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Hazardous Waste and Toxics Reduction Program
Department of Ecology
Olympia, Washington

Submitted via: Safer Products for Washington Public Online Comment Form

Subject: Comments on Priority Consumer Products Draft Report to the Legislature: Safer Products for Washington Implementation Phase 2, January 2020, Publication 20-04-004

The Alkylphenols & Ethoxylates Research Council (APERC) appreciates this opportunity to provide comments on the "Priority Consumer Products Draft Report to the Legislature: Safer Products for Washington Implementation Phase 2" (Draft Report). [1]

The Draft Report identifies priority consumer products, which are being proposed for the first five "priority chemical" classes that were indentified in the Revised Code of Washington (RCW) for the Safer Products for Washington law (Chapter 70.365 RCW). APERC's comments focus on alkylphenol ethoxylates (APEs), a subgroup of the priority chemical category "phenolic compounds" identified in the Safer Products for Washington law. The Draft Report correctly notes that the most common APEs are nonylphenol ethoxylates (NPE) and octylphenol ethoxylates (OPE).[2]

APERC is a North American research-based trade association representing manufacturers of nonylphenol (NP), 4-tert-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 assessment of NPEs, OPEs and their degradation intermediates.[3]

The Draft Report proposes priority consumer products that are in the view of the Department of Ecology (DoE) and the Department of Health (DoH) a "significant source or use" of priority chemicals that were specifically identified in the Safer Products for Washington Act. [4]

[1] Department of Ecology, State of Washington (DoE) (2020, January). Priority Consumer Products Draft Report to the Legislature: Safer Products for Washington Implementation Phase 2. https://fortress.wa.gov/ecy/publications/summarypages/2004004.html
[2] DoE. (2020, January). Pg. 48
[3] Members of APERC are The Dow Chemical Company, SI Group, Inc., and Dover Chemical Corporation.
[4] Washington State Pollution Prevention for Healthy People and Puget Sound Act, May 2019.

At this time there is no guidance provided to inform the determination of "significant source or use" under the new Safer Products for Washington regulatory process. DoE reasoning to support "significant sources" appears to be developed on a case-by-case basis in the Draft Report.

With this in mind, APERC offers the following comments regarding the Draft Report and the proposal to make APEs in laundry detergent a Priority Product under the "phenolics" chemical class in the Safer Chemicals for Washington law. One comment also addresses an inaccurate characterization of APEs as persistent and bioaccumulative in webinar slides from the February 19, 2020 webinar on implementation of phase 2 of Safer Products for Washington. [5]

1. The process to identify "significant sources or uses" of Priority Chemicals should consider risk and prioritize products that actually pose risk to human health or the environment in the state of Washington; in the case of APEs, screening level risk assessments do not indicate risk in the State of Washington from any use of APEs.

Since regulation of a Priority Product under the Safer Products regulations will potentially set into motion regulations that will be significant and burdensome to implement for both affected businesses and the Departments of Ecology and Health, APERC recommends that the Safer Products for Washington process for determining "significant sources or uses" focus on uses of priority chemicals that have been demonstrated to pose a risk and/or represent the greatest potential for human or environmental exposure. This approach would be consistent with the apparent intention of the "significant sources or uses" criteria in the Safer Products for Washington law. In the case of APEs, screening level occupational and environmental risk evaluations presented in Attachments I and II to these comments do not suggest any source or use of NPE or OPE that poses significant exposure or risk in Washington State.

2. Although screening assessments do not find risk to the environment or human health from the use of NPE in laundry detergent, this use does represent a potentially high volume use with a high percentage of this surfactant in a product category that is intentionally discharged to wastewater treatment plants.

As discussed in these comments, there is no indication that any use of NPEs (or APEs generally) results in releases or exposures that are sufficiently significant to pose a risk to human health or the environment in the State of Washington; nevertheless this new law directs the DoH to identify "significant sources or uses" of the priority chemical class "phenolics", which has been defined to include APEs. The Draft Report identifies laundry detergent as a significant source of APEs and references a study conducted by the California Department of Toxic Substances Control (DTSC), which found that institutional cleaners, including laundry detergent, are the largest use of NPE surfactants. In addition, the Draft Report notes that laundry detergents that are "discarded down-the-drain make their way through wastewater treatment plants to bodies of water". [6] These findings regarding NPE are consistent with APERC's understanding of the

[5] DoE and DoH. (2020, February 19). Safer Products for Washington Implementation Phase 2: Draft Report on Priority Consumer Product. Webinar slides.
[6] DoE and DoH. 2020, January, pg. 5

relative use of NPE surfactants as well as their intentional disposal to wastewater treatment plant when used at significant percent concentrations of up to 28% NPE in laundry detergents. [7]

3. A recent Canadian screening assessment found that uses of OPE do not result in releases to the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in to human life, health or the environment; since use patterns of OPE in the State of Washington are not expected to differ substantially from Canada, significant sources or uses of OPE that are relevant to the Safer Products for Washington regulations are unlikely.

Regarding OPEs, APERC understands that these surfactants are used primarily in industrial applications with minor use in laundry detergent and that the volume of OPEs used in North America is approximately one-third that of NPEs. In addition, Environment and Climate Change Canada and Health Canada (ECCC) recently released a draft screening risk assessment on OPEs, which concluded that OPEs are not toxic under the Canadian Environmental Protection Act (CEPA) because they are "not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends" and "are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health." [8] Since use patterns of OPE in Canada are not expected to differ significantly from those in the United States or the State of Washington, based on the Canadian draft screening assessment there does not appear to be any significant exposure or risk to human health or the environment or any significant sources or uses of OPE that are relevant to the Safer Products for Washington regulations.

4. The European Union (EU) Environmental Quality Standards (EQS) values for NP are scientifically unacceptable benchmarks for comparison to environmental concentrations of AP/APE in Washington State; United States Environmental Protection Agency (US EPA) Water Quality Criteria (WQC) for NP provide more scientifically robust benchmarks for assessment of the environmental risk of AP/APE in the State of Washington.

In a discussion of potential environmental exposure to AP and APEs in the State of Washington the Draft Report notes that “globally there are there is widespread detection of APEs and APs in water, air, and sediment” and “detection is often at levels well above the probable no effect

[7] Cheng,C.y and Ding, W.H. (2002). Determination of nonylphenol polyethoxylates in household detergents by high-performance liquid chromatography. *Journal of Chromatography A*, Vol. 968, Issues 1-2, pgs. 143-150

[8] Environment and Climate Change Canada and Health Canada (2019, December). Draft Screening Risk Assessment – Polyethers/polyalkoxylates. https://www.canada.ca/content/dam/eccc/documents/pdf/pded/poly(alkoxylates-ethers)/DSAR-Poly(alkoxylates_ethers)-EN.pdf

concentration for NP- determined by the EU to protect aquatic health – of 0.33 ug/L in water and 0.039 mg/kg in sediment.” [9]

It is APERC’s view that the EU EQS developed for NP under the EU Water Framework Directive are not appropriate benchmarks for use in the context of assessing the environmental occurrence of AP/APE in the State of Washington or elsewhere. The EU developed EQS Predicted No Effect Concentrations (PNECs) for NP based on the most sensitive endpoint in the dataset reviewed. The basis of the EU EQS PNEC was a toxicity study by Kopf, 1997 in the freshwater algae *Scenedesmus subspicatus*. [10] The PNEC (surface water) in the Kopf, 1997 study was calculated by dividing the $EC_{10(Biomass)}$ by an assessment factor of 10. This assessment factor was justified by the fact that long-term No Observed Effect Concentrations (NOECs) from at least three species representing three trophic levels were available. Therefore, the NOEC for this freshwater alga provided the basis of the PNEC (water) value of 0.33 µg/L. The EU PNEC(sediment) was calculated as 0.039 mg/kg wet wt using an equilibrium partitioning method, which assumes that sediment-dwelling organisms are equally sensitive to NP and is based on the PNEC(water) value of 0.33 µg/L. [11]

It is important to note that the Kopf, 1997 study was rejected for use by U.S. EPA in deriving WQC for NP because it did not meet the study quality criteria necessary to include it in a WQC derivation.[12] Environment Canada (now called Environment and Climate Change Canada) and the Canadian Council of Ministers of the Environment (CCME) also did not rely on the Kopf, 1997 study in their risk assessment of NP/NPE.[13,14] In addition, the EU EQS is based on an algal biomass endpoint, which according to current EU guidance on Information Requirements and Chemical Safety Assessment, is not the preferred algal endpoint, particularly for development of an EQS.[15]

In summary, the current EU EQS for NP was developed based on an endpoint that would not be acceptable to the EU today from a study that does not meet the study quality requirements of the U.S. EPA or ECCC. Therefore, it is APERC’s view that the EU EQS for NP is not sufficient from a scientific perspective for use in the context of the discussion of AP/APEs in the Draft Report.

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[9] DoE and DoH. (2020, January). pg. 52

[10] Kopf, W. (1997). The action of endocrine substances in biological tests with aquatic organisms. Papers on Wastewater, Fisheries and River Biology. Volume 50. R. Oldenbourg Verlag, Munich

[11] European Commission. (EC). (2005, July 31). Environmental Quality Standards Substance Data Sheet: Nonylphenol. Final Version, Brussels

[12] US Environmental Protection Agency (US EPA). (2005). Aquatic life ambient water quality criteria - nonylphenol. Report 822-R-05-005. US Environmental Protection Agency, Washington, DC, USA.

[13] Environment Canada and Health Canada (EC and HC). (2001). Priority substances list assessment report for nonylphenol and its ethoxylates. ISBN: 0-662-29248-0.

[14] Canadian Council of Ministers of the Environment (CCME). (2002). Canadian water quality guidelines for the protection of aquatic life: Nonylphenol and its ethoxylates. Environment Canada Publication Number 12999. ISBN 10896997-34-1.

[15] European Chemicals Agency (ECHA). (2017.June). Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.7b Endpoint Specific Guidance. Version 4.0

U.S. EPA developed Water Quality Criteria (WQC) for NP based on a robust aquatic toxicity database for NP that included adverse effects observed in *in vivo* toxicity studies that characterize population level effects in the environment (*i.e*. effects on survival, growth and development, and reproduction) and consideration of acute to chronic ratios. [16] NP has been the subject of attention due to its toxicity to aquatic organisms and because some studies have indicated that NP exhibits weakly estrogenic properties. In its final WQC document, EPA noted "the ability of nonylphenol to induce estrogenic effects has seldom been reported at concentrations below the freshwater final chronic value of 6.5965 μg/L." [17]

A review of more recent aquatic toxicity studies (17 freshwater species and 13 marine species) on NP, nonylphenol monoethoxylate (NP1EO) and nonylphenol diethoxylate (NP2EO) that were available after US EPA developed the WQC for NP was conducted by Coady *et al*, 2010, which confirmed that these newer data also support that the US EPA chronic WQC for NP in freshwater and saltwater are protective of aquatic species. [18]

U.S. EPA WQC for NP are appropriate from both a regulatory policy and scientific perspective for evaluating whether environmental exposure patterns indicate an environmental risk in the State of Washington. APERC provides a screening assessment of environmental concentrations of NP/NPE and OP/OPE in surface waters in the State of Washington relative to the EPA WQC for NP in comment number 5 below and in more detail in Attachment II to these comments. Since US EPA has not yet developed sediment quality criteria, toxicity-based PNECs for benthic organisms based on studies with sediment concentrations of NP and derived according to methods similar to US EPA guidance are provided in Attachment III and used for comparison to sediment concentrations in the State of Washington in Attachment II.

5. Available data on the environmental occurrence and concentrations of NPE, OPE and their degradants NP and OP in the State of Washington over a twenty-one year period between 1997 and 2018 indicate that these compounds are predominantly undetected, and when they are detected their concentrations are well below US EPA WQC for NP in fresh and marine water and relevant PNECs for NP in sediment.

Attachment II to these comments provides a review of the environmental occurrence and exposures of NPE, OPE and their environmental degradation intermediates NP and OP in the State of Washington. The dataset was drawn primarily from The DoE Environmental Information Management System (EIM) and the National Water Quality Monitoring Council Water Quality Portal. [19, 20] The available data show that these compounds are undetected in most

[16] US Environmental Protection Agency (US EPA). (2005). Aquatic life ambient water quality criteria - nonylphenol. Report 822-R-05-005. US Environmental Protection Agency, Washington, DC, USA.
[17] US EPA (2005)
[18] Coady, K., Staples, C. Losey, B., and Klecka, G. (2010). A Hazard Assessment of Aggregate Exposure to Nonylphenol and Nonylphenol Mono- and Di-ethoxylates in the Aquatic Environment. *Human and Ecological Risk Assessment*. Volume 16, Issue 5, pgs 1066-1094
[19] Department of Ecology (DoE), The State of Washington, Environmental Information Management System (EIM) https://ecology.wa.gov/Research-Data/Data-resources/Environmental-Information-Management-database

samples, and where they are detected concentrations are well below US EPA WQC for NP in fresh and marine water and relevant PNECs for NP in sediment. In fact, ***none*** of the valid detected OP, NP or Total NP Equivalent (TNPEQ) values reported for the twenty-one year period between 1997 and 2018 exceed US EPA WQC for NP in fresh surface water (6.6 µg/L NP) or marine surface water (1.7 µg/L NP). Also, ***none*** of the detected values for OP, NP or TNPEQ in sediment exceed toxicity-based PNECs for NP in freshwater sediment (6,150 ng/g-dw) or marine sediment (1,230 ng/g-dw). These findings do not indicate ***any*** uses or sources of NPE or OPE as being a significant source or posing a risk to the environment in the State of Washington.[21]

There were two cases in the dataset where reported concentrations of NP and/or TNPEQ exceeded these WQC and PNEC. The first case was related to proxy data reported for **non-detected** samples of NP and/or TNPEQ due to the fact that ½ the Reporting Limit (RL) or Minimum Detection Limit (MDL) for the analytical method exceeded the relevant WQC or PNEC. The second case was related to questionable data reported under a Lummi Nation monitoring program using a method that is not relevant to or validated for NP/NPE. Details for both of these cases are provided in Attachment II.

Unfortunately, sampling locations in the dataset were not selected for direct temporal comparison and there are an insufficient number of sample locations with actual measured detections both before and after 2005/2006, when retail driven deselection of NPE in consumer detergents began with a Wal-Mart initiative[22]; therefore there are insufficient data to provide a useful temporal comparison. However, the overall data do not suggest any uses of NPE or OPE over the twenty-one year sample period resulted in environmental exposures sufficient to result in risk to the environment in the State of Washington.

6. US EPA and other screening assessments find high Margins of Exposure (MoE) and low potential for risk to laundry workers and consumers from the use of NPE in Laundry Detergent.

The Draft Report raises exposure to laundry detergent as being particularly relevant for workers, who have a higher potential for exposure compared to the general population. [23]

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

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[20] National Water Quality Monitoring Counci, Water Quality Portal. https://www.waterqualitydata.us/
[21] Alkylphenols & Ethoxylates Research Council (2019, Nov 25.) Analysis of Environmental Monitoring for Nonylphenol, Octylphenol and their Ethoxylates in the State of Washington (Attachment II)
[22] Wal-Mart. (2006).Chemical Intensive Products Preferred Principles Fact Sheet. October .
[23] DoE and DoH. (2020, January). page 51

– that risk to laundry workers is extremely low. [24, 25] 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."[26,27]

While the exposure estimates developed in the EPA Engineering Report are useful to demonstrate low worker exposures to NPE during the use of laundry detergents, they are extremely conservative and can be further refined using other available data and models. [28] Therefore, APERC conducted an exposure screening assessment to calculate potential exposure and MoE, or margins of safety, of industrial and institutional laundry workers to NPE, which is presented in Attachment I. The MoEs are based on multiple, conservative assumptions regarding exposure and therefore represent an upper bound estimate of laundry worker occupational exposure - not actual exposure. All MoEs indicate a low potential for risk to laundry workers. MoEs for the risk to consumers are expected to be even lower based on their lower exposures.

7. Assessment of source-specific human exposure and aggregate human exposure, as measured by human biomonitoring, to NP and OP studies indicates reasonable certainty of no harm.

The Draft Report discusses the potential for exposure to sensitive populations and references findings related to AP in human biomonitoring, noting that APs are more often measured in studies than APEs and can serve as an indicator of APE exposure. [29] In fact, human biomonitoring studies can provide reliable estimates of aggregate exposure to NP and or OP from all sources and uses, including of their ethoxylates.

The Draft Report correctly references human biomonitoring conducted by the US Centers for Disease Control (CDC) that found concentrations of OP in human urine that were so negligible and declining in the United States between 2005 and 2010 that CDC stopped reporting monitoring for this compound in human urine after 2010.

The Draft Report also cites several human biomonitoring studies that measured NP in human tissues, blood and urine. Osimitz et al (2015) conducted a critical review of papers published between 1998 and 2003 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 MOEs.[30] The MOEs were based on the use of a No-Observed-Adverse-Effect-Level (NOAEL) for sensitive toxicological endpoints of interest, that is, systemic

[24] US EPA. (2007, July 18). Draft: Engineering report of nonylphenol (NP) and nonylphenol ethoxylates (NPEs) Exposure to Laundry Workers :Response to section 21 petition.
[25] 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.
[26] US EPA. (2007, July 18).
[27] US EPA. (2006, October 24).
[28] US EPA. (2007, July 18).
[29] DoE and DoH.(2020, January). pg. 50
[30] Osimitz, T.O., Droege, W., Driver, J. (2015). Human Risk Assessment for Nonylphenol. *Human and Ecological Risk Assessment*, 21: 1903-1919

and reproductive toxicity from continuous-feeding more than 3.5 generations (13 mg/kg/day). The MOEs were all greater than 1000, ranging from 2.9 x10^3 to 8.4 x10^7, indicating reasonable certainty of no harm to humans for source-specific and aggregate (based on biomonitoring) exposures to NP. [31]

8. AP/APEs are not persistent or bioaccumulative according to any governmental criteria, including those in Washington State.

While these comments are primarily directed at issues raised in the Draft Report, APERC would like to take this opportunity to provide corrections to a webinar presentation broadcast by DoE and DoH on February 19, 2020 on "Implementation Phase 2: Draft Report on Priority Consumer Products".[32]

While the Draft Report does not represent AP/APEs as persistent or bioaccumulative, the webinar presentation (slide 9) lists "persistent" and "bioaccumulative" as environmental hazards from chemicals within the "phenolic compounds" class.

Klecka et al, 2007 examined the persistence and bioaccumulation potential of C8- and C9-alkylphenols and their ethoxylates and concluded that the commercial APE products and their degradation intermediates do not meet any national or international criteria for identifying these compounds as PBT substances. [33] Environment Canada performed an assessment of all commercially relevant APE and AP and concluded that none of the substances met the CEPA criterion for either persistence or bioaccumulation. [34, 35] Further, the European Commission Subgroup for the Identification of PBT and vPvB Substances concluded that the persistence and bioaccumulation criterion were not fulfilled by NP. [36, 37] Also, NP is listed in the European Chemical Substances Information System (ESIS) as not fulfilling PBT and vPvB criteria.[38]

Most relevant is that Washington DoE selected NP as one of 65 candidate chemicals for PBT screening and prioritization as part of a proposed PBT strategy in 2000 and decided not to include this compound on the PBT Working List because it does not meet the state's criteria for

[31] Osimitz *et al*. (2015).

[32] Department of Ecology and Department of Health. (2020, February 19). Implementation Phase 2: Draft Report on Priority Consumer Products. Webinar Slides. https://www.ezview.wa.gov/Portals/_1962/Documents/saferproducts/February_2020_Webinar_Presentation.pdf

[33] Klecka, G. *et al* . (2008). C8- and C9-Alkylphenols and Ethoxylates: II. Assessment of Environmental Persistence and Bioaccumulation Potential. Human and Ecological Risk Assessment, 14:1025-1055

[34] Environment Canada (EC). 2005. Decision on Categorization of Nonylphenol, Octylphenol and their Ethoxylates: Letter in Response to Alkylphenols & Ethoxylates Research Council Comments. Gatineau, Quebec. November 21, 2005

[35] Environmental Canada (EC). 2007. Ecological categorization of substances on the Domestic Substance List; Categorization Decisions (Completed in September 2006).

[36] European Commission (EC). (2002, August 30). Identification of Potential PBTs or vPvBs among the IUCLID High Production Volume Chemicals. European Chemicals Bureau Doc. ECB. Ispra, Italy.

[37] European Commission (EC). (2003, October 27-28). Minutes of Third Meeting of TM Subgroup on Identification of PBT and vPvB Substances. Arona, Italy. October 27–28, 2003

[38] European Chemicals Bureau European Substances Information System. ECB-ESIS. (2007). ESIS Version 5 Existing Substances PBT Module.

persistence and bioaccumulative. [39,40] The DoE Response to Public Comments document stated "Ecology has reviewed the comments received on this issue and has decided not to include nonylphenol on the PBT Working List. The two main reasons why Ecology has elected not to include this substance on the PBT Working List are (1) the regional half-life values is below the criterion used to assess persistence; and (2) the bioconcentration factor is below the criterion used to assess bioaccumulation potential." [41]

If you have any questions regarding these comments or the attachments please contact me at blosey@regnet.com or (202) 419-1506.

Respectfully,

Barbara Losey
Director

Attachments
Attachment I. Laundry Worker Exposure and Margin of Exposure
Attachment II. Summary of Environmental Monitoring for Nonylphenol and Nonylphenol Ethoxylates in the State of Washington
Attach II Fig.1_NP_FW_SW_OBG_11.25.2019
Attach II Fig. 2_NP_Mar_SW_OBG_11.25.2019
Attach II Fig. 3_NP_FW_Sed_OBG_11.25.2019
Attach II Fig. 4_NP_Mar_Sed_OBG_11.25.2019
Attach II Fig. 5_TNPEQ_FW_SW_OBG_11.25.2019
Attach II Fig. 6_TNPEQ_Mar_SW_OBG_11.25.2019
Attach II Fig. 7_TNPEQ_FW_Sed_OBG_11.25.2019
Attach II Fig 8_TNPEQ_Mar_Sed_OBG_11.25.2019
Attach II Fig. 9_OP_FW_SW_OBG_12.05.2019
Attach II Fig 10_OP_Mar_SW_OBG_12.05.2019
Attach II Fig. 11_OP_FW_Sed_OBG_12.05.2019
Attach II Fig. 12_OP_Mar_Sed_OBG_12.05.2019
Attachment III. Staples, C. et al(2010, Nov.) Assessing the Effects and Potential Risks of Branched para-Nonylphenol to Sediment Dwelling Organisms. Poster at Society of Environmental Toxicology & Chemistry Annual Meeting, North America

[39] Washington Department of Ecology (DoE). (2000, December). Proposed Strategy to Continually Reduce Persistent , Bioaccumulative Toxins (PBTs) in Washington State. Publication 00-03-0054
[40] Washington Department of Ecology.(DoE) (2002, June). Ecology PBT Working List: Responses to Public Comments on Appendix E. Publication No. 02-03-030
[41] DoE. (2002, June).