Alkylphenols and Ethoxylates Research Council

See attachment for comments.

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Safer Products for Washington
Hazardous Waste and Toxics Reduction Program
Washington Department of Ecology
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Submitted via: SaferProductsWA@ecy.wa.gov

Subject: Comments on Draft Regulatory Determinations Report to the Legislature – Phase 3 Implementation of Safer Products for Washington (November 2021, Publication 21-04-047)

The Alkylphenols & Ethoxylates Research Council (APERC) appreciates this opportunity to provide comments on the Draft Regulatory Determinations Report to the Legislature for Phase 3 implementation of Safer Products for Washington regulations.[1] This draft report proposes to impose a restriction on Alkylphenol ethoxylates (APEs) as a class in laundry detergent. Nonylphenol ethoxylates (NPEs) and Octylphenol Ethoxylates (OPEs) are identified in the report as the most commonly used and well-studied APEs.

APERC is a North American research-based trade association representing manufacturers of nonylphenol (NP), octylphenol (OP) and their derivatives, including NPE and OPE. For more than twenty years, APERC and its member companies have been actively engaged in the conduct and review of the toxicity, ecotoxicity, environmental fate, occurrence and risk of NPEs, OPEs and their degradation intermediates.[2] As such, APERC submitted substantive comments on the Draft Phase 2 Priority Consumer Products Report to the Legislature, which are referenced in the following comments on the Draft Phase 3 Regulatory Determinations report to the legislature.[3]

[1] Department of Ecology State of Washington (Ecology) (2021, November). Draft Regulatory Determinations Report to the Legislature: Safer Products or Washington Implementation Phase 3. Publication 21-04-047
[2] Members of APERC are The Dow Chemical Company, SI Group, Inc., and Dover Chemical Corporation.
[3] Alkylphenols & Ethoxylates Research Council (APERC). (2020, March 2). Comments on Priority Consumer Products Draft Report to the Legislature: Safer Products for Washington Implementation Phase 2, January 2020, Publication 20-04-004

1. The Draft Regulatory Determination Report does not adequately consider the occurrence and exposure data for APEs and their degradants, which indicate that they are predominantly non-detectable in the environment and when detected are well below US EPA WQC for NP in Washington State with environmental exposures indicating reasonable certainty of no harm.

The Draft Phase 3 Regulatory Determination Report states "monitoring studies find APEs in almost all environmental media in Washington", however it does not provide supporting data or citations for this statement, which raises transparency issues.[4] It also does not provide any perspective on the occurrence and concentration of APEs in the environment in Washington. In its previous comments, APERC provided a review of the environmental occurrence and exposures of NPE, OPE and their environmental degradation intermediates NP and OP in the State of Washington over a twenty-one-year period between 1997 and 2018 that indicated that these compounds were predominantly undetected, and in all samples where they were detected, their concentrations are well below US EPA WQC for NP in fresh and marine water and relevant Predicted No Effect Concentrations (PNECs) for NP in sediment, even when considered in toxicity-adjusted aggregate.[5]

An equally important issue that should be recognized is the uncertainty more generally with the analytical methodology for measuring NP in water samples, which is related to a high occurrence of false positive detection of this compound even with validated analytical methods. The high degree of analytical bias for false positive detections of NP in surface waters indicates that available monitoring data overstate the actual occurrence and concentrations of this compound in the environment. A published paper by Vanderford et al, 2014 presented the results of a large scale interlaboratory comparison study conducted to assess the accuracy and precision of available analytical methods for NP that included spiked samples.[6] The paper presents the results of two single-blind interlaboratory comparisons conducted at 25 research and commercial labs located in the EU, the United States, Canada and Australia. The study evaluated 22 different analytical methods for measuring NP in water. The authors concluded that NP is difficult to analyze accurately at the low concentrations expected to be found in the environment and 69% of all unspiked samples were reported to have detectable NP, indicating an extremely high percentage of false positives. The rate of false negative results for NP was only 9%, suggesting only a low degree of concern for generating false negative results. The overall results for NP precluded the authors from recommending specific analytical methods for this compound. The

[4] Ecology (2021, November)
[5] APERC. (2020, March 2)
[6] Vanderford, B.J., Drewes, J.E., Eaton, A., Guo, Y.C., Haghani, A., Hoppe-Jones, C., Schluesener, M.P., Snyder, S.A., Ternes, A. and Wood, C.J. (2014). Results of an Interlaboratory Comparison of Analytical Methods for Contaminants of Emerging Concern in Water. Anal. Chem., 86 (1), pp 774–782

authors concluded: "Perhaps most importantly, results from this work likely suggest that some studies in the literature have very high degrees of analytical bias and/or large numbers of false positives. Further, the use of occurrence data from unsuitable analytical procedures may have resulted in inappropriate risk assessments and prioritization for regulation. Thus, it is important that the consequences these data potentially have had on past decisions is recognized and critical that analytical quality and reliability be considered in future assessments." [7]

2. The Draft Regulatory Determination Report does not adequately consider that assessments of human exposure to the APE transformation products NP and OP as measured by human biomonitoring and laundry-specific exposures, indicates reasonable certainty of no harm.

Assessments of human exposure to the APE transformation products NP and OP as measured by human biomonitoring and laundry-specific exposures, indicates reasonable certainty of no harm.[8] US EPA calculated worst-case laundry worker exposures to NPE based on a generic scenario for water-based washing operations at industrial and institutional laundries and with existing exposure estimation models available from US EPA and the Occupational Safety and Health Administration (OSHA) with results that indicate - even based on worst-case exposure estimates – that risk to laundry workers is extremely low. [9, 10] In addition, US EPA noted that due to "the low volatility and negligible dermal absorption of NP and NPE, EPA does not expect that, where liquid detergents are used, NPE will present a significant exposure potential to workers."[11,12]

Osimitz et al (2015) conducted a critical review of papers on human exposure to NP from both source-specific environmental monitoring (i.e., food, drinking water, air and dust) and human biomonitoring (blood, urine, breast milk) and calculated Margins of Exposure (MOEs).[13] The MOEs were based on the use of a No-Observed-Adverse-Effect-Level (NOAEL) for sensitive toxicological endpoints of interest, that is, systemic and reproductive toxicity from continuous-feeding more than 3.5 generations (13 mg/kg/day). The MOEs were all in the range of three to

[7] Vanderford, (2014).
[8] APERC. (2020, March 2).
[9] US EPA. (2007, July 18). Draft: Engineering report of nonylphenol (NP) and nonylphenol ethoxylates (NPEs) Exposure to Laundry Workers :Response to section 21 petition.
[10] US EPA. (2006, October 24).). Chemicals used in water-based washing operations at industrial and institutional laundries - generic scenario for estimating occupational exposures and environmental releases - draft. US Environmental Protection Agency, Washington, DC, USA.
[11] US EPA. (2007, July 18).
[12] US EPA. (2006, October 24).
[13] Osimitz, T.O., Droege, W., Driver, J. (2015). Human Risk Assessment for Nonylphenol. *Human and Ecological Risk Assessment*, 21: 1903-1919

seven orders of magnitude, indicating reasonable certainty of no harm to humans for source-specific and aggregate (based on biomonitoring) exposures to NP. [14]

3. The hazard assessment for APEs described in the Draft Regulatory Determination Report has some issues with transparency and data quality in the selection of hazard data and mischaracterizes APEs as "endocrine disruptors".

While APERC defers comment on the alternative assessments presented for alternative surfactants presented in the Draft Regulatory Determination Report, a review was conducted of the hazard assessment conducted for APEs.

APERC found that hazard data utilized in the GreenScreen® hazard assessment of APEs was not sufficiently transparent to allow an understanding of the actual hazard data used in the assessment. A GreenScreen® hazard assessment conducted on APEs by a licensed profiler (NSF Sustainability, 2014) is referenced, which scored these compounds as Benchmark (BM)1_{TP}, a score that was driven by the transformation products NP and OP. However, following the referenced link to the Pharos Project website it is not possible to review the specific hazard data used to calculate the specific GreenScreen® hazard assessment score. [15]

Also, the Pharos Project data set for NPE qualifies the data supporting the ranking of several hazard characteristics of NPE (i.e., developmental toxicity, endocrine activity, skin irritation/corrosivity, and persistence) as having "low confidence". Data quality should be considered in the selection of hazard data for alternative assessments and low confidence data should not be used when higher quality data are readily available. Moreover, the persistence classification of APEs in the Draft Report relies on modeled data citing work by Hansen & Lassen, 2008 when more robust measured laboratory and field data are available. [16,17]APERC provided extensive references for data related to the persistence of APEs and their degradants in its previous comments.[18]

Finally, while the hazard assessment correctly characterizes the toxicity of APEs as being driven by their environmental transformation products, it does not sufficiently distinguish this when discussing their endocrine activity. It incorrectly refers to NPEs and OPEs as "endocrine disruptors" and states that NPEs and OPEs are included on the European Chemicals Agency Substances of Very High Concern (SVHC) Authorization List as endocrine disruptors. In fact,

[14] Osimitz *et al*. (2015).
[15] PharosProject.net
[16] Ecology (2021, November)
[17] Hansen, A.B. & Larssen, P. (2008). Screening of phenolic substances in the Nordic environments
[18] APERC. (2020, March 2).

ECHA did not find NPEs and OPEs to be endocrine disruptors, they were added to the SVHC list because they were environmental sources (through degradation) of NP and OP, which were found to be endocrine disruptors. Also, the Pharos Project dataset for NPEs classifies the endocrine activity of NPEs as "moderate" but with a low confidence qualifier. Commercially available APEs that might be used in laundry detergent are not themselves estrogenically active and therefore are not endocrine disruptors. Uterotrophic studies in the rat conducted with APEs (specifically OPE5, NPE4 and NPE9) showed no estrogen-like activity up to maximum tolerable doses of these commercial surfactant products.[19, 20] Also, a study conducted by Balch and Metcalfe, 2006 in fish showed no estrogenic effect of the commercial product NPE9 based on measures of sex ratio and vitellogenin induction as well as supplemental endpoints including observations of external secondary sex characteristics and presence of testis-ova in male gonadal tissue .[21]

4. Regulatory determinations under Safer Products for Washington should reflect the least burdensome regulatory alternative in order to achieve the general goals of the law and should be proportional to the actual potential for hazards to human health or the environment; in the case of NPE in laundry detergents regulatory options less burdensome than restriction are available and appropriate.

Recognizing that the Safer Products regulations are generally framed to reduce use of hazardous priority chemicals from priority products, it is APERC's view that consideration of exposures relevant to Washington State, such as those discussed above, are useful to inform regulatory determinations.

The Safer Products law specifies that Ecology may make one of the following regulatory determinations for each priority chemical-product combination identified in the draft report:

- Determine that no regulatory action is currently required;
- Require a manufacturer to provide notice of the use of a priority chemical or class of priority chemicals; or
- Restrict or prohibit the manufacture, wholesale, distribution, sale, retail sale, or use, or any combination thereof, of a priority chemical or class of priority chemicals in a consumer product.

[19] Williams, J., Brady, A.M., Lewis, R.W., and Hughes, L. (1996). Assessment of alkylphenol derivatives for estrogenic activity in a rat uterotrophic model. Proceedings of the 4th World Surfactants Congress, 3, 34-41, Barcelona

[20] MB Research Labs (2007, May 30). Amended Report to Chemical Manufacturers Association: Uterine Weight Assay of p-Nonylphenol (NP) and p-Octylphenol Ethoxylate-5 (OPE-5) Administered Orally to Ovariectomized Sprague Dawley Rats. Project Number MB 96-4960.07

[21] Balch, G., Metcalfe, C. (2006) Developmental effects in Japanese medaka (*Oryzias latipes*) exposed to nonylphenol ethoxylates and their degradation products. Chemosphere. 62(2006) 1214-1223

To make a determination to restrict a priority chemical in a priority product, Ecology must confirm that safer alternatives are feasible and available and the restriction will either reduce a significant source or use of a priority chemical, or is necessary to protect the health of sensitive populations or sensitive species. Ecology is proposing restriction of APEs in laundry detergent in order to "reduce a significant source or use" and because Ecology considers safer alternatives "feasible and available" based on the Department's view that "manufacturers use safer surfactants in laundry detergents and they are available for purchase". [22] However, much of the alternative assessment relies on marketing literature, which may not be the best source of information for assessing the true feasibility of alternative and it does not appear that the cost of alternatives was considered, which will ultimately affect their feasibility.

Regardless of the availability and feasibility of alternatives, restriction of APEs in laundry detergent under the Safer Products regulations will be burdensome in terms of reformulation and possibly cost for affected manufacturers and downstream users. Considering that screening-level occupational and environmental risk evaluations, based on current uses and exposures, do not suggest any source or use of APEs currently result in exposures that pose risk in the State of Washington, restricting the use of APEs in laundry detergent is not likely to significantly impact the already low risk profile of these substances.[23] Therefore, it is APERC's view that less burdensome regulatory options such as no regulation or a notification requirement are more appropriate for APEs in laundry detergent.

Respectfully,

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Executive Director

[22] Ecology (2021, November).
[23] APERC. (2020, March 2).