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Washington State Department of Ecology
300 Desmond Drive SE
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Submitted via Public Comment Link

Re: Draft Identification of Priority Products Report to the Legislature: Safer Products for Washington Cycle 2 Implementation Phase 2

We appreciate the opportunity to comment on Washington State Department of Ecology's (Ecology) recent report, Draft Identification of Priority Products Report to the Legislature. We acknowledge the Washington State Department of Ecology's commitment to reducing environmental and public health risks associated with priority chemicals and the underlying statute which informs the Safer Products for Washington (SPW) program. However, we wish to express continued concerns with the implementation of the SPW program overall and the potential to undermine the effectiveness of the proposed SPW framework and its potential implications for industry, other stakeholders and Ecology's own operational capacity. These comments and recommendations are informed by our experience with implementation of Cycle 1 of the program.

We offer the following general comments to help inform Cycle 2 and enhance the overall SPW program.

The SPW Program Should Adopt a More Science-Based Approach to Source Characterization and Focus only on "Significant Sources"

The statute requires Ecology to identify priority consumer products that are a "significant source or use of priority chemicals."[1] Many of the identified priority product categories are not a significant source of exposure for the underlying priority chemicals. The proposed rule's approach to source identification for priority products is overly broad, likely leading to challenges for implementation and enforcement, while also undermining the effectiveness of the program. By casting such a wide net, the program risks implicating products and applications that may not contribute significantly to environmental or public health concerns. We encourage Ecology to take a more rigorous approach to assessing and determining if a product category is a significant source. This should include consideration of clear criteria to whether a source is significant or insignificant. The mere presence of a molecule of a chemical substance should not be deemed by the agency to be "significant" as a matter of course without some corresponding finding of significant risk of harm. We encourage Ecology to refine its methodology for identifying priority products by emphasizing specific, well-documented sources of concern. Other regulatory schemes explicitly consider specific criteria for evaluating source characterization and assessing whether certain uses exceed established thresholds and are likely to present a significant risk to human health or the environment. Indeed, Washington State has established such criteria for the assessment of priority chemical in RCW 70.430.050: including conducting a quantitative estimate of the potential human and environmental exposures associated with the use and release of the chemical. Such criteria and processes should be applied in the SPW program as well to help focus and guide its meaningful implementation. Likewise, the underlying statute for the SPW Program lays out specific criteria that "must" be considered in identifying proposed priority consumer products in its Report to the Legislature. Ecology has failed to conduct this required analysis with this information

[1] RCW 70A.350.030

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for some of the identified product categories. While Ecology is not required to give equal weight to each criteria, these factors must be considered. This is explicitly required at this stage of the SPW process to help focus and guide the selection of priority products and not waiting to assess these factors later in the regulatory process. We encourage Ecology to consider the feedback in this area from some of the chemical specific comments provided in Phase 1 and reiterated in this Phase.

Ecology's analysis should also include consideration of de minimis and established regulatory thresholds for levels of a chemical in a product category. Other regulatory schemes routinely identify concentrations, quantities, or exposures that are considered *de minimis*, no significant risk, or otherwise insignificant. California's Office of Environmental Health Hazard Assessment (OEHHA) promulgates No Significant Risk Levels, for example, under the Proposition 65 program that help describe chemical concentration levels in a product that do not require a label notification. FDA-regulated foods can use, for nutrition facts disclosures, language to denote when the presence of a nutrient is not a significant source. Environmental and health programs at the federal level routinely describe *de minimis* levels for a variety of purposes. The U.S. Occupational Health and Safety Administration (OSHA)'s Hazard Communication of Hazardous Materials standard (HazCom) generally does not require label disclosure below a concentration level of 1 percent. Significance in the regulatory context from a health and environmental risk standpoint is generally understood to mean more than negligible or insignificant but less than substantial.

The SPW Program Should Avoid Overly Broad Approaches to Classes of Chemistry and Focus on Science-Based Subcategory or Sub-Class Approaches

Some of the classes Ecology includes in the Report are so broad as to be unworkable with respect to conducting a hazard assessment of the class; a risk assessment of the class; and an alternatives assessment of the class. While we acknowledge the underlying statute's intent to consider categories of chemicals, the overly broad class-based approach is unworkable and will undermine the effectiveness of the program. Indeed, the Statute itself recognized this distinction and specifies classes or "members of a class of chemicals".

The National Academies of Sciences, Engineering, and Medicine (NASEM) concluded, for example, in a 2019 report that organohalogen flame retardants cannot be treated as a single class for purposes of a hazard assessment.[2] NASEM identified fourteen subclasses to support hazard assessment by subclass. NASEM specifically rejected the use of chemical function to define a class as opposed to using specific toxicity characteristics or other chemical-specific features such as physical-chemical properties. As such, Ecology's approach to identifying classes is not based on the best available science. Specific examples of this are highlighted in both past and current chemical specific comments for the identification of priority chemicals in Cycle 1 and this Cycle. We encourage Ecology to consider these chemical specific comments at this Phase. Ecology can further prioritize its efforts by focusing on relevant sub-categories of a class that meet established criteria.

The limitations of the overly broad class approach are clearly relevant in the implementation of Cycle 1 of the SPW Program. To effectively implement the SPW Program downstream users and manufacturers need to understand the specific chemicals that are being assessed and proposed for regulation. This includes identifying specific chemicals with specific CAS (Chemical Abstracts Service) numbers. It is impossible for downstream users and

[2] See National Academies *A Class Approach to Hazard Assessment of Organohalogen Flame Retardants* (2019)

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manufacturers to provide effective input and implement final regulations without this. They need greater clarity to effectively manage their supply chains, which can be complex with multiple-tired suppliers.

Ecology itself also recognized distinctions within broad classes of chemistry in its recent Exemption Request Process Resource for Cycle 1. Ecology should recognize those distinctions and apply them at this stage of the program as well which will further contribute to the overall Program's objectives.

The current class approach is likely to be arbitrary in both application and in results. Ecology should reconsider moving the program to the NAS Framework approach.

Ecology's Chemical Class Approach Is Unworkable and Will Lead to Inconsistent Application of its Hazard Criteria

Ecology's chemical class approach has led to inconsistent application of its hazard criteria. Ecology has chosen an approach that assumes all chemicals within an identified priority chemical class (even a class containing a large number of chemicals) will not qualify as safer. Conversely, in its desire to find acceptable alternatives, Ecology has applied a lower level of scrutiny to other chemicals. This is likely to lead to regrettable – or, at best, needless and costly – substitution that is not supported by the available science. For example, Ecology concluded that two halogenated flame retardants do not meet its "safer" criteria despite having achieved a GreenScreen score of BM-2. This is because, Ecology claims, those chemicals fail the within-class criteria. However, Ecology also concluded that two non-halogenated flame retardants (triphenyl phosphate (TPP); and resorcinol bis(diphenyl phosphate) (RDP) may meet the "safer" criteria for the sole reason that they have achieved the same GreenScreen score. For instance, regarding RDP, Ecology states that "RDP scored BM-2 in a GreenScreen(R) assessment, and the assessment was reviewed by TCO Certified. This meets our minimum criteria for safer…".

By applying a lower level of scrutiny to proposed alternatives than to chemicals already in use, Ecology risks that very result. Additionally, Ecology evaluates chemical classes based on several chemicals within the class that are "data rich," and does not perform a review of all data from the priority chemical class. For example, if some data rich chemicals within the chemical class do not meet Ecology's criteria for safer, but the class also includes some chemicals that are poorly characterized, then Ecology will classify the class as potentially hazardous based on the data rich chemicals. Ecology argues that this approach avoids assuming chemicals with no data are not hazardous. In practice, however, this approach builds in an inherent bias towards a more hazardous finding because the data rich chemicals are the most studied and already identified as hazardous. By taking this approach, Ecology does not appropriately consider the newer alternatives and instead compares new alternatives that have similar functional chemistry to older chemicals already considered to be some of the most hazardous chemicals.

The SPW Program Should Adopt A More Holistic Approach to Alternatives Assessment that Takes into Account Broader Product Design Factors and Avoids Regrettable Substitution

Throughout Cycle 1 of the program, industry and downstream users consistently reiterated the need for a more robust alternative assessment process that took into account overall product design, safety and performance. While a detailed alternative assessment is more relevant for the next phase of the SPW process, the underlying statute requires consideration of alternatives at this stage and in the report to the legislature. This analysis is missing for many of the product applications or is not sufficient.

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Alternatives assessment is an important science policy field, and Ecology should consider application of the framework approach and principles set out in the National Academies of Sciences' Framework to Guide Selection of Chemical Alternatives.[3] "Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives"[4] is a more recent publication by The Organization for Economic Co-operation and Development, (OECD), an intergovernmental collaborative of 37 industrialized countries. The NAS and OECD frameworks contain important policy considerations, science elements, and sequencing that can help inform Ecology's approach as it implements the Safer Products program.

The simplest and perhaps most effective approach to alternatives assessment for a given chemical is to identify a single, discrete chemical substance for an alternatives assessment, sometimes called a single chemical substitution.[5]This makes comparison with a defined range of alternatives a complex task, but the most straightforward. A single chemical, for example, can be evaluated against others in its own (same) appropriately defined and bounded category. A chemical category is a group of chemicals whose physiochemical and human health and/or ecotoxicological properties are likely to be similar or follow a regular pattern, usually as a result of structural similarity.[6] The mere condition of sharing one or more of these properties, however, is not sufficient, nor is structural similarity sufficient, to support a category by itself. For example, the classification, "solid at room temperature,"[7]while describing a group of chemicals with one similar characteristic, does not by itself predict similar or patterned physiochemical, human health, and ecotoxicological properties. (Chemicals that are solid at room temperature include quartz, carbon, salt (NaCl), and gold). Attempting to group solely by functional category for chemicals – e.g., colorants, antioxidants, flame retardants – is generally too broad a descriptor to arrive at a category with similar or patterned phys/chem, health, and ecotox properties.

The NAS framework takes the most straightforward approach to alternatives assessment. Step 1 of the framework is to identify a specific chemical of concern for entry into the framework. A selected chemical then moves to a scoping and problem formulation step, establishing the scope of assessment and plan for assessment. The assignment of a unique CAS or IUPAC (International Union of Pure and Applied Chemistry) number is generally indicative of a unique chemical substance, as CAS will register unique chemical substances that can be represented by completely defined molecular structures (i.e., all atoms and the chemical bonds joining them are known). Notably, CAS excludes substance classes from routine registration (e.g., silver compounds).[8]

The categories set out in the Draft Report are too broad to characterize distinct chemical properties that can be readily compared in an alternatives assessment. This includes hazard. ACC recommends that Ecology apply the NAS alternatives framework to selection of chemicals for entry into the alternatives assessment process.

Risk Considerations

In order to perform an alternatives assessment, the agency must also evaluate the actual risk (hazard x exposure) presented in various use scenarios and evaluate new risks that may be presented by a substitute formulation including other considerations relayed to product design, performance and safety. For example, proposed simple

[3] See A Framework to Guide Selection of Chemical Alternatives
[4] See, e.g., Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives, OECD 2021
[5] IBID
[6] Grouping of Chemicals: Chemical Categories and Read-Across, available at OECD.org.
[7] Descriptions of the state of matter – freezing point, melting point, and boiling point, are all universally recognized physical properties.
[8] See generally, CAS (Chemical Abstracts Service) Registration Criteria-Overview, available at cas.org.

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substitution of a less "hazardous substance" may not take into account that more of that substance may be required leading to greater potential exposure or that the alternative may have a different form (e.g., polymeric or reacted substance versus an additive substance) thereby undermining the assessment and possibly driving regrettable substitution.

Ecology Must Take Hazard, Exposure, and Risk into Account in its Alternatives Assessment Process

The OECD framework defines "safer alternative" to mean "a chemical, product, or technology that is preferable, in terms of both hazard and potential for exposure to humans and the environment, than the existing option. Evaluating comparative hazard and exposure is an element of the process."[9] The OECD notes that the "process of determining whether a chemical, product, or technology is "safer" consists of three steps: comparative hazard assessment, comparative exposure assessment, and integration of hazard and exposure information.[10] An alternatives assessment framework also considers broader sustainability factors and evaluates performance, technical feasibility, and economic feasibility before a conclusion may be reached regarding a preferred alternative.[11] A hazard-only approach, as Ecology takes in the Draft Report, is not a best practice for alternative assessment.

Under the statute, Ecology may restrict or prohibit a priority chemical in a priority consumer product when it determines, among other things, that the restriction is necessary to protect the health of sensitive populations or sensitive species and when safer alternatives are feasible and available. A hazard-only approach may result in regrettable substitution, with increased danger to those sensitive populations or sensitive species.

To avoid such regrettable outcomes, both the OECD and NAS alternative assessment frameworks recommend the use of comparative exposure assessment. Comparative exposure assessments help to determine the differences in human and environmental exposure potential of alternatives versus the priority chemical over their lifecycles and thus whether the alternative is preferable, equivalent to, or potentially worse than the priority chemical given the potential for exposure.[12] Comparative exposure assessments can be accomplished by looking at the outputs of simple exposure models or comparing key physical-chemical properties of the alternatives. Exposure models for various consumer products are widely available. Physical-chemical properties are generally available for most substances and can be used to compare exposure potential for both human and environmental receptors.[13] The exposure assessment should be integrated with the hazard assessment to identify safer alternatives. If the exposure potential of an alternative is preferable this can add further rationale for its selection.

The SPW Program Needs a More Complete Assessment of Existing Regulations Including Identification of Potentially Conflicting Regulations

We appreciate Ecology's acknowledgement that some new priority products identified in the Report are already subject to existing regulations in Washington. Understanding and mapping the current regulatory landscape is an essential first step that must precede consideration of whether any additional regulation is warranted. This should include consideration of whether such regulation would conflict with state, federal, or international requirements;

[9] Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives, OECD 2021 at 12.
[10] Id. at 15.
[11] Id. at 16.
[12] National Research Council 2014. A Framework to Guide Selection of Chemical Alternatives at 71.
[13] Greggs et al, Qualitative Approach to comparative Exposure in Alternatives Assessment, IEAM, 15(6), 880-894 https://doi.org/10.1002/ieam.4070.

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whether such regulation would be redundant or create unnecessary burdens; and whether such regulation could create compliance challenges. In that regard, Ecology's inclusion of Table 1 and Appendix B are useful additions to the Report. However, as Ecology prepares to move to the next stage of the process, we encourage the department make available its detailed analysis of existing regulatory requirements in order to support a side-by-side comparison of existing regulatory requirements with any new subsequently proposed requirements and to inform the next Phase. This side-by-side comparison should also include any relevant requirements (or prohibitions) under federal law, such as under the Resource Conservation and Recovery Act (RCRA); Toxic Substances Control Act (TSCA); Federal Food, Drug, and Cosmetic Act (FFDCA); Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); Consumer Product Safety Act (CPSA); Federal Hazardous Substances Act (FHSA); and the Fair Packaging and Labeling Act (FPLA). Other state laws should also be mapped and included in the analysis especially where there may be conflicting regulatory approaches.

As noted elsewhere in these comments, this evaluation should explicitly consider ongoing and final regulations under the federal TSCA. As final TSCA risk management rules are completed they take preemptive effect in the states and several TSCA regulations have recently been finalized for priority chemicals identified in the report. We therefore recommend that Ecology conduct an updated assessment of the products under review or proposed for review under the Safer Products for Washington program to ensure that there is no duplication of effort with the multi-million-dollar risk assessments being conducted at the federal level.

This side-by-side including federal law would help implement the statutory criteria to consider whether another state or nation has identified or taken regulatory action to restrict or otherwise regulate the priority chemical in the consumer product.

Appendix C of the Draft Technical Supporting Documentation for Priority Products is also helpful; however, we suggest that this document be further built out with additional detail regarding the specific regulatory provisions imposed by various state, federal, and international authorities.

Ecology Should Provide Follow-up Response to Survey Comments

We note that in many cases Ecology did not fully respond to public comments and concerns. We urge Ecology to more fully address stakeholder comments and feedback that can inform SPW implementation.

We also note that in some of the public comments in the Spring 2024 Survey Results, respondents expressed concern about chemicals that are regulated at the federal level. For example, a Washington State constituent responding to the survey had expressed a concern about aerosol perchloroethylene brake cleaner; however, the U.S. Environmental Protection Agency (EPA) has now completed a regulation under the amended TSCA specifically addressing this concern.[14] Where consumers have expressed specific concerns to Ecology about chemicals that are or will be subject to TSCA risk assessments and where appropriate regulatory action at the federal level, we recommend that Ecology provide updates about EPA's recent actions. Consumers can be referred to EPA's TSCA risk management website at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-existing-chemicals-under-tsca. EPA has now completed regulations for asbestos, methylene chloride, perchloroethylene, trichloroethylene, and carbon tetrachloride, with many more chemicals undergoing risk assessments.

[14] See U.S. EPA's Perchloroethylene (PCE); Regulation Under TSCA Rule

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ACC also notes for Ecology that as final TSCA risk management rules are completed they take preemptive effect in the states, and therefore we recommend that Ecology conduct an updated assessment of the products under review or proposed for review under the Safer Products for Washington program to ensure that there is no duplication of effort with the multi-million dollar risk assessments being conducted at the federal level. Ecology should also consider that where EPA undertakes a TSCA risk management rulemaking, it is conducting a review of whether there are technically feasible and available alternatives as part of that process. An EPA conclusion that there are no technically feasible and available alternatives would likewise also be binding on state programs covering the same chemical.

Resource Constraints

Washington State and Ecology have a finite level of resources and need to focus and prioritize its programs to maximize their effectiveness. The expansive scope of this rulemaking, while perhaps well-intentioned, may hinder the Department's ability to effectively focus its efforts. Competing priorities, limited staffing, and the complexity of the proposed rule present challenges that could dilute the impact of the program across its various initiatives. A more focused, streamlined approach may allow Ecology to better allocate resources and achieve measurable results without overextending its capacity.

Thank you for the opportunity to comment.

/s/

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