In order to address the Commission's October 2008 directive and EPA's June 1, 2010 disapproval action, on July 21, 2011 Oregon submitted new and revised numeric human health criteria and two WQS implementation provisions to EPA for action under CWA §303(c). This submission also contained a correction to a regulatory citation in the bacteria criteria provision and several other regulatory changes that are not WQS. Revised criteria for arsenic were adopted separately by the Commission on April 21, 2011 and submitted to EPA on July 12, 2011. All of the numeric criteria adopted in these actions were derived using a fish consumption rate of 175 grams per day.

The new and revised criteria, which serve as the basis for NPDES permit limits and other regulatory decisions, are located in Oregon's WQS in a new table called Table 40. ODEQ has consolidated the human health criteria which were previously contained in Tables 20, 33A and 33B into Table 40. The adoption of the new and revised human health criteria based on a fish consumption rate of 175 grams per day is ODEQ's remedy to EPA's disapproval of ODEQ's 2004 human health criteria based on a fish consumption rate of 17.5 grams per day.

Consistent with CWA §303(c)(2)(B), in adopting these new and revised human health criteria, Oregon has adopted human health criteria for all of the priority toxic pollutants for which EPA has published criteria under CWA §304(a). Forty-eight of the 104 pollutants for which Oregon adopted new or revised human health criteria are characterized as non-carcinogens (i.e., not having the potential to cause cancer). The remaining 56 pollutants are carcinogens (i.e., having the potential to cause cancer).

The calculations that Oregon used to derive the human health criteria for non-carcinogens and carcinogens differed depending upon the primary exposure pathway appropriate to the pollutant for which the criteria were derived and are further described separately in section IV below. Oregon's criteria were adopted to protect human health from chronic (lifetime) exposure to toxic substances through drinking water and eating fish[19] obtained from surface waters. Where the criteria are derived to protect human health from exposure through both drinking water and eating fish (in combination), Oregon has adopted "water + organism" criteria. Where the criteria are derived to protect human health from exposure through eating fish alone (not in combination with drinking water), Oregon has adopted "organism only" criteria. These two sets of criteria (i.e., "water + organism" and "organism only") are reflected in the column headings of Table 40

Standards. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/EPAHHLetter20100601.pdf
[19] As used throughout this technical support document, the term "fish" refers to finfish as well as shellfish.

in Oregon's WQS. Additional information can be found in ODEQ's Human Health Criteria Issue Paper.[20]

The criteria adopted by Oregon for methylmercury and arsenic were derived using variations to the methodology used for all other criteria. Thus, those two pollutants and the methods used to derive those criteria are addressed separately below.

Additional revisions related to the human health criteria, which are discussed below, include:

- The removal of 13 pollutants consistent with EPA's removal of 304(a) recommended criteria values for these same pollutants. Most of the previous criteria recommendations addressed families of pollutants for which the criteria recommendations were withdrawn when EPA developed criteria recommendations for the individual pollutants within each family of chemicals that present the greatest human health risk.
- Several new, revised and withdrawn footnotes to the criteria in order to provide clarification.
- Revisions to the water quality standards provision at OAR 340-041-0033 which provide narrative language explaining the human health and aquatic life criteria tables.

In response to the second, third and forth directives issued by the EQC on October 23, 2008, ODEQ also revised OAR 340-041 to include two WQS implementation provisions - a revised variance procedure and a site-specific background pollutant provision – and revised rule language addressing implementation for nonpoint sources. In addition, ODEQ adopted an intake credit rule (an NPDES permitting provision) and several changes to the TMDL rules in OAR 340-042 and 045. These latter changes were not submitted to EPA for consideration under CWA 303(c), are not WQS under the CWA, and are not addressed in this action.

[20] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf

IV. ODEQ'S NEW AND REVISED HUMAN HEALTH CRITERIA

A. *EPA REVIEW OF OREGON'S HUMAN HEALTH CRITERIA REVISIONS*

This section contains the basis for EPA's decisions under section 303(c) of the CWA and implementing regulations found at 40 CFR § 131.11 to approve Oregon's new and revised human health criteria. This section includes information regarding EPA's review of Oregon's human health criteria revisions which specifically evaluates the applicability of the human health criteria to Oregon's waters along with the methodology and input variables used by Oregon for their non-carcinogenic and carcinogenic criteria. This includes an evaluation of Oregon's revised fish consumption rate of 175 grams per day. Separate subsections address EPA's action on Oregon's new methylmercury human health criteria and revised human health criteria for arsenic. Finally, this section outlines EPA's review and action on new, revised and withdrawn footnotes, withdrawn human health criteria which were replaced by more specific criteria and the Table 40 summary language.

1. Human Health Criteria Applicability to Oregon's Waters

Oregon's water quality standards designate beneficial uses for waters of the state for each basin in OAR 340-041-0101 to 0340 and Tables 101(A) through 340(A), incorporated into Oregon rule by reference. Oregon's designated uses consist of the following:

- Public Domestic Water Supply
- Private Domestic Water Supply
- Industrial Water Supply
- Irrigation
- Livestock Watering
- Fish and Aquatic Life
- Wildlife and Hunting
- Fishing
- Boating
- Water Contact Recreation
- Aesthetic Quality
- Hydro Power
- Commercial Navigation and Transportation

Oregon's human health criteria were developed to protect human health from long-term exposure to toxic pollutants in drinking water and through eating fish and shellfish containing these pollutants. Waters to be protected for drinking water are those designated as either "Public Domestic Water Supply" or "Private Domestic Water Supply." Waters to be protected for consumption of fish and shellfish are designated as "Fishing."

Oregon's "water + organism" criteria were established to limit the pollutant to levels that protect the safe consumption of drinking water and fish, including shellfish. These criteria are applied where Oregon has designated public or private domestic water supply, and fishing as beneficial uses. Table 1 below identifies those waters in Oregon that have both a fishing designated use and either a public domestic water supply or a private domestic water supply designated use. Both the "water + organism" criteria and the "organism only" criteria apply to these waters.

The "organism only" criteria apply where Oregon has designated a fishing use but not a domestic or private water supply use.[21] Table 2 below identifies those waters in Oregon that have a fishing designated use but neither a public domestic water supply nor a private domestic water supply designated use.

Table 1: Waters in Oregon that have both a fishing designated use as well as a public domestic water supply or a private domestic water supply designated use. Both the "water + organism" criteria and the "organism only" criteria apply to these waters.

OR WQS Table No.	Basin Name	Segment Names
101A	Mainstem Columbia River	Columbia River (Mouth to RM 86); and Columbia River (RM 86 to 309)
121A	Mainstem Snake River	Snake River (RM 176 to 409)
130A	Deschutes Basin	Deschutes River Main Stem from Mouth to Pelton Regulating Dam; Deschutes River Main Stem from Pelton Regulating Dam to Bend Diversion Dam and for the Crooked River Main Stem; Deschutes River Main Stem above Bend Diversion Dam and for the Metolious River Main Steam; and All Other Basin Stems
140A	Goose and Summer Lakes Basin	Freshwater Lakes and Reservoirs; and Freshwater Streams
151A	Grande Ronde Basin	Main Stem Grande Ronde River (RM 39 to 165) and All Other Basin Waters
160A	Hood Basin	Hood River Basin Streams
170A	John Day Basin	John Day River and All Tributaries
180A	Klamath Basin	Klamath River from Klamath Lake to Keno Dam (RM 255 to 232.5); Lost River (RM 5 to 65) and Lost River Diversion Channel; and All Other Basin Waters
190A	Malheur Lake Basin	All Rivers and Tributaries

[21] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper*. Oregon Department of Environmental Quality. page 11. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf Also described in ODEQ. 2004. *Toxic Compounds Criteria. 1999-2003 Water Quality Standards Review. Issue Paper.* May 20-21, 2004 EQC Meeting. Agenda Item B, Rule Adoption: Water Quality Standards, including Toxics Criteria. Attachment H. Oregon Department of Environmental Quality. pages H-14, H-17. Available at: http://www.deq.state.or.us/about/eqc/agendas/attachments/may2004/5.20.04.ItemB.AttchH.pdf

OR WQS Table No.	Basin Name	Segment Names
201 A	Malheur River Basin	Malheur River from Namorf to Mouth; Malheur River from Beulah Dam and Warm Springs Dams to Namorf; Willow Creek from Brogan to Mouth; Willow Creek from Malheur Reservoir to Brogan; Bully Creek from Reservoir to Mouth; Malheur Reservoir, Bully Creek Reservoir, Beulah Reservoir, Warm Springs Reservoir; and Malheur River and Tributaries Upstream from Reservoirs
220A	Mid Coast Basin	Fresh Waters
230A	North Coast Basin	All Other Streams and Tributaries Thereto
250A	Owyhee Basin	Owyhee River (RM 0 to 18); Owyhee River (RM 18 to Dam); Antelope Reservoir, Cow Creek Reservoir, and Owyhee Reservoir; Owyhee River and Tributaries Upstream from Owyhee Reservoir; Main Stem of the South Fork of the Owyhee River from the Oregon-Idaho River border to Three Forks (the confluence of the North, Middle, and South Forks of Owyhee River); and Main Stem Owyhee River from Crooked Creek (RM 22) to the mouth of Birch Creek (RM 76)
260A	Powder/Burnt Basin	All Basin Waters
		Rogue River Main Stem from Estuary to Lost Creek Dam; Rogue River Main Stem above Lost Dam and Tributaries; and All Other Tributaries to Rogue River and Bear Creek
286A	Sandy Basin	Sandy River; and All Other Tributaries to Sandy River
300A	South Coast Basin	All Streams and Tributaries Thereto
310A	Umatilla Basin	Umatilla Sub-basin; Willow Creek Sub-basin; Umpqua River Main Stem from Head of Tidewater to Confluence of North and South Umpqua Rivers; North Umpqua River Main Stem; South Umpqua River Main Stem; and All Other Tributaries to Umpqua, North Umpqua, and South Umpqua Rivers
330A	Walla Walla Basin	Walla Walla River Main Stem from Confluence of North and South Forks to State Line; and All Other Basin Streams
340A	Willamette Basin	Main Stem Willamette River from Mouth to Willamette Falls, including Multnomah Channel; Main Stem Willamette River from Willamette Falls to Newberg; Main Stem Willamette River from Newberg to Salem; Main Stem Willamette River from Salem to Coast Fork; Clackamas River; Molalla River; Santiam River; McKenzie River; Tualatin River; and All Other Streams and Tributaries

Table 2: Waters in Oregon that have a fishing designated use but neither a public domestic water supply nor a private domestic water supply designated use. "Organism only" criteria apply to these waters.

OR WQS Table No.	Basin	Segment Name
140A	Goose and Summer Lakes Basin	Goose Lake; and Highly Alkaline and Saline Lakes
190A	Malheur Lake Basin	Natural Lakes
220A	Mid Coast Basin	Estuaries and Adjacent Marine Waters
230A	North Coast Basin	Estuaries and Adjacent Marine Waters
271A	Rogue Basin	Rogue River Estuary and Adjacent Marine Waters; and Bear Creek Main Stem
286A	Sandy Basin	Streams Forming Waterfalls Near Columbia River Highway
300A	South Coast Basin	Estuaries and Adjacent Marine Waters
320A	Umpqua Basin	Umpqua River Estuary to Head of Tidewater and Adjacent Marine Waters

Oregon's application of human health criteria is consistent with EPA's guidance to states and the methodology inherent in developing the criteria. EPA's *Water Quality Standards Handbook* recommends that states adopt human health criteria to protect waters designated for public water supply. In addition, for waters where fish ingestion is considered an important activity, EPA recommends that the criterion applicable to fish consumption be applied to protect the use.[22] Oregon's human health criteria are applied consistent with this recommendation.

EPA has published guidelines for developing criteria that protect human health endpoints and separate criteria guidance to protect aquatic life endpoints. Consistent with the science used to derive the criteria, EPA recommends that human health criteria be applied to uses where human health could be affected by exposure from consumption of water and/or aquatic life and aquatic life criteria be applied to uses associated with the protection of aquatic life. Thus, most states, including Oregon, have adopted two sets of criteria for toxic pollutants, one to address the effects to human health and the other to address the effects to aquatic life. For some pollutants, this results in a waterbody segment having multiple criteria for a single pollutant, in which case the WQS require the attainment of all of the applicable criteria.

Oregon's human health criteria are developed pursuant to methods presented in EPA's 2000 Human Health Methodology.[23] These criteria take into consideration the cancer potency or systemic toxicity of a pollutant, the exposure related to surface water exposure and a risk characterization. The criteria generated pursuant to the 2000 Human Health Methodology protect humans from toxicological effects from chronic exposure to a pollutant through drinking water or from eating fish living in a water body to which the criteria apply.

[22] EPA. 1994. *Water Quality Standards (WQS) Handbook: Second Edition.* August 1994. United States Environmental Protection Agency, Office of Water. EPA-823-B-94-005a. page 3-15. Available at http://water.epa.gov/scitech/swguidance/standards/handbook/index.cfm

[23] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. EPA-822-B-00-004. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

EPA's guidance for developing aquatic life criteria recommends that such criteria use toxicity information for aquatic life, establishing pollutant levels necessary for protection of aquatic life from both short and long term effects of the pollutant.[24] Toxicity tests are used to evaluate pollutant effects on survival, growth and reproduction of aquatic organisms.

EPA has reviewed Oregon's new and revised human health criteria in order to assess whether they are sufficient to protect Oregon's designated uses from human health impacts associated with the pollutants for which they were adopted. Other endpoints and uses (e.g., Fish and Aquatic Life) are addressed by other provisions in Oregon's WQS and are not before the Agency for review under § 303(c)(3) of the CWA as part of this action.

2. Non-Carcinogens: Criteria Methodology and Input Variables Used by Oregon[25]

EPA's 2000 Human Health Methodology provides guidance for deriving human health criteria for toxic pollutants.[26] Pursuant to Section 304(a) of the CWA, EPA has published a table of recommended criteria for use by states in adopting and revising criteria.[27] For each pollutant, this table also identifies whether EPA recommends the methodology specific to carcinogens or non-carcinogens, based on information relative to the human health endpoints of greatest significance.[28] For criteria recommendations for non-carcinogens, the values in this table reflect criteria derived using the 'national default' values identified in the 2000 Methodology: the reference dose (RfD) contained in the Integrated Risk Information System (IRIS) at the time of publication; the use of EPA's recommended bioconcentration factors (BCFs) (as opposed to site-specific bioaccumulation factors (BAFs)); and relative source concentration factors (RSC) as provided by the latest 304(a) recommendations.

While the 2000 Methodology provides national default values, it also provides guidance necessary to adjust criteria to reflect local conditions and encourages states to use the guidance to appropriately reflect local conditions and/or protect identifiable subpopulations.[29] Numerous states have adopted criteria derived through the use of site-specific input variables instead of the national default values, thus ensuring the criteria are protective of the human health uses

[24] EPA. 1985. *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses.* Available at: http://water.epa.gov/scitech/swguidance/standards/criteria/aqlife/upload/85guidelines.pdf
[25] For methylmercury, Oregon used an alternate approach that will be addressed in a separate section.
[26] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. EPA-822-B-00-004. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf
[27] EPA. *National Recommend Ambient Water Quality Criteria for the Protection of Aquatic Life and Human Health.* Published pursuant to section 304(a) of the Clean Water Act. Available at: http://www.epa.gov/waterscience/criteria/wqctable/index.html
[28] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004. pages 1-3. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf
[29] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004. pages iii, 1-11. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

designated in the waters where those criteria apply.

Criteria calculated pursuant to the 2000 Methodology are derived by applying a number of pollutant-specific and general risk-assessment values to an equation that generates a criteria protective of human health uses. Where a state uses this equation to develop criteria, the protectiveness of those criteria are dependent on whether the values used for each input variable are appropriate for protection of the uses specific to a pollutant and/or waterbody. With the exception of the methylmercury criterion, Oregon has directly applied this equation when deriving the new or revised human health criteria for the non-carcinogenic pollutants included in EPA's 2009 table of 304(a) criteria recommendations.[30] A simplified version of this equation is provided in Figure A below, followed by a discussion of the variables in the equation and the values utilized by Oregon to derive their new and revised criteria, and supporting information provided by Oregon. EPA's review of the protectiveness of the criteria is contained in a later subsection.

Figure A: Simplified version of the equation used by Oregon in deriving the human health criteria for non-carcinogens.

$$AWQC = RfD \bullet RSC \bullet \frac{(BW)}{[DI + (FCR \bullet BAF)]}$$

where:

AWQC	=	Ambient Water Quality Criterion (milligrams per liter)
RfD	=	Reference dose for noncancer effects (milligrams per kilogram per day)
RSC	=	Relative source contribution factor to account for non-water sources of exposure (unitless)
BW	=	Human body weight (kilograms)
DI	=	Drinking water intake (liters per day)
FCR	=	Fish Consumption Rate (kilograms per day)
BAF	=	Bioaccumulation factor (liters per kilogram)

a) Reference Done (RfD)

For non-carcinogens, EPA's 2000 Methodology recommends deriving human health criteria using a reference dose. A reference dose is defined as "an estimate (with uncertainty spanning approximately an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects over a lifetime."[31] In other words, individuals should not suffer from appreciable risks of deleterious effects if their exposure to a chemical is at or below the reference dose for that chemical. Thus,

[30] EPA. 2009. *EPA National Recommended Water Quality Criteria.* U.S. Environmental Protection Agency Office of Water. Office of Science and Technology. Available at: http://water.epa.gov/scitech/swguidance/standards/current/upload/nrwqc-2009.pdf

[31] EPA. 1993. *Reference Dose (RfD): Description and Use in Health Risk Assessments. Integrated Risk Information System (IRIS).* Intra-Agency Reference Dose (RfD) Work Group, Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, U.S. Environmental Protection Agency, Cincinnati, OH. Available at: http://www.epa.gov/ncea/iris/rfd.htm

the reference dose serves as a threshold level and is specific to each individual pollutant.

In deriving both the "water + organism" and "organism only" criteria for non-carcinogens, Oregon utilized the most recent reference doses recommended by EPA's current § 304(a) criteria.

b) Body Weight (BW)

Oregon used EPA's national default value of 70 kilograms for the body weight as recommended in the 2000 Methodology. The source of data for the human body weight value of 70 kilograms is the *National Health and Nutrition Examination Survey* (NHANES) conducted between 1988 and 1994 using a nationwide probability sample of over 30,000 persons. Body weights of 73 percent of those individuals included in the survey were carefully measured by survey staff (i.e., weights were not self-reported). The mean body weight value for men and women ages 18-74 years old from this survey was 75.6 kilograms. Another survey by the National Cancer Institute measured a mean body weigh value of 70.5 kilograms for adults aged 20-64 years old, and EPA's *Exposure Factors Handbook* recommends 71.8 kilograms for adults based on an earlier NHANES survey.[32] While these data are slightly higher than 70 kilograms, the derivation of cancer slope factors identified in EPA's IRIS database are based upon a body weight of 70 kilograms. Since consistency is advocated between the dose-response relationship and the exposure factors, a default value of 70 kilograms was recommended by EPA for use in deriving human health water quality criteria.[33]

c) Drinking Water Intake Rate (DI)

Oregon used EPA's national default value of two liters per day for the drinking water intake rate as recommended in the 2000 Methodology. This rate was based on the 1994-1996 *Continuing Survey of Food Intake by Individuals* (hereinafter referred to as the "CSFII survey") conducted by the U.S. Department of Agriculture. This rate represents the 86th percentile of drinking water intake data for adults collected from the CSFII survey.[34] While this rate was utilized for "water + organisms" criteria, a drinking water intake rate of zero liters per day was used for "organism only" criteria because the criteria are not intended to address human health effects from the consumption of drinking water.

d) Bioaccumulation/Bioconcentration Factor (BAF/BCF)

Bioconcentration factors (BCF) describe the uptake and retention of a pollutant by an aquatic organism from water only while bioaccumulation factors (BAF)describe the uptake and retention of a pollutant by an aquatic organism from all sources (e.g., water, ingestion, and sediment). The

[32] EPA. 1997. *Exposure Factors Handbook*. U.S. Environmental Protection Agency, National Center for Environmental Assessment, Office of Research and Development, Washington, D.C. EPA/600/P-95/002Fa. Available at: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12464
[33] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004. pages 4-18 to 4-19. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf
[34] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004. pages 4-21 to 4-22. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

magnitude of bioconcentration or bioaccumulation by aquatic organisms varies widely depending upon the pollutant but can be extremely high for some highly persistent and hydrophobic pollutants. For highly bioaccumulative pollutants, concentrations in aquatic organisms may pose unacceptable human health risks from fish consumption even when concentrations in water are too low to cause unacceptable health risks from drinking water consumption alone. EPA's 2000 Human Health Methodology recommends the use of national BAFs in the calculation of ambient water quality criteria. However, to date, EPA has only provided guidance on the calculation of national BAFs. BAF values have not been calculated for individual pollutants. EPA uses bioconcentration factors in their nationally recommended criteria. As explained below, States have the option to use these BCFs or to calculate BAFs using guidance documents published by EPA.

EPA's 2000 Human Health Methodology provides guidance on developing bioaccumulation factors for the protection of human health.[35] A subsequent technical support document to the 2000 Methodology entitled *Technical Support Document Volume 2: Development of National Bioaccumulation Factors* (2003) provides added detail to the BAF calculation procedures outlined in the Methodology.[36] In 2009, EPA published the *Technical Support Document Volume 3: Development of Site-Specific Bioaccumulation Factors.* This document provides guidance on different approaches that investigators can take to develop site-specific BAFs, and the factors that should be considered when selecting an approach for a given situation.[37]

EPA recommends that states use these methods when adopting human health criteria. Neither of the bioaccumulation technical support documents should be used alone to derive BAFs but should be used in conjunction with the 2000 Human Health Methodology. The bioaccumulation methodology documents encourage developing site-specific BAFs because EPA recognizes that BAFs vary not only between chemicals and trophic levels, but also among different ecosystems and waterbodies. National average BAF values for a given chemical and trophic level may not provide the most accurate estimate of bioaccumulation for certain water bodies in the United States. At a given location, the BAF for a chemical may be higher or lower than the national BAF, depending on the nature and extent of site-specific influences.

While EPA's 2000 Human Health Methodology recommends the use of bioaccumulation factors in deriving human health criteria, development of bioaccumulation factors is a time and resource intensive process and BAFs can vary from site-to-site. Thus, it is difficult to develop BAFs on a national or statewide scale and this has rarely been done. Therefore, until such time as

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[35] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. Section 5. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

[36] EPA. December 2003. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000).* Technical Support Document Volume 2: Development of National Bioaccumulation Factors. Available at: http://water.epa.gov/scitech/swguidance/standards/upload/2005_05_06_criteria_humanhealth_method_tsdvol2.pdf

[37] EPA. September 2009. *Methodology for Deriving Ambient Water Quality Criteria for Protection of Human Health (2000).* Technical Support Document Volume 3: Development of Site-Specific Bioaccumulation Factors. Available at: http://water.epa.gov/scitech/swguidance/standards/criteria/health/methodology/upload/2008_07_01_criteria_human health_method_tsdvol3.pdf

bioaccumulation factors are developed, EPA's national CWA § 304(a) human health criteria guidance values continue to be based upon the use of bioconcentration factors which reflect the uptake and retention of a pollutant by an aquatic organism from water alone. Given the lack of any Oregon-specific BAFs and consistent with EPA guidance, Oregon utilized bioconcentration factors instead of bioaccumulation factors in deriving its new and revised human health criteria. The bioconcentration factors utilized by Oregon are pollutant-specific and are consistent with the bioconcentration factors recommended by EPA in the most recent national CWA § 304(a) human health criteria recommendations.

e) Fish Consumption Rate (FC)

When establishing a single value/criterion as a regulatory endpoint, States and EPA must make several policy decisions relative to the members of the population that will be protected when using the waters for activities protected by the designated uses and the established criteria. In EPA's 2000 Human Health Methodology, EPA provides guidance to the States on the use of local and regional data to develop an appropriate fish consumption rate for the use in criteria derivation and encourages the states to use this data to determine the level of protection appropriate for State waters.

Between 2006 and 2008 Oregon conducted extensive outreach and information gathering and consulted with a group of public health experts (the Human Health Focus Group (HHFG)) in order to inform their decision-making regarding an appropriate fish consumption rate for use in developing human health criteria for Oregon. Based on the information gathered in this effort and the review of available fish consumption studies, ODEQ concluded that a fish consumption rate of 175 grams per day (about 23, 8 ounce fish meals per month) is a protective rate to use as the basis for Oregon's human health criteria. Oregon found that this rate reflected the goal of providing sufficiently clean water in the state such that people who wish to regularly eat fish for cultural, health or economic reasons may do so without risk of adverse health effects due to contaminants contained in the fish.[38]

Further detail regarding Oregon's process, information considered and the decision to use a fish consumption rate of 175 grams per day is available in Oregon's Human Health Criteria Issue Paper and the Human Health Focus Group Report and outlined in a separate EPA memo.[39]

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[38] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. page 21. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf
ODEQ. June 2, 2011. Memorandum from Dick Pedersen to Environmental Quality Commission; *Agenda item C, Rule adoption: Revised water quality standards for human health and revised water quality standards implementation policies,* June 15-17, EQC meeting. Oregon Department of Environmental Quality. page 5. Available at: http://www.deq.state.or.us/about/eqc/agendas/attachments/2011june/C-WQStdsStaffRpt.pdf

[39] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. At: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf
ODEQ. June 2008. *Human Health Focus Group Report. Oregon Fish and Shellfish Consumption Rate Project.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/HHFGFinalReportJune2008.pdf
EPA. October 17, 2011. Memorandum from Jannine Jennings to Record. *Fish Consumption Rate Analysis – Oregon's New and Revised Human Health Water Quality Criteria for Toxics and Associated Implementation Provisions Submitted July 12 and 21, 2011.*

f) Relative Source Contribution (RSC)

Criteria for pollutants that are non-carcinogens are based on a total cumulative dose over time that causes an observable effect. Because the human health water quality criteria address exposure only through drinking water and eating fish and not from other sources (e.g. skin absorption, inhalation, other foods and occupational exposure), a relative source contribution (RSC) factor is used to calculate the criteria. The RSC represents the proportion of exposure from water and fish relative to the total exposure (including water and fish - and other exposures such as air, food, dermal, etc.). This estimate allows for adjustment of the criteria value to reflect exposure from only water and fish. This is intended to make sure that the total exposure from all sources does not exceed the reference dose for lifetime exposure.

Developing an RSC value for a pollutant requires an evaluation of both the sources of potential exposure and quantifying the relative exposure from each source. EPA has derived RSC values for 17 of the pollutants with 304(a) recommended human health criteria. Most of these RSC values were developed by EPA's drinking water program under the Safe Drinking Water Act.

Oregon used 15 of the 17 RSC values recommended by EPA. These 15 RSC values are listed in table 5 below. Oregon chose to use RSC values that vary from those recommended by EPA for endrin (80% instead of 20%, discussed in more detail below) and methylmercury (a value of zero instead of 2.7×10^{-5} mg methylmercury/kg/day, discussed in the methylmercury section below).

Table 5: Criteria where Oregon applied EPA's recommended RSC values.

Pollutant	RSC Value
Antimony	40%
Chlorobenzene	20%
Chlorodibromomethane	80%
Cyanide	20%
Ethylbenzene	20%
gamma-BHC (Lindane)	20%
Hexachlorcyclopentadiene	20%
Thallium	20%
Toluene	20%
1,1,2-Trichloroethane	20%
1,1-Dichloroethylene	20%
1,2,4-Trichlorobenzene	20%
1,2-Dichlorobenzene(o)	20%
1,2-trans-Dichloroethylene	20%
1,4-Dichlorobenzene(p)	20%

RSC for Endrin

EPA's recommended RSC value of 20% for endrin was developed by the drinking water program and takes into account exposure through multiple pathways. Endrin is a pesticide that was banned under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in the 1980s, thus limiting current sources of exposure. Following the review of available data and

information, ODEQ determined that an RSC of 80% was appropriate for use in deriving the human health criteria for endrin.[40] Oregon's rationale is described below.

Due to the chemical properties of endrin and its prohibition by FIFRA in the 1980s, ODEQ believes it is unlikely that people in Oregon would gain only 20% of their exposure from water and fish while gaining 80% of their exposure from other sources identified in the RSC calculation performed by EPA and used in EPA's recommended 304(a) criteria.[41] The 80% RSC calculation for endrin used by Oregon accounts for the two main sources of exposure which they considered to have a potential to impact human health in Oregon: (1) drinking water and (2) the bioconcentration of endrin in aquatic organisms and thus potential accumulation in fish tissue. ODEQ found that the other sources or routes of exposure to endrin considered by EPA were not expected to occur in Oregon for the following reasons:

> 1) The use of endrin has been banned in the US since the 1980s. Endrin is not mobile in soil, it volatizes into the air rapidly, and has a conservative half life estimate in soil of 14 years.
>
> 2) The U.S. Food and Drug Administration concluded in 1995 that exposure to endrin through food products was no longer a concern, thus reducing concerns regarding exposure to endrin from food sources.
>
> 3) The one possible route of exposure to endrin that was identified in the literature was at hazardous waste sites where endrin has been detected in contaminated soils; however, no such sites were identified in Oregon. [42,43]

Based on the above considerations, Oregon found that human health exposure to endrin through routes other than fish tissue and drinking water is unlikely. In addition, although endrin bioconcentrates in aquatic organisms, it is not very soluble in water and therefore is not likely to be found in drinking water sources. Since the bioconcentration factor used to derive the human health criteria is very high (3970), the endrin criteria values for "water + organism" and "organism only" are the same when rounded to significant digits.[44] Therefore, Oregon concluded that the primary routes of exposure for endrin are anticipated to be through

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[40] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. pages 14-15. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf

[41] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. pages 14-15. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf

[42] U.S. Department of Health and Human Services. August 1996. *Toxicological Profile for Endrin.* Public Health Service. Agency for Toxic Substances and Disease Registry. Available at: http://www.atsdr.cdc.gov/toxprofiles/tp89.pdf

[43] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. pages 14-15. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf

[44] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. pages 14-15. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf

bioconcentration in aquatic organisms and its accumulation in fish tissue. These two exposure routes have already been accounted for through the BCF and fish consumption rate.

The purpose of the RSC is to ensure that the level of a chemical allowed by a criterion or multiple criteria, when combined with other identified sources of exposure common to the population of concern, will not result in exposures that exceed the RfD.[45] Where a state reviews exposure data and develops an alternate RSC value, EPA recommends that the RSC not be lower than 20% or higher than 80%.[46] Where it can be demonstrated that other sources and routes of exposure are not anticipated for the chemical in question (based on information about its known/anticipated uses and chemical/physical properties), EPA recommends a ceiling of 80%. This 80% ceiling is a way to provide adequate protection for those who experience exposures (from any or several sources) higher than available data may indicate.[47] Oregon adjusted the RSC value for endrin to 80% consistent with this guidance.[48]

3. Carcinogens: Criteria Methodology and Input Variables Used by Oregon[49]

As noted above, EPA's 2000 Methodology provides guidance for deriving human health criteria for toxic pollutants[50] and has published a table of recommended criteria for use by states in adopting and revising criteria.[51] For human health criteria, the values in this table reflect criteria derived using all of the 'national default' values identified in the 2000 Methodology, the reference dose (RfD) contained in the Integrated Risk Information System (IRIS) at the time of publication, the use of EPA's recommended bioconcentration factors (BCFs), relative source contribution factors (RSC) as provided by the latest 304(a) recommendations and a 10^{-6} carcinogenic risk factor. While the 2000 Methodology provides national default values, it also provides necessary guidance to adjust criteria to reflect local conditions and encourages states to use the guidance to appropriately reflect local conditions and/or protect identifiable subpopulations.[52] Numerous states have adopted criteria derived through the use of site-specific input variables or a carcinogenic risk level other than $1x10^{-6}$.

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[45] November 3, 2000. *Federal Register*, Volume: 65, Issue: 214, pages: 66472-3 (65 FR 66472-3). Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2000/November/Day-03/w27924.htm
[46] November 3, 2000. *Federal Register*, Volume: 65, Issue: 214, pages: 66472-3 (65 FR 66472-3). Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2000/November/Day-03/w27924.htm
[47] November 3, 2000. *Federal Register*, Volume: 65, Issue: 214, pages: 66472-3 (65 FR 66472-3). Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2000/November/Day-03/w27924.htm
[48] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. pages 14-15. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf
[49] Note: For arsenic, Oregon used an alternate approach that will be addressed in section IV.E of this document.
[50] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf
[51] EPA. *National Recommend Ambient Water Quality Criteria for the Protection of Aquatic Life and Human Health.* Published pursuant to section 304(a) of the Clean Water Act. Available at: http://www.epa.gov/waterscience/criteria/wqctable/index.html
[52] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004. pages iii, 1-11. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

For carcinogens, EPA's 2000 Methodology recognizes that states have the flexibility to adopt human health criteria within a risk level range of 1×10^{-6} to 1×10^{-5}, as long as highly exposed populations would at least be protected at the 1×10^{-4} (1:10,000) risk level. Furthermore, the 2000 Methodology recognizes that states have the flexibility to adopt human health criteria that protect the general population at a more protective risk level or target the protection of a higher proportion of its population at the targeted risk level. Oregon's new and revised criteria for carcinogens (except arsenic) target the protection of high consumers at the 1×10^{-6} risk level through the use of a fish consumption rate representative of the 95th percentile consumption from a study of a highly exposed subpopulation.

EPA's 2000 Methodology describes procedures that can be used as guidance by states for deriving human health water criteria. The 2000 Methodology includes an equation that Oregon used in deriving the "water + organism" and "organism only" new and revised human health criteria for 56 carcinogens. A simplified version of this equation is provided below in Figure B. Descriptions of the variables included in these equations, and the values that Oregon utilized for each variable, are also provided below.

Figure B: Simplified version of the equation used by Oregon in deriving the human health criteria for carcinogens.

$$AWQC = \frac{(Risk\ Level \bullet BW)}{[CSF \bullet (DI + (FCR \bullet BAF))]}$$

where:

AWQC	=	Ambient Water Quality Criterion (milligrams per liter)
Risk Level	=	Risk level (unitless)
CSF	=	Cancer slope factor (milligrams per kilogram per day)
BW	=	Human body weight (kilograms)
DI	=	Drinking water intake (liters per day)
FCF	=	Fish Consumption Rate (kilograms per day)
BAF	=	Bioaccumulation factor (liters per kilogram)

a) Body Weight, Drinking Water Intake Rate, Bioaccumulation/Bioconcentration Factor and Fish Consumption Rate

Four of the input variables used by Oregon in deriving its numeric human health water quality criteria for carcinogens are the same as those used by Oregon in deriving its numeric human health water quality criteria for non-carcinogens. A body weight of 70 kilograms and a drinking water intake of two liters per day were used, consistent with the default values that EPA utilized in deriving its national CWA § 304(a) human health criteria guidance values. Oregon also used bioconcentration factors consistent with those used by EPA in deriving its national CWA § 304(a) human health criteria guidance values.

Consistent with the criteria for non-carcinogens, a fish consumption rate of 175 grams per day was used in deriving the new and revised human health criteria for carcinogens. This value was

used by Oregon following an evaluation of local and regional data (discussed in greater detail above).

b) Cancer Slope Factor

For toxic pollutants identified as carcinogens and assumed to exhibit a linear dose-response relationship at low doses, EPA derives its national CWA § 304(a) human health criteria recommendations to correspond to incremental lifetime cancer risk levels, applying a risk management policy that ensures a reasonable level of protection for the general population.[53] Accordingly, a cancer slope factor is included in the calculation. A cancer slope factor expresses incremental, lifetime risk of cancer as a function of the rate of intake of the contaminant, and is combined with exposure assumptions to express that risk in terms of an ambient water concentration. Cancer slope factors are specific to individual pollutants. In deriving both the "water + organism" and "organism only" human health criteria for carcinogens, Oregon utilized the cancer slope factors recommended by EPA.

c) Carcinogenic Risk Level

EPA has identified a risk level range of 1 x 10^{-6} (1:1,000,000) to 1 x 10^{-5} (1:100,000) to be an appropriate risk management goal for the general population. EPA characterizes this acceptable risk range as the "upper-bound estimate of excess lifetime cancer risk," ranging from one case in a population of one million to one case in a population of one hundred thousand. The nationally recommended 304(a) criteria are intended to protect the general population at a cancer risk of 1 x 10^{-6}.

EPA's 2000 Methodology states that criteria based on a 10^{-5} risk level are acceptable for the general population as long as States and authorized Tribes ensure that the risk to more highly exposed subgroups (sport fishers or subsistence fishers) does not exceed the 10^{-4} risk level. If a state does not find that the 1 x 10^{-6} risk level adequately protects highly exposed populations, it has the flexibility to adopt water quality criteria based on a more stringent risk level or at a level more representative of highly exposed population groups. This flexibility extends to all variables used to calculate the criteria. [54]

Except where specifically identified, Oregon's new and revised human health criteria for carcinogens are calculated using a risk level of 1 x 10^{-6} (1:1,000,000). As discussed earlier, these criteria include the use of a fish consumption rate of 175 grams per day, a level representative of high fish consumers in the state. Oregon's goal in adopting the criteria was to protect high end consumers (as opposed to the general population) at a risk level of 10^{-6}.

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[53] EPA. 2000. *Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. *Federal Register*, Volume: 65, Issue: 214, page: 66443 (65 FR 66443), November 3, 2000. Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2000/November/Day-03/w27924.htm

[54] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 822-B-00-004. page 2-6. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

4. EPA Review of Input Variables for All New and Revised Human Health Criteria except Methylmercury and Arsenic[55]

As discussed above, EPA's 2000 Human Health Methodology provides guidance for deriving human health criteria for toxic pollutants. For each variable used in the criteria calculation, EPA provides a "national default value" and guidance on specific adjustments that may be necessary to reflect local conditions and/or protect identifiable subpopulations. As part of evaluating whether Oregon's criteria protect the designated uses, EPA looked at the input values used by Oregon and whether there was Oregon-specific information relative to each value that should be considered in the review.

EPA has not identified any local or regional data to indicate that the national values used by Oregon for the reference dose, relative source contribution, body weight, drinking water intake rate, or bioaccumulation factors are inappropriate for use in Oregon.

EPA's review indicates that there is local and regional fish consumption data available and that it should be considered consistent with EPA's 2000 Methodology. The 2000 Methodology recognizes the variability of fish consumption rates among population groups and by geographic region. In employing the 2000 Methodology to derive criteria, EPA urges States and Tribes to use a fish intake level derived from local or regional data instead of the national default recommendation to ensure the fish intake level chosen is protective of highly exposed subpopulations. A four preference hierarchy concerning the use of fish consumption rate data is set forth: (1) use of local data; (2) use of data reflecting similar geography/population groups; (3) use of data from national surveys; and (4) use of EPA's default intake rate.

As discussed in greater detail above, in 1996 Oregon initiated an extensive review of the fish consumption rate used for deriving its human health criteria. This process resulted in ODEQ and the Commission determining that a fish consumption rate of 175 grams per day was a reasonable and protective fish consumption rate to use as the basis for Oregon's human health criteria. EPA has reviewed the available information and the basis for ODEQ's determination and has found that Oregon has considered all relevant local and regional data, applied that data consistent with EPA's 2000 Methodology to select a fish consumption rate that would result in a level of protection consistent with that recommended by EPA in the 2000 Methodology. Thus, EPA finds that the FCR utilized to derive Oregon's criteria is consistent with EPA's recommendations in the 2000 Methodology.

B. *EPA ACTION ON ODEQ'S NEW HUMAN HEALTH CRITERIA*

ODEQ has adopted new human health criteria for 41 pollutants (excluding methylmercury which is discussed in further detail below). Previously, Oregon did not have EPA-approved values for these criteria in their WQS. These new criteria, found in Table 40 of Oregon's WQS, are

[55] Methylmercury and arsenic are addressed in sections IV.D and IV.E of this document.

consistent with EPA's current 304(a) criteria recommendations and utilize the 175 grams per day fish consumption rate.

Table 6: Oregon's new human health criteria.

No.	Pollutant	Carcinogen	Water + Organism (µg/L)	Organism Only (µg/L)
1	Acenaphthene		95	99
2	Anthracene		2900	4000
3	Benzo(a)anthracene	✓	0.0013	0.0018
4	Benzo (a)pyrene	✓	0.0013	0.0018
5	Benzo(b)fluoranthene 3,4	✓	0.0013	0.0018
6	Benzo(k)fluoranthene	✓	0.0013	0.0018
7	Bromoform	✓	3.3	14
8	Butylbenzyl phthalate		190	190
9	Chlorobenzene		74	160
10	Chlorodibromomethane	✓	0.31	1.3
11	Chloronaphthalene 2		150	160
12	Chlorophenol 2		14	15
13	Chrysene	✓	0.0013	0.0018
14	DDD 4,4'	✓	0.000031	0.000031
15	DDE 4,4'	✓	0.000022	0.000022
16	DDT 4,4'	✓	0.000022	0.000022
17	Dibenzo(a,h)anthracene	✓	0.0013	0.0018
18	Dichlorobenzene(o) 1,2		110	130
19	Dichlorobenzene(p) 1,4		16	19
20	Dichlorobromomethane	✓	0.42	1.7
21	Dichloroethylene 1,1		230	710
22	Dichloroethylene trans 1,2		120	1000
23	Dichloropropane 1,2	✓	0.38	1.5
24	Dimethylphenol 2,4		76	85
25	Dinitrophenol 2,4		62	530
26	Dinitrophenols		62	530
27	Diphenylhydrazine 1,2	✓	0.014	0.020
28	Endosulfan alpha		8.5	8.9
29	Endosulfan beta		8.5	8.9
30	Endosulfan sulfate		8.5	8.9
31	Endrin aldehyde		0.030	0.030
32	Fluorene		390	530
33	Heptachlor epoxide	✓	0.0000039	0.0000039
34	Indeno(1,2,3-cd)pyrene	✓	0.0013	0.0018
35	Methyl bromide		37	150
36	Methyl-4,6-dinitrophenol 2		9.2	28
37	Methylene chloride	✓	4.3	59
38	Nitrosodi-n-propylamine, N	✓	0.0046	0.051
39	Pyrene		290	400
40	Trichlorobenzene 1,2,4		6.4	7.0
41	Zinc		2100	2600

EPA Approval
In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves Oregon's new human health toxic criteria for these 41 pollutants that are consistent with EPA's current CWA § 304(a) criteria recommendations because they are protective of Oregon's fishing and water supply designated uses.

EPA Rationale
EPA's WQS regulations at 40 C.F.R. 131 require that criteria protect the designated uses. As noted previously, Oregon's human health criteria apply to waters with fishing and water supply uses and thus must be established at a level that will protect those uses. Therefore, EPA must evaluate whether the criteria protect Oregon's human health uses.

EPA's 2000 Human Health Methodology provides guidance for deriving human health criteria for toxic pollutants. For each variable used in the criteria calculation, EPA provides a "national default value" and guidance on specific adjustments that may be necessary to reflect local conditions and/or protect identifiable subpopulations. As part of evaluating whether Oregon's criteria protect the designated uses, EPA looked at the input values used by Oregon and whether there was Oregon-specific information relative to each value that should be considered in the review. As discussed above EPA has found that ODEQ has appropriately considered local and regional data in selecting input variables for use in deriving the criteria identified in Table 6.

The 2000 Methodology document provides an extensive technical basis and justification as to how EPA's recommended human health criteria adequately protect human health uses. Oregon's new criteria were developed consistent with these recommendations, therefore, EPA has determined that Oregon's new criteria protect human health uses in accordance with 40 C.F.R. Part 131.11(a)(1).

C. *EPA ACTION ON ODEQ'S REVISED HUMAN HEALTH CRITERIA*

ODEQ has adopted revised human health criteria for 62 pollutants (excluding arsenic which is described in further detail below). These revised criteria, found in Table 40 of Oregon's WQS, are consistent with EPA's current 304(a) criteria recommendations and utilize the 175 grams per day fish consumption rate.

Table 7: Oregon's revised human health criteria.

No.	Pollutant	Carcinogen	Water + Organism (µg/L)	Organism Only (µg/L)
1	Acrolein[56]		0.88	0.93
2	Acrylonitrile	✓	0.018	0.025
3	Aldrin	✓	0.0000050	0.0000050
4	Antimony		5.1	64

[56] Based on June 10, 2009 updates to EPA's IRIS system, Oregon's previous ADI value of 15.6 ug/kgram per day was replaced with an RfD value of 5.0 x 10^{-4}. EPA. *Integrated Risk Information System (IRIS).* U.S. Environmental Protection Agency, Office of Water, Washington, D.C. Available at: www.epa.gov/iris

No.	Pollutant	Carcinogen	Water + Organism (µg/L)	Organism Only (µg/L)
5	Benzene	✓	1.6	5.1
6	Benzidine	✓	0.000018	0.000020
7	BHC Alpha	✓	0.00045	0.00049
8	BHC Beta	✓	0.0016	0.0017
9	BHC Gamma (Lindane)		0.17	0.18
10	Carbon tetrachloride	✓	0.10	0.16
11	Chlordane	✓	0.000081	0.000081
12	Chloroethyl ether bis 2	✓	0.020	0.05
13	Chloroform[57]		260	1100
14	Chloroisopropyl ether bis 2		1200	6500
15	Chloromethyl ether, bis	✓	0.000024	0.000029
16	Cyanide[G]		130	130
17	Dichlorobenzene(m) 1,3		80	96
18	Dichlorobenzidine 3,3'	✓	0.0027	0.0028
19	Dichloroethane 1,2	✓	0.35	3.7
20	Dichlorophenol 2,4		23	29
21	Dichloropropene 1,3	✓	0.30	2.1
22	Dieldrin	✓	0.0000053	0.0000054
23	Diethyl phthalate		3800	4400
24	Dimethyl phthalate		84000	110000
25	Di-n-butyl phthalate		400	450
26	Dinitrotoluene 2,4	✓	0.084	0.34
27	Dioxin (2,3,7,8-TCDD)	✓	0.00000000051	0.00000000051
28	Endrin		0.024	0.024
29	Ethylbenzene		160	210
30	Ethylhexyl phthalate bis 2	✓	0.20	0.22
31	Fluoranthene		14	14
32	Heptachlor	✓	0.0000079	0.0000079
33	Hexachlorobenzene	✓	0.000029	0.000029
34	Hexachlorobutadiene	✓	0.36	1.8
35	Hexachlorocyclo-hexane-Technical	✓	0.0014	0.0015
36	Hexachlorocyclopentadiene		30	110
37	Hexachloroethane	✓	0.29	0.33
38	Isophorone	✓	27	96
39	Nickel[58]		140	170
40	Nitrobenzene		14	69
41	Nitrosamines	✓	0.00079	0.046

[57] Based on June 10, 2009 updates to EPA's IRIS system, Oregon's previous q1* value of 6.1 x 10^{-3} was replaced with an RfD value of 0.01 mg/kgrams per day. EPA. *Integrated Risk Information System (IRIS).* U.S. Environmental Protection Agency, Office of Water, Washington, D.C. Available at: www.epa.gov/iris

[58] Oregon's revised human health criteria for nickel are less stringent than Oregon's previous values despite Oregon's adoption of a 175 grams per day fish consumption rate. However, the equation used to calculate the revised criteria is consistent with EPA's current 304(a) recommendations. It is unclear how ODEQ derived their previous values for nickel. Nonetheless, EPA assessed protectiveness of the revised criteria using EPA's 304(a) recommendations and Oregon's human health designated uses.

No.	Pollutant	Carcinogen	Water + Organism (µg/L)	Organism Only (µg/L)
42	Nitrosodibutylamine, N	✓	0.0050	0.02
43	Nitrosodiethylamine, N	✓	0.00079	0.046
44	Nitrosodimethylamine, N	✓	0.00068	0.30
45	Nitrosodiphenylamine, N	✓	0.55	0.60
46	Nitrosopyrrolidine, N	✓	0.016	3.4
47	Pentachlorobenzene		0.15	0.15
48	Pentachlorophenol	✓	0.15	0.30
49	Phenol[59]		9400	86000
50	Polychlorinated biphenyls (PCBs)[L]	✓	0.0000064	0.0000064
51	Selenium[60]		120	420
52	Tetrachlorobenzene 1,2,4,5-		0.11	0.11
53	Tetrachloroethane 1,1,2,2	✓	0.12	0.40
54	Tetrachloroethylene	✓	0.24	0.33
55	Thallium		0.043	0.047
56	Toluene		720	1500
57	Toxaphene	✓	0.000028	0.000028
58	Trichloroethane 1,1,2	✓	0.44	1.6
59	Trichloroethylene	✓	1.4	3.0
60	Trichlorophenol 2,4,5-		330	360
61	Trichlorophenol 2,4,6	✓	0.23	0.24
62	Vinyl chloride	✓	0.02	0.24

Footnote G: They cyanide criterion is expressed as total cyanide (CN)/L
Footnote L: This criterion applies to total PCBs (e.g. determined as Aroclors or congeners).

EPA Approval

In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves Oregon's revised human health toxic criteria for these 62 pollutants, consistent with EPA's current CWA § 304(a) criteria recommendations, because they are protective of fishing and water supply uses.

EPA Rationale

EPA's WQS regulations require that criteria protect the designated uses. As noted previously, Oregon's human health criteria apply to waters with fishing and water supply uses and thus must be established at a level that will protect those uses. Therefore, EPA must evaluate whether the criteria protect Oregon's human health uses.

[59] Based on updates to EPA's IRIS system, the RfD value of 6.0×10^{-1} was replaced by Oregon with an RfD value of 3.0×10^{-1}. EPA. *Integrated Risk Information System (IRIS).* U.S. Environmental Protection Agency, Office of Water, Washington, D.C. Available at: www.epa.gov/iris

[60] Oregon's revised human health criteria for selenium are less stringent than Oregon's previous values despite Oregon's adoption of a 175 grams per day fish consumption rate. However, the equation used to calculate the revised criteria is consistent with EPA's current 304(a) recommendations. It is unclear how ODEQ derived their previous values for these two pollutants. Nonetheless, EPA assessed protectiveness of the revised criteria using EPA's 304(a) recommendations and Oregon's human health designated uses.

EPA's 2000 Human Health Methodology provides guidance for deriving human health criteria for toxic pollutants. For each variable used in the criteria calculation, EPA provides a "national default value" and guidance on specific adjustments that may be necessary to reflect local conditions and/or protect identifiable subpopulations. As part of evaluating whether Oregon's criteria protect the designated uses, EPA reviewed the input values used by Oregon and whether there was Oregon-specific information relative to each value that should be considered in the review. As discussed above EPA has found that ODEQ has appropriately considered local and regional data in selecting input variables for use in deriving the criteria identified in Table 7.

EPA provides an extensive technical basis and justification as to how its recommended human health criteria adequately protect human health uses in EPA's 2000 Methodology document. Oregon's revised criteria were developed consistent with these recommendations, therefore, EPA has determined that Oregon's revised criteria protect human health uses in accordance with 40 C.F.R. Part 131.11(a)(1).

D. *METHYLMERCURY CRITERION*

1. Methylmercury: Criteria Methodology and Input Variables Used by Oregon

On January 8, 2001, EPA published[61] a new national CWA § 304(a) human health criterion recommendation for methylmercury[62] which replaced EPA's previous recommendations for total mercury. The new recommendation is expressed as a fish tissue value, thus reflecting the latest science that indicates consumption of contaminated fish and shellfish is the primary human route of exposure to methylmercury.

In 1980, EPA published a water quality criterion for total mercury. The criterion was partially updated in 1997 to incorporate a change in the reference dose (RfD). Consistent with Section 304(a) of the Clean Water Act, EPA periodically revises water quality criteria to reflect the latest scientific knowledge on the type and extent of identifiable effects on human health from the presence of pollutants in a waterbody. In 2001, EPA completed a review of the water quality criterion for protection of human health for methylmercury. This criterion recommendation considered the bioaccumulation of methylmercury as well as the latest science and data regarding health effects from intake of mercury and the primary routes of exposure. The new criterion for methylmercury was derived consistent with the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (2000). The 2001 recommendation

[61] EPA. January 8, 2001. *Water Quality Criteria: Notice of Availability of Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. *Federal Register*, Volume: 66, Issue: 5, page: 1344 (66 FR 1344). Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2001/January/Day-08/w217.htm

[62] EPA. January 2001. *Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 823-R-01-001. Available at: http://www.epa.gov/waterscience/criteria/methylmercury/document.html

is expressed as a fish tissue concentration for methylmercury and replaces the water column concentration for mercury that was contained in EPA's previous recommendation.[63]

As part of the 2001 reevaluation of the mercury criterion, EPA evaluated the sources and form of mercury that humans are exposed to when eating fish or consuming water from the nation's waters. It was found that humans are exposed primarily to methylmercury rather than to inorganic mercury and that the dominant exposure pathway is through consumption of contaminated fish and shellfish rather than from ambient water.[64] EPA found that if a criterion addressed the potential health effects from methylmercury, it would protect humans from the most toxic form of mercury and the primary route of exposure. Thus, in considering the fate of mercury in the environment and available toxicological data, EPA concluded that it is more appropriate to derive a water quality criterion for methylmercury rather than inorganic mercury. In addition, "EPA believes that the latest data and science on methylmercury exposure, effects, and environmental fate support the derivation of a fish tissue residue criterion," instead of a water column criterion.[65]

"Methylmercury is highly bioaccumulative and is the form of mercury that bioaccumulates most efficiently in the aquatic food web. Methylation of mercury is a key step in the entrance of mercury into food chains. The biotransformation of inorganic mercury species to methylated organic species in water bodies can occur in the sediment and the water column. Inorganic mercury can be absorbed by aquatic organisms but is generally taken up at a slower rate and with lower efficiency than is methylmercury."[66]

"Methylmercury continues to accumulate in fish as they age. Predatory organisms at the top of aquatic and terrestrial food webs generally have higher methylmercury concentrations because methylmercury is typically not completely eliminated by organisms and is transferred up the food chain when predators feed on prey; for example, when a largemouth bass feeds on a bluegill sunfish, which fed on aquatic insects and smaller fish, all of which could contain some amount of methylmercury that gets transferred to the predator. Nearly 100 percent of the mercury that bioaccumulates in upper trophic level fish (predator) tissue is methylmercury (Bloom, 1992; Akagi, 1995; Kim, 1995; Becker and Bigham, 1995.)"[67]

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[63] EPA. January 2001. *Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 823-R-01-001. page 1-1. Available at: http://www.epa.gov/waterscience/criteria/methylmercury/document.html

[64] EPA. January 8, 2001. *Water Quality Criteria: Notice of Availability of Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. *Federal Register*, Volume: 66, Issue: 5, Page: 1344 (66 FR 1344). page 1345. Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2001/January/Day-08/w217.htm

[65] EPA. January 2001. *Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 823-R-01-001. page 1-2. Available at: http://www.epa.gov/waterscience/criteria/methylmercury/document.html

[66] EPA. January 8, 2001. *Water Quality Criteria: Notice of Availability of Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. *Federal Register*, Volume: 66, Issue: 5, Page: 1344 (66 FR 1344). page 1348. Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2001/January/Day-08/w217.htm

[67] EPA. January 8, 2001. *Water Quality Criteria: Notice of Availability of Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water,

In consideration of the environmental fate of mercury, a fish tissue residue water quality criterion was found to be appropriate for many reasons. "Such a criterion integrates spatial and temporal complexity that occurs in aquatic systems and that affects methylmercury bioaccumulation. A fish tissue residue water quality criterion is more closely tied to the CWA goal of protecting the public health because it is based directly on the dominant human exposure route for methylmercury. The concentration of methylmercury is also generally easier to quantify in fish tissue than in water and is less variable over the time periods in which water quality standards are typically implemented in water quality-based. Thus, the data used in permitting activities can be based on a more consistent and measurable endpoint. A fish tissue residue criterion is also consistent with how fish advisories are issued. Fish advisories for mercury are based on the amount of methylmercury in fish tissue that is considered acceptable, although they are usually issued for a certain fish or shellfish species in terms of a meal size. A fish tissue residue water quality criterion should enhance harmonization between these two approaches for protecting the public health."[68]

Consistent with EPA's 304(a) recommendation published in 2001, Oregon has replaced its "water + organism" and "organism only" water column human health criteria for total mercury with a new fish tissue-based "organism only" human health criterion for methylmercury. Similar to the 2000 Methodology, the computation of the methylmercury criterion uses several input variables, described in Figure C below.

Figure C: Simplified version of the equation used by Oregon in deriving its new fish tissue-based "organism only" human health criterion for methylmercury.

$$TRC = \frac{(RfD - RSC) \bullet (BW)}{(FCR)}$$

where:

TRC	=	Fish Tissue Residue Criterion (milligrams per kilogram)
RfD	=	Reference dose for noncancer effects (milligrams per kilogram per day) = 0.0001mg/kg-day
RSC	=	Relative source contribution factor to account for non-water sources of exposure (milligrams per kilogram per day) = 0
BW	=	Human body weight (kilograms) = 70 kg
FCR	=	Fish Consumption Rate (kg/day) = 175 g/day

In the 2001 methylmercury criteria document, EPA strongly encourages States and authorized Tribes to consider developing a criterion using local or regional data over the default values if they believe that appropriate for protection of the target population. EPA recommends that these

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Washington, D.C. *Federal Register*, Volume: 66, Issue: 5, Page: 1344 (66 FR 1344). page 1348. Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2001/January/Day-08/w217.htm

[68] EPA. January 2001. *Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 823-R-01-001. page xv. Available at: http://www.epa.gov/waterscience/criteria/methylmercury/document.html

adjustments be applied consistent with the guidance provided in the 2000 Human Health Methodology.[69]

Consistent with EPA's recommendation, Oregon replaced its "water + organism" and "organism only" water column human health criteria for total mercury with a new fish tissue-based "organism only" human health criterion for methylmercury equal to 0.040 micrograms per kilogram (mg/kg). In deriving this new criterion, Oregon used the equation below and the following values for each variable: reference dose equal to 0.0001 milligrams per kilogram per day; relative source contribution of 0; body weight equal to 70 kilograms and; fish consumption rate equal to 175 grams per day. As discussed in greater detail above, the reference dose and body weight are the values recommended by EPA and the fish consumption rate was derived using local and regional data. The RSC is discussed below.

a) Relative Source Contribution (RSC) for Methylmercury

Following review of available data and information specific to the exposure pathways for methylmercury, Oregon used EPA's subtraction method to derive an RSC of zero for use in deriving the human health criterion for methylmercury.[70]

In establishing a recommended RSC value, EPA found that the most significant source of exposure to methylmercury was the ingestion of marine fish. EPA also found that the estimated exposure from ambient water, drinking water, nonfish dietary foods, air, and soil were all, on average, at least several orders of magnitude less than those from marine fish ingestion. Therefore, these later exposure pathways were not factored into EPA's recommended RSC value. An RSC of 2.7×10^{-5} mg methylmercury/kg/day is recommended by EPA as an estimated exposure from marine fish intake.[71]

EPA's above recommendation is based on the assumption that the fish consumption rate does not include fish of marine origin (as would be the case for most inland states/waters and is true of EPA's national default value for fish consumptions of 17.5 grams per day). However, as part of Oregon's reevaluation of local and regional data and the selection of a fish consumption rate of 175 grams per day, Oregon did take into consideration the consumption of salmon (an anadromous species identified as marine in the CSFII study) and regional consumption rates that included estuarine finfish and shellfish. Therefore, in reviewing this information, Oregon determined that it was not necessary to provide additional protection from ingestion of marine fish through the use of an RSC value. As a result, Oregon subtracted out the exposure related to marine fish, resulting in an RSC of zero.

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[69] EPA. January 2001. *Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 823-R-01-001, page 7-2. Available at: http://www.epa.gov/waterscience/criteria/methylmercury/document.html

[70] November 3, 2000. *Federal Register*, Volume: 65, Issue: 214, pages: 66472-3 (65 FR 66472-3). Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2000/November/Day-03/w27924.htm

[71] EPA. January 2001. *Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 823-R-01-001. page xiv. Available at: http://www.epa.gov/waterscience/criteria/methylmercury/document.html

EPA's 2000 Human Health Methodology recognizes that if States include marine fish in the fish consumption rate they may need to adjust the RSC consistent with this decision to appropriately represent overall exposure to a pollutant.

"States and Tribes need to ensure that when evaluating overall exposure to a contaminant, [and that] marine fish intake is not double-counted with the other dietary intake estimate used. Coastal States and authorized Tribes that believe accounting for total fish consumption (i.e., fresh/estuarine and marine species) is more appropriate for protecting the population of concern may do so, provided that the marine intake component is not double-counted with the RSC estimate." [72]

Oregon's use of the subtraction method for deriving the RSC for methylmercury is consistent with this guidance.

2. New human health criteria for methylmercury

Oregon has adopted the following new criterion for methylmercury:

Table 8: Oregon's criterion for methylmercury.

Pollutant	Carcinogen	Water + Organism (µg/L)	Organism Only (µg/L)
Methylmercury (mg/kg)[J]		--	0.040 (mg/kg)

Footnote J: This value is expressed as the fish tissue concentration of methylmercury. Contaminated fish and shellfish is the primary human route of exposure to methylmercury.

Oregon's new criterion of 0.040 mg/kg is expressed as a fish tissue residue concentration, not a water column concentration as all other human health criteria adopted by Oregon. Thus, when applying the criterion, ODEQ may need to consider data collected from either the water column or fish tissue or express a limitation as a water column value (e.g. provide a discharger with an effluent limit in an NPDES permit that can be measured in their effluent). Recognizing this fact, EPA has encouraged "states and authorized tribes to develop a methylmercury criterion implementation plan to ensure environmentally protective and effective administration of all water quality related programs with respect to methylmercury". Furthermore, to assist the States in this process, in April 2010 EPA published recommended methods for implementing these criteria. [73] In recognition of this need, Oregon's Human Health Criteria Issue Paper states that "…DEQ intends to develop implementation procedures similar to EPA's *Guidance for Implementing the January 2001 Methylmercury Criterion.*"[74]

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[72] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. EPA-822-B-00-004. page 4-25. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf
[73] EPA. January 2001. *Water Quality Criterion for the Protection of Human Health: Methylmercury*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA 823-R-01-001. pages 21-22. Available at: http://www.epa.gov/waterscience/criteria/methylmercury/document.html
[74] ODEQ. May 24, 2011. *Human Health Criteria Issue Paper.* Oregon Department of Environmental Quality. page 26. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/HumanHealthToxicCriteriaIssuePaper.pdf

3. EPA Action and Rationale Regarding Oregon's Methylmercury Criterion

EPA Action
In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves Oregon's new human health criterion for methylmercury, consistent with EPA's current CWA § 304(a) criteria recommendations, because it is protective of Oregon's fishing and water supply uses. EPA is also approving the first sentence of footnote J which states: *This value is expressed as the fish tissue concentration of methylmercury.*

EPA Rationale
EPA's WQS regulations require that criteria protect the designated uses. As noted previously, Oregon's human health criteria apply to waters with fishing and water supply uses and thus must be established at a level that will protect those uses. Therefore, EPA must evaluate whether the criteria protect Oregon's human health uses.

EPA's 2000 Human Health Methodology and 2001 Criteria Recommendations for Methylmercury provide guidance for deriving human health criteria for methylmercury. For each variable used in the criteria calculation, EPA provides a "national default value" and guidance on specific adjustments that may be necessary to reflect local conditions and/or protect identifiable subpopulations. As part of evaluating whether Oregon's criteria protect the designated uses, EPA reviewed the input values used by Oregon and whether there was Oregon-specific information relative to each value that should be considered in the review.

For all input variables except for the fish consumption rate and the RSC value, Oregon used EPA's recommended 304(a) national default values for calculating the methylmercury criterion. EPA has not identified any local or regional data to indicate that the national values for the reference dose, body weight, or drinking water intake rate are inappropriate for use in Oregon.

Oregon has used local and regional data to develop the fish consumption rate and RSC values used to calculate the methylmercury criterion. EPA has reviewed the information used in developing these values and has found that ODEQ appropriately considered the available data and developed input values consistent with EPA guidance.

EPA's 2001 Methylmercury Criteria document provides an extensive technical basis and justification as to how EPA's recommended criterion adequately protects human health uses. Based on Oregon's consistency with EPA's recommendations in the 2001 Methylmercury Criteria document and as discussed above, EPA has determined that Oregon's new methylmercury criterion protects human health uses in accordance with 40 C.F.R. Part 131.11(a)(1).

In addition, EPA is approving the first sentence of footnote J which states: *This value is expressed as the fish tissue concentration of methylmercury.* This sentence of the footnote provides clarification that the human health criterion for methylmercury is expressed as a fish tissue concentration rather than as a water column concentration. Oregon's new footnote

language along with the human health criterion value for methylmercury are consistent with EPA's recommended 304(a) national default values for calculating the criterion. This sentence of the footnote establishes a legally binding requirement under state law and helps describe a desired ambient condition of a waterbody to support a particular designated use and is therefore considered a WQS subject to EPA review and approval under 303(c) of the CWA. The description of the applicable expression of methylmercury is a component of the overall level of protection afforded by the criterion. Since this sentence of the footnote specifies the applicable expression of the methylmercury criterion Oregon adopted, EPA has approved this sentence of the footnote as a WQS.

EPA acknowledges the second sentence of footnote J which states: *Contaminated fish and shellfish is the primary human route of exposure to methylmercury.* This sentence of the footnote provides details on the primary route of human exposure to methylmercury, but does not establish a legally binding requirement under State law and it does not describe a desired ambient condition of a waterbody to support a particulate designated use. For this reason, this sentence of footnote J is not considered a WQS subject to EPA review and approval under 303(c) of the CWA. As a result, EPA is taking no action to approve or disapprove the second sentence of footnote J for methylmercury.

E. *INORGANIC ARSENIC CRITERIA*

1. Background

The Oregon Environmental Quality Commission directed ODEQ to revise Oregon's human health criteria for toxic pollutants based on an increased fish consumption rate of 175 grams per day as well as to carefully consider cost effective and environmentally meaningful implementation of the criteria and review the data and science behind the criteria for earth metals.[75] ODEQ reviewed the science supporting the EPA's recommended 304(a) arsenic criteria and considered the appropriateness of revising the criteria to more closely reflect the levels of arsenic that naturally occur in Oregon waters. Oregon's revised arsenic criteria, submitted to EPA on July 12, 2011 are the result of that review. Oregon's goal in reevaluating the criteria was to protect human health, reduce toxic pollutants and to achieve meaningful environmental results commensurate with the cost.[76]

Oregon made the following arsenic-related regulatory revisions (including some changes other than revisions to arsenic criteria):

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[75] Oregon Environmental Quality Commission (OEQC). October 23, 2008. *Oregon Environmental Quality Commission Minutes of the Three Hundred and Forty-sixth Meeting.* Available at: http://www.deq.state.or.us/about/eqc/minutes/2008/2008octEQCMinutes.htm

[76] ODEQ. April 5, 2011. *Memo from Dick Pedersen, Director ODEQ, to the Environmental Quality Commission. Agenda Item E. Rule adoption: Amending water quality standards for arsenic, April 21-22, 2011EQC meeting.* Oregon Department of Environmental Quality. pages 1-2. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/EQCItemEStaffReport.pdf

- Revised the numeric criteria human health criteria for arsenic in OAR 340-04-0033 Table 20.
- Identified the form of arsenic addressed by the criteria as inorganic arsenic.
- Added footnote A which states "The arsenic criteria are expressed as total inorganic arsenic. The 'organism only' criteria are based on a risk level of approximately 1.1 x 10^{-5}, and the 'water + organism' criterion is based on a risk level of 1.1 x 10^{-4}."[77]
- Revised the drinking water M.C.L. from 0.05 mg to 10 µg/l in Table 20 and added footnote 1 which states "The arsenic value is shown here for informational purposes only and is not a water quality criterion."
- Added a new provision, OAR 340-04-0033(2)(b), that states the arsenic criteria become effective for purposes of State law and the CWA at the time of EPA approval.[78]
- Added an arsenic reduction policy under State law to address the reduction of arsenic from some anthropogenic sources in the vicinity of public drinking water intake supplies.[79]

The revised arsenic criteria were adopted through a public notice and rulemaking action separate from that used to adopt the June 16, 2011 human health criteria revisions. This separate rulemaking process is described in Section III above.

ODEQ reviewed the available scientific literature on bioaccumulation of arsenic and the ratio of inorganic arsenic to total arsenic in freshwater and marine environments. ODEQ also reviewed data specific to waters in Oregon and used the information to derive arsenic criteria for Oregon's waters.

Arsenic is a known carcinogen that may cause cancer in skin or internal organs such as the liver, kidneys, lungs and bladder. Other potential health impacts from arsenic include cardiovascular, kidney, central nervous system and hyper-pigmentation or keratosis effects.[80] In its 304(a) criteria recommendations EPA states that arsenic criteria should be based on cancer endpoints and be applied as inorganic arsenic.

Naturally-occurring arsenic in Oregon comes from geologic sources. It is typically present at natural levels in fresh surface waters at background levels that range from less than 1 microgram per liter (µg/l) to 3 µg/l. ODEQ data indicate that much higher arsenic levels (greater than 5-10 µg/l) may be present in some south central and southeastern Oregon watersheds but it is not known whether these levels represent solely natural geologic sources or are elevated due to

[77] Footnote A for arsenic was established in Table 40 in ODEQ's July 21, 2011 submittal to EPA.
[78] This language was deleted as part of ODEQ's July 21, 2011 submittal to EPA since effective dates of the criteria are addressed in OAR 340-041-0033(1), which includes arsenic.
[79] To accommodate additional revisions associated with ODEQ's submittal to EPA on July 21, 2011 ODEQ moved the location of this rule from OAR 340-041-0033(4) to OAR 340-041-0033(7). However, the rule language was not revised.
[80] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. page 2-6. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

anthropogenic activity.[81] ODEQ's review of the scientific literature indicates natural total arsenic levels of the oceans to be in the range of 1 to 3 µg/l.[82]

EPA's current 304(a) human health criteria recommendations for arsenic, published in 1986, are derived using a fish consumption rate of 6.5 grams per day and a cancer slope factor of 1.75 and are recommended to be applied as inorganic arsenic.[83] As is the case for all pollutants, EPA's 2000 Human Health Methodology encourages states to use local and regional data when making risk management decisions inherent in developing criteria, including decisions inherent in selecting the appropriate fish consumption rate, target risk level and bioaccumulation factor.[84]

2. Numeric Criteria Revisions

Based on its review of current data and information, ODEQ found differences in the bioconcentration (BCF) of arsenic in freshwater and saltwater organisms. In addition, DEQ found the ratio of inorganic arsenic relative to total arsenic differs in the freshwater and marine environments. Based on these findings, Oregon adopted two sets of criteria, one applying to freshwater and the other to saltwater. The revised criteria and the input variables used to calculate the criteria are presented in Tables 9 and 10 below.

Oregon has adopted the following new criterion for inorganic arsenic:

Table 9: Oregon's revised arsenic criteria (as inorganic arsenic).

Pollutant	Carcinogen	Water + Organism (µg/L)	Organism Only (µg/L)
Arsenic (inorganic)[A]	✓	2.1	2.1 (freshwater) 1.0 (saltwater)

Footnote A: The arsenic criteria are expressed as total inorganic arsenic. The "organism only" criteria are based on a risk level of approximately 1.1 x 10^{-5}, and the "water + organism" criterion is based on a risk level of 1.1 x 10^{-4}.

Table 10. Input variables for Oregon's revised arsenic criteria.

	Water + organism: freshwater	Organism only: freshwater	Organism only: saltwater
Revised Criteria	2.1 µg/l	2.1 µg/l	1.0 µg/l
Input Variables	FCR=175	FCR=175	FCR=175

[81] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. page 6. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf
[82] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. page 14. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf
[83] EPA. May 1, 1986. *Quality Criteria for Water.* U.S. Environmental Protection Agency, Office of Water. 440/5-86-001. At: https://owpubauthor.epa.gov/scitech/swguidance/standards/upload/2009_01_13_criteria_goldbook.pdf
[84] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health.* U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. page 2-6. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

	BCF=14 IF=10% CSF=1.5 Risk level=$1x10^{-4}$	BCF=14 IF=10% CSF=1.5 Risk level=$1.1x10^{-5}$	BCF=26 IF=10% CSF=1.5 Risk level=$1x10^{-5}$

FCR = Fish Consumption Rate
BCF = Bioconcentration Factor
IF = Inorganic Factor
CSF = Cancer Slope Factor

Oregon's arsenic criteria revisions were adopted into Table 20 (Water Quality Criteria Summary), OAR 340-04-0033. It should be noted that in Oregon's June 16, 2011 action, all human health criteria in Table 20 were moved to Table 40. Thus, the arsenic criteria are now located in Table 40.

Oregon's revised numeric criteria for arsenic were derived using the same general methodology and equation used to calculate EPA's current 304(a) criteria for carcinogens. However, based on its review of scientific studies and Oregon specific data,[85] Oregon applied an inorganic to total arsenic ratio in the criteria calculation because the arsenic criteria are expressed in terms of inorganic arsenic, but the toxicity data used to develop EPA's BCF are reported in the form of total arsenic. Therefore, Oregon applied the inorganic to organic arsenic ratio to the criteria calculated using BCF values they derived based on state-specific data. Oregon also applied a fish consumption rate based on state-specific data. Oregon used the cancer slope factor listed in EPA's IRIS database available at the time of criteria adoption (April 2011). The input variables used by Oregon to derive their revised criteria are listed in Table 10 above.

a) Freshwater Criteria

Body weight and drinking water intake rate

Oregon used EPA's recommended national default rates for body weight and drinking water intake rates. These are the same values that Oregon used to derive all other criteria addressed in this action. Further detail on these variables was provided above.

Fish consumption rate

A fish consumption rate of 175 grams per day was used to derive the freshwater arsenic criteria. This is the same fish consumption rate that Oregon used to derive all other criteria addressed in this action. As discussed in detail above, this rate was determined by ODEQ to be appropriate for use in Oregon's human health criteria following a thorough review of local and regional data.

The fish consumption rate of 175 grams per day was selected by Oregon to ensure protection of all people in Oregon who may consume fish and shellfish from state waters including those who traditionally consume large amounts of fish for subsistence, health, economic or other reasons.[86] It reflects the 95th percentile of tribal members surveyed as part of the CRITFC Survey and the

[85] For more detail, see previous description in this document of methodology for deriving criteria for carcinogens.
[86] ODEQ. October 6, 2008. *Memo from Dick Pederson, Director ODEQ, to the Environmental Quality Commission. Agenda Item G, Action Item: Oregon's Fish Consumption Rate – For Use in Setting Water Quality Standards for Toxic Pollutants October 23, 2008 EQC Meeting.* Oregon Department of Environmental Quality. page 7. Available at: http://www.deq.state.or.us/about/eqc/agendas/attachments/2008oct/ItemG.pdf

90th percentile of subsistence consumers surveyed in regional fish consumption studies. The Human Health Focus Group formed by ODEQ to provide technical recommendations for selecting a fish consumption rate appropriate for Oregon found that fish consumers generally eat a variety of species that are the most readily available geographically and seasonally and that the range of consumption rates among fish consumers tend to be comparable regardless of the species that are available at any given time.[87] Thus, Oregon determined the rate of 175 grams per day appropriate for protection of high consumers from both freshwater and saltwater environments throughout the state.

Bioconcentration factor

Limited data are available regarding bioaccumulation (BAF) and bioconcentration (BCF) of arsenic in aquatic species. As discussed above, EPA recommends bioaccumulation data be used when available in order to take into consideration all pathways of accumulation, not merely the concentration that is received from water as reflected in bioconcentration data. EPA review of the literature found no relevant BAF data was available and thus EPA recommended that BCF data be used by Oregon to determine appropriate BCFs for use in deriving their arsenic criteria.[88]

EPA reviewed the available literature that might be relevant to recalculating a BCF specific to Oregon's waters and provided that information to ODEQ.[89] Only six published studies were identified and only four of the studies were found suitable for use in recalculating a BCF. Limitations in the data reported in two of the studies resulted in EPA determining they were not appropriate for use and thus were not used in either ODEQ's recalculations or EPA's review of the recalculated BCFs. The four studies found to be appropriate for this purpose and thus used provided data for only three species. One data set is from a test of a saltwater mollusk, the eastern oyster, and the others tested two freshwater finfish, bluegill and rainbow trout. Additional information on these studies can be found in ODEQ's April 2011 review document.[90]

Oregon determined that a BCF of 14 was appropriate for use in developing arsenic human health criteria for freshwaters of the state based on their review of the data contained in the above mentioned studies. A BCF of 14 represents the geometric mean of the data available from the studies of freshwater organisms (two publications on rainbow trout[91] and one on bluegill[92]). Oregon determined that the BCF data for the eastern oyster, a marine mollusk, was not appropriate for use in deriving a freshwater BCF because the oyster was a marine organism and available data indicate marine organisms are more likely to bioaccumulate arsenic than freshwater organisms. Furthermore, DEQ stated that they were not aware of data showing

[87] ODEQ. June 2008. *Human Health Focus Group Report. Oregon Fish and Shellfish Consumption Rate Project.* Oregon Department of Environmental Quality. pages 18-19. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/HHFGFinalReportJune2008.pdf
[88] EPA. November 2011. Oregon Arsenic BCF and 304(a) Calculations.
[89] EPA. November 2011. Oregon Arsenic BCF and 304(a) Calculations.
[90] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf
[91] McGeachy and Dixon, 1990. Canadian Journal of Fisheries and Aquatic Sciences. 47: 2228-2233; Rankin and Dixon, 1994. Canadian Journal of Fisheries and Aquatic Sciences. 51: 372-380.
[92] Barrows, et al. 1980. Ann Arbor Science Pub., Inc., Ann Arbor, MI. pages 379-392.

harvesting or consumption of mollusks or other shellfish from freshwaters in Oregon and thus, freshwater mollusks were not likely to comprise a significant portion of the fish consumed from freshwaters in Oregon. Thus Oregon assumed finfish would be the primary exposure route for arsenic ingested from freshwaters and therefore, used only the data from finfish studies to calculate the freshwater BCF.[93,94] Based on this evaluation, ODEQ found that a BCF of 14 was a reasonable and protective value to use in calculating the arsenic criteria for Oregon's freshwaters.

Cancer Slope Factor

Similar to all other criteria addressed in this action, for arsenic, ODEQ used the cancer slope factor identified in EPA's Integrated Risk Information System (IRIS) data base at the time of rule adoption (April 2011). For arsenic this value is 1.5 $(mg/kg/day)^{-1}$ and was last modified in 1998.

Inorganic Proportion Factor (Inorganic to Total Arsenic Ratio)

Arsenic is present in the environment and in fish tissue in both organic and inorganic forms. Inorganic arsenic, specifically arsenite (trivalent or As III), is the form that is most toxic to humans and used to develop toxicity data for cancer and other end points. Thus, EPA recommends that human health criteria for arsenic are developed specific to inorganic arsenic and apply to the inorganic portion of arsenic in the water column. The inorganic portion may be referred to as either "inorganic arsenic" or "total inorganic arsenic". When both inorganic and organic arsenic are included, it is referred to as "total arsenic".[95]

All of the bioconcentration studies identified by EPA and used by Oregon reported arsenic as total arsenic, not inorganic arsenic. In order to address this difference in form and toxicity, Oregon multiplied the BCF by an "inorganic proportion factor" that reflects the ratio of inorganic to total arsenic likely to be present in the water. The proportion varies geographically and between fresh and marine waters so must be determined using state or local data.

Only limited data are available relative to the ratio of inorganic to total arsenic in Oregon's freshwaters. Previous studies have reported the proportion of inorganic arsenic found in fish tissue collected in the Columbia and Willamette rivers to contain an average of 6.5% inorganic arsenic while the ratios reported for individual species of fish ranged from 0.5% to 9.2% inorganic arsenic.[96] ODEQ also found several other sources of information indicating that an

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[93] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. pages 12-13. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf
ODEQ. March 2011. *Summary of Public Comment and Agency Response. Amending Oregon's Water Quality Standards: Revising Human Health Criteria for Arsenic.* Oregon Department of Environmental Quality. pages 16-17. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AttCArsenicPublicComment.pdf

[94] EPA's review of this decision is documented later in this subsection.

[95] EPA. 2009. *EPA National Recommended Water Quality Criteria.* U.S. Environmental Protection Agency Office of Water. Office of Science and Technology. Available at: http://water.epa.gov/scitech/swguidance/standards/current/upload/nrwqc-2009.pdf

[96] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. page 13. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

inorganic proportion of 10% or less was typical of freshwater environments.[97] Based on these findings, Oregon determined that an inorganic factor of 10% was a conservative ratio and appropriate for use in deriving the arsenic criteria for Oregon's freshwaters.

To incorporate the inorganic factor (IF) into the calculation, ODEQ used the following revised equations:

$$\text{Water + fish ingestion Criterion } (\mu g/L) = 1000 \times \frac{RF \times BW}{q1^*[DW + (BCF \times FCR \times \mathbf{IF})]}$$

$$\text{Org Only Criterion } (\mu g/L) = 1000 \times \frac{RF \times BW}{q1^*[BCF \times FCR \times \mathbf{IF}]}$$

Carcinogenic Risk Level

In the 2000 Human Health Methodology EPA states that it believes States and authorized Tribes have the flexibility to adopt the carcinogenic risk level they find appropriate for protection of the designated uses as long as the general population is protected at a 10^{-5} or 10^{-6} risk level and highly exposed populations are protected at a risk level that does not exceed 10^{-4}.[98] With the exception of arsenic, Oregon has used a risk rate of 10^{-6} when developing water quality criteria for carcinogenic pollutants. However, due to the natural levels of arsenic in Oregon's waters and the exposure levels resulting from natural sources of arsenic, Oregon has chosen to use a risk level of 10^{-4} for the arsenic criteria. Oregon made this policy decision following consideration of several alternatives and consideration of public comments received on the proposed criteria. The lower level of protection afforded by the proposed criteria was clearly identified by ODEQ in the documents provided to the public during both public notice periods and in the materials presented to the EQC at the time the rule was adopted.[99] ODEQ has stated that they made this

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EPA. 2002. *Columbia River Basin Fish Contaminant Survey, 1996-1998*. U.S. Environmental Protection Agency, Region 10, Seattle, Washington. EPA 910-R-02-006. Available at: http://yosemite.epa.gov/r10/oea.nsf/0703bc6b0c5525b088256bdc0076fc44/c3a9164ed269353788256c09005d36b7/$FILE/Fish%20Study.PDF

EVS Environmental Consultants. November 21, 2000. *Human Health Risk Assessment of Chemical Contaminants in Four Fish Species from the Middle Willamette River, Oregon*. Prepared for the Oregon Department of Environmental Quality, Portland, Oregon. Available at: http://www.deq.state.or.us/wq/willamette/docs/studies/hhrarpt.pdf

[97]ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. page 13. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[98] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. page 2-6. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

[99] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

ODEQ. April 5, 2011. *Memo from Dick Pedersen, Director ODEQ, to the Environmental Quality Commission. Agenda Item E. Rule adoption: Amending water quality standards for arsenic, April 21-22, 2011EQC meeting.* Oregon Department of Environmental Quality. pages 1-2. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/EQCItemEStaffReport.pdf

decision because of the special circumstances associated with natural levels of arsenic but believed that the 10^{-6} risk level used to derive all other criteria continued to be appropriate.[100] In determining the acceptable risk level for the arsenic criteria, ODEQ considered the natural background levels of arsenic commonly found in Oregon and evaluated the likely risk associated with exposure to these levels for the general population and high fish consumers. As noted earlier, ODEQ found that naturally occurring arsenic in many surface waters of the state range from less than 1 µg/l up to 3 µg/l and may occur at much higher levels. Therefore, ODEQ evaluated the risks that would be associated with arsenic criteria of 2-3 µg/l.

Using the input variables identified above, Oregon determined that a freshwater water plus organism (water + org) criterion of 2.1µg/l would result in a carcinogenic risk of $1x10^{-4}$. Since this value would protect high fish consumers of the State (those consuming 175 grams of fish per day) at a 10^{-4} risk level, Oregon found this criterion would protect the human health uses in State waters at a level consistent with the risk levels recommended by EPA in the 2000 Human Health Methodology.[101] Thus, Oregon adopted an arsenic water plus organism criterion of 2.1 µg/l for freshwaters.

Oregon similarly evaluated the criterion for protection of waters where fish consumption was a designated use but drinking water was not a designated use (organism (org) only criterion). Using the same variables discussed above, Oregon determined that a criterion of 19 µg/l would protect at a $1x10^{-4}$ risk level while a criterion value of 1.9 µg/l would protect at a $1x10^{-5}$ risk level. Oregon noted that establishing the org only criterion at the same risk level as the water + org criterion would result in a criterion that was nearly an order of magnitude less stringent than the water + org criterion. Therefore, after reviewing several options Oregon established the organism only criterion at the same level as the water + org criterion (2.1 µg/l). Oregon's revised freshwater arsenic org only criterion of 2.1 µg/l represents a carcinogenic risk of 1.1 x 10^{-5} to high consumers of the State (at a fish consumption rate of 175 grams/day). Oregon found this level of protection appropriate as it was within the risk range identified in EPA's 2000 Human Health Methodology and took into consideration the natural levels of arsenic found in Oregon's waters.[102]

ODEQ. April 21, 2011. Recommended Revisions to Oregon's Human Health Criteria for Arsenic, Presentation to the EQC. See Action Item E audio presentation. Available at: http://www.deq.state.or.us/about/eqc/minutes/2011/2011aprEQCMinutes.htm

[100] ODEQ. March 2011. *Summary of Public Comment and Agency Response. Amending Oregon's Water Quality Standards: Revising Human Health Criteria for Arsenic.* Oregon Department of Environmental Quality. page 25. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AttCArsenicPublicComment.pdf
ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. pages 10-11. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf
ODEQ. April 5, 2011. *Memo from Dick Pedersen, Director ODEQ, to the Environmental Quality Commission. Agenda Item E. Rule adoption: Amending water quality standards for arsenic, April 21-22, 2011EQC meeting.* Oregon Department of Environmental Quality. pages 4-5. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/EQCItemEStaffReport.pdf

[101] ODEQ. April 5, 2011. *Memo from Dick Pedersen, Director ODEQ, to the Environmental Quality Commission. Agenda Item E. Rule adoption: Amending water quality standards for arsenic, April 21-22, 2011EQC meeting.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/EQCItemEStaffReport.pdf

[102] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon

b) Saltwater Criteria

Oregon's objectives in developing an arsenic criterion for saltwater was to protect those who consume fish and shellfish from Oregon's marine and estuarine waters to which a criterion applies, taking into consideration the presence of naturally occurring levels of arsenic in marine waters. Uncertainties in the scientific community's current knowledge of the various species of arsenic in the saltwater environment and in marine and estuarine species also were considered in the evaluation.[103]

Oregon has not designated any saltwaters of the state as a drinking water use. Consistent with this designation, the only human health criterion applicable to and derived for saltwaters in Oregon are the organism only criteria (i.e. developed to protect humans from health effects incurred while ingesting fish and shellfish). As identified in Table 9 above, Oregon adopted an organism only criterion of 1.0 µg/l inorganic arsenic for all saltwaters of the State. The following discusses the input variables used and the conclusions reached by ODEQ in establishing this criterion.

Body weight, fish consumption rate and cancer slope factor
The input variables used for body weight, fish consumption rate and the cancer slope factor to derive Oregon's arsenic human health water quality criteria applicable to saltwater are the same as those used to derive the freshwater criteria discussed above.

Bioconcentration factor and inorganic proportion factor
Oregon's arsenic criterion for saltwater was calculated using a BCF of 26 (the geometric mean of all BCFs for fresh and saltwater species combined) and an inorganic proportion factor of 10%.

As discussed in the freshwater section above, bioconcentration data for arsenic is limited. EPA's review of the literature found only four studies appropriate for use in calculating BCFs and only one of those tested an organism from a saltwater environment (eastern oyster).[104] When ODEQ reviewed the available studies, they found a large difference in BCF values found in the study of the Eastern oyster (BCF of 350) relative to those found in the freshwater finfish studies (BCFs of 4 to 27). Given the differences in the BCFs and recognizing that people consume both mollusks and finfish from the Oregon waters where this criterion would apply, ODEQ evaluated potential options for criteria using two scenarios (see Table 11 below). The first scenario considered criterion calculated using a BCF of 26, the geometric mean of all available BCF data (both saltwater and freshwater). The second evaluated options using a BCF of 350, the geometric mean from the one study of a saltwater organism. Under both scenarios, the criteria that would result from using inorganic proportion factors of 1% and 10% were calculated. Results of the various options were compared to levels of arsenic naturally present in estuarine and marine

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Department of Environmental Quality. page 14. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[103] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. page 14. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[104] Zaroogian and Hoffman. 1982. *Arsenic uptake and loss in the American oyster, Crassostrea virinica.* Environmental Monitoring and Assessment 1:345-358.

waters. Following analysis of the options generated under the two scenarios ODEQ evaluated the level of protection provided by each and compared the criteria to the concentrations of arsenic naturally present in estuarine and marine waters. Based on this analysis ODEQ determined that a criterion of 1.0 µg/L inorganic arsenic was appropriate for protection of the fish consumption use in Oregon's saltwaters.

Table 11. Scenarios evaluated by Oregon and/or EPA.

Scenario	**A**	**B**	**C**	**D**	**E**	**F**
Fish Consumption	175 g/day	175 g/day	175 g/day	175 g/day	175 g/day	
Bioconcentration	26	26	350	350	350	
Inorganic portion	10%	1%	1%	10%	7.3%	
Risk level	1×10^{-5}	1×10^{-6}	1×10^{-5}	1.3×10^{-5}	9.6×10^{-5}	
Natural ocean level						1 – 1.2 µg/l
Resultant Criterion	**1.0 µg/l**	**1.0 µg/l**	**0.8 µg/l**	**1.0 µg/l**	**1.0 µg/l**	**1.0 µg/l**

As part of this evaluation, ODEQ evaluated the appropriate species to be considered in deriving a BCF value, the ratio of inorganic to total arsenic in the ocean environment, and the natural level of arsenic in Oregon's salt waters. When evaluating BCF data, ODEQ found that bioconcentration of arsenic in the tissue of invertebrates tended to be higher than that for vertebrates. In particular, they found that crustaceans and mollusks tended to accumulate more inorganic arsenic in their tissue (the form toxic to humans) than anadromous or marine fish. While data specific to consumption levels of various species from Oregon's saltwaters was not available, ODEQ knew that both shellfish and finfish were harvested and consumed from saltwaters in Oregon. ODEQ's literature review also indicated that, for the general US population, estuarine and marine mollusks represent only a small percent (3-13%) of the total fish and shellfish consumption. Given the small percentage of shellfish consumption relative to fish consumption and the much higher bioconcentration rate in shellfish, ODEQ concluded that a criterion calculated using only the oyster data (BCF = 350) was likely to be overly conservative.[105]

Oregon's literature review found a growing body of literature indicating that while saltwater organisms may contain more total arsenic than freshwater fish, the predominant form of arsenic in marine species is organic arsenic (i.e. rather than inorganic arsenic).[106] One analysis of five types of ocean finfish and ocean shrimp found that inorganic arsenic in the organism's tissues was less than 0.1% of the total arsenic present in tissues.[107] Other literature reported values of less than 3% and more recent surveys report values less than 1%.[108] A summary of the data from

[105] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. pages 15-16. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[106] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. pages 16-17 in EPA 2003; Neff 1997; Schoof and Yager 2007; Tanaka and Santosa 1995; TetraTech 1996, IN EPA 2002; and Williams et.al. 2006. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[107] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. pages 16-17 in Schoof et. al., 1999 in BorakandHosgood. 2007. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[108] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon

20 studies is provided below and indicates that the inorganic arsenic in tissues of marine fish and marine shellfish ranged from 0.0001% to 7.3% of the total arsenic present; anadromous fish ranged from 0.3% to 3.04% and freshwater fish tissue contained between 0.5% and 26.6% inorganic arsenic.[109]

Inorganic arsenic as a % of total arsenic in seafood measured as ng/g wet weight

	Mean	Range
Freshwater	7.2	0.5-26.6
Anadromous fish	1.1	0.03-3.04
Marine fish	1.0	0.001-6.9
Marine Crustaceans	1.3	0.001-7.3
Marine Mollusks	1.8	0.04-6.5

Based on the review of the above information, ODEQ concluded it appropriate to use an inorganic factor of 1% if used in association with a conservative BCF of 350. However, if using the less conservative BCF of 26, ODEQ used a more conservative inorganic factor of 10% in their initial scenarios. ODEQ found comparison of these scenarios was a reasonable approach to take into account the variability and uncertainty in both the BCFs and inorganic factors while not resulting in an overly conservative criterion.[110]

Natural ocean levels and complexities in the marine environment

Oregon's review of the literature found natural total arsenic levels of oceans waters to be in the range of 1 to 3 µg/l. Data cited from the Pacific Ocean indicated average concentrations of 1.1 – 1.2 µg/l.[111]

Oregon did not have any data from Oregon's marine waters where inorganic and total arsenic were measured simultaneously. Thus, they relied on the above literature for their conclusion that the natural concentrations of arsenic in Oregon salt waters contain 1.0 µg/l or more of inorganic arsenic and that a waterbody criterion of 1.0 µg/l should not present any greater human health risk than that naturally present.[112]

Department of Environmental Quality. pages 16-17 in Borak and Hosgood, 2007; EPA 2003; Neff, 1997. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[109] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. pages 16-17 in Schoof and Yager, 2007. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[110] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[111] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. pages 15-16 in Tanaka, Shigeru and Sri Juari Santosa. 1995. The concentration distribution and chemical form of arsenic compounds in sea water. Biogeochemical Processes and Ocean Flux in the Western Pacific, Eds. H. Sakai and Y. Nozake, page. 1590170. Terra Scientific Publishing Company, Tokyo. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

[112] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. page 15. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

Carcinogenic Risk Level
For the saltwater organism only criterion of 1.0 µg/l inorganic arsenic represents a carcinogenic risk level of 10^{-5}. Since this value would protect high fish consumers of the State (those consuming 175 grams of fish per day) at a 10^{-5} risk level, Oregon found this criterion would protect the human health uses in State waters at a level consistent with the risk levels recommended by EPA in the 2000 Human Health Methodology.[113] Furthermore, ODEQ determined it was appropriate to use a different carcinogenic risk level for this criterion than that used for other criteria in the state (10^{-6}) since the resultant criterion concentration reflected that which naturally occurred in marine waters.[114] (See the discussion regarding carcinogenic risk level for the freshwater arsenic criteria for more detail regarding EPA's 2000 Human Health Methodology.)

Based on the above findings, Oregon considered the scenarios in Table 11 above when selecting an appropriate org only criterion for arsenic in Oregon's saltwaters. Based on the conservative nature of a BCF of 350, the variability in the data, the uncertainties in the scientific communities current knowledge and ODEQ's determination that "there does not appear that an unacceptable human health risk with eating fish from an unpolluted marine environment," Oregon revised the saltwater criterion for inorganic arsenic to 1.0 µg/l.

c) EPA Review of Oregon's Revised Arsenic Criteria

EPA has reviewed the information provided by Oregon regarding the literature considered during their review of the arsenic criteria. EPA determined that Oregon's review considered the relevant and available information relative to selecting appropriate input variables for deriving the arsenic criteria. EPA conducted a more detailed review of several of the variables used in deriving the criteria. This review is presented below.

(1) FRESHWATER CRITERIA

BCF for Freshwater Criteria
EPA has reviewed the literature used by Oregon to calculate a BCF and finds that all relevant studies were identified. The use of a geometric mean value from available studies is appropriate for deriving a single BCF value. As determined by Oregon, a BCF of 14 is representative of the available BCF data relative to freshwater species.

In EPA's review of the literature relative to bioaccumulation of arsenic in aquatic organisms, no BAF studies specific to bioaccumulation in Oregon or models which could readily produce

[113] ODEQ. April 5, 2011. *Memo from Dick Pedersen, Director ODEQ, to the Environmental Quality Commission. Agenda Item E. Rule adoption: Amending water quality standards for arsenic, April 21-22, 2011EQC meeting.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/EQCItemEStaffReport.pdf
[114] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. pages 15-16 in Tanaka and Santosa. 1995 National Academy of Sciences, 1972 and EPA. 2003. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf

bioaccumulation factors specific to Oregon's waters were found. Thus, ODEQ's use of a bioconcentration factor is appropriate in this situation.

In selecting the appropriate BCF for use in deriving freshwater criteria, Oregon reviewed the available data for both saltwater and freshwater organisms and considered whether that data was representative of organisms likely to be consumed from waters to which the criteria would apply. In evaluating the use of the data from a study of the eastern oyster, a saltwater mollusk, Oregon noted that saltwater mollusks are not present in freshwaters of Oregon and that they were "not aware of any mollusks or other shellfish harvested and consumed from Oregon's freshwaters".[115] In order to verify this assertion, EPA consulted the Oregon Department of Fish and Wildlife website.[116] According to the regulations posted on this site, Oregon prohibits the harvest or possession of all freshwater mussels or clams (except for Zebra mussels or Asian clams) except as authorized by a Scientific Take Permit.[117] Furthermore, EPA noted that no freshwater mussels or shellfish were included in the species identified in the CRITFC Fish Consumption Study. While this later fact does not speak to all mussels or shellfish from freshwaters of Oregon, it is one indication that traditional and cultural consumption of these organisms is not occurring in a large portion of Oregon. Based on this information, EPA finds the assumption made by Oregon as to type of organisms consumed from Oregon's freshwaters to be reasonable. While including BCF data from the eastern oyster in the calculations would have expanded the scope of represented species to include mollusks, it would have also contributed BCF data from a marine species into the calculation of freshwater criteria. EPA concludes that Oregon's decision not to include the BCF data from the eastern oyster was appropriate, in light of the above data with respect to the low likelihood of human consumption of freshwater mollusks in Oregon.

One commenter provided numerous comments relative to the use of a BCF instead of a site-specific BAF. In the 2000 Human Health Methodology EPA recommends using a BAF in cases where data are available. EPA's review of the literature indicates that data and models are not currently available to develop a state-specific BAF for waters in Oregon. Additional information on this topic can be found in the above description of the methodology used to develop criteria for noncarcinogens and in EPA's Response to Comments document developed in association with the recent June 1, 2010 action on Oregon's human health criteria adopted in 2004.[118] The same commenter noted that recent studies of arsenic bioaccumulation indicate use of a regression approach to developing arsenic criteria may be more appropriate than using a single criterion applicable to all waters. EPA reviewed the cited study and agrees that it is an approach that has been applied on a site-specific basis and could be applied by a state in developing criteria for arsenic. However, EPA has not developed a recommended approach for

[115] ODEQ. April 4, 2011. *Issue Paper: Water Quality Standards Review and Recommendations: Arsenic.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AppEArsenicIssuePaper.pdf
[116] Oregon Department of Fish and Wildlife (ODFW). *Oregon Wildlife Species: Sport Fish Species of Oregon.* Available at: www.dfw.state.or.us/species/fish/index.asp
[117] Oregon Department of Fish and Wildlife (ODFW). *2011 Sport Fishing Regulations.* Available at: http://www.dfw.state.or.us/fish/docs/2011_Oregon_Fish_Regs.pdf
[118] EPA. June 1, 2010. Supplemental Response to Comments Submitted by Northwest Environmental Advocates (NWEA) as They Pertain to Oregon's New and Revised Human Health Water Quality Criteria for Toxics Submitted on July 8, 2004.

incorporating this approach into a water quality criterion and no state has used it to develop a water quality criterion. Utilization of a regression approach would result in a criterion expressed as an equation for calculating a criterion concentration which varies with the ambient level of arsenic present in a waterbody in order to take into account the fact that the fraction of total arsenic that is inorganic arsenic tends to decrease as the concentration in the tissues increase. Additional questions regarding whether the criteria would more appropriately be expressed as a water column or tissue concentration would also need to be addressed. While utilizing this approach to developing a state-wide criterion would result in a site-specific criterion that may more accurately reflect the desired level of protection at any particular site (i.e. a 10^{-5} risk level), it would not necessarily provide for a greater level of protection. Given that this level of detail is not needed to protect the use and that this method has never been applied to derive a water quality criterion, EPA finds that it was reasonable for Oregon to establish a single criterion concentration and not use this new approach in this rule revision.

Inorganic Proportion Factor for Freshwater Criteria

EPA's review of available information finds that an inorganic proportion factor of 10% represents a reasonable and conservative estimate of the proportion of total arsenic present in an inorganic form in the tissue of organisms collected from freshwaters in Oregon. EPA notes that this same value was used by EPA when conducting site-specific risk assessments in the Columbia and Willamette Rivers that considered the same data set. No additional data have become available since the EPA assessments.

Level of Protection Provided by the Freshwater Criteria

Oregon's arsenic criteria for fresh waters are established at a level that protect high fish consumers in Oregon at carcinogenic risks levels of between 1×10^{-4} to 1×10^{-5} (see more detailed discussion above). EPA's 2000 Human Health Methodology states that states have the flexibility to choose an appropriate risk level for use in deriving water quality criteria as long as it protects the use to the levels recommended by EPA. Those risk levels are a 10^{-5} or 10^{-6} risk level for the general population and a risk level that does not exceed 10^{-4} for highly exposed populations.

Oregon's criteria were established using a fish consumption rate of 175 grams per day, reflective of the 95th percentile of consumption in a high-consuming subpopulation in Oregon and the 90th percentile of data from regional surveys of high consuming subpopulations. Therefore, the criteria represent the level of exposure expected to occur in highly exposed populations of Oregon. As such, Oregon's freshwater arsenic criteria protect highly exposed populations of Oregon at a level consistent with EPA's recommendations (does not exceed 10^{-4} risk level).

EPA has recommended using a fish consumption rate for the general US population of 17.5 grams per day if no local or regional data is available. There is currently no available fish consumption data specific to the general population of Oregon. If one were to evaluate the protectiveness of Oregon's arsenic criteria at EPA's default fish consumption rate of 17.5 grams per day, the result would indicate a carcinogenic risk level between $1x10^{-6}$ and $1x10^{-5}$. This risk level is consistent with that recommended by EPA. Therefore, EPA finds that ODEQ's revised arsenic criteria for freshwater are established at a level protective of both the general population and high fish consuming populations consistent with the levels recommended by EPA in the

2000 Human Health Methodology.

(2) SALTWATER CRITERIA

BCF for Saltwater Criteria

EPA has reviewed the literature used by Oregon to calculate the BCF used to derive the saltwater criterion and finds that all relevant studies were identified. EPA also found the use of a geometric mean value to be appropriate for deriving a BCF. As considered by Oregon, a BCF of 26 is representative of all available BCF data for both saltwater and freshwater species (one study of a saltwater mollusk and three studies of freshwater finfish). A BCF of 350 reflects all of the available BCF data for saltwater species (one study of a saltwater mollusk). Oregon considered both of these BCF values when evaluating the protectiveness of the revised criterion.

As noted by Oregon, there is relatively little BCF data available for arsenic and only one study that addresses saltwater species. Given the limited data and the differences in BCF between the finfish and mollusk data, EPA finds Oregon's approach of comparing the outcomes of scenarios for both a BCF of 26 and a BCF of 350 in terms of protectiveness to be reasonable. (See Table 11 above). Given the limited data and the variability in the available data, EPA believes that evaluating the level of protection provided by a range of inorganic proportion factors in association with the different BCF values is also appropriate. EPA's evaluation of whether the criteria derived using these input values is protective of the use is provided below.

Inorganic Proportion Factor for Saltwater Criterion

EPA's review of the literature relative to the ratio of inorganic to total arsenic in the tissue of saltwater organisms indicated that ODEQ reviewed the available information on this subject. EPA concurs that the information is limited, especially specific to Oregon waters, but it does indicate that the ratio of inorganic to total arsenic in tissues of saltwater organisms is typically lower than that found in freshwater organisms. Thus, using the 10% inorganic ratio that is also used in the freshwater criteria serves to provide a conservative estimate of the ratio—i.e., one that is larger than the mean ratio values found in various studies (1 to 3%). Given the variability in these factors and in the BCF values discussed above, EPA believes it was appropriate for ODEQ to have considered several different exposure scenarios when developing this criterion and that ODEQ's use of inorganic factors of 10% and 1% in the scenarios was also reasonable. EPA's evaluation of whether the criteria derived using these input values is protective of the use is provided below.

Level of Protection Provided by the Saltwater Criteria

Oregon adopted a saltwater criterion of 1 µg/l and relied on multiple lines of evidence in determining it is protective of Oregon's human health uses. Consistent with Oregon's approach at evaluating scenarios, EPA has evaluated the level of protection provided by each scenario presented. As illustrated in Table 11 above, when the more conservative BCF (350) was paired with the less conservative inorganic proportion factor (1%), a criterion of 1.0 µg/L was found to protect high fish consuming populations (175 g/day) at a 1.3×10^{-5} risk level. When the less conservative BCF (26) was paired with the more conservative inorganic proportion factor (10%), a criterion of 1.0 µg/l was found to protect high consumers (175 g/day) at a 1.0×10^{-5} risk level. Both of these scenarios provide a level of protection consistent with that recommended by EPA

in the 2000 Human Health Methodology. However, when EPA evaluated the level of protection that would be provided using the more conservative of both factors (BCF of 350 and inorganic proportion factor of 10%), a criterion of 1.0 µg/l resulted in a 1.3 x 10^{-4} risk level. This level is a higher risk than that recommended by EPA in the 2000 Human Health Methodology. EPA notes that the highest ratio of inorganic to total arsenic in fish tissue of saltwater organisms identified by ODEQ was 7.3%. ODEQ used 10% as a conservative inorganic proportion value for marine criteria (incorporating data from freshwater species) but EPA believes 7.3% is also a conservative estimate for marine organisms as it is the highest data value reported. Combining an inorganic factor of 7.3% (not as conservative a value as selected by Oregon but still sufficiently conservative based on a reasonable assessment of the available data) with a BCF of 350 (more conservative than the value ultimately selected by Oregon), EPA calculated that a criterion of 1.0 µg/L would protect high fish consuming populations at a risk level of 9.6 x 10^{-5}. Thus, a criterion of 1.0 µg/l calculated using a conservative inorganic proportion factor of 7.3% would protect high fish consumers in Oregon at a level consistent with that recommended by EPA in the 2000 Human Health methodology.

Oregon has presented a reasonable scientific basis to not rely solely on the BCF from the eastern oyster (350) in calculating the saltwater criterion, and instead rely on a BCF that incorporates data from other species (26).[119] Furthermore, the percentage of total arsenic that occurs in an inorganic form that Oregon paired with this BCF (10%) was more than sufficiently conservative based on the available data. Based on the calculations discussed in the paragraph above and these additional considerations, EPA believes that Oregon's saltwater criterion for arsenic will protect human health consistent with the level recommended by EPA.

(3) GENERAL CONSIDERATIONS

Risk level applied to arsenic criteria relative to that applied to other criteria

EPA reviewed the information provided by Oregon related to establishing criteria for arsenic at a level different than that used for all other criteria in the State. EPA notes that ODEQ stated that they were addressing arsenic as a special case and clearly stated their reasons for evaluating risk management decisions relative to this pollutant. The public notice, memorandum presenting recommendations to the EQC and ODEQ's document presenting its review and recommendations for the arsenic criteria all clearly identify that the criteria recommendations were established at a level providing less protection than for other pollutants in Oregon. Thus, the Commission was made aware of the policy decision inherent in their decision to adopt the recommended criteria. Thus, EPA finds that Oregon was reasonably exercising its discretion when establishing an alternate risk level for the arsenic criteria.

Cancer Slope Factor

One commenter noted that a cancer slope factor of 1.75$(mg/kg/day)^{-1}$ was used by EPA to develop the current 304(a) criteria recommendation while another stated that EPA was currently

[119] Mollusks tend to accumulate arsenic to a greater extent than other species and mollusks represent only a small percent (3-13%) of the U.S. general population's total fish and shellfish consumption. A marine BCF that is only based on mollusk data is therefore not ideally representative of marine species overall. EPA concludes that it was reasonable for Oregon to incorporate data from non-mollusk species to arrive at a more representative BCF, even though those non-mollusk species were not marine species.

reviewing the science behind the cancer slope factor. Both of these assertions are correct. EPA's 304(a) criteria recommendations for arsenic were first published in 1986 and uses a cancer slope factor of $1.75(mg/kg/day)^{-1}$. This recommendation has not been updated to reflect the latest value identified in the IRIS database, in part because the science behind that number is currently under review. A draft document was circulated for public comment and peer review by the Science Advisory Board in 2010.[120] EPA is currently reviewing these comments and has yet to make a final determination on potential revisions to the cancer slope factor for arsenic. Thus, EPA does not believe it appropriate for ODEQ to use the draft value in revising these criteria. EPA expects to coordinate with ODEQ regarding the potential need for reevaluation of the criteria if a new value is established in IRIS and/or changes are made to EPA's 304(a) criteria recommendations for arsenic.

3. EPA Action and Rationale Regarding Oregon's Arsenic Criteria

EPA Action
In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves Oregon's revised human health toxic criteria for inorganic arsenic because they are protective of Oregon's fishing and water supply uses. EPA is also approving footnote A which states: *The arsenic criteria are expressed as total inorganic arsenic. The "organism only" criteria are based on a risk level of approximately 1.1 x 10^{-5}, and the "water + organism" criterion is based on a risk level of 1.1 x 10^{-4}.*

EPA Rationale
EPA's WQS regulations require that criteria protect the designated uses. As noted previously, Oregon's human health criteria apply to waters with fishing and water supply uses and thus must be established at a level that will protect those uses. Therefore, EPA must evaluate whether the criteria protect Oregon's human health uses.

As discussed in detail above, EPA has found that Oregon considered the available and relevant literature in revising Oregon's arsenic criteria. Oregon provided a reasonable basis for the decisions made in developing the criteria. All three of the criteria adopted by ODEQ were found to protect human health uses consistent with recommendations provided in EPA's 2000 Human Health Methodology.

Inorganic Arsenic and Footnote A in Table 40
EPA's current 304(a) human health criteria recommendations are specifically identified as criteria for inorganic arsenic. As noted above, inorganic arsenic is the form most toxic to humans. As such, EPA's recommendations relative to this criteria and the associated risk assessment input variables are expressed as inorganic arsenic. In this revision, Oregon specifically identified that the criteria as inorganic arsenic in Table 40 by placing the word "inorganic" in parentheses.

[120] February 19, 2010. *Federal Register*, Volume: 75, No.: 33, page: 7477 (78 FR 7477). Available at: http://www.gpo.gov/fdsys/pkg/FR-2010-02-19/pdf/FR-2010-02-19.pdf

In addition, EPA is approving footnote A to the arsenic criteria in Table 40 which states: *The arsenic criteria are expressed as total inorganic arsenic. The "organism only" criteria are based on a risk level of approximately 1.1 x 10^{-5}, and the "water + organism" criterion is based on a risk level of 1.1 x 10^{-4}.*

The first sentence of the footnote provides clarification that the human health criterion for arsenic is expressed as total inorganic. This new footnote language for arsenic is consistent with EPA's recommended 304(a) national default expression for the arsenic criterion. The second sentence of the footnote clearly articulates the input variables regarding risk levels that were used to derive the arsenic criteria. This footnote establishes a legally binding requirement under State law and helps describe a desired ambient condition of a waterbody to support a particular designated use and is therefore considered a WQS subject to EPA review and approval under 303(c) of the CWA. The description of the applicable expression of arsenic associated risk level is a component of the overall level of protection afforded by the arsenic criteria. Therefore, EPA approves this footnote as a WQS.

Acknowledgement of Maximum Contaminant Level (MCL) in Table 20
ODEQ revised the drinking water MCL for arsenic from 0.05 mg to 10 µg/l in Table 20 and added footnote 1 which states: *The arsenic value is shown here for informational purposes only and is not a water quality criterion.*

Drinking water standards are regulations that EPA sets to control the level of contaminants in the nation's drinking water. In most cases, the standard is a MCL**,** the maximum permissible level of a contaminant in water which is delivered to any user of a public water system. The Safe Drinking Water Act gives individual states and tribes the opportunity to set and enforce their own drinking water standards if the standards are at least as stringent as EPA's national standards. When making a determination to regulate, the Safe Drinking Water Act requires consideration of these three criteria:

- the potential adverse effects of the contaminant on the health of humans;
- the frequency and level of contaminant occurrence in public drinking water systems; and
- whether regulation of the contaminant presents a meaningful opportunity for reducing public health risks.

ODEQ revised their MCL value for arsenic from 0.05 mg to 10 µg/l in Table 20. This revision reflects the current level set under the Safe Drinking Water Act and is consistent with EPA recommended drinking water MCL.[121] ODEQ also added a clarifying footnote which explains that the MCL value is not a water quality criterion.

[121] January 22, 2001. *Federal Register*, Volume: 66, No.: 14, page: 6976 (66 FR 6976). *Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring Final Rule.* Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2001/January/Day-22/w1668.htm
March 25, 2003. *Federal Register*, Volume: 68, No.: 57, page: 14501 (68 FR 14501). *Minor Clarification of National Primary Drinking Water Regulation for Arsenic; Final Rule.* Available at: http://www.gpo.gov/fdsys/pkg/FR-2003-03-25/html/03-7048.htm

Since Oregon has not adopted the arsenic MCL value as a water quality criterion, is not considered WQS under the CWA. Instead, the MCL is a value that the State uses to set the maximum permissible level of arsenic in drinking water delivered to the tap (after treatment) consistent with the Safe Drinking Water Act, not a value that surface waters of the State must meet. MCLs are enforceable standards under the Safe Drinking Water Act, and are not required under the Clean Water Act unless determined by the State to be needed to protect the designated uses. For these reasons, EPA is taking no action to approve or disapprove the revised MCL value for arsenic.

Based on the above, EPA has determined that Oregon's MCL value for arsenic is not a WQS subject to EPA review and approval under Section 303(c) of the CWA. As a result, EPA is taking no action to approve or disapprove this MCL value.

Provision Establishing the Effective Date for Arsenic at OAR 340-041-0033(2)(b)
The following language was added to Oregon's WQS at OAR340-041-0033 – Toxic Substances as part of Oregon's April 21, 2011 rule revisions submitted to EPA on July 12, 2011:

OAR 340-041-0033(2)(b) The arsenic criteria in Table 20 established by this rule do not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act unless and until they are approved by EPA pursuant to 40 CFR 131.21 (4/27/2000).

As part of Oregon's subsequent June 16, 2011 rule revisions submitted to EPA on July 21, 2011, Oregon removed and renumbered the provision cited above language at OAR 340-041-0033(3)(b) when it reformatted the toxics criteria tables, thus moving the arsenic criteria to Table 40. Since the deleted language was submitted to EPA as part of the June 16, 2011 rule revisions, the provision is no longer applicable under state law and there is no requirement for EPA to act on the provision under Section 303(c) of the CWA.
~~*OAR 340-041-0033(3)(b) The arsenic criteria in Table 20 established by this rule do not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act unless and until they are approved by EPA pursuant to 40 CFR 131.21 (4/27/2000).*~~

Since ODEQ deleted the language l as part of the July 21, 2011 submittal to EPA, the provision is not applicable under State law and there is no requirement for EPA to evaluate the provision under Section 303(c) of the CWA.

In the July 21, 2011 submittal, ODEQ addressed the effective dates of the criteria, including arsenic, in the associated revisions at OAR 340-041-0033(1) which describe the dates when the toxics criteria in Tables 20, 33A, 33B and 40 become effective under State law and the Clean Water Act. EPA's rationale for approval of OAR 340-041-0033(1) is explained in section V of this document.

Acknowledgement of the Arsenic Reduction Policy at OAR 340-041-0033(7)
In conjunction with this rule and in recognition that the revised criteria provide a lower level of protection than other human health criteria in Oregon, an Arsenic Reduction Policy was adopted under State law at OAR 340-041-033(4). To accommodate additional revisions associated with the rulemaking submitted to EPA on July 21, ODEQ reorganized the location of the rule and

moved the arsenic reduction policy section to OAR 340-041-0033(7). However, ODEQ did not revise any of the rule language that was previously adopted. The policy was included in Oregon's WQS regulation in the same section as the arsenic criteria to help ensure it was applied where applicable. The policy requires that, in situations where water bodies have background levels below the arsenic criteria, dischargers with the potential to affect a drinking water supply develop an arsenic reduction plan and take feasible steps to reduce arsenic loading.

The new policy does not establish a legally binding ambient condition for a waterbody to support a particular designated use. Nor does it establish a binding process whereby the State would establish an alternate ambient condition for a waterbody following a public process. Rather, this policy outlines permitting requirements that the State will place on selected dischargers (those located in a surface water drinking water protection area as delineated under the Safe Drinking Water Act). These permitting requirements are not tied to what is necessary to protect the designated uses of Oregon's waters, but rather to what measures are "feasible" to reduce arsenic loading. The permitting requirements are to be used in association with other implementation tools to encourage further arsenic reductions below the established criteria, but they do not modify those criteria.

In the Response to Comments, ODEQ states that the arsenic reduction policy is an important component of Oregon's WQS but that the intent of the policy is not to alter the numeric criteria. Furthermore, ODEQ specifies that the policy applies to specific sources and circumstances and requires that feasible reduction steps be taken.[122]
Based on the above, EPA has determined that this policy is not a WQS subject to EPA review and approval under Section 303(c) of the CWA. As a result, EPA is taking no action to approve or disapprove this provision.

F. *NEW, REVISED AND WITHDRAWN FOOTNOTES*

As part of the July 21, 2011 submittal, ODEQ added, revised and withdrew several footnotes. In addition to footnote J (for methylmercury) and footnote A (for arsenic) which are discussed separately above with those individual criteria, these changed footnotes are described in further detail below.

1. New Footnotes

ODEQ has added new footnotes for the following three pollutants: barium, cyanide, and PCBs.

Footnote C: Barium
The human health criterion for barium is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The

[122] ODEQ. March 2011. *Summary of Public Comment and Agency Response. Amending Oregon's Water Quality Standards: Revising Human Health Criteria for Arsenic.* Oregon Department of Environmental Quality. page 26. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/metals/AttCArsenicPublicComment.pdf

"water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.

Footnote G: Cyanide
The cyanide criterion is expressed as total cyanide (CN)/L.

Footnote L: PCBs
This criterion applies to total PCBs (e.g. determined as Aroclors or congeners).

Acknowledgement of Barium Footnote C
The new footnote C for barium clarifies the source of information upon which the criterion is based. However, the footnote does not establish a legally binding requirement under State law nor does it describe a desired ambient condition of a waterbody to support a particular designated use. Therefore this footnote is not considered a WQS subject to EPA review and approval under 303(c) of the CWA. As a result, EPA is taking no action to approve or disapprove the new footnote for barium. The underlying criterion for barium was unrevised and therefore EPA is not reviewing the underlying criterion as part of this action.

EPA acknowledges that the footnote provides accurate information respecting the human health criterion development for barium. The new footnote for barium explains that the criterion is based upon a Safe Drinking Water MCL value along with the rationale for why an "organism only" criterion does not exist. The human health criterion for barium was not derived using EPA's 2000 Methodology, but instead was based upon EPA's national 304(a) criteria recommendations in EPA's 1986 Gold Book.

EPA Approval of Footnotes for Cyanide (footnote G) and PCBs (footnote L)
In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves Oregon's addition of the two footnotes, Footnote G for cyanide and Footnote L for PCBs, as consistent with EPA's current CWA § 304(a) criteria recommendations.

EPA Rationale Regarding Footnotes for Cyanide (footnote G) and PCBs (footnote L)
Oregon's new footnote G for cyanide explains that the criterion is expressed as total cyanide (CN)/L. EPA has reviewed this footnote language and the 304(a) criteria recommendation, which states that the "recommended water quality criterion is expressed as total cyanide, even though the IRIS RfD used to derive the criterion is based on free cyanide. The multiple forms of cyanide that are present in ambient water have significant differences in toxicity due to their differing abilities to liberate the CN-moiety. Some complex cyanides require even more extreme conditions than refluxing with sulfuric acid to liberate the CN-moiety. Thus, these complex cyanides are expected to have little or no 'bioavailability' to humans. If a substantial fraction of the cyanide present in a water body is present in a complex form (e.g., $Fe_4[Fe(CN)_6]_3$), this criterion may be over conservative."[123] Oregon's new footnote language along with the human

[123] EPA. *National Recommend Ambient Water Quality Criteria for the Protection of Aquatic Life and Human Health.* Published pursuant to section 304(a) of the Clean Water Act. Footnote jj. Available at: http://www.epa.gov/waterscience/criteria/wqctable/index.html

health criterion values for cyanide are consistent with EPA's recommended 304(a) national default values for calculating the criterion.

This footnote establishes a legally binding requirement under state law and helps describe a desired ambient condition of a waterbody to support a particular designated use and is therefore considered a WQS subject to EPA review and approval under 303(c) of the CWA. The description of the applicable form of cyanide is a component of the overall description of the level of protection afforded by the criterion. Since this footnote specifies the applicable form of the cyanide criterion Oregon adopted, EPA approves this footnote as a WQS. EPA is approving the associated numeric criteria for cyanide as discussed above in section IV.

Oregon's new footnote L for PCBs explains that the criterion applies to total PCBs. EPA has reviewed this footnote language and the 304(a) criteria recommendations, which states that the "criterion applies to total PCBs, (e.g., the sum of all congener or all isomer or homolog or Aroclor analyses.)"[124] Oregon's new footnote language along with the human health criterion values for PCBs are consistent with EPA's recommended 304(a) national default values for calculating the criterion.

This footnote establishes a legally binding requirement under state law and helps describe a desired ambient condition of a waterbody to support a particular designated use and is therefore considered a WQS subject to EPA review and approval under 303(c) of the CWA. The description of the applicable form of PCBs is a component of the overall description of the level of protection afforded by the criterion. Since this footnote specifies the applicable form of the PCB criterion Oregon adopted, EPA approves this footnote as a WQS. EPA is approving the associated numeric criteria for PCBs as discussed above in section IV.

2. Revised Footnotes

ODEQ has revised the footnotes below for the following six pollutants: footnote B: asbestos, footnote D: chlorophenoxy herbicide (2,4,5,-TP), footnote E: chlorophenoxy herbicide (2,4,-D), footnote F: copper, footnote I: methoxychlor, and footnote K: nitrates.

Table 12: Revised Footnotes.

Id.	Pollutant	Previous Footnote	New Footnote
B	Asbestos	*Human health criteria for carcinogens reported for three risk levels. Value presented is the 10-6 risk level, which means the probability of one cancer case per million people at the stated concentration.*	*The human health risks from asbestos are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*
D	Chlorophenoxy Herbicide (2,4,5,-TP)	*This value is based on a Drinking Water regulation.*	*The Chlorophenoxy Herbicide (2,4,5,-TP)criterion is the same as originally*

[124] EPA. *National Recommend Ambient Water Quality Criteria for the Protection of Aquatic Life and Human Health.* Published pursuant to section 304(a) of the Clean Water Act. Footnote N. Available at: http://www.epa.gov/waterscience/criteria/wqctable/index.html

			published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.
E	Chlorophenoxy Herbicide (2,4,-D)	*This value is based on a Drinking Water regulation.*	*The Chlorophenoxy Herbicide (2,4,-D) criterion is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*
F	Copper	*This value is based on a Drinking Water regulation.*	*Human health risks from copper are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*
I	Methoxychlor	*No BCF was available; therefore, this value is based on that published in the 1986 EPA Gold Book.*	*The human health criterion for methoxychlor is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water + organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.*
K	Nitrates	*No BCF was available; therefore, this value is based on that published in the 1986 EPA Gold Book.*	*The human health criterion for nitrates is the same as originally published in the 1976 EPA Red Book which predates the 1980 methodology and did not utilize the fish ingestion BCF approach. This same criterion value was also published in the 1986 EPA Gold Book. Human health risks are primarily from drinking water, therefore no "organism only" criterion was developed. The "water +*

			organism" criterion is based on the Maximum Contaminant Level (MCL) established under the Safe Drinking Water Act.

EPA Review
All six of these revised footnotes clarify the sources of information upon which the criteria are based. The footnotes are not considered water quality standards because they do not establish legally binding requirements under State law and do not describe a desired ambient condition of a waterbody to support a particular designated use. Therefore they are not water quality standards subject to EPA review and approval under 303(c) of the CWA. As a result, EPA is taking no action to approve or disapprove the revised footnotes for these six pollutants.

The revised footnotes identified above explain in more detail than the previous footnotes that the criteria are based upon a Safe Drinking Water MCL value in addition to an explanation concerning the rationale for why an "organism only" criterion does not exist. These human health criteria were not derived using EPA's 2000 Methodology, but instead were based upon EPA's national 304(a) criteria recommendations in EPA's 1986 Gold Book and developed under the Safe Drinking Water Act. EPA has reviewed these footnotes and found them to be accurate regarding the human health criteria development for these six pollutants. The underlying toxics criteria for asbestos and copper were approved by EPA on June 1, 2010. The underlying toxics criteria for chlorophenoxy herbicide (2,4,5,-TP), chlorophenoxy herbicide (2,4,-D), methoxychlor, and nitrates have not been revised and thus are not addressed in this action. These values remain consistent with EPA's current 304(a) criteria recommendations.

3. Withdrawn Footnotes

ODEQ has removed the footnote below for the three pollutants to which it applied: hexachlorocyclo-hexane-technical, nitrosamines, and nitrosodiethylamine, N:
No BCF was available; therefore, this value is based on that published in the 1986 Gold Book.

EPA Review
EPA's current CWA 304(a) criteria recommendations include the following BCF values for these three pollutants:

- Hexachlorocyclo-hexane-technical: BCF value = 130
- Nitrosamines: BCF value = 0.20
- Nitrosodiethylamine, N: BCF value = 0.20

At the time of Oregon's previous adoption of human health criteria for these three pollutants, EPA's 304(a) criteria recommendations were not derived using a methodology that accounted for bioconcentration through the use of a BCF. EPA now recommends the use of the BCF values listed above. Consistent with EPA's recommended 304(a) national default values for calculating the human health criteria, ODEQ has updated the criteria for these three pollutants to include EPA's recommended BCF values and therefore the three footnotes are no longer accurate or relevant. EPA is approving Oregon's human health criteria for hexachlorocyclo-hexane-

technical, nitrosamines, and nitrosodiethylamine, N as discussed above in section IV as consistent with EPA's 304(a) guidance.

Therefore, as a result of updating the human health criteria for these three pollutants, the footnotes are no longer accurate and relevant and removing them is appropriate. Furthermore, these three footnotes were not water quality standards because they did not establish legally binding requirements under state law and they did not describe a desired ambient condition of a waterbody to support a particulate designated use. Rather, the footnotes clarified the source of information, EPA's 1986 Gold Book, upon which the criteria were based. For this reason, the footnotes were not considered WQS subject to EPA review and approval under 303(c) of the CWA. As a result, EPA is taking no action to approve or disapprove the removal of the footnote as applied to hexachlorocyclo-hexane-technical, nitrosamines, and nitrosodiethylamine, N.

G. *WITHDRAWN HUMAN HEALTH CRITERIA WHICH WERE REPLACED BY MORE SPECIFIC CRITERIA*

During this rule revision, Oregon updated its numeric human health toxics criteria to reflect EPA's most recent science and refinements as published in EPA's current CWA § 304(a) criteria recommendations. Included in the refinements recommended by EPA was the removal of 13 general human health criteria developed for families of pollutants and the replacement of these criteria by other criteria that address the specific chemical(s) of concern for human health protection. The 13 chemicals that ODEQ has removed and replaced with criteria for specific chemical compounds are consistent with EPA's current 304(a) criteria recommendations. They are listed and explained in Table 13 below.

Table 13: Withdrawn human health criteria replaced with more specific criteria.

No.	Withdrawn Criteria	Replacement Criteria	Explanation[125]
1	Dinitrotoluene	*Dinitrotoluene 2,4*	More specific and more stringent of the two compounds was retained.
2	Dinitro-o-Cresol 2,4	Dinitrophenol 2,4; Dinitrophenols	Alternative compounds, including a synonym, in the same family identified.
3	Diphenylhydrazine	Diphenylhydrazine 1,2	More specific compound in the same family identified.
4	Endosulfan	Endosulfan Alpha; Endosulfan Beta; Endosulfan Sulfate	More specific compounds in the same family identified.
5	Halomethanes	Chlorodibromomethane; Dichlorobromomethane; Bromoform; *Chloroform*	More specific compounds in the same family identified.
6	Monochlorobenzene	Chlorobenzene	Identical compound, the two criteria names are synonyms.

[125] Explanations in the table were developed with information from EPA's "Gold Book". EPA. May 1, 1986. *Quality Criteria for Water*. U.S. Environmental Protection Agency, Office of Water. 440/5-86-001. Available at: https://owpubauthor.epa.gov/scitech/swguidance/standards/upload/2009_01_13_criteria_goldbook.pdf

7	Polynuclear Aromatic Hydrocarbons	Acenaphthene; Anthracene; Fluorene; *Fluoranthene;* Pyrene; Chyrsene; Dibenzo(a,h)anthracene; Benzo(a)anthracene; Benzo(a)pyrene; Benzo(b)fluorantehene 3,4; Benzo(k)fluoranthene; Indeno(1,2,3-cd)pyrene	More specific compounds in the same family identified.
8	Chlorinated Benzenes	Chlorobenzene	More specific compound in the same family identified.
9	DDT	DDD 4,4'; DDE 4,4'; DDT 4,4'	More specific compounds in the same family identified.
10	Dichlorobenzenes	*Dichlorobenzene(m) 1,3*; Dichlorobenzene(o)1,2; Dichlorobenzene(p) 1,4	More specific compounds in the same family identified.
11	Dichloroethylenes	Dichloroethylene 1,1; Dichloroethylene trans 1,2	More specific compounds in the same family identified.
12	Dichlorobenzidine	*Dichlorobenzidine 3,3'*	More specific and more sensitive of the two compounds was retained.
13	Dichloropropene	*Dichloropropene 1,3*	More specific and more sensitive of the two compounds was retained.

Note: Chemicals listed in *italics* are criteria that Oregon had previously adopted and which EPA had previously approved. EPA is taking no action on these criteria. All other pollutants listed in the replacement criteria column, new criteria have been adopted by Oregon and are approved by EPA as part of this action.

EPA Review

In 2000 and 2003 EPA refined its "priority" list of toxic pollutants and 304(a) human health criteria recommendations specific to a number of pollutants on that list.[126] The criteria for the 13 pollutants listed above have been refined in three ways:

1. EPA previously had established recommended criteria for large chemical families of pollutants. Advances in scientific information have allowed EPA to refine its criteria recommendations by developing criteria for specific chemical forms (i.e. isomers or congeners) of a pollutant within the larger chemical family. For example, while the *Gold Book* published only a single criterion for DDT, subsequent revisions (see EPA's 2004 *National Recommended Water Quality Criteria*) have resulted in multiple criteria for DDT and two metabolites: 4,4' DDT, 4,4' DDE and 4,4' DDD. Similarly, while the *Gold Book* recommended a single criterion for dichlorobenzenes in the *Gold Book,* EPA's 2004 *National Recommended Water Quality Criteria*, recommends criteria for 1,2-dichlorobenzene, 1,3-dichlorobenzene, and 1,4-dichlorobenezene;

[126] November 3, 2000. *Federal Register*, Volume: 65, Issue: 214, page: 66443 (65 FR 66443). Available at: http://www.epa.gov/fedrgstr/EPA-WATER/2000/November/Day-03/w27924.htm
December 31, 2003. *Federal Register*, Volume: 68, Issue: 250, page: 75507 (68 FR 75507). Available at: http://edocket.access.gpo.gov/2003/pdf/03-32211.pdf

2. EPA has replaced some of the toxic pollutant names with synonyms for specific chemicals.[127] For example, while the *Gold Book* contained criteria for hexachlorocyclohexane-alpha, hexachlorocyclohexane-beta, and hexachlorocyclohexane-gamma, these criteria are now listed under the synonyms alpha BHC, beta BHC and gamma BHC in EPA's *National Recommended Water Quality Criteria*; and
3. EPA has condensed certain pollutants from several chemical forms of a given compound into a single compound, such as recommending criteria for total arsenic in EPA's 2004 *National Recommended Water Quality Criteria* to replace the previously recommended criteria for arsenic (tri) and arsenic (pent) as published in the *Gold Book*.

In updating its numeric toxics human health criteria, Oregon revised the criteria consistent with EPA's most recent CWA § 304(a) criteria recommendations, including withdrawing and/or revising the criteria as recommended by the above changes. The criteria withdrawn based on these refinements in chemical names are identified in Table 13 above. The table further identifies the pollutants for which Oregon has adopted new criteria to address the human health impacts associated with these pollutants. EPA action on the new criteria were addressed previously as part of EPA's action on Oregon's new criteria in section IV.B.

EPA Approval

In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves the withdrawal of Oregon's human health criteria for the 13 pollutants identified in Table 13, coupled with EPA's approval of new criteria (in section IV.B), as protective of human health. These changes are consistent with EPA's current CWA § 304(a) criteria recommendations to replace the specified criteria with more specific criteria for associated pollutants consistent with the latest science. EPA has approved the more specific pollutant replacement criteria above as consistent with 40 C.F.R. part 131. Since these new criteria address the same human health affects as the withdrawn criteria, EPA finds the criteria for the 13 pollutants identified above are not necessary to protect Oregon's fishing and water supply uses.

EPA Rationale

The CWA requires that, whenever a state or authorized tribe revises or adopts new WQS, it adopt criteria for all toxic pollutants listed pursuant to CWA § 307(a)(1) for which EPA has developed recommended criteria under CWA § 304(a), the discharge or presence of which in the affected waters could reasonably be expected to interfere with the adopted designated uses (CWA § 303(c)(2)(B)). As noted above, Oregon has refined the list of criteria for which it has established human health criteria to reflect recent science incorporated by EPA into the § 304(a)

[127] In addition, the following pollutant names were modified by ODEQ from their previous human health criteria for consistency with EPA terminology. These compounds are synonyms.

1. Dibutylphthalate was changed to Di-n-butyl Phthalate
2. Di-2-ethylhexyl phthalate was changed to Ethylhexyl phthalate bis 2
3. Hexachlorocyclohexane-alpha was changed to BHC alpha
4. Hexachlorocyclohexane-beta was changed to BHC beta
5. Hexachlorocyclohexane-gamma was changed to BHC gamma (Lindane)

human health criteria recommendations, including the removal of several pollutants representing chemical families and replacing them with criteria for more specific chemical compounds within the same general family. As such, the changes in the pollutant names listed above and the criteria adopted for these pollutants represent a refinement of criteria for individual chemicals within families, not withdrawals of criteria identified for pollutants in CWA § 307(a). Therefore, Oregon's withdrawal of its previous human health water quality criteria for these 13 pollutants is consistent with CWA § 303(c)(2)(B).

As stated above, Oregon's removal of these 13 pollutants and the associated criteria is consistent with EPA's removal of 304(a) criteria recommendations. Although the criteria for these 13 pollutants have been withdrawn, Oregon has developed individual criteria for the most toxic of chemicals in that family or retained the more specific criteria or a synonym for the chemical compounds. Therefore, while withdrawing the criteria for these 13 pollutants, Oregon has adopted new criteria to protect the same human health endpoints which these criteria were originally developed to protect. Therefore, EPA has determined that the withdrawal of these criteria coupled with the adoption of new criteria for similar pollutants (approved above in section IV.B) will protect Oregon's human health uses in accordance with 40 C.F.R. part 131.11(a)(1).

H. *TABLE 40 HUMAN HEALTH CRITERIA SUMMARY*

Oregon has added the following summary language prior to the human health criteria in Table 40 which explains the purpose of the criteria, criteria derivation and the format of the table.

TABLE 40: Human Health Water Quality Criteria for Toxic Pollutants

Human Health Criteria Summary
The concentration for each pollutant listed in Table 40 was derived to protect Oregonians from potential adverse health impacts associated with long-term exposure to toxic substances associated with consumption of fish, shellfish, and water. The "organism only" criteria are established to protect fish and shellfish consumption and apply to waters of the state designated for fishing. The "water + organism" criteria are established to protect the consumption of drinking water, fish, and shellfish, and apply where both fishing and domestic water supply (public and private) are designated uses. All criteria are expressed as micrograms per liter (µg/L), unless otherwise noted. Pollutants are listed in alphabetical order. Additional information includes the Chemical Abstract Service (CAS) number, whether the criterion is based on carcinogenic effects (can cause cancer in humans), and whether there is an aquatic life criterion for the pollutant (i.e. "y"= yes, "n" = no). All the human health criteria were calculated using a fish consumption rate of 175 grams per day unless otherwise noted. A fish consumption rate of 175 grams per day is approximately equal to 23 8-ounce fish meals per month. For pollutants categorized as carcinogens, values represent a cancer risk of one additional case of cancer in one million people (i.e. 10-6), unless otherwise noted. All metals criteria are for total metal concentration, unless otherwise noted. Italicized pollutants represent non-priority pollutants. The human health criteria revisions established by OAR 340-041-0033

and shown in Table 40 do not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act until approved by EPA pursuant to 40 CFR 131.21 (4/27/2000).

Acknowledgement of Table 40 Summary Language

The new introductory summary language for Table 40 explains the purpose of the criteria, criteria derivation and the format of the table. However, this language does not establish a legally binding requirement under State law and it does not describe a desired ambient condition of a waterbody to support a particular designated use it is not considered a WQS subject to EPA review and approval under 303(c) of the CWA. EPA has addressed the new and revised underlying human health criteria in Table 40 and the narrative language at OAR 340-041-0033(4) in this technical support document. This summary language further explains how the state derived the criteria values in Table 40. EPA incorporated the explanatory information provided in this summary into its analysis of the individual criteria values in Table 40. But because this summary does not operate as an independent water quality standard, in isolation from the criteria values in Table 40 and the narrative language at OAR 340-041-0033(4) (which EPA acted on individually), EPA is taking no action to approve or disapprove this summary language.

V. NARRATIVE STATEMENT

Oregon's revisions to its narrative toxics provisions found at OAR 340-041-033(1), (3) and (4) are shown in underline/strikeout format below. Underlined text represents added text, while text with a line through the middle (strikeout) represents deleted text. Non-revised words are also provided below for context. Additionally, Oregon reorganized sections of OAR 340-041-0033, thus renumbering several of the provisions without substantively changing any of the regulatory language.

340-041-0033
Toxic Substances
(1) Amendments to sections (4) and (6) of this rule (OAR 340-041-0033) and associated revisions to Tables 20, 33A, 33B and 40 do not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act unless and until EPA approves the provisions it identifies as water quality standards pursuant to 40 CFR 131.21 (4/27/2000).

(3) Aquatic Life Criteria. Levels of toxic substances in waters of the state may not exceed the applicable aquatic life criteria listed in Tables 20, 33A, and 33B. Tables 33A and 33B, adopted on May 20, 2004, update Table 20 as described in this section.

EPA Action
In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves the new and revised language at OAR 340-041-0033(1) and (3).

EPA Rationale
The new and revised provisions at OAR 340-041-0033(1) and (3) describe dates when the toxics criteria in Tables 20, 33A, 33B and 40 become effective under state law and the Clean Water Act. The effective date of WQS provisions under the CWA is determined by the date of EPA approval. These timing provisions are WQS that provide for the new and revised criteria to be immediately in effect at the time of EPA's approval action. EPA has addressed the new and revised underlying human health criteria in this technical support document. OAR 340-041-0033(3) clarifies that only aquatic life criteria remain in Tables 20, 33A and 33B. EPA will address the aquatic life criteria in these tables and their corresponding footnotes in a separate action.

(4) Human Health Criteria. The criteria for waters of the state listed in Table 40 are established to protect Oregonians from potential adverse health effects associated with long-term exposure to toxic substances associated with consumption of fish, shellfish, and water.

EPA Action
In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves the new language at OAR 340-041-0033(4).

EPA Rationale

The new provision at OAR 340-041-0033(4) adopts the human health criteria in Table 40. EPA approves this language which adopts the criteria and describes the intent of the criteria to protect human health uses in Oregon. This language explains the purpose of the human health criteria and describes that the criteria in Table 40 are established to protect Oregonians from potential adverse health effects association with long-term exposure to toxic substances associated with fish, shellfish and water consumption. EPA's action on each individual criterion in Table 40 is described in detail above.

VI. BACKGROUND POLLUTANT CRITERIA PROVISION

A. *BACKGROUND*

As previously discussed, in October 2008, the Oregon Environmental Quality Commission directed ODEQ to revise the State's human health criteria to incorporate a fish consumption rate of 175 grams per day. The fish consumption rate of 175 grams per day was selected by Oregon to ensure protection of all people in Oregon who may consume fish and shellfish from State waters including those who traditionally consume high amounts of fish for subsistence, health, economic or other reasons.[128] The rate reflects the 95th percentile of tribal members surveyed as part of the CRITFC Survey[129] and the 90th percentile of subsistence consumers surveyed in regional fish consumption studies. When providing this direction, the Commission also directed ODEQ to "propose rule language that would allow [O]DEQ to implement the standards in NPDES permits and other Clean Water Act programs in an environmentally meaningful and cost-effective manner" and to carefully consider the costs and benefits associated with elements of the new rule. This latter directive came following testimony from several stakeholders regarding potential implementation difficulties and economic burden of adopting the more stringent criteria.[130]

In response to this direction, ODEQ not only revised the human health criteria but also developed several new and revised rules addressing the implementation of the revised criteria. Each revised implementation rule targeted specific situations raised as potential concerns by ODEQ staff and stakeholders. The adoption of a new site-specific background pollutant criterion provision and the revisions to the variance provision (discussed in previous section) were submitted to EPA for action under Section 303(c) of the CWA while other rules were adopted pursuant to state law and were not submitted to EPA. All revisions are addressed separately in this document.

Oregon developed an *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking*[131] that discusses how ODEQ will implement the revised criteria in NPDES permits. Section IV.3 of this paper speaks directly to the site-specific background pollutant criterion provision and provides greater detail on its purpose, development and content as well as providing some discussion of how the resultant

[128] ODEQ. October 6, 2008. *Memo from Dick Pederson, Director ODEQ, to the Environmental Quality Commission. Agenda Item G, Action Item: Oregon's Fish Consumption Rate – For Use in Setting Water Quality Standards for Toxic Pollutants October 23, 2008 EQC Meeting.* Oregon Department of Environmental Quality. page 7. Available at: http://www.deq.state.or.us/about/eqc/agendas/attachments/2008oct/ItemG.pdf
[129] Columbia River Inter-Tribal Fish Commission (CRITFC). October 1994. *A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin.* Technical Report 94.3. Available at: http://www.critfc.org/tech/94-3report.pdf
[130] Oregon Environmental Quality Commission (OEQC). October 23, 2008. *Oregon Environmental Quality Commission Minutes of the Three Hundred and Forty-sixth Meeting.* Available at: http://www.deq.state.or.us/about/eqc/minutes/2008/2008octEQCMinutes.htm
[131] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

criterion would be applied to NPDES permits.[132] Other issue papers were developed to address implementation of the criteria outside of the NPDES program including papers that address nonpoint sources, antidegradation and source control.[133]

One situation identified during the workgroup process as potentially problematic to dischargers as well as ODEQ when issuing NPDES permits as a result of the revised human health criteria is when a NPDES discharger takes in water from and discharges to the same waterbody, which contains pollutants from upstream sources over which the discharger has little to no control. ODEQ adopted an intake credit provision at OAR 340-045-0105 that does not hold facilities accountable for removing these upstream pollutants if the concentration of the pollutant does not exceed the water quality criteria, the facility does not chemically or physically modify the pollutant and several other conditions described in the rule are met.

However, facilities that concentrate pollutants in their discharge above the levels in the intake water are not eligible for the intake credit rule. For example, such an increase in concentration may occur when a facility's process involves evaporation (e.g. non-contact cooling water), and the facility recycles water, thus resulting in the same mass of the pollutant but a lower volume of water. If the upstream concentration of the pollutant in the waterbody exceeds the underlying criterion, a permit limit is established such that the criterion is met at the end of the discharge pipe and the facility would need to treat the water prior to discharge regardless of the upstream concentration.[134]

ODEQ discussed numerous options for addressing this type of situation with the objective for providing an approach that:

- protects human health;
- establishes reasonable implementation of the revised water quality standards for facilities in the situation described above;
- allocates limited State resources efficiently; and

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[132] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. Section IV.3, pages 44-61. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

[133] ODEQ. May 26, 2011. *Issue Paper: Revisions to the Water Quality Standards and TMDL Rules (Divisions 41 and 42), Clarifications on How Nonpoint Sources Meet Water Quality Standards, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/Div4142IssuePaper.pdf
ODEQ. December 29, 2010. *Issue Paper: Evaluating the Antidegradation Policy as a Means to Reduce Nonpoint Sources of Toxic Pollutants to Oregon Waters, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/AntidegIssuePaper.pdf
ODEQ. December 29, 2010. *Issue Paper: Source Control Small Group, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/SourceControlIssuePaper.pdf

[134] ODEQ. April 20, 2010. *Implementing Water Quality Standards for Toxic Pollutants in Clean Water Act Permits.* DRAFT. RWG April 27, 2010 Discussion. Oregon Department of Environmental Quality. page 6. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/BackgroundPollutantsIssuePaper20110427.pdf

- ensures that regulatory requirements and costs for a facility are commensurate with the environmental threat they pose.[135]

Oregon proposed a draft rule and accepted public comment on that rule during the public process described above for all other elements of this action submitted by Oregon on July 21, 2011. In EPA's public comments to ODEQ on March 21, 2011 regarding the previous version of the background pollutant criteria provision proposed for public comment, EPA stated that ODEQ could:

- Implement the criterion on a site specific basis and submit each application to EPA for evaluation on a case by case basis; or
- Revise the provision consistent with a performance-based approach as a viable alternative to submitting each revision to EPA on a site specific basis. If ODEQ were to choose this option, sufficiently detailed implementation procedures would need to be adopted directly into the WQS regulations which establish a framework that is binding, clear, predictable and transparent.

Following consideration of the comments received, ODEQ adopted a performance-based water quality standard that can be used to adopt site-specific criteria for human health carcinogens where all of the following conditions apply:

- The criterion at issue is a human health criterion, for a pollutant identified as a carcinogen.
- The discharge does not increase the mass load of the pollutant in the receiving water. The mass load of the pollutant discharged to a waterbody may not exceed the mass load of the pollutant taken in from the same waterbody or a hydrologically connected water.
- The pollutant concentration in the receiving water is not increased by more than 3% above the upstream ambient concentration.
- The water body concentration does not exceed a calculated value that represents the human health criterion calculated at a risk level of 10^{-4}.
- The discharger uses any feasible pollutant reduction measures known and available to minimize the pollutant concentration in their discharge.
- The criterion must be evaluated and revised, if appropriate, when the permit is reissued.
- No TMDL has been developed for the waterbody and pollutant at issue.[136]

The provision authorizes ODEQ to develop a site-specific criterion for the waterbody in the vicinity of a discharge and use that criterion to develop an effluent limit for the pollutant if all conditions of the rule are met. The criterion established would be based upon the most stringent of 1) the instream concentration following receipt of the current level of discharge from the

[135] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. pages 45-46. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf
[136] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. pages 44-45. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

facility, 2) a 3% increase in the ambient instream concentration of the pollutant, or 3) a concentration value that represents a 1×10^{-4} risk level. In addition, the criterion could not be established at a level that would allow the facility to increase the mass load of the pollutant from that in their intake water.[137]

A site-specific background pollutant criterion may only be developed under this provision if the waterbody serves as the receiving water for a NPDES discharge and the effluent discharged meets certain requirements. Oregon's rule limits the criteria developed under this rule by requiring the criteria be established at the most stringent of several options that are based on applying certain limitations on the effluent from the facility and on the resultant instream criteria. Therefore, the process outlined in Oregon's rule uses the same type of calculations made in establishing NPDES permit limits to calculate the resultant instream concentration at various effluent conditions. Once a site-specific criterion is adopted, it is to be used to develop permit effluent limits in the same manner as any other criteria.[138]

In order to provide further guidance to their permit writers ODEQ will be developing an Internal Management Directive (IMD) within 180 days of EPA's approval action.[139] This is one of several items identified by ODEQ as actions necessary to assist ODEQ staff and the public in implementing the provisions approved in this action.

B. *ODEQ'S JULY 21, 2011 SUBMITTAL*

ODEQ has added a new provision which establishes a site-specific background pollutant criteria at OAR 340-041-0033(6). This provision is a performance-based water quality standard that results in site-specific human health water quality criteria under the conditions and procedures specified within the rule. It addresses existing permitted discharges of a pollutant removed from the same body of water, as defined in the provision.

Below is Oregon's background pollutant criteria provision, found at OAR 340-041-0033(6).

340-041-0033(6)

Establishing Site-Specific Background Pollutant Criteria: This provision is a performance-based water quality standard that results in site-specific human health water quality criteria under the conditions and procedures specified in this rule section. It addresses existing permitted discharges of a pollutant

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[137] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 44. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

[138] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 60. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

[139] ODEQ. June 2, 2011. Memorandum from Dick Pedersen to Environmental Quality Commission; *Agenda item C, Rule adoption: Revised water quality standards for human health and revised water quality standards implementation policies,* June 15-17, EQC meeting. Oregon Department of Environmental Quality. Supplemental Attachment 10, Timeline for Follow-Up Actions, WQS for Human Health Toxic Pollutants Rulemaking.

removed from the same body of water. For waterbodies where a discharge does not increase the pollutant's mass and does not increase the pollutant concentration by more than 3%, and where the water body meets a pollutant concentration associated with a risk level of $1x10^{-4}$, DEQ concludes that the pollutant concentration continues to protect human health.

(a) Definitions: For the purpose of this section [OAR 340-041-0033(6)]:

(A) "Background pollutant concentration" means the ambient water body concentration immediately upstream of the discharge, regardless of whether those pollutants are natural or result from upstream human activity.

(B) An "intake pollutant" is the amount of a pollutant that is present in public waters (including groundwater) as provided in subsection (C), below, at the time it is withdrawn from such waters by the discharger or other facility supplying the discharger with intake water.

(C) "Same body of water": An intake pollutant is considered to be from the "same body of water" as the discharge if the department finds that the intake pollutant would have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee. This finding may be deemed established if:

(i) The background concentration of the pollutant in the receiving water (excluding any amount of the pollutant in the facility's discharge) is similar to that in the intake water;

(ii) There is a direct hydrological connection between the intake and discharge points; and

(I) The department may also consider other site-specific factors relevant to the transport and fate of the pollutant to make the finding in a particular case that a pollutant would or would not have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee.

(II) An intake pollutant from groundwater may be considered to be from the "same body of water" if the department determines that the pollutant would have reached the vicinity of the outfall point in the receiving water within a reasonable period had it not been removed by the permittee, except that such a pollutant is not from the same body of water if the groundwater contains the pollutant partially or entirely due to past or present human activity, such as industrial, commercial, or municipal operations, disposal actions, or treatment processes.

(iii) Water quality characteristics (e.g., temperature, pH, hardness) are similar in the intake and receiving waters.

(b) Applicability

(A) Site-specific criteria may be established under this rule section only for carcinogenic pollutants.

(B) Site-specific criteria established under this rule section apply in the vicinity of the discharge

for purposes of establishing permit limits for the specified permittee.
(C) The underlying waterbody criteria continue to apply for all other Clean Water Act programs.

(D) The site-specific background pollutant criterion will be effective upon department issuance of the permit for the specified permittee.

(E) Any site-specific criteria developed under this procedure will be re-evaluated upon permit renewal.

(c) A site-specific background pollutant criterion may be established where all of the following conditions are met:

(A) The discharger has a currently effective NPDES permit;

(B) The mass of the pollutant discharged to the receiving waterbody does not exceed the mass of the intake pollutant from the same body of water, as defined in section 6(a)(C) above, and, therefore, does not increase the total mass load of the pollutant in the receiving water body;

(C) The discharger has not been assigned a TMDL wasteload allocation for the pollutant in question;

(D) The permittee uses any feasible pollutant reduction measures available and known to minimize the pollutant concentration in their discharge;

(E) The pollutant discharge has not been chemically or physically altered in a manner that causes adverse water quality impacts that would not occur if the intake pollutants were left in-stream; and,

(F) The timing and location of the pollutant discharge would not cause adverse water quality impacts that would not occur if the intake pollutant were left in-stream.

(d) The site-specific background pollutant criterion must be the most conservative of the following four values. The procedures deriving these values are described in the sections (6)(e) of this rule.

(A) The projected in-stream pollutant concentration resulting from the current discharge concentration and any feasible pollutant reduction measures under (c)(D) above, after mixing with the receiving stream.

(B) The projected in-stream pollutant concentration resulting from the portion of the current discharge concentration associated with the intake pollutant mass after mixing with the receiving stream. This analysis ensures that there will be no increase in the mass of the intake pollutant in the receiving water body as required by condition (c)(B) above.

(C) The projected in-stream pollutant concentration associated with a 3% increase above the background pollutant concentration as calculated:

(i) For the mainstem Willamette and Columbia Rivers, using 25% of the harmonic mean flow of the waterbody.

(ii) For all other waters, using 100% of the harmonic mean flow or similar critical flow

value of the waterbody.

(D) A criterion concentration value representing a human health risk level of 1×10^{-4}. This value is calculated using EPA's human health criteria derivation equation for carcinogens (EPA 2000), a risk level of 1×10^{-4}, and the same values for the remaining calculation variables that were used to derive the underlying human health criterion.

(e) Procedure to derive a site-specific human health water quality criterion to address a background pollutant:

(A) The department will develop a flow-weighted characterization of the relevant flows and pollutant concentrations of the receiving waterbody, effluent and all facility intake pollutant sources to determine the fate and transport of the pollutant mass.

(i) The pollutant mass in the effluent discharged to a receiving waterbody may not exceed the mass of the intake pollutant from the same body of water.

(ii) Where a facility discharges intake pollutants from multiple sources that originate from the receiving waterbody and from other waterbodies, the department will calculate the flow-weighted amount of each source of the pollutant in the characterization.

(iii) Where intake water for a facility is provided by a municipal water supply system and the supplier provides treatment of the raw water that removes an intake water pollutant, the concentration and mass of the intake water pollutant shall be determined at the point where the water enters the water supplier's distribution system.

(B) Using the flow weighted characterization developed in Section (6)(e)(A), the department will calculate the in-stream pollutant concentration following mixing of the discharge into the receiving water. The resultant concentration will be used to determine the conditions in Section (6)(d)(A) and (B).

(C) Using the flow weighted characterization, the department will calculate the in-stream pollutant concentration based on an increase of 3% above background pollutant concentration. The resultant concentration will be used to determine the condition in Section (6)(d)(C).

(i) For the mainstem Willamette and Columbia Rivers, 25% of the harmonic mean flow of the waterbody will be used.

(ii) For all other waters, 100% of the harmonic mean flow or similar critical flow value of the waterbody will be used.

(D) The department will select the most conservative of the following values as the site-specific water quality criterion.

(i) The projected in-stream pollutant concentration described in Section 6(e)(B);

(ii) The in-stream pollutant concentration based on an increase of 3% above background described in Section 6(e)(C); or

(iii) A water quality criterion based on a risk level of 1×10^{-4}.

(f) Calculation of water quality based effluent limits based on a site-specific background pollutant criterion:

> *(A) For discharges to receiving waters with a site-specific background pollutant criterion, the department will use the site-specific criterion in the calculation of a numeric water quality based effluent limit.*
>
> *(B) The department will compare the calculated water quality based effluent limits to any applicable aquatic toxicity or technology based effluent limits and select the most conservative for inclusion in the permit conditions.*

(g) In addition to the water quality based effluent limits described in Section (6)(f), the department will calculate a mass-based limit where necessary to ensure that the condition described in Section (6)(c)(B) is met. Where mass-based limits are included, the permit shall specify how compliance with mass-based effluent limitations will be assessed.

(h) The permit shall include a provision requiring the department to consider the re-opening of the permit and reevaluation of the site-specific background pollutant criterion if new information shows the discharger no longer meets the conditions described in subsections (6)(c) and (e).

(i) Public Notification Requirements.

> *(A) If the department proposes to grant a site-specific background pollutant criterion, it must provide public notice of the proposal and hold a public hearing. The public notice may be included in the public notification of a draft NPDES permit or other draft regulatory decision that would rely on the criterion and will also be published on the water quality standards website;*
>
> *(B) The department will publish a list of all site-specific background pollutant criteria approved pursuant to this rule. A criterion will be added to this list within 30 days of its effective date. The list will identify: the permittee; the site-specific background pollutant criterion and the associated risk level; the waterbody to which the criterion applies; the allowable pollutant effluent limit; and how to obtain additional information about the criterion.*

C. *EPA ACTION ON ODEQ'S NEW BACKGROUND POLLUTANT CRITERIA PROVISION*

EPA Action

In accordance with its CWA authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves Oregon's new background pollutant criteria provision at OAR 340-041-0033(6), as detailed below, because it is consistent with the Clean Water Act and the implementing Federal water quality standards regulations governing EPA's review and approval or disapproval of new or revised water quality standards as required in 40 C.F.R. part 131. In EPA's review of Oregon's background pollutant criteria provision, the Agency considered information submitted on July 21, 2011 including ODEQ's NPDES Implementation Issue Paper[140] and Response to

[140] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. Available at:

Comments document.[141]

In its review and action on the background pollutant provision, EPA also considered the following three key elements:

- Whether the site-specific human health criteria to be generated under the provision are sufficient to protect Oregon's human health uses, as required under 40 CFR 131.6.
- Whether the site-specific human health criteria to be generated under the provision are consistent with EPA's regulatory specifications for criteria at 40 CFR 131.11.
- Whether this implementation procedure contains sufficient detail, and suitable safeguards, such that additional § 303(c) review of individual criteria generated under the provision would be redundant.

As described in further detail below, EPA has concluded that the site-specific background pollutant provision adequately addresses all three of these elements and thus is consistent with CWA § 303(c) and its implementing regulations.

EPA Rationale

The provision establishes site-specific human health criteria at a level to protect Oregon's human health uses

Oregon's site-specific background pollutant provision contains a binding restriction that any site-specific criterion to be generated under the provision must be established at the most conservative (stringent) of the conditions specified in OAR 340-041-033(6)(d) and reflect no net addition of the pollutant from the discharger to the waterbody segment. In no case may a criterion developed under this provision represent a carcinogenic human health risk level greater than 1.0 x10^{-4}, however, it may be more stringent. Since the least stringent scenario for a site-specific criterion generated under the provision (i.e., one generated based on a 10^{-4} risk level) is itself within EPA's recommended range of risk levels protective of human health designated uses, EPA concludes that a criterion developed using Oregon's site-specific background pollutant provision would be protective of Oregon's human health uses.

EPA's Human Health Methodology recognizes that States and Tribes have discretion in selecting appropriate risk ranges and recommends that states adopt criteria for carcinogens based on either a 1 x 10^{-6} or 1 x 10^{-5} risk level to protect the general population, as long as highly exposed populations do not exceed a 1 x 10^{-4} risk level.[142] Consistent with the flexibility accorded to States in developing risk ranges for carcinogenic pollutants, Oregon has chosen to exercise this discretion by allowing the risk level for carcinogens in waters in the vicinity of certain NPDES discharges not to exceed 10^{-4}. As discussed previously, Oregon used a fish consumption rate reflective of highly exposed consumers and a risk level of 1 x 10^{-6} for deriving their human

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http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

[141] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. page 21. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf

[142] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, EPA-822-B-00-004. page 2-6. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

health criteria. In this case, the site specific criteria would continue to protect the highly exposed consumer but at a risk level between 1 x 10^{-6} and 1 x 10^{-4}. Thus, EPA concludes that any site-specific criterion calculated based on a 1 x 10^{-4} risk level would be consistent with EPA's guidance with respect to highly exposed populations, since the fish consumption rate already reflects highly exposed populations. EPA has recommended using a fish consumption rate for the general US population of 17.5 grams per day if no local or regional data is available. There is currently no available fish consumption data specific to the general population of Oregon. If one were to evaluate the protectiveness of a site-specific criterion developed under this provision at a 10^{-4} risk level but using EPA's default fish consumption rate of 17.5 grams per day, the result would protect at a carcinogenic risk level of 1 x 10^{-5}. This risk level is consistent with that recommended by EPA by EPA in the 2000 Human Health Methodology. Therefore, EPA finds that criteria established under this provision would be established at a level protective of both the general population and high fish consuming populations consistent with the levels recommended by EPA in the 2000 Human Health Methodology.

In response to several comments regarding the use of a 1 x 10^{-4} risk level, ODEQ affirmed that the criterion would be established at "the most protective of the following results: the current ambient pollutant concentration after discharge; the background concentration plus three percent; or the criteria value calculated at a 1 x 10^{-4} risk level" (emphasis added)).[143] In several other responses to comments as well as at several places in the Issue Paper, ODEQ has also stated that a 1 x 10^{-4} risk would be the greatest possible risk allowed under the criterion and that other conditions within the provision would often limit the criterion further.[144] ODEQ also specifies this fact in their July 21, 2011 letter to EPA requesting the review and approval of these rules.[145] In ODEQ's response to comments, they explained why they found this additional level of risk to be protective in this site-specific situation. They note that several restrictions have been included in the rule in order to limit any additional risk to the human health use.

- First, the rule requires that the pollutant be from the "same body of water" and that the mass of the pollutant associated with the facility may not be increased from its intake water to the effluent water. These requirements ensure that any discharge limits based on the site specific criterion would not add any additional mass to the waterbody, although the discharger may slightly increase the pollutant concentration relative to background (up to a maximum of three percent). In other words, the pollutant present in the

[143] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. page 54. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf
[144] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. pages 49; 55-58. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf
ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. pages 47; 49; 50; 58. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf
[145] ODEQ. July 21, 2011. Letter from Neil Mullane, Water Quality Division Administrator, to Michael Bussell, Office of Water and Watersheds, EPA Region 10. *Re: Oregon Submission of Revised State Water Quality Standards for Toxic Pollutants, Including a New Background Pollutant Provision and a Revised Variance Rule for EPA Review and Approval.*

waterbody segment to which the criteria will apply would have reached the vicinity of the outfall point had it not been intercepted by the discharger and there is no addition of pollutants by the facility.[146]

- Second, the application of the criterion is limited to the sole purpose of accommodating existing discharges from an existing NPDES discharger. In no case could a criterion decrease in stringency such that the current discharge concentration to a water body would be allowed to increase as a result of the revision.[147]
- Third, the underlying water quality criterion will remain in effect for all other CWA purposes including 303(d) listing and TMDL development. (as explained above)
- Finally, the rule requires that the criterion be re-evaluated upon permit renewal (OAR 340-041-0033(6)(b)(E)), thus making the criterion effective only for the duration of the permit and requiring that the site-specific criterion be reevaluated and revised, if appropriate, upon permit renewal using current ambient and effluent data in situations where all the prerequisite conditions continue to be present.[148] As noted above, if a TMDL was established prior to this renewal, a site-specific criterion could not be obtained under this rule and the facility's effluent limit must be consistent with the WLA in the TMDL.

ODEQ therefore determined that the relative increase in ambient concentration does not result in a significant change to human health risk[149] and that the criterion developed under this provision would be protective of the beneficial uses of that waterbody.[150]

Since this provision establishes a process for developing individual site-specific criteria, the exact location of each application cannot be specified in advance. However, the provision does specify criteria location relative to the pertinent discharger ("in the vicinity of the discharge for purposes of establishing permit limits for the specified permittee"). (OAR 340-041-0033(6)(b)). Thus, dischargers other than the specified permittee would not be able to use the site-specific criterion in permit calculations.[151] For the specified permitee, a site-specific criterion

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[146] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. page 51. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf

[147] OAR 340-041-0033(6)(d)(A) and (B)
ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 44. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

[148] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. page 60. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf

[149] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 44. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

[150] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. page 65. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf

[151] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 44. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf
ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water*

corresponding to a risk level of 1 x 10^{-4} or safer would be applicable to the water in the vicinity of the discharge.[152] Since the site-specific conditions are themselves predicated on the characteristics of the discharger, an appropriate matching of the criterion to discharger is an adequate specification of where the site-specific criteria will apply.

EPA notes that one commenter was concerned that the approach in the proposed rule introduced an inconsistency into Oregon's water quality criteria. The commenter questioned whether it was consistent with the Clean Water Act for Oregon to determine that a single risk target is both protective (where site-specific criteria apply) and non-protective (where site-specific criteria do not apply) of human health uses. ODEQ addressed this comment by adding additional detail in the final rule. In addition, EPA evaluated this concern relative to the final rule in light of the fact that Oregon already had the discretion, consistent with EPA's Human Health Methodology, to adopt criteria based on a risk range between 1 x 10^{-6} and 1 x 10^{-4} (in conjunction with a fish consumption rate that reflects high-consuming populations). If Oregon had adopted state-wide criteria reflecting a risk range less stringent than 1 x 10^{-6}, Oregon could have exercised its discretion, based on its own policy priorities and consistent with CWA § 510, to apply *more stringent* site-specific criteria where it deemed appropriate. Under these circumstances, a single risk target would be both protective (where site-specific criteria do not apply) and non-protective (where site-specific criteria apply). The only practical distinction between this scenario and the one raised in public comments is which risk level is treated as the normative baseline, and which is treated as site-specific departure from the baseline.

Since multiple risk levels for carcinogenic pollutants are within the range identified as acceptable in EPA's Human Health Methodology, and States/Tribes have the ability to define "local conditions" when establishing site specific criteria, EPA concludes that Oregon has discretion to apply both one risk level as a generally applicable value and other risk levels on a site-specific basis (i.e., as "site-specific conditions" under 40 CFR 131.11(b)). While the target risk level is combined with other values (based on a scientific rationale) to generate a criterion value for a carcinogenic pollutant, site-specific variation in the target risk level itself is based on Oregon's risk management judgment. In order for the overall site-specific criterion to be "based on sound scientific rationale," under 40 CFR 131.11(a)(1), it is sufficient that Oregon has clearly identified the rationale for the site-specific criteria as a policy decision within its discretion and consistent with EPA's Human Health Methodology.

EPA also notes that one commenter expressed concern about the interaction between the proposed background pollutant provision and Oregon's existing mixing zone policy. EPA acknowledges that, as with other Oregon criteria, the site specific criteria generated under the background pollutant provision would be used in developing water quality based effluent limits for the NPDES permit discharging to the waterbody. EPA also acknowledges that, in certain instances, Oregon's current mixing zone policy may be applied when developing such limits. In

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Quality Standards Implementation Policies. Oregon Department of Environmental Quality. page 56. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf

[152] As discussed below, Oregon's existing mixing zone policy would still affect the calculation of effluent limits based on the criterion. Nevertheless, the applicable criterion in the receiving water is constrained, by OAR 340-041-0033(6)(D), to be at least as stringent as the value calculated based on a risk level of 1x10^{-4}.

the Issue Paper ODEQ states that once the site-specific background pollutant criterion has been determined, the criterion will be used to establish a numeric permit effluent limit using the same procedures and guidance used for establishing permit limits for any human health criteria.[153] Furthermore, ODEQ's response to comments specifies that any mixing will be determined based on the guidance provided in [O]DEQ's Reasonable Potential Internal Management Directive (IMD) and that [O]DEQ's published guidelines (Regulated Mixing Zones IMD) would govern the siting and sizing of any zones of mixing.[154] Any mixing zone allowed would be required under the CWA to comply with the all requirements of the State's mixing zone provision prior to a mixing zone being authorized. In certain circumstances it is possible that a mixing zone for a site-specific criterion generated under this provision (or any other human health criterion for a carcinogen) may allow a limited area of the waterbody in which the cancer risk associated with the pollutant concentration would exceed 1×10^{-4}. However, EPA does not therefore conclude that the criterion is inconsistent with its Human Health Methodology. The potential for criteria to be implemented in concert with an EPA-approved state mixing zone policy is a background assumption of EPA's Human Health Methodology, not an additional factor that would weigh in favor of further limiting states' risk management discretion.

Furthermore, the language of OAR 340-041-0033(6)(d)(A) and (B) that speaks to the projected instream concentration "after mixing with the receiving stream" addresses the calculation of a projected instream value under specified effluent conditions. It does not establish a new mixing zone policy. EPA finds it appropriate that ODEQ utilize calculations similar to those used to develop permits when projecting this instream value as this allows the results of applying limitations to the effluent to be expressed as an insteam concentration and thus to be directly compared to the options limited by instream concentration. Furthermore, it provides that, for purposes of the stringency analysis, all options are expressed in the same units as the final criterion value. A similar practice is commonly used when EPA and States determine whether a discharge needs a water quality based effluent limit (see, e.g., 40 CFR 122.44(d)(1)(ii) "When determining whether a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above a narrative or numeric water quality standard, the permitting authority shall use procedures which account for … where appropriate, the dilution of the effluent in the receiving water." (emphasis added)).

EPA considered whether implementation of the background pollutant provision is consistent

[153] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 60. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

[154] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. page 55. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf
ODEQ. August 2011. *Internal Management Directive: Reasonable Potential Analysis Process for Toxic Pollutants, Version 3.0. Oregon Department of Environmental Quality.* Available at: http://www.deq.state.or.us/wq/pubs/imds/rpaIMD.pdf
ODEQ. December 2007. Oregon Department of Environmental Quality. *Regulatory Mixing Zone Internal Management Directive. Part 1: Allocating Regulatory Mixing Zones.* Available at: http://www.deq.state.or.us/wq/pubs/imds/rmz/RMZIMDpart1.pdf and *Regulatory Mixing Zone Internal Management Directive. Part 2: Reviewing Mixing Zone Studies.* Available at: http://www.deq.state.or.us/wq/pubs/imds/rmz/RMZIMDpart2.pdf

with the requirements of 40 CFR 131.10. For the following reasons, EPA concludes that it is. Oregon has expressly stated that a criterion based on a higher risk level, established pursuant to the provision, "continues to protect human health." OAR 340-041-0033(6). Thus, the background pollutant provision does not represent the revision of a human health use, but rather the articulation (within the range of the state's discretion) of the risk range the State considers protective of human health uses in this site-specific situation. The revision of criteria within the State's range of discretion for a designated use does not represent the removal or impairment of such a designated use. In conclusion, the provision contains a clear, predictable and transparent restriction that any site-specific criterion to be generated under the background pollutant provision must not correspond to a human health risk level of less stringent than 1×10^{-4}.[155] This minimum risk level is the most critical of the restrictions contained in the provision since it sets the least stringent criterion possible under the procedure. The least stringent criterion possible under the procedure is protective of Oregon's human health uses and is consistent with EPA's Human Health Methodology. Thus, EPA's approval of the provision may also serve as the Clean Water Act § 303(c)(3) approval of the individual site-specific criteria to be generated under the provision.

The provision generates site-specific human health criteria consistent with 40 CFR 131.11

EPA's regulations at 40 CFR 131.11 require States to adopt water quality criteria that protect the designated use and must be that are based on sound scientific rationale. It also allows States to modify criteria in order to reflect site-specific situations.[156] In OAR 340-041-0033(6) Oregon establishes a procedure to develop a site-specific human health criterion for carcinogens in a limited number of site-specific situations when developed consistent with the procedures specified in the rule.

Oregon has restricted the use of the site-specific background pollutant criteria provision to waterbodies where an existing NPDES discharger withdraws water from a waterbody and returns it to the same waterbody without adding any mass to the pollutant of concern. It is further limited to carcinogenic pollutants[157] and utilizes information about the discharge to limit the criterion. The rule provides a structured framework for developing a site-specific criterion which is limited by a number of factors, including a requirement that the criterion never exceed a criterion calculated at a 1×10^{-4} risk level. Further limitations are derived based on the pre-existing quantity and quality of the discharge into the receiving water, no greater than a three percent increase in instream concentration and no increase in mass load of the pollutant from the discharger. In no case will the criteria allow greater than a 10^{-4} carcinogenic risk level (as established using the same methodology used for all other human health criteria addressed in this action).

EPA has reviewed whether Oregon had supplied appropriate grounds to derive a site-specific human health criterion for carcinogens, consistent with 40 CFR 131.11. EPA's water quality standards regulations provide that water quality criteria "must be based on sound scientific

[155] OAR 340-041-0033(6)(d)
[156] 40 CFR 131.11 (A)(1); 40 CFR 131.11(b)(1)(ii)
[157] OAR 340-041-0033(6)(b)(A)

rationale,"[158] and contemplate that a State may adopt site-specific criteria, and provide that these site-specific criteria "should . . . reflect site-specific conditions."[159] EPA's Human Health Methodology further clarifies a State's flexibility to derive site-specific criteria for human health criteria. Human health criteria may be modified to reflect, in a justifiable manner, "local environmental conditions." Local conditions may be those which prevail over a particular river reach, an entire river, regionally, or Statewide.[160] In other guidance, EPA has acknowledged that *less stringent* site specific modifications to human health criteria may be appropriate (in that case, either based on local variation in fish consumption rates or applicable bioaccumulation factors).[161] Thus, EPA finds that the criteria are based on a sound scientific rationale, will reflect site-specific conditions and, as discussed above, are established at a level that will protect Oregon's human health uses.

The provision establishes site-specific human health criteria using the performance-based criterion approach

Finally, EPA reviewed whether the background pollutant provision contains sufficient detail, and suitable safeguards, that EPA's approval of the provision may also serve as the Clean Water Act § 303(c)(3) approval of the individual site-specific criteria to be generated under the provision**.**

EPA's water quality standard regulations at 40 CFR 131.21 provide that a state water quality standard adopted after May 30, 2000 is not applicable for Clean Water Act purposes until "EPA approves that water quality standard [under § 303(c)(3) of the CWA]." However, when EPA promulgated this regulation it made clear that states have the option to streamline this process by pursuing a "performance-based" approach whereby the state adopts a "process (i.e., a criterion derivation methodology) rather than a specific outcome (i.e., concentration limit for a pollutant) consistent with 40 CFR 131.11 and 131.13."[162] Under the performance-based approach, EPA conducts a CWA § 303(c)(3) review of the procedure and the criteria that would be generated under that procedure. EPA approval of the provision can encompass approval of the individual criteria to be generated under the provision where the procedure is "sufficiently detailed and has suitable safeguards to ensure predictable and repeatable outcomes." To this end, the procedure should establish a "structure or decision-making framework that is binding, clear, predictable, and transparent." [163] EPA further specified that the performance-based approach is particularly well suited to the derivation of site-specific numeric criteria where the proper construction and implementation of such an approach can result in defensible site-specific adjustments to numeric ambient water quality criteria.[164]

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[158] 40 CFR 131.11(a)
[159] 40 CFR 131.11(b)
[160] EPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. U.S. Environmental Protection Agency, Office of Water, EPA-822-B-00-004. pages 2-13. Available at: http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf
[161] 40 CFR 132 App. F., Proc. 1, A. 4
[162] April 27, 2000. *Federal Register*, Volume: 65, No.: 82, page: 24648 (65 FR 24648). Available at: http://www.gpo.gov/fdsys/pkg/FR-2000-04-27/pdf/00-8536.pdf
[163] April 27, 2000. *Federal Register*, Volume: 65, No.: 82, page: 24648 (65 FR 24648). Available at: http://www.gpo.gov/fdsys/pkg/FR-2000-04-27/pdf/00-8536.pdf
[164] April 27, 2000. *Federal Register*, Volume: 65, No.: 82, page: 24648 (65 FR 24648). Available at: http://www.gpo.gov/fdsys/pkg/FR-2000-04-27/pdf/00-8536.pdf

Oregon's site-specific background pollutant criterion provision was adopted as a performance-based approach to develop site-specific human health criteria for carcinogens under the conditions and procedures specified in their rule.[165] Oregon's July 21, 2011 submission letter specifically states that the provision was "adopted [as] a new performance-based water quality standard" and that it "establishes the procedure by which a site-specific criterion may be developed for a limited portion of the waterbody".[166] ODEQ's staff report EQC at the time of rule adoption indicates a clear intent for the rule to be adopted as a procedure by which, when approved by EPA, could be used to develop site-specific criteria that will not need subsequent approval by EPA.[167]

A performance-based approach relies on the State to specify methodologies and decision thresholds in their water quality standards regulations so that a structure or decision-making framework that is binding, clear, predictable and transparent is established. As with all other modifications to state water quality standards, EPA requires that the state provide opportunity for the public to comment on this rule and that the regulation be adopted consistent with state law. Oregon's site-specific pollutant criterion provision has been promulgated in OAR 340-041-0033(6) of Oregon's Water Quality Standards, has undergone public review and hearing through the process used for all other revisions adopted by the State on June 16, 2011, and has been certified as having been adopted pursuant to State law.[168] Therefore, EPA finds that this provision provides a regulatory framework for decision-making (i.e. criteria development) that is binding, predictable and transparent and that the public has had the opportunity to provide comment on the proposed rule.

EPA's guidance further notes that a performance-based "approach is particularly useful for criteria which are heavily influenced by site-specific factors."[169] In this case, Oregon has restricted the use of this provision to waterbodies where a waterbody contains a pollutant upstream of a water supply source and a NPDES discharger withdraws water from the waterbody and returns it to the same waterbody without adding any mass to the pollutant of concern. Additionally, the background pollutant provision specifies that it only applies to carcinogenic pollutants, OAR 340-041-0033(6)(b)(A), and utilizes information about the discharge to limit the criterion. Thus, EPA believes it is appropriate that such criterion be developed on a site-specific basis.

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[165] OAR 340-041-0033(6)
[166] ODEQ. July 21, 2011. Letter from Neil Mullane, Water Quality Division Administrator, to Michael Bussell, Office of Water and Watersheds, EPA Region 10. *Re: Oregon Submission of Revised State Water Quality Standards for Toxic Pollutants, Including a New Background Pollutant Provision and a Revised Variance Rule for EPA Review and Approval.*
[167] ODEQ. June 2, 2011. Memorandum from Dick Pedersen to Environmental Quality Commission; *Agenda item C, Rule adoption: Revised water quality standards for human health and revised water quality standards implementation policies,* June 15-17, EQC meeting. Oregon Department of Environmental Quality. page 11. Available at: http://www.deq.state.or.us/about/eqc/agendas/attachments/2011june/C-WQStdsStaffRpt.pdf
[168] Oregon Department of Justice. General Counsel Division. July 20, 2011. Letter from Larry Knudsen, Assistant Attorney General, Natural Resources Section, to Michael Bussell, EPA Region 10. *Re: Certification of Water Quality Standard Amendment (Fish Consumption Rate).*
[169] April 27, 2000. *Federal Register*, Volume: 65, No.: 82, page: 24648 (65 FR 24648). Available at: http://www.gpo.gov/fdsys/pkg/FR-2000-04-27/pdf/00-8536.pdf

Finally, EPA's guidance specifies that such procedures "must include a public participation step to provide all stake-holders and the public an opportunity to review the data and calculations supporting the site-specific application of the implementation procedures." The State would also need to maintain a publically available, comprehensive list of all site-by-site decisions made

using the procedures.[170] Oregon's WQS regulation at OAR 340-041-0033(6)(i) establishes the public notification requirements for any criterion to be adopted under this provision. It specifically requires ODEQ to provide public notice of the proposal and hold a public hearing. In addition to other public notification procedures in place by the State, ODEQ will publish the proposal on their WQS website. Furthermore, the provision requires ODEQ to publish a list of all criteria approved pursuant to the rule within 30 days of its effective date and identifies the minimum elements to be contained in this list. EPA believes that the public process required by Oregon within OAR 340-041-0033(6)(i) is consistent with that described in EPA's guidance and required by 40 CFR 131.11.

In order to provide further guidance to ODEQ staff and to ensure consistent implementation of the provision, ODEQ will develop an Internal Management Directive (guidance document) within 180 days of EPA's action on this provision.[171] This document will be available on ODEQ's website and thus facilitate even greater clarity and transparency for the public.

In consideration of the above factors, EPA concludes that the provision contains a binding, clear, predictable, and transparent framework such that any site-specific criterion generated under the provision must not result in a human health risk level of greater than 1×10^{-4} and will protect the human health uses of Oregon's waters. Therefore, any additional oversight by EPA would be redundant. Thus, the provision contains sufficient detail, and suitable safeguards, that EPA's approval of the provision serves as the Clean Water Act § 303(c)(3) approval of the individual site-specific criteria to be generated under the provision. Since this procedure is adopted into State regulation and Oregon is bound by the decision-making framework contained therein, any criteria which are not derived in accordance with the approved procedures would need separate approval from EPA to be applicable under the CWA.

When EPA reviews the results of Oregon's triennial review, EPA expects to evaluate a representative subset of the site-specific decisions to ensure that Oregon is adhering to the EPA-approved procedure. Finally, EPA notes that if Oregon fails to follow these procedures and does not obtain separate CWA § 303(c)(3) approval for the site-specific criterion, this would provide EPA with a basis to object to an NPDES permit for not deriving from or complying with the applicable standards.[172]

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[170] April 27, 2000. *Federal Register*, Volume: 65, No.: 82, page: 24648 (65 FR 24648). Available at: http://www.gpo.gov/fdsys/pkg/FR-2000-04-27/pdf/00-8536.pdf

[171] ODEQ. June 2, 2011. Memorandum from Dick Pedersen to Environmental Quality Commission; *Agenda item C, Rule adoption: Revised water quality standards for human health and revised water quality standards implementation policies,* June 15-17, EQC meeting. Oregon Department of Environmental Quality. Supplemental Attachment 10, Timeline for Follow-Up Actions, WQS for Human Health Toxic Pollutants Rulemaking.

[172] 40 CFR 122.44(d)
April 27, 2000. *Federal Register*, Volume: 65, No.: 82, page: 24648 (65 FR 24648). Available at: http://www.gpo.gov/fdsys/pkg/FR-2000-04-27/pdf/00-8536.pdf

VII. VARIANCE PROVISION

A. *BACKGROUND*

EPA's regulations at 40 C.F.R. Part 131.13, provides that states may, at their discretion, include in state water quality standards policies generally affecting the application and implementation of water quality standards, such as general policies for variances. If a state chooses to adopt such a variance policy, the regulation specifies that such policies are required to be submitted to EPA for review and approval.

The objective of the Clean Water Act is to restore and maintain the chemical, physical and biological integrity of the Nation's waters. The CWA further specifies an interim goal that, "wherever attainable," water quality provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water.

40 C.F.R. Part 131.10(g) specifies the factors a state may use to determine that a designated use, which is not an existing use, is not ultimately attainable. These factors are:

1. Naturally occurring pollutant concentrations prevent the attainment of the use; or
2. Natural, ephemeral, intermittent or low flow conditions or water levels prevent the attainment of the use, unless these conditions may be compensated for by the discharge of sufficient volume of effluent discharges without violating state water conservation requirements to enable uses to be met; or
3. Human caused conditions or sources of pollution prevent the attainment of the use and cannot be remedied or would cause more environmental damage to correct than to leave in place; or
4. Dams, diversions or other types of hydrologic modifications preclude the attainment of the use, and it is not feasible to restore the water body to its original condition or to operate such modification in a way that would result in the attainment of the use; or
5. Physical conditions related to the natural features of the water body, such as the lack of a proper substrate, cover, flow, depth, pools, riffles, and the like, unrelated to water quality, preclude attainment of aquatic life protection uses; or
6. Controls more stringent than those required by sections 301(b) and 306 of the Act would result in substantial and widespread economic and social impact.

In 1977, an Office of General Counsel legal opinion[173] considered the practice of temporarily downgrading the designated use and criteria, as it applies to a specific discharger rather than permanently[174] downgrading an entire water body or water body segment and determined that

[173] EPA. March 29, 1977. *Office of General Counsel on Matters of Law Pursuant to 40 CFR Section 125.36(m). No. 58.* U.S. Environmental Protection Agency. Washington, D.C. Available at: http://water.epa.gov/scitech/swguidance/standards/upload/2008_08_04_standards_section40cfr3.pdf

[174] "Permanent" used in the context of a designated use is intended solely to differentiate from a time-limited variance. EPA's regulations at 131.20 require states to review uses that do not include those specified in CWA section 101(a)(2) and to revise standards accordingly if information becomes available to indicate such uses are attainable.

such a practice is acceptable as long as it is adopted consistent with the substantive requirements for permanently downgrading a designated use. EPA continued to articulate this position in its *Water Quality Standards Handbook* (Section 5.3) specifically stating:

> *Variance procedures involve the same substantive and procedural requirements as removing a designated use , but unlike use removal, variances are both discharger and pollutant specific, are time limited, and do not forego the currently designated use*.

Thus, the six 131.10(g) factors, which are used to justify a designated use change through a use attainability analysis, consistent with 131.10(g), are the same factors that must be evaluated when justifying a variance.

Variances allow for a more site-specific and time-limited consideration of attainability than a permanent designated use revision. They encourage states to maintain the underlying designated uses and criteria as goals instead of declaring them unattainable prematurely when they may be attainable in the long term. For example, technology improvements could lower treatment costs in the future such that attaining the designated use and criteria would no longer cause substantial and widespread economic and social impact. Variances are typically specific to a pollutant(s) and either apply to specific permittees or geographic areas. Variances only apply to the pollutants, permittees and geographic areas for which they were written; all other applicable standards remain in place.

Variances must be of a limited or temporary duration for a fixed term.[175] Variances are time-limited designated uses and associated criteria and are thus considered water quality standards. As such, any variances granted by the state must be submitted to EPA for review and approval or disapproval under CWA section 303(c). The preamble to EPA's 1983 regulation[176] states that EPA has approved state-adopted variances in the past and will continue to do so if each individual variance is adopted as a water quality standard and subject to the same public review as other changes in the water quality standards. EPA's *Water Quality Standards Handbook*[177] reiterates the 1983 Preamble as did EPA's Advanced Notice of Proposed Rulemaking (ANPRM), in 1998, seeking comments on possible revisions to the Water Quality Standards Regulation.[178]

EPA's *Water Quality Standards Handbook* also specifies that EPA has approved state-adopted variances in the past and will continue to do so if:

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[175] EPA. January 24, 1992. Office of General Counsel Memorandum *Re: Request for Views on Allowable Duration of Water Quality Standards Variances.* U.S. Environmental Protection Agency. Catherine A Winer, Attorney. Available at: http://water.epa.gov/scitech/swguidance/standards/upload/1999_11_03_standards_variancememo.pdf

[176] November 8, 1983. *Federal Register*, Volume: 48, No.: 217, page 51403 (48 FR 51403). Available at: http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=20003ZVR.txt

[177] EPA. 1994. *Water Quality Standards (WQS) Handbook: Second Edition.* August 1994. United States Environmental Protection Agency, Office of Water. EPA-823-B-94-005a. page 5-12. Available at http://water.epa.gov/scitech/swguidance/standards/handbook/index.cfm

[178] July 7, 1998. *Federal Register*, Volume: 63, No.: 129, page: 36759 (63 FR 36759). Available at: http://water.epa.gov/scitech/swguidance/standards/handbook/upload/1998_07_07_1998_July_Day-07_w17513.pdf

- The State includes the individual variance as part of the water quality standard.
- The state demonstrates that meeting the standard is unattainable based on one or more of the factors in 131.10(g).
- The justification submitted includes documentation that treatment more advanced than that required by sections 301(b)(1)(b) and 306 of the Clean Water Act has been carefully considered and that alternative effluent control strategies have been evaluated.
- The more stringent State criterion is maintained and is binding upon all other dischargers on the stream or stream segment.
- The discharger who is given a variance for one particular constituent is required to meet the applicable criteria for other constituents.
- The variance was granted for a specific period of time.
- The discharger either must meet the standard upon the expiration of this time period or must make a new demonstration of "unattainability."
- Reasonable progress is being made toward meeting the water quality standards.
- The variance was subjected to public notice and opportunity for comment.

In summary, states have the discretion to include variance policies in their water quality standards regulation. Such policies are subject to EPA review and approval. In addition, if a state chooses to revise standards by granting a variance, states must adopt such variances pursuant to state law and each individual variance is subject to public review, consistent with EPA's regulations. Variances are not effective for Clean Water Act purposes until approved by EPA.

B. *ODEQ'S JULY 21, 2011 SUBMITTAL*

ODEQ has removed the variance language found at OAR 340-041-0061(2) and replaced it with new language at OAR 340-041-0059. Oregon's revised variance provision lays out the necessary process for obtaining a variance, the conditions under which a variance will be granted, and the requirements during a variance. DEQ's objective for these revisions is to ensure that variances and their accompanying pollutant reduction plans continue to ensure progress toward meeting standards, to streamline the administration process, to require pollutant reduction plans with specific milestones that will result in water quality improvement, and to add general clarification to the rule.[179]

Below is ODEQ's revised variance provision, found at OAR 340-041-0059.

OAR 340-041-0059
Variances

This rule (OAR 340-041-0059) does not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act unless and until EPA approves the provisions it identifies as water quality

[179] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

standards pursuant to 40 CFR 131.21 (4/27/2000).

(1) Applicability. Subject to the requirements and limitations set out in sections (2) through (7) below, a point source may request a water quality standards variance where it is demonstrated that the source cannot feasibly meet effluent limits sufficient to meet water quality standards. The director of the department will determine whether to issue a variance for a source covered by an existing NPDES permit. The commission will determine whether to issue a variance for a discharger that does not have a currently effective NPDES permit.

(a) The variance applies only to the specified point source permit and pollutant(s); the underlying water quality standard(s) otherwise remains in effect.

(b) The department or commission may not grant a variance if:

(A) The effluent limit sufficient to meet the underlying water quality standard can be attained by implementing technology-based effluent limits required under sections 301(b) and 306 of the federal Clean Water Act, and by implementing cost-effective and reasonable best management practices for nonpoint sources under the control of the discharger; or

(B) The variance would likely jeopardize the continued existence of any threatened or endangered species listed under section 4 of the Endangered Species Act or result in the destruction or adverse modification of such species' critical habitat; or

(C) The conditions allowed by the variance would result in an unreasonable risk to human health; or

(D) A point source does not have a currently effective NPDES permit, unless the variance is necessary to:

(i) Prevent or mitigate a threat to public health or welfare;

(ii) Allow a water quality or habitat restoration project that may cause short term water quality standards exceedances, but will result in long term water quality or habitat improvement that enhances the support of aquatic life uses;
(iii) Provide benefits that outweigh the environmental costs of lowering water quality. This analysis is comparable to that required under the antidegradation regulation contained in OAR-041-0004(6)(b); or

(E) The information and demonstration submitted in accordance with section (4) below does not allow the department or commission to conclude that a condition in section (2) has been met.

(2) Conditions to Grant a Variance. Before the commission or department may grant a variance, it must determine that:

(a) No existing use will be impaired or removed as a result of granting the variance and

(b) Attaining the water quality standard during the term of the variance is not feasible for one or

more of the following reasons:

(A) Naturally occurring pollutant concentrations prevent the attainment of the use;

(B) Natural, ephemeral, intermittent, or low flow conditions or water levels prevent the attainment of the use, unless these conditions may be compensated for by the discharge of sufficient volume of effluent discharges to enable uses to be met without violating state water conservation requirements;

(C) Human-caused conditions or sources of pollution prevent the attainment of the use and cannot be remedied or would cause more environmental damage to correct than to leave in place;

(D) Dams, diversions, or other types of hydrologic modifications preclude the attainment of the use, and it is not feasible to restore the waterbody to its original condition or to operate such modification in a way which would result in the attainment of the use;

(E) Physical conditions related to the natural features of the waterbody, such as the lack of a proper substrate, cover, flow, depth, pools, riffles, and unrelated to water quality preclude attainment of aquatic life protection uses; or

(F) Controls more stringent than those required by sections 301(b) and 306 of the federal Clean Water Act would result in substantial and widespread economic and social impact.

(3) Variance Duration.

(a) The duration of a variance must not exceed the term of the NPDES permit. If the permit is administratively extended, the permit effluent limits and any other requirements based on the variance and associated pollutant reduction plan will continue to be in effect during the period of the administrative extension. The department will give priority to NPDES permit renewals for permits containing variances and where a renewal application has been submitted to the director at least one hundred eighty days prior to the NPDES permit expiration date.

(b) When the duration of the variance is less than the term of a NPDES permit, the permittee must be in compliance with the specified effluent limitation sufficient to meet the underlying water quality standard upon the expiration of the variance.

(c) A variance is effective only after EPA approval. The effective date and duration of the variance will be specified in a NPDES permit or order of the commission or department.

(4) Variance Submittal Requirements. To request a variance, a permittee must submit the following information to the department:

(a) A demonstration that attaining the water quality standard for a specific pollutant is not feasible for the requested duration of the variance based on one or more of the conditions found in section (2)(b) of this rule;

(b) A description of treatment or alternative options considered to meet limits based on the applicable underlying water quality standard, and a description of why these options are not technically, economically, or otherwise feasible;

(c) Sufficient water quality data and analyses to characterize ambient and discharge water pollutant concentrations;

(d) Any cost-effective and reasonable best management practices for nonpoint sources under the control of the discharger that addresses the pollutant the variance is based upon;

(e) A proposed pollutant reduction plan that includes any actions to be taken by the permittee that would result in reasonable progress toward meeting the underlying water quality standard. Such actions may include proposed pollutant offsets or trading or other proposed pollutant reduction activities, and associated milestones for implementing these measures. Pollutant reduction plans will be tailored to address the specific circumstances of each facility and to the extent pollutant reduction can be achieved; and

(f) If the discharger is a publicly owned treatment works, a demonstration of the jurisdiction's legal authority (such as a sewer use ordinance) to regulate the pollutant for which the variance is sought. The jurisdiction's legal authority must be sufficient to control potential sources of that pollutant that discharge into the jurisdiction's sewer collection system.

(5) Variance Permit Conditions. Effluent limits in the discharger's permit will be based on the variance and not the underlying water quality standard, so long as the variance remains effective. The department must establish and incorporate into the discharger's NPDES permit all conditions necessary to implement and enforce an approved variance and associated pollutant reduction plan. The permit must include, at a minimum, the following requirements:

(a) An interim concentration based permit limit or requirement representing the best achievable effluent quality based on discharge monitoring data and that is no less stringent than that achieved under the previous permit. For a new discharger, the permit limit will be calculated based on best achievable technology;

(b) A requirement to implement any pollutant reduction actions approved as part of a pollutant reduction plan submitted in accordance with section (4)(e) above and to make reasonable progress toward attaining the underlying water quality standard(s);

(c) Any studies, effluent monitoring, or other monitoring necessary to ensure compliance with the conditions of the variance; and

(d) An annual progress report to the department describing the results of any required studies or monitoring during the reporting year and identifying any impediments to reaching any specific milestones stated in the variance.

(6) Public Notification Requirements.

(a) If the department proposes to grant a variance, it must provide public notice of the proposal and hold a public hearing. The public notice may be included in the public notification of a draft NPDES permit or other draft regulatory decision that would rely on the variance;

(b) The department will publish a list of all variances approved pursuant to this rule. Newly approved variances will be added to this list within 30 days of their effective date. The list will identify: the discharger; the underlying water quality standard addressed by the variance; the waters of the state to which the variance applies; the effective date and duration of the variance;

the allowable pollutant effluent limit granted under the variance; and how to obtain additional information about the variance.

(7) Variance Renewals.

(a) A variance may be renewed if:

(A) The permittee makes a renewed demonstration pursuant to section (2) of this rule that attaining the water quality standard continues to be infeasible,

(B) The permittee submits any new or updated information pertaining to any of the requirements of section 4,

(C) The department determines that all conditions and requirements of the previous variance and actions contained in the pollutant reduction plan pursuant to section (5) have been met, unless reasons outside the control of the discharger prevented meeting any condition or requirement, and

(D) All other requirements of this rule have been met.

(b) A variance renewal must be approved by the department director and by EPA.

C. *EPA ACTION ON ODEQ'S REVISED VARIANCE PROVISION*

EPA Action

In accordance with its CWA authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves certain sections of Oregon's revised variance provision at OAR 340-041-0059, as detailed below, because they are consistent with the Clean Water Act and the implementing Federal water quality standards regulations governing EPA's review and approval or disapproval of new or revised water quality standards as required in 40 C.F.R. part 131. These federal regulations as well as EPA's guidance, to date, on variances are detailed above. EPA outlines below the sections of the provision it is approving as water quality standards pursuant to CWA section 303(c) and the sections of the provision which are not water quality standards under CWA section 303(c) and therefore upon which EPA is taking no action. Oregon may use the full variance provision (both those sections approved as WQS and those identified as not being WQS) when developing and implementing any individual variance. Each individual variance the State adopts consistent with the regulations at OAR 340-041-0059, must be submitted to EPA for review and approval prior to its use in a NPDES permit or other CWA action. In EPA's review of Oregon's revised variance provision, the Agency considered information submitted on July 21, 2011 including ODEQ's NPDES Implementation Issue Paper[180] and Response to Comments document.[181]

[180] ODEQ. May 24, 2011. *Issue Paper: Implementing Water Quality Standards for Toxic Pollutants in NPDES Permits, Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/NPDESIssuePaper.pdf

[181] ODEQ. May 2011. *Response to Comments: Proposed Water Quality Standards for Human Health and Water Quality Standards Implementation Policies.* Oregon Department of Environmental Quality. page 21. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ResponseToComments.pdf

EPA Rationale
EPA has reviewed the provision at OAR 340-041-0059 in Oregon's water quality standards regulations, entitled, "Variances". EPA previously approved Oregon's existing variance provision at OAR 350-041-0061(2).

Oregon's revised variance provision adds more definition to what was required in OAR 350-041-0061(2) and requires the applicant to develop a schedule for improvements by implementing a pollution reduction plan. These revisions will assist in meeting the goal of facilitating water quality improvements and attaining the underlying criteria.

EPA is approving the specified sections of Oregon's variance regulation explained below as a "general policy" under §131.13. ODEQ is still required to submit each individual variance to EPA for review and action before it is effective for purposes of the CWA because the variances themselves are also water quality standards. Accordingly, each variance submitted for EPA's review must include the Attorney General's certification and be consistent with the CWA and EPA's implementing regulations, including all applicable public participation requirements. Thus, EPA's review of Oregon's variance authorizing provision need not evaluate each hypothetical variance the State may issue under OAR 340-041-0059 and consider whether such a variance would be consistent with the CWA and EPA's implementing regulation. EPA's approval of Oregon's variance provision at OAR 340-041-0059 is not an automatic approval of any future variance the State wishes to grant pursuant to these provisions.

Below, EPA outlines the sections it is approving as water quality standards pursuant to CWA section 303(c) and the sections upon which EPA is taking no action. EPA's approval reflects EPA's determination that the specific section adopted at OAR 340-041-0059 is consistent with the Clean Water Act and the implementing Federal water quality standards regulations in 40 C.F.R. part 131.

Introductory Language to OAR 340-041-0059
EPA is approving the introductory language which states, "This rule (OAR 340-041-0059) does not become applicable for purposes of ORS chapter 468B or the federal Clean Water Act unless and until EPA approves the provisions it identifies as water quality standards pursuant to 40 CFR 131.21 (4/27/2000)."

In accordance with its Clean Water Act authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves this new language. This language describes when Oregon's revised variance provision becomes effective under state law and the Clean Water Act. The effective date of water quality standards provisions under the CWA is determined by the date of EPA approval. This language regarding timing is a water quality standard that provides for the sections of the revised variance provision to be immediately in effect at the time of EPA's approval action.

OAR 340-041-0059(1) "Applicability"
EPA is approving OAR 340-041-0059(1) "Applicability" and OAR 340-041-0059(1)(a) which reflects that the variance only applies to the specified point source and pollutant; the underlying water quality standards remain in effect. This scope of applicability is consistent with EPA interpretive Guidance and the 1977 Office of General Counsel legal opinion discussing

variances.

Moreover, EPA is approving OAR 340-041-0059(1)(b) and (1)(b)(A) as they are consistent with 131.10(h)(2) which prohibits a State's removal of a designated uses where "[s]uch uses will be attained…by implementing cost-effective and reasonable best management practices for nonpoint source control." EPA has concluded that Oregon's language at (1)(b)(A) that prohibits the State from issuing a variance where *"effluent limitations sufficient to meet the underlying water quality standards can be attained by…implementing cost-effective and reasonable best management practices for nonpoint sources under the control of the discharger,"* is consistent with 131.10(h)(2) because Oregon's variance authorizing provision only allows the State to issue discharger-specific variances.[182] Given this scope of Oregon's variance authorizing provision, EPA believes it is reasonable for the State to limit the prohibition in (1)(b)(A) to those cost-effective and reasonable best management practices for nonpoint sources to those practices under the control of the discharger.[183]

EPA is approving OAR 340-041-0059(1)(b)(B)-(E) because these sections are not inconsistent with the CWA and EPA's implementing regulations. While OAR 340-041-0059(1)(b)(D) does not categorically prohibit the issuance of a variance to a new discharger, neither do the CWA or EPA's implementing regulations. While 40 CFR 122.4(i) limits discharges from "a new source or a new discharger" that "will cause or contribute to the violation of water quality standards," a variance is a revision to the water quality standard itself, and therefore 122.4(i) is not relevant. EPA notes, however, that the circumstances in which a new discharger will be able to meet the other requirements for a variance (e.g., a demonstration that [a]ttaining the water quality standard during the term of the variance is not feasible,") are likely to be significantly more limited for a new discharger than an existing discharger. EPA acknowledges that granting a variance to a new discharger may be appropriate under very specific and limited circumstances. It will review the appropriateness of particular circumstances on an individual variance basis.

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[182] OAR 340-041-0059(1)(a) provides that the "variance applies only to the specified point source permit and pollutant(s); the underlying water quality standard(s) otherwise remain in effect."

[183] EPA disagrees with the contrary contention, made in public comments, that the BMP requirements of 40 C.F.R. § 131.10(h)(2) must apply to "all nonpoint sources in the consideration of a variance application, not just those under the control of the applicant." Northwest Environmental Advocates (NWEA). March 17, 2011. Letter from Nina Bell, Executive Director, NWEA to Andrea Matzke, ODEQ, *Re: Proposed Revised Water Quality Standards for Human Health Toxic Pollutants and Revised Water Quality Standards Implementation Policies.* page 32. In support of this proposition, the commenter cites a 1994 EPA interpretive memorandum ("Tudor Davies memo") and a 1995 EPA economic guidance document. The Tudor Davies memo discusses how the requirements of 40 CFR 131.12(a)(2) apply to antidegradation policies, not the applicability of 40 CFR 131.10(h)(2) to variances. The citation to the 1995 Interim Economic Guidance for Water Quality Standards is similarly inapposite. This guidance addresses how an economic analysis under 131.10(g)(6) should be conducted to demonstrate that a variance is needed. Sections 40 C.F.R. 131.10(d) and (h)(2) are independent requirements from 131.10(g). EPA recognizes that the introduction section of the guidance document states that polluting entities can be point or nonpoint sources of pollution and that attainment of water quality standards is not limited to controls placed on point sources. However, this statement should be viewed in context of the stated scope of the guidance, which is to address economic factors considered under 131.10(g) and 131.12. Even if this statement could be read to apply to 131.10(d) and (h)(2), Oregon's provision at OAR 340-041-0059(1)(b)(A) is consistent with EPA's 1995 economic guidance document because the guidance contemplates that financial impacts are determined by the costs the entity itself would face by implementing the necessary pollution controls.

OAR 340-041-0059(2) "Conditions to Grant a Variance"

EPA is approving OAR 340-041-0059(2), (2)(a) and (2)(b) "Conditions to Grant a Variance" because it is consistent with the substantive requirements of permanently changing designated uses at §131.10, specifically §131.10(g).

OAR 340-041-0059(2)(a) requires the state to determine that "[n]o existing use will be impaired or removed as a result of granting the variance." One commenter argues that this section is inconsistent with EPA's regulations because it "does not explicitly require variances to meet the antidegradation policy[,]…falls short of full protection of existing uses[,]… [and] makes no reference to the water quality that is required to maintain and protect existing uses."[184] EPA disagrees that OAR 340-041-0059(2)(a) is inconsistent with EPA regulations. OAR 340-041-0059(2)(a) is consistent with 131.10(h)(1) and (g) which both prohibit a state from removing the protection for an existing use. While a state's adoption of new or revised water quality standards is not itself subject to antidegradation review, EPA notes that OAR 340-041-0059(2)(a) is also consistent with 131.12(a)(1): requiring the that "[e]xisting instream water uses and the level of water quality necessary to protect the existing uses shall be maintained and protected." EPA believes that prohibiting the impairment or removal of an existing use will achieve the goals of "maintain[ing] and protect[ing]" the "level of water quality necessary to protect the existing use."

Section OAR 340-041-0059(2)(b) is consistent with the substantive requirements at §131.10(g).

OAR 340-041-0059(3) "Variance Duration"

EPA is approving OAR 340-041-0059(3) and the first sentence of OAR 340-041-0059(3)(a) "Variance Duration" as a water quality standard that states "The duration of a variance must not exceed the term of the NPDES permit." EPA understands this section to mean that each variance will expire five years after the State adopts the variance, the maximum length of a NPDES permit consistent with federal regulations and OAR 340-045-0035(8), or the variance will specify a specific expiration date of less than five years after the variance was adopted into state regulation. As discussed earlier, the 1977 Office of General Counsel legal opinion explains that time-limited revisions to the designated use and criteria are environmentally preferable as compared with the permanent removal of a designated use because the more stringent standards apply to all other dischargers not covered by the variance. EPA is approving this sentence as it states the specific time limit for which the designated use and criteria have been determined to be "unattainable" consistent with §131.10(g).

EPA is taking no action on the last two sentences of OAR 340-041-0059(3)(a) "Variance Duration" that states "If the permit is administratively extended, the permit effluent limits and any other requirements based on the variance and associated pollutant reduction plan will continue to be in effect during the period of the administrative extension. The department will give priority to NPDES permit renewals for permits containing variances and where a renewal application has been submitted to the director at least one hundred eighty days prior to the

[184] Northwest Environmental Advocates (NWEA). March 17, 2011. Letter from Nina Bell, Executive Director, NWEA to Andrea Matzke, ODEQ, *Re: Proposed Revised Water Quality Standards for Human Health Toxic Pollutants and Revised Water Quality Standards Implementation Policies.* page 39.

NPDES permit expiration date." These sections are NPDES permitting requirements because they describe the permitting process for handling situations where there is a delay in reissuing a permit. Such language does not affect how long the variance applies as the approved water quality standard and the administrative extension of a permit is not subject to EPA WQS approval or disapproval.

EPA is also taking no action on OAR 340-041-0059(3)(b) "Variance Duration" because that section of the provision reiterates the permitting provisions at §122.44(d)(vii) requiring the NPDES permit limit to derive from and comply with the applicable water quality standards once the variance expires. Therefore, EPA does not consider this section to be a water quality standard.

EPA is approving OAR 340-041-0039(3)(c) "Variance Duration" as a water quality standard because it clearly states that the variance is not effective for CWA section 402 permitting purposes until EPA approves it, consistent with §131.21(c). EPA notes that once an individual variance has been approved, it is a water quality standard applicable for CWA section 402 permitting purposes (see 40 CFR 131.21) and thus becomes subject to the triennial review requirements at 40 C.F.R. 131.20.

OAR 340-041-0059(4) "Variance Submittal Requirements"
EPA is approving OAR 340-041-0059(4) "Variance Submittal Requirements" and OAR 340-041-0059(4)(a) consistent with §131.10(g) because it requires a demonstration that one of EPA's regulatory factors precludes attainment of the use. EPA is also approving OAR 340-041-0059(4)(b)-(f) because these sections provide substantive requirements for what the applicant must submit to the State to obtain a variance, and are not inconsistent with the requirements of the CWA and EPA's regulations.

OAR 340-041-0059(5) "Variance Permit Conditions"
EPA is approving OAR 340-041-0059(5), (5)(a) and (5)(b) "Variance Permit Conditions" because these sections establish the water quality requirements during a variance. While those requirements might typically be presented in the form of instream water quality criteria, EPA considers the requirement for a permit limit to include the best achievable effluent quality to be a surrogate for identifying the instream water quality criteria at the highest attainable condition. Thus, EPA is approving sections 5(a) and 5(b) because they describe the resulting instream concentration and together act as a surrogate for interim criterion applicable during a variance. Based on Oregon's regulatory language in this section, the best achievable effluent quality will be appropriately determined on a case-by-case basis.

EPA is not taking action on OAR 340-041-0059(5)(c) and (5)(d) because they are monitoring and reporting requirements applicable to a discharger's NPDES permit. These requirements are not considered WQS under CWA section 303(c) or addressed in EPA's water quality standards regulations because they are NPDES permitting requirements.

OAR 340-041-0059(6) "Public Notice Requirements"
EPA is approving OAR 340-041-0059(6) "Public Notice Requirements" and OAR 340-041-0059(6)(a) and 0059(6)(b) because they address the requirements for public notice of a variance

consistent with §131.20(b), and explain what information will be provided to the public. EPA notes that this section states that public notification for a variance can be included in the public notification of a draft NPDES permit or draft regulatory decision that would rely on the variance. In addition, EPA must approve the variance before it can be implemented and thus the State cannot finalize the NPDES permit with a limit that reflects a variance until EPA has approved the variance.

OAR 340-041-0059(7) "Variance Renewals"

EPA is approving OAR 340-041-0059(7) "Variance Renewals". EPA is approving OAR 340-041-0059(7)(a)(A) as consistent with 131.10(g) as it requires the permittee to demonstrate that attaining water quality standards during the term of the variance is still not feasible based on factors consistent with 131.10(g)(1)-(6). EPA is approving all other language in OAR 340-041-0059(7) because this regulatory language is not inconsistent with the CWA or EPA's implementing regulations. EPA notes that since variances are water quality standards, the state will need to include variances in the applicable water quality standards that the state reviews during its triennial review processes under §131.20(a). EPA understands that OAR 340-041-0059(7)(D) ("[a]ll other requirements of this rule have been met.") will require a new round of public notice, comporting with the requirements of OAR 340-041-0059(6), and all other requirements in OAR 340-041-0059 to be met when any variance is renewed.

VIII. BACTERIA

Oregon's revisions to its bacteria provision found at OAR 340-041-0009(10) are shown in underline/strikeout format below. Underlined text represents added text, while text with a line through the middle (strikeout) represents deleted text. The revised text corrects a citation based on renumbering in OAR 340-041-0061.

(10) Water Quality Limited for Bacteria: In those water bodies, or segments of water bodies identified by the Department as exceeding the relevant numeric criteria for bacteria in the basin standards and designated as water-quality limited under section 303(d) of the Clean Water Act, the requirements specified in section 11 of this rule and in OAR 340-041-0061(11~~2~~) must apply.

EPA Action
In accordance with its CWA authority, 33 U.S.C § 1313(c)(3) and 40 C.F.R. part 131, EPA approves this minor editorial change as a non-substantive revision to water quality standards at OAR 340-041-0009.

EPA Rationale
The minor editorial change in this provision to correct the citation due to a renumbering revision in OAR 340-041-0061(12) does not alter the underlying provision that EPA previously approved and EPA is not acting on the underlying provision. EPA approves this non-substantive revision to Oregon's WQS under section 303(c) of the CWA and the implementing regulations at 40 CFR Part 131.

IX. REVISED RULES REGARDING IMPLEMENTAIN FOR NONPOINT SOURCES

A. *STATEWIDE NARRATIVE CRITERIA*

Oregon's revisions to OAR 340-041-0007(5) are shown in underline/strikeout format below. Underlined text represents added text, while text with a line through the middle (strikeout) represents deleted text. The revised rule clarifies the state regulatory mechanisms for water quality control applicable to forest management activities.

(5) Logging and forest management activities must be conducted in accordance with the ~~Oregon~~ rules established by the Environmental Quality Commission and must not cause violation of water quality standards. Nonpoint sources of pollution from forest operations on state and private forest lands are subject to best management practices and other control measures established by the Oregon Board of Forestry as provided in ORS 527.765 and 527.770. Forest ~~Practices~~ operations conducted in good faith compliance with the best management practices and control measures established under the Forest Practices Act ~~to minimize adverse effects on water quality~~ are generally deemed not to cause violations of water quality standards as provided in ORS 527.770. Forest operations are subject to load allocations established under ORS 468B.110 and OAR Division 340-042 to the extent needed to implement the federal Clean Water Act.

Acknowledgement of OAR 340-041-0007(5)
EPA acknowledges the revised language contained in OAR 340-041-0007(5). ODEQ has revised their regulations to explain how the control measures applicable to forestry nonpoint sources under the Forest Practices Act are presumed to meet water quality standards and that forest operations are subject to load allocations in TMDLs.[185] Furthermore, the rule clarifies the water quality regulatory requirements for forest management activities in Oregon.

This rule states that certain activities related to logging and forest management are generally deemed not to cause violations of water quality standards if best management practices and control measures under the Forest Practices Act are followed. The CWA requires NPDES permits for discharges from point sources and compliance with that permit, but does not require that states develop enforceable regulatory programs for nonpoint sources. Whether a State chooses to make water quality standards directly enforceable for nonpoint sources is solely a matter of state law and the State has discretion as to how it enforces its laws. This provision is applicable only to nonpoint sources and their compliance with water quality standards and TMDL load allocations. As such EPA does not consider this provision to be a water quality standard under section 303(c) of the CWA. Water quality standards are provisions of State or Federal law which consist of a designated use or uses for waters of the United States, and water quality criteria necessary to protect the uses (40 CFR 131.3(i)).

[185] ODEQ. June 7, 2011. *Executive Summary. Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 9. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ExecSummary.pdf

In addition, this provision does not include language that has the effect of changing the level of protection provided by Oregon's water quality criteria and therefore does not constitute a new or revised water quality standard. The provision defines how logging and forest management nonpoint sources activities must control their discharges in order to comply with Oregon's water quality standards, but it does not establish or revise any of the components of the water quality standards themselves.

Therefore, this provision is not considered a water quality standard subject to EPA review and approval and EPA is taking no action to approve or disapprove this provision.

B. *OTHER IMPLEMENTATION OF WATER QUALITY*

Oregon's revisions to implementation provisions found at OAR 340-041-0061(9)(a)(E), (10), and (11) are shown in underline/strikeout format below. Underlined text represents added text, while text with a line through the middle (strikeout) represents deleted text. The revised rule at (9)(a)(E) corrects an error to the cross-reference to the antidegradation policy. The revised rules in (10) and (11) explain how the mechanisms for forestry and agricultural nonpoint sources work to meet water quality standards and the total maximum daily load (TMDL) load allocations under the Forest Practices Act and Agriculture Water Quality Management Act.[186] Finally, the revised rule contains revised paragraph numbers for subsections (2) through (16) as the variance rule in section (2) was moved to OAR 340-041-0059.

(9)(a)(E) Mass loads assigned as described in paragraphs (B) and (C) of this subsection will not be subject to OAR 340-041-0004(~~9~~7);

Acknowledgement of OAR 340-041-0061(9)(a)(E)
EPA acknowledges the changed cross-reference located in OAR 340-041-0061(9)(a)(E) Other Implementation of Water Quality Criteria. Water quality standards are provisions of State or Federal law which consist of a designated use or uses for waters of the United States, and water quality criteria necessary to protect the uses (40 CFR 131.3(i)). EPA has determined this provision is not a WQS. Instead, the provision at section (9)(a)(E) is a NPDES permitting implementation provision and corrects an error to a regulatory citation to the antidegradation policy.

*(10) Forestry on state and private lands. ~~For~~ Nonpoint sources of pollution from forest operations on state or private lands~~, water quality standards~~ are ~~intended to be attained and are implemented through~~ subject to best management practices and other control ~~mechanisms~~ measures established ~~under the Forest Practices Act (ORS 527.610 to 527.992) and rules thereunder, administered~~ by the Oregon Department of Forestry~~. Therefore,~~ under the Forest Practices Act, (ORS 527.610 to 527.992) Such forest operations ~~that are~~ when conducted in good faith compliance with the Forest Practices Act requirements are ~~(except for the limits set out in ORS 527.770) deemed in compliance with this division. DEQ will work with the Oregon~~

[186] ODEQ. June 7, 2011. *Executive Summary. Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 9. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ExecSummary.pdf

~~*Department of Forestry to revise the Forest Practices program to attain water quality standards.*~~ *generally deemed not to cause violations of water quality standards as provided in ORS 527.770. Forest operations on state and private lands are subject to load allocations under ORS 468.110 and OAR 340, Division 42, to the extent necessary to implement the federal Clean Water Act.*

(11) ~~*Agricultural water quality management plans to reduce agricultural nonpoint source pollution are developed and implemented by the Oregon Department of Agriculture (ODA) through a cooperative agreement with the department to implement applicable provisions of ORS 568.900 to 568.933 and 561.191. If the department has reason to believe that agricultural discharges or activities are contributing to water quality problems resulting in water quality standards violations, the department may consult ODA. If water quality impacts are likely from agricultural sources and the department determines that a water quality management plan is necessary, the director may write a letter to the director of the ODA requesting that such a management plan be prepared and implemented to reduce pollutant loads and achieve the water quality criteria.*~~ *In areas subject to the Agricultural Water Quality Management Act, the Oregon Department of Agriculture (ODA) under ORS 568.900 to 568.933 and 561.191 develops and implements agricultural water quality management area plans and rules to prevent and control water pollution from agricultural activities and soil erosion on agricultural and rural lands. Area plans and rules must be designed to achieve and maintain water quality standards. If the department determines that the area plan and rules are not adequate to achieve and maintain water quality standards, the department will provide ODA with comments on what would be sufficient to meet WQS or TMDL load allocations. If a resolution cannot be agreed upon, the department will request the Environmental Quality Commission (EQC) to petition ODA for a review of part or all of water quality management area plan and rules. If a person subject to an ODA area plan and implementing rules causes or contributes to water quality standards violations, the department will refer the activity to ODA for further evaluation and potential requirements.*

Acknowledgement of OAR 340-041-0061(10) and (11)

EPA acknowledges the revised language in OAR 340-041-0061(10) and (11) Other Implementation of Water Quality Criteria. The revised rules in (10) and (11) explain how state rules for forestry and agricultural nonpoint sources are to be implemented consistent with water quality standards and the total maximum daily load (TMDL) load allocations.[187] These provisions set forth the extent to which Oregon requires nonpoint sources of pollution from forest operations under the Forest Practices Act and agricultural activities under the Agricultural Water Quality Management Act to control their discharges in order to protect water quality.

These rules state that forest operations and agricultural activities generally will not be deemed to cause violations of water quality standards if best management practices and control measures under the Forest Practices Act and water quality management area plans under the Agricultural Water Quality Management Act are followed and identify the process to be used when water quality concerns arise. Thus, the rule clarifies mechanisms for WQS implementation and

[187] ODEQ. June 7, 2011. *Executive Summary. Human Health Toxics Rulemaking.* Oregon Department of Environmental Quality. page 9. Available at: http://www.deq.state.or.us/wq/standards/docs/toxics/humanhealth/rulemaking/ExecSummary.pdf

compliance.

Whether a State chooses to make water quality standards directly enforceable for nonpoint sources is solely a matter of state law. The CWA requires NPDES permits for discharges from point sources and compliance with that permit, but does not require that states develop enforceable regulatory programs for nonpoint sources. These provisions are applicable only to nonpoint sources and how they comply with water quality standards and TMDL load allocations and as such are not water quality standards under section 303(c) of the CWA. Water quality standards are provisions of State or Federal law which consist of a designated use or uses for waters of the United States, and water quality criteria necessary to protect the uses (40 CFR 131.3(i)).

In addition, these provisions do not include language that has the effect of changing the level of protection provided by Oregon's water quality criteria and therefore do not constitute new or revised water quality standards. The provisions define the extent to which forest operations and agricultural operations that result in nonpoint source discharges must control their discharges in order to comply with Oregon's water quality standards, but they do not establish or revise any of the components of the water quality standards themselves.

Therefore, these provisions are not considered water quality standards subject to EPA review and approval and EPA is taking no action to approve or disapprove the provisions.

Acknowledgment of Section Renumbering in OAR 340-041-0061(2)-(16)
The revised rule contains revised paragraph numbers for subsections OAR 340-041-0061(2) through (16) as the variance rule in section (2) was moved to OAR 340-041-0059. EPA acknowledges the renumbering for subsections that were previously approved by EPA under 303(c) of the CWA as a non-substantive formatting change which does not require EPA action.

RESPONSES TO PUBLIC COMMENTS RELATING TO MAINE'S JANUARY 14, 2013, SUBMISSION TO EPA FOR APPROVAL OF CERTAIN OF THE STATE'S NEW AND REVISED WATER QUALITY STANDARDS (WQS) THAT WOULD APPLY IN WATERS THROUGHOUT MAINE, INCLUDING WITHIN INDIAN TERRITORIES OR LANDS

January 30, 2015

INTRODUCTION

This document contains responses to the significant comments EPA received concerning Maine's January 14, 2013, submittal to EPA Region 1, in which Maine proposed certain revisions to its surface water quality standards (WQS or standards) pursuant to section 303(c) of the federal Clean Water Act (CWA). EPA Region 1 solicited comments from the public specifically relating to the aspect of Maine's request that EPA approve the State's WQS revisions to apply in waters within Indian territories or lands (hereinafter referred to as "Indian lands") located in Maine. It is important to note that, in the Agency's judgment, the public comments EPA received in relation to Maine's January 14, 2013, submission raised both significant legal and technical questions, which extend equally to the EPA's decisions addressed in its letter approving and disapproving certain of Maine's standards in waters within Indian lands. EPA's responses to the comments below will be presented in the context of Maine's January 14, 2013, submittal, but EPA applied the principles articulated in this document to our decision on all the WQS the State has asked the Agency to approve for waters in Indian lands.

Maine's 2013 submittal specifically included a request that EPA approve the WQS revisions as applying to all waters throughout the State of Maine, including to waters within Indian lands located within the State. Neither the CWA (and its implementing regulations), nor the federal Administrative Procedure Act (APA), specify any notice and comment requirements that EPA must satisfy before approving or disapproving a state's new or revised WQS submittal. EPA's longstanding position has been that it is sufficient for EPA to review the adequacy of a submitting state's public process for revisions to its WQS and to rely on that process if it adequately notified and involved the public. See 40 C.F.R. §§ 131.5(a)(3), 131.6(e), and 131.20(b) and 40 CFR part 25 for public participation requirements relevant to state adoption of WQS. The State of Maine's Department of Environmental Protection (ME DEP) provided public notice and an opportunity to comment (including a public hearing), at the state level, on the WQS revisions included in the State's January 14, 2013, submittal to EPA.

However, while ME DEP provided public notice of the substance of the WQS revisions as they would apply generally in the State, the State's notice may not have sufficiently informed the public that ME DEP intended to seek EPA's approval of these revisions to apply in waters within Indian lands. To ensure adequate public participation and development of a complete administrative record for EPA's subsequent decisions, EPA decided to seek further comment due to the possibility that the State's notice may not have been sufficiently clear to some members of the public about the State's intent to apply its WQS revisions to waters in

Indian lands. Accordingly, in August of 2013, EPA solicited additional comment on the approvability of these WQS for waters in Indian lands. In particular, EPA sought comments regarding the State's legal authority to establish WQS in waters in Indian lands under the Maine Implementing Act (MIA, 30 M.R.S.A § 6401, et seq.) as ratified by the Maine Indian Claims Settlement Act (MICSA, 25 U.S.C. § 1721, et seq.) and on whether these WQS revisions would adequately protect water quality in Indian lands.

This responses to comments (RTC) document contains EPA's responses to the significant comments EPA received. We reiterate that EPA lawfully used its discretion to seek additional public input to better inform its approval/disapproval decision and to ensure that any potential flaws in the State's public process are remedied. There is no legal prohibition in the CWA, the Administrative Procedure Act, or any other applicable legal requirement that precludes EPA from seeking such comment to better inform its decision when the administrative record before it is potentially incomplete. Adequate public participation in the context of a federal agency's decision-making process, where regulatory decisions are being made that potentially impact the public or where there is significant public interest, is a fundamental aspect of administrative law in our system of government. Furthermore, we emphasize that EPA's having sought public comment in this one instance, in addition to the State's public participation process, does not in any way set a legal or policy precedent that could in any way be used by any person in the future to require EPA to solicit public comment on any State's WQS submission for EPA review and approval or disapproval. As explained throughout EPA's RTC document and Decision Support Document related to EPA's decision on Maine's WQS submissions, the Agency has been presented with a unique set of circumstances due to the highly atypical legal framework that MIA and MICSA establish for Indian lands in Maine; circumstances which do not exist in other areas of the United States.

The WQS revisions in Maine's 2013 submittal include five new or revised WQS criteria, including three human health criteria (HHC) for the allowable levels or concentrations in surface waters for three toxic pollutants: arsenic, acrolein, and phenol. For arsenic, ME DEP changed the cancer risk level, fish consumption rate, and percentage of inorganic arsenic (relative to organic arsenic) used in calculating the criteria for *inorganic* arsenic, which is the form of arsenic that is harmful to human health. For acrolein and phenol, ME DEP updated its ambient water quality criteria consistent with updates EPA has made to its recommended criteria for those two pollutants based on newly published reference doses.

This RTC document is a source of information about EPA's decision on Maine's submissions, and should be read in conjunction with EPA's letter communicating its decision on these and other WQS to Maine DEP and with the accompanying Decision Support Document; the latter focusing specifically on, among other things, the question whether Maine has adequate legal authority to establish WQS in waters located in Indian lands and on whether Maine's standards meet the requirements of the CWA. This RTC document incorporates the terminology and reasoning presented in those other two documents, while expanding on it in certain respects to address the more specific individual comments EPA received. This responsiveness summary digests and organizes the significant comments received. Opposing comments concerning each issue were grouped together where EPA received comments on both sides of an issue. We received

comments from the State of Maine's Office of the Attorney General, the Commissioner of the ME DEP, and from three of the four federally recognized Indian Tribes in Maine – the Penobscot Nation, the Houlton Band of Maliseet Indians, and the Aroostook Band of Micmacs; no other parties provided comments to EPA.

The particular language used in the summary of each issue presented below may derive primarily from one set of comments. But this does not mean that EPA has not considered each of the comments received on the issue in question. EPA did not limit its analysis of the comments submitted to the digest presented below, and we have reviewed each comment in its entirety. This outline and its digest of the comments are simply designed to structure our responses and make them more accessible to the interested public, while addressing the substantive content of all of the significant comments received.

Comments and Responses to Comments on EPA's 2003 NPDES Program Approval

Some of the key issues relevant to Maine's WQS submission were also the subject of public comments EPA received in the context of EPA's 2003 action on Maine's National Pollution Discharge Elimination System (NPDES) program application. In fact, the Penobscot Nation and the Houlton Band of Maliseet Indians specifically incorporated by reference into their comments on Maine's WQS submission those Tribes' earlier comments on Maine's NPDES program application. Consequently, EPA's responses today to some of those same issues, or at least to certain aspects of those same issues, parallel EPA's earlier responses to comments received on Maine's NPDES program application. For completeness and efficiency, rather than repeat in this RTC document all of EPA's responses to the Tribes' comments on Maine's NPDES program, EPA hereby incorporates by reference its responses to public comments received on Maine's NPDES program application, but only to the extent those earlier responses are consistent with, and are not superseded by, the First Circuit's decision in *Maine v. Johnson*, 498 F.3d 37 (1st Cir. 2007), and the responses expressly articulated in this document and in EPA's accompanying Decision Support Document.

Federal Indian Common law cited by Maine Indian Tribes and Protecting the Tribes' Sustenance Fishing

As discussed in detail below in EPA's specific responses to specific public comments, many of the Maine Tribes' (primarily the Penobscot Nation's) legal arguments opposing Maine's jurisdiction to establish WQS in waters within Indian lands included citations to federal case law. EPA addresses that case law in more detail later in this RTC document. Many of the Tribes' comments rely heavily on the case law. It is therefore worth noting here in summary, for purposes of orienting the reader to what follows, that EPA found many of those cited cases compelling from the standpoint of supporting the proposition that the CWA requires protection of the quality of the water that supports the Maine Tribes' sustenance fishing practices, culture and lifestyle. The cases cited also represent a strong collection of federal Indian common law on subjects such as the federal government's trust responsibility to Indian tribes, the sovereign status of Indian tribes in

the United States, and the canons of statutory construction used by the federal courts to interpret treaties and statutes addressing the rights of Indian tribes.

With one very important and dispositive exception that arises due to the unique nature and jurisdictional provisions of the settlement acts[1], EPA does not disagree that the cases cited by the Maine Tribes articulate valid and accurate general principles of federal Indian common law. In EPA's view, however, none of these cases answers or is dispositive of the question whether Maine has legal jurisdiction to establish WQS in waters within Indian lands in Maine, but that is precisely the argument that the Maine Tribes frequently assert is supported by those cases. As EPA explains in this RTC document and in its Decision Support Document, the settlement acts clearly undermine the Maine Tribes' use of those cases to oppose Maine's assertion of jurisdiction. Moreover, EPA reads the vast majority of the Maine Tribes' comments as taking the position that protection of their sustenance fishing practices and a legal conclusion that Maine has jurisdiction to establish WQS in waters within Indian lands in Maine are mutually exclusive. The inaccuracy of that position is demonstrated by EPA's Decision Support Document. That is, EPA has determined that Maine has jurisdiction to establish WQS in waters within Indian lands in Maine and that EPA has no discretion to find otherwise given the settlement acts. At the same time, however, EPA has also disapproved certain of Maine's WQS as not being adequately protective of the applicable CWA designated uses, which encompass the Maine Tribes' sustenance fishing practices. Consequently, the jurisdictional scheme embodied in the settlement acts renders those cases inapposite to EPA's decision. In addition, to the extent that the Maine Tribes cite

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[1] Settlement Acts in Maine

MIA and MICSA

In 1980, Congress passed the Maine Indian Claims Settlement Act (MICSA), which resolved litigation in which the Southern Tribes asserted land claims to a large portion of the State of Maine. 25 U.S.C. §§ 1721, et seq. MICSA ratified a state statute passed in 1979, the Maine Implementing Act (MIA), which was designed to embody the agreement reached between the State and the Southern Tribes. 30 M.R.S. §§ 6201, et seq. In 1981, MIA was amended to include provisions for land to be taken into trust for the Houlton Band of Maliseet Indians, as provided for in MICSA. 30 M.R.S. § 6205-A, 25 U.S.C. § 1724(d)(1). Since it is Congress that has plenary authority as to federally recognized Indian Tribes, MIA's provisions concerning jurisdiction and the status of the Tribes are effective as a result of, and consistent with, the Congressional ratification in MICSA.

MSA and ABMSA

In 1989, the Maine legislature passed the Micmac Settlement Act (MSA) to embody an agreement as to the status of the Aroostook Band of Micmacs. 30 M.R.S. §§ 7201, et seq. In 1991, Congress passed the Aroostook Band of Micmacs Settlement Act (ABMSA), which ratified the MSA. 25 U.S.C. § 1721, Act Nov. 26, 1991, P.L. 102-171, 105 Stat. 1143. One principal purpose of both statutes was to give the Micmacs the same settlement that had been provided to the Maliseets in MICSA. See ABMSA § 2(a)(4) and (5). In 2007, the Federal Court of Appeals for the First Circuit confirmed that the Micmacs and Maliseets are subject to the same jurisdictional provisions in MICSA. Aroostook Band of Micmacs v. Ryan, 484 F.3d 41 (1st Cir. 2007).

Where appropriate, this document will refer to the combination of MICSA, MIA, ABMSA, and MSA as the "settlement acts."

to the First Circuit's opinions interpreting MIA and MICSA, EPA's RTC document explains why those cases also do not support the Tribes' assertion that Maine does not have jurisdiction.

Two examples illustrate this general point. While EPA agrees that *U.S. v. Adair*, 723 F. 2d 1394 (9th Cir. 1984); *Winters v. United States*, 207 U.S. 564 (1908); and *Washington v. Washington State Commercial Passenger Fishing Ass'n*, 443 U.S. 658 (1979), may be cited in support of arguments that address tribal sustenance fishing practices and the associated quantity and/or quality of the waters that support those fishing practices, nothing in those cases does or can supersede or affect the jurisdictional arrangement embodied in the settlement acts. Similarly, while *Wisconsin v. E.P.A.*, 266 F. 3d 741 (7th Cir. 2001); *State of Washington, Dep't of Ecology v. U.S.E.P.A.* 725 F. 2d 1465 (9th Cir. 1985); *Merrion v. Jicarilla Apache Tribe*, 455 U.S. 130 (1982); *New Mexico v. Mescalero Apache Tribe*, 462 U.S. 324 (1983); *Oklahoma Tax Comm'n v Sac & Fox Nation*, 508 U.S. 114 (1993); and *Three Affiliated Tribes of Ft. Berthold v. Wold Eng'g*, 476 U.S. 877 (1986), may each stand for or support in some manner the proposition that states generally lack jurisdiction in Indian reservations absent express authorization by Congress, those cases cannot properly be cited to support an argument that Maine has no jurisdiction to apply state law in Indian lands in Maine, because Congress expressly granted Maine such authority in the settlement acts.

EPA's Specific Responses

I. Maine's legal authority or jurisdiction to establish WQS in Indian waters.

A central issue raised by Maine's WQS submission is whether Maine has the necessary legal authority, or jurisdiction, to establish WQS applicable to surface waters (both reservation and trust land waters) situated in Indian lands located within the exterior boundaries of the State of Maine. EPA received many comments about this legal issue from three of the Maine Indian Tribes and from the State of Maine.

EPA's Decision Support Document contains, among other things, a legal analysis of the specific statutory provisions of the settlement acts and their respective legislative histories. That analysis supports EPA's legal determination that Maine has the necessary legal authority to establish WQS in surface waters located in Indian lands in Maine. While the legal analysis constitutes EPA's reading of the language and legislative history of the statutes themselves, it does not always address directly the way in which the Maine Tribes' articulated their jurisdictional arguments opposing Maine's legal authority to establish WQS in waters in Indian lands in Maine.

The reason for that is that the Tribes' public comments on the jurisdictional question rely, to a great extent, on two concepts derived from principles of

federal Indian common law, i.e., the federal government's trust relationship to Indian tribes generally and the concept of inherent tribal sovereignty. It is for that reason that EPA's responses below to the Maine Tribes' public comments on the jurisdictional question principally are organized around the way in which the Tribes specifically crafted their jurisdictional arguments, i.e., primarily in terms of the federal trust responsibility and the concept of inherent tribal sovereignty. After addressing those comments from the Tribes, EPA's responses also address the State of Maine's comments on the federal trust responsibility and tribal sovereignty.

A. Does the federal trust responsibility affect or determine whether Maine has jurisdiction to establish WQS in waters within Indian lands?

Many of the Tribes' comments relating to whether Maine has jurisdiction focused on the federal trust responsibility to the Maine Indian Tribes. The Tribes asserted that the EPA's trust responsibility obligates EPA to conclude that Maine does not have jurisdiction. Examples of those comments are identified below first, followed by examples of the State of Maine's comments about the trust. EPA's responses to the comments are provided after the listed representative examples received from the parties who commented.

Representative examples of comments from Maine's Indian Tribes

1. EPA's federal trust responsibility and duties under the CWA preclude EPA from finding that Maine has jurisdiction to promulgate WQS applicable to waters in Indian lands.

2. EPA's Constitutionally-based trust responsibility and federal Indian common law require EPA to reject Maine's WQS application as to waters within Indian lands.

3. EPA's trust responsibility requires it to protect the Tribes' natural resources and sovereign authority against state encroachment.

4. Approval of Maine's WQS in waters within Indian lands would be an unlawful abdication of EPA's trust responsibility because it would empower Maine to control tribal resources when Maine does not even recognize the existence of the Penobscot Nation's sustenance fishery.

5. The authority to establish WQS under the CWA applicable to the Southern Tribes' sustenance fishery established under MIA and MICSA must reside with EPA in the first instance, as the Tribes' trustee, or, eventually with the Penobscot Nation.

6. Congress acquired the Houlton Band of Maliseet Indians' trust lands for the purpose of preserving the Tribe's riverine culture, including traditional fishing, hunting and gathering activities. EPA therefore has a trust responsibility to protect the quality of the waters in the Tribes' lands.

Representative examples of comments from the State of Maine

1. The concept of a federal "trust responsibility" to Indian tribes does not apply under the CWA because there are no substantive or procedural requirements written into the CWA that anyone may review to assess whether a particular action that EPA takes complies with a "trust responsibility." EPA cannot establish procedural or substantive requirements, pursuant to a trust responsibility, that are not already embodied in the CWA. The federal trust responsibility toward Indian tribes in Maine is fully and exclusively expressed through the substance of the statutes and regulations that an agency is charged with administering.

2. Even if the concept of a federal "trust responsibility" otherwise would apply toward the Maine Indian Tribes under the CWA, Title 25 U.S.C. section 1725(h) of MICSA makes clear that federal Indian law that would otherwise affect or preempt the jurisdiction of Maine relating to "environmental matters" has no effect in Maine.

3. Reservation lands in Maine are not held in trust by the federal government.

EPA's responses to comments concerning the general nature of the federal trust responsibility to the Maine Tribes in this case and the extent to which that trust responsibility is relevant or dispositive to the question whether Maine has adequate legal authority or jurisdiction to establish WQS for surface waters within Indian lands located in Maine

As EPA previously noted in its responses to public comments received on Maine's NPDES program application in 2003, the commenters' arguments (on both sides) regarding the federal government's trust responsibility to the Maine Indian Tribes do not accurately articulate the scope of the trust responsibility as relevant to EPA's decisions in this matter; and, more specifically, do not accurately articulate the scope of the trust responsibility to the Maine Indian Tribes as EPA exercises its authorities under the CWA.

First, it is important to note that the existence, operation and extent of the federal trust responsibility to the Maine Indian Tribes under the United States Constitution and

applicable federal statutory and common law cannot be determined in isolation from the allocation of legal jurisdiction among the tribal, State, and federal governments under the the settlement acts. For example, the jurisdictional framework set forth in the MIA was ratified by Congress in MICSA, and it is well-established law that Congress has plenary authority to legislate in the area of Indian affairs. EPA does not have the legal authority to alter the jurisdictional arrangement ratified by Congress in the settlement acts, either pursuant to the trust responsibility to the Maine Indian Tribes in relation to the CWA or pursuant to any other law.

At the same time, however, EPA still must consider the trust responsibility toward the Maine Indian Tribes when implementing the CWA, but must do so within the bounds of the jurisdictional scheme that Congress ratified in the settlement acts and the requirements of the CWA. It is for this reason that the federal trust cases cited by the Penobscot Nation in its comments are inapposite, i.e., none of these cases discusses the federal trust obligation against the backdrop of statutes such as the settlement acts, and they cannot properly be cited for the proposition that the trust obligation should or does override Congress' jurisdictional arrangement in those settlement acts such that Maine cannot establish WQS in waters in Indian lands in Maine. The cases cited by the Tribe include, e.g., *HRI, Inc. v. E.P.A.*, 198 F.3d 1224 (10th Cir. 2000); *Cherokee Nation v. State of Georgia*, 30 U.S. 1 (1831); *United States v. Mitchell (Mitchell II)*, 463 U.S. 206 (1983); *Seminole Nation v. United States*, 316 U.S. 286 (1942).

As EPA earlier explained in its responses to public comments on EPA's proposed approval of Maine's NPDES program, the trust responsibility towards the Maine Indian Tribes continues to operate in Maine in relation to the CWA, even under the settlement acts, but that the trust's reach and effect are more limited than might typically be the case in other states. In other words, the settlement acts significantly revise in Maine the jurisdictional arrangement that more typically exists elsewhere in the United States among Indian tribes, a state, and the federal government. EPA notes that the Penobscot Nation's comments cite to a number of federal court opinions that address the trust. See for example, *Worcester v. Georgia*, 31 U.S. 515 (1832); *Oneida County v. Oneida Indian Nation*, 470 U.S. 226 (1985); and *State of Washington, Dep't of Ecology v. U.S. E.P.A.*, 752 F.2d 1465 (9th Cir. 1985); *HRI, Inc. v. E.P.A.* 198 F.3d 1224 (10th Cir. 2000); *Cherokee Nation v. State of Georgia*, 30 U.S. 1 (1831); *United States v. Mitchell (Mitchell II)*, 463 U.S. 206 (1983); *Seminole Nation v. United States*, 316 U.S. 286 (1942). These cases and others of their kind, which may have addressed the federal trust, are not relevant to the analysis of whether Maine has jurisdiction to establish WQS in waters within Indian lands in Maine because the courts in those cases were not confronted with statutes like the settlement acts which, as EPA said above, alters the typical framework within which the trust operates.

The trust and federal Indian common law

As a threshold matter, when delving into the meaning of the settlement acts, EPA is employing, and always has employed, where appropriate, the interpretive canons of federal Indian common law that derive from the general trust responsibility. For

example, we agree that any ambiguity in the meaning of statutory provisions that attempt to limit tribal sovereignty must be narrowly construed and that such ambiguities must be resolved in favor of the tribes. EPA also agrees that the federal government's general trust responsibility charges the Agency with a responsibility to protect the tribes' inherent sovereignty from unwarranted state encroachment. Adhering to these basic common law elements of the trust doctrine does not run afoul of the settlement acts. They do not result in any alteration of the jurisdictional arrangement ratified in the settlement acts and simply require the Agency to consider the Maine Indian Tribes' interests and welfare consistent with Maine's authority, when EPA implements the CWA. In so doing, we are not thereby affecting or preempting Maine's jurisdiction, but merely applying the law which provides that jurisdiction to the State, and analyzing how that grant of authority from Congress affects EPA's CWA decisions in relation to the Maine Indian Tribes. We note that the First Circuit, without much comment, has invoked the general trust in support of the idea that ambiguities in MICSA should be interpreted in favor of the Tribes where possible. *Penobscot Nation v. Fellencer*, 164 F.3d 706 (1st Cir. 1999).

Consistent with the discussion above, the settlement acts do not create a complete barrier to the application of the federal common law concerning the federal government's trust responsibility in Maine. For one example, MICSA itself provides for certain lands and natural resources to be held in trust for the Penobscot Nation and the Passamaquoddy Tribe (hereinafter referred to for convenience as the "Southern Tribes") and the Houlton Band of Maliseet Indians. 25 U.S.C. § 1724. (Also for convenience, the Houlton Band of Maliseet Indians and the Aroostook Band of Micmacs will hereinafter be referred to as the "Northern Tribes," where appropriate). So the mechanism of having the federal government serve as a trustee for tribal resources operates expressly under MICSA. The trust relationship is also evident elsewhere in the statute, albeit in a more inchoate form. MICSA clearly establishes that the Houlton Band of Maliseet Indians and the two Southern Tribes are federally recognized and it specifically charges them to document how their governments are structured. 25 U.S.C. §§ 1721(a) (3), (4), and (5), 1722(a), (h) and (k), and 1726. The Aroostook Band of Micmacs Settlement Act, Pub. L. 102-171, Nov. 26, 1991, 105 Stat. 143, contains similar provisions at Sec. 2(a)(1) and Sec. 3(1) and Sec. 7.[2] These various provisions are perfectly consistent with EPA's work with the Tribes on a government-to-government basis consistent with a trust relationship with the federal government. In addition, MICSA and MIA combine to explicitly reserve to the Southern Tribes the right to take fish for their individual sustenance within their reservations and to manage their lands and natural resources more generally. 30 M.R.S.A. § 6207(4); 25 U.S.C. § 1724(h); see also 25 U.S.C. § 1724(g)(3) for provisions relating to management of natural resources for the Southern Tribes and for the Houlton Band of Maliseet Indians. In addition, Pub. L. 102-171, Nov. 26, 1991, 105 Stat. 143, contains similar provisions at Sec. 5(b)(3) for the Aroostook Band of Micmacs. The Southern Tribes' statutorily reserved sustenance fishing right establishes an interest that the Southern Tribes have in the protection of specific natural resources, the fish that may

[2] In 1989, the Maine legislature passed the Micmac Settlement Act (MSA) to embody an agreement as to status of the Aroostook Band of Micmacs. 30 M.R.S. §§ 7201 et seq. In 1991, Congress passed the Aroostook Band of Micmacs Settlement Act (ABMSA), which ratified the MSA. 25 U.S.C. § 1721, Act Nov. 26, 1991, P.L. 102-171, 105 Stat. 1143.

sustain them and the water quality on which the quality of that fishing right depends. In addition, as articulated in EPA's Decision Support Document, EPA has determined that Congress's intent in the settlement acts was to establish a land base for the four federally recognized Maine Tribes permitting them to sustain their unique culture and lifestyle practices. The legislative record regarding the trust land provisions in MIA, MICSA, MSA and ABMSA demonstrate Congress's intent to provide the Tribes with the opportunity to exercise their sustenance life ways, including sustenance fishing in waters of tribal trust lands. For additional discussion relevant to the Maine Tribes' sustenance fishing practices, see EPA's Decision Support Document and the Department of the Interior's (DOI) January 30, 2015 letter to EPA. In sum, it is relatively easy to conclude that all the elements of a trust relationship exist under the settlement acts for the four federally recognized Maine Tribes, consistent with the trust doctrine as it has been developed in the federal common law. The Tribes are federally recognized; the Tribes have an interest in specific natural resources which the CWA charges EPA to protect; and the federal government, including EPA, has a responsibility to consider the Tribes' interests, consistent with applicable law.

As stated earlier, however, the existence of this trust relationship does not and cannot legally alter the jurisdictional arrangement Congress ratified in the settlement acts. The trust by itself does not and cannot compel, or constitute an independent basis for, EPA to disapprove Maine's surface WQS as applied in waters within Indian lands in Maine on the grounds that the State does not have jurisdiction to do so where, in fact, the settlement acts and their jurisdictional provisions actually *do* provide Maine with the requisite legal authority. Accordingly, EPA disagrees with the Penobscot Nation's comments that cite to and characterize several of the First Circuit's legal opinions as providing a basis for applying the full suite of federal Indian common law principles and the trust *prior to* analyzing MIA and MICSA.. See Page 11 of the Penobscot Nation's comments, citing *Pènobscot Nation v. Fellencer*, 164 F.3d 706 (1st Cir. 1999) and *State of Rhode Island v. Narragansett Indian Tribe*, 19 F.3d 685 (1st. Cir. 1994).

Tribal comments that the trust obligates EPA to find that Maine does not have jurisdiction because the trust requires EPA to protect the Tribes from state encroachment

Outside Maine, EPA has typically excluded Indian country from EPA-approved state environmental programs based on the absence of state jurisdiction in Indian country. See, e.g., *HRI, Inc. v. EPA*, 198 F.3d 1224, 1247 (2000). By contrast, in Maine, the jurisdictional provisions of the settlement acts provide the State jurisdiction to administer WQS in waters in Indian lands. Moreover, MICSA's savings clauses (see more detailed discussion in EPA's Decision Support Document), in effect, prevent any federal law applicable to Indians from rewriting those jurisdictional provisions (*i.e.*, from preempting or affecting the application of Maine law) without explicit Congressional action made specifically applicable in Maine. Therefore, as discussed above in this RTC document, EPA has carefully considered how the trust operates consistent with MIA, MICSA and the CWA in the context of Maine's surface WQS submission. EPA is not relying on the trust to determine whether Maine has jurisdiction to establish water quality standards for waters in Indian lands. As discussed elsewhere in this RTC document, the jurisdictional

scheme established in the settlement acts bears on how the Agency implements our decision consistent with the trust responsibility.

However, notwithstanding that Maine does have jurisdiction to establish surface WQS that apply in waters within Indian lands in Maine, EPA's implementation role under the CWA and the trust responsibility to the Tribes nonetheless require EPA to consider the effects that Maine's WQS would have on the Maine Indian Tribes' interests and welfare as we exercise our existing CWA authority. This is not different in kind from the way in which the CWA generally obligates EPA to consider and comply with the requirements of the CWA in assessing impacts of state and EPA decisions on the interests and welfare (in this instance human health, specifically) of persons in light of the goals of the CWA. In other words, EPA must evaluate the adequacy of Maine's WQS as they apply to waters within Indian lands using a standard or methodology that is consistent with the requirements of the CWA. The trust responsibility to the Maine Indian Tribes together with the Agency's authorized means of implementing the CWA require EPA to consider impacts on the Tribes in relation to protections of tribal resources that are addressed by the settlement acts and the CWA. See e.g., the discussion in EPA's Decision Support Document regarding the "designated use" of sustenance fishing and its protection under the CWA.

In addition, as we will discuss further below, the CWA assigns EPA a very important role in overseeing state surface WQS programs. Therefore, EPA's decision finding that Maine has the authority to establish WQS for waters within Indian lands will not prevent EPA from continuing to work with the Tribes and will not prevent EPA from communicating with all interested parties to improve coordination in protecting water quality in the surface waters in question. In fact, EPA's decision letter to ME DEP is a concrete example and manifestation of how CWA requirements provide for EPA's protection of the Maine Indian Tribes' interests and welfare in a way that is consistent with the jurisdictional framework established by Congress in Maine through the settlement acts and with the trust responsibility to the Tribes.

Maine's comments about the trust

As EPA earlier articulated in its responses to comments on Maine's NPDES program application in 2003, EPA disagrees with Maine's assertion that the federal government has no trust relationship or responsibility with respect to the Southern Tribes' reservations. While it is true that Congress curtails the applicability of the Non-Intercourse Act to the Penobscot Nation and the Passamaquoddy Tribe in MICSA Section 1724(g)(1), Congress also created similar responsibilities in Sections 1724(g)(2) and (3) that apply post-MICSA. Section 1724(g)(3) requires the approval of the Secretary of the Interior for six specific types of land transfers within the Southern Tribes' "territories,"

which have been defined, in MIA,[1] to include the reservations.[2] See 25 U.S.C. §1724(g)(3). Section 1724(g)(2) states that "any transfer of land or natural resources within Passamaquoddy Indian Territory or Penobscot Indian Territory ... shall be void ab initio and without any validity in law or equity." 25 U.S.C. §1724(g)(2). This language is very similar to that of the Non-Intercourse Act which states that no transfer of land or title to land from any Indian nation or Tribe "shall be of any validity in law or equity, unless the same be made by treaty or convention entered into pursuant to the Constitution." 25 U.S.C. §177. More importantly, Congress intended for these MICSA sections to replace the Non-Intercourse Act as a source of federal trust responsibility. Both houses of Congress, in responding to concerns about federal protection of the Southern Tribes, acknowledged that "[o]ne of the most important federal protections is the restriction against alienation of Indian lands without federal consent. [The sections that eventually became Sections 1724(g)(2) and (3)] specifically provide] for such a restriction and, as was made clear during the hearings, this provision is comparable to the Indian Non-Intercourse Act, 25 U.S.C. §177." H.R. DOC. NO. 96-1653, at 15 (1980); S.R. DOC. NO. 96-957 at 15(1980). As Congress confirms, Sections 1724(g)(2) and (3) essentially replace the Non-Intercourse Act as a source of federal trust responsibility. Reading MICSA as Congress intended would mean that the reservations are subject to a federal trust responsibility by nature of their inclusion as delineated parts of Penobscot Indian Territory and Passamaquoddy Indian Territory. See 25 U.S.C. §§1724(g)(2) and (3); 30 M.R.S.A. §6205.

Additionally, there are other sources of the federal trust relationship with respect to the reservations, as well as to the Southern and Northern Tribes' trust lands. It is obvious that the reservation lands are central to federally protected rights reserved for the Penobscot Nation and the Passamaquoddy Tribe. MICSA federally recognizes the Passamaquoddy Tribe, the Penobscot Nation, and the Houlton Band of Maliseet Indians. 25 U.S.C. §1721. The Aroostook Band of Micmacs Settlement Act, Pub. L. 102-171, Nov. 26, 1991, 105 Stat. 143, contains a similar provision at Sec. 2 (a)(1). In addition, MIA reserves, for the Southern Tribes, hunting and fishing rights within their reservations. 30 M.R.S.A. §6207(4). Both the House and Senate Committee reports relating to MICSA confirm that Congress intended for the Southern Tribes to have "the permanent right to control hunting and fishing ... within their reservations" according to the terms set out in MIA. H.R. DOC. NO. 96-1653, at 17 (1980); S.R. DOC. NO. 96-957 at 16 (1980). MICSA also reserves, for the Penobscot Nation and the Passamaquoddy Tribe, the right to manage their natural resources. 25 U.S.C. §1724(h). See also 25 U.S.C. § 1724(g)(3) for provisions relating to management of natural resources for the Southern Tribes and for the Houlton Band of Maliseet Indians. In addition, Pub. L. 102-171, Nov. 26, 1991, 105 Stat. 143, contains similar provisions at Sec. 5(b)(3) for the Aroostook Band of Micmacs. Therefore, it is reasonable to conclude that Congress reserved the trust lands in order to preserve the Maine Tribes' cultural activities, in

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[1]The Maine statute that is ratified by MICSA. See 30 M.R.S.A. §6205.

[2]The First Circuit has recognized that the necessity of the signature of the Secretary of the Interior implicates a federal trust responsibility. See Key Bank 112 F.3d. 538 at 553.

particular sustenance fishing, and intended that there be some federal responsibility to protect these activities consistent with the trust responsibility and the requirements of the CWA. For additional discussion relevant to the Maine Tribes' sustenance fishing practices, see EPA's Decision Support Document and DOI's January 30, 2015 letter to EPA.

Ultimately, the CWA provides the relevant authority for EPA to approve or disapprove Maine's surface WQS. 33 U.S.C. §1251 et. seq. As mentioned before, MIA, in 30 M.R.S.A. Section 6207(4), reserves for the Penobscot Nation and the Passamaquoddy Tribe, a sustenance fishing right within their reservations. MICSA, in 25 U.S.C. Section 1724(h), reserves for these Tribes, the right to manage their natural resources. See also 25 U.S.C. § 1724(g)(3) for provisions relating to management of natural resources for the Southern Tribes and for the Houlton Band of Maliseet Indians. In addition, Pub. L. 102-171, Nov. 26, 1991, 105 Stat. 143, contains similar provisions at Sec. 5(b)(3) for the Aroostook Band of Micmacs. Federal common law principles, and Congressional intent, support the position that the Tribes have the ability to practice sustenance fishing in their reservation and trust land waters. Section 303(c) of the CWA specifically gives EPA the authority to ensure that states adopt WQS that are protective of human health and the environment. 33 U.S.C. § 1313(c). EPA is the federal body charged with protecting the very resource that is reserved for Maine's federally recognized tribes, and the CWA gives EPA the authority to oversee state WQS. EPA should account for tribal resources, such as their fishing rights, in exercising that oversight authority, as required by the CWA and consistent with CWA authority and the trust relationship.

Moreover, it is clear that the State of Maine itself contemplated that sustenance fishing practices for the Maine Tribes would be part of the settlement embodied in MIA and subsequently ratified by Congress through MICSA. MIA section 6207(1) provides that "[i]n addition to the authority provided in this subsection, the Passamaquoddy Tribe and the Penobscot Nation, subject to the limitations of subsection 6, may exercise within their respective Indian territories all the rights incident to ownership of land under the laws of the State." The legislative history to MIA clearly indicates that both reservation lands and lands acquired pursuant to MIA after its enactment (trust lands) would enjoy riparian or littoral rights under state law and/or principles of common law.

> The boundaries of the Reservations are limited to those areas described in the bill, but include any riparian or littoral rights expressly reserved by the original treaties with Massachusetts or by operation of state law. Any lands acquired by purchase or trade may include riparian or littoral rights to the extent they are covered by the selling party or included by general principles of law. State of Maine, Maine Legislature, Joint Select Committee on the Indian Land Claims, Report of the Joint Select Committee on Indian Land Claims Relating to LD 2037 "AN ACT to provide for Implementation of the Settlement of Claims by Indians in the State of Maine and to Create the Passamaquoddy Indian Territory and Penobscot Indian Territory." Paragraph 14. 1980.

In support of the State's assertion that no trust relationship exists with respect to the reservations, Maine cites in its comments to a letter from DOI in which that Agency, according to Maine, stated that "fee title to the islands in the Penobscot River was held by Maine in trust for the benefit of the Penobscot Nation" and also cited to *Bangor Hydro-Electric Co.*, 83 FERC ¶ 61,037, 1998 WL292768 (F.E.R.C.). Bangor is a Federal Energy Regulatory Commission (FERC) case regarding the licensing of a hydro-electric project under the Federal Power Act (FPA). 16 U.S.C. §§797, 808. The Penobscot Nation and DOI intervened regarding parts of the Penobscot Nation's lands that were inundated when the project was originally built. Both Bangor and the case upon which it relies, *Federal Power Comm'n v. Tuscarora Indian Nation*, 362 U.S. 99,115 (1960), recognized that the narrow definition of "reservations," which relies on a strictly property oriented understanding of the term, is confined to the FPA. Bangor at 10. Tuscarora plainly says that "the national 'paternal interest' in the welfare and protection of the Indians is not the 'interests in lands owned by the United States' required, as an element of 'reservations' by § 3(2) of the Federal Power Act." Tuscarora, at 115. FERC's assertion in Bangor that "no trust relationship exists" with respect to aboriginal lands, should therefore be understood in this limited capacity, that "no trust relationship exists" for the purposes of the FPA, which requires an interest in lands owned by the United States. Bangor is therefore irrelevant in determining whether there is a federal trust responsibility with respect to the reservations outside the context of the FPA, and therefore does not establish or constitute precedent for the trust responsibility in the context of EPA's implementation of under the CWA.

Tuscarora, however, highlights the difference between 1) a narrow trust responsibility relating to lands "held in trust" and 2) a more general interest in the welfare and protection of the Indians, which points to a general federal trust responsibility, a distinction which is important to this discussion. In federal Indian law, the federal government's general trust responsibility derives from the United States Constitution as further developed by the Supreme Court and other federal courts of the United States, and has become a key aspect of federal Indian common law. The general trust responsibility includes the notion that the federal government has a responsibility, as a general matter, to consider and protect Indian tribes' interests when implementing federal statutes or evaluating decisions that may affect tribes. The federal government's attention to the Indian law canons of statutory construction that have evolved in the common law is an element of this general trust responsibility. The general trust responsibility does not, however, create or establish substantive obligations on the part of the federal government.

The specific trust on the other hand derives from substantive rights established in statutes or regulations that are implemented by the federal government on behalf of Indian tribes. The specific trust is sometimes referred to as an obligation that entails fiduciary duties on the part of the federal government to protect specified tribal rights. As noted in Cohen's Handbook of Federal Indian Law, "[t]he concept of a federal trust responsibility to Indians evolved from early treaties with tribes; statutes, particularly the Trade and Intercourse Acts; and the opinions of the Supreme Court." Cohen explains that the Supreme Court played a major role in defining the relationship between the federal government and Indian tribes. The Court's cases established principles, among others,

such as tribes' right to own land and to set land use policies for those subject to tribal authority, as a federal duty to protect tribal rights including tribal property rights, and as a rationale for canons of construction of various legal documents in light of the federal government's obligation to protect tribal sovereignty and property. See generally section 5.04[3][a] of Cohen's Handbook. In this case, EPA has attended to the general trust responsibility to the Maine Tribes by consulting with them about and understanding their interests in the decisions we are making regarding Maine's WQS in tribal waters, and by implementing the requirements of the CWA that apply to the WQS program. The substance of EPA's review of those WQS is governed by the generally applicable requirements of the CWA that guide EPA's implementation, not by any authority that creates a specific fiduciary obligation to any particular tribe in Maine.

We note that Maine also argues that CWA Section 518, a provision that allows Indian tribes to apply for treatment in the same manner as a state ("treatment as a state" or "TAS") status for purposes of certain CWA programs, is not available to the Tribes in Maine. Accordingly, says Maine, that fact is another reason why EPA has no trust responsibility to the Maine Tribes. EPA responds that its decision on Maine's WQS submissions relates to *Maine's* submission regarding WQS for waters in Indian lands, which is governed by EPA's CWA authorities and responsibilities, and which is unaffected by the separate issue of potential tribal roles under Section 518.[3] Even assuming, only for purposes of responding to Maine's specific comment, that none of the Maine Tribes could qualify for TAS status under CWA Section 518, EPA strongly disagrees that such fact, even if true, would mean that no trust responsibility exists to the Maine Tribes. This RTC document and EPA's Decision Support Document each address and demonstrate EPA's exercise of its CWA authority consistent with the trust responsibility to the Maine Tribes notwithstanding EPA's determination that Maine has adequate legal authority to establish WQS for waters within Indian lands. Maine's comment about CWA section 518 is not relevant to the question of whether a federal trust responsibility exists in Maine under the settlement acts and the CWA.

From the perspective of EPA's earlier description of the general and specific trust responsibilities, and for all of the other reasons discussed above, a federal trust relationship clearly does exist with respect to the Penobscot Nation and Passamaquoddy Tribes' reservations as well as with respect to the Southern and Northern Tribes' trust lands. In summary, although MICSA Section 1724(g)(1) negates the application of the Non-Intercourse Act (a statute often identified as a source of the federal government's specific, as opposed to general, trust responsibility) to these Indians, Congress intentionally included modern non-intercourse provisions in MICSA Section 1724(g)(2) and (3), thereby continuing a federal trust responsibility to the Tribes, and more specifically to their reservations. In addition to these non-intercourse provisions and the common law sources of the federal government's general trust responsibility, the CWA

[3] EPA notes that on October 8, 2014, the Penobscot Nation submitted to EPA an application "to administer water quality standards program and for federal approval of the standards" covering the Maine Stem of the Penobscot River from Indian Island north to the confluence of the east and west branches of the river. Included in the Nation's submission was a TAS application. EPA has not commenced a formal review of the Nation's application, wanting first to address Maine's submissions.

gives EPA the authority to review the State's WQS for consistency with the statute and thereby to utilize its existing authority to protect the reservations and trust lands and the practices and rights associated with them. The relevant settlement acts established trust lands for the Northern and the Southern Maine Tribes, and specifically defined those holdings to include "land or natural resources," which in turn specifically includes "fishing and fishing rights." The settlement acts contain provisions about the potential disposition and management of those resources. The relevant statutory provisions have been cited earlier in this RTC document. So in utilizing our existing CWA authority to protect the Maine Tribes' interests and welfare in relation to the reservations and trust lands, EPA is acting consistently with the settlement acts in Maine and the trust responsibility.

The State also cites in its comments to the First Circuit's opinion in *Nulankeyutmonen Nkihttaqmikon v. Impson*, 503 F.3d 18, 31 (1st Cir. 2007) in support of its contention that EPA has no trust responsibility to the Maine Indians Tribes in making decisions under the CWA. Maine claims that the CWA contains no set of written standards that anyone may review to assess whether a particular implementation decision EPA may render complies with its trust obligation under the CWA. Thus, Maine asserts, an EPA decision that breathes substantive or procedural requirements into the CWA pursuant to its trust relationship, but independent of the CWA, would be arbitrary and capricious, citing to *Michigan v. EPA*, 268 F.3d 1075, 1085 (D.C. Circuit 2001).

EPA agrees with Maine's assertion that any specific requirements that flow from a specific trust relationship must derive their content from and are the product of applicable law, whether treaties, statutes, or regulations. See *Shoshone-Bannock Tribes v. Reno*, 56 F.3d 1482 (D.C. Cir. 1995); *State of California v. Watt*, 668 F.3d 1290, 1324 (D.C. Cir. 1981). However, EPA disagrees with Maine to the extent the State argues that EPA may not, in exercising our existing authority and discretion under the CWA, be informed by our consideration of tribal interests consistent with the general trust relationship. The CWA includes requirements for how EPA must review the adequacy of WQS, and EPA must apply those requirements to Maine's WQS in Indian waters. In considering the impacts of Maine's WQS on the water quality-related interests and welfare of the Indian Tribes in Maine, and most notably on the tribal sustenance fishing practices associated with Indian land waters, EPA is exercising its CWA authority consistent with the trust relationship, the requirements of the CWA, and the settlement acts. EPA's decision that Maine's human health criteria are not sufficiently protective of the CWA "designated uses" that apply to waters in Indian lands is directly tied to a fundamental requirement of the CWA, *i.e.* that WQS must protect designated uses. See EPA's Decision Support Document for a more detailed discussion. In this regard, EPA's decision to disapprove certain of Maine's WQS is entirely consistent with the holding in *Nulankeyutmonen Nkihttaqmikon v. Impson* in the sense that EPA's decision is derived from CWA requirements, provisions in the settlement acts, and Congress's intent to preserve the Tribes' sustenance fishing practices, culture, and lifestyle.

B. Many comments from the Maine Tribes relating to the question of Maine's jurisdiction focused on the concept of the Tribes' inherent sovereignty, and/or the concept of "internal tribal matters" as an explicit expression in MIA/MICSA of the Southern Tribes' retained inherent sovereign status. Maine submitted comments along the lines that MIA/MICSA provide the State with jurisdiction, at least implying that these concepts raised by the Tribes do not function to alter that outcome.

Examples of the Tribes' comments

1. Establishing an appropriate fish consumption rate (FCR) and cancer risk level (CRL) for use in establishing WQS under the CWA are each an "expressly retained sovereign activity."

2. Setting CRLs and FCRs amounts to regulation of the Tribes' sustenance fishing right, which the State is not authorized to do under MIA and MICSA.

3. Establishing WQS under the CWA is an inherent sovereign right and is an internal tribal matter.

4. If the Indian Tribes, as opposed to the State, were establishing WQS in Indian waters, the Tribes would not be regulating any non-tribal members.

5. An Indian Tribe's inherent authority or tribal sovereignty cannot be divested unless Congress expressly acts to do so.

6. Water quality in Indian waters is something that may directly threaten the "health or welfare of the tribe." Water rights and governmental jurisdiction are "critical elements necessary for tribal sovereignty."

7. Congress did not "unequivocally abrogate the Tribe's inherent authority to protect the sustenance fishery."

8. The legislative history to MICSA indicates that MICSA's sustenance fishing right is an example of an "expressly retained sovereign activity."

9. Inherent sovereignty applies in this context and allows Indian tribes to protect subsistence practices embodying cultural, spiritual, and physical elements.

10. Inherent sovereignty precludes Maine from regulating in this way. Sustenance fishing is an aboriginal right.

11. The notion that establishing WQS in Indian waters is an internal tribal matter is supported by federal and State governments' adoption of principles in the United Nations declaration on the Rights of Indigenous Peoples.

12. Determining a CRL that tribal members will be subjected to is an internal tribal matter. Maine is asking EPA to approve Maine's policy judgment about the level of risk the Tribes should face, which is inappropriate and inconsistent with the Tribes' inherent sovereignty.

13. Protection of tribal health and welfare is an internal tribal matter over which the State may not exercise jurisdiction, and includes environmental regulation.

Examples of the State's comments

1. The CWA and MIA/MICSA provide Maine with the authority to establish WQS in waters within Indian lands in Maine.

2. MICSA's savings clauses would preclude the Maine Indian Tribes from implementing a WQS program in Maine.

EPA's responses to comments concerning principles of inherent tribal sovereignty (and MIA's and MICSA's internal tribal matters provision) and its effect on Maine's legal authority to establish WQS for waters within Indian lands

Basic tenets or principles of federal Indian common law as they relate to tribal sovereignty

EPA agrees with the comments that set forth the basic tenets of federal Indian common law supporting the idea that Indian tribes have retained their inherent powers as sovereign entities (unless expressly abrogated by Congressional action), that such sovereign status has existed since long before contact with European nations, and that Indian tribes' sovereignty it is not something that was delegated or granted to the tribes by Congress. EPA has consistently sought to uphold the inherent sovereignty of Indian tribes wherever applicable. See, e.g., EPA's 1984 Indian Policy.

Many of the federal court opinions cited by the Penobscot Nation in its comments reflect or discuss certain aspects of these common law principles of federal Indian law. See, e.g., *Wisconsin v. E.P.A.*, 266 F. 3d 741 (7th Cir. 2001); *State of Washington, Dep't of Ecology v. U.S.E.P.A.* 725 F. 2d 1465 (9th Cir. 1985); *Merrion v. Jicarilla Apache Tribe*, 455 U.S. 130 (1982); *New Mexico v. Mescalero Apache Tribe*, 462 U.S. 324 (1983); *Oklahoma Tax Comm'n v Sac & Fox Nation*, 508 U.S. 114 (1993); *Three Affiliated Tribes of Ft. Berthold v. Wold Eng'g*, 476 U.S. 877 (1986); *Kiowa Tribe of Oklahoma v. Mfg techs, Inc.* 523 U.S. 751 (1998); *Santa Clara Pueblo v. Martinez*, 436 U.S. 49 (1978); *Williams v. Lee*, 358 U.S. 217 (1959); *Aroostook Band of Micmacs v. Ryan*, 404 F.3d 48 (1st Cir. 2005); *Montana v. United States*, 450 U.S. 544 (1981); *City of Albuquerque v. Browner*, 97 F. 3d 415 (10th Cir. 1996).

These general principles of Indian common law cited by the Penobscot Nation, however, are not dispositive of and do not directly answer the fundamental jurisdictional question before EPA in this matter: what effect do the settlement acts have on the jurisdictional relationship among the Southern and Northern Tribes, the State of Maine, and the federal government when implementing the CWA WQS program applicable to Indian waters within Indian lands in Maine? The cases cited by the Penobscot Nation were not decided against the backdrop of statutes like MIA and MICSA which, as EPA has explained throughout this RTC document, alter in certain important respects the Maine Indian Tribes' inherent sovereign status as compared to the more typical situation that exists in parts of the United States that do not have statutes like MIA and MICSA.[4]

EPA recognizes the fundamental principles of federal Indian law relating to inherent tribal sovereignty, and is aware that Congress has plenary power over Indian affairs as established in the Indian commerce clause of the Constitution. *Santa Clara Pueblo v. Martinez*, 436 U.S. 49, 56 (1978). As a result, only Congress may change the jurisdictional relationships in Indian country by expanding or contracting state, tribal and federal jurisdiction. If Congress takes any action to limit a tribe's sovereignty, it must do so expressly and any ambiguities must be resolved in the tribe's favor. Congress may provide for state law to apply in Indian country, but it must do so expressly. *See California v. Cabazon Band of Mission Indians*, 480 U.S. 202, 207 (1987).

In this matter, EPA is applying the Congressional grant of legal authority to Maine in the Southern and Northern Tribes' Indian lands which is adequate to support the State's assertion of legal authority to implement a CWA WQS program applicable to waters in Indian lands located in Maine. See EPA's Decision Support Document for a more detailed discussion and analysis. Both MIA and MICSA, as further elucidated in MIA's and MICSA's legislative histories, embody a jurisdictional framework that serves as a compromise in settlement of the land claims that gave rise to these statutes. The Senate Report accompanying MICSA specifically addressed concerns about the impact of these

[4] The Penobscot Nation also cites to *Aroostook Band of Micmacs v. Ryan*, 404 F.3d 48 (1st Cir. 2005) as a First Circuit opinion that addresses tribal sovereignty "absent their divestment by the federal government." See Page 14 of the Penobscot Nation's comments. This case, however, like the others cited by the Tribe, does not stand for the proposition that MICSA did not give Maine the legal authority to establish WQS in waters within Indian lands.

two statutes on the Penobscot and Passamaquoddy Tribes' sovereign rights and jurisdiction. "While the settlement represents a compromise in which State authority is extended over Indian territory to the extent provided in the Maine Implementing Act, in keeping with [certain legal precedent] the settlement provides that henceforth the Tribes will be free from State interference in the exercise of their internal affairs. Thus, rather than destroying the sovereignty of the Tribes, by recognizing their power to control their internal affairs and by withdrawing the power which Maine previously claimed to interfere in such matters, the settlement strengthens the sovereignty of the Maine Tribes." Page 14, Special Issues. The Senate Report goes on to describe other ways in which the Tribes' sovereignty is protected, including, but not limited to, the hunting and sustenance fishing right provisions in the statutes and the provisions granting to the Southern Tribes state constitutional status of municipalities. However, the nature of this compromise in retaining certain aspects or elements of the Tribes' sovereignty does not override or conflict with the fact that Congress in MICSA ratified a jurisdictional relationship among the Tribes and the State that gave Maine the authority to apply state law to those matters not falling within either:1) the internal tribal matters provision in the statute; 2) the Southern Tribes' reservation hunting and fishing rights or 3) certain other matters specifically reserved by the statutes to the Tribes.[5] EPA's conclusion that Maine has the legal authority to establish WQS in waters within Indian lands is consistent with MIA and MICSA because, as discussed below in more detail, doing so is not an internal tribal matter and does not alter or regulate the Southern Tribes' right to take fish within their reservations for their individual sustenance. In fact, EPA's Decision Support Document explains that the Southern and Northern Tribes' fishing rights are being protected under the CWA notwithstanding Maine's authority to establish WQS in waters within Indian lands.

Consistent with the analysis above of the Maine Tribes' sovereign status, as expressed in MICSA, which ratifies MIA, the federal Indian common law cases cited by the Penobscot Nation are generally inapposite here. The vast majority of the cases did not address the scope of the sovereign status of an Indian tribe under statutes similar to MIA and MICSA. See e.g., *Kiowa Tribe of Oklahoma v. Mfg techs, Inc.* 523 U.S. 751 (1998); *New Mexico v. Mescalero Apache Tribe*, 462 U.S. 324 (1983); *Santa Clara Pueblo v. Martinez*, 436 U.S. 49 (1978); *Williams v. Lee*, 358 U.S. 217 (1959); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174 (1988); *Montana v. United States*, 450 U.S. 544 (1981); *Wisconsin v. E.P.A.*, 266 F. 3d 741 (7th Cir. 2001); *City of Albuquerque v. Browner*, 97 F. 3d 415 (10th Cir. 1996). In addition, although the Penobscot Nation also cites to several First Circuit cases discussing some aspects of inherent tribal sovereignty generally, none of those cases held that Maine law did not generally apply to the Maine Indian Tribes under MIA section 6204 and MICSA sections 1725(a) and 1725(b)(1) on the basis of the Tribes' inherent sovereign status. See, e.g., *Akins v. Penobscot Nation*, 130 F. 3d 482 (1st Cir. 1997); *Penobscot Nation v. Fellencer*, 164 F. 3d 706 (1st Cir. 1999); *Bottomly v. Passamaquoddy Tribe*, 599 F. 2d 1061 (1st Cir. 19179); and *Aroostook Band of Micmacs v. Ryan*, 404 F.3d 48 (1st Cir. 2005).

[5] The other matters referenced here are not pertinent to EPAs decision.

The effect of the settlement acts on federal Indian common law as they relate to tribal sovereignty

The settlement acts clearly represent a substantial revision to the relationship between state and Indian jurisdiction that would apply in Maine absent the settlement acts. Virtually every court that has reviewed the statutes has emphasized that it is impossible in Maine to simply apply federal Indian common law without first starting with the settlement acts. See, e.g. *Akins v. Penobscot Nation*, 130 F.3d 482, 484 (1st Cir. 1997); *Penobscot Nation v. Fellencer*, 164 F.3d 706, 708 (1st Cir. 1999), cert. denied 527 U.S. 1022 (1999); *Penobscot Nation v. Georgia-Pacific*, 254 F.3d 317, 320 (1st Cir. 2001), cert. denied 534 U.S. 1127 (2002); *Penobscot Nation v. Stilphen*, 461 A.2d 478, 482 (Me. 1983), app. dismissed 464 U.S. 923 (1983); *Great Northern Paper Inc. v. Penobscot Nation*, 770 A.2d 574, 580 (Me. 2001), cert. denied -- U.S. –, 122 S.Ct. 543 (2001); *Maine v. Johnson*, 498 F.3d 37, 42 (1st Cir. 2007). For example, the settlement acts create a status for the Northern and Southern Tribes (although there are statutory differences for each of the two groups) that is unique in the nation, and extends state authority over the Tribes to an unusual extent. Therefore, to say simply that federal Indian common law applies to the Maine Tribes (without any qualification) understates the critical role the settlement acts play in revising the customary formula for gauging Indian sovereignty.

On the other hand, it overstates the effect of the settlement acts to say that federal Indian law is irrelevant to interpreting how the settlement acts apply in Maine. As a threshold matter, for example, MICSA is a federal statute that modifies tribal jurisdiction, and therefore is subject to the interpretive doctrines in federal common law giving the tribes the benefit of the doubt where the statute is ambiguous. *Fellencer*, 164 F.3d at 709. Additionally, MICSA ratified the jurisdictional formulation in MIA for the Southern Tribes, and MIA specifically preserves "internal tribal matters" from state regulation. When analyzing the scope of "internal tribal matters," the First Circuit has twice referred to general principles of federal Indian law, both common law (*Akins*, 130 F.3d at 489-90) and statutory provisions (*Fellencer*, 164 F.3d at 711), to help understand the extent of that term. MICSA and its legislative history make it clear that "internal tribal matters" is not a reservation of the Southern Tribes' full inherent sovereignty that predated passage of MICSA. But the term nevertheless protects key elements of the Southern Tribes' inherent sovereignty from state regulation. Therefore, when confronted with MICSA, courts have looked to the body of federal Indian law to better understand how a tribe's inherent sovereignty works in the customary case. In EPA's decision on Maine's WQS submission, EPA has similarly filtered the body of general federal Indian common law through the lens of MICSA, recognizing its unique requirements, while understanding at the same time that the statute operates against the backdrop of federal Indian common law.

EPA would disagree with any assertion that the Southern or Northern Tribes are no longer sovereigns, notwithstanding that the Southern and Northern Tribes are treated differently by the settlement acts in certain respects. Congress specifically recognized the tribal governments of the Southern and Northern Tribes. 25 U.S.C. §§ 1721(a) (3),

(4), and (5), 1722(a), (h) and (k); Aroostook Band of Micmacs Settlement Act, Pub. L. 102-171, Nov. 26, 1991, 105 Stat. 143, at Sec. 2 (a)(1) and Sec. 3(1). Congress charged the Tribes with developing written instruments to govern their affairs when acting in a governmental capacity. 25 U.S.C. § 1726 and Aroostook Band of Micmacs Settlement Act, Pub. L. 102-171, Nov. 26, 1991, 105 Stat. 143, at Sec. 7. It is explicitly clear in MIA and MICSA that the Southern Tribes exercise sovereignty in the sense of having governmental authority over their internal affairs and may take fish for their individual sustenance within their reservations. Using the term sovereignty when referring to the activities of these tribal governments is completely consistent with, indeed is compelled by, the terms of MICSA and The Aroostook Band of Micmacs Settlement Act. But the focus of this matter is the extent of the State's authority in relation to that which may be reserved to the Southern and Northern Tribes, and simply embracing or banishing the term "sovereignty" (without any qualifications or more nuanced explanations) contributes little to answering that question.

Penobscot Nation's sovereignty argument in relation to MIA section 6204

The Penobscot Nation asserts that the Tribe's full aboriginal inherent sovereignty was intended by Congress to be retained in MICSA. The Penobscot Nation argues this is true notwithstanding the language in MIA section 6204 generally subjecting all Indian Tribes in Maine to the laws of the State and to the civil and criminal jurisdiction of the courts of the State to the same extent as any other person or lands or other natural resources therein. The Penobscot Nation argues that section 6204 "merely confirms that the Nation will adopt Maine law as its own, but it does not expressly impose any form of State regulatory authority upon the Tribe or its natural resources." The Tribe cited to *Wauneka v. Campbell*, 22 Ariz. App. 287, 526 P. 2d 1085 (C.A. 1974), a case included in one section of MICSA's legislative history.

Although the Tribe's comment doesn't refer to MIA section 6202, "Legislative findings and declaration of policy," EPA notes that this language may also be relevant to the Tribe's argument:

> The foregoing agreement between the Indian claimants and the State also represents a good faith effort by the Indian claimants and the State to achieve a just and fair resolution of their disagreement over jurisdiction on the present Passamaquoddy and Penobscot Indian reservations and in the claimed areas. To that end, the Passamaquoddy Tribe and the Penobscot Nation have agreed to adopt the laws of the State as their own to the extent provided in this Act. The Houlton Band of Maliseet Indians and its lands will be wholly subject to the laws of the State.

As part of this overall argument in support of the Tribe's assertion of full aboriginal inherent sovereignty, the Tribe also references certain passages from MICSA's legislative history and federal case law. For a number of reasons, EPA disagrees that this particular argument, either on its own, or in conjunction with the Tribe's other arguments about

inherent tribal sovereignty, results in a legal conclusion that Maine is precluded by MIA and MICSA from establishing WQS in waters within Indian lands in Maine.

First, as set forth in EPA's Decision Support Document, and as explained in various other portions of this RTC document, the statutory provisions of MIA and MICSA and those statutes' legislative histories, very clearly establish that state law applies to the Penobscot Nation and the Passamaquoddy Tribe (and the other Maine Tribes) in the context of environmental regulation. Moreover, as the First Circuit said in *Maine v. Johnson*:

> In our view, the Settlement Acts make ordinary Maine law apply, even if only tribal members and tribal lands are affected in the particular case, *unless* the internal affairs exemption applies; and the scope of that exemption is determined by the character of the subject matter. Discharging pollutants into navigable waters is not of the same character as tribal elections, tribal membership or other exemplars that relate to the structure of Indian government or the distribution of tribal property. [*Maine v. Johnson*, 498 F. 3d 37, 46.]
>
> In addition to Maine's explicit authority over tribal lands and natural resources, the Settlement Acts expressly divested the Maine Tribes of sovereign immunity, *25 U.S.C. § 1725(d)*, and with limited exceptions, made the Maine Tribes subject to the general criminal and civil law of Maine even with respect to activities carried out on tribal lands. *25 U.S.C. § 1725(a), (c)*; *30 M.R.S.A. § 6204*. [*Maine v. Johnson*, 498 F. 3d 37, 42-43.]
>
> [T]he question here is whether *Maine* has adequate authority to implement permitting as to the tribes' lands, and *section 6204* on its face is about as explicit in conferring such authority as is possible. [*Maine v. Johnson*, 498 F. 3d 37, 43.]

Each of these passages from *Maine v. Johnson* directly conflicts with the Tribe's argument that MIA and MICSA did not intend to provide Maine with the legal authority to regulate the Penobscot Nation under state law because the Settlement Acts intended to preserve the Maine Tribes' full aboriginal inherent sovereignty. Indeed, every time the U.S. Court of Appeals for the First Circuit has adjudicated the extent of Maine's jurisdiction in Indian territories, it is clear the court held that MICSA applies the laws of the State to the Southern Tribes.

Five different First Circuit cases adjudicating the application of state law in the Southern Tribes' territories have never hinted at the idea that state law applies to the Tribes as anything other than state law. *Passamaquoddy Tribe v. Maine*, 75 F.3d at 789, n. 1 (1st Cir. 1996) ("Among other things, the Gaming Act, if it applied, would preempt various provisions of Maine's criminal law, including 17–A Me. Rev. Stat. Ann. §§ 953–954."); *Akins v. Penobscot Nation*, 130 F.3d 482 (1st Cir. 1997) ("This case turns on whether the issuance of stumpage permits is an 'internal tribal matter.' If this is an internal tribal matter, then under both Settlement Act and the Implementing Act, Maine law does not apply and no claims arise under the Maine Constitution or under the Maine

Administrative Procedure Act. Thus no claim arises under state law warranting the exercise of diversity jurisdiction." 130 F.3d at 485); *Penobscot Nation v. Fellencer*, 164 F.3d 706 (1st Cir. 1999), cert. denied, 527 U.S. 1022, 119 S. Ct. 2367, 144 L. Ed. 2d 771 (1999) (Maine state law did not apply only because the decision whether to employ a tribal member or a non-tribal member as a community nurse fell within the "internal tribal matter" exception to the applicability of state law under MIA and MICSA); *Penobscot Nation v. Georgia Pacific Corporation*, 254 F. 3d 317 (1st Cir. 2001) (Company demanded documents from Maine Tribes based on Maine's Freedom of Access Act. "Under Maine law, the Tribes are regulated in certain respects as municipalities, and municipalities are covered by the Access Act." 254 F.3d at 318.); *Maine v. Johnson*, 498 F.3d 37, 43 (1st Cir. 2007) ("The Southern tribes say that state authority over land and water resources can coexist with tribal authority, pointing to certain provisions of the Settlement Acts that explicitly make state authority 'exclusive.' So, the tribes say, the existence of Maine's authority does not automatically negate concurrent tribal authority over the same subject matter. But the question here is whether Maine has adequate authority to implement permitting as to the tribes' lands, and section 6204 on its face is about as explicit in conferring such authority as is possible. What the tribes might do if Maine did not legislate is beside the point. The Southern tribes' concurrency argument would have bite only if their own 'concurrent' regulatory authority, if it existed, took priority over enacted Maine law. But this would turn on its head the explicit language of the Settlement Acts giving Maine authority over land and water resources in the tribes' territories. If there is 'concurrent' jurisdiction at all, it is subordinate to Maine's overriding authority to act within the scope of section 6204, which clearly includes Maine's power to regulate discharge permitting consistent with the Clean Water Act.") And none of these cases held that the reference to W*auneka v. Campbell*, 22 Ariz. App. 287, 526 P. 2d 1085 (C.A. 1974), in MICSA's legislative history, supports the proposition that Maine state law does not apply as state law to the Southern Tribes under MIA section 6204.

MIA's internal tribal matters provision

In this subsection of EPA's RTC document, EPA provides a legal analysis of the "internal tribal matters" provision in MIA, as ratified by MICSA, as well as a discussion of how the First Circuit has construed the provision in its decisions to date. As explained below, EPA concludes that establishing WQS in waters within Indian lands is not an internal tribal matter. That conclusion is well-supported by First Circuit precedent, which strongly suggested that the balancing factors from *Akins* and *Fellencer*, that should be used in circumstances that constitute close questions of the applicability of the internal tribal matters provision, would be *inappropriate* if applied to the question of Maine's authority to establish WQS in waters within Indian lands. *Maine v. Johnson,* at 46. Nevertheless, because of the prominence of the concept of internal tribal matters in the Penobscot Nation's comments, EPA analyzes the concept below in detail. EPA even analyzes the balancing factors from *Akins* and *Fellencer* as applied to the WQS question to demonstrate that, even if it were appropriate to apply the factors, the analysis shows that Maine has authority to establish WQS in waters in Indian lands and that such

authority is not inconsistent with and does not run afoul of the internal tribal matters provision in MIA.

EPA recognizes the importance of the "internal tribal matters" provisions in MIA section 6206(1), as ratified by MICSA section 1725(b)(1), which by its terms only applies to the two Southern Tribes. We agree that, to the extent a subject is an internal tribal matter, the State is precluded from regulating that subject and that it falls beyond the reach of the grant of state authority in MIA section 6204, as ratified by Congress. Therefore, the scope of the internal tribal matters concept essentially defines the boundary of the State's jurisdiction and the State's ability to regulate activities in the Southern Tribes' territories.[6]

The internal tribal matters provision in MIA and MICSA is a reservation of authority to the Southern Tribes based on their inherent sovereignty that predates MICSA. Congress did not intend, however, to reserve through MICSA the *full scope* of the Southern Tribes' inherent sovereignty which the federal courts had recently recognized prior to MICSA. *Bottomly v. Passamaquoddy Tribe*, 599 F.2d 1061, 1065-66 (1st Cir. 1979); *Joint Trib. Coun. of Passamaquoddy Tribe v. Morton*, 528 F.2d 370, 379 (1st Cir. 1975). That interpretation would cause the exception of internal tribal matters to swallow the rule Congress created, which is that state law generally applies to the Maine Tribes and their lands. But as we discuss further below, the common law generally interpreting Indian Tribes' inherent sovereignty is relevant to assessing the scope of internal tribal matters, at least as a threshold test. If a subject matter would be beyond the reach of any Indian Tribe's inherent sovereignty, it could not qualify as an internal tribal matter under MICSA. If a subject matter is generally within the inherent authority of a Tribe to govern (and one decides it is appropriate to undertake an internal tribal matters analysis), EPA concludes that the next step in the analysis consists of using the factors that the First Circuit has derived in analyzing the provisions of MIA and MICSA. In short, EPA has concluded that "internal tribal matters" under MICSA is a subset of the inherent authority Indian Tribes generally retain as reflected in the general principles of federal Indian common law.

In addition, we note that it would be difficult to reconcile the unique wording of MICSA section 1725(f) with the interpretation that internal tribal matters reserves the Southern Tribes' unimpaired inherent sovereignty. This section provides:

> The Passamaquoddy Tribe and the Penobscot Nation are hereby authorized to exercise jurisdiction, separate and distinct from the civil and criminal jurisdiction of the State of Maine, *to the extent authorized by the Maine Implementing Act, and any subsequent amendments thereto.*

25 U.S.C. § 1725(f) (emphasis added). These provisions of MICSA show that the jurisdictional arrangement Congress ratified in MICSA results in an atypical scope for the Southern Tribes' inherent authority. That is because an Indian Tribe's inherent

[6] MIA and MICSA also identify areas of jurisdiction specifically reserved to the Southern Tribes, but those provisions are not relevant to this WQS analysis under the CWA. See e.g. sections 6209-A and 6209-B.

sovereignty typically is not dependent on or subject to definition by state law in the United States, and it requires no affirmative grant of authority from Congress for a Tribe to assert its inherent sovereignty in relation to state law. See *Merrion v. Jicarilla Apache Tribe*, 455 U.S. 130, 148 n. 14 (1982) ("[N]either the Tribe's Constitution nor the Federal Constitution is the font of any sovereign power of the Indian tribes."], see also id. at 168 ("Tribal sovereignty is neither derived from nor protected by the Constitution. Indian tribes have, however, retained many of the powers of self-government that they possessed at the time of their incorporation into the United States." (Stevens, J. dissenting; footnote omitted)). But Congress has plenary authority to alter the scope of an Indian tribe's inherent sovereign authority.

Congress understood that MIA had essentially flipped the presumption against state law applying in Indian country, and the wording of section 1725(f) therefore makes sense. Faced with ratifying a state statute that included an aggressive extension of state authority over the Southern Tribes and their territories, using sweeping language creating a presumption that state law applies, Congress was being careful to point out that the Southern Tribes still exercised independent jurisdictional authority for certain purposes under the terms of the MIA. The wording of section 1725(f) is fully consistent when we conclude that internal tribal matters reserved some subset of the Southern Tribes' inherent sovereignty, and that Congress was expressly confirming that residual authority. MICSA, however, also ratifies a substantial grant of authority to the State, which includes adequate authority to establish WQS in waters in Indian lands. Normally, outside Maine, establishing WQS in Indian lands would fall outside state jurisdiction. Here, MIA and MICSA provide that authority to the State.

Consistent with the discussion above regarding the scope and limitations of the internal tribal matters provision, the portion of MICSA's legislative history which specifically speaks to the States' authority to regulate the *environment* in the Southern Tribes' territories is direct and compelling. Most notably, when discussing the specific section of MICSA that ratifies MIA's jurisdictional arrangement for the Southern Tribes, the Senate Report concludes:

> . . . State law, including but not limited to laws regulating land use or management, conservation and environmental protection, are fully applicable as provided in this Section and Section 6204 of the Maine Implementing Act. That the regulation of land or natural resources may diminish or restrict maximization of income or value is not considered a financial encumbrance and is not barred from application under this Act.

S. Rep. at 27(emphasis added).

The only other place in the Congressional Committee Reports that speaks directly to regulation by the State of environmental matters in Indian lands is the discussion of the first savings clause in MICSA, section 1725(h). This provision makes federal Indian law up to 1980 generally applicable in Maine, but only if that law does not affect or preempt state jurisdiction:

> Except as other wise [sic] provided in this subchapter, the laws and regulations of the United States which are generally applicable to Indians, Indian nations, or tribes or bands of Indians or to lands owned by or held in trust for [them] shall be applicable in the State of Maine, except that no law or regulation of the United States (1) which accords or relates to a special status or right of or to any Indian, Indian nation, tribe or band of Indians, Indian lands, Indian reservations, Indian country, Indian territory or land held in trust for Indians, and also (2) which affects or preempts the civil, criminal, or regulatory jurisdiction of the State of Maine, including, without limitation, laws of the State relating to land use or environmental matters, shall apply within the State.

25 U.S.C. § 1725(h)(emphasis added). This provision does not control what jurisdiction Maine received under MICSA; it simply protects the jurisdiction granted to the State elsewhere in MICSA from inadvertent intrusion by general federal Indian law. As a structural matter, however, it is notable that Congress specifically identified "environmental matters" as an area of state law to be protected, strongly supporting our conclusion that environmental regulation was included in the grant of authority to the State. The Senate Report confirms this conclusion:

> It is also the intent of this subsection, however, to provide that federal laws according special status or rights to Indian [sic] or Indian Tribes would not apply within Maine if they conflict with the general civil, criminal, or regulatory laws or regulations of the State. Thus, for example, although the federal Clean Air Act, 42 U.S.C. § 7474, accords special rights to Indian Tribes and Indian lands, such rights will not apply in Maine because otherwise they would interfere with State air quality laws which will be applicable to the lands held by or for the benefit of the Maine Tribes. This would also be true of police power laws on such matters as safety, public health, environmental regulations or land use.

S. Rep. at 31; see also H.R. Rep. at 29. This passage makes it very clear that Congress understood it was making state environmental law applicable to Indian lands.

As noted earlier, the First Circuit's precedent interpreting MIA and MICSA is consistent with Congress' intent to make Maine environmental law apply to Indian lands. And establishing WQS is, in character, much more akin to discharging pollutants into navigable waters than it is to such matters as tribal elections, tribal membership or other exemplars that relate to the structure of Indian government or the distribution of tribal property.

First Circuit precedent interpreting MIA's and MICSA's internal tribal matters provision, including an analysis of the *Akins* and *Fellencer* factors

In its decision in *Maine* v. *Johnson*, the First Circuit squarely addressed the "internal tribal matters" provision in MIA, ratified by MICSA. In *Maine* v. *Johnson,* the Court noted that its decisions in *Akins* and *Fellencer* were the only two in which the Court had

directly construed the phrase "internal tribal matters" as applied to the Maine Tribes. The Court clearly distinguished both of those prior cases from the CWA NPDES program case before it, noting, among other things, that in each of *Akins* and *Fellencer*, the State disclaimed any interest in regulation or superintendence over the activities in question. The Court noted further that the Settlement Act's jurisdictional provisions clearly affirmed Maine's asserted power in the context of regulating discharges of pollutants into navigable waters, even for facilities located on tribal lands discharging into tribal waters. The Court stated that "[i]f the internal affairs exemption negated so specific a ground of state authority, it is hard to see what would be left of the compromise restoration of Maine's jurisdiction." *Maine* v. *Johnson,* at 45. The Court subsequently noted that "[i]n our view, the Settlement Acts make ordinary Maine law apply, even if only tribal members and tribal lands are affected in the particular case, *unless* the internal affairs exemption applies," finding that discharging pollutants into navigable waters is not of the same character as the enumerated examples of internal tribal matters contained in the MIA. *Id.* At 46. The Court clearly rejected EPA's use of the "balancing test" that the Agency stated was consistent with the Court's analysis in *Akins* and *Fellencer*, noting that "discharging pollutants into navigable waters is not a borderline case in which balancing . . . or ambiguity canons . . . can alter the result." *Id.* At 46.

As noted above, in *Maine* v. *Johnson* the First Circuit suggested that EPA's application of the balancing factors and method of analysis derived from *Akins* and *Fellencer* was misplaced in an area of regulatory authority so clearly reserved to the State under MIA and MICSA. It therefore behooves EPA first to ask the question whether the facts and surrounding circumstances pertinent to Maine's WQS submissions are more akin to the circumstances present in *Maine v Johnson* or to those present in *Akins* and *Fellencer*. That is, is Maine's request to apply its WQS to waters within Indian lands clearly within its regulatory authority under MIA and MICSA in the way that the Court in *Maine v. Johnson* viewed regulating discharges of pollutants into navigable waters (where Maine expressed a strong interest in doing so)? Or does the WQS context before EPA now involve circumstances and relative tribal and state interests more akin to a dispute over whether non-tribal members have timber rights in Indian territory (where the State had disclaimed an interest in regulating the issue), or to a situation in which a tribe wanted the ability and right to determine who, as between a tribal member and non-tribal member, could work as a community nurse (and where the State disclaimed any interest in applying its anti-discrimination laws to that decision)?

Upon examination, the factual circumstances and relative tribal and state interests presented by Maine's establishment of WQS in tribal waters are clearly are more analogous and pertinent to those at issue in *Maine v. Johnson* than they are to those in *Akins* and *Fellencer*. Maine's WQS program falls within a broad area of environmental regulation; Maine has expressed a strong desire to exercise regulatory authority in this area; and there potentially would be non-trivial impacts on non-tribal members outside of tribal lands were EPA to find that MIA and MICSA preclude Maine from applying its WQS in waters in Indian land. Following the First Circuit's reasoning then, it would not even be appropriate for EPA to apply the balancing factors from *Akins* and *Fellencer* to determine whether Maine has jurisdiction to establish WQS for waters in Indian lands.

The Court found that the circumstances present in *Akins* and *Fellencer* were much closer legal questions as to whether the internal tribal matters provisions of MIA and MICSA applied, as compared to whether those provisions applied to the question whether Maine had authority to implement an NPDES program in Indian lands. Two critical factors that informed the Court's holding were the potential effects of a tribal NPDES program on non-members outside of Indian territories and the State's strongly expressed desire to implement such program itself throughout the State, including in waters within Indian lands. The Court's holding is consistent with the idea that the jurisdictional provisions of MICSA establish a presumption that Maine was provided with regulatory authority over a particular activity absent a finding that the internal tribal matter exception applied (and absent a showing that other explicitly reserved areas of tribal jurisdiction, clearly not relevant to the WQS context, applied).

Thus, the Penobscot Nation's use in its public comments of the *Akins* and *Fellencer* balancing factors as a basis of its jurisdictional analysis would be rejected by the First Circuit. Of central importance to the First Circuit's analysis of the internal tribal matters provision in MICSA is that its scope is *not* defined by the idea that the concept is intended to cover any and all matters that a sovereign government would typically have authority to regulate, but, rather, under MIA and MICSA the *character* of the activity at issue must be so internal to *tribal* government that it does not impact the State's authority in a way that affects non-tribal members or that is contrary to the State's interest in exercising its authority consistent with the atypical allocation of state jurisdiction under MIA and MICSA. At bottom, it is hard to discern how, given the potential effects of a tribal CWA WQS program on non-member upstream dischargers and on the application of State law, in an area of regulation where the State has expressed a strong desire that its standards apply throughout the State, that the First Circuit would decide that Maine did not have adequate jurisdiction to set WQS for waters in Indian lands. See EPA's Decision Support Document for additional discussion.

A direct comparison of the various factors, dynamics, and impacts described above in relation to a WQS program, with the factors considered by the First Circuit in its decision that Maine has jurisdiction under MIA and MICSA to issue NPDES permits to tribally-owned facilities located on tribal land and which discharge only to tribal waters, compels a legal conclusion that Maine has jurisdiction to establish WQS in waters within Indian lands. As discussed elsewhere in this document and in EPA's Decision Support Document, however, the State's authority and discretion to set such standards is not unbounded and must still comply with CWA requirements, including those that would protect the designated use of sustenance fishing in waters in Indian lands.

Nonetheless, EPA would like to respond fully and comprehensively to the Penobscot Nation's comments. Consequently, EPA provides below specific responses to the Penobscot Nation's internal tribal matters argument, even though the logic of the First Circuit's analysis in *Maine v. Johnson* suggests that these factors are not appropriately applied to the facts presented by Maine's WQS submission.

Before delving into the specifics of the Penobscot Nation's comments on this issue, we note that federal Indian common law plays a limited role in our interpretation of the internal tribal matters exception. The First Circuit has stated that:

> We stress that we do not read the reference by Congress to Santa Clara Pueblo in the legislative history of the Settlement Act as invoking all of prior Indian law . . . . But we also do not agree that reference to such law is never helpful in defining what is an internal tribal matter. Congress was explicitly aware of such law, and explicitly made existing general federal Indian law applicable to the Penobscot Nation in the Settlement Act. In other areas, courts have long presumed that Congress acts against the background of prior law.

Akins, at 489. Insofar as federal Indian common law provides insight into the sorts of activities that Congress and the courts considered to be matters of inherent tribal sovereignty, and thus what rights Congress may have reserved under the settlement acts, it is a useful aid for determining whether water quality regulation is an internal tribal matter. The First Circuit directs us to examine that common law. The court does say that federal Indian common law defines the scope of internal tribal matters. The internal tribal matter exception under MICSA is essentially a reservation of some elements of inherent tribal sovereignty. *Akins*, at 489. Therefore, in order to qualify as an internal tribal matter, an activity must, as a threshold matter, qualify as a matter of inherent tribal sovereignty. However, concluding that a matter would be treated as part of a tribe's inherent tribal sovereignty under federal Indian common law does not end the inquiry. The First Circuit then provides us a series of factors to determine whether the issue or activity is an internal tribal matter under MICSA.

EPA's responses to the Penobscot Nation's *Akins* and *Fellencer* factors analysis

Factors:

a. Does the activity regulate only tribal members?

Tribal comment: There would only be an indirect effect on non-tribal members. Non-tribal members are not being regulated directly.

EPA's response:

To the extent that the *Akins* and *Fellencer* balancing factors are analyzed, the degree to which an activity may affect non-tribal members has been a primary consideration for the First Circuit. A finding that Maine does not have authority to establish WQS for waters in Indian lands, and the corresponding finding that the Maine Indian Tribes do have that authority for those waters, could have a non-trivial effect on non-member facilities in Maine subject to effluent limitations in NPDES permits that must ensure compliance with WQS. *See*, e.g., *City of Albuquerque v. Browner*, 97 F. 3d 415 (10th Cir. 1996), *cert. denied*, 522 U.S. 965 (1997). In *City of Albuquerque v. Browner*, the City of Albuquerque challenged EPA's approval of the Isleta Pueblo's water quality standards on

a number of grounds, including that certain of the Tribe's standards were allegedly unattainable because they were too stringent, and would have an adverse effect on an upstream discharger located outside of Indian Country. The Tenth Circuit upheld the district court's opinion affirming EPA's approval of the Tribe's WQS. Under the First Circuit's analysis in *Akins* and *Fellencer*, the *potential* for impacts on non-members of a tribal CWA WQS program weighs heavily against finding that Maine does not have authority under MIA and MICSA to establish WQS in waters in Indian lands under the concept of internal tribal matters.

b. Does the activity relate to lands that define the Tribes' territories, particularly to the commercial use of tribal lands?

Tribal comment: The matter at hand concerns the harvesting or deriving of value from tribal resources.

The second factor in the *Akins* and *Fellencer* analysis concerns a tribe's ability to decide how to use its own resources to protect the interests of its members. The First Circuit found that the Tribe's decisions regarding commercial use of "the very land that defines the territory of the Nation" fell within the realm of internal tribal matters. Id. at 487, 488. This factor is not necessarily limited to commercial use of land, however. Rather, it has to do with resources within the tribe's territory that have a direct effect on tribal well-being. In *Fellencer*, the court analogized control of natural resources on tribal land to control of human resources on tribal land. *Fellencer*, 164 F.3d at 710. The particular "human resource" at issue was a community nurse who was not a tribal member, but who practiced on the Penobscot reservation serving tribal members, and whose practice had a direct effect on the health of tribal members. In this case, the court recognized that "Indian tribes may 'retain inherent power to exercise civil authority over the conduct of non-Indians on fee lands within its reservation when that conduct threatens or has some direct effect on the ... health or welfare of the tribe.' " Id., quoting *Montana v. United States*, 450 U.S. at 566.

Fellencer confirms that in order to protect tribal health and welfare, tribes may control activities of non-members *within* Indian territory. However, tribes do not generally have authority to control such activities outside of Indian territory. *Montana v. United States*, 450 U.S. at 565-66. Here, many of the waters in question, *e.g.*, the Penobscot River, and the fish in those waters, are resources used by Maine, its citizens, and the Maine Tribes. The First Circuit's holdings in *Akins* and *Fellencer* do not provide EPA with any grounds to deny the state jurisdiction over setting WQS in any waters within Indian lands, and even more certainly not for waters and resources that are used by tribal and non-tribal members. Again, however, it is important to note that notwithstanding Maine's jurisdictional authority, EPA has the authority under the CWA to protect the Maine Tribes' sustenance fishing practices provided for under the settlement acts by ensuring that WQS applicable to waters in Indian lands protect the quality of water necessary to support those sustenance fishing practices.

c. Does the activity affect the Tribes' ability to regulate their natural resources?

Tribal comment: The matter concerns the regulation or conservation of tribal resources.

EPA's response

The First Circuit has held that an activity predominantly affecting a tribe's ability to control the use of its own resources is likely to be an internal tribal matter. *Akins* in particular examined an example of natural resource regulation, stumpage permits, which it determined was an internal tribal matter. However, the *Akins* holding is a narrow one. Under *Akins*, the test is not whether the assertion of state law interferes with the tribe's regulation of its natural resources, but whether the assertion of *tribal authority* over such resources interferes with *state* regulation. The court emphasized that "[b]y its own terms, the Implementing Act, § 6204, makes State laws regulating land use or management, conservation and environmental protection applicable to tribal lands. The absence of an assertion that any such [State] laws are involved here is telling." *Akins*, 130 F.3d at 488. The deciding element in the court's analysis of this factor seems to be that the stumpage permit system, "involving tribal lands, appears to have no significant impact on Maine's environmental or other interests." Id.

Also important in the First Circuit's consideration was the geographic component of inherent tribal sovereignty. Id. at 489. The court determined that timber permitting qualified as an internal tribal matter in part because "the policy concerns the harvesting of a natural resource from [land that defines Indian territory]." Id. at 487. The timber subject to the disputed permitting system was located entirely on the Penobscot Nation's territory. Because the resource was confined to Indian territory, the associated permitting system did not impair the State's ability to regulate its own natural resources.

The issue we face today is vastly more complicated than in *Akins* because many of the rivers and streams that are tribal waters flow through and touch both tribal and non-tribal lands. In addition, the WQS regulations at issue involve potential impacts to discharging facilities that operate inside and outside Indian territories. Following the First Circuit's analysis of MICSA, EPA begins with the assumption that the State's laws are generally applicable in all waters. See 25 U.S.C. § 1725(b)(1). Certain activities may be excluded from state regulation as internal tribal matters, but the general presumption is that state laws apply to all water bodies in Maine.

Based on this factor, the State has clear jurisdiction to establish WQS that may have the potential to affect the effluent limitations contained in NPDES permits issued to facilities that are largely located and operate outside of tribal territories and, under the reasoning in

Maine v. Johnson, even to sources that are on tribal lands and owned by tribal members and which have no measurable impact on non-members.[7]

d. Does the activity implicate or impair an interest of the State of Maine?

Tribal comment: The State's only interest in establishing WQS is in subverting sustenance fishing.

EPA response

Another important factor in the First Circuit's prior consideration of internal tribal matters was whether the State had asserted any interest in regulating the matter at issue. The *Akins* court noted at the outset that "[t]his is not a dispute between Maine and the Nation over the attempted enforcement of Maine's laws" and that the tribe's regulation of its own timber resources was "not of central concern to ... Maine." *Akins*, at 487, 488. In *Fellencer*, the court clarified that a general state interest in regulating a matter such as employment discrimination was not sufficient to remove the matter from the scope of internal tribal matters. But because the State expressly disavowed an interest in regulating *tribal* governmental employment decisions, the court found that tribal regulation of its own employees did not impair any *state* interest. *Fellencer*, at 710-11.

In its WQS submission, Maine has vigorously asserted its interest in regulating water quality throughout the State, including within waters located in Indian lands. That is a very different dynamic between the State and the Indian Tribes than the one that existed in the *Fellencer* and *Akins* disputes. Id., *Akins*, 130 F.3d at 488 ("This is ... a question of allocation of jurisdiction among different fora and allocation of substantive law to a dispute between tribal members where neither the Congress nor the Maine Legislature has expressed a particular interest."). In *Maine v. Johnson*, 498 F.3d 37, 45, the First Circuit stated:

> In both those cases, unlike this case, Maine disclaimed any interest in regulation or superintendence. *Akins*, 130 F.3d at 488; *Fellencer*, 164 F.3d at 710-11. By contrast, in the present case, Maine affirmatively asserts authority as to both tribal and non-tribal land to regulate discharges into navigable waters. The Settlement Act provisions just quoted affirm that power. If the internal affairs exemption negated so specific a ground of state authority, it is hard to see what would be left of the compromise restoration of Maine's jurisdiction.

[7] As discussed below, EPA is requiring the State to consider impacts on tribal resources and amend its WQS accordingly. However, the State is not required to cede regulatory authority simply because its activities have an impact on tribal resources.

e. Is defining the activity as an "internal tribal matter" consistent with prior legal understandings?

Tribal comment: Under federal Indian common law principles, the matter at hand involves the inherent authority of an Indian tribe, which must be free from undermining by a state.

EPA's response:

As explained earlier, Maine's jurisdiction to establish WQS in Indian lands is consistent with the First Circuit's analysis of MIA and MICSA and its holdings in *Maine v. Johnson, Akins* and *Fellencer* and, to the extent applicable given MIA and MICSA's unique jurisdictional arrangement, other federal Indian common law.

In order to understand the internal tribal matters exception, we must recognize that MICSA, while legislated against the backdrop of federal Indian common law, altered the operation of that common law in Maine. Under federal Indian common law, Indian tribes may have a paramount interest in regulating their own water quality that supersedes that of the state in which the tribes' territory is located. However, as discussed earlier and below, federal Indian common law may aid us in interpreting MICSA but cannot change the statute's general provision for state jurisdiction over natural resources. We must look carefully at what Congress and the courts have said regarding the extent of the internal tribal matters exception to state jurisdiction.

Following the First Circuit's example, we look first to the legislative history of MICSA, and then to federal Indian common law for prior legal understandings of internal tribal matters. As mentioned earlier, we rely largely on the Senate Report, which the House Report "accepts as its own" in part. H.R. Rep. at 20; *Garcia v. United States*, 469 U.S. 70, 76 (1984) (committee reports are an authoritative source for determining legislative consent), cited by *Akins*, at 489. The few references that the Senate Report makes to natural resource regulation are telling. In its discussion of the application of state environmental law under section 1725(b)(1), the provision of MICSA ratifying the MIA and its jurisdictional provisions, the Senate Report states:

> State law, including but not limited to laws regulating land use or management, conservation and environmental protection, are fully applicable as provided in this Section and Section 6204 of the Maine Implementing Act. That the regulation of land or natural resources may diminish or restrict maximization of income or value is not considered a financial encumbrance and is not barred from application under this Act.

S. Rep. at 27.

In addition, when explaining the operation of the savings clauses discussed earlier, the Senate Report provides a specific example of a federal environmental law that would be

excluded from operating in Maine Indian Country to avoid interfering with state environmental law. Although the example in this passage focuses on the provision in the Clean Air Act that allows Indian tribes to redesignate their lands to a new air quality classification under the prevention of significant deterioration (PSD) air permitting program, the passage ends by emphasizing that this exclusion would also operate more generally as to "police power laws on such matters as . . . environmental regulation."

> It is also the intent of this subsection, however, to provide that federal laws according special status or rights to Indian [sic] or Indian Tribes would not apply within Maine if they conflict with the general civil, criminal, or regulatory laws or regulations of the State. Thus, for example, although the federal Clean Air Act, 42 U.S.C. § 7474, accords special rights to Indian Tribes and Indian lands, such rights will not apply in Maine because otherwise they would interfere with State air quality laws which will be applicable to the lands held by or for the benefit of the Maine Tribes. This would also be true of police power laws on such matters as safety, public health, environmental regulations or land use.

S. Rep. at 31; see also H.R. Rep. at 29. In addition, this passage makes clear that Congress was not limiting the application of federal Indian law in Maine solely to avoid any interference with state environmental regulation as it applies to lands outside Indian territories. The report specifically discusses Congress's intent to protect the application of state air quality laws which will be applicable to land held "for the benefit of the Maine Tribes." Again, this discussion would be pointless if Congress did not specifically intend to make state environmental regulation applicable in the Southern Tribes' territory.

This passage in MICSA's legislative history is telling in the context of analyzing the State's authority to set WQS under the CWA. The Clean Air Act provision cited by the Senate report refers to the authority tribes have outside Maine to redesignate the air quality classification for their territory so that PSD permits for upwind facilities must include emission limits that protect the air quality consistent with the tribe's chosen classification of its territory. This example is strikingly similar to the function of the WQS program in the context of the CWA. Both programs involve the authority of non-federal sovereigns to determine the level of environmental quality that must be maintained within their territories, and that determination has the effect of controlling the content of permits issued to facilities that might impact those territories. Indeed, the "Area Redesignation" provisions in section 164 of the Clean Air Act are about as direct a cognate to the WQS program in the CWA as one could find in federal environmental law. It is reasonable then, for EPA to conclude, that Congress intended its grant of jurisdiction to the State to include a program like the CWA WQS.

Our inquiry does not end here. *Akins* opens the possibility that even in the area of natural resource regulation, activities may fit within the internal tribal matters exception and be free of state regulation. Here we turn to the federal Indian common law to help us define the contours of inherent tribal sovereignty, which in turn form the basis for internal tribal matters. The analysis of federal Indian common law in *Akins* draws a clear distinction

between inherent tribal authority over the activities of members and non-members. Tribes generally have authority over their own members. In some circumstances, federal Indian common law has found that tribal authority extends to non-member conduct on tribal territory, but not to non-member conduct outside of tribal territory. See *Akins*, at 490. MICSA constricted the common law understanding of inherent tribal sovereignty by establishing the general presumption that state law applies even within tribal territories. 33 U.S.C. § 1725(b)(1). Therefore, the fact that an activity takes place on or off reservation no longer answers the question. Instead, the relative involvement of tribal members and non-members becomes decisive.

Of course, *Akins* and *Fellencer* themselves form part of our prior legal understanding of internal tribal matters. However, these cases provide little more than an analytical framework for considering the issue. Neither case offers a definitive interpretation of the scope of internal tribal matters. To the contrary, the First Circuit emphasized that "[w]e tread cautiously and write narrowly, for the problems and conflicting interests presented by this case will not be the same as the problems and interests presented in the next case." *Akins*, 130 F.3d at 487. *Akins*, while recognizing one example of natural resource regulation as an internal tribal matter, was narrowly drawn to address only stumpage permits where state legal requirements were not at issue. Overall, *Fellencer* went somewhat further in addressing impacts on non-members, holding that a tribe could regulate the activities of a non-member who was acting on tribal territory, serving tribal members, and whose activities had a direct impact on tribal health and welfare. It is tempting to read these cases together to say that natural resource management decisions having a direct impact on tribal health and welfare are an internal tribal matter. But these holdings, as discussed earlier, are not so broad. *Akins* emphasized that tribal authority extended to activities of tribal members, and in some case non-members, *within* tribal territory. *Akins*, 130 F.3d at 489. *Fellencer* relied heavily on its understanding of employment discrimination law as a major source of support for its decision that tribal employment decisions are internal tribal matters. The law surrounding the employment issue indicated quite clearly that tribal governmental employment decisions were retained as an element of inherent tribal sovereignty under MICSA.

Although the situation outside Maine may be quite different, under MICSA EPA has concluded that establishing WQS in Indian water in Indian lands in Maine is not an internal tribal matter. Tribal comments have suggested that under *Fellencer*, tribes may regulate non-member activities that have a direct effect on tribal health and welfare. This reading, however, stretches the First Circuit's decision far past its boundaries. In finding that the Tribe could exercise authority over a non-member to protect tribal health and welfare, the *Fellencer* court emphasized the minimal effects on non-members versus the significant effect on tribal members, as well as the clear statutory basis for the Tribe's control over its governmental employment decision. Here, tribal WQS under the CWA potentially could impact non-tribal members. EPA cannot extend the results of these cases to such vastly different circumstances, particularly when the reasoning of the cases counsels us to do the opposite.

Tribal government as an element of internal tribal matters, including establishing cancer risk levels and fish consumption rates as a matter of tribal policy judgments.

The Tribes argue that establishing cancer risk levels and fish consumption rates are matters of tribal government policy that are part of a distinctly governmental function, that of establishing WQS under the CWA. The Tribes assert that this should lead EPA to conclude that as a legal matter Maine does not have jurisdictional authority to set such standards.

EPA's response

EPA agrees that Maine's fishing designated uses and the Northern and Southern Tribes' trust land and reservation land sustenance fishing practices require adequate protection under the CWA. However, that fact, as important as it is to the Tribes' physical, spiritual and cultural existence, does not alter the jurisdictional framework embodied in the settlement acts. Those vital interests and cultural practices of the Tribes, as critical elements of their survival and well-being may still be protected to the extent authorized under the CWA, and EPA's disapproval of Maine's HHC as they would apply to waters within Indian lands demonstrates that very important point. As the First Circuit has stated, not every matter that might fall within the notion of a governmental function necessarily constitutes an internal tribal matter under MIA and MICSA. "That a tribe attempts to govern a matter does not render it an internal tribal matter." *Akins* at 486.

We agree with the comments from the Tribes' advocates that water quality regulation is of central importance to these Tribes and is a critical issue in maintaining their culture and way of life. We also understand the Tribes' desire to exercise as direct a control over that water quality as possible. Outside the context of the settlement acts, we agree with the Tribes that water quality management is a core governmental function, and therefore that it should generally be reserved to tribal governments. EPA cannot agree, however, that MIA's reference to "tribal government" as one of the examples of internal tribal matters sweeps into that concept all the attributes generally associated with Indian self-governance outside Maine.

C. Tribes commented that EPA will be unable to protect tribal resources if EPA determines Maine has authority to establish WQS in waters within Indian lands.

EPA's response

Certain comments from the Tribes generally raised concerns about the protection of tribal resources if EPA determines Maine has authority to establish WQS in waters within Indian lands. EPA recognizes that if Maine is the standard-setting authority, the State will have the first opportunity to make the judgment calls involved in implementing the WQS program. However, the State's WQS must still meet CWA requirements, which include establishing water quality criteria that assure uses are protected. As demonstrated

by EPA's decision to disapprove certain of Maine's WQS on the basis that they do not adequately protect tribal sustenance fishing practices, EPA's oversight of the State's program through authority established in the CWA plays an important role in protecting water quality in Indian lands notwithstanding the jurisdictional arrangement established by the settlement acts.

Notwithstanding the Tribes' concerns, the practical realities of how a state's WQS program operates do not suffice as a basis for ignoring the jurisdictional arrangement in the settlement acts. As discussed extensively above, Congress has revised that customary jurisdictional formula in Maine. So, pursuant to the settlement acts and the CWA, EPA must acknowledge that the State has the authority to establish WQS applicable to Indian lands, just as the First Circuit has already determined that Maine has the authority to issue federal NPDES permits in Indian lands.

EPA does not agree that finding Maine has authority to implement the WQS program in Indian lands constitutes some sort of delegation to the State of the trust responsibility. As already explained in this RTC document, EPA has discussed the proper interpretation of the trust responsibility to the Maine Tribes generally, and in this matter specifically. EPA has also explained its continuing role in CWA program oversight, in which the trust plays a role. The Agency's continuing role in program oversight does provide adequate tools under the CWA for protecting the Maine Tribes' interests. But before discussing those oversight mechanisms, it is important to understand the context within which EPA's oversight authority operates and how that relates to MICSA's provisions. There are various provisions in the CWA that assign EPA the task of reviewing a state's decisions in implementing the CWA. The Act expresses this authority in various ways, but essentially EPA is either charged with intervening or provided the opportunity to intervene when state decisions do not comply with the requirements of the CWA.[8]

Maine's comments suggest that MICSA's provisions, especially the savings clauses, prevent EPA from exercising its CWA oversight authorities on behalf of the Tribes consistent with the trust responsibility. In EPA's view, Maine inaccurately characterizes EPA's oversight in this matter as "apply[ing] heightened scrutiny to Maine's WQS before approving them as to Indian Territory." See page 10 of Maine's September 13, 2013 WQS comments. EPA is not applying heightened scrutiny to Maine's WQS, but rather is exercising its responsibility as required under the CWA, and consistent with the settlement acts, to protect the Maine Tribes' sustenance fishing practices. See EPA's Decision Support Document. In so doing, EPA is at the same time acting consistently with the trust responsibility to the Tribes. The implication embedded within Maine's comment is that such a decision by EPA would accord the Tribes a special status and that intervening in a state regulatory decision under the CWA would affect or preempt the

[8] See e.g., 33 U.S.C. § 1342(d)(2)(when objecting to a proposed State NPDES permit, EPA shall provide a State with "a statement of the reasons for such objection and the effluent limitations and conditions which such permit would include if it were issued by the Administrator") and 40 CFR 123.44(c), or 33 U.S.C. § 1313(c)(4)(B)(EPA shall promulgate a water quality standard "if a revised or new water quality standard submitted by such State . . . is determined by the Administrator not to be consistent with the applicable requirements of this chapter").

State's jurisdiction to make that decision, which would run afoul of MIA and MICSA. Ultimately, the CWA establishes EPA's relevant authority, which EPA is exercising consistent with the federal trust responsibility. 33 U.S.C. §1251 et. seq. As mentioned before, MIA, in 30 M.R.S.A. Section 6207(4), reserves for the Penobscot Nation and the Passamaquoddy Tribe a right to take fish for their individual sustenance within their reservations. MICSA, in 25 U.S.C. Section 1724(h), reserves for these Indians the right to manage their natural resources. The CWA specifically gives EPA the authority to administer the statute to protect surface waters. 33 U.S.C. § 1251 et. seq. More specifically, the CWA gives EPA certain authority to oversee state water quality standards to ensure that they adequately protect human health and the environment. 33 U.S.C. § 1313. And EPA is exercising that authority to protect the resource uses that are here of interest to the Tribes -- the sustenance fishing uses of those waters -- consistent with the trust relationship and the requirements of the CWA.

EPA does not agree with Maine's interpretation of the effect of MICSA's savings clauses on the trust, because the Agency's disapproval of Maine's HHC as they would apply to waters within Indian lands is grounded in the requirements of both the CWA and the settlement acts. No state in the nation has "jurisdiction" to establish WQS contrary to the requirements of the CWA, at least in the sense that states cannot do so without running the risk that EPA will disapprove them. Therefore, the savings clauses in MICSA do not shield Maine from EPA's oversight under the CWA when EPA bases its objections on CWA requirements, for such objections do not affect any authority or jurisdiction that Maine has.

D. EPA must protect a broad range of cultural, spiritual, and physical aspects of the Tribes' lifestyles and associated resources. Sustenance fishing touches on all of these aspects of the Tribes' existence and culture.

EPA's response

EPA fully recognizes, respects and appreciates the broad range of cultural, spiritual, and physical aspects of the Tribes' lifestyles and associated resources, and the ways in which a sustenance fishing lifestyle touches on all of these aspects of the Tribes' existence and culture. EPA's disapproval of Maine's HHC as they would apply to waters within Indian lands reflects the extent to which, under the CWA, EPA has the authority to ensure that Maine's WQS adequately protect the Tribes' sustenance fishing practices in relation to the Tribes' fish consumption and therefore their health. EPA notes, however, that notwithstanding EPA's recognition of and respect for the multi-faceted nature of the Tribes' sustenance fishing lifestyle and the various ways in which the Tribes' existence and culture depends on that practice, the focus of EPA's decision to disapprove certain of Maine's WQS in Indian lands necessarily is specific to the physical health-related fish consumption practices of the Tribes. That focus is necessary pursuant to the authority

provided by Congress to EPA under the CWA and the WQS program when human health criteria are established.[9]

However, EPA recognizes that in so protecting the Maine Tribes' sustenance fishing practices, through a focus on human health impacts, other cultural and spiritual aspects of grave importance to the Tribes may also be protected. This does not mean that EPA is overreaching or extending its authority under the CWA; it simply means that there are collateral benefits that arise due to the fact that protecting the Tribes' health through protection of their sustenance fishing practices has implications for other important aspects of their lifestyle and culture.

E. Tribal comment: Maine's regulatory actions and expressed legal positions demonstrate that the Maine Tribes' subsistence practices will not be protected by Maine.

EPA's response

As explained earlier in this RTC document, the accuracy or inaccuracy of factual statements such as this one is not a factor that can affect the jurisdictional arrangement established by the settlement acts. EPA's earlier explanation in this document about its ability and obligation to ensure that the Maine Tribes' sustenance fishing practices are protected under Maine's WQS program shows how the Tribes' concerns about Maine's future intentions are being addressed by EPA in accordance with CWA requirements. See EPA's Decision Support Document for a more detailed discussion.

II. Tribal comment: Even if EPA approves Maine's WQS to apply in waters in Indian Territory, EPA should ensure that the Tribes have a "decisive role in decision-making that affects its waters."

EPA's response

Prior to EPA's decision today to approve and to disapprove certain of Maine's WQS, EPA complied with its obligations to consult with the Maine Indian Tribes about Maine's WQS submissions. EPA carefully considered the Tribes' views, interests, and policy and legal arguments, along with all other pertinent information, including public comments and other sources of information in the administrative record, in reaching its decision to approve and to disapprove certain of Maine's WQS for waters in Indian lands. EPA will continue to act within the confines of the CWA consistent with the trust responsibility in reviewing any future new or revised WQS by Maine that would affect tribal waters and

[9] Tribes have argued that in addition to fishing for their individual consumption, the definition of sustenance traditionally incorporated other components, including but not limited to barter and exchange. Commission Saltwater Fisheries Report, at p. 22-33. EPA is not deciding in its approval and disapproval of certain of Maine's new and revised WQS whether any of these other components, beyond the Tribes' individual consumption of fish, are properly part of the definition of the term "sustenance" as those other components are not, in any event, relevant to development of human heath criteria under the CWA.

uses. EPA will ensure that the Maine Tribes remain involved in any such matters through the government-to-government consultation process EPA is committed to follow.

III. Tribal comment: Even if EPA approves Maine's WQS to apply in waters in Indian Territory EPA should put written procedures in place to moderate between the State and Tribes.

EPA's response

See response to comment immediately above. In addition, EPA agrees that such written procedures would be very helpful, and EPA is prepared to facilitate discussions among the Maine Tribes and Maine. However, EPA notes that there is no legal basis for EPA to *demand* that such written procedures exist as a precondition to the State exercising its jurisdiction to establish WQS in waters in Indian lands.

IV. Tribal comment: EPA must ensure that "designated uses" are protected.

EPA's response

EPA's disapproval of certain of Maine's WQS demonstrates that EPA is fulfilling its CWA obligation to ensure that designated uses under the CWA are protected by water quality criteria. See EPA's Decision Support Document for a detailed discussion and explanation.

V. Tribal comment: A fundamental Congressional purpose in creating the Southern Tribes' reservations was to protect the sustenance fishery.

EPA's response

EPA agrees that a fundamental purpose behind creation of the Southern Tribes' reservations was to protect the sustenance fishery. As discussed earlier in this document, and in greater detail in EPA's Decision Support Document, this Congressional purpose supports EPA's decision to insist on criteria that protect the sustenance fishing rights associated with waters in the Southern Tribes' reservations in Maine. At the same time, however, this Congressional purpose does not function to alter the jurisdictional arrangement among the State, the federal government, and the Maine Tribes, established by Congress in MICSA.

VI. Tribal comment: MICSA sets forth a sustenance fishing right reserved to Southern Tribes (not abrogated by any provisions of MICSA).

EPA's response

EPA agrees that MICSA sets forth a sustenance fishing right reserved to Southern Tribes that has not been abrogated by any provisions of MICSA or any other federal law. As discussed earlier in this document, and in greater detail in EPA's Decision Support Document, this fact supports EPA's decision to insist on criteria that protect the sustenance fishing use associated with the Southern Tribes' reservations. At the same time, however, the sustenance fishing right reserved to the Southern Tribes does not function to alter the jurisdictional arrangement among the State, federal government, and the Maine Tribes, established by Congress in MICSA.

VII. Tribal comment: Maine fails to recognize the Maine Tribes as separate sovereigns, for purposes of downstream water quality protection.

EPA's response

EPA has addressed earlier in this RTC document the question of the sovereign status of the Maine Tribes and the extent to which that factor does or does not play a part in EPA's analysis of whether Maine has jurisdiction to establish WQS in Indian lands and how EPA views the general trust responsibility to the Maine Tribes.

Further, as noted earlier in relation to a similar comment about Maine's interactions with the Maine Tribes, the accuracy of factual statements such as this one is not a factor that can affect the jurisdictional arrangement established by MIA and MICSA. EPA's earlier explanation in this document about its ability and obligation to protect the Maine Tribes' fishing practices under the CWA, as demonstrated by EPA's disapproval of Maine's HHC as they would apply to waters within Indian lands, shows how the Tribes' concerns about Maine's future intentions with regard to their sustenance fishing practices under the CWA are being addressed by EPA in compliance with CWA requirements.

Additionally, any NPDES permits issued by Maine must ensure adequate protection of WQS that may apply in tribal waters. Thus, if Maine or EPA were to promulgate more stringent WQS applicable to waters in Indian lands in Maine, in response to EPA's disapproval of Maine's HHC, any NPDES permits issued by Maine must ensure adequate protection of such WQS.

VIII. Maine's comments (not already responded to earlier in this RTC document).

1. **Maine's comment: Under the operative statutes Maine has authority and responsibility to establish WQS for all state waters, including waters near or within Indian territories.**

EPA's response

EPA's letter to Maine in response to its WQS submissions indicates that EPA agrees that Maine has adequate legal authority to establish WQS for all state waters, including waters in Indian lands. See EPA's Decision Support Document for a more detailed discussion.

2. **Maine's comment: The applicable statutes don't permit EPA or the Tribes to establish WQS in the State's stead.**

EPA's response

Today, EPA is affirming that Maine has the legal authority to set WQS for waters in Indian lands. Maine's assertion that the Tribes and EPA do not have the legal authority to establish such standards instead of Maine no longer is pertinent given EPA's determination that Maine has such authority. However, if Maine does not address in a timely manner under the CWA the WQS deficiencies EPA's decision letter has identified, the CWA *requires* EPA to promulgate such standards in the State's stead. Furthermore, as noted earlier in this RTC document in relation to Maine's assertion that the Maine Indian Tribes are not eligible for TAS status under CWA section 518, EPA's decision is not addressing whether the Tribes separately have such authority.

3. **Maine's comment: EPA must make a formal finding that the State lacks jurisdiction before it can assert federal jurisdiction, which EPA cannot do under MIA and MICSA and *Maine v. Johnson*.**

EPA's response

Today, EPA is affirming that Maine has such legal authority but has found that certain of Maine's WQS are not approvable under the CWA. In addition, Maine's assertion that EPA does not have the legal authority at this time to establish such standards is no longer pertinent given EPA's determination that Maine has such authority. However, if Maine does not address in a timely manner under the CWA the WQS deficiencies EPA's decision letter has identified, the CWA *requires* EPA to promulgate such standards in the State's stead.

4. **Maine's comment: EPA approved many WQS submissions, some including in the Penobscot River, without mentioning jurisdictional issues, and also approved designated uses that do not mention anything about tribal interests or sustenance fishing. EPA's NPDES record belies EPA's own legal position.**

EPA's response

See EPA's Decision Support Document for a partial response to and discussion of the issues raised by this comment.

In addition, as of 2004, EPA's letters to Maine responding to the State's proposed new and revised water quality standards expressly stated that EPA's decision to approve or disapprove did not apply to waters within Indian Country. Consequently, there would not have been a reason for EPA to address in those letters tribal interests in waters in Indian lands, including sustenance fishing. Moreover, the fact that ME DEP may have issued NPDES permits to facilities that discharged directly or indirectly into the Penobscot River, and that EPA may not have offered any comments about those permits, does not constitute an acknowledgment by EPA that Maine's WQS had been approved by EPA to apply in waters in Indian lands.

As to NPDES permits that EPA issued to the Penobscot Nation's POTW, EPA included language that indicated, not that Maine's WQS directly applied to such discharges as a legal matter, but that as a practical matter Maine's WQS provided some guidance as to how the NPDES permit's effluent limits for pollutants should be written or determined. When EPA recited that those permits met Maine WQS that applied "in the proximity" of the discharge, the Agency very consciously used a formulation that did not recite that Maine's WQS applied at the point of discharge. Basically, EPA looked to the nearest approved WQS as guidance for the discharge limits in those permits. The State's WQS approved outside Indian lands provided that guidance. In the absence of federal, state or Indian WQS applicable under the CWA at the point of discharge, this course of action makes abundant practical sense.

5. **Maine's comment: The State has asked EPA to explain its legal basis for not applying State WQS in Indian Territory and EPA has never responded.**

EPA's response

Whether or not the State's comment is accurate is no longer a relevant point because EPA's decision today has answered that question. In addition, EPA notes that a lack of a response before its decision today would, in any event, not be able to affect the outcome of a legal analysis dictated by the settlement acts and the CWA.

6. **Maine's comment: The "trust responsibility" only applies to trust lands, not reservation lands in Maine (which are not held in trust).**

EPA's response

See discussion above beginning at page 11.

7. **Maine's comment: MICSA's savings clauses render the "the trust obligation" inapplicable in Maine.**

EPA's response

See discussion above beginning at page 38.

8. **Maine's comment: Indian Tribes in Maine are not eligible for TAS status under CWA Section 518.**

EPA's response

See discussion above beginning at page 15.

9. **Maine's comment: Maine asserts that there is no basis for EPA to treat waters within Indian territories any differently than the waters in Maine outside of Indian territories.**

EPA's response

EPA's Decision Support Document demonstrates the inaccuracy of Maine's comment and discusses in detail the reasons why EPA has determined that there is a significant difference between such waters and their uses for purposes of the CWA.

10. **Maine's comment: EPA's current review is unlawful and unnecessary.**

    a. **Statute gives EPA 90 days to act and require changes to submitted WQS. EPA did not require changes within 90 days, so EPA cannot require changes now.**

EPA's response

EPA disagrees with Maine's reading of the CWA provisions at issue. As described by the United States Department of Justice in legal pleadings filed in Maine's case filed against EPA, State of Maine, et. al. v. McCarthy et. al., Civil Action No. 1:14cv264, (United States District Court for the District of Maine 2014), no provision of the CWA or its implementing regulations preclude EPA from disapproving a state's WQS on the basis that EPA did not inform such state within 90 days of its WQS submission to EPA that

changes to the state's proposed WQS are necessary. The following description of the relevant CWA authorities sets forth the correct sequence of events in relation to a state's WQS submission and EPA's review.

States must hold public hearings for the purpose of reviewing their WQS, and, as appropriate, modifying and adopting standards, at least once every three years beginning with October 18, 1972. 33 U.S.C. § 1313(c)(1). This review and revision process is commonly referred to as the triennial review process. Any new or revised WQS adopted by a state must be submitted to EPA for a determination of whether it meets the CWA's requirements. 33 U.S.C. § 1313(c)(1) and (3); 40 C.F.R. §§ 131.5, 131.6 and 131.20. EPA's review of such WQS involves the application of EPA's legal, scientific and policy expertise. *See* 40 C.F.R. § 131.5. If EPA determines that the new or revised WQS is consistent with the CWA, then EPA shall so notify the relevant state within 60 days from the date of submission. 33 U.S.C. § 1313(c)(3); 40 C.F.R. § 131.21(a)(1).

If EPA determines that the new or revised WQS is not consistent with the CWA, EPA shall notify the state within 90 days from the date the WQS is submitted that it is disapproved, and must specify necessary changes. 33 U.S.C. § 1313(c)(3); 40 C.F.R. § 131.21(a)(2). If the state then fails to adopt the specified changes within 90 days of EPA's notice, EPA must "promptly" propose a federal WQS for the waters involved. 33 U.S.C. § 1313(c)(4)(A); 40 C.F.R. § 131.22(a). Then, unless the state revises its WQS and EPA approves that revision, EPA must proceed to promulgate the WQS itself. 33 U.S.C. § 1313(c)(4)(A).

In the context of its CWA citizen suit claim, Maine asserted that EPA has waived its authority to disapprove Maine's outstanding WQS, that EPA is barred from disapproving such WQS, and that EPA is required to approve such WQS, apparently on the theory that EPA loses its authority to disapprove WQS when it misses the statutory deadline to do so. Congress provided EPA with authority to approve or disapprove new or revised WQS regardless of whether EPA has met the statutory deadline for doing so under CWA section 303(c)(3).
As discussed above, new and revised WQS must be submitted to EPA for review. 33 U.S.C. § 1313(c)(2)(A). *If* EPA determines that the new or revised WQS meets the requirements of the CWA, EPA shall approve the WQS within 60 days. *Id.* at § 1313(c)(3). *If* EPA determines that the new or revised WQS is not consistent with the requirements of the CWA, EPA shall within 90 days of submission disapprove the WQS and specify necessary changes. *Id.* "On its face, this language plainly supports . . . that Congress did not intend new or revised state standards to be effective until after EPA had reviewed and approved them." *Alaska Clean Water Alliance v. Clarke*, 1997 WL 446499 * 3 (W.D. Wash. July 8, 1997). Indeed, the CWA does not even remotely suggest that Congress intended for EPA to lose its authority to approve or disapprove a WQS, or that the WQS must automatically be deemed approved, if EPA fails to act by the 60 or 90-day statutory deadlines. *See* 33 U.S.C. § 1313(c)(2)(A); *United States v. James Daniel Good Real Property*, 510 U.S. 43, 63 (1993) ("[I]f a statute does not specify a consequence for noncompliance with statutory timing provisions, the federal courts will not in the ordinary course impose their own coercive sanction.").

Moreover, to the extent the CWA is ambiguous on this point, EPA has explained in the context of a CWA rulemaking that "the concept of a default approval of state and tribal WQS submissions is not consistent with section 303 of the CWA [because] [s]ection 303(c)(3) requires EPA to make an affirmative finding that the standards revisions submitted to EPA are consistent with the CWA." 65 Fed. Reg. 24,641, 24,646 (Apr. 27, 2000). EPA's interpretation of CWA section 303(c) as not providing for automatic approvals or disapprovals of WQS if EPA does not act within the 60 or 90 day windows of that section is entitled to deference. *See Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984). In addition, Congress has expressly provided a remedy when EPA fails to timely respond to a WQS submission. The CWA citizen suit provision provides the district courts with jurisdiction to order EPA to perform its mandatory duty to approve or disapprove a new or revised WQS when EPA has failed to timely respond. 33 U.S.C. § 1365(a). As the Supreme Court has explained, "[w]hen, as here, there are less drastic remedies available for failure to meet a statutory deadline, courts should not assume that Congress intended the agency to lose its power to act." *Brock v. Pierce County*, 476 U.S. 253, 260 (1986).

b. Maine's comment: There is no basis for separate federal notice and comment.

EPA's response

See EPA's introduction to this RTC document for a response to this comment.

c. Maine's comment: The Maine Tribes were well aware and participated in the State's action.

EPA's response

EPA reviewed Maine's notice to the public and the public's comments on Maine's proposed WQS revisions. In the first instance, while the Tribes in Maine participated in the State's public process, their comments focused entirely on the adequacy of the state standards and whether they would protect sustenance fishing. The Tribes' comments did not focus on the State's authority to set standards for waters in the Tribes' lands. It is reasonable to assume that the Tribes were concerned about how Maine's WQS might impact sustenance fishing opportunities in waters outside Indian lands. It was not clear that Maine's notice alerted the public and the Tribes to the State's assertion of jurisdiction to set WQS for waters in the Tribes' lands.

Ultimately, EPA determined that, in light of the great deal of interest in the jurisdictional and technical issues involved in Maine's proposal, it would be prudent to err on the side of caution by taking additional steps to ensure that the Maine Tribes and other members of the public had clear notice of the implications of Maine's proposed WQS revisions.

EPA had never before approved or disapproved in Maine WQS revisions to be applied to waters within Indian lands. Moreover, EPA received additional comments from the Maine Tribes and from the ME DEP and the Maine Office of the Attorney General that were not part of Maine's administrative record for its WQS revisions at the state level; and to that extent the record before EPA is now more complete.

d. Maine's comment: Maine accuses EPA of bad faith, "creating" jurisdictional controversy where there is none.

EPA's response

As set forth in great detail in EPA's Decision Support Document, EPA's decision has two essential components, a legal jurisdictional component and a scientific/technical component. The latter required a complex assessment by EPA of the adequacy of Maine's criteria in relation to the designated uses of the waters in Indian lands, once EPA determined that Maine had jurisdiction. The complexity of the issues with which EPA was confronted, demonstrated by the content of its decision documents both as to the jurisdictional analysis and technical determinations, shows that EPA was not creating a jurisdictional controversy where there was none. In fact, it is a significant mischaracterization of the issues confronting EPA, and of EPA's deliberative process, to portray EPA's activities and process as nothing more than "creating" a jurisdictional controversy.

In the end, EPA concluded that there is no valid legal basis to distinguish or depart from the First Circuit's reasoning and decision in *Maine v. Johnson* that Maine has jurisdiction to implement the CWA NPDES program in Indian lands. A careful analysis was warranted, however, due to the arguable differences between the NPDES and WQS programs, and due to the copious substantive comments EPA received from the State and Maine Tribes on the jurisdictional question. For EPA not to have ensured that its decision had the benefit of the full explanation of the State's and the Tribes' views on this question could have led to a decision for which there was an incomplete and possibly flawed administrative record.

11. Maine's comment: Maine's submitted WQS are approvable and there is no basis upon which EPA may disapprove them.

EPA's response

EPA's Decision Support Document explains in detail the bases upon which EPA has decided to disapprove Maine's HHC for waters in Indian lands. EPA disagrees with Maine's assertion that "there is no basis upon which EPA may disapprove" any of Maine's WQS. In summary, EPA's disapproval of Maine's HHC for waters in Indian lands is based on the fact that Maine did not use a fish consumption rate that results in criteria that are sufficient to protect the designated use of sustenance fishing in those waters. EPA's Decision Support Document also contains an explanation of EPA's

identification of the sustenance fishing designated uses for waters in Indian lands that derives from Congress's purpose in confirming and establishing, through the settlement acts, sustenance fishing in the Southern Tribes' reservations and in the trust land waters of the Southern and Northern Tribes. We refer the reader to EPA's Decision Support Document for more detailed information relevant to Maine's comment.

12. Maine's comment: Maine's WQS protect sensitive subpopulations that engage in sustenance fishing.

EPA's response

EPA's Decision Support Document discusses EPA's determination, consistent with the requirements of the CWA, that Maine's HHC do not adequately protect the Maine Tribes' health given the Tribes' sustenance fishing practices and the designated use of sustenance fishing in waters in Indian lands. EPA also disagrees with Maine's characterization of the Maine Tribes as "sensitive subpopulations" of the State's general population. EPA's Decision Support Document explains that the Maine Tribes constitute their own *general* population in the geographic areas defined by their reservations and trust lands and that it would therefore be inappropriate to treat the Tribes merely as a "sensitive subpopulation" of Maine's general population in waters located within Indian lands. We refer the reader to EPA's Decision Support Document for more detailed information relevant to Maine's comment.

13. Maine's comment: Maine's WQS are based on technically sound and objective data and analysis regarding cancer risk, fish consumption rates and bioconcentration.

EPA's response

EPA has approved many of Maine's WQS as being technically sound regarding cancer risk, fish consumption rates and bioconcentration. However, for the reasons set forth in EPA's Decision Support Document, EPA does not agree that Maine's HHC meet CWA requirements as applied in waters within Indian lands in Maine, because the fish consumption rate on which they are based is not representative of the Tribes' sustenance fishing. See also EPA's responses to comments VIII. 10 and 11 above, regarding fish consumption rates used by Maine and the fact that it would not be consistent with the requirements of the CWA, as informed by the settlement acts, to treat the Maine Indian Tribes as a "sensitive subpopulation" of Maine's general population.

14. Maine's comment: EPA has used in the past some of this data (meaning the data used in establishing the WQS submitted to EPA in January 2013).

EPA's response

EPA has never "used" the data Maine refers to in its comment for purposes of determining whether Maine's WQS meet CWA requirements in waters within Indian lands in Maine. The fact that EPA may have considered this data in the past to approve Maine's HHC in waters outside Indian lands, including whether such criteria are protective of highly exposed subpopulations fishing in waters outside of Indian lands, is not relevant to the question whether Maine's WQS meet CWA requirements for the target population of tribal members engaged in sustenance fishing in waters located in Indian lands.

15. Maine's comment: Maine's human health criteria are grounded in the empirical, local population-specific data that EPA prefers.

EPA's response

EPA acknowledges that Maine's HHC are based in part on local, population-specific fish consumption data, and EPA has approved those criteria for waters outside of Indian lands. However, as discussed in EPA's Decision Support Document and summarized briefly in earlier responses above to some of Maine's other comments, EPA has determined that the localized data are not representative of unsuppressed tribal sustenance fish consumption in waters in Indian lands, and therefore the HHC that are based on the localized data are not adequate to protect the sustenance fishing use in those waters. Maine must use fish consumption data that are representative of unsuppressed tribal sustenance fish consumption in waters in Indian lands, such as the data from the Wabanaki Cultural Lifeways Exposure Scenario ("Wabanaki Study"), which was completed in 2009, rather than the 1990 study conducted by McLaren/Hart – ChemRisk, of Portland, Maine (the "ChemRisk Study"[10]) that was actually used by Maine. See also EPA's responses above relating to Maine's calculation of a fish consumption rate and the fact that the Maine Tribes are the general population to which HHC should be targeted for waters in Indian lands.

[10] ChemRisk, A Division of McLaren Hart, and HBRS, Inc., *Consumption of Freshwater Fish by Maine Anglers,* as revised, July 24, 1992. See also Ebert, E.S., N.W. Harrington, K.J. Boyle, J.W. Knight, R.E. Keenan, *Estimating Consumption of Freshwater Fish among Maine Anglers,* North American Journal of Fisheries Management, 13:4, 737-745 (1993); http://dx.doi.org/10.1577/1548-8675(1993)013<0737:ECOFFA>2.3.CO;2

IX. Maine Tribes' comments regarding the adequacy of Maine's WQS

1. **Tribal comment: Apart from the jurisdictional question, Maine's WQS for arsenic, phenol and acrolein are scientifically and legally flawed, and are arbitrary and capricious.**

EPA's response

EPA's Decision Support Document explains in detail the bases of EPA's decision to disapprove the three HHC identified in the comment, along with the rest of Maine's HHC, as applied to waters within Indian lands. We therefore refer the reader to that document. See also EPA's responses to comments VIII. 10, 11 and 12 above, regarding fish consumption rates used by Maine and the fact that it is not consistent with the requirements of the CWA to treat the Maine Indian Tribes as a "sensitive subpopulation" of the general population in Maine.

2. **Tribal comment: As to arsenic, EPA received comments from the Maine Tribes that Maine's arsenic standard failed to consider other exposure routes and synergistic effects; that the ChemRisk Study used by Maine to establish a fish consumption rate is flawed for a number of reasons; that unscientific manipulation of variables used by Maine to calculate in-stream criteria shouldn't be accepted by EPA; and that the fish consumption rate and cancer risk level used for arsenic by Maine are unacceptable.**

EPA's response

EPA's Decision Support Document sets forth in detail the bases for EPA's disapproval of Maine's arsenic standard as it would apply to waters within Indian lands in Maine. While EPA's decision was not based on all of the objections raised by the Maine Tribes' comments, EPA agrees that Maine's arsenic criteria are not approvable under the CWA for waters in Indian lands. See also EPA's responses to comments VIII. 10, 11 and 12 above, regarding fish consumption rates used by Maine and the fact that it is not consistent with the requirements of the CWA to treat the Maine Indian Tribes as a "sensitive subpopulation" of the general population in Maine.

3. **Tribal comment: Using inconsistent fish consumption rates and cancer risk levels for different WQS is arbitrary and capricious.**

EPA's response

EPA's Decision Support Document sets forth in detail the bases for EPA's disapproval of Maine's HHC as they would apply to waters within Indian lands in Maine. Because EPA is disapproving all of the HHC for waters in Indian lands due to an inadequate fish

consumption rate, it is not necessary at this time to consider the extent to which differing fish consumption rates or cancer risk levels for different criteria might be approvable for those waters.

4. **Tribal comment: The arsenic in-stream concentration is increasing as compared to Maine's prior in-stream concentration for arsenic, which imposes increased risks to tribal members.**

EPA's response

EPA's Decision Support Document sets forth in detail the bases for EPA's disapproval of Maine's HHC, including arsenic, as they would apply to waters within Indian lands in Maine. Because EPA is disapproving Maine's arsenic criteria as it would apply to waters in Indian lands, it is premature to address how Maine's arsenic HHC for waters in Indian lands will compare with the prior criterion.

5. **Tribal comment: The Penobscot Nation comments that the Wabanaki study contains "site specific" data, and that the CWA does not preclude the use of site-specific data from any particular time period in establishing WQS.**

EPA's response

EPA's Decision Support Document sets forth in detail the bases for EPA's disapproval of Maine's HHC as they would apply to waters within Indian lands in Maine. EPA agrees with the Penobscot Nation that, based on the data and information available at this time, fish consumption data from the Wabanaki Study is the best available representative data and thus, barring any better data being collected, must be used in establishing HHC for waters in Indian lands in Maine. See also EPA's responses to comments VIII. 10, 11 and 12 above, regarding fish consumption rates used by Maine and the fact that it is not consistent with the requirements of the CWA to treat the Maine Indian Tribes as a "sensitive subpopulation" of the general population in Maine.

6. **Tribal comment: The Penobscot Nation comments that its sustenance fishing right is an "existing use" and a "designated use" as those terms are used in the CWA. The Tribe further comments that Maine's human health WQS submission shows that these uses will not be protected in waters within Indian lands.**

EPA's response

EPA's Decision Support Document sets forth in detail the bases for EPA's disapproval of Maine's HHC as they would apply to waters within Indian lands in Maine. Included in the Decision Support Document is EPA's explanation of its identification of the designated use of sustenance fishing for waters within Indian lands and its relationship

both to CWA requirements and to Congress's purpose in establishing the Maine Tribes' reservations and trust lands under the settlement acts. EPA agrees that Maine's current HHC are not adequate to protect the designated use of sustenance fishing that applies to waters in Indian lands and therefore has disapproved those criteria. See also EPA's responses to comments VIII. 10, 11 and 12 above, regarding fish consumption rates used by Maine and the fact that it is not consistent with the requirements of the CWA to treat the Maine Indian Tribes as a "sensitive subpopulation" of the general population in Maine.

7. **Tribal comment: EPA has a duty to collect more accurate fish consumption rate data, and such data must account for suppression of fish consumption. Maine's WQS fail to consider and account for suppressed fish consumption.**

EPA's response

EPA does not agree that the CWA imposes a duty to collect more accurate fish consumption rate data. But states (or EPA, if EPA is developing the HHC) must use the best available fish consumption data or information to derive HHC that represent an unsuppressed fish consumption rate. EPA agrees that the fish consumption data used by Maine to establish its HHC is not representative of unsuppressed fish consumption associated with tribal sustenance fishing in waters in Indian lands. EPA's Decision Support Document explains the bases of the data derived from the Wabanaki Study and the ChemRisk Study Maine actually used. The Decision Support Document also explains EPA's basis for concluding that the Wabanaki Study provides the best available existing fish consumption data and information for deriving HHC based on an unsuppressed sustenance fish consumption rate for waters in Indian lands in Maine.

8. **Tribal comment: The situation at the Penobscot Nation is not dissimilar to that at other tribes, traditionally dependent upon a subsistence fishery. As EPA concluded in studying fish consumption rates at such tribes in the Northwest, there is "a simple relationship between tribal fish-consuming populations in the Pacific Northwest; people eat what's available to them, what's culturally preferred and at high consumption rates." EPA, TECHNICAL SUPPORT DOCUMENT FOR ACTION ON THE STATE OF OREGON'S NEW AND REVISED HUMAN HEALTH WATER QUALITY CRITERIA FOR TOXICS AND REVISIONS TO NARRATIVE TOXICS PROVISIONS SUBMITTED ON JULY 8, 2004 (June 1, 2010) at 47.**

EPA's response

See EPA's response to comment IX. 7., immediately above.

ATTACHMENT A

Analysis Supporting EPA's February 2, 2015 Decision to Approve, Disapprove, and Make No Decision on, Various Maine Water Quality Standards, Including Those Applied to Waters of Indian Lands in Maine

EXECUTIVE SUMMARY

Maine's Department of Environmental Protection (DEP) submitted numerous new or revised water quality standards (WQS) to EPA for review and approval under the Clean Water Act (CWA) between 2003 and 2014. In its decisions from 2004-2013 following review of such WQS, EPA limited its approvals of the new or revised WQS to state waters outside of Indian territories and lands in Maine ("Indian lands"), and explicitly refrained from taking any action on the WQS for waters in Indian lands. In its decision today, EPA is responding to the outstanding new and revised WQS from 2003-2014 as they relate to waters in Indian lands, and, in the case of some of the WQS, also as they relate to state waters outside of Indian lands.

As summarized below and explained in more detail in the body of this decision support document, Maine has the authority to establish WQS for waters in Indian lands, subject to EPA's authority under the CWA to review and approve or disapprove such standards. After evaluating the various new and revised WQS contained in DEP's submissions from 2003-2014, EPA is today approving all of the aquatic life criteria for toxic pollutants for waters in Indian lands except for ammonia, and all but one of the new aquatic life criteria submitted in 2013 for all waters, including in Indian lands.[1] EPA is also approving a number of other WQS provisions for waters in Indian lands, as well as Maine's classifications and designated uses for those waters. EPA is disapproving Maine's human health criteria as they apply to waters in Indian lands. Finally, EPA has identified a number of provisions on which it is taking no action because they are not WQS and therefore are not subject to EPA review.

The bases for two aspects of EPA's decision today are summarized below because of their complexity -- EPA's conclusion that Maine has the authority to establish WQS in waters in Indian lands, and EPA's conclusion that Maine's human health criteria do not protect the designated uses and therefore must be disapproved.

[1] EPA is taking no action on the ammonia criteria and certain provisions related to bacteria and pesticides, based on our understanding from discussions with DEP staff that DEP will be revising these criteria and provisions in light of recent EPA criteria recommendations and to ensure the protection of designated uses, nor is EPA taking action on the reclassification of a non-tribal water (Long Creek), pending further discussion with DEP. See section 4.8 below. EPA is also taking no action on one of the new phenol criteria for all waters pending DEP's correction of a mathematical error, which DEP has agreed to correct. See section 4.3 below. Finally, EPA is taking no action on the cancer risk level for arsenic in light of EPA's disapproval of the arsenic criteria for waters in Indian lands. See section 4.2.4 below.

The Issue: The State of Maine submitted numerous new and revised water quality standards (WQS) for EPA to approve under the Clean Water Act in the territories and lands of the federally recognized Indian Tribes in Maine – the Penobscot Nation, Passamaquoddy Tribes, Houlton Band of Maliseet Indians, and Aroostook Band of Micmacs. Under well-established principles of federal Indian law, states generally do not have authority to regulate the environment in Indian country. Maine asserts that in the Maine Indian Claims Settlement Act (MICSA) Congress granted the State jurisdiction to regulate the environment in the Tribes' lands, including the authority to set WQS. The Tribes contest that assertion, noting especially that state WQS have the potential to determine how much fish they may safely eat in waters where the Tribes fish for their sustenance. The Tribes assert the State has not adequately accounted for their sustenance fishing practices in setting the WQS submitted to EPA.

Jurisdiction to set WQS: EPA analyzed the jurisdictional provisions of MICSA extensively, including a careful review of comments from the Tribes and Maine on the jurisdictional provisions of the statute. EPA concludes that under the unique jurisdictional formula Congress established in Maine, the State has jurisdiction to set WQS in the waters on the Tribes' lands. See *Maine v. Johnson*, 498 F.3d 37 (1st Cir. 2007). But the Agency also finds that this authority is not unconstrained. EPA is required under the Clean Water Act to review state WQS, and will approve them when they comply with the Act. In these circumstances, where Maine is authorized to set WQS in tribal waters, EPA is informed by the operation of the Indian settlement acts in Maine and will require that WQS in tribal waters protect the Tribes' sustenance fishing use of those waters.

Sustenance Fishing Use in Tribal Waters: The first step in establishing and reviewing WQS is to determine the uses of the waters. In tribal waters, EPA must harmonize the CWA requirement that WQS must protect uses with the fundamental purpose for which land was set aside for the Tribes under the Indian settlement acts in Maine. Those settlement acts, which include MICSA and other state and federal statutes that resolved Indian land claims in the State, provide for land to be set aside as a permanent land base for the Indian Tribes in Maine. One clear purpose of that set aside is to provide a land base on which these Tribes could continue their unique cultures. A critical element of tribal cultural survival is the ability to exercise sustenance living practices, including sustenance fishing. There are multiple provisions in the Indian settlement acts that specifically codify the Tribes' sustenance practices. Maine general law regulating fish take accommodates sustenance fishing, and in several regards also specifically codifies the Tribes' ability to sustenance fish. The legislative record supporting the Indian settlement acts in Maine makes it clear that the statutes intend to create a land base on which the Tribes in Maine may fish for their sustenance. Therefore, EPA interprets the State's "fishing" designated use, as applied in tribal waters, to mean "sustenance" fishing; and EPA is approving a specific sustenance fishing right reserved in one of the settlement acts as a designated use for certain tribal reservation waters.

Protecting the Sustenance Fishing Use: To adequately protect that sustenance fishing use, the State must revisit two aspects of its analysis supporting the human health criteria that determine how clean the waters must be to allow the Tribes to safely consume fish for their sustenance. First, the analysis must treat the tribal population exercising the sustenance fishing use as the target general population, not as a high-consuming subpopulation of the State. EPA guidance

calls for WQS that provide a high level of protection for the general population, while recognizing that small subpopulations may face greater levels of risk. However, the Tribes are not a subpopulation using the waters on their own lands; they are the population for which that land base was established and set aside. Second, the data used to determine the fish consumption rate for tribal sustenance consumers must reasonably represent tribal consumers taking fish from tribal waters and fishing practices unsuppressed by concerns about the safety of the fish available to them to consume. The data on which the State relied to develop fish consumption rates for these WQS did not include information about the sustenance practices of tribal members fishing in their own waters, nor did they represent consumption levels that were unsuppressed by concerns about pollution. EPA concludes that the best available data that represent the unsuppressed sustenance fishing practices of tribal members fishing in tribal waters are contained in the Wabanaki Lifeways study, which looked at the historic sustenance practices of the Tribes in Maine.

EPA has received a written legal opinion dated January 30, 2015 from the Solicitor of the Department of the Interior (DOI) addressing several of the issues involved in EPA's decision. EPA sought DOI's advice because the Department is the federal government's expert agency on matters of Indian law and is charged with administering the settlement acts in Maine. *Passamaquoddy Tribe v. State of Maine*, 75 F.3d 784, 794 (1st Cir. 1996) (DOI is the department that administers MICSA). DOI has provided EPA important insight into how the Indian settlement acts in Maine address the Tribes' right to fish and the critical relationship between those rights and water quality. In making our decision on Maine's WQS, EPA has carefully considered and relied upon the DOI Solicitor's analysis, which is reflected in DOI's written opinion and is included in the administrative record for this decision.

The Remedy: EPA is disapproving Maine's human health criteria because they are not protective of human health for the target population. They are based on a fish consumption rate of 32.4 grams per day, with the exception of arsenic which is based on 138 grams per day. However, the Wabanaki study indicates that consumption values between 286 and 514 grams per day represent the sustenance fishing use in tribal waters. EPA is approving Maine's regulation requiring that human health criteria, except for arsenic, be based on a cancer risk level of no more than one in a million (10^{-6}) as applied to the Tribe's waters, because that is a reasonable level of risk for a general target population. EPA is approving nearly all the State's aquatic life criteria, because they are consistent with the Clean Water Act and unlike the human health criteria, they do not implicate the safety of fish for human consumption. The Clean Water Act gives the State 90 days to address the bases for EPA's disapproval of the human health criteria, after which time, if the State does not do so, EPA will propose and promulgate appropriate human health criteria for waters in Indian lands in Maine.

why?

1 Background

1.1 Overview

On January 14, 2013, the Maine Department of Environmental Protection (DEP) submitted a request to EPA to approve five new or revised water quality criteria (WQC) and specifically asked EPA to approve them in all waters located in the State of Maine, including waters in the territories and lands of the federally recognized Indian Tribes in Maine.

EPA's review of the State's submission determined that when the State provided public notice on its proposed WQS revisions, it was not clear on the record that the State had solicited comment on the question of the State's authority to set WQS in waters in the Tribes' territories and lands (as explained further below, hereinafter EPA will use the term Indian or tribal "lands" to refer to the entire tribal land base in Maine). Although EPA does not customarily provide public notice for state WQS submissions, the Agency exercised its discretion in the unique circumstances of this submittal to invite public comment on the issue of applying state WQS in waters in Indian lands in Maine. EPA identified two general areas for comment. First, has the State demonstrated adequate authority to set WQS in waters in Indian lands? Second, if so, are the WQC that the State submitted based on sound scientific rationale and adequate under the Clean Water Act (CWA) to protect uses in those waters?

This document contains the detailed explanation to accompany EPA's decision letter acting on the State's request that EPA approve these WQS for waters in Indian lands. In addition, from 2004 through 2010, in response to Maine's 2003 to 2009 submittals of new or revised WQS, EPA approved WQS for waters outside of Indian lands, but specifically stated that EPA was taking no action to approve or disapprove WQS within Indian lands. Today's decision addresses all of Maine's WQS submissions from 2003 through 2014 as they relate to waters in Indian lands, as well as certain submissions on which EPA has not yet acted for any waters in Maine.[2]

In summary, EPA finds that Maine has jurisdiction to set WQS for waters in Indian lands. Because EPA has not yet approved any of Maine's WQS for waters in Indian lands, EPA is first approving the State's classifications and associated designated uses for these waters. All of the relevant classifications include a designated use of "fishing," which the Agency interprets to include sustenance fishing consistent with these Tribes' sustenance practices in waters on their lands. EPA is also approving a specific sustenance fishing use for the inland waters of the reservations of the Penobscot Nation and Passamaquoddy Tribe. EPA is approving all but one of the State's aquatic life criteria. EPA has determined that Maine's human health criteria, however, do not adequately protect the designated use of sustenance fishing in the waters in tribal lands and, therefore, do not comply with the CWA's requirement that criteria protect the

[2] EPA is also approving today certain pre-2004 WQS for waters in Indian lands to the extent necessary to act on the submissions from 2003 through 2014. EPA intends to act on other pre-2004 WQS applicable to those waters as soon as possible. Before 2004, EPA's approvals or disapprovals of new or revised WQS in Maine did not address waters in Indian lands, or expressly consider the State's jurisdiction to establish WQS for such waters or the sufficiency of the State's WQS for such waters under the CWA. EPA thus takes the position that it has not previously approved any of the State's pre-2004 WQS for waters in Indian lands in Maine.

uses of the waters to which they apply. In a separate document EPA will respond to specific comments that interested parties submitted.

1.2 Indian Tribes in Maine

There are four federally recognized Indian Tribes in Maine represented by five governing bodies. The Penobscot Nation and the Passamaquoddy Tribe have reservations and trust land holdings in central and coastal Maine. The Passamaquoddy Tribe has two governing bodies, one on the Pleasant Point Reservation and another on the Indian Township Reservation. The Houlton Band of Maliseet Indians and the Aroostook Band of Micmacs have trust lands further north in the State. To simplify the discussion of the legal framework that applies to each Tribe's territory, EPA will refer to the Penobscot Nation and the Passamaquoddy Tribe together as the "Southern Tribes" and the Houlton Band of Maliseet Indians and Aroostook Band of Micmacs as the "Northern Tribes." EPA acknowledges that these are collective appellations the Tribes themselves have not adopted, and the Agency uses them solely to simplify drafting this decision.

1.3 Settlement Acts in Maine

1.3.1 MIA and MICSA

In 1980, Congress passed the Maine Indian Claims Settlement Act (MICSA), which resolved litigation in which the Southern Tribes asserted land claims to a large portion of the State of Maine. 25 U.S.C. §§ 1721, *et seq.* MICSA ratified a state statute passed in 1979, the Maine Implementing Act (MIA), which was designed to embody the agreement reached between the State and the Southern Tribes. 30 M.R.S. §§ 6201, *et seq.* In 1981, MIA was amended to include provisions for land to be taken into trust for the Houlton Band of Maliseet Indians, as provided for in MICSA. 30 M.R.S. § 6205-A, 25 U.S.C. § 1724(d)(1). Since it is Congress that has plenary authority as to federally recognized Indian Tribes, MIA's provisions concerning jurisdiction and the status of the Tribes are effective as a result of, and consistent with, the Congressional ratification in MICSA.

1.3.2 MSA and ABMSA

In 1989, the Maine legislature passed the Micmac Settlement Act (MSA) to embody an agreement as to the status of the Aroostook Band of Micmacs. 30 M.R.S. §§ 7201, *et seq.* In 1991, Congress passed the Aroostook Band of Micmacs Settlement Act (ABMSA), which ratified the MSA. 25 U.S.C. § 1721, Act Nov. 26, 1991, P.L. 102-171, 105 Stat. 1143. One principal purpose of both statutes was to give the Micmacs the same settlement that had been provided to the Maliseets in MICSA. See ABMSA § 2(a)(4) and (5). In 2007, the Federal Court of Appeals for the First Circuit confirmed that the Micmacs and Maliseets are subject to the same jurisdictional provisions in MICSA. *Aroostook Band of Micmacs v. Ryan*, 484 F.3d 41 (1st Cir. 2007).

Where appropriate, this document will refer to the combination of MICSA, MIA, ABMSA, and MSA as the "settlement acts."

1.4 Indian Territories and Lands in Maine

MICSA, MIA, MSA and ABMSA establish a unique framework for confirming and enhancing the Tribes' land base in Maine. For the Southern Tribes, MIA uses the term "Indian territory" to describe the combination of the Southern Tribes' reservations, as described in treaties with the States of Maine and Massachusetts, plus 150,000 acres of land for each Tribe to be held in trust for the Tribes by the United States. 30 M.R.S. § 6205(1) and (2). As such, the Southern Tribes' land base is made up of both the reservations continuously occupied by the Tribes, and subsequently acquired trust lands.

The land base for the Northern Tribes is made up entirely of trust lands. MIA provides for the Houlton Band of Maliseet Indians to acquire trust land, and Congress provided $900,000 in MICSA to fund that acquisition. 30 M.R.S. § 6205-A, 25 U.S.C. § 1724(d)(1). Similarly, the MSA provides for the Aroostook Band of Micmacs to acquire trust land, and Congress again provided $900,000 in ABMSA to fund that acquisition. 30 M.R.S. § 7204, ABMSA §§ 4(a) and 5(a).

In this document, where appropriate depending on the context, EPA will refer to the tribal land base relevant to this decision as follows: "territories" for the Southern Tribes' land base, which as described above includes both reservations and trust lands; "trust lands" for the Northern Tribes' land base; and "Indian" or "tribal" lands for the entirety of all the Tribes' land base in Maine.[3]

1.4.1 Identification of waters covered by this decision

The Penobscot Indian Nation and Passamaquoddy Tribe have reservation lands as defined in MIA. 30 M.R.S. § 6203(5) (defining Passamaquoddy Indian Reservation); § 6203(8) (defining Penobscot Indian Reservation). The trust lands acquired for the Maine tribes are the product of modern conveyances. Generally, based on the default Maine property rule under which owners of riparian land also own out to the thread, or middle, of most streams, *Wilson & Son v. Harrisburg*, 107 Me. 207, 212-213 (1910), Indian waters include waters adjacent to land held in trust by the Secretary of the Interior and lands in the Tribes' reservations as defined in the Settlement Acts.[4] In addition, Maine common law provides that owners of shore land above the mean high water mark presumptively hold title in fee to intertidal land. *Bell v. Town of Wells*, 557 A.2d 168 (Supreme Judicial Court of Maine, 1989). In *Bell* (often referred to as the "Moody Beach case"), the court explained that such title is subject only to the public's right to fish, fowl, and navigate, and that the rule of law governing titles to intertidal land has its origin in the

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[3] In addition to their reservations and trust lands, the Tribes also hold certain lands in fee, which are not at issue in this matter. Any action EPA has taken to approve Maine WQS for waters outside Indian lands would apply to waters in these fee lands.

[4] See Report of the Joint Select Committee on Indian Land Claims, Maine Legislature (1980), par. 14. ("The boundaries of the Reservations are limited to those areas described in the bill, but include any riparian or littoral rights expressly reserved by the original treaties with Massachusetts or by operation of State law. Any lands acquired by purchase or trade may include riparian or littoral rights to the extent they are conveyed by the selling party or included by general principles of law. However, the Common Law of the State, including the Colonial Ordinances, shall apply to this ownership. The jurisdictional rights granted by this bill are coextensive and coterminous with land ownership.")

Colonial Ordinance of 1641-47 of the Massachusetts Bay Colony. As stated in an article written by the Marine Law Institute, University of Maine School of Law, "[t]he Moody Beach Case affirms that in Maine owners of beachfront property or property adjoining tidelands (also called littoral or riparian owners) have property rights to the low water mark or low tide area subject only to a public easement for fishing, fowling, and navigation." See Citizens' Guide to Ocean and Coastal Law, Public Shoreline Access and the Moody Beach Case, August, 1990. Therefore, the Passamaquoddy Tribe's reservation at Pleasant Point would include at least the waters present in the intertidal zone.

EPA acknowledges that there are remaining uncertainties over what waters are associated with Indian lands in Maine in a few locations. For instance, the boundaries of the Penobscot Nation's reservation are currently the subject of litigation in the United States District Court for the District of Maine. *Penobscot Nation v. Mills,* Case No. 1:12-cv-254-GZS. The United States has intervened in that case, and it is the Government's position that the reservation includes Penobscot River waters, while the State of Maine alleges it does not. Pending resolution of this dispute, EPA's decision to approve or disapprove Maine's WQS for Indian waters includes at least some portion of the Penobscot River in the main stem from Indian Island north surrounding the islands in the Nation's reservation.

In addition, this decision treats the Passamaquoddy Tribe's reservation as including the "15 islands in the St. Croix River in existence on September 19, 1794 and located between the head of the tide of that river and the falls below the forks of that river . . ." as specifically enumerated in MIA's definition of the reservation. 30 M.R.S. 6203(5).

It is not necessary or reasonable for EPA to suspend its decision on the State's WQS submissions to await an authoritative resolution of disputes over the boundaries of Indian waters. If any disputes over reservation boundaries result in an authoritative adjudication inconsistent with the assumptions made in this decision, EPA will revisit or clarify the scope of the Agency's determinations in this decision.

2 EPA's Determination that Maine has Authority to Set WQS in Indian Territories

EPA concludes that MICSA provides the State with jurisdiction to set WQS in the Northern Tribes' trust lands and that the federal statute ratifies provisions of MIA that provide the State with such authority in the Southern Tribes' territories. Although in both cases the settlement acts provide the State jurisdiction to establish WQS, EPA notes that MICSA provides a different jurisdictional framework for the Northern Tribes than that which applies to the Southern Tribes.

2.1 Northern Tribes

MICSA provides that the Northern Tribes are subject to state law:

> Except as provided in section 1727(e) and section 1724(d)(4) of this title, all Indians, Indian nations, or Tribes or bands of Indians in the State of Maine, other than the Passamaquoddy Tribe, the Penobscot Nation, and their members, and any lands or natural resources owned by any such Indian, Indian nation, Tribe or band of Indians and any

> lands or natural resources held in trust by the United States, or by any other person or entity, for any such Indian, Indian nation, Tribe, or band of Indians shall be subject to the civil and criminal jurisdiction of the State, the laws of the State, and the civil and criminal jurisdiction of the courts of the State, to the same extent as any other person or land therein.

25 U.S.C. 1725(a). In addition, MICSA ratified MIA, which also provides that all tribes in Maine, including the Northern Tribes are subject to state law:

> Except as otherwise provided in this Act, all Indians, Indian nations, and Tribes and bands of Indians in the State and any lands or other natural resources owned by them, held in trust for them by the United States or by any other person or entity shall be subject to the laws of the State and to the civil and criminal jurisdiction of the courts of the State to the same extent as any other person or lands or other natural resources therein.

30 M.R.S. § 6204. Both statutes make it clear that laws of the State include regulation and that lands and natural resources include water and water rights. 25 U.S.C. §§ 1722(b) and (d); 30 M.R.S. § 6203(3) and (4). The only exceptions to state jurisdiction provided in MIA apply to the Southern Tribes. There are no such exceptions for the Northern Tribes. Notably, the U.S. Court of Appeals for the First Circuit has expressly found that the State's jurisdictional reach in the Northern Tribes' lands is greater than in the Southern Tribes' territories. *Houlton Band of Maliseet Indians v. Ryan*, 484 F.3d 73, 74-75 (1st Cir. 2007). That same year the First Circuit ruled that, even as to the Southern Tribes, MICSA and MIA grant the State jurisdiction to regulate surface water discharge permitting. *Maine v. Johnson,* 498 F.3d 37 (1st Cir. 2007). As discussed below, EPA has concluded that the court's analysis controls our decision as to the State's authority to set WQS in the Southern Tribes' territories. Given that MICSA gives the State a broader scope of jurisdiction over the Northern Tribes than over the Southern Tribes, which are nevertheless subject to the State's authority to set WQS, it is clear that state law applies to the Northern Tribes, and the State has authority to set WQS for waters in these Tribes' trust lands.

The Aroostook Band of Micmacs has argued that the passage of ABMSA impliedly repealed the application of MICSA to the Tribe, and, therefore, that the Micmacs were not subject to the same jurisdictional framework as the Houlton Band of Maliseet Indians. The First Circuit, however, rejected that argument. *Aroostook Band of Micmacs v. Ryan*, 484 F.3d 41, 60-62 (1st Cir. 2007).

2.2 Southern Tribes

MICSA addresses the jurisdictional relationship between the Southern Tribes and the State by reference to MIA, which MICSA ratifies:

> The Passamaquoddy Tribe, the Penobscot Nation, and their members, and the land and natural resources owned by, or held in trust for the benefit of the Tribe, nation, or their members, shall be subject to the jurisdiction of the State of Maine to the extent and in the

> manner provided in the Maine Implementing Act and that Act is hereby approved, ratified, and confirmed.

25 U.S.C. § 1725(b)(1). As discussed above, MIA in turn provides generally that all Indian Tribes in the State are subject to state law:

> Except as otherwise provided in this Act, all Indians, Indian nations, and Tribes and bands of Indians in the State and any lands or other natural resources owned by them, held in trust for them by the United States or by any other person or entity shall be subject to the laws of the State and to the civil and criminal jurisdiction of the courts of the State to the same extent as any other person or lands or other natural resources therein.

30 M.R.S. § 6204. Importantly, MIA section 6204 refers to exceptions to the grant of state jurisdiction found elsewhere in the statute, and those exceptions are all applicable to the Southern Tribes. *See, e.g.*, §§ 6206 (internal tribal matters); 6207 (hunting and fishing in Indian territories); 6209-A & B (minor crimes, small claims, child custody, and domestic relations). EPA has carefully considered whether any of the exceptions provided in MIA operate to block the grant of jurisdiction to the State in the area of setting WQS in the Southern Tribes' waters. EPA concludes that they do not impede the State's jurisdiction to establish WQS under the CWA for the Southern Tribes' waters.

2.2.1 Maine v. Johnson Decision

The U.S. Court of Appeals for the First Circuit previously adjudicated the issue of Maine's authority to regulate water quality protection in the Southern Tribes' territories. In 2003, EPA approved the State to issue national pollutant discharge elimination system (NPDES) permits under the CWA generally in the Southern Tribes' territories, except for those dischargers where EPA concluded that permitting would qualify as an internal tribal matter. MIA section 6206 exempts the Southern Tribes' internal tribal matters from state regulation. EPA determined that two tribally owned and operated public treatment works, which served only tribal members on the Tribes' reservations and had minimal water quality impacts at the point of discharge, qualified as internal tribal matters, and thus excluded those two facilities from the State's approved permitting program. In *Maine v. Johnson,* 498 F.3d 37 (1st Cir. 2007), the First Circuit upheld EPA's approval of the State's program in the Southern Tribes' territories, but reversed EPA's decision to withhold approval of the State to issue the permits for the two tribal treatment works.

> In ordinary statutory construction, the [internal tribal matters] proviso thus reserves to the tribe matters pertaining to tribal membership and governance structure, expenditure of fund income and *other matters of the same kind . . .;* but it does not displace general Maine law on most substantive subjects, including environmental regulation. . . . [W]e readily uphold the position of the EPA and Maine that the nineteen non-Indian discharge sources draining into tribal waters can be regulated by the state. The only real question is the EPA's carve-out of the two source points that are on tribal lands and are owned by Tribe entities. . . .

> In our view, the Settlement Acts make ordinary Maine law apply, even if only tribal members and tribal lands are affected in the particular case, *unless* the internal affairs exemption applies; and the scope of that exemption is determined by the character of the subject matter. Discharging pollutants into navigable waters is not of the same character as tribal elections, tribal membership or other exemplars that relate to the structure of Indian government or the distribution of tribal property.

Id. at 44-46 (emphasis in original; citations omitted). EPA has concluded that the *Maine v. Johnson* decision makes it clear that the grant of jurisdiction to the State includes the area of environmental regulation, certainly as it applies to surface water discharge permitting. The Agency also finds no basis to distinguish the analysis in that case as applied to the State's authority to set WQS for surface waters in the Southern Tribes' territories.

2.2.2 Arguments Maine Tribes have Advanced for Exceptions to State Jurisdiction for Southern Tribes

EPA considered whether, given the jurisdictional provisions of the applicable statutes and the precedent set in *Maine v. Johnson*, there is any basis for concluding that the State's authority to administer the NPDES permitting program would not apply equally to the State's WQS program. EPA concludes there is no such basis.

2.2.2.1 Internal Tribal Matters

As a threshold matter, the court in *Maine v. Johnson* concluded that environmental regulation was part of the jurisdictional grant to the State in Indian lands:

> [T]he [internal tribal matters] proviso thus reserves to the tribe matters pertaining to tribal membership and governance structure, expenditure of fund income and *other matters of the same kind* . . .; but it does not displace general Maine law on most substantive subjects, including <u>environmental regulation</u>.

Id. at 45 (emphasis in original; underscore added). The WQS program is clearly a form of environmental regulation that would be covered by this characterization of the State's authority. Strictly speaking, the facts on which the court's holding rests only presented the question of the State's authority to issue waste water discharge permits. Nevertheless, the court's reasoning in that case makes it clear that this exception to State jurisdiction would not block the State from setting WQS.

When the Agency withheld approval from Maine to permit the two tribal treatment works, EPA conducted an analysis of the factors the First Circuit articulated in two prior cases examining whether a particular subject matter qualifies as an internal tribal matter not subject to state regulation. *Akins v. Penobscot Nation*, 130 F.3d 482, 486-490 (1st Cir. 1997); *Penobscot Nation v. Fellencer*, 164 F.3d 706, 710-713 (1st Cir. 1999). In its review of EPA's decision, the *Johnson* court found it unnecessary to apply the factors developed in the *Akins* and *Fellencer* cases; rather it concluded that this multi-factor assessment is relevant only when an area of regulation is

"arguably close to the (perhaps blurred) statutory borderline" of what might qualify as an internal tribal matter. 498 F.3d at 46. The court concluded that "discharging pollutants into navigable waters is not a borderline case in which balancing . . . or ambiguity canons . . . alter the result." *Id.* (citations omitted).

EPA evaluated whether the authority to set WQS is any closer to the statutory borderline the First Circuit has outlined and, therefore, might properly be analyzed using the *Akins/Fellencer* factors rather than the more categorical analysis in the *Johnson* decision. The Penobscot Nation commented to EPA that setting WQS directly affects the quality of fish the Tribe is able to consume for its sustenance, an area of concern at the core of the Nation's existence. The Penobscot Nation's view is that this effect on the Tribe's ability to safely consume fish makes setting WQS an internal tribal matter. EPA does not agree. Indeed, the Agency concludes that setting WQS is an exercise of jurisdiction even further from the "borderline" between state jurisdiction and internal tribal matters that the *Johnson* court posited.

The decision EPA is making is approval of WQS that are an integral part of a larger legal framework provided for in the CWA. Within that framework, the CWA and EPA's regulations provide that NPDES permits for upstream dischargers must include limits that assure compliance with downstream WQS. 40 C.F.R. § 122.44(d)(4) and CWA § 401(a)(2). In reviewing Maine's NPDES program, EPA found that permitting the two tribal treatment works involved only tribal members and would have minimal effect on water quality outside the Tribes' territories. See 498 F.3d at 45 n. 8. EPA cannot make a corresponding finding here that setting a WQS would not have the potential for an effect on non-members or on water quality outside the Tribes' territories. When it established the multi-factor internal tribal matters analysis, the *Akins* court noted that "*First, and foremost*, the [stumpage policy at issue] purports to regulate only members of the Tribe . . .." 130 F.3d at 486 (emphasis added). On this "foremost" factor, EPA concludes that the WQS program can have regulatory effects beyond the Tribe. Generally, downstream WQS determine what limits upstream dischargers must meet to assure protection of those WQS, which is a legal effect that could reach beyond the membership of the Tribes and the boundaries of their territories. These effects put the setting of WQS even further from the "(perhaps blurred) statutory borderline" of what qualifies as an internal tribal matter under the MIA and MICSA.

In *Maine v. Johnson* the court was prepared to accept EPA's finding that permitting the two tribal treatment works would not have a substantial effect outside the Tribes' territories, and it still refused to treat the category of waste water discharge permitting as an internal tribal matter. Here, EPA cannot find that setting WQS will have no potential for a substantial effect outside the Tribes' territories. Therefore, under the principles announced in *Maine v. Johnson*, EPA concludes that setting WQS does not qualify as an internal tribal matter.

2.2.2.2 The Southern Tribes' Sustenance Fishing Right

EPA has also considered whether the reservation in MIA of the Southern Tribes' right to take fish for their individual sustenance within their reservations provides an exception to the State's jurisdiction. That right is reserved to the Southern Tribes "[n]otwithstanding . . . any other law of the State." 30 M.R.S. § 6207(4). Arguably, if a state law interfered with the Southern Tribes' right to take fish for their individual sustenance, this provision would block that law's

application in the Southern Tribes' reservations. However, EPA concludes that the State's administration of WQS, subject to CWA requirements and EPA's oversight, does not have the potential to interfere with the Southern Tribes' sustenance fishing right.

MIA is clear that the basic grant of jurisdiction to the State includes the authority to apply laws of the State, which include regulations, to the Tribes' natural resources, which include "water and water rights and hunting and fishing rights." 30 M.R.S. §§ 6204, 6203(3) and (4). To conclude that the reserved fishing right precludes the operation of all state laws affecting environmental regulation that might indirectly affect the fishing right, one would have to conclude that the State's regulation of water quality is inherently and necessarily inimical to the Tribes' ability to take fish for their individual sustenance. EPA cannot reach that conclusion.

First, there are many state WQS that are reasonably adequate to support a fishery that could provide for an individual tribal member's sustenance. Indeed, as discussed below, EPA is approving many state WQS provisions that EPA has determined are sufficient to protect aquatic life. In *Maine v. Johnson* the court made it clear that decisions about the scope of the State's jurisdiction in the Southern Tribes' territories should be made on the basis of the category of the subject matter at issue – the court specifically rejected EPA's attempt to find or reject state jurisdiction based on the facts of any particular application of state jurisdiction within a subject matter category. "So we accept the EPA's factual premise as to the [limited] impact of the discharges but not the EPA's legal characterization. . . . [T]he scope of [the internal tribal matters] exemption is determined by the character of the subject matter." 498 F.3d at 45-46. The subject category at issue in *Maine v. Johnson* was environmental regulation of pollutants in surface waters, the same category at issue here. The impact of a specific state WQS regulation on the Tribes' sustenance fishing rights might provide the basis for a challenge to that specific regulation, but the bare potential for such a specific challenge at some point provides no basis for precluding all state regulation of that subject area. It is possible for the State to exercise jurisdiction to set WQS without necessarily or inevitably interfering with the Tribes' fishing rights.

Second, if the State does submit a new or revised WQS that would interfere with the Tribes' reserved fishing right, EPA has authority under the CWA to ensure that the Tribes' fishing right is protected. As described further below, EPA is approving the reserved sustenance fishing right as a designated use for the tribal waters to which the right applies. Where the State adopts a new or revised WQS, EPA has the authority and the obligation under the CWA to review and determine whether such new or revised WQS is consistent with the CWA. If EPA disapproves, the CWA directs EPA to propose and promulgate a new or revised WQS unless the State adopts an adequate revision to protect the use. The CWA thus provides the mechanism to protect the sustenance fishing use and prevent interference with the Southern Tribes' reserved fishing right. EPA's oversight of Maine's WQS is adequate to protect the Tribes' right while maintaining the basic statutory grant of jurisdiction to Maine, including the authority to set WQS, as provided under MICSA in the first instance.

2.3 The Relationship Among MISCA, Jurisdiction, and the Trust Responsibility

Several Tribes in Maine commented that it would be inconsistent with the federal government's trust relationship with the Tribes for EPA to approve the State to set WQS for waters in the Tribes' lands. On the other hand, the State argues that the trust relationship does not apply in the State because of MICSA.

EPA has consistently maintained that there is a trust relationship between the federal government and the Tribes in Maine in the general sense that the Tribes are federally recognized, they have sovereign governments that EPA interacts with on a government-to-government basis, and EPA has a responsibility to consult with the Tribes to understand and consider their interests when EPA is making a decision that affects the Tribes. This general trust relationship, however, does not alter the jurisdictional framework Congress ratified in MICSA. MICSA impacts the jurisdictional relationship among the Tribes and the State, within which EPA works to address the Tribes' interests as appropriate. It is consistent with the trust relationship for EPA to approve the State's authority to set WQS for waters in the Tribes' lands, because MICSA has dramatically revised the jurisdictional framework within which the trust operates in Maine as compared to the customary jurisdictional framework that applies in Indian country outside Maine. EPA intends to continue to act consistently with the trust relationship, to consult with the Tribes, and to consider their interests as we oversee the State's WQS under the CWA.

2.4 The Penobscot Nation's Application for Treatment in the Same Manner as a State

On October 8, 2014, the Penobscot Nation submitted to EPA an application "to administer water quality standards program and for federal approval of the standards" covering the Main Stem of the Penobscot River from Indian Island north to the confluence of the east and west branches of the river. EPA is not acting today on the Nation's application. EPA is only deciding today that the State of Maine has authority to set WQS for waters in Indian lands, and then acting on the State's WQS as applied to those waters. The Nation's application raises complicated issues that EPA will address in a separate decision.

3 EPA's Determination to Approve Classifications and Designated Uses for Waters in Indian Lands

In Section 2, above, EPA focused on the settlement acts and judicial interpretation of those statutes to analyze Maine's assertion of jurisdiction to set WQS in the waters in Indian lands. Having concluded that the State has jurisdiction to set those standards, EPA must now analyze whether the State's WQS as applied to waters in Indian lands are approvable under the CWA. So the balance of this document will focus primarily on the requirements of the CWA, as applied to the unique circumstances EPA must address here where a state is setting WQS for waters in lands that Congress has set aside for federally recognized Indian tribes.

The first step in developing and reviewing WQS under the CWA is to determine the uses of the waters to which the WQS apply. Here the State is not writing on a blank slate in the selection of uses for tribal waters. As described in detail in this section 3, EPA has concluded that the settlement acts operate to require Maine and the Agency to focus on the sustenance fishing use that federal and state law provide for the Tribes in Maine in waters in Indian lands. In light of

the sustenance fishing use, the CWA requires the State's water quality criteria to protect that use as explained in section 4, below.

3.1 Status of Previous State WQS as Applied to Waters in Indian Lands

3.1.1 EPA's Prior Decisions on Maine WQS

Maine has periodically submitted new or revised WQS to EPA for review and approval or disapproval. Before 2004, EPA acted on those WQS without expressly considering or approving the State's jurisdiction to establish WQS for waters in Indian lands or the sufficiency of the State's WQS for such waters under the CWA. Since 2004, EPA has expressly stated, in all decisions that it made to approve or disapprove new or revised WQS, that its decisions applied only to Maine waters outside of Indian lands.

3.1.2 EPA's Approach to State Programs in Indian Country

The State has commented to EPA that, prior to 2004, EPA approved state WQS submissions without reference to or exclusion of waters in tribal lands. From this the State infers that EPA approved the State's WQS for waters in tribal lands prior to 2004. EPA disagrees with this inference.

First, Maine did not obtain authority to regulate in tribal lands until Congress passed MICSA in 1980. While the State asserted the authority to govern the Tribes prior to MICSA, the First Circuit's decision in *Joint Tribal Council of the Passamaquoddy Tribe v. Morton*, 528 F.2d 370 (1st Cir. 1975), cast considerable doubt on that proposition, and the decision in *Bottomly v. Passamaquoddy Tribe*, 599 F.2d 1061 (1st Cir. 1979), effectively foreclosed this argument. So any WQS that Maine submitted prior to MICSA's passage could have no legal effect in tribal lands. At that point the State had no clear authority to set WQS in those waters.

But even as to WQS that Maine submitted following the passage of MICSA in 1980, EPA's position is that none of the State's WQS, whether submitted prior to or following enactment of MICSA, were approved under the CWA for waters in Indian lands. Prior to the Agency's decision today, EPA has never made a formal determination on the record expressly addressing either the State's jurisdictional authority or the sufficiency under the CWA of the State's WQS as applied to waters in Indian lands.

Today's decision demonstrates that in acting on new or revised state WQS for waters in Indian lands, EPA must consider the adequacy of such WQS to protect the uses in those specific waters. Where, as here, waters in Indian lands have a different designated use (*i.e.*, sustenance fishing) than waters outside of Indian lands, the analysis of the adequacy of criteria will necessarily be different. It would be arbitrary for EPA to assume, without analysis, that if criteria are protective for waters outside of Indian lands, they are also protective for waters in Indian lands.

In addition, under basic principles of federal Indian law, states generally lack civil regulatory jurisdiction within Indian country as defined in 18 U.S.C. § 1151. *Alaska v. Native Vill. Of Venetie Tribal Gov't*, 522 U.S. 520, 527 n.1. (1998) ("[g]enerally speaking, primary jurisdiction

over land that is Indian country rests with the Federal Government and the Indian Tribe inhabiting it, and not with the States."). See also *Okla. Tax Comm'n v. Sac and Fox Nation*, 508 U.S. 114, 128 (1993) ("[a]bsent explicit congressional direction to the contrary, we presume against a State's having the jurisdiction to tax within Indian Country . . . ."). Thus, EPA cannot presume a state has authority to establish WQS or otherwise regulate in Indian country. Instead, a state must demonstrate its jurisdiction, and EPA must determine that the state has made the requisite demonstration and expressly determine that the state has authority, before a state can implement a program in Indian country.[5] Such a demonstration and approval of Maine's authority to administer WQS in waters of Indian lands has not occurred prior to the decision EPA is making today.[6]

Maine cites to several actions by EPA employees that, in the State's view, indicate EPA's recognition that state WQS approved before 2004 apply in at least some tribal waters. EPA notes that some of those actions applied to stretches of rivers that either included both tribal and state waters or that were then and continue to be the subject of disputes over whether they included both tribal and state waters. As a result, those actions were inherently ambiguous as to their relevance to the tribal portions of the waters. But the Agency concedes that in some instances the Agency appeared to assume, without any express consideration or decision regarding the jurisdictional or CWA issues, that state WQS applied in certain tribal waters. For example, there are instances when the Region asked Maine DEP to certify under section 401 of the CWA that NPDES permits for tribal facilities discharging into tribal waters complied with state WQS. Simply put, those prior actions were mistakes that do not affect this decision. At the time, EPA had made no finding that Maine had jurisdiction to adopt WQS for tribal waters and had not approved the State's WQS for such waters. EPA notes that unexplained mistakes by mid-level Agency officials cannot unilaterally revise a considered Agency-wide policy. *Puerto Rican Cement Co. v. EPA*, 889 F.2d 292, 299 (1st Cir. 1989).

3.2 EPA Approval of Water Classifications and Associated Designated Uses

Many of the WQS revisions under review for approval or disapproval for waters in Indian lands are water quality criteria, and the CWA requires that criteria be protective of designated uses. In order to evaluate whether the submitted criteria are protective of designated uses, EPA must first approve designated uses for these waters. Accordingly, EPA also reviewed and is approving

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[5] Consistent with EPA's responsibility to consult with Indian tribes about decisions affecting their interests, as embodied in the Agency's 1984 Indian Policy and EPA's more recent Tribal Consultation Policy, EPA would offer to consult with any Indian tribe in the context of an Agency determination that a state has authority to set standards in that tribe's territory. Notably, no such consultations occurred in the context of EPA's prior decisions on the State's WQS submissions, further evidencing that the Agency's prior approvals were not intended to extend to waters in Indian lands.

[6] Indeed, as described above in the Agency's analysis of the State's jurisdictional authority to set WQS in Indian waters, EPA's review and assessment of how Maine's WQS affect tribal uses in Indian waters is an essential step in the argument that it is possible to reconcile the State setting WQS in Indian waters with the fishing rights that MICSA reserves to Tribes in Maine. Ignoring or side-stepping EPA's role in overseeing Maine's WQS submissions as they apply to Indian waters risks creating an irreconcilable conflict between the jurisdictional grant to the State in MICSA and the provision for Tribes in Maine to sustain themselves on the land base that the Maine settlement acts established for the Tribes. Respecting EPA's oversight role effectively harmonizes those elements of the settlement acts in Maine.

Maine's surface water classifications and corresponding designated uses, adopted and submitted to EPA for review to date[7], for waters in Indian lands.[8]

The general classifications and their corresponding uses consist of the following:

- 38 M.R.S. § 465(1.A) Class AA freshwater uses: drinking water after disinfection, fishing, agriculture, recreation in and on the water, navigation, and as habitat for fish and other aquatic life. The habitat must be characterized as free-flowing and natural.
- 38 M.R.S. § 465(2.A) Class A freshwater uses: drinking water after disinfection; fishing; agriculture; recreation in and on the water; industrial process and cooling water supply; hydroelectric power generation, except as prohibited under Title 12, section 403; navigation; and as habitat for fish and other aquatic life. The habitat must be characterized as natural.
- 38 M.R.S. § 465(3.A) Class B freshwater uses: drinking water supply after treatment; fishing; agriculture; recreation in and on the water; industrial process and cooling water supply; hydroelectric power generation, except as prohibited under Title 12, section 403; navigation; and as habitat for fish and other aquatic life. The habitat must be characterized as unimpaired.
- 38 M.R.S. § 465(4.A) Class C freshwater uses: drinking water supply after treatment; fishing; agriculture; recreation in and on the water; industrial process and cooling water supply; hydroelectric power generation, except as prohibited under Title 12, section 403; navigation; and as a habitat for fish and other aquatic life.
- 38 M.R.S. § 465-A(1.A) Class GPA lake and pond uses: drinking water after disinfection, recreation in and on the water, fishing, agriculture, industrial process and cooling water supply, hydroelectric power generation, navigation, and as habitat for fish and other aquatic life. The habitat must be characterized as natural. This section applies to great ponds (as defined in 38 M.R.S. § 480-B (5)), natural lakes and ponds less than 10 acres in size, and impoundments of rivers that are defined as great ponds pursuant to 38 M.R.S. § 480-B (5).
- 38 M.R.S. § 465-B (1.A) Class SA estuarine and marine water uses: recreation in and on the water, fishing, aquaculture, propagation and harvesting of shellfish, navigation, and as habitat for fish and other estuarine and marine life. The habitat must be characterized as free-flowing and natural.
- 38 M.R.S. § 465-B (2.A) Class SB estuarine and marine water uses: recreation in and on the water, fishing, aquaculture, propagation and harvesting of shellfish, industrial process and cooling water supply, hydroelectric power generation, navigation, and as habitat for fish and other estuarine and marine life. The habitat must be characterized as unimpaired.
- 38 M.R.S. § 465-B (3.A) Class SC estuarine and marine water uses: recreation in and on the water, fishing, aquaculture, propagation and restricted harvesting of shellfish,

[7] This includes the addition of "agriculture" as a designated use for freshwaters, submitted to EPA on August 26, 2003.

[8] There are other provisions of Maine's WQS that EPA is not approving or disapproving at this time because they are not directly related to the scope of this decision, which is responding to new and revised WQS submitted to EPA from 2003 to 2014. These remaining provisions include, for example, definitions, antidegradation policies, and WQS implementation policies in regulation and statute. EPA will review those elements in the coming months and make decisions accordingly.

industrial process and cooling water supply, hydroelectric power generation, navigation and as a habitat for fish and other estuarine and marine life.

Waters throughout Maine are identified by classification in 38 M.R.S. § 467 (classifications of major river basins), § 468 (classifications of minor drainages), and § 469 (classifications of estuarine and marine waters), which results in the assignment of designated uses for each waterbody.

Each of the classification categories identified above contains designated uses that are consistent with the requirements of Section 303(c)(2)(A) of the Clean Water Act and 40 C.F.R. § 131.6(a). In addition, EPA has concluded that the classifications as applied to specific waters in Indian lands are reasonable. Therefore, EPA is approving the general classifications and associated designated uses in 38 M.R.S. § 465(1.A), (2.A), (3.A), and (4.A); § 465-A(1.A) (and the definition of "great ponds" in 38 M.R.S. § 480-B (5)); and § 465-B(1.A), (2.A), and (3.A); as well as the classification of specific waters in 38 M.R.S. § 467, § 468, and § 468, as applied to waters in Indian lands, because they are consistent with Sections 101(a)(2) and 303(c)(2)(A) of the Clean Water Act and 40 C.F.R. §131.10(a). EPA is including in its approval of specific waterbody classifications the reclassifications, submitted to EPA on December 7, 2009, of Otter Creek, a tributary of Seboeis Stream, and Alder Stream from Class B to Class A; and of Grand Falls Flowage between Route 1(Princeton and Indian Township) and Black Cat Island from Class B to Class GPA.

3.3 EPA's Identification of the "Fishing" Designated Use as "Sustenance Fishing" in Waters in Indian Lands in Maine

3.3.1 The Purpose of the Tribal Land Base and Tribal Sustenance Fishing in Maine

The settlement acts in Maine include extensive provisions to confirm and expand the Tribes' land base, and the legislative record makes it clear that a key purpose behind that land base is to preserve the Tribes' culture and support their sustenance practices. MICSA section 1724 establishes a trust fund to allow the Southern Tribes and the Maliseets to acquire land to be put into trust. In addition, the Southern Tribes' reservations are confirmed as part of their land base. 30 M.R.S. § 6205(1)(A) and (2)(A). MICSA combines with MIA sections 6205 and 6205-A to establish a framework for taking land into trust for those three Tribes, and laying out clear ground rules governing any future alienation of that land and the Southern Tribes' reservations. Sections 4(a) and 5 of the ABMSA and 7204 of the state MSA accomplish essentially the same result for the Micmacs, consistent with the purpose of those statutes to put that Tribe in the same position as the Maliseets.

EPA has concluded that one of the over-arching purposes of the establishment of this land base for the Maine Tribes was to ensure their continued opportunity to engage in their unique cultural practices to maintain their existence as a traditional culture. An important part of the Maine Tribes' traditional culture is their sustenance life ways. The legislative history for MICSA makes it clear that one critical purpose for assembling the land base for the Tribes in Maine was to preserve their culture. The Historical Background in the Senate Report for MICSA opens with the observation that "All three Tribes [Penobscot, Passamaquoddy and Maliseet] are riverine in

their land-ownership orientation." Sen. Rep. No. 96-957, at 11. The Report's "Special Issues" section specifically refutes the concern that:

> *The Settlement will lead to acculturation of the Maine Indians.* – Nothing in the settlement provides for acculturation, nor is it the intent of Congress to disturb the cultural integrity of the Indian people of Maine. To the contrary, the Settlement offers protections against this result being imposed by outside entities by providing for tribal governments which are separate and apart from the towns and cities of the State of Maine and which control all such internal matters. The Settlement also clearly establishes that the Tribes in Maine will continue to be eligible for all federal Indian cultural programs.

Id. at 17. As the Tribes have extensively documented in their comments, their culture relies heavily on sustenance practices, including sustenance fishing. So if a purpose of MICSA is to avoid acculturation and protect the Tribes' continued political and cultural existence on their land base, then a key purpose of that land base is to support those sustenance practices.

As explained in more detail below, MICSA, MIA, ABMSA, and MSA include very different provisions governing sustenance practices, including fishing, depending on the type of Indian lands involved. But each set of provisions in its own way is designed to make a homeland for these Tribes where they may safely practice their sustenance life ways.

3.3.1.1 Southern Tribes' Sustenance Fishing Right Reserved in Their Reservations in MIA/MICSA

If there were any doubt that sustenance practices are central to tribal culture, MICSA ratifies the MIA's reservation of the Southern Tribes' right to take fish for their individual sustenance:

> SUSTENANCE FISHING WITHIN THE INDIAN RESERVATIONS. Notwithstanding any rule or regulation promulgated by the commission or any other law of the State, the members of the Passamaquoddy Tribe and the Penobscot Nation may take fish, within the boundaries of their respective Indian reservations, for their individual sustenance subject to the limitations of subsection 6.

30 M.R.S. § 6207(4). Under this section, "fish" is defined as "a cold blooded completely aquatic vertebrate animal having permanent fins, gills and an elongated streamlined body usually covered with scales and includes inland fish and anadromous and catadromous fish when in inland water." 30 M.R.S. § 6207(9).

The only limitation on the Southern Tribes' right to take fish for their individual sustenance on their reservations is the State's ability to limit the take based on a finding that the Tribes' fishing practices are threatening stocks outside the Tribes' reservations in a process in which the State carries the burden of proof. 30 M.R.S. § 6207(6). To date the State has made no such determination. So a plain language reading of this provision entitles the Southern Tribes to take as much fish as they deem necessary to sustain individual members.

The legislative history for MIA makes it clear that the Maine legislature intended to continue and ratify the State's practice of not regulating the Southern Tribes' sustenance fishing practices. See transcript of the public hearing held on March 28, 1980 by the Maine Legislature's Joint Select Committee on the Maine Indian Claims Settlement at 55-56. The special issues section of the Senate Report on MICSA confirms that the intent of this provision is to shield the Southern Tribes' right to take fish from the prospect that the State might someday interfere with it. By responding to a rhetorical assertion (in italics below), the report confirms that the Southern Tribes have a right to take fish that is subject to state regulation only under very limited circumstances:

> *Subsistence hunting and fishing rights will be lost since they will be controlled by the State of Maine under the Settlement.* – Prior to the settlement, Maine law recognized the Passamaquoddy Tribe's and Penobscot Nation's right to control Indian subsistence hunting and fishing within their reservations, but the State of Maine claimed the right to alter or terminate these rights at any time. Under Title 30, Sec. 6207 as established by the Maine Implementing Act, the Passamaquoddy Tribe and the Penobscot Nation have the permanent right to control hunting and fishing not only within their reservations, but insofar as hunting and fishing in certain ponds is concerned, in the newly-acquired Indian territory as well. The power of the State of Maine to alter such rights without the consent of the affected tribe or nation is ended by Sec. 6(e)(1) of S. 2829. The State has only a residual right to prevent the two tribes from exercising their hunting and fishing rights in a manner which has a substantially adverse effect on stocks in or on adjacent lands or waters. This residual power is not unlike that which other states have been found to have in connection with federal Indian treaty hunting and fishing rights. The Committee notes that because of the burden of proof and evidence requirements in Title 30, Sec. 6207(6) as established by the Maine Implementing Act, the State will only be able to make use of this residual power where it can be demonstrated by substantial [evidence] that the tribal hunting and fishing practices will or are likely to adversely affect wildlife stock outside tribal lands.

Sen. Rep. No. 96-957, pp. 16-17. Importantly, MIA section 6207 did not create a fishing right for the Southern Tribes. Rather it confirmed an aboriginal right the Tribes have continuously exercised, and shielded that right from state regulation absent a finding of depletion. DOI's legal opinion confirms that this statutorily reserved fishing right is rooted in treaty guarantees that were upheld through the settlement acts.

The Senate Committee's discussion of the similarity between MIA section 6207 and the structure of more traditional Indian treaty hunting and fishing rights is instructive. Essentially, the State of Maine has adopted into state law and Congress has ratified a reserved fishing right like the rights reserved to other Indian tribes by treaties, executive orders, or other statutes. It is axiomatic that the settlement acts in Maine significantly revised the customary formulae of federal Indian law that apply outside the State. *Akins*, 130 F.3d at 484. But it is equally important to recognize those elements of the settlement acts where both the state and federal governments made careful provision for tribal rights that mirror those more commonly seen elsewhere in Indian country. *See Washington v. Washington State Commercial Passenger Fishing Vessel Association*, 443 U.S. 658, 674 (1979) (Stevens Treaties explicitly reserved to the Pacific Northwest tribes "'[t]he

right of taking fish, at all usual and accustomed grounds and stations . . . in common with all citizens of the Territory'"). The Southern Tribes' reserved aboriginal right to take fish for their individual sustenance within their reservations is such a right.

3.3.1.2 Federal Law Framework for Sustenance Fishing in Trust Lands

Similarly, to understand how the Maine Tribes' sustenance fishing practices are provided for in their newly acquired trust lands, it is helpful to review the federal law background against which Congress and the State of Maine were legislating when they provided for land to be taken into trust for the benefit of the Maine Tribes. Courts have found that when Congress sets aside land for a fishing tribe, it implicitly grants to the tribe the right to carry out its traditional fishing practices on that land. See *Menominee v. U.S.*, 391 U.S. 404, 405-406 (1968) (holding that lands acquired for the Menominee Tribe included the implicit right to hunt and fish on those lands); *Parravano v. Babbitt*, 70 F.3d 539, 544 (9th Cir. 1995) (recognizing the doctrine "that the grant of hunting and fishing rights is implicit in the setting aside of a reservation 'for Indian purposes.'"); see also *Katie John v. U.S.*, 720 F.3d 1214, 1230 (9th Cir. 2013) (Reserved water rights "are created when the United States reserves land from the public domain for a particular purpose, and they exist to the extent that the waters are necessary to fulfill the primary purposes of the reservation.").

Courts have found an implicit fishing right based on legislative history indicating that, in setting aside land for a tribe, Congress intended to preserve a tribe's fishing culture/practices. See *Menominee*, 391 U.S. at 405 ("The essence of the Treaty of Wolf River was that the Indians were authorized to maintain on the new lands ceded to them as a reservation their way of life which included hunting and fishing."); *Parravano*, 70 F.3d at 542 (In enacting the Hoopa-Yurok Settlement Act, "[o]ne of the concerns of Congress at the time" was "to protect the Tribes' fisheries."); see also id. at 546 ("Although the 1988 Hoopa-Yurok Settlement Act did not explicitly set aside fishing rights, it did make clear that partitioning would not dispossess the Tribes of their assets. The legislative history of the 1988 Act indicates that Congress was aware that each Tribes' interests in their salmon fisheries was one of its principal assets."). As explained in greater detail below, there is such legislative history here.

There is an important distinction between the Southern Tribes' aboriginal fishing right, which Congress explicitly reserved on those Tribes' reservations, and tribal sustenance fishing on the trust lands, which Congress provided for based on its demonstrated intent to preserve the Tribes' riverine culture. EPA is not determining that the Tribes in Maine have an aboriginal fishing right in their trust lands. The Agency acknowledges there is dispute over the scope of the Tribes' aboriginal resource rights following enactment of MICSA. See 25 U.S.C. §§ 1722(b) and 1723(b) and Assessment of the Intergovernmental Saltwater Fisheries Conflict between Passamaquoddy and the State of Maine, Maine Indian Tribal-State Commission: Special Report 2014/1 (June 17, 2014) at 7.

But regardless of the status of aboriginal fishing rights outside the Southern Tribes' reservations, it is possible for Congress to make provision for tribal sustenance fishing on trust lands, not based on the reservation of aboriginal rights, but based on Congressional intent to establish a land base for a tribe in order to sustain its unique culture. As described in detail below, EPA has

determined that Congress did just that in the Maine settlement acts, and when Congress did so, it acted against the backdrop of the principles outlined in the cases above. The legislative record regarding the trust land provisions in MIA, MICSA, MSA and ABMSA demonstrate Congress's intent to provide the Tribes with the opportunity to exercise their traditional sustenance lifeways, including traditional sustenance fishing in waters of tribal trust lands.

3.3.1.2.1 Sustenance Fishing in the Trust Lands of the Southern Tribes

Both MICSA and MIA make it clear that the land acquisition fund for the benefit of the Passamaquoddy and Penobscot Tribes was established to ensure these Tribes not only had a land base to occupy, but also access to natural resources to sustain their continued existence as a unique culture, including their ability to exercise their fishing rights. "The Secretary is authorized and directed to expend . . . the land acquisition fund for the purpose of acquiring land or natural resources for the Passamaquoddy Tribe, [and] the Penobscot Nation . . . and for no other purpose." 25 U.S.C. § 1724(b) (emphasis added). "Land or natural resources" are defined to include "water and water rights, and hunting and fishing rights." 25 U.S.C. § 1722(b).[9]

As excerpted more fully above, MICSA's legislative history also makes it clear that the Southern Tribes would be engaged in sustenance fishing in the newly-acquired trust lands:

> Under Title 30, Sec. 6207 as established by the Maine Implementing Act, the Passamaquoddy Tribe and the Penobscot Nation have the permanent right to control hunting and fishing not only within their reservations, but insofar as hunting and fishing in certain ponds is concerned, in the newly-acquired Indian territory as well.

Sen. Rep. No. 96-957, pp. 16-17 (emphasis added). The legislative history of MIA also makes it clear that the Maine Legislature understood that MIA was designed to accommodate sustenance fishing practices in the Southern Tribes' trust lands. See transcript of the public hearing held on March 28, 1980 by the Maine Legislature's Joint Select Committee on the Maine Indian Claims Settlement at 151-152.[10] So it is clear that in creating the authority to take land into trust for the Southern Tribes, Congress understood that MIA made provision for the Tribes to engage in sustenance fishing in those trust lands and intended the trust lands to provide a base for the Tribes to engage in sustenance practices.

As recognized by Congress in MICSA's legislative history, the Southern Tribes' control of fishing in certain trust waters was specifically codified in MIA. Section 6207(1) provides that

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[9] Unlike MICSA, when MIA refers to Penobscot and Passamaquoddy trust lands, it uses the term "land acquired by the secretary [of Interior] for the benefit" of each tribe, without reference to natural resources. Compare 25 U.S.C. § 1724(d) with 30 M.R.S. § 6205(1)(B) and (2)(B). As explained in the section above, other provisions of MIA make it clear that the statute anticipated that those lands would include the attendant natural resources acquired with the land, especially fishing rights. Moreover, to the extent that this differing terminology suggests a conflict between MICSA and MIA in defining the scope of the tribes' interest in their trust lands and natural resources, the provisions of MICSA would control. 25 U.S.C.
§ 1735(a).

[10] "[The Tribes can adopt ordinances with respect to . . . fishing but only on ponds of less than ten acres in size. Those ordinances have to be equally applicable to Indians and non-Indians except that the Indians can make special provisions for sustenance hunting . . ." and fishing per MIA § 6207(1). Id. at 151.

the Southern Tribes have exclusive authority to enact ordinances regulating the taking of fish on ponds of less than ten acres in their trust lands. As with the Southern Tribes' fishing right in their reservations, this authority is subject only to the State's authority to limit the take after carrying the burden of proof that the Tribes are depleting fish stocks. MIA specifically anticipates that any tribal ordinances regulating fishing in these waters "may include special provisions for the sustenance of the individual members of the Passamaquoddy Tribe or the Penobscot Nation." *Id.*

As to greater ponds and rivers and streams in or along the Southern Tribes' trust lands, MIA also codifies the understanding that the Tribes would be engaged in sustenance fishing in those waters. MIA creates the Maine Indian Tribal-State Commission (defined as the "commission" 30 M.R.S. § 6203(1)), made up of representatives appointed by the State and the Southern Tribes. 30 M.R.S. § 6212. MIA provides that commission the exclusive authority to promulgate fishing rules in these waters. When it does so "the commission shall consider and balance" several factors, including "the needs or desires of the Tribes to establish fishery practices for the sustenance of the tribes or to contribute to the economic independence of the tribes, [and] the traditional fishing techniques employed by and ceremonial practices of Indians in Maine." 30 M.R.S. § 6207(3). Importantly, as analyzed in the record supporting this decision, none of the fishing regulations adopted by the commission would impinge on the ability of the Tribes to sustain themselves on fish taken from these waters.[11]

MICSA and MIA combine to authorize the establishment of trust lands for the Southern Tribes to provide a land base in which the Tribes can exercise their sustenance fishing practices. As compared with the sustenance fishing right reserved to the Southern Tribes within their reservations, MICSA and MIA allow for a greater, although still sharply limited, role for the State, through the commission, to participate in the development of fishing regulations on certain of the waters in the trust lands. But in exercising even that authority, the commission is charged with considering the Tribes' sustenance fishing practices. Therefore, it is clear that a critical purpose behind establishing the Southern Tribes' trust lands is to give the Tribes an opportunity to engage in sustenance fishing.

3.3.1.2.2 Sustenance Fishing in the Trust Lands of the Northern Tribes

Compared with the Southern Tribes' territories, the arrangement for the Northern Tribes' trust lands provides for more direct state regulation of fishing practices. Nevertheless, it appears Congress intended these trust lands to preserve the Northern Tribes' unique cultures as well. So the Northern Tribes' trust lands provide a land base in which the Tribes are able to exercise sustenance fishing practices to the extent consistent with the legal limits on their fishing. Again, similar to the situation for the Southern Tribes' trust lands, EPA is not concluding that there is an aboriginal fishing right reserved to the Northern Tribes on their trust lands. But the Agency does conclude that there is sufficient evidence in the legislative record to indicate that Congress intended the Northern Tribes to engage in sustenance practices on their trust lands to the extent they could.

[11] See memorandum from Ralph Abele to the file for this decision, regarding Effects of Maine Fishing Regulations on Sustenance Fishing by Maine Tribes, dated January 30, 2015.

Authority to establish the Northern Tribes' trust lands came in several rounds of legislation. The first involved the Maliseets, who came to the negotiations around MIA and MICSA late in the legislative process. In 1980, MICSA provided that "[t]he Secretary is authorized and directed to expend . . . the land acquisition fund for the purpose of acquiring land or natural resources for the . . . the Houlton Band of Maliseet Indians and for no other purpose." 25 U.S.C. § 1724(b) (emphasis added). "Land or natural resources" is defined to include "water and water rights, and hunting and fishing rights." 25 U.S.C. § 1722(b) (emphasis added).

At the time Congress authorized land to be taken into trust for the Maliseets, it specifically acknowledged that "[a]ll three tribes [Penobscot, Passamaquoddy and Maliseet] are riverine in their land-ownership orientation." Sen. Rep. No. 96-957, at 11. Congress also specifically noted that one purpose of MICSA was to avoid acculturation of the Maine Tribes:

> *The Settlement will lead to acculturation of the Maine Indians.* – Nothing in the settlement provides for acculturation, nor is it the intent of Congress to disturb the cultural integrity of the Indian people of Maine. To the contrary, the Settlement offers protections against this result being imposed by outside entities by providing for tribal governments which are separate and apart from the towns and cities of the State of Maine and which control all such internal matters. The Settlement also clearly establishes that the Tribes in Maine will continue to be eligible for all federal Indian cultural programs.

Id. at 17. Congress's purpose in providing for the establishment of the Maliseet trust lands was to provide a land base on which the Tribe could maintain its "cultural integrity." The Maliseets have submitted extensive comments documenting the sustenance fishing practices central to the Tribe's culture.

In 1981, the Maine Legislature added provisions to MIA to correspond to the action Congress took in MICSA to recognize the Maliseets and authorize trust lands to provide a resource base for the Tribe. In contrast to MIA's language describing the Southern Tribes' trust lands, the statute explicitly defines the Maliseet trust lands to include natural resources. 30 M.R.S.A §§ 6203(2-A) ("'Houlton Band Trust Land' means land or natural resources acquired by the secretary in trust for the Houlton Band of Maliseet Indians . . .."); see also § 6205-A ("Land or natural resources" may be taken into trust for the Maliseets). As in MICSA, MIA makes it clear that natural resources acquired for the Maliseets may include fishing rights. *Id.* at § 6203(3) ("'Land or other natural resources' means any real property or other natural resources . . . including, but without limitation, . . . water and water rights and hunting and fishing rights.")

It was not until 1989 that the Micmacs negotiated a settlement with Maine as codified in the MSA. Similar to the settlement with the Maliseets, MSA provides that the Micmacs' trust lands include natural resources. 30 M.R.S. § 7202(2) ("'Aroostook Band Trust Land' means land or natural resources acquired by the secretary in trust for the Aroostook Band of Micmacs . . .."). MSA further defines natural resources to include fishing rights. *Id.* at § 7202(3) ("'Land or other natural resources' means any real property or other natural resources . . . including, but without limitation . . . water and water rights and hunting and fishing rights.")

In 1991, Congress passed ABMSA, one key purpose of which was to ratify the MSA. ABMSA § 1(b)(4). Congress specifically found and declared that:

> It is now fair and just to afford the Aroostook Band of Micmacs the same settlement provided to the Houlton Band of Maliseet Indians for the settlement of that Band's claims, to the extent they would have benefited from inclusion in the Maine Indian Claims Settlement Act of 1980.

Id. at § 1(a)(5). To that end, Congress established the Aroostook Band of Micmacs Land Acquisition Fund, *id.* at § 4(a), and provided that:

> the Secretary is authorized and directed to expend, at the request of the Band, the principal of, and income accruing on, the Land Acquisition Fund for the purposes of acquiring land or natural resources for the Band and for no other purposes. Land or natural resources acquired within the State of Maine with funds expended under the authority of this subsection shall be held in trust by the United States for the benefit of the Band.

Id. at § 5(a). ABMSA defines "Band Trust Land" to mean "land or natural resources acquired by the Secretary of the Interior and held in trust by the United States for the benefit of the Band" and defines "land or natural resources" to mean "any real property or natural resources, or any interest in or right involving any real property or natural resources, including (but not limited to) . . . water and water rights, and hunting and fishing rights." *Id.* at § 3(3) and (4). As with the Maliseets, Congress clearly intended that the Micmacs' trust lands could encompass fishing rights.

The Senate conference report from the Select Committee on Indian Affairs on ABMSA indicates that Congress intended to remedy the plight of the Micmacs, who had been deprived of a land base on which to secure the Tribe's continuation as a unique culture. "As Maine's only Native American community without a tribal land base, the Aroostook Band of Micmacs faces major challenges in its quest for cultural survival." 102 S. Rpt 136 (1991). The report describes the cultural practices of the band, including its historic homeland range along the west bank of the St. John River. "The ancestors of the Aroostook Micmac made a living as migratory hunters, trappers, fishers and gatherers until the 19th century." It goes on to note that "[t]oday, without a tribal subsistence base of their own, most Micmacs in Northern Maine occupy a niche at the lowest level of the social order." The discussion of the Band's history ends by observing:

> It is remarkable that the Aroostook Band of Micmac Indians, as a long disenfranchised and landless native group, has not withered away over the centuries. To the contrary, this community in Northern Maine has demonstrated an undaunted collective will toward cultural survival.

As with the Maliseets, it is clear Congress intended to establish a land base for the Micmacs that would enable the Tribe to secure its "cultural survival" and avoid acculturation. Congress intended for the Northern Tribes' trust lands to provide a "subsistence base" on which the Tribes

could assure their continued existence as a unique culture. And Congress was aware that part of that subsistence base for the Northern Tribes was their sustenance fishing practices.

While Congress intended that the Indian lands in Maine provide a land base to support all the Tribes' sustenance practices, it ratified dramatically different regulatory frameworks within which the Southern and Northern Tribes could operate in exercising those practices. In their reservations and lesser ponds in their trust lands, the Southern Tribes are substantially free from state fishing regulations, and elsewhere in their trust lands any regulation of the Southern Tribes' fishing must consider their sustenance practices. As explained in the discussion of the State's jurisdictional authority above, the Northern Tribes and their trust lands are subject to the laws of the State, including the regulation of natural resources, which includes fishing rights. So unlike the Southern Tribes, the ability of the Northern Tribes to exercise their sustenance fishing practices is potentially subject to regulation directly under state law. As DOI's legal opinion explains, the Northern Tribes' trust lands include fishing rights appurtenant to those land acquisitions, which are subject to state regulation.

But this jurisdictional arrangement does not alter the fact that Congress established the Northern Tribes' trust lands for the purpose of providing these Tribes a land base on which to exercise their sustenance practices to the extent possible. Finding that state law applies to the Northern Tribes' fishing rights does not answer the question how those Tribes intend to use the waters on their trust lands consistent with the purpose of setting aside their land base. And the state law applicable to the Northern Tribes' fish take makes it clear that there are generous take limits that allow a catch sufficient to support sustenance fishing. As analyzed in the review of state fishing regulations supporting this decision, it appears state fishing regulations applicable to the Northern Tribes' trust lands do not impose limits that would prevent individual members of the Northern Tribes from taking fish sufficient to support a sustenance diet.[12] Further, under state law, the Department of Inland Fisheries and Wildlife has authority to set take limits on fisheries for the purposes of their preservation, protection, enhancement and use as well as the propagation of fish for the effective management of inland fisheries resources in public waters of the State. 12 M.R.S. § 10053.[13] While this regulatory process does not include the same kind of procedural and burden of proof protections MIA provides for the Southern Tribes' fishing rights, it still requires the State to have a legitimate, non-arbitrary reason for limiting the take in the Northern Tribes trust lands based on the need to preserve and protect state fisheries. So as provided under state law, there appears to be ample ability for the Northern Tribes to fish for their sustenance in tribal waters associated with their trust lands.

3.3.1.3 Passamaquoddy Marine Sustenance Fishing

The Passamaquoddy Tribe's Pleasant Point reservation is located on marine, not inland, waters. There is a dispute among the Tribe, the State, and the commission about whether the Tribe's aboriginal right to take fish in marine waters survived the passage of MICSA. See 25 U.S.C. §§ 1722(b) and 1723(b) and Assessment of the Intergovernmental Saltwater Fisheries Conflict between Passamaquoddy and the State of Maine, Maine Indian Tribal-State Commission: Special

[12] See memorandum from Ralph Abele to the file for this decision, regarding Effects of Maine Fishing Regulations on Sustenance Fishing by Maine Tribes, dated January 30, 2015.

[13] See memorandum from Greg Dain, re: Maine Fishing Regulation, December 23, 2014.

Report 2014/1 (June 17, 2014) at 7. EPA is taking no position at this time as to the Tribes' aboriginal rights to take fish in marine waters or the scope of the sustenance fishing right codified in MIA section 6207 in marine waters. Nonetheless, the marine waters that are part of the Pleasant Point reservation serve a function in supporting the sustenance of the Tribe identical to the inland waters in the Tribe's reservation and trust lands.

First, Congress understood that the Passamaquoddy Tribe exercised subsistence practices on its reservations, including the Pleasant Point Reservation. The Senate Report's discussion of Special Issues noted that "[p]rior to the settlement, Maine law recognized the Passamaquoddy Tribe's and Penobscot Nation's right to control Indian subsistence hunting and fishing within their reservations, but the State of Maine claimed the right to alter or terminate these rights at any time." As quoted more extensively above, the Senate Report then goes on to describe in detail MIA's provisions for the reserved sustenance fishing right of the Southern Tribes. Sen. Rep. No. 96-957 at 16-17. While some dispute whether the Southern Tribes' sustenance fishing extends into marine waters, at a minimum Congress understood that the Passamaquoddy Tribe fished for its sustenance on its reservation and that the State had accommodated that practice under state law.

Notably, Maine has continued its practice of recognizing and providing for the Passamaquoddy Tribe's sustenance marine fishing practices under state law. In 2013, the State codified a "tribal exemption" from otherwise applicable state fishing regulation of marine species for all four Indian Tribes in Maine to exercise a "sustenance use if the tribal member holds a valid sustenance fishing license issued by the tribe, nation or band . . .." That same subsection goes on to define "sustenance use" as:

> . . . all noncommercial consumption or noncommercial use by any person within Passamaquoddy Indian territory, as defined in Title 30, section 6205, subsection 1, Penobscot Indian territory, as defined in Title 30, section 6205, subsection 2, or Aroostook Band Trust Land, as defined in Title 30, section 7202, subsection 2, or Houlton Band Trust Land, as defined in Title 30, section 6203, subsection 2-A, or at any location within the State by a tribal member, by a tribal member's immediate family or within a tribal member's household.

12 M.S.A. § 6302-A(2)(emphasis added). This section imposes seasonal limits on the taking of sea urchins and limits on the number of lobster traps used to harvest lobsters for sustenance use. But it is a clear acknowledgement of and provision for the Passamaquoddy Tribe to take marine species for their sustenance "within Passamaquoddy Indian territory" as defined in MIA, which includes the Tribe's reservations.

Again, EPA acknowledges that there is a current dispute about the extent of the State's authority to regulate the Tribes' marine fishing practices. In citing section 6302-A, EPA does not take a position on the merits of that dispute. EPA is concluding, however, that even if EPA accepts the State's position on its ability to regulate the Passamaquoddy Tribe's marine fishing practices, state law makes ample provision for sustenance fishing on the Tribe's reservation. Therefore, as with the Northern Tribes' trust lands, even if the State has authority to regulate the Tribe's take of marine species, EPA concludes that one important purpose of the Tribe's reservation is to