Draft Regulatory Determinations Report to the Legislature
Safer Products for Washington Implementation Phase 3

Comments of the American Chemistry Council

January 28, 2022

Introduction

On behalf of the American Chemistry Council (ACC),[1] we are pleased to submit these comments to the Washington State Department of Ecology's (Ecology) Draft Regulatory Determinations Report to the Legislature: Safer Products for Washington Implementation Phase 3 (Draft Report).[2] ACC supports strong, science-based regulations that are protective of human health and the environment. Regulatory decision making and reviews of chemistries should be evidence-based, efficient, effective, scientifically driven and risk based, best-evidence based reviews of chemistries. Increasingly, achieving social justice and environmental objectives are being taken into account as part of these processes. Likewise, the business of chemistry is at the forefront of driving innovative solutions in chemistry and plastics that enable a variety of applications that help save energy and reduce emissions every day as part of the broader climate dialogue – from solar panels and wind turbines to electric and fuel-efficient vehicles, high-performance building materials, advanced batteries, energy efficient lighting, and more.

ACC recognizes that alternatives assessment is an important science policy field, and generally supports 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.

As part of the Safer Products program, the agency (based on direction from the Legislature) identified five priority chemicals/chemical classes for alternatives assessment: flame retardants; PCBs; PFAS; phenolic compounds (alkylphenol ethoxylates); phenolic compounds (bisphenols); and phthalate (esters). The Phase 2 report for priority products identifies a range of consumer products and food packaging that contain one or more of the priority chemicals. By statute, a final report on regulatory determinations is

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[1] The American Chemistry Council represents the leading companies engaged in the business of chemistry in the United States. ACC members apply the science of chemistry to make innovative products, technologies and services that make people's lives better, healthier, and safer. ACC is committed to improved environmental, health, safety, and security performance through Responsible Care®, common sense advocacy addressing major public policy issues, and health and environmental research and testing. ACC members and chemical companies are among the largest investors in research and development, and are advancing products, processes and technologies to address climate change, enhance air and water quality, and progress toward a more sustainable, circular economy. These comments incorporate the comments of several groups participating at ACC that represent specific chemistries.
[2] This report is made pursuant to the Pollution Prevention for Healthy People and Puget Sound Act (the "Act"), codified at 70A.350 RCW. The law directs Ecology to consult with the State Department of Health to implement a regulatory program to reduce toxic chemicals in consumer products. The implementation program is referred to as the Safer Products for Washington program.
[3] National Research Council 2014. A Framework to Guide Selection of Chemical Alternatives. Washington DC: The National Academies Press. https://doi.org/10.17226/18872.
[4] Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives, OECD 2021.

due to the Legislature by June 1, 2022. The comment period on a draft rule as part of Phase 3 is expected to be late 2022-2023. Regulatory options available by statute include taking no action; requiring reporting from manufacturers to collect or generate additional data; and restricting a chemical in a product in all eleven of the identified priority consumer products, or a subset thereof. The State may of course, in addition to any of these paths, choose to lead or participate in product and chemistry innovations, testing of labeling and instructions, piloting of handling and/or training and certification programs, and private sector standard development.

Inputs as part of the Phase 3 process will help Ecology assess whether safer alternatives are feasible and available. This will be followed by a determination of whether a restriction or reporting requirement, or no action, or a request for additional research, should be issued. In order to proceed with a restriction, Ecology must complete analyses that show that a safer alternative:

- Is feasible;
- Is available;
- Will reduce a significant source of or use of a priority chemical (or is necessary to protect the health of sensitive species or populations);
- Delivers benefits that outweigh the costs; and
- Determine that the proposed restriction is the least burdensome alternative.

Ecology's review would also be well-informed by careful consideration and integration of other elements of alternatives life-cycle thinking and analysis, a critical tool that helps with the evaluation of sustainability and environmental trade-offs. Even if the function of a priority product is equivalent or better with the use of an alternative chemistry, substitution can have unwanted or adverse sustainability impacts that should be carefully evaluated. A substitute chemistry may require long distance transport, process changes, increased energy use or greenhouse gas emissions across its lifecycle, for example. Global markets and supply chain impacts and disruptions should also be included in the availability and benefit-cost analysis, as we have seen play out in the recent pandemic where products and materials sourced from facilities outside the United States have been stressed with various availability constraints and delays. Social justice considerations may also be a relevant factor. For example, President Biden signed the Uyghur Forced Labor Prevention Act into law on December 23, 2021, which could ultimately affect imports from that region.[5]

We present below general comments with respect to Ecology's approach to alternatives assessment in Section I, and specific comments with respect to the approach taken for the 5 classes of priority products in Section II. Our comments here include comments of ACC's High Phthalates Panel and Polycarbonate-BPA Global Alliance. ACC also notes, supports, and incorporates by reference here, several sets of separately filed comments:

- The separate submission by the North American Flame Retardant Alliance (NAFRA). The NAFRA comments relative to organohalogen flame retardants (FRs) in plastic casings for electronics and electrical equipment reinforce many of the points raised in the ACC comments and the proposed recommendations relative to the extremely broad range of electronics and electrical equipment.

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[5] For example, Table 10-3 of the NAS Framework set out a number of social impact categories that could be possible characterization factors, including labor practices, work conditions, and violation of property rights including those of U.S. companies and individuals. In an availability analysis, for example, criteria excluding sourcing from venues that fail to meet selected minimum social impact criteria that could be relevant.

- The separate submission by the Alliance for Telomer Chemistry Stewardship (ATCS). ATCS is a global organization that advocates on behalf of C6 fluorotelomer-based products. ATCS promotes the responsible production, use and management of fluorotelomers, while also advocating for a sound science- and risk-based approach to regulation.
- The separate submission of the FluoroCouncil, which represents a diverse range of fluorinated chemistries. These chemistries play a wide range of roles in many products, including products that consumers rely on every day, from cell phones and fuel-efficient cars to solar panels and stain-resistant furniture.

We urge Ecology to take these comments into consideration for these important and complex product categories.

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I. General Comments

A. The Feasibility Analysis Should Clarify that Both Technical and Economic Feasibility are Required and Take Additional Factors into Account.

Under Ecology's criteria, for an alternative to be feasible, it must meet at least one of the following criteria:

- Already used for the application of interest or a similar application;
- Marketed for the application of interest or a similar application; or
- Identified as feasible by an authoritative body.

"Feasibility" under the NAS Framework includes an analysis of both technical feasibility and economic feasibility. The criteria should specify that both technical and economic feasibility must be evaluated and satisfied.

Technical feasibility requires a demonstration that a substitute chemistry or formulation provides equivalent or better <u>performance</u> for the relevant performance criteria for a particular product. As presented, these criteria do not support a robust review of the feasibility of substituting a particular chemistry, as used in a particular application, with a substitute chemistry. In any given class of chemistry, different individual chemistries may be used or marketed for different applications with different levels of necessary performance. A marine paint; an outdoor paint for a bridge; an outdoor paint for a building; and an interior paint for a kitchen, for example, may have performance requirements that differ significantly.

To continue the paint example, to complete a feasibility analysis, there should be careful consideration of how the alternative affects formulation of a stable product, product performance, specific or niche uses cases, or customer preferences. For example, Ecology found paints with lower (or no) concentrations of PCBs safer than paints with higher concentrations of PCBs. In its analysis, Ecology noted that PCB concentrations in children's paint, spray paint, road paint, and building paint range approximately from zero to 100 ppb. Ecology also noted that of the 105 paint samples tested, 89% had PCB concentrations under 25 ppb, and 78% had concentrations under 10 ppb. To support its conclusion that paints with lower PCB concentrations are feasible and available, Ecology noted that paints with low concentrations of PCBs were sold at stores and marketed as paints. Ecology's analysis did not discuss or consider performance of any of these low PCB paints in any of the paint use categories. Similarly, Ecology proposed using untreated leather, or inherently stain-resistant materials, such as wool, polyester, or polypropylene, as alternatives to leather treated with PFAS. Ecology failed to analyze the impact these suggested alternatives may have on the product's performance or consumer desirability. Ecology's analysis of alternative products should explicitly consider these factors as they speak directly to the question of whether the alternative is feasible.

We are concerned that both the "already used" criteria, and the "marketed for the application of interest" criteria, are insufficiently robust to support alternatives assessment under the Safer Products program. For example, an identified use of the substitute chemistry may still be in a pilot or test market phase where it is unclear that the performance of the substitute meets consumer or user needs. Undesirable substitutions that affect product performance, including the stability, look, feel, sound, or smell of a product, can affect consumer acceptance of a product and can result in different use patterns and even adherence to safety and use instructions. An unacceptable product may result in rejection and drive consumers to use less sustainable products.

Likewise, we are concerned that the "marketed for the application of interest" is insufficiently robust to support conclusions about feasibility. A manufacturer trying to enter a new market may itself not have sufficiently tested performance and consumer uptake with customers. A product with sustainability trade-offs, such that if a product containing the substitute is no longer eligible for a sustainability claim important to the customer base for example, may not get market uptake at all. The "similar application" language further weakens this provision, as it is unclear what a "similar application" is – in other words, what degree of similarity is required, and does this take into account different regulatory, code-based, standards, and customer performance requirements.

The third criteria, identified as feasible by an authoritative body, should be refined. We believe there to be very few bodies that can conduct an in-product equivalency performance review, including testing. Reviews based on performance standards, with testing and certification by accredited third party laboratories, of specific chemistries in specific products could be a useful indication of feasibility, but we suggest the criteria be rephrased to make this clarification. A statement by a non-consensus based organization that it is feasible to replace a particular chemistry or class with another, without a robust technical foundation to support this conclusion, should not be used as an authoritative body. In addition, the criteria should make clear that no party can "self-certify" the feasibility of a substitute chemistry or class; only independent, consensus-based standard and certification systems should be accepted, or the conclusion of a comprehensive review by a government conducting an alternatives assessment based on NAS Framework principles.

B. The Availability Analysis Criteria Should Take Current Market Factors and other Externalities into Consideration, Including Production Scale and Globally Supply Chain Issues.

The Draft Report indicates that for an alternative to be available, it must meet at least one of the following criteria:

- Currently used for the application of interest.
- Offered for sale at a price that is close to the current.

For an alternative chemical, process, or material not in use to be considered feasible it would need to meet at least one of a number of criteria. Some of these criteria would include:

- An authoritative body identified the alternative as favorable with some indications that it might not perform as well, but the difference in performance is not crucial to the product.

- An authoritative body identified the alternative as unfavorable, i.e., not a viable alternative based on performance. However, modifications to the process could make the alternative feasible.
- An authoritative body identified the alternative as unfavorable, but the application is not identical to the application of interest, and the process or product can be modified to accommodate the alternative.

This approach presents a number of shortcomings that point to an incomplete, and insufficiently robust, economic feasibility analysis. The mere fact that a particular chemical is in use in an application of interest does not mean that global supply chains can provide the substitute chemical in the volumes and delivery times needed to support substitution. If global supply chain disruption occurs where a chemical is sole-sourced from an importer or US facilities do not have sufficient capacity to meet US market needs, availability is adversely impacted and the substitute chemistry is not economically available. In addition, the availability/economic feasibility analysis must take into consideration costs other than price as part of the availability analysis. A substitute chemistry may require process or equipment changes; labor force changes; raw material sourcing changes; and so forth that impact the total cost of the substitution well beyond what an equivalent or similar price is for purchase of the chemical would be.

While consideration of cost is listed in Ecology's criteria for feasible and available, cost is not discussed in any of Ecology's determinations regarding priority chemicals. In other words, Ecology has failed in every case to actually apply the benchmarks it set for itself. As a result, it is unclear to what extent Ecology actually considered cost and what data it will rely on when considering cost in the future. For example, in the electronics section, five phosphate flame retardant alternatives are put forth but cost is not mentioned, nor does Ecology claim that all five alternatives are currently used in the plastic enclosures of electronics. Similarly, in the bisphenols section, Ecology identifies a certain product as a feasible and safer alternative for BPA and BPS in thermal paper and that the product is available online, but Ecology does not mention the cost of substituting the product for current bisphenols in thermal paper. In some instances, Ecology suggests that a safer alternative is a change of process or design, rather than the use of an alternative chemical. For example, for PFAS, Ecology suggests using untreated leather, textiles, or other materials to replace or cover products treated with PFAS. Ecology also suggests using inherently stain-resistant materials, such as wool, or polyester, or using removable upholstery that can be machine washed. However, Ecology's analysis does not mention the costs associated with switching to untreated fabrics or materials, nor does Ecology consider the costs associated with changing its design or processes to accommodate a new material. Similarly, in the flame retardants section, Ecology states that "another alternative for meeting flammability requirements is using an internal enclosure made of inherently flame-resistant material (e.g., metal) to serve the function of a fire enclosure[.]" Nowhere in this analysis does Ecology mention the associated costs to the electronics industry if it switched from using plastic enclosures to an entirely different material (e.g., metal). Moreover, Ecology fails to recognize the implausibility of the entire electronics industry switching to a different enclosure material within the short time frame. Ecology even concedes that switching to an inherently flame-resistant material, such as metal, is not feasible in some applications. When Ecology finalizes the determinations, it must appropriately consider costs.

In addition to production scale and global supply chain issues, Ecology should consider regulatory barriers. Ecology's proposed alternatives include chemicals that other agencies are either currently or are actively considering regulating. Further, although Ecology purports to analyze the commercial availability of a chemical, it has failed to consider whether that chemical will be available at production scales in order to support an entire industry switching from one chemical to another. Consumer products are designed for worldwide compliance. Companies do not, and simply cannot, design products tailored to different regulatory environments. Thus, if a chemical Ecology regards as a feasible alternative were to be restricted by another agency – whether foreign or domestic – Ecology's conclusion that the chemical was a feasible alternative would be inaccurate.

It is important to assess whether chemicals Ecology identifies as alternatives are regulated elsewhere and factor this into its assessment. The draft determination does not do so. To illustrate this point, a cursory (not exhaustive) regulatory review of the potential alternatives Ecology has identified in the draft report reveal troubling results. This speaks not only to the over-simplicity of Ecology's feasibility determinations, but the potential for this oversimplicity to lead to regrettable substitution. One chemical Ecology holds out as a potential alternative to halogenated flame retardants is triphenyl phosphate (TPP). This chemical is currently undergoing a risk evaluation under the U.S. Toxic Substances Control Act. Ecology also notes that many or most applications that use organophosphate flame retardants must also use an anti-drip additive, such as a fluoroorganic additives. This is necessary to prevent "flaming drips" during a fire event. As Ecology points out elsewhere in the draft determination fluoroorganic chemicals are already highly regulated and becoming even more so. For instance, Maine recently enacted a wholesale ban on products that contain perfluoroalkyl and polyfluoroalkyl substances (PFAS), effective January 1, 2030. Ecology identified benzyl alcohol as a safer alternative for phthalates in beauty products. However, benzyl alcohol is listed in Annex III of EU Regulation.

Ecology has also failed to consider whether the potential alternatives it has put forth will be available at scale during any phase-out period Ecology enacts. If an entire industry were to switch on a short time-scale from one chemical to another, this would create significant scale-up pressures on existing manufacturers. Ecology has not established that such scale-up, at a reasonable cost, would be feasible.

We note a recent supply chain challenge regarding the chemical PIP (3:1). Subject to a risk management action under TSCA, the agency moved earlier this year to a restriction with a phase-out schedule that could not be met by global supply chains. PIP (3:1) was present in manufactured durable goods, like washing machines, and electronics that have multi-year sell inventory and sell-through schedules. The risk of global supply chain disruption from discontinuation of the availability of a commercially important chemical without adequate due diligence with respect to the availability of alternatives can have real, and significant consequences as this example illustrates.

This is even more relevant for complex products like electronics and electrical equipment which have multiple components and require product testing to ensure they meet designated safety and performance standards. In these cases, product must be carefully redesigned, reengineered and recertified. Such product redesign and recertification processes for complex sectors like electronics may take several years so the lead time for these changes needs to be factored into the assessment.

C. Ecology Should Perform a Least Burdensome Analysis.

When promulgating a significant legislative rule, Washington's Administrative Procedure Act (APA) requires Ecology to determine that the rule to be adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives. Although that test is applicable to the end restrictions that Ecology will apply after the conclusion of the next phase of its rulemaking (rather than to the regulatory determinations phase), the choices that Ecology has made in its interpretations and analytical framework make it unlikely that Ecology will be able to meet its "least burdensome" analysis burden. For example, Ecology suggests that products be redesigned without analysis of how that redesign would affect cost, performance, or desirability. Ecology also suggests chemical alternatives that would create regulatory problems in other jurisdictions without analysis of cost.

A proposed rule restricting the use of flame retardants could require manufacturers to use new materials (i.e., metal instead of plastic in electronics) that may be inconsistent with product performance and consumer preference (e.g., for low product weight), and would likely increase costs. This would be burdensome on manufacturers by increasing costs (both for product redesign and during production) and affecting sales, as well as on consumers for affecting product weight.

Likewise, a requirement for manufacturers to redesign flame retardant material (i.e., an internal enclosure) would likely increase costs to manufacturers and could also affect availability of products to consumers during the redesign process. It could require industry to requalify parts or products that contain safer alternative chemicals for the relevant existing flammability standards. This would be burdensome on manufacturers because it requires them to complete new assessments, and would create a backlog of products that need to be requalified, which would decrease the number and variety of products available to consumers.

The suggestion to require manufacturers to employ a change in process or design that reduces the flammability requirement of the exterior electric or electronic enclosure through the use of an internal fire barrier would be quite burdensome to manufacturers. It would increase costs, perhaps significantly, and it could limit the type and number of product manufacturers can make available to consumers.

We also recommend that Ecology consider at least screening-level cost-benefit review early in the process, and preceding any recommendation of a restriction. An analysis of substitution risk[6] can help determine if adoption of a preferred alternative would do more good than harm. This will first entail some effort to understand the expected behavioral response of the market to the proposed restriction. For example, suppose it is expected that a producer will simply and easily substitute a priority chemical with a safer alternative chemical, with no change in prices or consumer welfare. The agency could then employ a screening-level risk assessment to see whether each preferred alternative is likely to pose risks of concern. If no concerns arise from this screening level assessment, the agency can move forward with a proposed restriction, subject to opportunity for notice and comment and a more robust cost-benefit review.

D. Ecology Should Apply a Reasonable, Common-Sense Definition of Consumer Product.

The statute defines “consumer product” as “any item, including any component parts and packaging, sold for residential or commercial use.” The breadth of this definition allows for varying interpretations of what a consumer product is. For example, there is no distinction between commercial products and industrial products used within the production chain. Thus far, Ecology has not provided a detailed interpretation of this term. When it finalizes the determinations document, Ecology should clarify that “sold for residential or commercial use” is limited to products designed for use in a home or commercial (i.e., office) setting. This would include, for example, table-top coffee makers and personal computers in scope of the “consumer product” definition. Ecology should clarify that products intended for professional use or use only in an industrial setting (e.g., factory equipment, large-scale fixed installations, enterprise electronics, equipment used only for research and development, etc.) are not “consumer products.” This interpretation would comport with both the statutory definition of “consumer product” and a common-sense understanding of the term. Providing this clarification now would ease Ecology’s burden in enacting the statute by reducing the scope of interested stakeholders.

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[6] Economists refer to *ancillary benefits* and *ancillary costs*, the indirect impacts of a regulation that can influence net benefits. *Substitution risk*, which is a type of ancillary benefit (disbenefit), is not uncommon when a regulation has the effect of causing market participants to switch from a regulated activity to one that is not regulated. When the purpose of a regulation is to reduce risk of a product, analysis of substitution risk is often important to determine if the regulation is warranted on a net basis.

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

Ecology's flawed 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…".

Similarly, regarding bisphenols, Ecology found that while tetramethyl bisphenol F (TMBPF) scored a BM-2 and that it meets the minimum criteria, it fails to meet the within-class criteria that a chemical score low for endocrine disruption, reproductive toxicity, and developmental toxicity. TMBPF scored moderate for both endocrine activity and developmental toxicity. Ultimately, Ecology concluded that TMBPF does not meet the within-class criteria for safer if it is intentionally added or present as a residual monomer above 100ppm. The safer alternative proposed scored moderate for developmental toxicity, and there was a data cap noted for endocrine activity. Ecology concluded that this met their minimum requirements for safer. Ecology's key rationale for the class approach is to avoid regrettable substitution. 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 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. 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.[7] 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.[8] 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

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[7] See, e.g., Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives, OECD 2021 at 11.
[8] Grouping of Chemicals: Chemical Categories and Read-Across, available at OECD.org.

classification, "solid at room temperature,"[9] 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 (Chemical Abstracts Service) 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).[10]

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 framework to selection of chemicals for entry into the alternatives assessment process.

F. 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."[11] 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.[12] 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.[13] 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. For example, early air conditioners and refrigerators used acutely toxic ammonia, methyl chloride or sulfur dioxide as refrigerants. Due to human safety concerns, these were replaced by chlorofluorocarbons -- lower toxicity, highly stable, non-flammable and noncorrosive substances -- which ended up damaging the ozone layer.

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[9] Descriptions of the state of matter – freezing point, melting point, and boiling point, are all universally recognized physical properties.
[10] See generally, CAS (Chemical Abstracts Service) Registration Criteria-Overview, available at cas.org.
[11] Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives, OECD 2021 at 12.
[12] *Id.* at 15.
[13] *Id.* at 16.

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.[14] 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.[15] 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.

G. Use of Default Lists, Such as the GreenScreen List Translator, Should be Avoided.

DOE's use of the GreenScreen list translator (GSLT) is problematic because GSLT relies, in part, on third-party generated chemical "red lists" for score assessment rather than actual toxicology data. A hazard-only based list used as part of the chemical identification process for input into an alternative assessment, or in initial screening, can have value. As the NAS and OECD frameworks both indicate, however, the AA process itself must include the comparative hazard assessment, and the comparative exposure assessment, and an integration step of the hazard and exposure information to help characterize risk. Hazard lists have no place in the assessment itself and cannot substitute for current data.

An alternative assessment that forms the basis of a regulatory determination must be based on reliable, quality data, including best available science and information that is up to date. Both hazard and exposure data, and the data integration, should be informed by best available science. Over time, chemistries may undergo additional toxicological testing or be informed by new epidemiological data, for example, so while hazard classifications for data-rich chemicals tend to be relatively static as new data comes in, there can be important changes over time, and third-party managed lists are lagging indicators. Exposure profiles can certainly change over time, as use patterns, treatment methods, market patterns, and other variables shift. Something as simple as a YouTube video, for example, can change consumer purchase and use patterns or safety practices in a short period. Manufacturer changes in product concentration, coating and encapsulation, and packaging can directly affect exposure scenarios. So too can innovated new product entries into the market; new standards and certification requirements; and new regulatory requirements.

Using chemical lists in lieu of data leads to overbroad assumptions that lack information specific to a given use that can provide important context on the risk that a chemical may present. In addition to the possibility that the list is outdated, incorrect, or does not apply the best available science to the hazard assessment and classification, use of hazard-based red lists fails to take exposure data and scenarios into account. Hazard and exposure data cannot be integrated of course if the exposure data is entirely lacking. Relying on GSLT alone to characterize the inherent hazard of a chemical or to avoid making a risk-based assessment does not represent the best available science.

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[14] National Research Council 2014. A Framework to Guide Selection of Chemical Alternatives at 71.
[15] Greggs et al, Qualitative Approach to comparative Exposure in Alternatives Assessment, IEAM, 15(6), 880-894 https://doi.org/10.1002/ieam.4070.

II. Specific Comments

A. Bisphenol-A

Bisphenols are listed as a priority chemical class by the Washington State Legislature and discussed in Chapter 4 of the Draft Regulatory Determinations Report to the Legislature: Safer Products for Washington Implementation Phase 3. Bisphenol A (BPA) is an extraordinarily well studied, building block chemical used in the manufacture of epoxy resins. The Draft Report fails to address the largest study ever conducted on BPA, the CLARITY Study. Chapter 4 should be revised to incorporate the results of the CLARITY Study so that any regulatory determinations about BPA are based on the best available science.

The Consortium Linking Academic and Regulatory Insights on BPA Toxicity (CLARITY-BPA) program was developed to assess the potential health effects of long-term exposure to BPA.[16] CLARITY was a multi-year collaborative effort involving the U.S. Food and Drug Administration (FDA), the National Toxicology Program (NTP) and the National Institute of Environmental Health Sciences (NIEHS). The FDA is responsible for regulating BPA in food contact materials.

CLARITY is an important piece of research and should be included in any assessment of BPA hazard. The methodology for conducting the CLARITY Core Study was consistent with established testing guidelines and the study was conducted according to Good Laboratory Practice requirements to ensure study quality. Importantly, the draft report was peer-reviewed by a panel of independent scientists convened by NTP. After a thorough review of the draft report, the panel discussed their findings in a public meeting and issued a report with their recommendations. In general, the panel endorsed the design and execution of the study as well as FDA's interpretation of the results. Their recommendations to improve the report were incorporated into the final report, released in 2018. The results of the CLARITY Core Study confirm that there is no risk of health effects from BPA at typical human exposure levels, even if people are exposed to BPA throughout their lives. [17]

U.S. government reviews have concluded consumer exposure to BPA is extremely low and that BPA is rapidly eliminated from the body. Based on these results, in combination with the results of the CLARITY Core Study, BPA is unlikely to cause health effects. [18] [19] [20]

The results of the CLARITY Study, along with many others, support the Q&A on FDA's website regarding the safety of BPA: "Is BPA safe?" – "Yes."[21] FDA further states, "FDA's current perspective, based on its most recent safety assessment, is that BPA is safe at the current levels occurring in foods.

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[16] https://ntp.niehs.nih.gov/whatwestudy/topics/bpa/index.html
[17] https://ntp.niehs.nih.gov/ntp/about_ntp/rrprp/2018/april/peerreview_20180426_508.pdf
[18] Centers for Disease Control and Prevention (CDC). Fourth National Report on Human Exposure to Environmental Chemicals. Updated Tables, 2019. [online] Available at URL: https://www.cdc.gov/exposurereport/.
[19] Thayer KA, Doerge DR, Hunt D, Schurman SH, Twaddle NC, Churchwell MI, Garantziotis S, Kissling GE, Easterling MR, Bucher JR, Birnbaum LS. Pharmacokinetics of bisphenol A in humans following a single oral administration. Environ Int. 2015 Oct;83:107-15. doi: 10.1016/j.envint.2015.06.008. Epub 2015 Jun 24. PMID: 26115537; PMCID: PMC4545316.
[20] Teeguarden JG, Twaddle NC, Churchwell MI, Yang X, Fisher JW, Seryak LM, Doerge DR. 24-hour human urine and serum profiles of bisphenol A following ingestion in soup: Individual pharmacokinetic data and emographics. Data Brief. 2015 Mar 17;4:83-6. doi: 10.1016/j.dib.2015.03.002. PMID: 26217767; PMCID: PMC4510366.
[21] https://www.fda.gov/food/food-additives-petitions/questions-answers-bisphenol-bpa-use-food-contact-applications

Based on FDA's ongoing safety review of scientific evidence, the available information continues to support the safety of BPA for the currently approved uses in food containers and packaging."[22] Replacing BPA with an alternative that is not as well studied would be potentially regrettable. It is not likely that any alternative has been as thoroughly tested and frequently reviewed by government agencies as BPA. The scientific evidence supporting the safety of BPA speaks for itself and should not be dismissed.

B. Phthalate Esters

With respect to phthalate esters, Ecology has not established a sound basis for proposing a restriction on phthalates in vinyl flooring. As noted above, the Washington State Legislature identified phthalates as a priority chemical class, with Washington Ecology and Health identifying vinyl flooring products containing phthalates as one of its priority products. Pursuant to RCW § 70A.350.040(3), in order to restrict or prohibit priority chemicals in priority products, Ecology must demonstrate that:

- The restriction will reduce a significant source or use of a priority chemical, or
- The restriction is necessary to protect the health of sensitive populations or sensitive species.

Ecology's Underlying Assumptions And Calculations About Phthalate Esters Are Incorrect.

There is sufficient evidence to indicate that vinyl flooring is not a significant source or use of phthalates, and therefore any restriction will not reduce a significant source or use of phthalates, as a priority chemical. Furthermore, the low levels of use and exposure to phthalates in vinyl flooring, coupled with rapid biodegradability in the environment, means that phthalates release from vinyl flooring is unlikely to pose a health concern to sensitive subpopulations and the environment.

Ecology estimates that approximately 10 – 37 million pounds of phthalates are sold in new vinyl flooring each year in Washington State. Ecology has derived that estimate based on the following assumptions:

- Approximately 90,000 metric tons (100 million square feet) of vinyl flooring are sold in Washington annually;
- Flooring contains 9 – 32 % by weight of phthalates; and
- Roughly half of all vinyl flooring sold in Washington State annually contains phthalates.

Based on the above assumptions, Ecology estimated that 0.17 metric tons (374 pounds or approx. 170 kg) of phthalates are released to the environment in Washington from vinyl flooring annually.[23] The basis for Ecology's assumption that roughly half of all vinyl flooring sold annually in Washington State contains phthalates, however, is outdated. Ecology based this assumption on a non-peer reviewed study by The Ecology Center (2015) that found phthalates in 38 of 65 vinyl flooring tiles tested, or 58%.[24] The Ecology Center conducted a follow-up study in 2019. As noted in Ecology's Priority Consumer Products Report to the Legislature, the follow-up study found that none of the 26 samples (0%) tested contained phthalates at concentrations above 1% (including the top and bottom layers).[25] In January 2022, Ecology published the results of its data call from manufacturers on types of plasticizers currently used in vinyl flooring.[26] Of 14

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[22] https://www.fda.gov/food/food-additives-petitions/bisphenol-bpa-use-food-contact-application

[23] Department of Ecology. July 2020. Priority Consumer Products – Report to the Legislature (wa.gov)
[24] New Study Finds Toxic Chemicals Widespread in Vinyl Flooring | Ecology Center (ecocenter.org)
[25] Department of Ecology. July 2020. Priority Consumer Products – Report to the Legislature (wa.gov)
[26] VinylFlooring_ManufacturerData (wa.gov)

manufacturers who responded to the data call, 12 manufacturers confirmed that they have phased out the use of ortho-phthalates, most between 2013 and 2016. No manufacturer reported exclusively using ortho-phthalates. Ecology confirmed that the "vast majority of flooring products did not use ortho-phthalates." In addition, Ecology acknowledged that "we expect ortho-phthalate use is lower than the estimate in our 2020 Priority Products Report to the Legislature." As a result, we can conclude that the 58% assumption (proportion of vinyl flooring using ortho-phthalates), on which Ecology based its initial calculations of the amount of phthalates released into the environment annually from vinyl flooring (approx. 170 kg) is grossly over-estimated. Hence, it is reasonable to assume that the amount of phthalates released from vinyl flooring annually would be significantly less than 170 kg.

The Draft Report Deviates, Without Grounds, From Ecology's Previous Report, Which Found Vinyl Flooring To Be A Minor Source Of Phthalate Release To The Environment.

In its draft report, Ecology cites its 2011 report estimating vinyl flooring contributes 220 pounds (0.1 metric tons) of phthalate chemicals to Puget Sound annually.[27] This value appears to come from Figure 40 in the 2011 report, containing a breakdown of the major releases of DEHP from primary sources (Ecology assumes that DEHP is the dominant phthalate used as a plasticizer, accounting for approximately 40% of total annual release in 2011). Notably, the 2011 Puget Sound report by Ecology concludes that release of phthalates to Puget Sound from PVC flooring accounts for <1% of the total phthalates release (both via release to air and fugitive dust) (see Table C-1). By comparison, the Puget Sound report indicates that personal care products, industrial and institutional point sources, vehicles and roads, lacquers and paints account for 32%, 28%, 10% and 5%, respectively. Considering that more than 10 years have passed since that report was issued, and the majority of vinyl flooring manufacturers no longer use phthalates in vinyl flooring,[28] we would expect vinyl flooring to account for an even smaller proportion of the annual phthalate release to Puget Sound today.

In summary, we conclude the following:

- Ecology's 2011 Puget Sound report confirms that vinyl flooring is not a significant source of phthalate release to the environment. The Draft Report should be revised to adopt the 2011 conclusions.
- Ecology's manufacturer data call confirms that vinyl flooring is not a significant source or use of phthalates.

Ecology Has Not Adequately Demonstrated That Restricting Use Of Phthalates In Vinyl Flooring Will Reduce A Significant Source Or Use Of Phthalates, In Order To Justify A Restriction.

The Proposed Restriction Does Not Protect The Health Of Sensitive Populations Or Sensitive Species.

There is no evidence that phthalate exposure in dust and indoor air is a human health concern to children Ecology indicates that the proposed restriction will protect the health of sensitive subpopulations (infants and children), exposed to phthalates via direct exposure to residential air and dust. However, Ecology failed to cite any study that justifies this purported concern. By contrast, several published studies have confirmed that exposure to phthalates in dust and indoor air do not pose a health concern to sensitive

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[27] Control of Toxic Chemicals in Puget Sound Assessment of Selected Toxic Chemicals in the Puget Sound Basin, 2007-2011. Department of Ecology, State of Washington. Publication No. 11-03-055. [1103055.pdf (wa.gov)]
[28] See discussion above.

subpopulations.[29,30,31,32] One of the studies cited by Ecology reached the same conclusion. For example, in quantifying the level of BBP (and other phthalates) present in dust and indoor air in vinyl flooring in the home, Hammel et al., (2019)[33] found that the highest range (95th percentile) of BBP exposure in the urinary metabolites of children ages 3 – 4 years was approximately 25-times below the safe threshold. In other words, regardless of the potential hazard of the substance, the levels of exposure were too low to be of any health concern and banning the use of vinyl flooring in those homes would have had no protective effect on the health of children.

Phthalate Release From Vinyl Flooring Does Not Pose An Environmental Concern.

As noted above, vinyl flooring is not a significant source of phthalate exposure to the environment, as phthalates are rapidly degraded in the environment, including sediments.[34] For example, in its 2015 State of the Science Report on DINP, Health Canada concluded that DINP is readily biodegradable, has low bioaccumulation and biomagnification potential and is not expected to persist in the environment.[35] Similarly, Canada's State of the Science report notes that DIDP is rapidly biodegraded in aerobic conditions (and even under conditions of low oxygen), with 68% removal within 1 day and 90-100% removal of parent substance within 10-28 days. With respect to bioaccumulation, Canada states, "Empirical bioconcentration factors (BCFs) of <14 and 147 L/Kg wet weight and biota-soil/sediment accumulation factors (BSAFs) of 0.015 and 0.16 suggest that DIDP has low potential to bioaccumulate in aquatic and terrestrial organisms."[36] Thus, it is unlikely that phthalates pose any significant source of harm to the environment.

We conclude the following:

- Ecology has offered no evidence showing that phthalate exposure in dust and indoor air has been proven to be harmful in children. It must be stressed that mere presence is not evidence of harm.

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[29] Scientific Committee on Health and Environmental Risks (SCHER). Opinion on risk assessment on indoor air quality (2007) – https://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_055.pdf.
[30] European Chemicals Agency (2013) – Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006. Final review report. https://echa.europa.eu/documents/10162/31b4067e-de40-4044-93e8-9c9ff1960715.
[31] Christia C, Poma G, Harrad S, de Wit CA, Sjostrom Y, Leonards P, Lamoree M, Covaci A (2019) Occurrence of legacy and alternative plasticizers in indoor dust from various EU countries and implications for human exposure via dust ingestion and dermal absorption. *Environmental Research* **171:** 204-212.
[32] Kim H-H, Yang J-Y, Kim S-D, Yang S-H, Lee C-S, Shin D-C, Lim Y-W (2011) Health Risks Assessment in Children for Phthalate Exposure Associated with Childcare Facilities and Indoor Playgrounds. *Environ Anal Health Toxicol* **26:** e2011008.
[33] Hammel SC, Levasseur JL, Hoffman K, Phillips AL, Lorenzo AM, Calafat AM, Webster TF, Stapleton HM: Children's exposure to phthalates and non-phthalate plasticizers in the home: The TESIE study. *Environment International* 2019, 132:105061.
[34] Otton SV, Sura S, Blair J, Ikonomou MG, Gobas FAPC: **Biodegradation of mono-alkyl phthalate esters in natural sediments**. *Chemosphere* 2008, **71**(11):2011-2016.
[35]Environment Canada and Health Canada State of the Science Report. 2015. Phthalate Substance Grouping: 1, 2-Benzenedicarboxylic acid, diisononyl ester 1, 2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich (Diisononyl Phthalate; DINP). Screening Assessment Report Template (ec.gc.ca)
[36] Environment Canada and Health Canada State of the Science Report. 2015. Phthalates Substance Grouping: Long-chain Phthalate Esters, 1,2-Benzenedicarboxylic acid, diisodecyl ester (diisodecyl phthalate; DIDP) and 1,2-Benzenedicarboxylic acid, diundecyl ester (diundecyl phthalate; DUP). Environment and Climate Change Canada - State of the Science Report - Phthalates Substance Grouping - Long-chain Phthalate Esters

- Available evidence, from independent risk assessors and peer-reviewed literature, confirms that phthalate exposure in dust and indoor air is low and is not a human health concern.
- Available evidence confirms that phthalate release to the environment in Washington is low (<<170 kg annually), and that phthalates do not bioaccumulate and are rapidly biodegraded in the environment.

Ecology has not demonstrated that restricting the use of phthalates in vinyl flooring will have any impact in protecting the health of sensitive populations or sensitive species.

WA Ecology Should Wait To Act Until The EPA Risk Evaluation Process Is Completed.

U.S. EPA is currently conducting risk evaluations on five phthalates it designated as High Priority, several of which have been identified by Washington State as used in vinyl flooring, including DBP, BBP, and DEHP. Under federal law, state level restrictions are paused to provide EPA sufficient time to conduct its risk evaluations. Additionally, EPA is conducting risk evaluations on DINP and DIDP. EPA's final determinations on the phthalates it is currently evaluating may have a permanently preemptive effect on Washington state restrictions. Thus, it may be more prudent for the State to give EPA sufficient time to complete its review of certain phthalates (expected by December 2022 or mid-2023, if EPA takes a six-month extension) before deciding what type of action to take with respect to individual phthalates in vinyl flooring.

We request that Ecology reconsider its proposal to restrict phthalates in vinyl flooring, at a minimum waiting for EPA to complete its review of certain phthalates before taking any further action.

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Thank you for the opportunity to comment on the Draft Report. For any questions about this submission, please contact Karyn Schmidt, Senior Director, Regulatory and Scientific Affairs, Karyn_Schmidt@americanchemistry.com, or Tim Shestek, Senior Director, State Affairs, Tim_Shestek@americanchemistry.com.