Northwest Pulp and Paper Association

Summary of Health Risk Assessment Decisions in Environmental Regulations

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Danielle Pfeiffer

Danielle Pfeiffer
Technical Expert

Paul D. Anderson
National Expert

Prepared for:

Northwest Pulp & Paper Association

Prepared by:

ARCADIS U.S., Inc.
Tel 978 322 4504

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Acronyms and Abbreviations

CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CWA	Clean Water Act
DBCP	dibromochloropropane
FFDCA	Federal Food, Drug and Cosmetic Act
g/day	grams per day
HHWQC	Human Health Water Quality Criteria
HQ	hazard quotient
LFC	lowest feasible concentration
LoREX	low release and exposure
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
mg/L	milligrams per liter

mg/yr	milligrams per year
MTCA	Model Toxics Control Act
NCEL	New Chemical Exposure Limit
NIOSH	National Institute of Occupational Safety and Health
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
PCB	polychlorinated biphenyls
PEL	Permissible Exposure Limit
REL	Recommended Exposure Limit
RfD	reference dose
SDWA	Safe Drinking Water Act
THM	trihalomethane
TSCA	Toxic Substances Control Act
TWA	time weighted average
USEPA	United States Environmental Protection Agency
USFDA	United States Food and Drug Administration

Summary of Health Risk Assessment Decisions in Environmental Regulations

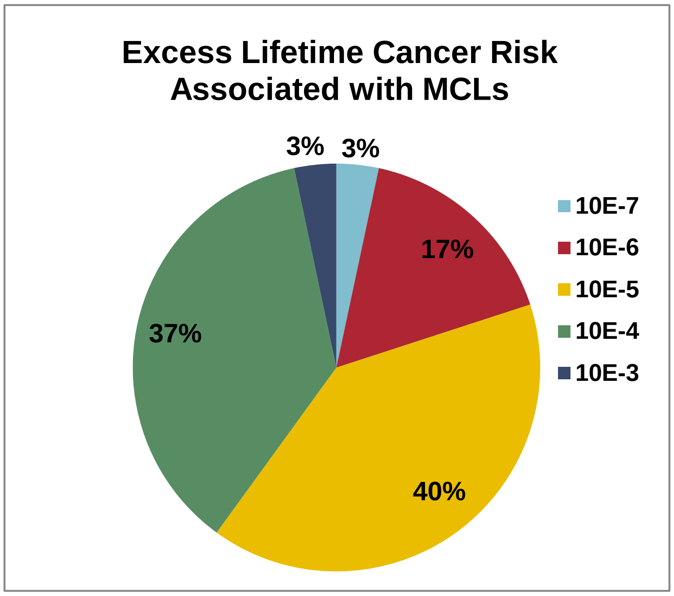
Executive Summary

This white paper provides perspective on how we protect human health through the choices reflected in environmental regulations. Limits on the concentrations of chemicals in the environment reflect a combination of science and policy. Regulators estimate the risks to human health from exposure to chemicals and then decide, as a matter of policy, what level of risk is acceptable. Those decisions are multi-faceted and reflect many smaller choices about both how to apply scientific knowledge and our values as a society. Wise choices must consider such decisions within the broader context of all the sources of risks to our health and the consequences of over-regulation.

Laying the groundwork: risk assessment concepts

Regulators estimate the potential risks to human health from exposure to chemicals in the environment by considering two factors: toxicity and exposure. The amount of a chemical to which people are exposed depends on how much of the chemical is in the air, water, soil, or food. It also depends on the amount of contact that people have with those media. The degree of contact – for example, the amount water that people drink or the amount of fish that people eat – can vary widely between people. Whether assessing the possible risks from environmental exposure or in setting limits on the acceptable concentrations in environmental media, regulators must decide what assumptions to make about the degree of exposure.

The risk of getting cancer from a lifetime of exposure to a carcinogenic chemical is expressed as a probability of developing cancer above and beyond the background risk that already exists, also known as the excess lifetime cancer risk. A $1\text{x}10^{-4}$ risk (or 1E-04) is a one in ten thousand chance of getting cancer over and above the background risk assuming a lifetime of exposure; a $1\text{x}10^{-6}$ risk (or 1E-06) is a one in a million chance. These risk levels represent the upper bound probability that an individual exposed to the chemical in the environment will develop cancer as a result of that exposure.



Putting risks into perspective

The debate over Human Health Water Quality Criteria (HHWQC) in Washington concerns in part the level of acceptable risk. Washington chose $1\text{x}10^{-6}$ as the acceptable risk level for all carcinogenic chemicals except Polychlorinated biphenyls (PCBs)[1]. USEPA proposes to use the same acceptable risk level (1×10^{-6}) and apply it to PCBs as well, even though a cancer risk level of 1×10^{-5} is consistent with USEPA's 2000 Methodology (USEPA 2000) and the level Idaho relied on to derive the USEPA approved Idaho HHWQC (USEPA 2019). This white paper discusses three factors that bear on this debate.

1. Acceptable risk from exposure to chemicals in the environment

Various statutes and associated regulations define acceptable risks differently. Standards set under the Occupational Safety and Health Act to protect workers on the job reflect an excess lifetime cancer risk on the order of 1×10^{-3}. The limits on the concentrations of chemicals in our drinking water at the Maximum Contaminant Levels (MCLs) allowed reflect a range of excess lifetime cancer risks as depicted in the pie chart. Regarding HHWQC, the United States Environmental Protection Agency (USEPA) says this (USEPA 2000):

> *EPA also believes 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} level.*

USEPA's decision to consider the tribal populations as the general population (USEPA 2015) coupled with their current proposal to base Washington's HHWCC on 10^{-6}, results in a level of protection that is one hundred times greater than envisioned by USEPA's own guidance.

2. Comparison between risk of cancer from environmental exposure to regulated chemicals and risk of cancer from all causes.

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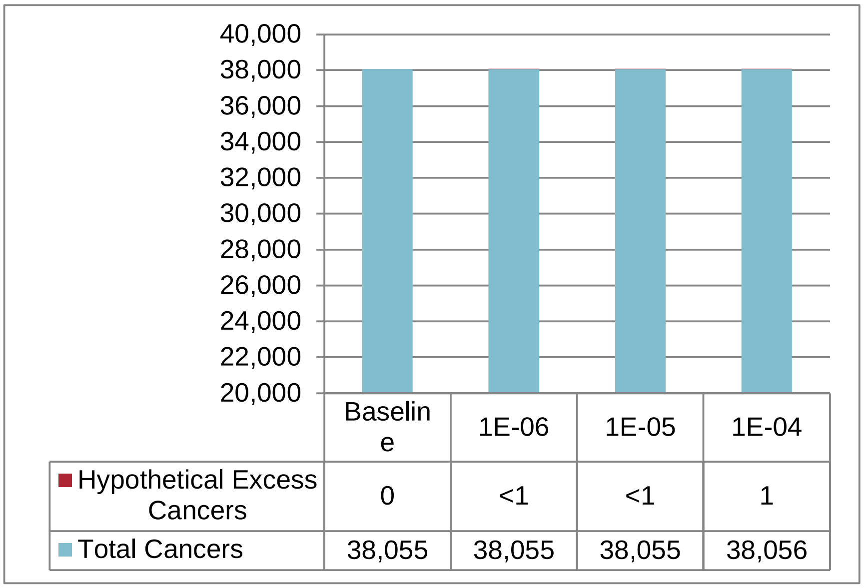
[1] For PCBs, Washington's criteria were based on a chemical-specific cancer risk level of 2.3×10^{-5}.

The risk of cancer from all causes far outweighs the possible risk of cancer from exposure to chemicals in the environment. The figure to the right shows how these risks translate to an estimated number of cancer occurrences per year in Washington State[2]. Compared to total cancer incidence in Washington, the increase in cancers associated with the excess lifetime cancer risks between $1x10^{-4}$ and $1x10^{-6}$ are far smaller (on the order of a thousandth of percent at an allowable excess lifetime cancer risk of $1x10^{-4}$ or less) than other causes of cancer. This finding is consistent with the comparisons of mortality risk associated with various allowable risk levels to mortality risk from various activities that are part of everyday life, as discussed below.



	Baseline	1E-06	1E-05	1E-04
🟥 Hypothetical Excess Cancers	0	<1	<1	1
🟦 Total Cancers	38,055	38,055	38,055	38,056

3. Comparison between risk of cancer from environmental exposure and everyday risks

We face risks every day. When risk assessors want to be able to compare the relative risks from various activities, they sometimes describe those risks in terms of “micromorts”. A micromort is an activity that typically occurs over time or distance which presents a risk of $1x10^{-6}$ (one in one million). As illustrated below, we routinely accept – whether we realize it or not – risks that far exceed an excess lifetime cancer risk of $1x10^{-4}$ to $1x10^{-6}$. The average American faced an unintentional injury-related mortality risk of approximately 610 micromorts per year in 2020, or 1.7 micromorts per day. In the U.S. population of 329 million people, the unit of 1.3 micromorts per day means that about 559 people die each day from an unintentional injury. This means that every day, every American has a risk of slightly greater than $1x10^{-6}$ of dying from unintentional injury. This every day, accepted risk provides context for discussions about protecting the general population and highly exposed subgroups.

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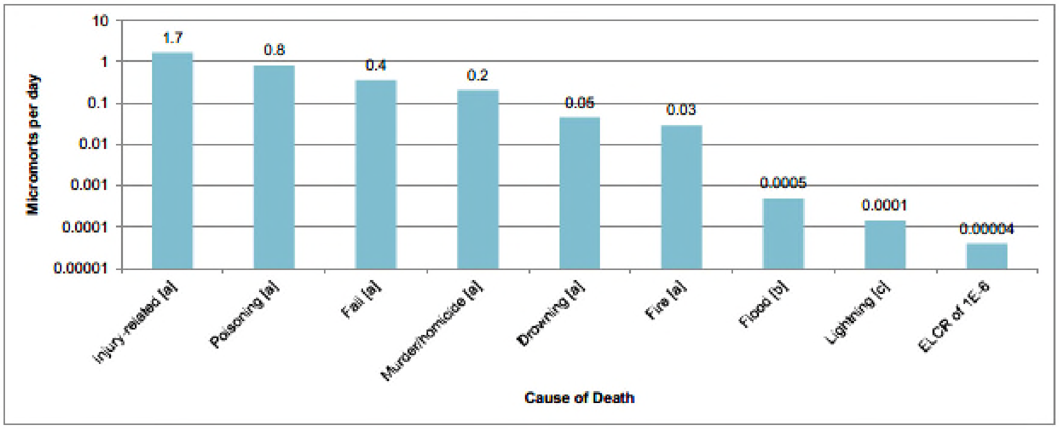
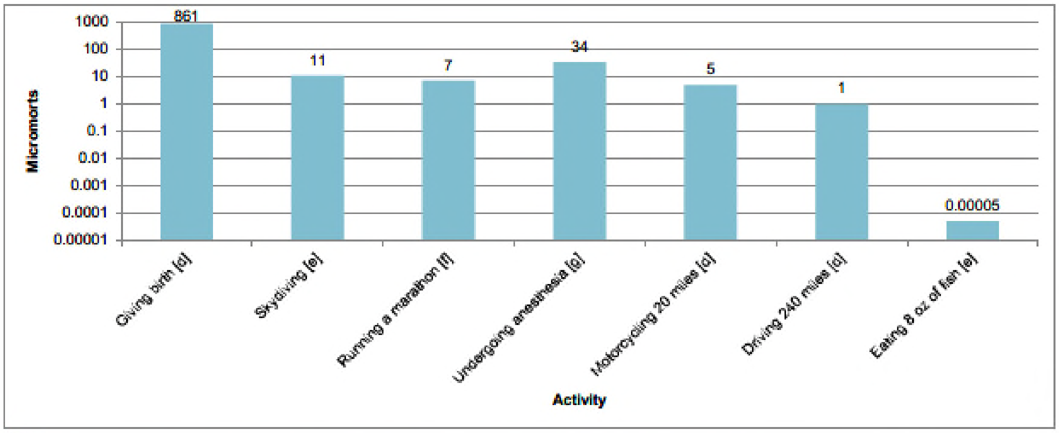
[2] Note that in order to make the hypothetical excess cancers visible on the bar graph, the Y axis was set to start at 20,000 rather than 0.





Notes:

[a] NCHS Vital Statistics System for numbers of deaths. Bureau of Census for population estimates via WISQARS (2020)

[b] NOAA (2020a)

[c] NOAA (2020b)

(d) Hoyert (2020)

(e) United States Parachute Association (2020)

[f] Blastland and Spiegelhalter (2014)

(g) Guohua et al. (2009)

[e] Assuming organism-only AWQC are based on a fish consumption rate of 175 grams per day and risk level of $1x10^{-6}$.

Assumptions underlying risk characterization

Risk assessors must make many assumptions to estimate the possible risks from exposure to chemicals in the environment. These include assumptions about the degree of exposure. Assumptions about the amount of fish Washingtonians eat each day are particularly critical to the discussion about HHWQC though many other assumptions are important as well.

Outdated basis for the fish consumption rate of 175 g/day.

The proposed criteria for carcinogenic and non-carcinogenic chemicals assume that citizens in Washington State, specifically Native Americans, consume 175 grams per day (g/day) of fish. This fish consumption rate was derived from Columbia River Inter-Tribal Fish Commission (CRITFC) fish consumption rate survey (CRITFC 1994) using survey methods that have been shown to not represent the true, long-term fish consumption rate as now defined by USEPA and referred to as the usual fish consumption rate (UFCR) by USEPA (2014A), The State of Washington has reviewed and summarized a range of fish consumption rates developed using both the older survey methods and the newer National Cancer Institute (NCI) methodology (Tooze et al., 2006; Tooze et al., 2010) used by USEPA (2014A) and others to derive UFCRs representative of long-term fish consumption. The NCI method is currently believed to be the state-of-the-art approach for conducting dietary intake surveys, including consumption of fish. Per USEPA (2014A), "*the NCI Method is preferred because it accounts for days without consumption; distinguishes within-person from between-person variation; allows for the correlation between the probability of consumption and the consumption-day amount; and can use covariate data to better predict usual intake*". Idaho considered these survey results in developing its new and revised state HHWQC (Idaho 2016). These more recent estimates derived by the newer NCI methodology show that the fish consumption rate of 175 g/day used in the proposed HHWQC for carcinogenic and non-carcinogenic chemicals is based on an outdated survey methodology that overstates the long-term fish consumption rate of the general population and tribal populations (as shown below) and is no longer an appropriate method to use to derive HHWQC.

Population	Method	50%	Mean	75%	90%	95%	99%
Nez Perce[1]	Food Frequency Questionnaire	70.5	123	---	270	437	796
Nez Perce[1]	NCI	49.5	75.0	---	173	232	---
Shoshone Bannock[1]	Food Frequency Questionnaire	74.6	158	---	392	603	1058
Shoshone Bannock[1]	NCI	14.9	34.9	---	94.5	141	---
General Population[2]	Short-term consumption survey data	37.9	56	78.8	128	168	---
General Population[2]	NCI	12.7	18.8	24.8	43.3	56.6	--=

[1] Polissar et al. (2016).

[2] National Survey: NHANES 2003–2006, Adult Respondents, values as reported in Ecology (2013)

Compounded conservatism

Water quality criteria based on a high-end fish consumption rate (e.g., 175 g/day) and an excess lifetime cancer risk of 1×10^{-6} present a risk that is far more protective than the acceptable range as defined by USEPA (2000) for both the general population and highly exposed subpopulations, such as Native Americans. Why? Because conservative assumptions add up. If a decision maker chooses a conservative value for every variable in a risk calculation, the results will be far more protective than intended. Consider the hypothetical example of a risk assessment that is based on three independent and log-normally distributed parameters. In the case of a fish consumption calculation, those parameters might be the amount of fish eaten each day, the source of the fish, and the number of years over the course of a lifetime that people live in a certain place and eat fish from a local source. Each value represents the 95th percentile, or in other words that 9,500 out of 10,000 people have a lower exposure: they eat less fish, do not only eat fish from local waters, or do not eat local fish for their entire life, for example. Combining those three variables would result in a risk estimate that would fall at the 99.78th percentile of the resulting distribution. The risk to 9,978 out of 10,000 people would be lower than the allowable risk level used to establish the standard. So, if 1×10^{-6} was selected as the allowable risk level for a criterion based on those assumptions, 9,978 people would have a risk less than 1×10^{-6} and only 22 would have a risk greater than 1×10^{-6}. Decisions made on the basis of this hypothetical calculation, which compounds conservative factors, are far more protective than intended if the goal was to protect the average member of the population (or the 90th percentile or even the 95th percentile of the population) at the selected allowable risk level. Additionally, USEPA's proposed criteria go beyond the type of compounded conservatism of exposure assumptions described above and designate Native Americans as the general population and then apply acceptable risk levels previously used for the general population to the Native American subpopulation. The effect of this designation is to add an additional level of conservatism such that the general population and high-end consumers such as Native Americans, are protected at levels far greater than required by USEPA guidance cited above (2000).

This may look like an academic calculation. Some readers may think that overestimating risks is a good thing because it allows us to be extra-cautious, and that regulatory decisions based on risk estimates should be as conservative and protective as possible. But the consequences of such choices also need to be considered. There's a cost to reducing the levels of chemicals in the environment to meet more-stringent limits, a cost that may be measured in dollars, energy usage and therefore carbon dioxide (CO2) emissions exacerbating climate change, or the risk of injury to workers who have the job of reducing the levels of those chemicals. Chemicals may be used to treat wastewater to meet lower standards, for example, and the sludge that results has to be trucked to a landfill or incinerated. Generating the power used to operate the wastewater treatment plant uses natural resources and creates air emissions. Each of these aspects of the life cycle of wastewater treatment operations, and their related risks, should be weighed against the value of regulatory decisions based on the combination of several conservative assumptions, referred to as compounded conservatism. In addition, although more difficult to qualify, communicating overestimated risks to the public can lead to unnecessary psychological stress in community members that can contribute to real (as opposed to predicted) adverse human health effects (USEPA 2003).

Compounding conservative values for multiple variables (including a high fish consumption rate, long duration of residence, and upper percentile drinking water rate) to estimate risks with a low target excess lifetime cancer risk will have an unintended consequence. It will result in HHWQC that are far more protective of the vast majority of the population than reflected by the target excess lifetime cancer risk. That additional degree of protection must be weighed against the risks and environmental impacts, as well as increased public utility treatment costs borne by ratepayers and financial implications on private industry, that would result from the additional treatment needed to meet such criteria.

Health Benefits of fish consumption

Risk managers should also consider how the risks incurred from eating fish compare to the benefits gained. Researchers and public health officials have been aware for several decades that consumption of fish has associated with it many benefits (specifically the reduced risk of mortality from coronary heart disease). Recent expert reviews and regulatory agency recommendations continue to urge that people regularly consume fish. In fact, it is recommended that the general population eat 1 to 2 fish meals per week and that pregnant women eat 2 to 4 meals per week because of the benefits to the infants they are carrying (EFSA 2014). Such benefits almost always outweigh the possible risks of chemical exposure.

1. Risk assessment concepts

This section provides some background information relevant to the topics discussed in this white paper. It begins with a general discussion of how both cancer and non-cancer risks are evaluated by the United States Environmental Protection Agency (USEPA) (Section 1.1). It then puts those risks into perspective by describing what risk assessment conclusions mean with respect to an individual or a larger group of people, and how cancers resulting from exposure to chemicals in the environment, if they occur, compare to the general incidence of cancer (Section 1.2).

1.1 Evaluation of cancer and noncancer health endpoints

Risk generally depends on the following factors (USEPA 2012A):

- Amount of exposure, that depends on:
  - How much of a chemical is present in an environmental medium, such as soil, water, air, or fish;
  - How much contact (exposure) a person has with the environmental medium, containing the chemical; and
  - The toxicity of the chemical.

Scientists consider two types of toxic effects, cancer and noncancer, when they assess the possible risks to human health from exposure to chemicals in the environment. The ways in which most United States regulatory agencies evaluate these risks differ because of one fundamental assumption, that the human body can tolerate some low dose of a chemical that causes harm other than cancer but that no dose of a carcinogen (a chemical that may cause cancer) is entirely safe.

Chemicals that may cause cancer – or, in scientific terminology, those with a carcinogenic endpoint – are, with a very few exceptions, conservatively assumed to have some probability of causing an adverse health effect (cancer) at any dose, by typical regulatory risk assessment practice. There is no safe dose. Thus, *any* exposure to a chemical believed to cause cancer has associated with it a risk.

Scientific Notation

One in a million is the same as…
1 in 1,000,000 or
1/1,000,000, or
0.000001, or
1×10^{-6}, or
1E-6, or
0.0001%

Carcinogenic risk is expressed as a probability of developing cancer as a result of a given level of exposure over a lifetime (USEPA 1989) above and beyond the background risk that already exists. This additional risk of getting cancer associated with exposure to chemicals is often referred to as the excess lifetime cancer risk. The excess lifetime cancer risk is usually described in scientific notation. A 1×10^{-4} risk (or 1E-04) is a one in ten thousand chance of getting cancer over and above the background risk assuming a lifetime of exposure; a 1×10^{-6} risk (or 1E-06) is a one in a million chance. These risk levels represent the upper bound probability that an individual exposed to the chemical in the environment will develop cancer as a result of that exposure. It's important to note that the probability pertains to the risk of getting cancer, not the risk of dying from cancer. These probabilities apply only to people who are exposed to the chemicals under the conditions and to the extent that was assumed in estimating the risk. (Typically, these risk levels correspond to 70 years of exposure and represent the risk over an entire lifetime.) It is also important to recognize that these are upper-bound estimates of risk that depend on numerous assumptions. The actual risks are expected to be lower and may even be zero (USEPA 1986). Public health policy makers must choose some "acceptable" excess lifetime cancer risk (also referred to in this white paper as an allowable risk) when developing limits for chemicals in the environment.

Chemicals that cause non-cancer adverse health effects are assumed to have some threshold dose below which no adverse health effects are expected to occur. In other words, test data show that there is a safe (or allowable) dose. Scientists use the hazard quotient (HQ) to indicate the degree of risk from exposure to a noncarcinogenic chemical:

HQ = (estimated exposure or dose) / (allowable dose).

An HQ of less than or equal to one indicates that the estimated exposure is less than or equal to the allowable dose (referred to by the USEPA as a reference dose or RfD) and that no adverse health effects are expected, even over a lifetime of continuous exposure. In other words, such exposures are considered safe. An HQ of greater than one indicates that estimated exposure is greater than the RfD. An exceedance of the RfD indicates that the potential exists for an adverse health effect to occur. However, because of the multiple conservative assumptions used to estimate exposures and to derive RfDs, an HQ somewhat greater than one is generally not considered to represent a substantial public health threat. The USEPA has offered this perspective (USEPA 1996):

> *Because many reference [doses] incorporate protective assumptions designed to provide a margin of safety, a hazard quotient greater than one does not necessarily suggest a likelihood of adverse effects. A hazard quotient less than one, however, suggests that exposures are likely to be without an*

> *appreciable risk of noncancer effects during a lifetime. Furthermore, the hazard quotient cannot be translated into a probability that an adverse effects [sic] will occur, and is not likely to be proportional to risk. A hazard quotient greater than one can be best described as only indicating that a potential may exist for adverse health effects.*

The United States Department of Health and Human Services (2013) provides further perspective:

> *If the hazard quotient exceeds unity, the toxicant may produce an adverse effect but normally this will require a hazard quotient of several times unity; a hazard quotient of less than one indicates that no adverse effects are likely over a lifetime of exposure.*

In short, while an HQ less than one provides substantial certainty that exposure will not result in a risk, exposure that results in an HQ of somewhat greater than one (even up to several times one) is also unlikely to result in an adverse effect. An HQ of 1.0 was used to derive the proposed HHWQC for non-carcinogenic chemicals.

1.2 Perspective on cancer risks

The excess lifetime cancer risk that may occur as a result of exposure to a carcinogen in the environment, as described above, is the excess risk above and beyond the background risks that we all face. The Center for Disease Control and Prevention provides perspective on background risks. It estimates that in 2018, 1,708,921 new cancer cases were diagnosed in the United States and 599,265 people died of cancer. These numbers include 38,055 new diagnoses and 12,791 deaths in the state of Washington. **Table 1** summarizes the incidence of invasive cancer in the United States and in the state of Washington in 2018.

Table 1 Incidence of Cancer in 2018, from all causes

Geography	Cancer Cases Diagnosed in 2018*	Estimated Population in 2018**	Annual Cancer Incidence Rate
U.S. (national)	1,708,921	326,687,501	$5.3\text{x}10^{-3}$
Washington State	38,055	7,523,869	$5.06\text{x}10^{-3}$
Washington State (tribal population)	163	174,111	$9.3\text{x}10^{-4}$

* Center for Disease Control and Prevention 2018.

** U.S. Census Bureau 2018.

As the data in Table 1 show, a person living in the United States has about a 5/1,000 chance ($5.3\text{x}10^{-3}$), *per year*, equal to about a 3.7 in 10 chance (37%) over a 70-year lifetime (5.3 times 70 years divided by 1,000), of being diagnosed with cancer and a member of the tribal population living Washington has about a

9/10,000 chance ($9.3x10^{-4}$), per year, equal to 0.6 in 10 chance (6%) over a 70-year lifetime if being diagnosed with cancer (9.3 times 70 years divided by 10,000). In contrast, many regulatory agencies believe that an "acceptable" excess lifetime cancer risk that should be used to set limits on chemicals in the environment should correspond to a risk of 1/10,000 ($1x10^{-4}$) to 1/1,000,000 ($1x10^{-6}$) over the course of a *lifetime* and a level of $1x10^{-6}$ was selected as the "acceptable" excess lifetime cancer risk for the proposed HHWQC for carcinogens. Based on the current population of 174,111 tribal members in Washington (U.S. Census Bureau 2018), an acceptable cancer risk of $1x10^{-6}$ correlates to 0.17 total cancer in the tribal population over 70 years (USEPA's assumed lifetime). Expressing an increase in predicted lifetime cancer incidence as a fraction of a cancer is a bit unusual given that people either get cancer or don't. We don't get a fraction of a cancer. Another way to express the fraction of a cancer that might occur in Washington's tribal population assuming a $1x10^{-6}$ acceptable risk is the number of years, or generations, it would take for a single cancer to occur in the tribal population. At the current tribal population size, it would take 402 years for a single excess cancer to occur as a result of exposure to a substance given USEPA's proposed HHWQC. Assuming each generation is 70 years, it would take 5.7 generations before a single cancer would be expected in the tribal population at an acceptable risk level of $1x10^{-6}$. In that same time period, given the current cancer rates in the tribal population summarized above (Table 1), about 65,000 cancers would have occurred from other causes. The single excess cancer is immeasurable when compared to the background incidence of cancers.

Table 2 shows how the annual risk of cancer from all causes, based on the 2018 data shown in Table 1, compares to the annual cancer risk that would result from exposure to compounds in the environment that met environmental standards based on a lifetime cancer risk of $1x10^{-4}$ to $1x10^{-6}$. The cancer risk from exposures to environmental pollutants at or below their environmental standards is a tiny fraction (0.028% to 0.00028%) of the background cancer risk we all face. Further, in proposing to consider tribal populations as the general population and recommending a cancer risk level of $1x10^{-6}$ rather than $1x10^{-4}$ when deriving the HHWQC, the effect is that the true general population has a risk of between $1x10^{-7}$ and $1x10^{-8}$. Therefore, the annual risk of cancer associated with environmental pollutants is even lower than what is presented below in Table 1.

Table 2 Incidence of Cancer in 2018 Compared to Acceptable Risk under Environmental Regulations

Geography	Annual Cancer Incidence Rate based on 2018 Data	Annual Risk of Cancer associated with Lifetime Excess Lifetime Cancer Risk $1x10^{-4}$	Annual Risk of Cancer associated with Lifetime Excess Lifetime Cancer Risk $1x10^{-6}$
United States (national)	$5.2x10^{-3}$ (0.52%)	$1.4x10^{-6}$ (0.00014%)	$1.4x10^{-8}$ (0.0000014%)
Washington State	$5.1x10^{-3}$ (0.51%)	$1.4x10^{-6}$ (0.00014%)	$1.4x10^{-8}$ (0.0000014%)

2. Risk assessment choices in federal regulatory programs

We've been assessing the risks from exposure to chemicals in the United States for just over half a century. In 1958, scientists knew of just four human carcinogens; by 1978, they knew of 37 human carcinogens and over 500 animal carcinogens (Wilson 1978). The National Toxicology Program (NTP) currently lists 256 agents, substances, mixtures, and exposure circumstances that *are* known or reasonably anticipated *to* cause cancer in humans (NTP 2021). Environmental legislation that developed in the United States in parallel to the study of what could cause cancer reflected both our scientific understanding of the hazards of chemical exposure and the socioeconomic factors of the times. Much of the legislation requiring assessment of risks of exposure to chemicals in the environment originated between 1972 and 1980[3].

This perspective is important when considering the risk assessment choices expressed in federal regulatory programs. Congress and regulators had to articulate their thinking about risk and what levels of risk were acceptable over a relatively short period of time. We had little time to test and debate ideas, as a society, about how what levels of risk are acceptable to us. It is useful, then, to take the "big picture" view of acceptable risk as we discuss risk-based water quality criteria in Washington State.

Various federal laws and regulations define 'acceptable risk' in different ways. These definitions typically fall into one or more of the general categories shown in **Table 3** (Schroeder 1990).

Table 3 Ways of Reflecting Risk Considerations in Environmental Laws

Type of standard	Variation	Premise
Health based standards	Zero risk	Risk should be reduced to zero or to some other level that is acceptable to society
	Significant risk	
Balancing standards	Cost-benefit	Possible risks must be balanced against the economic benefits of using a chemical or the costs of controlling risks
Technology based standards	Feasibility analysis	Limits are set based on the levels achievable by the best available treatment technology that the regulated industry can afford to install.

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[3] Includes: Clean Water Act (1972), Clean Air Act (1972), Safe Drinking Water Act (1974), Resource Conservation and Recovery Act (1976), Comprehensive Environmental Response, Compensation, and Liability Act (1980).

As a result of the different ways of thinking about acceptable risk and the factors that must be taken into account when regulating exposure to chemicals, regulators have defined goals for limiting cancer risks in different ways in various regulatory programs. **Table 4** summarizes benchmark criteria. Those criteria and some of the striking differences between programs are described below.

Table 4 Benchmarks for "Acceptable" Risk

Law / Regulation	Focus	Risk Standard	Criterion for Carcinogens
Clean Water Act	Surface water	Adverse health impacts	$1x10^{-4}$ to $1x10^{-6}$
Safe Drinking Water Act	Public drinking water	Any adverse effect	Goal: 0 Enforceable standard: $1x10^{-4}$ to $1x10^{-7}$
Toxic Substances Control Act	Chemicals manufactured or imported into the United States	Unreasonable risk	$1x10^{-4}$ (inferred, absent clear policy)
Occupational Safety and Health Act	Worker protection	Significant risk over 45-year working life	$1x10^{-3}$
Comprehensive Environmental Response, Compensation, and Liability Act, or Superfund	Uncontrolled hazardous waste sites	No significant risk	$1x10^{-4}$ to $1x10^{-6}$

2.1 The beginning of "minimal risk" discussions: the Delaney Clause

Delaney Clause – 1958
Health based standards ✓
Balancing standards
Technology based standards

The debate over what level of exposure to a carcinogen could be considered safe began in the United States when people became concerned about pesticide residues in processed foods. This debate produced the 1958 Food Additives Amendment (section 409) to the 1954 Federal Food, Drug and Cosmetic Act (FFDCA), which said:

> *…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…*

This "zero risk" clause, named for Congressman James Delaney, was a landmark decision in the regulation of compounds that might cause cancer. The Delaney Clause sounds simple enough, but soon ran into practical limitations: How low of a dose do we need to test to assure ourselves that a chemical does not cause cancer? And how, given the limits of analytical chemistry, do we know when a chemical that can induce cancer is present in a food product?

The United States Food and Drug Administration (USFDA) faced this challenge in regulations proposed in 1973 (USFDA 1973), saying:

> *If the results of the test for carcinogenicity establish that the compound or its metabolites will induce cancer in test animals, the required sensitivity of the regulatory assay method will be determined based on the Mantel-Bryan procedure ….*
>
> *Absolute safety can never be conclusively demonstrated experimentally. The level defined by the Mantel-Bryan procedure is an arbitrary but conservative level of maximum exposure resulting in a minimal probability of risk to an individual (e.g., 1/100,000,000), under those exposure conditions of the basic animal studies.*

In describing the benchmark (1/100,000,000 or 10^{-8}) provided as an example of minimal probability of risk to an individual, the USFDA cited a groundbreaking paper by Mantel and Bryan (1961) that said:

> *We may, for example, assume that a risk of 1/100 million is so low as to constitute "virtual safety." Other arbitrary definitions of "virtual safety" may be employed as conditions require.*

Many of the comments on the regulation proposed in 1973 pertained to how the proposed regulation dealt with the risk of cancer and the 1/100,000,000 benchmark. After considering those comments the USFDA promulgated a final regulation in 1977. In doing so it re-defined the benchmark risk level. The preamble to the final rule explains that tests for carcinogens must be able to measure the concentration corresponding to the 1/1,000,000 (or 10^{-6}) risk level, which the USFDA described as an "insignificant public health concern". (USFDA 1977)

In this rulemaking, the USFDA was careful to point out that it was not making an explicit judgment on an acceptable level of risk, simply seeking to set a practical benchmark that could be used to design animal experiments:

> *[10^{-6}] does not represent a level of residues "approved" for introduction into the human diet. The purpose of these regulations is to establish criteria for the evaluation of assays for the measurement of carcinogenic animal drugs. These criteria must include some lowest level of reliable measurement that an assay is required to meet. In defining a level of potential residues that can be considered "safe", therefore, the Commissioner is establishing a criterion of assay measurement that, if it can be met for a compound, will ensure that any undetected residues resulting from the compound's use will not increase the risk of human cancer.*

Despite this caution, many people took this regulatory action as a precedent for defining an “acceptable” level of risk as 1x10^{-6}. In fact, the Delaney Clause was replaced in 1996 by legislation that specifies 10^{-6} as an acceptable level of risk[4] (Moran 1977).

2.2 Clean Water Act

Under the Clean Water Act (CWA), States and authorized Native American tribes set water quality standards for the surface water bodies under their jurisdiction. A water quality standard has two parts: the designated uses of a body of water, and the criteria (or concentration limits for specific chemical compounds) necessary to protect those uses. The USEPA develops Human Health Water Quality Criteria (HHWQC) that States and Native American tribes can use to set those concentration limits (USEPA 2000). In general (USEPA 2000),

CWA – 1972

Health based standards	ü
Balancing standards	
Technology based standards	

> *Water quality criteria are derived to establish ambient concentrations of pollutants which, if not exceeded, will protect the general population from adverse health impacts from those pollutants due to consumption of aquatic organisms and water, including incidental water consumption related to recreational activities.*

For compounds that may cause cancer in people exposed to surface water, those criteria must correspond to some level of risk that is thought to be acceptable.

The USEPA’s 1980 HHWQC National Guidelines simply represented a range of risks. In other words, the guidance presented a range of chemical concentrations corresponding to incremental cancer risks of 10^{-7} to 10^{-5}. Revised guidelines published in 2000 corresponded to the 10^{-6} risk level, with this explanation (USEPA 2000):

> *With [HHWQC] derived for carcinogens based on a linear low-dose extrapolation, the Agency will publish recommended criteria values at a 10^{-6} risk level. States and authorized Tribes can always*

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[4] The Delaney Clause is no longer in effect. The Food Quality Protection Act of 1996 changed the standard for the residues of carcinogens in foods from the “zero risk” criterion implicit in the Delaney Clause to a standard of "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue.” The law allows for chemical residues if the risk of causing cancer in less than one-in-a-million people over the course of a typical life-span. The USEPA must consider the benefits of pesticides in supporting an adequate, wholesome, and economical food supply in determining an acceptable level of risk.

> *choose a more stringent risk level, such as 10^{-7}. EPA also believes 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 (sportfishers or subsistence fishers) does not exceed the 10^{-4} level.*

The Agency elaborated on this policy with respect to more highly exposed people, saying:

> *EPA understands that highly exposed populations may be widely distributed geographically throughout a given State or Tribal area. EPA recommends that priority be given to identifying and adequately protecting the most highly exposed population. Thus, if the State or Tribe determines that a highly exposed population is at greater risk and would not be adequately protected by criteria based on the general population, and by the national … criteria in particular, EPA recommends that the State or Tribe adopt more stringent criteria using alternative exposure assumptions….*
>
> *EPA understands that fish consumption rates vary considerably, especially among subsistence populations, and it is such great variation among these population groups that may make either 10^{-6} or 10^{-5} protective of those groups at a 10^{-4} risk level. Therefore, depending on the consumption patterns in a given State or Tribal jurisdiction, a 10^{-6} or 10^{-5} risk level could be appropriate. In cases where fish consumption among highly exposed population groups is of a magnitude that a 10^{-4} risk level would be exceeded, a more protective risk level should be chosen.*
>
> *…changing the exposure parameters also changes the risk. Specifically, the incremental cancer risk levels are relative, meaning that any given criterion associated with a particular cancer risk level is also associated with specific exposure parameter assumptions (e.g., intake rates, body weights). When these exposure parameter values change, so does the relative risk. For a criterion derived on the basis of a cancer risk level of 10^{-6}, individuals consuming up to 10 times the assumed fish intake rate would not exceed a 10^{-5} risk level. Similarly, individuals consuming up to 100 times the assumed rate would not exceed a 10^{-4} risk level. Thus, for a criterion based on EPA's default fish intake rate (17.5 gm/day) and a risk level of 10^{-6}, those consuming a pound per day (i.e., 454 grams/day) would potentially experience between a 10^{-5} and a 10^{-4} risk level (closer to a 10^{-5} risk level).*[5]

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[5] In 2014, USEPA updated the default fish consumption rate to 22 g/day which represents the 90th percentile consumption rate of fish and shellfish from inland and nearshore waters for the U.S. adult population 21 years of age and older, based on NHANES data from 2003 to 2010 (USEPA 2014). This change does not impact the meaning of this statement.

In other words, the USEPA generally sets HHWQC at the 10^{-5} to 10^{-6} risk level, but allows states and tribes flexibility in setting enforceable criteria. In regions where some groups may eat more fish than is typical and by doing so perhaps increase their exposure to chemicals in fish, the Agency advises that the criterion set for the general population should not result in a risk to those who eat more fish that is greater than 10^{-4}. USEPA's proposal to set HHWQC at the 10^{-6} risk level for tribal populations who may eat more fish than is typical for the general population is not consistent with USEPA policy. The general population with more typical consumption rates is effectively being protected at a level lower (i.e., more stringent) than what was intended by the CWA. As discussed earlier, there are costs and consequences that must also be considered when setting substantially more stringent standards then intended or required by statute or EPA policy.

USEPA concluded that Washington's state-adopted HHWQC for PCBs does not meet the requirements of the CWA. The HHWQC for PCBs was derived using the fish ingestion rate of 175 g/day and corresponds to a cancer risk level of 2.3×10^{-5}. When the state-adopted HHWQC for PCBs is combined with a higher ingestion rate of 797 g/day (the amount eaten by members of the Suquamish tribe at the 95th percentile, who eat the largest amounts of fish of all the people in Washington State (Washington State Department of Ecology 2013), the resulting risk is 1×10^{-4} (calculated as 797 x 2.3E-5 / 175). Therefore, even the most highly exposed populations would be protected in a manner consistent with the CWA. USEPA is incorrect in its conclusion that Washington's state-adopted HHWQC for PCBs does not meet the requirements of the CWA.

2.3 Safe Drinking Water Act

The USEPA sets two kinds of criteria for chemicals in public water supplies, Maximum Contaminant Level Goals (MCLGs) and Maximum Contaminant Levels (MCLs). Here's how the Agency describes the process of determining those criteria (USEPA 2013A):

> *If there is evidence that a chemical may cause cancer, and there is no dose below which the chemical is considered safe, the MCLG is set at zero. If a chemical is carcinogenic and a safe dose can be determined, the MCLG is set at a level above zero that is safe….*
>
> *Once the MCLG is determined, EPA sets an enforceable standard. In most cases, the standard is a Maximum Contaminant Level (MCL), the maximum permissible level of a contaminant in water which is delivered to any user of a public water system. …The MCL is set as close to the MCLG as feasible….. EPA may adjust the MCL for a particular class or group of systems to a level that maximizes health risk reduction benefits at a cost that is justified by the benefits.*

The USEPA also determines non-enforceable Drinking Water Specific Risk Level Concentrations. It has described the Drinking Water Specific Risk Level Concentration as being based on the 1x10^{-4} excess lifetime cancer risk (USEPA 2012B). In some cases, as illustrated in **Table 5**, adjustments to the MCL have resulted in a concentration limit that corresponds to a higher risk. In other cases, the MCL for a chemical is lower than the concentration corresponding to the 10^{-4} risk level and therefore represents a lower risk level.

SDWA – 1972

Health based standards	ü
Balancing standards	ü
Technology based standards	ü

Table 5 Comparison of Drinking Water MCLs and Cancer Risk Levels for Potential Carcinogens

Compound	MCL* (mg/L)	Concentration (mg/L) at 10^{-4} Cancer Risk*	Approximate Risk Level of MCL
Alachlor	0.002	0.04	5x10^{-6}
Arsenic	0.01	0.002	5x10^{-4}
Benzene	0.005	1 to 10	5x10^{-7} to 5x10^{-6}
Benzo(a)pyrene	0.0002	0.0005	4x10^{-5}
Bromodichloromethane (THM**)	0.081	0.1	8x10^{-5}
Bromate	0.01	0.005	2x10^{-4}
Bromoform (THM**)	0.081	0.8	10^{-5}
Carbon tetrachloride	0.005	0.05	10^{-5}
Chlordane	0.002	0.01	2x10^{-5}
Di(2-ethylhexyl)adipate	0.4	3	10^{-5}
Di(2-ethylhexyl)phthalate	0.006	0.3	2x10^{-6}
Dibromochloromethane (THM**)	0.082	0.08	10^{-4}
Dibromochloropropane (DBCP)	0.0002	0.003	7x10^{-6}
Dichloroacetic acid^{+}	0.063	0.07	10^{-4}
Dichloroethane (1,2-)	0.005	0.04	10^{-5}
Dichloroethylene (1,1-)	0.007	0.006	10^{-4}
Dichloromethane	0.005	0.5	10^{-6}
Dichloropropane (1,2-)	0.005	0.06	10^{-5}
Epichlorohydrin	TT^{++}	0.3	7x10^{-7}
Ethylene dibromide	0.00005	0.002	2.5x10^{-6}
Heptachlor	0.0004	0.0008	5x10^{-5}
Heptachlor epoxide	0.0002	0.0004	5x10^{-5}
Hexachlorobenzene	0.001	0.002	5x10^{-5}
Pentachlorophenol	0.001	0.009	10^{-5}
Polychlorinated biphenyls (PCBs)	0.005	0.01	5x10^{-5}

Compound	MCL* (mg/L)	Concentration (mg/L) at 10^{-4} Cancer Risk*	Approximate Risk Level of MCL
2,3,7,8-TCDD (dioxin)	$3x10^{-8}$	$2x10^{-8}$	10^{-4}
Toxaphene	0.003	0.003	10^{-4}
Trichloroethane (1,1,2-)	0.005	0.06	$8x10^{-6}$
Trichloroethylene	0.005	0.3	10^{-6}
Vinyl chloride	0.002	0.002	10^{-4}

* USEPA 2018.

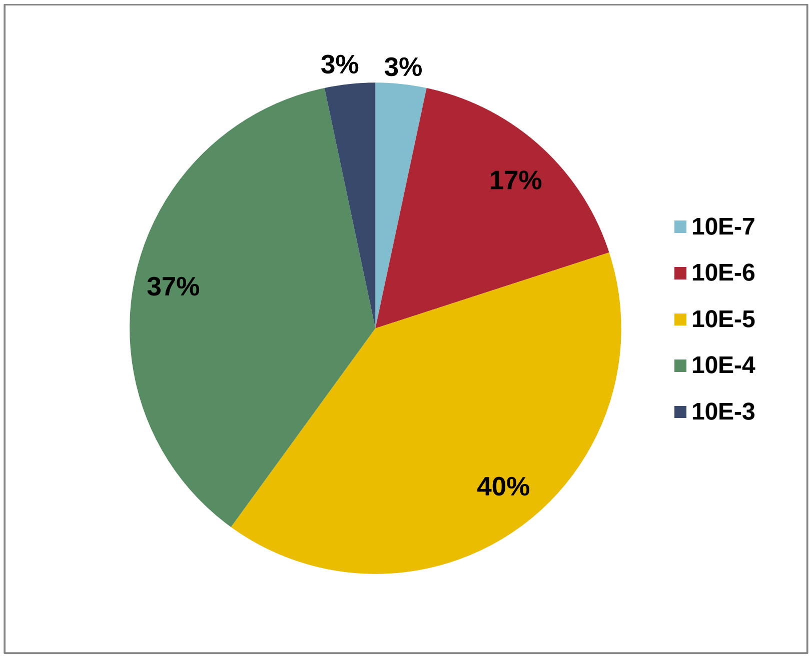
** Total trihalomethane (THM) concentration should not exceed 0.08 mg/L.

$^{+}$ The total for five haloacetic acids is 0.063.

$^{++}$ When epichlorohydrin is used in drinking water systems, the combination (or product) of dose and monomer level shall not exceed that equivalent to an epichlorohydrin-based polymer containing 0.01% monomer dosed at 20 mg/L. (0.01/100 * 20 mg/L = 0.002 mg/L)

As these examples show and as illustrated in **Figure 1**, the excess lifetime cancer risks associated with a single drinking water contaminant present in a water supply at its MCL may fall within a range of several orders of magnitude. Thirty-seven percent of MCLs correspond to an estimated lifetime risk of $1x10^{-4}$ to $1x10^{-3}$; 40% of MCLs represent a potential risk of cancer after a lifetime of exposure of $1x10^{-5}$ to $1x10^{-4}$. While the USEPA may consider the benchmark excess lifetime cancer risk of 10^{-4} in setting a standard, the requirement to set the MCL as close to the MCLG as feasible or to adjust the MCL to a level that "maximizes health risk reduction benefits at a cost that is justified by the benefits" may result in a MCL that represents a very different risk level for that compound. And the combined risks of exposure to multiple chemicals, if they are present in the water supply, may increase the potential risk further.

Figure 1 Approximate Risk Levels associated with MCLs in Drinking Water



2.4 Occupational Safety and Health Act

The United States Occupational Safety and Health Administration (OSHA) develops standards to protect workers under the Occupational Safety and Health Act of 1970. OSHA first promulgated standards in 1974 to regulate the industrial use of 13 chemicals identified as potential occupational carcinogens. Those standards did not set limits on exposure, simply mandated the use of engineering controls, work practices, and personal protective equipment to limit exposure.

OSHA has since promulgated standards for certain carcinogens, including the regulations at 1910 Subpart Z, Toxic and Hazardous Substances. Those standards reflect a landmark decision by the Supreme Court known as the “Benzene Decision”, more formally known as *Industrial Union Department v. American Petroleum Institute, 448 U.S. 607*, in 1980, At issue was whether setting worker protection standards for carcinogens such as benzene at the lowest technologically feasible level that would not impair the viability of the industries regulated conformed to the statutory requirement that such standards be "reasonably necessary or appropriate to provide safe and healthful employment". The decision read, in part,

> *… "safe" is not the equivalent of "risk-free." A workplace can hardly be considered "unsafe" unless it threatens the workers with a significant risk of harm…. [T]he requirement that a "significant" risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first*

> *instance, what it considers to be a "significant" risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it. Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as "unsafe."*

The Supreme Court essentially stated that a risk of fatality of 1 x 10^{-3} in an occupational setting was unacceptable. OSHA applied this benchmark to excess lifetime cancer risk. (Again, it is worth noting that not all cancers are fatal: an excess lifetime cancer risk of 1 x 10^{-3} corresponds to a far lower risk of cancer-related death.) For example, when OSHA set the Permissible Exposure Limit (PEL) for methylene chloride as a time weighted average (TWA) concentration, it offered an explanation that indicated how it thought about acceptable risk and acknowledged the level of risk associated with the standard being replaced (OSHA 1997):

> *OSHA's final estimate of excess cancer risks at the current PEL of 500 [parts per million] ppm (8-hour TWA) is 126 per 1000. The risk at the new PEL of 25 ppm is 3.62 per 1000. The risk at 25 ppm is similar to the risk estimated in OSHA's preliminary quantitative risk assessment based on applied dose of [methylene chloride] on a mg/kg/day basis (2.3 per 1000 workers) and clearly supports a PEL of 25 ppm. Risks greater than or equal to 10(-3) are clearly significant and the Agency deems them unacceptably high. However, OSHA did not collect the data necessary to document the feasibility of a PEL below 25 ppm across all affected industry sectors, and so the Agency has set the PEL at 25 ppm in the final rule.*
>
> *Further guidance for the Agency in evaluating significant risk and narrowing the million-fold range provided in the "Benzene decision" is provided by an examination of occupational risk rates, legislative intent, and the academic literature on "acceptable risk" issues. For example, in the high risk occupations of mining and quarrying, the average risk of death from an occupational injury or an acute occupationally-related illness over a lifetime of employment (45 years) is 15.1 per 1,000 workers. The typical occupational risk of deaths for all manufacturing industries is 1.98 per 1,000. Typical lifetime occupational risk of death in an occupation of relatively low risk, like retail trade, is 0.82 per 1,000. (These rates are averages derived from 1984-1986 Bureau of Labor Statistics data for employers with 11 or more employees, adjusted to 45 years of employment, for 50 weeks per year).*

The National Institute of Occupational Safety and Health, or NIOSH, is the research and development counterpart to OSHA. Part of the organization’s mission is to develop recommendations for health and safety standards. Their work provides guidance on limits for occupational exposures that supplements and informs OSHA rulemaking.

In 1976, NIOSH published its first guidelines on carcinogens in the workplace. Those guidelines called for "no detectable exposure levels for proven carcinogenic substances" (NIOSH 2016). NIOSH set Recommended Exposure Limits (RELs) for most carcinogens at the "lowest feasible concentration (LFC)." In 1995, NIOSH revised its policy (NIOSH 2010):

> *NIOSH recommended exposure limits (RELs) will be based on risk evaluations using human or animal health effects data, and on an assessment of what levels can be feasibly achieved by engineering controls and measured by analytical techniques. To the extent feasible, NIOSH will project not only a no-effect exposure, but also exposure levels at which there may be residual risks.*
>
> *The effect of this new policy will be the development, whenever possible, of quantitative RELs that are based on human and/or animal data, as well as on the consideration of technological feasibility for controlling workplace exposures to the REL.*

The 1995 NIOSH policy recommended exposure limits for potentially carcinogenic chemicals at concentrations corresponding to an excess risk of 1 in 1,000 workers exposed to the substance for a 45-year working lifetime (NIOSH 1995). Both the 2011 Current Intelligence Bulletin for titanium dioxide and the 2013 Criteria Document for hexavalent chromium compounds used 1 in 1,000 as the risk level for carcinogenic effects in setting RELs [NIOSH 2011, 2013].

In 2016, NIOSH issued another new carcinogen policy. In a document titled *NIOSH Current Intelligence Bulletin 68: NIOSH Chemical Carcinogen Policy* (NIOSH 2016), NIOSH states that they will no longer use the term REL for occupational carcinogens and instead will use the term “risk management limit for carcinogen” (RML-CA) to acknowledge there is no safe exposure. NIOSH 2016 further states the following:

> *NIOSH will set the RML-CA for an occupational carcinogen at the estimated 95% lower confidence limit on the concentration (e.g., dose) corresponding to 1 in 10,000 (10-4) excess lifetime risk, when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10-3). This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess*

> *risks greater than 10-4. will set the RML-CA for an occupational carcinogen at the estimated 95% lower confidence limit on the concentration (e.g., dose) corresponding to 1 in 10,000 (10-4) excess lifetime risk, when analytically possible to measure.*

In summary, the levels of risk considered to be acceptable for workers have varied over time at OSHA and at NIOSH. In the latest evolution of policy, an excess risk of 1/10,000 ($1x10^{-4}$) over a working lifetime of 45 years of exposure has been adopted as the basis for workplace standards, although some standards, former and current, have exceeded that limit. By comparison to the other definitions of acceptable risk described in this white paper, this risk equates to an annual risk of $2x10^{-6}$ or an excess lifetime cancer risk (70 years) of approximately $2x10^{-4}$.

2.5 Toxic Substances Control Act

The Toxic Substances Control Act, abbreviated TSCA, regulates most chemical substances manufactured or imported into the United States. Under this law the USEPA can require reporting, record-keeping and testing of chemical substances, and may impose restrictions on their manufacture or use. The law defines the conditions under which the USEPA can take action. If an “unreasonable risk of injury to health or the environment” from a chemical substance has been proven, for example, the Agency can require risk-abatement action such as labeling chemical substances, regulating uses, restrictions on disposal, and prohibiting or limiting manufacture. But neither the law nor the regulations that implement the law define “unreasonable risk” clearly.

The USEPA has not published explicit guidance on how it reaches a finding of “unreasonable risk” but has described it generally as follows (USEPA 2013B):

> *EPA's determination that manufacture, processing, use, distribution in commerce, or disposal of an individual substance which has been the subject of a notice under section 5 of the TSCA may present an unreasonable risk of injury to human health or the environment is based on consideration of (i) the size of the risks identified by EPA; (ii) limitations on risk that would result from specific safeguards (generally, exposure and release controls) sought based on Agency review and (iii) the benefits to industry and the public expected to be provided by new chemical substances intended to be manufactured after Agency review. In considering risk, EPA considers factors including environmental effects, distribution, and fate of the chemical substance in the environment, disposal methods, waste water treatment, use of protective equipment and engineering controls, use patterns, and market potential of the chemical substance.*

TSCA – 1976	
Health based standards	✓
Balancing standards	✓
Technology based standards	✓

What does this mean with respect to the acceptable level of cancer risk for workers manufacturing a new chemical or consumers who might be exposed to it? The USEPA has not published a clear statement on acceptable risk under TSCA, but the cases described below shed some light on the question[6]. The first is a publication by an Agency official early in the TSCA program regarding the determination of acceptable risks under TSCA, and the second, the USEPA's explanation of how it derives limits for worker exposure to new chemicals under TSCA.

In 1983, a USEPA official indicated that the objective is to reduce risks to an "insignificant" level but that the USEPA did "not employ any predetermined statistical risk level since this will vary depending on a variety of factors." (Todhunter 1983). In other words, at that time "unreasonable risk" did not correspond to a benchmark level or range (such as 10^{-4} to 10^{-6}). The USEPA has not apparently published anything since that time to suggest that a benchmark level exists under TSCA, with one exception.

The Agency sometimes sets New Chemical Exposure Limits (NCELs) for new chemicals regulated under TSCA. An NCEL is the concentration that a worker who makes or uses a chemical can be exposed to safely. To derive an NCEL for a potential carcinogen, the USEPA reportedly begins with the policy that a cancer risk of 10^{-4} is acceptable (USEPA 1995). But in some cases the Agency finds that the calculated NCEL may be difficult to attain or monitor. In such cases the risks to workers may be higher than 10^{-4} (Sellers 2015).

2.6 Superfund

CERCLA/ SARA – 1980 / 1986	
Health based standards	✓
Balancing standards	
Technology based standards	

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), also known as Superfund, defines the significant risks at uncontrolled hazardous waste sites that must be cleaned up. The regulations at 40 CFR 300.430(e)(2)(i)(A) specify that remediation goals shall consider the following:

> *For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between* 10^{-4} *and* 10^{-6}

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[6] This discussion is adapted from: Sellers, K., 2015. *Product Stewardship, Life Cycle Analysis, and the Environment*. (Taylor & Francis/ CRC Press)

> *using information on the relationship between dose and response. The 10^{-6} risk level shall be used as the point of departure for determining remediation goals ….*

2.7 Inconsistent results

The different benchmarks for acceptable risks have led to some striking inconsistencies in the ways in which some chemicals are regulated in the United States. Consider the example below, which contrasts risk management decisions under TSCA and the Safe Drinking Water Act (SDWA).

While the USEPA has not published a direct statement under TSCA on what level of risk is acceptable, it is interesting to compare risk-related benchmarks under TSCA to those under the SDWA[7].

When the exposure to a new chemical will be quite limited – or more specifically ‘low release and exposure’ (LoREX) – the manufacturer or importer can be exempt from TSCA regulations. Regulations at 40 CFR 723.50(2) specify the criteria for the LoREX exemption. They include the case where no exposure in drinking water would exceed a 1 milligram per year (mg/yr) estimated average dosage. While this exemption does not define serious human health effects or significant environmental effects to a degree that helps to explain the concept of “unacceptable risk” under TSCA, it does provide a point of reference: the risks from exposure to any compound at 1 mg/yr in drinking water are anticipated to be acceptable.

The USEPA has also considered the possible risk from chemicals in drinking water under the SDWA. A risk assessor working under USEPA guidelines has typically assumed that an adult drinks 2.4 liters of water per day (USEPA 2014B). An adult drinking 2 liters of water per day for an entire year could drink water containing up to 0.0014 milligrams per liter (mg/L) of a chemical before reaching the LoREX criterion of 1 mg/yr of exposure:

2 liters water / day * 365 days/year * 1 year * 0.0014 milligrams / liter * = 1 mg/yr

The MCLs for 10 chemical (nonradionuclide) substances are below 0.0014 mg/L (USEPA 2013C). Put another way, for 13% of the chemicals regulated under the SDWA (that is, 10/76) the USEPA has found that exposure to 1 mg/yr in drinking water – which is considered to be a negligible exposure under the TSCA New Chemicals program – was acceptable. If such chemicals were brought onto the market now, they could be exempted from regulation under TSCA.

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[7] This discussion is adapted from: Sellers, K., 2015. *Product Stewardship, Life Cycle Analysis, and the Environment*. (Taylor & Francis/ CRC Press)

2.8 Summary

The level of risk considered to be acceptable varies widely between different federal regulatory programs. The risks we experience at work or by drinking from a public water supply can be on the order of $1x10^{-4}$ or even higher. Under other programs, such as the cleanup of hazardous waste sites, a risk level of $1x10^{-6}$ is the point of departure for determining the goals for cleanup, though as long as excess lifetime cancer risk is equal to or less than $1x10^{-4}$ a site generally does not require cleanup. Perhaps most relevant to this discussion are the risk goals set under the Clean Water Act. Federal water quality criteria are typically based on a risk of $1x10^{-6}$; the USEPA has noted that criteria based on a 1/100,000 risk are acceptable for the general population as long as groups of people who may be more highly exposed (such as subsistence anglers) would encounter a risk less than or equal to $1x10^{-4}$. USEPA's proposal to set HHWQC at the 10^{-6} risk level for more highly exposed tribal populations is not consistent with USEPA policy.

3. Estimating risks: importance of underlying assumptions

The preceding paragraphs described the variation in one important assumption, the level of acceptable risk. That value may vary from 10^{-7} to more than 10^{-3}, depending upon the regulatory program and the context of the decision. Risk assessors must make other assumptions to estimate the possible risks from exposure to chemicals in the environment. These include assumptions about the degree of exposure. To illustrate the range of assumptions that can be factored into calculations of risks, Section 3.1 describes fish consumption estimates. Section 3.2 describes the effects of compounding a series of assumptions, if the assessor selects the most conservative value for each.

3.1 A closer look at one critical assumption: fish consumption

Calculations of the risk from eating fish containing chemicals in the environment typically reflect a simple assumption about the amount of fish eaten by each person per day or per year. But such values represent some complicated variables. Different people eat different amounts of fish. Those fish may come from different places, some very far from the area being considered in the risk assessment. The ways in which fish are cooked can decrease the amount of chemicals in the fish. The assumptions that are made to account for these variables and simplify the calculations can have a big effect on the calculated risk.

95th Percentile Values

The 95th percentile value for a variable like fish consumption means that 95 out of 100 people eat less fish than that amount.

The amount of fish a person eats every day depends in part on geographic region, age, gender, and body size (USEPA 2021), as well as cultural or taste preferences. Estimates of fish consumption can also vary based on the way in which the fish consumption rate is estimated. While a detailed discussion of all of those factors and their effect on estimated fish consumption rates is beyond the scope of this white paper, it is crucial to recognize that in that last 10 years USEPA (USEPA 2014A), Washington (Ecology 2013), Idaho

(2019) and others have determined that methods used to estimate fish consumption rates prior to about 2010, are not appropriate to estimate long-term fish consumption rates (USEPA (2014A) refers to fish consumption rates representative of long-term behavior as "Usual Fish Consumption Rates" (UFCRs).

The USEPA 2011 Exposure Factors Handbook (USEPA, 2011, p. 10–16) qualified the older fish dietary estimates as follows:

> *…it should be noted that the distribution of average daily intake rates generated using short-term data (e.g., 2-day) does not necessarily reflect the long-term distribution of average daily intake rates. The distributions generated from short-term and long-term data will differ to the extent that each individual's intake varies from day to day…..*
>
> *…Short-term consumption data may not accurately reflect long-term eating patterns and may under-represent infrequent consumers of a given fish species. This is particularly true for the tails (extremes) of the distribution of food intake.*

Usual fish consumption rates are derived using the National Cancer Institute (NCI) method (see Table 6) and per USEPA (2014A) "*the NCI Method is preferred because it accounts for days without consumption; distinguishes within-person from between-person variation; allows for the correlation between the probability of consumption and the consumption-day amount; and can use covariate data to better predict usual intake.* Fish consumption rates estimated using the older methods, such as the 175 g/day rate used in the current and proposed HHWQC, overstate long-term fish consumption and are no longer recommended or used by USEPA. USEPA (2014A) outlines how newer NCI statistical and dietary survey methodologies can be used to derive more credible usual fish consumption rates; however, they are ignoring their own guidance in selecting the fish consumption rate of 175 g/day for the derivation of the proposal HHWQC.

As shown in the table below when the NHANES fish dietary data for the national general population were reevaluated using the newer NCI statistical methodology (Polissar et al., 2012) the 90th percentile fish consumption rate decreased from 128 g/day to a more statistically representative value of 43.3 g/day. A reevaluation of the fish ingestion rates using the NCI method also results in a more statistically representative value that is lower than the fish consumption rate derived using the older statistical method (the 90th percentile for the Nez Perce Tribe decreased 35% from 270 g/day to 173 g/day, while the 90th percentile for the Shoshone Bannock Tribe decreased 76% from 603 grams/day to 141 g/day.

Table 6 A Comparison of Fish Consumption Rates (All Fish) using Different Statistical Survey Methods

Population	Method	50%	Mean	75%	90%	95%	99%
Nez Perce Tribe[1]	Food Frequency Questionnaire	70.5	123	---	270	437	796
Nez Perce Tribe[1]	NCI	49.5	75.0	---	173	232	---
Shoshone Bannock Tribe[1]	Food Frequency Questionnaire	74.6	158	---	392	603	1058
Shoshone Bannock Tribe[1]	NCI	14.9	34.9	---	94.5	141	---
General Population[2]	Short-term consumption survey data	37.9	56	78.8	128	168	---
General Population[2]	NCI	12.7	18.8	24.8	43.3	56.6	---

[1] Polissar et al. (2016). Statistics are for species of CWA relevance (freshwater, near coastal and estuarine species) for the Nez Perce and Shoshone-Bannock Tribes

[2] National Survey: NHANES 2003–2006, Adult Respondents, values as reported in Ecology (2013)

The conclusions of Polissar et al. (2016), A Fish Consumption Survey of the Nez Perce Tribe, state the following:

> *In summary, the NCI method's rates based on the 24-hour recall interviews are likely to be closer to the actual rates than the rates from the FFQ (Food Frequency Questionnaire) analysis, due to the lighter demand on memory required by the 24-hour recall approach*

Keeping the above caution about historic FCRs in mind, fish consumption rates do vary between populations. Consider the values listed in **Table 7** (Washington State Department of Ecology 2013) for illustration.

Table 7 Variations in fish consumption rates

Population	Key Variable	Fish	Mean fish ingestion (g/day)	95% Percentile (g/day)
Washington's Model Toxics Control Act (MTCA) Cleanup Regulation	Default fish consumption rate	All	54	
General population, Washington State, consumers only	NCI estimation method	All	19	57
Columbia River Tribes	All sources of fish	All	63	194
Tulalip Tribes	All sources of fish	All	82	268
Squaxin Island Tribe	All sources of fish	All	84	280
Suquamish Tribe	All sources of fish	All	214	797
Recreational Fishers, Washington State	Freshwater	All	6.0 to 22	42 to 67

How do we account for such varying rates of fish consumption in estimating risk and setting protective environmental standards? One way is to incorporate the range of values into risk calculations in a method known as probabilistic risk assessment. Another way is to pick a value for fish consumption that protects the majority of the population at the target excess lifetime cancer risk to set a criterion, and then to make sure that the standard represents a reasonable level of risk for more highly exposed groups of people. **Tables 8a and 8b** illustrate the results of a series of hypothetical calculations. It shows how the calculated risk varies with the amount of fish eaten, as described below.

Table 8a Excess Lifetime Cancer Risk (using an acceptable level of 1E-06) versus Fish Consumption Rates

	MTCA Default	Washington State, mean	Washington State, 95th Percentile	Current and Proposed HHWQC	Suquamish Tribe, 95th percentile
Fish consumption rate (g/day)	54	19[a]	57[a]	175	797
Excess Lifetime Cancer Risk	1E-06	4E-07	1E-06	3E-06	1E-05
	3E-06	1E-06	3E-06	9E-06	4E-05
	9E-07	3E-07	1E-06	3E-06	1E-05
	3E-07	1E-07	3E-07	1E-06	5E-06
	7E-08	2E-08	7E-08	2E-07	1E-06

[a] These fish consumption rates are UFCRs (i.e., they represent long-term consumption rates. The other consumption rates shown in the table overstate long-term consumption because they are derived using outdated fish consumption survey methods.

Table 8b Excess Lifetime Cancer Risk (using an acceptable level of 1E-05) versus Fish Consumption Rates

	MTCA Default	Washington State, mean	Washington State, 95th Percentile	Current and Proposed HHWQC	Suquamish Tribe, 95th percentile
Fish consumption rate (g/day)	54	19[a]	57[a]	175	797
Excess Lifetime Cancer Risk	1E-05	4E-06	1E-05	3E-05	1E-04
	3E-05	1E-05	3E-05	9E-05	4E-04
	9E-06	3E-06	1E-05	3E-05	1E-04
	3E-06	1E-06	3E-06	1E-05	5E-05
	7E-07	2E-07	7E-07	2E-06	1E-05

[a] These fish consumption rates are UFCRs (i.e., they represent long-term consumption rates. The other consumption rates shown in the table overstate long-term consumption because they are derived using outdated fish consumption survey methods.

Five fish consumption rates are shown. These five daily consumption rates cover the range of rates shown previously in Table 7. Included in Table 8a and 8b are the amounts eaten by fish consumers throughout Washington as represented by the MTCA default value, fish consumers throughout Washington as represented by the mean and 95th percentile UFCRs, and the value of fish consumption included in the current Washington HHWQC, equal to the consumption rate USEPA proposes to use in the updated criteria. The tables also include the amount eaten by members of the Suquamish tribe at the 95th percentile, who eat the largest amounts of fish of all the people in Washington State (Washington State Department of Ecology 2013).

The rows labelled excess lifetime cancer risk in Table 8a show how the calculated risk varies with the amount of fish eaten. In each row, the shaded box shows the group that was “assigned” a $1x10^{-6}$ (or 1E-06) risk, equal to the acceptable risk level in Washington’s current and USEPA’s proposed HHWQC. For example, calculations summarized in the first excess lifetime cancer risk row started with the assumption that the risk to people eating 54 g/day of fish (Washington State MTCA default value) should be no more than $1x10^{-6}$ or 1E-06. The risk to the group that eats the most fish (Suquamish Tribe, 95th percentile) would then be $1x10^{-5}$ or 1E-05, well within the range of acceptable risk set forth in USEPA guidance (USEPA 2010), if all of the other variables in the calculation remained the same. Similarly, the second to last row in the table shows that if one uses the acceptable risk level of $1x10^{-6}$ (or 1E-06) combined with the FCR in the current and proposed HHWQC, the most highly exposed people in the Suquamish Tribe (95th percentile) would be protected at 5 $x10^{-6}$, far below the $1x10^{-4}$ indicated in USEPA guidance and the 95th percentile of the general population would be protected at a $3x10^{-7}$ level, about three times lower than the most stringent acceptable risk level identified in USEPA guidance (USEPA 2010).

Table 8b follows the same pattern as Table 8a except for using an acceptable risk level of $1x10^{-5}$ (instead of $1x10^{-6}$). A $1x10^{-5}$ acceptable risk is consistent with USEPA guidance for the general population (USEPA 2010) and state-wide HHWQC using an acceptable risk level of $1x10^{-5}$ have been approved by USEPA. In each row, the shaded box shows the group that was “assigned” a $1x10^{-5}$ (or 1E-05) risk. In this case, combining an acceptable risk of $1x10^{-5}$ and a consumption rate of 54 g/day of fish (Washington State MTCA default value) results in a potential risk of no more than $1x10^{-4}$ for the group that eats the most fish (Suquamish Tribe, 95th percentile) if all of the other variables in the calculation remained the same, consistent with USEPA guidance. Similarly, the second to last row in the table shows that if one uses the acceptable risk level of $1x10^{-5}$ (or 1E-05) combined with the FCR in the current and proposed HHWQC, the most highly exposed people in the Suquamish Tribe (95th percentile) would be protected at 5 $x10^{-5}$, consistent with USEPA guidance. The 95th percentile of the general population would be protected at a $3x10^{-6}$ level, within the range of acceptable risk for the general population identified in USEPA guidance (USEPA 2010).

In 2016, Washington proposed a HHWQC for PCBs that is protective of potential non-cancer effects and corresponds to a cancer risk level of $2.3x10^{-5}$ (or 2.3E-5). This proposed HHWQC was derived using the fish ingestion rate of 175 g/day. As shown in Table 8b, when a fish ingestion rate of 175 g/day that corresponds to a risk of about 3E-5 is increased to a fish ingestion rate of 797 g/day, the resulting risk is 1E-4. Therefore, even the most highly exposed populations would be protected in a manner consistent with the CWA if the cancer risk level for PCBs is set at $2.3x10^{-5}$. USEPA is incorrect in its conclusion that Washington’s state-adopted HHWQC for PCBs does not meet the requirements of the CWA.

What do these calculations mean with respect to public policy? Water quality criteria based on the consumption rate in the current Washington and proposed USEPA criteria combined with an excess lifetime cancer risk of 1x10-5 (1E-05) present a risk that, even to the most highly exposed populations, is within the acceptable range as defined by USEPA (2000) and is also within the range of acceptable risk set by USEPA for the general population. Criteria derived using a fish consumption rate of 175 g/day and an acceptable risk level of 1x10-6 lead to levels of protection for both the general and highly exposed populations that are inconsistent with USEPA guidance. Either the allowable risk level in the current and proposed criteria needs to be increased or the fish consumption rate needs to be decreased such that the people of Washington State are protected from unreasonable risk at levels consistent with existing USEPA guidance.

3.2 Compounded conservatism

Conservative assumptions add up. If a decision maker chooses a conservative value for every variable in a risk calculation, the results will be far more protective than intended. Consider the hypothetical example of a risk assessment that is based on three independent and log-normally distributed parameters (Burmaster and Harris 1993). In the case of a fish consumption calculation, those parameters might be the amount of fish eaten each day, body weight, and the number of years over the course of a lifetime that people live in a certain place and eat fish from a local source. Each value represents the 95th percentile, or in other words that 9,500 out of 10,000 people have a lower exposure: they eat less fish, or do not eat fish from a stream for as many years, for example. Combining those three variables would result in a risk estimate that would fall at the 99.78th percentile of the resulting distribution. The risk to 9,978 out of 10,000 people would be lower than the allowable risk level used to establish the standard. Decisions made on the basis of this hypothetical calculation, which compounds conservative factors, would be far more protective than originally planned by the decision makers who intended to protect the average member of the population (or the 90th percentile or even the 95th percentile of the general population) at the selected allowable risk level.

The above example reflects the traditional interpretation of compounded conservatism. Namely the selection of conservative assumptions for multiple parameters used to estimate exposure and risk. USEPA's proposed HHWQC for Washington add another layer of conservatism outside of the selection of conservative exposure assumptions. In the proposed HHWQC USEPA has designated Native Americans as the general population and assigned to Native Americans an acceptable risk level of $1x10^{-6}$, an acceptable risk level, as well as $1x10^{-5}$, that USEPA's guidance indicates is for the general population. However, Native Americans are not the general population, comprising 2.3 percent of the Washington population (U.S Census Bureau, 2018). Native Americans are clearly a subpopulation, albeit with higher rates of fish consumption than the general population. Historic USEPA HHWQC guidance (USEPA 2000) recognizes the possible existence of such high-consuming subpopulations and indicates the potential risk to such subpopulations should not exceed $1x10^{-4}$. By designating Native Americans as the general population and assigning the most stringent general population acceptable risk level to Native Americans, the general Washington population and Native Americans are protected at levels far lower than envisioned by existing USEPA guidance.

This may look like an academic calculation and exercise. Some readers may think that overestimating risks is a good thing because it allows us to be extra-cautious, and that regulatory decisions based on risk estimates should be as conservative and protective as possible. But the consequences of such choices also need to be considered. There's a cost to reducing the levels of chemicals in the environment to meet more-stringent limits, a cost that may be measured in dollars, energy usage, or the risk of injury to workers who have the job of reducing the levels of those chemicals. Chemicals may be used to treat wastewater to meet lower standards, for example, and the sludge that results has to be trucked to a landfill or incinerated. Generating the power used to operate the wastewater treatment plant uses natural resources and creates air emissions. Each of these aspects of the life cycle of wastewater treatment operations, and their related risks, should be weighed against the value of regulatory decisions based on compounded conservatism.

Compounding the use of a high fish consumption rate, long duration of residence, upper percentile drinking water rate, and other high-end assumptions to estimate risks combined with changing the acceptable risk policy to designate a potentially high-consuming subpopulation Native Americans as the general population), with a low target excess lifetime cancer risk historically applied to the general population will result in water quality standards that are far more protective of the vast majority of the population than reflected by the target excess lifetime cancer risk. That additional degree of protection must be weighed against the risks and environmental impacts that would result from the additional treatment needed to meet such a standard.

4. Environmental Justice considerations

Environmental justice is, in the words of USEPA (2014C),

> *… the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. …. It will be achieved when everyone enjoys the same degree of protection from environmental and health hazards and equal access to the decision-making process to have a healthy environment in which to live, learn, and work.*

But how do we know what's fair treatment? The USEPA (2006) has developed guidelines relevant to risk-based decision-making. After defining the problem to be solved and collecting relevant information, we are to assess the potential for "adverse" environmental and human health effects or impacts, and to assess the potential for "disproportionately high and adverse" effects or impacts before deciding on a course of action.

Within the context of setting HHWQC within the State of Washington and the discussion in this white paper, the adverse human health effect of particular concern is cancer. At issue is whether the higher rates of fish consumption by Native Americans could lead to a disproportionate and unfair risk. The proposed HHWQC reflect two key assumptions: that Native Americans in Washington State consume 175 g/day of fish, and that the maximum acceptable risk to the subpopulation of Native Americans should be 1×10^{-6}, a risk level typically applied to the general population. These two assumptions are each conservative and they need not be compounded to achieve environmental justice.

As demonstrated in Table 8b, a standard based on the premise that those eating an average amount of fish each day would be protected to 1×10^{-5} risk level would assure that even the most highly exposed population, represented by the 95th percentile of the Suquamish Tribe, would encounter a risk of 1×10^{-4}. Such a risk would not be "disproportionately high and adverse". As indicated in Section 2.2,

> *EPA also believes 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 (sportfishers or subsistence fishers) does not exceed the 10^{-4} level.*

Further, the 10^{-4} risk level is embedded in many other standards, including drinking water; our standards for protecting workers on the job reflect the judgment that a 10^{-3} risk is acceptable. As a society, we accept that level of risk as reasonable.

Increasing the assumed amount of fish consumption or capping the acceptable level of risk is not necessary to develop standards that correspond to risks within acceptable bounds. Nor is it necessary to achieve environmental justice.

5. Putting environmental risks in perspective: everyday risks

Consider how a 1x10^{-6} lifetime risk of developing cancer compares to risks we face in our daily lives. For ease of discussion, we can refer to mortality risks in terms of micromorts[8], units representing a one in one million chance of death. For example, one micromort is the risk incurred by the average person driving 240 miles in the United States. The micromort allows different kinds of risk to be compared on a similar scale. Motorcycling 20 miles or undergoing anesthesia are equivalent to 5 micromorts apiece, skydiving or running a marathon are equivalent to 7 micromorts apiece, and giving birth in the United States is equivalent to 210 micromorts (Blastland and Spiegelhalter 2014). When we compare a lifetime risk of developing cancer to such micromorts, we need to keep two important distinctions in mind. Not all cancers are fatal. And many of the micromort statistics described below represent the risk of death *each year*, not over the course of a lifetime.

In 2010, approximately 200,955 people died in the United States from unintentional injury-related deaths (e.g., poisoning, motor vehicle traffic, firearms, falls) (CDC, 2020). This means that given a total population of about 300 million people, the average American faced an unintentional injury-related mortality risk of approximately 610 micromorts per year in 2020, or 1.7 micromorts per day. In other words, about 559 people die each day from an unintentional injury. This means that *every day*, *every American* has a risk of slightly greater than 1x10^{-6} of dying from unintentional injury.

Compare this to an excess lifetime cancer risk of 1x10^{-6}, which (if we assume a lifetime corresponds to 70 years as does USEPA (USEPA 1989, USEPA 2014B)) translates to a worse-case 0.01 micromorts per year or 0.00004 micromorts per day; this is worse case from the perspective that not all cancers are fatal and the risks estimated by risk assessments are *upper bound estimates* of risk and *do not* represent *actual* risks. Thus, USEPA's definition of "acceptable" risk is several orders of magnitude below (i.e., more stringent) the average American's daily risk of dying from an unintentional injury; it is also approximately 5,200 times lower than the 2020 risk of dying from a murder/homicide (24,576 deaths or 0.2 micromorts per day), 12 times lower than the 2020 risk of dying from a flood (59 deaths or 0.0005 micromorts per day) and 4 times lower than the 2020 risk of dying from a lightning strike (17 deaths or 0.0001 micromorts per day) in the United States (CDC, 2020, NOAA 2020a; NOAA 2020b) (**Figure 2**). This is consistent with the concept of 1x10^{-6}

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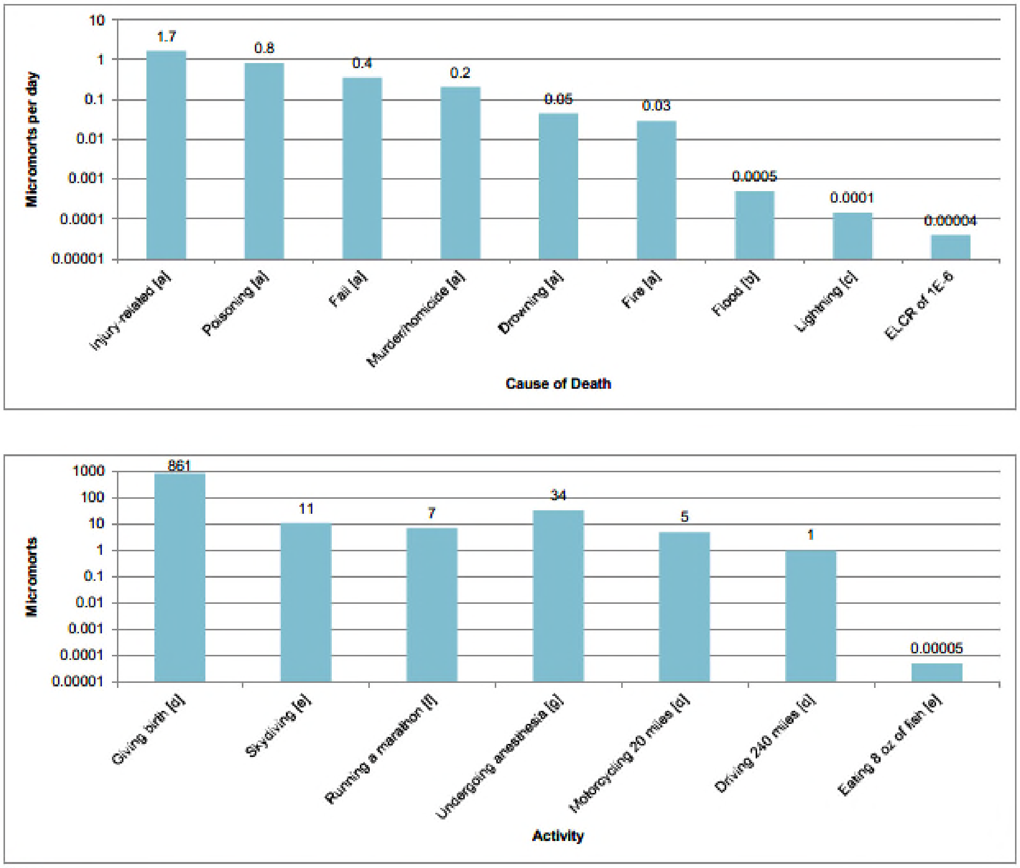
[8] A micromort is a unit of risk that represents a one-in-a-million (1x10^{-6}) probability of death. Risk assessors use micromorts to characterize and compare the riskiness of various day-to-day activities.

being a *de minimus* level of risk, because risks within this range are not risks that most members of the general public are concerned with and attempt to actively avoid.

Consider next that many regulatory agencies employ the USEPA-recommended $1\text{x}10^{-6}$ risk level to deriving HHWQC that relies on conservative upper-end values to estimate exposure. If one were to derive organism-only HHWQC by selecting a fish consumption rate of 175 g/day and targeting a risk level of $1\text{x}10^{-6}$, this means that a person would need to consume approximately 4,500 kilograms of locally-caught fish in his or her lifetime just to reach this *de minimus* level of risk, assuming ambient water always contains chemicals present at the resulting HHWQC. This also means that the risk associated with a single meal of fish would be $5\text{x}10^{-11}$, or 0.00005 micromorts, which for perspective should be noted is 20,000 times lower than the risk an average person faces when driving 250 miles in the United States (1 micromort) (**Figure 2**). Given that 175 g/day is an upper-end consumption rate estimate, the average member of the population would have an excess lifetime cancer risk lower than $1\text{x}10^{-6}$. For example, if we assume the average member of the population eats 8 g/day of fish, he or she would have an excess lifetime cancer risk of $5\text{x}10^{-8}$, roughly 20 times lower than the high-end consumer. If, on the other hand, one was to derive organism-only HHWQC by selecting an average fish consumption rate of 8 g/day and targeting a risk level of $1\text{x}10^{-6}$, the high-end consumer eating 175 g/day would have an excess lifetime cancer risk of $2\text{x}10^{-5}$, higher than $1\text{x}10^{-6}$ but still nearly an order of magnitude below the level USEPA (2000) recommends for highly exposed populations. Risk managers must make decisions such as these, recognizing that if highly exposed individuals are protected at $1\text{x}10^{-6}$, the average member of the population – and in fact the majority of the population itself – will have risks well below this *de minimus* level.

Figure 2 Common Risks Expressed as Micromorts



Notes:

[a] NCHS Vital Statistics System for numbers of deaths. Bureau of Census for population estimates via WISQARS (2020)

[b] NOAA (2020a)

[c] NOAA (2020b)

(d) Hoyert (2020)

(e) United States Parachute Association (2020)

[f] Blastland and Spiegelhalter (2014)

(g) Guohua et al. (2009)

[e] Assuming organism-only AWQC are based on a fish consumption rate of 175 grams per day and risk level of $1x10^{-6}$.

Another perspective when thinking about allowable risk is to consider the reduction or change in cancers associated with a particular allowable risk level. Allowable risk levels that result in large reductions in expected cancers clearly have a greater public health benefit than allowable risk levels that result in little change. The average excess lifetime cancer risk can be combined with the estimated size of the population of Washington (7,523,869 in 2018) and the cancer rate in Washington in 2018 (38,055 new cancers) to see how large of a change in incidence is associated with using various allowable risk levels to set regulatory standards such as water quality criteria[9]. **Figure 3** shows that comparison.

The comparison illustrated in Figure 3 demonstrates that the annual increased incidence of cancer in the state of Washington associated with various alternative allowable cancer risks is very small when compared to the baseline incidence of cancer. This is true even at an allowable lifetime risk of $1x10^{-4}$ where 1 (and for the reasons described above, almost certainly less than 1) additional cancer may occur in the State compared to the 38,230 cased diagnosed in 2014. The change is two thousandths of a percent in overall incidence. Clearly, compared to total cancer incidence, the increases in cancers associated with the above allowable risk levels are small and are swamped by other causes of cancer. This finding is consistent with the comparisons of mortality risk associated with various allowable risk levels to mortality risk from various activities that are part of everyday life shown above.

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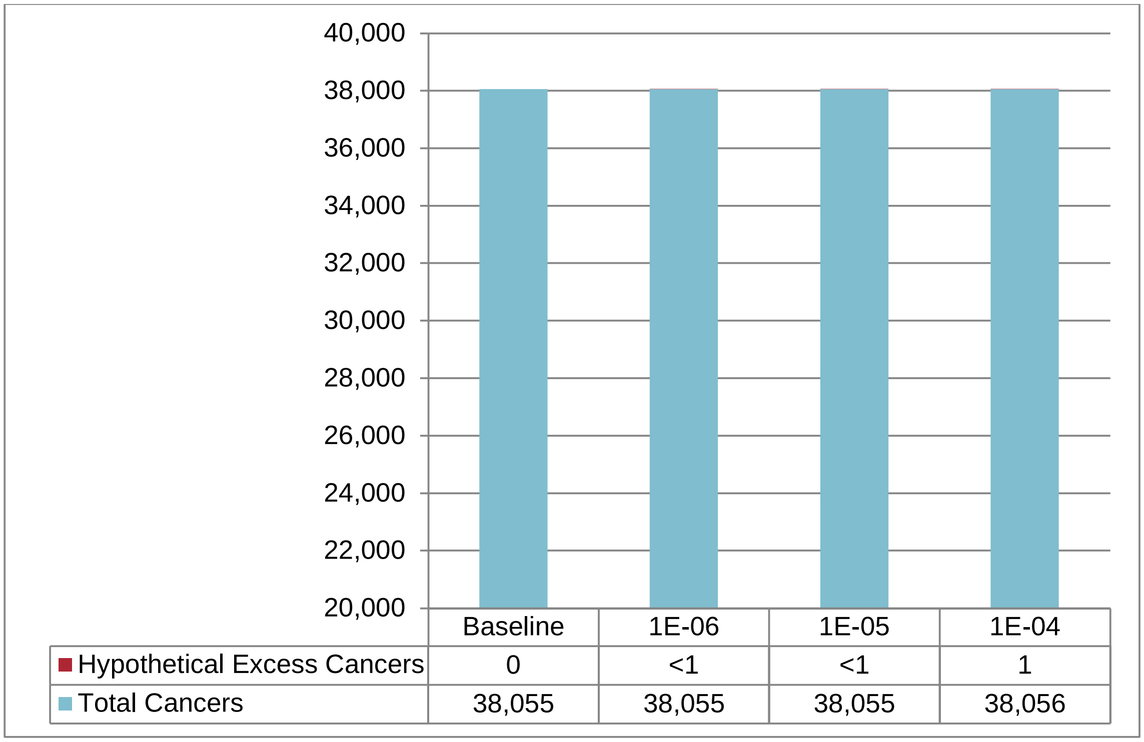
[9] Assumptions used when deriving most criteria represent an upper percentile of the exposed population, not the average person in the population. To estimate the increased state-wide cancer incidence an average excess lifetime cancer risk needs to be used otherwise increased state-wide incidence will be overestimated. Based on the work we have completed using probabilistic approaches, criteria derived using the typical deterministic approach may overestimate the potential risk to an average member of the population by 10, 100, or more fold. Because a probabilistic evaluation of the proposed Washington criteria is beyond the scope of this paper an exact estimate of the excess lifetime cancer risk for an average Washingtonian could not be developed. However, we do know that the average Washingtonian eats about 19 grams of fish per day (Ecology 2013), not 175 as assumed by the proposed criteria. Therefore, that assumption ***by itself***, results in a nearly 10-fold overestimate of excess lifetime cancer risk for the average Washingtonian. Use of other conservative assumptions in the derivation of the proposed criteria means that the excess lifetime cancer risk for the average Washingtonian is more than 10-fold lower than the allowable excess lifetime cancer risk used to derive the proposed criteria. Based on the difference between the average fish consumption rate and the 175 g/day assumed by proposed criteria, the increased incidence of cancers associated with different excess lifetime cancer risks was estimated by multiplying the expected annual cancer incidence associated with each of the excess lifetime cancer risks by the ratio of consumption rates (19 g/d/175 g/d = 0.109). The adjusted incidence of cancers based on a conservative estimate of excess lifetime cancer risk for the average Washingtonian are shown in Figure 3.

Figure 3 **Comparison between Total Cancer Incidence and the Hypothetical Excess Annual Cancer Incidence Associated with Various Allowable Risk Levels**



	Baseline	1E-06	1E-05	1E-04
🟥 Hypothetical Excess Cancers	0	<1	<1	1
🟦 Total Cancers	38,055	38,055	38,055	38,056

*Total cancers estimated by adding the number of hypothetical excess cancers to the number of cancers reported for Washington in 2018 (38,055 cases (CDC 2018)).

6. Health benefits of fish consumption

Finally, risk managers should also consider how the risks incurred from eating fish compare to the benefits gained. Researchers and public health officials have been aware for several decades that consumption of fish has associated with it many benefits. Early comparisons of those benefits to the potential risks associated with exposure to possible chemicals in the environment suggested that the benefits (specifically the reduced risk of mortality from coronary heart disease) far outweighed any increased cancer risks that might be associated with the allowable risk levels used in the derivation of HHWQC (e.g., $1x10^{-6}$, $1x10^{-5}$, and $1x10^{-4}$) (Anderson and Weiner 1995, Patterson 2002, Daviglus et al. 2002, Dourson et al. 2002, Anderson et al. 2002, US Department of Agriculture 2015, Xue and Hing 2021). A great deal of research continues on the health benefits and risks of consuming fish with measurable levels of chemicals. A literature search of publications since 2005 revealed over 400 citations, including three recent reviews by expert panels or recommendations by regulatory agencies (Nesheim and Yaktine 2007, WHO 2011, EFSA 2014). All of those recent expert reviews and regulatory agency recommendations continue to urge that people regularly consume fish. In fact, in the recommendation is that the general population eat 1 to 2 meals per week and that pregnant women eat 2 to 4 meals per week because of the benefits to the infants they are carrying (EFSA 2014). Such benefits almost always outweigh the possible risks of chemical exposure.

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