

Response to Comments: Phthalates Action Plan

Hazardous Waste and Toxics Reduction Program

Washington State Department of Ecology Olympia, Washington

December 2023 Publication 23-04-068





Publication Information

This document is available on the Department of Ecology's website at: <u>https://apps.ecology.wa.gov/publications/summarypages/2304068.html</u>

This project has been funded wholly or in part by the United States Environmental Protection Agency under assistance agreement PC-01J18101 to the Washington State Department of Ecology. The contents of this document do not necessarily reflect the views and policies of the Environmental Protection Agency, nor does mention of trade names or commercial products constitute endorsement or recommendation for use.

Related Information

Publication 23-04-067: Phthalates Action Plan¹

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¹ https://apps.ecology.wa.gov/publications/SummaryPages/2304067.html

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Central	Benton, Chelan, Douglas, Kittitas, Klickitat, Okanogan, Yakima	1250 W Alder St Union Gap, WA 98903	509-575-2490
Eastern	Adams, Asotin, Columbia, Ferry, Franklin, Garfield, Grant, Lincoln, Pend Oreille, Spokane, Stevens, Walla Walla, Whitman	4601 N Monroe Spokane, WA 99205	509-329-3400
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Hazardous Waste and Toxics Reduction Program Washington State Department of Ecology

Olympia, Washington

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Participating Programs and Offices

- Washington Department of Ecology programs: Air Quality, Environmental Assessment, Hazardous Waste and Toxics Reduction, Solid Waste Management, Toxics Cleanup, Water Quality
- Washington Department of Health offices: Drinking Water, Environmental Public Health Sciences

Washington Department of Fish and Wildlife

Washington Department of Commerce

Washington Department of Enterprise Services

Advisory Committee

Washington Departments of Ecology and Health created an external advisory committee to provide input and expertise from interested parties. Beginning in early 2022, we convened committee members from industry, government, non-governmental organizations, a tribal organization, and community organizations. The following organizations and government agencies were represented on the advisory committee:

- American Chemistry Council
- Association of Washington Business
- BASF Corporation
- ChemForward
- City of Tacoma
- Collaborative on Health and the Environment
- Exxon Mobil Chemical Company
- Healthy Building Network
- Household and Commercial Products Association
- King County Hazardous Waste Management Program
- Multicare Health System
- National Tribal Toxics Council
- Northwest Biosolids Board
- Public Health Seattle & King County
- Seattle Children's Pediatric Environmental Health Specialty Unit
- Snohomish County Health Department
- Spokane Regional Health
- Toxic-Free Future
- True North Public Affairs
- Vinyl Institute
- Vizient
- Washington Refuse and Recycling Association
- Zero Waste Washington

Table of Contents

Overview7
Introduction7
Response to Comments 10
General issues
Background17
References
Draft Phthalates Action Plan recommendations18
Background and appendices
Appendix A. References
Appendix B. List of Acronyms and Abbreviations
Appendix B. List of Acronyms and Abbreviations
Appendix B. List of Acronyms and Abbreviations 42 Abbreviations and acronyms used in this response to comments
Appendix B. List of Acronyms and Abbreviations 42 Abbreviations and acronyms used in this response to comments 42 Chemical names 43 Appendix B. List of Commenters 44
Appendix B. List of Acronyms and Abbreviations 42 Abbreviations and acronyms used in this response to comments 42 Chemical names 43 Appendix B. List of Commenters 44 Agencies 44
Appendix B. List of Acronyms and Abbreviations 42 Abbreviations and acronyms used in this response to comments 42 Chemical names 43 Appendix B. List of Commenters 44 Agencies 44 Organizations 44
Appendix B. List of Acronyms and Abbreviations 42 Abbreviations and acronyms used in this response to comments. 42 Chemical names 43 Appendix B. List of Commenters 44 Agencies 44 Individuals 44

Overview

Introduction

Using Washington Administrative Code (WAC) <u>173-333-430(6)</u>⁴ as guidance, the Washington State Department of Ecology (Ecology) and the Washington State Department of Health (Health) (jointly "we") issued the <u>Draft Phthalates Action Plan (AP)</u>⁵ on May 1, 2023 for review by the public.

Public comment notification

We notified the public of the issuance of the Draft Phthalates Action Plan for comment using the following methods:

- Publication in the Washington State Register (WSR)⁶
- Announcement on the project webpage
- Announcement on Ecology's public input and events page
- Notification sent to the Chemical Action Plan email list
- Social media announcements sharing the comment period opening on:
 - o Instagram
 - Ecology's blog post
 - o Twitter
 - o Facebook

Public comment submission process

Public comments could be submitted via an automated comment form available from the project webpage or through email.

Public comment duration

The Draft Phthalates Action Plan was open for comment from May 1, 2023 to June 14, 2023.

We conducted virtual public meetings as follows:

- May 17, 2023, 6 p.m. (PDT)
- May 18, 2023, 9 a.m. (PDT)

⁴ https://app.leg.wa.gov/wac/default.aspx?cite=173-333-430

⁵ https://apps.ecology.wa.gov/publications/SummaryPages/2304025.html

⁶ https://lawfilesext.leg.wa.gov/law/wsrpdf/2023/08/23-08-045.pdf

Verbal comments were not allowed or collected during these meetings; however, we did address some questions about the Draft Phthalates Action Plan and our comment process.

Comments received

Ecology received a total of 16 letter submissions. We posted all comments—whether submitted via the automated form or other means—to the project <u>eComments page</u>⁷ to make them accessible to the public.

We identified issues raised by each commenter and included the content just before our responses in the Response to Comments section below. Table 1 lists the number of comments by the type of person or organization who submitted them. <u>Appendix C</u> lists the persons and organizations who submitted a comment letter.

Source of submissions	Number of submissions
Community organizations and non-governmental organizations	3
Individual	2
Local Government	3
Public Agencies (other than local government departments)	3
Business and industry (including professional associations)	5
Total submissions	16

Table 1: Summary of Comments on the Draft Phthalates Action Plan.

Comment response overview

We used chapter 173-333-430(6) WAC⁸ as guidance to develop this response to comments document. This rule requires Ecology to provide a response to public comments.

Ecology and Health reviewed the comments received and, on a topic-by-topic basis, responded to the substantive concerns in response to the Draft Phthalates Action Plan, on material association with a specific section, or in an appendix of the Draft Phthalates Action Plan. Several submissions address the same issue from different perspectives. Therefore, we subdivided each of the comment letters into the "comments" addressed.

We identified 189 comments and considered comments in combination with similar concerns raised by others which are presented in the <u>Response to Comments section</u>. We organized the issues and responses by the location of where the topic is addressed in the Phthalates Action Plan, with the following exceptions:

• We grouped general or procedural comments and responded to them as "general" comments.

⁷ https://hwtr.ecology.commentinput.com/comment/extra?id=haD3V

⁸ https://app.leg.wa.gov/wac/default.aspx?cite=173-333-430

• We grouped comments on the recommendations by each recommendation and section.

Each issue is presented in a consistent manner as follows:

- Each comment is numbered.
- The persons or organizations who contributed comments are identified following the number.
- The comments submitted on each comment topic are summarized in a summary statement.
- Occasionally, additional details about the issue are provided following the summary statement.
- The response to the issue starts following the bolded word "response."

We updated the recommendation numbering system in the Phthalates Action Plan after the public comment period to provide more clarity to readers and to align with the new numbering system.

This is an example of how we organized comments and responses:

1. Individual Person 1, Individual Person 2, Organization 1, Local Government 1

Commenter stated: The comment is described in a summary statement. The persons or organizations who submitted comments grouped in this comment topic are noted in the brackets at the end of the summary statement.

Occasionally, additional details are added to further describe the issue.

Response

The response to the comment follows the summary statement and includes additional details, if any. The response also indicates if changes were made to the Phthalates Action Plan as a result of considering the comment.

Response to Comments

General issues

General comments

1. CarolLee Braithwait

Commenter stated: As a retired special education teacher, developmental difficulties are very real to me. I am aghast that no more progress has been made in getting this horrible compound out of our food supply. And by food supply, I mean anything that can conceivably end up inadvertently being consumed. If this stuff is "outgassing". from flooring, babies end up consuming it. We've gotten lead out of paint; let's get phthalates out of our environment.

Response

Thank you for taking the time to review the action plan. Ecology and Health identified phthalates as a priority issue and have been working hard over the last several years to develop this. The intent of the action plan is to reduce sources and exposures to phthalates in humans and the environment. Recommendations #3 and #4, in the section, addresses sources of phthalates in food and beverages. Recommendation #5 in the Daycare and Early Childcare Facilities section proposes product replacement programs for vinyl flooring and other children's products. We appreciate your support and look forward to implementing these recommendations.

2. Wendy Farrell

Commenter stated: I am very concerned about the plastic gear used by aquaculture companies in Puget Sound. They cover the tide flats with gigantic sheets of netting, along with plastic bags, that show up on shorelines as debris. They also drill millions of polyvinyl chloride (PVC) pipes into the substrate to protect their shellfish. Aquaculture does not need to use these new (plastic) methods right in our fragile waters and seabed. Degradation of this gear over time and the seeping of micro plastics into Puget Sound is shocking. They need to go back to the old ways and methods of aquaculture that were successful and kinder to the environment without all the modern gear and plastic.

Response

We appreciate your concern about aquaculture-related plastic marine debris in Puget Sound and its potential impacts to the environment. The Phthalates Action Plan isn't intended to specifically address impacts of aquaculture or other activities on marine debris or microplastic occurrence in Puget Sound or to propose new rules or restrictions (for example, rules of aquacultural practices). However, we agree that more research is needed to understand if the weathering of the plastic materials used in aquaculture may leach phthalates into the marine environment.

Regulations

3. Public Health – Seattle & King County, Seattle Public Utilities Hazardous Waste Management Program, Toxic-Free Future, Zero Waste Washington

Commenters stated: The Draft Phthalates Action Plan should include more language on enforcement and banning, or regulating, phthalates in products and building materials.

Response

Ecology doesn't have the authority to ban or regulate chemicals through an action plan. Action plans are non-regulatory documents.

It is outside the scope and purpose of this document to recommend bans or regulations regarding phthalates. The Phthalates Action Plan serves as a long-term planning document for actions to reduce human and environmental exposure to phthalates. It includes various recommendations to assess and minimize releases of phthalates to the environment as well as to reduce exposures to humans.

Both Ecology and Health maintain websites to disseminate information regarding toxic chemicals, including phthalates, to the public. See these webpages for more information:

- <u>Reducing toxic chemicals</u>⁹
- <u>BPA and Phthalates</u>¹⁰
- <u>Biomonitoring in Washington State</u>¹¹

Evaluating phthalates as a class

4. American Chemistry Council, BASF

Commenters stated: That phthalates should not be regulated as a class and should be addressed individually.

Response

We disagree that phthalates cannot be addressed as a chemical class through recommendations in the action plan. Phthalates as a class are associated with adverse effects in both animal studies and in epidemiological studies in humans. This, in combination with their high production volume and use, is a concern for people and the environment.

While we acknowledge diversity between phthalates, with respect to physical and chemical properties and relative potency with respect to some hazard endpoints, they

⁹ https://ecology.wa.gov/Waste-Toxics/Reducing-toxic-chemicals

¹⁰ https://doh.wa.gov/public-health-healthcare-providers/healthcare-professions-and-facilities/best-practices/environmental-chemicals/bpa-and-phthalates

 $^{^{11}\,}https://doh.wa.gov/data-statistical-reports/environmental-health/biomonitoring/projects/king-county-subsidized-housing$

share a common structural moiety and functional uses, among other shared characteristics. The subgroups as laid out by Environment Canada and Health Canada are useful in the context of discussing the environmental fate of phthalates. Chemicals within a class often will not have identical characteristics, but some members of the class may be more similar in certain aspects than others.

Recognizing this similarity using subgroupings can be useful for communicating the general characteristics of large classes of chemicals such as phthalates. This isn't incompatible with considering phthalates as a class of chemicals based on a shared chemical structure, physical and chemical properties, and hazard traits.

A class approach also enables us to consider cumulative impacts of phthalates more easily. The broad potential for exposure from many sources and by many routes makes this a valuable tool. For similar examples of this approach, please review the <u>Per- and</u> <u>Polyfluoroalkyl Substances (PFAS) Chemical Action Plan</u> (Ecology & Health, 2022)¹² and <u>Polybrominated Diphenyl Ethers (PBDE) Chemical Action Plan</u> (Ecology & Health, 2006).¹³

Addressing cumulative exposure and risk

5. Public Health – Seattle & King County, Seattle Public Utilities - Hazardous Waste Management Program

Commenters asked for more emphasis on the cumulative risks of exposure to multiple phthalates.

Response

We share your concern about this issue and thank you for your comment.

Ecology and Health recognize that the presence of phthalates in multiple categories of consumer products, health care, and environmental media requires consideration of the combined effects of exposure from all sources and through multiple routes and pathways of exposure. People are exposed to mixtures containing different phthalates at home, work, school, and play by ingestion, inhalation, and skin contact with many source products. Reducing the cumulative impacts of this combined exposure is a priority for our Phthalates Action Plan implementation phase.

Our implementation projects will undergo a planning and prioritization process that will include weighing the opportunities for cumulative exposure reduction. At this time, we believe that by taking action to reduce phthalates in exposure sources associated with high exposures, widespread exposures, and disproportionate exposures, we will reduce cumulative exposure.

¹² https://apps.ecology.wa.gov/publications/summarypages/2104048

¹³ https://apps.ecology.wa.gov/publications/summarypages/0507048

We made some edits to the Health and Exposure Appendix (Appendix B) and added more context on cumulative exposure to the action plan's Introduction. We placed more emphasis on combined exposure to multiple phthalates in several places where it was mentioned in the draft but not well highlighted.

6. American Chemistry Council, BASF

Commenters asked that the Phthalates Action Plan consider relative risk of phthalate exposure before making recommendations, and state that the work is too similar to the Environmental Protection Agency's (EPA's) ongoing phthalate risk assessment.

Response

We disagree with the assessment that this action plan is comparable to the work the Environmental Protection Agency (EPA) is currently conducting to determine the risk of commonly used phthalates. It is not applicable to the whole of the United States, as EPA's work will be, nor is it a risk assessment.

Ecology identified phthalates as chemicals of concern for Washington state. As such, Ecology and Health work to provide actionable items which will reduce Washington residents' exposure to phthalates and minimize the introduction of phthalates into Washington's natural environment. This action plan can then be used by state and local governments to secure funding for implementation of recommendations—something the EPA risk assessment isn't used for.

Implementation

7. Zero Waste Washington

Commenter stated: Concerns about a lack of an implementation timeline and the three-year review timeline being too long.

Response

It is not the intent of the Phthalates Action Plan to provide strict timelines for implementation of recommendations. The three-year review doesn't guarantee that all recommendations will be implemented or ready for a review at the three-year mark after publication.

These recommendations cover a wide variety of topic areas, agencies, and partners, which will take time to coordinate. The timing of implementing recommendations is up to each lead agency.

Many of these recommendations don't have established funding, which will need to be acquired before implementation. The Phthalates Action Plan is a starting point, which may be used to provide evidence and support in acquiring funding.

8. Public Health – Seattle & King County, Zero Waste Washington

Commenters requested that recommendations be prioritized.

Response

It is not the intent of the Phthalates Action Plan to prioritize the recommendations for implementation. We purposefully left prioritization of those to the lead agencies listed in the document. Available funding, staff, and other work priorities all impact when and how a recommendation may be implemented.

9. Public Health - Seattle & King County, Toxic Free Future

Commenters requested more detailed implementation plans.

Response

It is not the Phthalates Action Plan's intent to provide detailed implementation plans for recommendation. We purposefully kept the implementation details limited to provide lead and partner agencies flexibility. In addition, the way we implement some of the recommendations, such as further studies, may be influenced by results we obtain from other recommendations.

10. Friends of Miller Peninsula State Park

Commenter stated: Ecology outlines many data collection steps to monitor phthalate levels in the environment. These studies should be designed to assess other hazardous chemicals at the same time, to build our understanding of people's exposures to a complex array of avoidable chemicals in air, water, soil, and food crops.

Response

We appreciate your comment. While we agree that monitoring studies should be both comprehensive and efficient, this action plan isn't intended as an implementation document. Rather, the implementation team will use the recommendations laid out here to devise their own strategies. The Phthalates Action Plan doesn't direct or assist actions to clean up contamination related to a specific release event, nor does it lay out how data collection studies should be performed.

11. Public Health – Seattle & King County, Toxic-Free Future

Commenters expressed concern over recommendations that involve Safer Products for Washington, and how Ecology will ensure funding and staff resources are available within that program to implement action plan recommendations.

Response

The action plan isn't regulatory and doesn't propose new rules or restrictions. Safer Products for Washington is the regulatory program developed to address chemicals in consumer products in Washington, and considers the entire class of phthalates, including those regulated by the Children's Safe Products Act (CSPA). We have recommended several consumer product categories for consideration by Safer Products for Washington with respect to phthalates; we believe the most efficient path forward is to use this established regulatory and implementation process to address consumer products that contain phthalates.

We appreciate your concern about sufficient staffing and resources for Safer Products for Washington. Staffing and resources for another program are outside the scope of this document and will be reviewed and discussed during the implementation of Phthalates Action Plan recommendations.

12. Public Health - Seattle & King County, Toxic-Free Future

Commenters shared concerns about recommendations that involve Safer Products for Washington, and how long it may take for the Safer Products for Washington team to get to the Action Plan recommendations.

Response

The Phthalates Action Plan is a general statewide document that recommends actions. The action plan has recommended several products for consideration by Safer Products for Washington (Recommendations #1, #4, and #7). Any decisions for current and future implementation cycles remain with the Safer Products for Washington program.

The Phthalate Action Plan's intent is not to ban phthalates; the focus is on recommending actions for pollution prevention and exposure reduction. We understand that Safer Products for Washington cycles take time, and that time is needed to identify priority products and thoroughly assess safer alternatives.

Environmental justice and equity

13. Public Health – Seattle & King County, Seattle Public Utilities - Hazardous Waste Management Program

Commenters requested improvements to the discussion and evaluation of environmental justice and equity within the action plan.

Response

We recognize that environmental justice and equity are important considerations for the Phthalates Action Plan, and they were foundational in our work. We looked for information on impacts to sensitive populations and made recommendations to lessen these impacts. We emphasized this with subsections on environmental justice and equity.

In addition, we requested Ecology's Office of Environmental Justice and Equity and Hazardous Waste and Toxics Reduction program's Environmental Justice workgroup

provide a second review of the action plan. Based on their recommendations, we made the following revisions to the Action Plan:

- Removed the term "stakeholder" from the document and replaced with more appropriate terms such as "interested parties."
- Aligned terms with chapter 70A.02.010 Revised Code of Washington (RCW).
- Reorganized all the equity and environmental justice information to be more consistent throughout the document.
- Added a clarifying statement regarding the use of "woman/women/girl/girls" and "man/men/boy/boys." We also added a statement that more research is needed as to disproportionate exposures and impacts to lesbian, gay, bisexual, transgender, intersex, queer/questioning, asexual (LGBTIQA+) individuals.
- Added additional information about specific groups with disproportionate exposures and impacts where supported by literature.

Implementation teams will further assess the needs and considerations of equity and environmental justice during the implementation of recommendations. We welcome any information about where our efforts could be put to best use, as well as any organization contacts that may be interested in partnering on recommendations. We can be reached at <u>ChemActionPlans@ecy.wa.gov</u>.

Specific document changes

14. Public Health - Seattle & King County

Commenters asked Ecology to add a table of regulations.

Response

We added two tables of regulations to the Phthalates Action Plan's introduction. Table 3 contains federal regulations and Table 2 contains Washington State regulations.

15. American Chemistry Council, BASF, Public Health – Seattle & King County, Seattle Public Utilities - Hazardous Waste Management Program, Toxic Free Future

Commenters pointed out typos and corrections.

Response

We thank all our commenters for taking the time to carefully review the document. We made many minor edits, corrections, and formatting changes based on feedback from our commenters. We updated our bibliography and our communications team thoroughly reviewed the final action plan prior to publication. In addition, we renumbered all the recommendations to provide clarity to readers.

16. Public Health – Seattle & King County

Commenter stated: A table that would help highlight what is known relative to exposures of concern, impacts of concern, and populations of concern would be helpful.

Response

Thank you for the suggestion. We agree that more tables and figures would be helpful to our readers. We developed a figure that provides visual information on exposure sources; please see Figure 3 in the Phthalates Action Plan. We've included additional figures within the document to address other sections. We prioritized the tables and illustrations that were most needed due to resource limitations.

17. Public Health – Seattle & King County

Commenter recommended that each recommended action include: 1) the currently known status in WA, 2) what gaps exist, 3) what action is proposed, 4) why the action is needed, and 5) how it will be conducted.

Response

Thank you for your suggestions. This is generally the format we followed within the Phthalates Action Plan. However, some of the information was not available for every recommendation. Please see <u>comment response #9</u> for a description of our intent for implementation.

Background

18. Public Health - Seattle & King County

Commenter requested Ecology include additional information relating to phthalate use in the state of Washington.

Response

We appreciate and acknowledge your concern about the limited information specific to the use of phthalates in Washington. During the planning and research stages of this action plan, we searched for as much information as possible related to this issue, and included what we could find.

However, the information available specific to Washington state is extremely limited. If you have sources or additional information on this topic we may have missed, please share it with us so that it may be considered during the implementation phase of the Action Plan as well as during future reviews. We can be contacted at <u>ChemActionPlans@ecy.wa.gov</u>.

19. Public Health - Seattle & King County

Commenter asked Ecology to clarify and define what an action plan is and how it differs from a chemical action plan.

Response

We discuss the action plan's approach in the Approach section of the <u>Phthalates Action</u> <u>Plan's Introduction</u>.¹⁴ We also added additional language to further define and clarify the difference between an action plan and a chemical action plan.

References

20. Friends of Miller Peninsula State Park

Commenter stated: We would encourage your citations to include those of Dr. Anne Steinemann. Dr. Steinemann, while at the University of Washington, helped to initiate research on phthalates. She has taught at several universities within the United States and in other countries, and the James Cook University, Australia. She now serves as Honorary Professor of Civil Engineering at both universities and serves as adviser to governments and industries around the world. She could advise on your agency's phthalates studies, if willing.

Response

Thank you for recommending Dr. Steinemann's work. While our team did extensive reading of source material prior to scoping the action plan, we didn't cite every work we reviewed. We only cited sources we directly used as references. We hope to consult with the universities during implementation of the action plan recommendations.

Draft Phthalates Action Plan recommendations

Partnerships

21. Coalition for Clean Water, Public Health – Seattle & King County, Washington Association of Sewer & Water Districts

Commenters noted that some potential partners were excluded from the recommendations laid out in the action plan such as academic institutions, local partners and applicable organizations.

Response

Thank you for your suggestion. Ecology only identified partners in the action plan when we were able to consult with them ahead of time to ensure they are committed to participating in the implementation of the recommendation. Other potential partners were not specifically identified.

The Phthalates Action Plan's intent is to provide recommendations for future studies; it isn't a regulatory document and thus cannot restrict future studies or future partners. We intend to reach out to universities and other potential partners during the implementation phase of this project.

¹⁴ https://apps.ecology.wa.gov/publications/documents/2304025.pdf

We updated the background of the biosolids section to include language specifying that Ecology and Health will work with relevant agencies and academic institutions to implement the recommendations, as needed. We added language that Ecology will need to work with both users and producers to plan and coordinate sampling efforts in biosolid-amended fields—see Recommendations #16 and #17 in the Biosolids section.

Consumer products

22. Public Health - Seattle & King County

Commenter asked Ecology to consider fragrance products that are not personal care products.

Response

We appreciate your suggestion. We added a discussion of air fresheners to the consumer products background section to address the omission.

23. Public Health – Seattle & King County

Commenter pointed out that the action plan doesn't include updated information about the newly passed cosmetics law.

Response

Thank you for noticing this oversight. We updated the section on consumer products to include text from the new cosmetics law and clarify how that might impact phthalate use.

24. Public Health – Seattle & King County, Seattle Public Utilities - Hazardous Waste Management Program

Commenters requested Ecology include second hand and reused products in the recommendations.

Response

While we don't directly have a recommendation to address secondhand materials, this topic relates to the action plan's Recommendation #2 under Consumer Products, to support increased transparency and certifications for consumer products.

Transparency in product labeling and product certifications can help people who purchase previously owned products to identify products that don't contain harmful chemicals such as phthalates. In our action plan, we recommend that Ecology's product replacement program develop a swap-out program for durable products in childcare facilities that contain phthalates. We highlight vinyl flooring as an initial opportunity in Recommendation #5, Daycare and Early Childcare Facilities.

At present, addressing vinyl flooring that contains phthalates in childcare facilities seems like a good first step. As we learn more, we may identify other opportunities to address additional durable goods. We know that addressing phthalates in products, including previously owned products, is an important step toward our goal to equitably reduce exposure to toxic chemicals. It is important for everyone to have access to safer consumer products.

Building materials

25. Public Health – Seattle & King County

Commenter requested Ecology include consideration of PVC decking in building materials recommendations.

Response

We thank you for taking the time to thoroughly read the recommendations and provide feedback with your concerns. During the background research for this section, no information regarding phthalates in PVC decking was found in the primary literature or in documentation published by government bodies like the EPA or Centers for Disease Control and Prevention (CDC). Due to this lack of source material, Polyvinyl Chloride (PVC) decking wasn't included as a specific consideration in the building materials recommendations.

26. BASF, American Chemistry Council

Commenters disagreed with recommendations to avoid the use of phthalate-containing building materials.

Response

The Phthalates Action Plan makes recommendations aimed to reduce phthalates in the environment and the potential for exposure. Reducing use of building materials that contain phthalates, when there are less-hazardous alternatives available and suitable for the application of interest, is one way to reduce the volume of phthalates entering the environment and the potential for exposure.

27. Friends of Miller Peninsula State Park

Commenter stated: Ecology should leverage existing resources that can facilitate the state purchasing of less-toxic building materials, including phthalate-free materials. Procurement guidelines should avoid other toxins like flame retardants, dioxins, and formaldehyde.

Response

Thank you for your comment. The recommendations within the building materials section of the Phthalates Action Plan discuss state purchasing and use of existing resources and guidance for phthalate-free materials in state building projects. Inclusion of chemicals such as flame retardants, dioxins, and formaldehyde are outside the scope of this action plan, but other Ecology programs may have existing or future projects related to these topics.

28. Public Health - Seattle & King County

Commenter stated: Recommendation #11 - Add County owned buildings to state owned buildings to ensure that public housing is included by the housing authorities that are managed by cities/counties.

Response

Thank you for your comment. We agree that we should make sure that we don't exclude any public housing. As such, we adjusted the language in Recommendation #12 to include county-owned buildings as well as state-owned.

Health care

29. BASF, Public Health – Seattle & King County

Commenters expressed concern over availability of alternative blood storage and other medical products.

Response

Thank you for your comment about the availability of blood storage products that are made with alternative plasticizers, not DEHP.

In conversations with stakeholders, we learned that the function of this chemical in stabilization of red blood cells remained a concern for many, despite the growing availability of alternatives to phthalates for many other medical products. Our Draft Phthalates Action Plan was worded to highlight that concern. We made updates in the final version that include the suggested references and place a greater emphasis on the availability of blood storage products made without DEHP. We hope to highlight that availability during the implementation phase of this work.

30. Public Health – Seattle & King County

Commenter suggested Ecology and Health include patients in outreach when appropriate so they can advocate when they prefer phthalate free items (concerning recommendation 3) and target specific outreach to women, particularly of reproductive age, to raise awareness of this issue and allow them to understand approaches to reduce exposures (concerning Recommendation #4).

Response

Thank you for this suggestion.

Under Recommendation #3, we added development of health education materials to help patients advocate for the use of phthalate-free products in their care when possible.

For Recommendation #4, we added health education materials that could be developed for users of absorbent personal care products to learn how to select phthalate free

options when purchasing these items, should the results of the proposed product testing indicate that would reduce exposure to phthalates.

Food contact articles

31. Washington Potato Commission, Food Northwest

Commenters requested to join the workgroup tasked with reducing sources of phthalates in food and beverages (Recommendation #3) and the workgroup tasked with establishing voluntary reporting and labeling protocols for phthalates (Recommendation #4).

Response

Thank you for your support. We will reach out with more information once we are ready to convene the workgroups. As a note, we aren't proposing labelling at this time, although the specific implementation projects will be determined by the workgroups.

Food and Drug Administration (FDA) action and authority on phthalates

32. American Chemistry Council

Commenter stated: Concerning the following statement in the draft action plan, "In May 2022, the FDA revoked authorizations for the food contact use of 23 phthalates, while eight phthalates remained authorized for use as plasticizers and one phthalate as a monomer in food contact uses." Commenter noted that: this paragraph fails to provide the context that these authorizations were revoked because the specific uses were abandoned (87 Fed Reg. 31080). As written, it leaves the impression that these authorizations may have been revoked for other reasons.

Response

We added text to the report to reflect that revoked authorizations were motivated by abandoned uses.

33. Food Northwest

Commenter asked the departments of Ecology and Health to coordinate with the FDA as it assesses current food contact uses, use levels, dietary exposure, and safety levels.

Response

Thank you for the suggestion to work with U.S. Food and Drug Administration (FDA) on questions of phthalates in food contact articles. The section of the Phthalates Action Plan that proposes activities for the food contact articles workgroup was edited in our final draft to recommend more direct engagement with FDA.

As context, Health staff met with FDA scientists in December 2022 to discuss analytical methods available for detecting phthalates in food contact articles and opportunities to build upon their earlier results, pending funding. Concerning FDA's process to re-evaluate the safety of phthalates in food articles, we tracked the public comments submitted during FDA's 2022 request for information.

34. American Chemistry Council

Commenter stated that no phthalates were found to be used as primary plasticizers in PVC film for food service and commercial wraps (e.g., wrapping films for meat, vegetables or sandwiches at grocery stores and delis) or paper-based packaging for fast food.

Response

Thank you for pointing out that the U.S Food and Drug Administration (FDA) research publications we cited didn't find phthalates in commercial food films (Carlos et al, 2018). We edited the final draft to reflect that correction.

We disagree slightly with the comment concerning paper-based packaging, however. FDA reported the presence of phthalates in paper-based fast-food packaging, such as pizza boxes and sandwich wraps. In agreement with the comment, FDA then concluded that the relatively low levels detected could suggest that the phthalates found weren't added to provide a plasticizing function.

35. Public Health – Seattle & King County

Commenter stated: Concerning Recommendation #3, in the Food Contact Articles section the equity focus here is great, but please also include a discussion about children as a sensitive exposure group that should be prioritized, particularly when they are part of a vulnerable population.

Response

We added mention of children's dietary exposure as a priority for the activities of the proposed food contact article workgroup. We agree that young children are a vulnerable population for exposure to toxic chemicals found in foods because of their higher dietary intake per body weight and active growth and development.

36. Public Health – Seattle & King County

Commenter stated: Concerning Recommendation #3, in the Food Contact Articles section it would be helpful on this recommendation to understand what kind of manufacturers we have in Washington and where the biggest impact would be – in this recommendation are you targeting food processing manufacturers, food packaging groups, or food packing production manufacturers? Describe where most of our processed food is coming from in Washington.

Response

Thank you for this comment.

We weren't able to include a market analysis for production and sales of processed food in Washington in the Phthalates Action Plan due to time and resource constraints. During implementation, we anticipate that the workgroup on food contact articles will begin with a scoping exercise to determine which uses of phthalate containing food contact articles should be prioritized to have the highest impact for reducing people's exposure, and which uses are the most feasible to replace from a technological and economic standpoint. We edited the action plan to include a new first objective for the workgroup: to survey food producers and manufacturers, as the commenter suggested. Manufacturing, packaging, and food service are all mentioned in the action plan as industry sectors we hope to engage in this work.

Early childcare facilities and daycares

37. Public Health – Seattle & King County

Commenter stated: On page 43-44, add to the list of why kids are a sensitive population of concern that: because of their small size relative to body proportions, they have a large surface area and a much higher metabolism than adults, which also impacts exposure levels and metabolism of chemical exposures.

Response

We added a bullet point about this in the Daycare and Early Childcare Facilities section of the Action Plan. It reads, "They have small size relative to body proportions, have a large surface area and a much higher metabolism than adults, which also impacts exposure levels and metabolism of chemical exposures." The report cites the EPA Exposure Factors Handbook in this section.

38. Public Health - Seattle & King County

Commenter stated: In the daycare/childcare section discuss the various kinds of day cares that range from neighborhood family care to licensed facilities, and who is attending each of these facilities in WA. NeighborCare facilities are run by families in their own homes, likely leading to very different exposures to phthalates based on the kind/type of facility.

Response

In the problem statement we added this: "The facilities that provide childcare are numerous and diverse. This includes licensed childcare centers, home-based childcare providers, and neighborhood family care facilities that are run by families in their own homes."

39. Toxic-Free Future

Commenter stated: The plan should clarify that a safer substitute for vinyl flooring will be used for these replacements.

Response

Thank you for your comment. We added text to the Recommendation #5 project description to clarify that any substitutes for vinyl flooring should be safer than the vinyl itself.

40. Public Health – Seattle & King County

Commenter stated: To prioritize facilities with the greatest needs, I would include small family friendly, neighborhood care facilities that are either unlicensed or licensed, especially in low-

income neighborhoods. These are likely the ones with the fewest resources and in the poorest facilities, often resident's homes.

Response

We added the following language to the action plan in the Daycare and Early Childcare Facilities section:

Recommendation implementation should prioritize existing childcare facilities in overburdened communities or those that serve vulnerable populations. Outreach and engagement efforts may need to be translated into several languages besides English. Implementation teams should also include Early Childhood Education and Assistance Program (ECEAP) facilities that serve children from vulnerable populations.

41. Public Health – Seattle & King County

Commenter stated: Recommendation #5, Daycare and Early Childcare Facilities—Justification makes it sound like Ecology's requirement for restriction of phthalates in vinyl flooring is already happening. More information should be provided about when this starts, how long it will take, etc.

Response

Thank you for your comment. We added text to Recommendation #5, Daycare and Early Childcare Facilities, to clarify the recent rulemaking on phthalates in vinyl flooring under Safer Products for Washington and include the information you requested. The Phthalates Action Plan doesn't recommend restrictions to the use of new vinyl flooring; the recommendation focuses on how to help daycares transition to newer floors that have safer alternatives.

42. Public Health – Seattle & King County

Commenter asked Ecology to consider an additional recommendation for the development of a co-op purchasing program for childcares that makes selecting phthalate free cleaning and other materials easy and less expensive.

Response

We added the following text to the Recommendation #6 project description and implementation:

Implementing these recommendations requires action by other state agencies over the next several years. We will explore additional funding such as a cooperative purchasing program for childcares that choose to select phthalate free cleaning and other materials. This would need to be coordinated with DCYF, Ecology, and Health. Health can leverage its relationship with DCYF to reduce phthalate hazards in daycares.

43. Public Health - Seattle & King County

Commenter stated: Providing education and information is more effective with assistance in providing safer products. Ecology should commit to finding funding that can help. It would be helpful here to understand what safer products exist and if swapping will be a prohibitive cost for facilities.

Response

We added the following text to Recommendation #6, Daycare and Early Childcare Facilities: "Educate childcare providers to understand what safer products exist and provide them with assistance by choosing safer alternatives."

44. Public Health - Seattle & King County

Commenter stated: Ecology should make all efforts to reach the facilities and communities most impacted and this would include the unlicensed, family neighborhood care.

Response

We added the following text to Recommendation #6, Daycare and Early Childcare Facilities:

Work with and reach out to childcare facilities and providers, particularly those most impacted (e.g., those in overburdened communities or serving vulnerable populations) to identify ways to reduce the use of phthalate containing materials in daycares (for example, avoiding fragranced cleaning products, using tongs to serve food instead of vinyl gloves, and avoiding single use plastic items).

45. Public Health – Seattle & King County

Commenter asked Ecology and Health to clarify how the regulatory authority would be used in Recommendation #6 under the Daycare and Early Childcare Facilities section.

Response

We added this due to regulatory considerations:

Phthalate prevention and reduction activities can be accomplished using existing statutory authority. We will coordinate with DCYF and local ECE programs on the use of Washington state laws and regulations that establish the process and requirements for obtaining a license and the minimum criteria for operating the childcare facility.

DCYF states that regulation of ECE programs is primarily a local responsibility, and site related contamination is not "evaluated" by licensing staff unless there are concerns raised at the inspection. Thus, local programs have the authority to adopt their own childcare licensing programs and requirements. These local programs generally must include health and safety requirements that are at least as stringent as the state requirements. None of these recommendations violate existing federal (e.g., CPSIA) or state laws (e.g., CPSC and CSPA).

Biosolids and solid wastes

46. Discovery Clean Water Alliance, The Coalition for Clean Water, Washington Refuse and Recycling Association, Washington Association of Sewer, and Water Districts

Commenters pointed out that landfills, composters, recyclers and wastewater treatment plants and other waste handlers do not manufacture phthalate-containing products and Ecology should focus upstream on producers of phthalates.

Response

We acknowledge that the waste industry isn't the manufacturer of phthalate-containing products. Unfortunately, phthalate-containing products have the potential to enter the waste stream through various pathways where they can be a continuing source of phthalate exposures for humans and the environment. All stages of the lifecycle of phthalate-containing products should be evaluated to provide information on where the greatest impacts are and where meaningful changes could be made.

Biosolids

47. Discovery Clean Water Alliance, King County Department of Natural Resources and Parks Wastewater Treatment Division, Public Health – Seattle & King County, The Coalition for Clean Water

Commenters recommended we broaden the scope of the biosolids recommendations to include assessment of exposure to phthalates from all agricultural sources (e.g., fertilizers, pesticides, seeds, irrigation water) and practices (e.g., application method, storage).

Response

Recommendations #17 and #18 have been revised to include sampling soils, without historical land application of biosolids, for phthalates to compare to phthalate levels in biosolids-amended soils. Although this doesn't directly include the sampling of other soil amendments like fertilizers, pesticides, and manures, it will shed light on the presence of phthalates in the environment that cannot be attributed to biosolids use. This will give us a baseline level of phthalates present in non-biosolid-amended agricultural soil for comparison with phthalate levels measured from biosolid-amended fields.

Regulation of fertilizers and pesticides fall under Washington State Department of Agriculture (WSDA). Also, thousands of fertilizers are used in agriculture, and so comprehensive sampling can't reasonably be accomplished under the scope of this action plan.

48. Seattle Public Utilities, Washington Association of Sewer and Water Districts

Commenters recommended adding language to clarify and give context about the potential exposure to phthalates from biosolids and emphasize source reduction as a means to limit exposure.

Response

We revised the background section of the biosolids recommendations to include:

- Wastewater Treatment Plants (WWTPs) and biosolids aren't a source of phthalates, rather they receive them from upstream sources.
- Source reduction will have the biggest impact on reducing exposure to phthalates from biosolids.
- Amount of nonexceptional quality biosolids produced annually and amount of acreage with nonexceptional biosolids land-applied annually are included for context.
- Our hope is that implementation of the recommendations in the entirety of the action plan will identify sources of phthalates and lead to a reduction in their use and thus a reduction in what goes into our wastewater treatment plants and biosolids as a result.

49. King County Department of Natural Resources and Parks Wastewater Treatment Division, Public Health – Seattle & King County

Commenter stated: Recommendation #19: Merge this recommendation with Recommendation #21, Compost. Modify as follows: "Ecology should develop and implement a plan to test the levels of phthalates in finished compost that comes from various feedstocks, including yard and food waste, biosolids, and manure".

Response

We updated Recommendation #19 to tie it more closely with Recommendation #16 by suggesting that phthalate levels detected in biosolids measured in Recommendation #16 are used for comparison, where possible, with phthalate levels detected in composted biosolids sampled in Recommendation #19. Additionally, we updated Recommendation #16 to suggest the results pair with Recommendation #19.

50. Friends of Miller Peninsula State Park

Commenter stated: For a few years, Ecology has promised a map of locations where sewage wastes are spread. Supposedly a staff person was working on it. This information has not been forthcoming. It is important that the scientists, advocates, and the public have this information to figure out if there are burdens to communities living near these disposal sites, including threats to drinking water.

Response

Ecology's biosolids program has been working for several years, as time and resources allow, towards generating a map that shows where biosolids are produced and land applied in Washington state. We hope to complete this project and maintain it on our webpage soon. Although we can't yet produce a map, anyone can submit a <u>public records request</u>¹⁵ to Ecology for information about the locations of land application of non-exceptional quality biosolids in Washington state.

51. Seattle Public Utilities

Commenter stated: Ecology could propose actions that help the state prioritize where actions are most needed through, for example, recommending development of regulatory or other mechanisms for required monitoring and reporting of biosolids, leachate, dust swipes, compost, etc. by businesses and utilities.

Response

Ecology can only require sampling as outlined in the Biosolids Management Rules (<u>Chapter 173-308 WAC¹⁶</u>), however several of our recommendations include voluntary ongoing monitoring of phthalates in biosolids, soils, crops, and compost. Our hope is that implementing the recommendations in the entirety of the action plan will identify sources of phthalates and lead to a reduction in their use and thus, a reduction in what goes into our wastewater treatment plants and biosolids as a result.

52. Discovery Clean Water Alliance, Coalition for Clean Water

Commenters recommended the biosolids recommendations be removed from the Solid Waste section of the Phthalates Action Plan, as biosolids are not considered a waste in Washington State.

Response

We renamed the section to **Solid Waste and Biosolids** to discern that biosolids are seen as a valuable resource, not a solid waste.

Compost

53. Public Health – Seattle & King County

Commenter asked: Please include compost related products (e.g., hydroseed matrix) to understand phthalates content, Recommendation #21, Compost.

Response

At this time, we are starting with a recommendation for testing compost to gather information about potential phthalate contamination. If phthalates are verified as a valid concern for compost, then additional testing of compost related products could occur in the future.

¹⁵ https://ecology.wa.gov/footer-pages/public-records-requests

¹⁶ https://apps.leg.wa.gov/wac/default.aspx?cite=173-308

Recycling

54. Public Health - Seattle & King County

Commenter stated: Recommendation #22 – Discuss and include a recommendation focused on occupational and residential exposures from the recycling process itself and phthalates that are released into the environment: The potential for a plastic recycling facility to release microplastic pollution and possible filtration remediation effectiveness – ScienceDirect (this likely ties into the equity section as well).

Response

At this time, we don't have enough information to be able to discuss or include recommendations for occupations and residential exposures to phthalates from the recycling process. Microplastic pollution and exposures are outside the scope of the Phthalates Action Plan.

55. Public Health – Seattle & King County

Commenter stated: Recommendations #16 and #17. In this section it would be helpful to know which jurisdictions have done voluntary testing and what those results look like, or what to expect from other testing that has been done elsewhere. Could jurisdictions that are doing voluntary testing be approached for a study with Ecology given the lack of funding? Same for gases? Include a recommendation to seek funding from/with air agencies in the state to do this work?

Response

This request is outside the scope of the Phthalates Action Plan. However, this is something we may investigate in future work.

Aquatics, sediment, and biota

56. Public Health - Seattle & King County

Commenter asked Ecology to note which six phthalates have been monitored in Puget Sound sediments by Ecology since 1989 and whether trends in levels mirrors shifts seen in human biomonitoring from DEHP to DINP, for example.

Response

We added which six phthalates have been monitored in Puget Sound sediments. We didn't include a discussion on whether sediment concentration trends mirror human biomonitoring trends, as that would be outside of the scope for this Aquatics, Sediment, and Biota recommendation.

57. Public Health – Seattle & King County

Commenter stated: Recommendation #28 – Bullet #2: regarding, "Testing species and tissues that are most likely to be eaten by overburdened communities and sensitive populations." Please add "or contribute to traditional practices or livelihood,".

Response

We added additional language as requested to the Environmental justice and equity section of the Aquatics: surface water, sediment, and biota section.

58. Public Health - Seattle & King County

Commenter asked Ecology to include/discuss data on phthalates in sediment/surface water/fish tissue from Remedial Investigation/Feasibility Study (RI/FS) studies from cleanup sites in WA.

Response

We added text to acknowledging phthalate contamination of cleanup sites and two references to the background of the Aquatics: Surface Water, Sediment, and Biota section. We didn't provide a discussion on data from cleanup sites, as that would require a literature review beyond the scope of this action plan.

59. Public Health - Seattle & King County

Commenter stated: The Toxic Substances Control Act (TSCA) tends to focus only on the data/exposures within their regulatory purview. Ecology should note whether this information referred to here includes non-TSCA literature/exposures/impacts (e.g., from Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) or other regulations like cleaning products and personal care product contributions to environmental concentrations).

Response

We updated language to clarify that the initial results of the Toxics Substances Control Act (TSCA) systematic review cited in the Aquatics: Surface Water, Sediment, and Biota section are specific to environmental hazard (toxicity) data for aquatic and terrestrial organisms and are broadly applicable.

The toxicity studies captured in the TSCA systematic review process focus on mortality, growth, development, and reproductive endpoints in experimental studies. We don't refer to draft environmental exposure estimates in media determined under TSCA and agree that they wouldn't necessarily be specific enough for Washington state, nor would they include phthalates used in pesticides, which would be regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

However, the use of phthalates in consumer and personal care products is included in the scope of the TSCA risk evaluations the Environmental Protection Agency (EPA) is currently completing.

Background and appendices

General organization

60. Public Health - Seattle & King County

Commenters did not support the split organization of background information and requested changes to the background sections and the appendices.

Response

Our intent by splitting up background information was to include as much information as possible that was directly relevant to specific recommendations. Our overall goal was for the action plan to be accessible and understandable for a wide variety of audiences with varying levels of technical expertise.

We know that some readers with more technical understanding of phthalates would benefit from a more in-depth discussion. That in-depth technical information was included as appendices.

Appendix B. Human health and phthalates background

61. American Chemistry Council, BASF

Commenters pointed out human health hazards of individual phthalates and did not support the decision to approach phthalates hazards as a chemical class.

Response

Ecology and Health approached the Phthalates Action Plan using a class approach. Where the health effects section identifies specific phthalates, the purpose is to illustrate hazards that are associated with the class generally. We recognize that the depth of research and the specific toxicities that have been noted to date vary among members of the class. Please see <u>comment response #6</u> for more context.

62. American Chemistry Council, BASF

Commenters expressed concern about the role of animal toxicology and human epidemiological data in hazard identification.

Response

Thank you for your careful review and comments.

Comments on several specific sections of Appendix B raised limitations of human epidemiology studies for use in identifying the hazards of phthalates. We added some further explanation of our approach to summarizing the potential health impacts of phthalate exposure for this action plan, found in the second section of Appendix B: Health Hazard Evaluation. We also made many small edits to this appendix to better clarify how evidence from animal toxicology and human epidemiology were both used to identify potential hazards of phthalate exposure. We consider environmental epidemiology as a critical part of an overall body of evidence on the human health effects of environmental chemicals generally, and phthalates specifically (Maffini et al., 2021). Epidemiological study designs may not be able to definitively establish causal relationship between exposure and observed health effects. However, epidemiological studies of human populations help us understand health effects in real-world settings and in diverse populations.

Laboratory studies in animal models provide information on toxic mechanisms, and in controlled environments and genetically identical animals with controlled exposure levels. Interpretation can be complicated by species differences, particularly for studies of brain development and function, endocrine effects, and other endpoints that have significant differences in humans.

People have diverse genetics, health status, and behaviors that cannot be captured in controlled laboratory experiments in animals. Further, epidemiology can provide important information about the effects cumulative exposure to mixtures of chemicals and non-chemical stressors that modify human responses to chemicals. For these reasons, we consider peer-reviewed publications of studies in human populations a critical component of the overall evidence that identifies the health hazards of phthalates.

We also wish to clarify that Appendix B isn't intended to be a comprehensive literature review. To identify the key hazards of phthalate for human health, we relied on authoritative reports and hazard assessments first, then consulted peer reviewed literature for human epidemiological evidence to identify hazards that are less well characterized in animal studies or are emerging toxicological topics for phthalates. Our epidemiological literature sources were primarily systematic reviews and meta-analyses. We supplemented these sources with peer-reviewed publications from the most recent years or where specific studies added to the other sources.

63. Public Health - Seattle & King County

Commenter requested a standalone chapter on cumulative health effects of phthalates.

Response

Thank you for the suggestion. We agree that the presence of phthalates in multiple categories of consumer products, workplaces, and health care requires consideration of the combined effects of exposure from all sources, and through multiple routes and pathways of exposure.

Reducing cumulative impacts of people's exposure is a priority for our Phthalates Action Plan implementation phase. We made some edits to the Health and Exposure Appendix to highlight our concerns more clearly for cumulative exposure and we added more cumulative exposure context to the phthalates background information in the main body of the action plan. Throughout the report, we placed more emphasis on cumulative exposure and effects in several places where it had been mentioned in the draft but was not worded clearly enough.

64. BASF

Commenter provided an alternative interpretation of epidemiologic review publications on semen quality and other adult male reproductive parameters.

Response

Radke et al (2018), in their review of epidemiological studies on male reproductive toxicity, concluded:

In summary, there is moderate to robust evidence of an association between Din-butyl phthalate (DBP), Benzyl butyl phthalate (BBP), Di(2—ethylhexyl) phthalate (DEHP), and Diisononyl phthalate (DINP) exposure and sperm parameters, slight evidence for Di-isobutyl phthalate (DIBP), and indeterminate evidence for Diethyl phthalate (DEP).

We believe this is appropriately cited in the Phthalates Action Plan. Further we note that a recent longitudinal study measured phthalate metabolites in spot urine samples in boys taken at four different times during pubertal development and reported significant associations with some phthalates and sperm parameters at age 18 (Mínguez-Alarcón et al., 2022). This paper, which used a different study design, adds to the overall science that supports our concern for the hazards of phthalates exposure for semen quality.

Thank you very much for pointing our typo that substituted Di-isodecyl phthalate (DIDP) for Di-isobutyl phthalate (DIBP).

65. BASF

Commenter asked Ecology and Health to clarify our citation and interpretation of epidemiological reviews on neurodevelopment.

Response

We rewrote paragraph 2 of the neurodevelopment section to clarify the conclusions of each of the three reviews that were cited on phthalates and neurodevelopment. We also added some text about the limitations of epidemiological studies on neurodevelopment.

Overall, we agree that the associations between phthalate exposure and neurodevelopmental outcomes do not prove causality. However, we consider human epidemiology studies an important piece of evidence for human health hazards of phthalates, particularly for neurodevelopmental effects. The profound differences in human brains and behaviors compared with those of laboratory animals limit the ability of animal models to capture important outcomes for human brain toxicity.

Regarding the use of epidemiology, we looked for longitudinal studies and strong metaanalyses of human epidemiology where available. See more in <u>comment response #62.</u>

66. BASF

Comments were received pertaining to the Phthalate Action Plan's discussion of developmental toxicity, systemic effects on the liver and kidney and cancer-causing potential of DINP, the sources cited in the draft report, and citation of the EPA Technical Review of DINP.

Response

EPA's July 2022 Technical Review of Diisononyl Phthalate has been correctly cited and we updated content on pages 150, 152, and 157 (as numbered in the Draft Action Plan) to reflect the citation accurately.

Thank you for pointing out the incorrect citation on page 150. We removed the citation of Center for Regulatory Effectiveness and American Chemistry Council (CRE & ACC 2003) and replaced it with the EPA 2022 Technical Review of DINP. We also revised the text to reflect the most current conclusions surrounding reproductive toxicity in laboratory animals by the EPA.

On page 152, we removed text referencing the EPA's conclusion that "DINP can be reasonably anticipated to cause cancer" due to variations in this conclusion across that document's revisions.

Thank you for pointing out the missing citation on page 157. We have correctly cited the EPAs 2022 Technical Review of DINP. We also revised the language to better reflect the EPA's conclusions regarding liver and kidney toxicity in rodents and their relevance to human health.

67. BASF

Commenter requested clarification regarding developmental toxicity of DIDP.

Response

We added a citation to the Greenscreen[®] on DIDP; thank you for noting this oversight.

The classification of DIDP as a developmental hazard was based on the findings of skeletal malformations in rats after exposure to pregnant dams, not anti-androgenic toxicity. The 2003 National Toxicology Program (NTP) evaluation (NTP-CHRHR, 2003) states, "NTP judges the scientific evidence sufficient to conclude that DIDP is a developmental toxicant and could adversely affect human development if the levels of exposure were sufficiently high."

That committee concluded the animal evidence for adverse effects is clear, but that there is minimal concern for adverse effects in humans at current exposure levels. The California Proposition 65 listing is derived from the NTP evaluation. For the purposes of the Phthalates Action Plan appendix on hazard evaluation, we discuss DIDP as a developmental toxicant because this finding is relevant to the hazards of phthalates as a class.

When we are in the implementation phase of this work, carrying out actions to reduce phthalate impacts in Washington state, the levels of population exposure that may be

associated with harms will help guide our focus to the products or exposure reduction projects that will have the highest impact.

68. BASF

Commenter noted: The major source for human exposure to phthalates is food. Therefore, in case food intake is increased phthalate intake will be increased. These associations may be a random finding.

Context

This comment referred to the following draft text in the Phthalates Action Plan:

Phthalates may increase the risk of type 2 diabetes, gestational diabetes, and insulin resistance in people. In laboratory animals some phthalates can alter glucose balance and impair glucose uptake. Phthalates are associated with glucose homeostasis disruption in people (T. Huang et al., 2014) and they can interact with receptors that may play a role in the development of type 2 diabetes and obesity (Begum & Carpenter, 2021).

Response

We added text to Appendix B to acknowledge the possibility that reported associations between phthalate exposure and the various metabolic outcomes that have been reported could be driven by differences in study populations in total food calorie intake, rather than being caused by the phthalates present in the food. Thank you for raising this issue concerning interpretation of the epidemiological observations.

69. BASF

Commenter questioned the relevance of dust as an exposure pathway, asking, "Is dust a relevant source of phthalate acid esters (PAE) exposure?" Commenter suggested additional citations of published literature could be added to the action plan.

Context

Please add the following references and use in the discussion:

- Becker K et al. (2004). DEHP metabolites in urine of children and DEHP in house dust. International Journal of Hygiene and Environmental Health 207:409-417. DOI: https://doi.org/10.1078/1438-4639-00309.
- Fromme H et al. (2013). Phthalates in German daycare centers: Occurrence in air and dust and the excretion of their metabolites by children (LUPE 3). Environment international 61:64-72. DOI: https://doi.org/10.1016/j.envint.2013.09.006.

Response

We reformatted the relevant section for clarity. The report cites analyses of chemicals in house and day care dust samples that consistently find that phthalates dominate the semi-volatile chemical fraction of house dusts, including the suggested Fromme et al,
2013 reference. Some of these citations are found in Appendix B and others in the recommendation sections on Consumer Products, Building Materials, and Day Care and Early Childcare Facilities sections.

The recommendation sections add details and references about the connection of products, dust, and exposure. We believe the evidence overall clearly supports dust as a relevant source of exposure to phthalates, particularly for small children.

70. Public Health – Seattle & King County

Commenter stated: Please mention other racial groups that are disproportionately exposed to phthalates in personal care products.

Response

Thank you for your comment. We added references and notes of other groups of women who may have disproportionate exposure to personal care products to Appendix B, based on research of exposure patterns performed in California.

71. Public Health – Seattle & King County

Commenter provided several notes on improvements that could be made to Appendix B .

Response

Thank you for conducting a thoughtful reading and suggestions for improvement. We strengthened the reproductive toxicity content as requested by the commenter, and noted some research by Dr. Jody Flaws, as raised by the commenter.

At this time, we aren't able to expand Appendix B to incorporate a complete discussion of Environmental Protection Agency's (EPA) process under the Toxic Substances Control Act (TSCA) to develop cumulative risk assessment guidance for phthalates. We highlighted parts of the Phthalates Action Plan that are relevant to cumulative exposure concerns, and we cited EPA's webpage on that work so that interested parties can learn more and follow the development of the cumulative risk assessment being performed under TSCA.

72. Public Health – Seattle & King County

Commenter stated: Occupational exposures should include workers at transfer and recycling facilities.

Response

We added mention of possible occupational exposure to people handling waste plastic to Appendix B; however, we did not locate studies of phthalate exposure in this population.

73. Public Health – Seattle & King County

Commenter stated: The WEBS data seem like a significant piece to follow up on. Where are these elevated exposures coming from? Include a recommendation around this. Mention the

ECHO study and data from that on pregnant people's exposures and other phthalates of concern not included in National Health and Nutrition Examination Survey (NHANES).

Response

Health hasn't had resources available in recent years to continue work on our past biomonitoring study. A time-limited grant from the federal Centers for Disease Control had funded collection and analysis of urine samples, as well as surveys and other work.

Language was added to the Exposure section of Appendix B that mentions findings of non-NHANES phthalates in one of the published studies from the Environmental Influences on Child Health Outcomes program (ECHO).

More information about ECHO can be found on the <u>National Institutes of Health's ECHO</u> webpage.¹⁷

74. Public Health - Seattle & King County

Commenter asked Ecology and Health to provide citations for the statement on boys of color being potentially more exposed and impacted.

Response

We identified this population in our draft to raise concern about the potential health impacts of phthalates exposure related to asthma. The draft did not state that boys of color are more highly exposed.

That concern was based on two findings:

- Links between phthalates exposure and asthma in published epidemiology studies. Epidemiological studies, as summarized in Appendix B, have linked in utero and early life exposures, measured by urinary metabolites of phthalates, with respiratory symptoms in children.
- The higher prevalence and severity of asthma in Black boys and Native American children compared to other populations, cited in Appendix B.

We have elected to remove the content that identified boys of color as a particular population of concern because literature that provides clear support for the potential of phthalates to pose disproportionate risks of respiratory toxicity for this population is not available.

Appendix C. Phthalates in the Environment

75. Public Health – Seattle & King County

Commenter stated: This appendix should be improved so that it contains more information and matches the scope and depth of the human health appendix.

¹⁷ https://www.nih.gov/research-training/environmental-influences-child-health-outcomes-echo-program

Response

The action plan's intent is to be an accessible guidance document, rather than a comprehensive literature review. The appendices vary in length based on how much information was deemed vital to provide context to the recommendations. Please see <u>comment response #9</u> and <u>comment response #19</u> for more information.

76. American Chemistry Council

Commenter stated: The extended discussion regarding algal degradation of phthalates and possible downstream impacts on the distribution of algal/toxins appears extremely speculative. It is not clear how this speculative discussion is appropriate here, particularly in the absence of discussion of other factors that could impact the algal community (e.g., nutrient loading).

Response

We removed the discussion on algal degradation of phthalates. While relevant to the environmental fate of phthalates, as biological degradation is the primary means by which phthalates are removed from the environment, the overall discussion was deemed not necessary for the Phthalate Action Plan as a whole.

77. American Chemistry Council

Commenter had questions about the inclusion of phthalates in reports on large-scale remediation efforts.

Context

Specific Comments on language from the Draft Action Plan:

- Page 23: "Failure to reduce these constant sources of phthalate release has led to recontamination of sediments in the Puget Sound area following large-scale chemical remediation efforts (Ecology, 2009a)."
- Page 169: "Failure to reduce these constant sources of phthalate release has led to the recontamination of sediments in the Puget Sound area following large-scale chemical remediation efforts (Ecology, 2010)."

This sentence suggests that the presence of phthalates in sediments negated previous remediation efforts of sediments, which is unlikely to be the case. The suggestion that phthalates were a primary driver for previous remediation efforts is also questionable. Ecology Publication 11-03-008, titled "Control of Toxic Chemicals in Puget Sound, Characterization of Toxic Chemicals in Puget Sound 8 EU Risk Assessment Report (39uropa.eu)" for example, does not appear to highlight phthalates at all, despite being authored in the same time period as the two references provided.

Response

The reports cited provide clear evidence that, following a large-scale effort to clean up toxic chemicals in Puget Sound (which included cleanup of phthalates, although they

were not the main focus of the project), phthalates were reintroduced and recontaminated the sediments in the years following the remediation project.

Appendix F. Preliminary regulatory analysis

78. Public Health – Seattle & King County

Commenter asked Ecology to include in the introduction a description of what costs were considered. Are these costs to the state to manage each recommendation?

Response

Cost considerations are described in Appendix F: Final Regulatory Analysis (FRA).

State agencies would incur the majority of the estimated costs since they are responsible for implementing the recommendations. Where nongovernmental entities—such as private businesses or organizations—would incur costs, we presented total costs across all parties in quantified cost estimates, and we explain the distribution of those costs in the corresponding section in the FRA.

79. Public Health – Seattle & King County

Commenter stated: It would be helpful for stakeholders if Ecology could include health cost calculations for each recommendation to demonstrate the estimated benefit of each action.

Response

Computing economic costs and benefits of our phthalate reduction actions was beyond the scope of the action plan. The analysis considers only the cost of resources to perform the work.

Appendix A. References

Ecology, & Health. (2006). <u>Washington State Polybrominated Diphenyl Ether (PBDE) Chemical</u> <u>Action Plan: Final Plan, Department of Ecology Publication No. 05-07-048, Department of</u> <u>Health Publication No. 333-060.</u> https://apps.ecology.wa.gov/publications/documents/2104048.pdf

- Ecology, & Health. (2022). <u>Per- and Polyfluoroalkyl Substances Chemical Action Plan, Publication</u> <u>21-04-048</u>. https://apps.ecology.wa.gov/publications/documents/0507048.pdf
- Maffini, M. V., Geueke, B., Groh, K., Carney Almroth, B., & Muncke, J. (2021). <u>Role of</u> <u>epidemiology in risk assessment: a case study of five ortho-phthalates</u>. *Role of epidemiology in risk assessment: a case study of five ortho-phthalates - PubMed (nih.gov).* https://pubmed.ncbi.nlm.nih.gov/34775973/
- Mínguez-Alarcón, L., Burns, J., Williams, P. L., Korrick, S. A., Lee, M. M., Bather, J. R., Kovalev, S. V., Sokolov, S. A., Lebedev, A. T., Smigulina, L., Ghayda, R. A., Koch, H. M., Sergeyev, O., & Hauser, R. (2022). <u>Urinary phthalate metabolite concentrations during four windows</u> <u>spanning puberty (prepuberty through sexual maturity) and association with semen</u> <u>quality among young Russian men</u>. *International Journal of Hygiene and Environmental Health*, *243*, 113977. https://doi.org/10.1016/J.IJHEH.2022.113977
- National Toxicology Program. (2003). <u>NTP-CERHR Monograph on the Potential Human</u> <u>Reproductive and Developmental Effects of Di-Isodecyl Phthalate (DIDP).</u> *NTP CERHR MON, 3,* i-III90. http://www.ncbi.nlm.nih.gov/pubmed/15995727

Appendix B. List of Acronyms and Abbreviations

Abbreviations and acronyms used in this response to comments

Table 2: Abbreviations and acro	iyms for the terms used in	this response to comments.

Acronym or Abbreviation	Definition
AP	Action Plan
CDC	Centers for Disease Control and Prevention
CSPA	Children's Safe Products Act
DCYF	Washington State Department of Children, Youth, and Families
ECE	Early Childhood Education
ECHO	Environmental Influences on Child Health Outcomes program
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
HEALTH	Department of Health
LGBTQA+	Lesbian, Gay, Bisexual, Transgender, Queer, Questioning, Asexual, and more
MRF	Material Recovery Facility
NHANES	National Health and Nutrition Examination Survey
NTP	National Toxicology Program
PAE	Phthalate Acid Esters
PVC	Polyvinyl Chloride
RCW	Revised Code of Washington
RI/FS	Remedial Investigation/Feasibility Study
SPWA	Safer Products for Washington
TSCA	Toxic Substances Control Act
U.S.	United States of America
WA	Washington
WAC	Washington Administrative Code

Acronym or Abbreviation	Definition
WEBS	Washington Environmental Biomonitoring Survey
WSDA	Washington State Department of Agriculture
WSR	Washington State Register
WWTP	Wastewater Treatment Plant

Chemical names

 Table 3: Acronyms for the chemicals discussed in this response to comments.

Acronym	Chemical Name
BBP	Benzyl butyl phthalate
DBP	Di-n-butyl phthalate
DEHP	Di(2-ethylhexyl) phthalate
DEP	Diethyl phthalate
DIBP	Di-isobutyl phthalate
DIDP	Di-isodecyl phthalatetion
DINP	Diisononyl phthalate

Appendix B. List of Commenters

Agencies

King County Wastewater Treatment Division

Public Health – Seattle & King County

Seattle Public Utilities - Hazardous Waste Management Program

Organizations

American Chemistry Council

BASF Corporation

Coalition for Clean Water

Discovery Clean Water Alliance

Food Northwest

Friends of Miller Peninsula State Park

Toxic-Free Future

Washington Association of Sewer & Water Districts

Washington Refuse and Recycling Association

Washington State Potato Commission

Zero Waste Washington

Individuals

CarolLee Braithwait

Wendy Ferrell

Appendix C. Comments Received

Please see below for comments we received in their original form.



Department of Natural Resources and Parks Wastewater Treatment Division King Street Center, KSC-NR-5501

201 South Jackson Street Seattle, WA 98104-3855

May 26, 2023

Kimberly Grieves Phthalates Action Plan Project Manager Washington State Department of Ecology c/o <u>ChemActionPlans@ecy.wa.gov</u>

RE: <u>Phthalates Action Plan Comments</u>

Dear Ms. Grieves:

Thank you for the opportunity to comment on the Washington State Department of Ecology's (Ecology) draft Phthalates Action Plan. We appreciate the work that Ecology is undertaking to address this pervasive class of chemicals, in support of human and environmental health.

King County's Wastewater Treatment Division (WTD) serves about 1.8 million people within a 424 square mile service area including most urban areas of King County and parts of Snohomish and Pierce Counties. In 2022, our three regional treatment plants and two smaller treatment plants treated a combined daily average of 178 million gallons of wastewater, and together produced 123,500 wet tons of biosolids that were land applied to forests and farms in Washington as a beneficial soil amendment.

As the largest wastewater treatment utility in the state, we support regulations and programs that result in fewer chemicals in the wastewater stream as a positive step. Wastewater should not be viewed a "source" of these chemicals, instead it receives the chemicals that are produced or used in our homes and businesses. Wastewater treatment is designed to remove pathogens, but not chemicals. Therefore, source control is the most efficient and effective action mechanism to control exposure for humans and the environment. We appreciate the opportunity to work with Ecology and others to prevent and mitigate impacts to water quality and public health.

Approximately 8.2 million acres, or 18 percent of the land area of Washington state, is cropland. It is important to note that less than one-quarter of one percent of that cropland acreage receives biosolids land application.¹ This is an extremely small amount of acreage. We assume that Ecology's intent in making these recommendations is to assess human exposure pathways from contaminated agricultural soil. We appreciate and share this concern, however focusing solely on cropland that has been land applied with biosolids will only minimally and

¹ Washington — National Biosolids Data Project

Kimberly Grieves May 26, 2023 Page 2

not fully address the question of human exposure pathways from contaminated agricultural soil. We urge Ecology to not miss the bigger picture in answering this important question.

Research indicates that the presence of phthalates in agricultural soil comes from diverse sources such as chemical fertilizer and additives, agricultural activities such as plastic film mulching and other plastic waste, application of biosolids or other organic soil amendments to cropland, and airborne emissions from open burning in uncertified facilities or industrial emissions.² With the myriad of potential sources of phthalates to agricultural land, it is possible and perhaps likely that all agricultural land in Washington state is contaminated with phthalates to some degree.

Research has also shown that chemical fertilizers have higher phthalate content than organic fertilizers (such as biosolids and compost). A quote from a December 2022 literature review is as follows: "Organic fertilizers are often produced from organic wastes via compost, which makes them less phthalate polluted, while chemical fertilizers may involve plastic in their production and final presentation (packaging)."³ Again, to focus solely on biosolids would not effectively address the question of human exposure pathways from contaminated agricultural soil and would miss the bigger picture in answering this important question.

Given this information, we offer the following suggested modifications to the current biosolidsrelated recommendations listed in the draft Phthalates Action Plan. Our intent is aligned with Ecology's, to understand and address sources of phthalates and potential impacts on human and environmental health. We believe that these modifications would further these goals and strengthen the Phthalates Action Plan overall.

² <u>Groundwater contamination pathways of phthalates and bisphenol A: origin, characteristics, transport, and fate</u> <u>– A review - ScienceDirect</u>, see Section 4.3 "Contaminated soil"

³ <u>Groundwater contamination pathways of phthalates and bisphenol A: origin, characteristics, transport, and fate – A review - ScienceDirect, see Section 4.3.1 "Chemical products"</u>

Kimberly Grieves May 26, 2023 Page 3

Suggested modifications to	Biosolids-related	recommendations:
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Торіс	Number	Existing	Suggested modification
		recommendation in	
		Phthalates Action Plan	
Biosolids	Recommendation #1	Ecology should evaluate the transport and breakdown of upstream sources of phthalates in Washington's WWTP influent, effluent, sludge, and biosolids.	None. Agree with recommendation.
Biosolids	Recommendation #2	Ecology should evaluate the transfer potential of phthalates from biosolids to soil and groundwater.	 Create a new topic "Agriculture" for this instead of Biosolids. Modify as follows: "Ecology should evaluate the transfer potential of phthalates from <u>soil</u> <u>amendments</u> to soil and groundwater."
Biosolids	Recommendation #3	Ecology should evaluate plant update of crops and fodder grown in or on biosolids-amended soils and fields in Washington state.	 Create a new topic "Agriculture" for this instead of Biosolids. Modify as follows: "Ecology should evaluate plant uptake of crops and fodder grown <u>in or on</u> <u>contaminated soil</u> in Washington state."
Biosolids	Recommendation #4	Ecology should evaluate the fate of phthalates in composted biosolids in Washington state.	 Merge this recommendation with "Compost" Recommendation #2. Modify as follows: "Ecology should develop and implement a plan to test the levels of phthalates in finished compost that comes from <u>various</u> <u>feedstocks, including yard and</u> <u>food waste, biosolids, and</u> <u>manure."</u>
Agriculture (suggested new topic)	Suggested new recommendation		Add new recommendation stating: <u>"Ecology should develop and</u> <u>implement a plan to test the levels</u> <u>of phthalates in various inputs to</u> <u>agricultural land outside of</u> <u>biosolids and compost, including</u> <u>commercial fertilizers and</u> <u>pesticides."</u>

Kimberly Grieves May 26, 2023 Page 4

It is important that Ecology continue to lead on this issue, in the interest of consistency across our state, and avoiding an overly narrow focus on just wastewater agencies and our ratepayers. As passive receivers of contaminants such as phthalates, we want to do our part to address the problem, and we believe others who have a responsibility should do so as well.

Finally, we offer our continued support. We understand that Ecology will need funding and staff resources to implement these recommendations. Please let us know if we can provide letters of support and biosolids samples to assist with this important work. We appreciate the opportunity to offer comments on the draft Phthalates Action Plan. This vital work will help with source control and preventing and minimizing impacts to human and environmental health.

If you have any questions regarding WTD's comments, please contact WTD's Resource Recovery Policy & Research Supervisor Erika Kinno at erika.kinno@kingcounty.gov or 206-477-0942.

Sincerely,

DocuSigned by: 6F7ECDE169354C2...

Kamuron Gurol, Division Director Wastewater Treatment Division

Public Health - Seattle & King County

Kimberly, Thank you again for the opportunity to comments and for your flexibility with our delay! Attached is our comment letter. Please do not hesitate to contact us with any questions or clarification. We're very excited to see this work moving forward and happy to provide support when we are able! Best wishes, Shirlee Tan, PhD Senior Toxicologist Environmental Health Services Public Health – Seattle & King County Shirlee.tan@kingcounty.gov 206-477-7978

Environmental Health Services Division

401 Fifth Avenue, Suite 1100 Seattle, WA 98104-1818 **206-263-9566** Fax 206-296-0189 TTY Relay: 711 www.kingcounty.gov/health



June 14, 2023

Kimberly Grieves Phthalates Action Plan Project Manager Washington State Department of Ecology c/o ChemActionPlans@ecy.wa.gov RE: Phthalates Action Plan Comments

Dear Ms. Grieves:

Public Health – Seattle & King County (PHSKC) would like to thank the Washington State Department of Ecology (Ecology) and the Washington State Department of Health (Health) for the opportunity to comment on the State's Phthalate Action Plan (AP). We applaud Ecology and Health for their work to address human and environmental exposures to this large and ubiquitous class of chemicals. PHSKC is pleased to see the evolution of more specific draft actions since the previous version described to the advisory committee. Below are overarching comments on the Draft AP followed by a table with specific comments relevant to the relevant chapters and recommendations.

It is unclear how Ecology will prioritize the large number of recommendations. Because there are so many recommendations across multiple areas of concern, it would be helpful for Ecology to provide an indication of how feasibly and impactful each recommendation is, and a schedule for implementation in the overall table that indicates prioritization based on feasibility and impact.

Safer Products for Washington (SPWA) capacity limitations are a concern. Ecology is recommending that SPWA "consider" identifying additional consumer products as sources or uses of phthalates including non-fragrance personal care products, cleaning products, textiles and apparel, packaging (food and non-food), automotive products, building materials, medical devices and products, other food contact articles, and vinyl products. Many of these categories could be quickly incorporated into the actions for SPWA round 2 but will require staff time to conduct the background research and identify safer alternatives for each product category. SPWA is already overburdened. Actions not included in round 2 will not be regulated for over 10 years. PHSKC is concerned that the large number of categories being pushed to SPWA will lead to a bottleneck and delays in addressing many categories that need swift action. We recommend that Ecology prioritize product categories and identify staff that can continue to conduct work to identify safer alternatives for phthalates in priority categories so that SPWA can maintain a rapid pace and actions on phthalates are not delayed to future rounds of SPWA. It would be helpful for stakeholders to understand the timeline for the phthalates product categories that have been referred to SPWA and for Ecology to outline how SPWA will manage these requests with respect to everything else proposed for round 2, include if additional staffing/funding be provided for the phthalates work within SPWA. We recommend that Ecology identify a way to ensure staffing and resources are provided to SPWA for all phthalate products recommended for action through this legislation, especially those that are most feasible and impactful.

Ecology should include more discussion of cumulative impacts and actions to address them. National discussion is occurring on cumulative risk assessment and how best to act on potential impacts of

multiple phthalates while also considering additional chemicals and stressors that make individuals more sensitive or vulnerable to phthalate exposures. PHSKC recommends that Ecology further explore how the AP can account for cumulative impacts, including:

- The discussion on cumulative impacts of multiple phthalates and co-exposure with other chemicals in appendix B is useful and should be highlighted as a standalone section upfront in the document, and relevant information pulled into the proposed recommendations, particularly in the environmental justice sections.
- Ecology should document and track possible cumulative exposures/impacts described to date and work to identify where similar trends or issues exist within WA (both across the class of phthalates, for other chemicals, e.g., other endocrine disruptors, that Ecology is regulating (within our outside SPWA) and for other stressors).
- Ecology should propose actions to reduce cumulative risks in the AP.
- Ecology Should consider information that could be applicable to the AP that was raised, discussed, or submitted by comment letters submitted during EPA's Science Advisory Committee on Chemicals meeting on EPA's Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act and EPA's Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substances Control Act.
- Ecology should explore where overlapping uses of phthalates from different product categories may lead to large exposures to sensitive and vulnerable populations (e.g., children and pregnant people in neighborhoods, occupations, cultural groups), who incur greater exposures or impacts from phthalates. For example, as described in our previous comment letter, there are currently eight phthalates that are approved for food contact use by FDA, however a number of these are banned or restricted by the Consumer Products Safety Commission or the WA State Children's Safe Products Act. PHSKC recommends that as part of the AP, Ecology examine overlapping uses and differences in restrictions across routes of exposure that suggest the need for actions that reduce cumulative exposure risks for sensitive populations like children. For example, Ecology may consider a proposal in the AP that would ban or restrict the use of phthalates that are already banned or restricted in children's products. This would limit exposures to phthalates that are known to be harmful to children.

Ecology should create consistency among equity actions across recommendations. PHSKC appreciates that each recommendation includes a discussion about environmental justice and equity considerations, and in many cases, actions to prioritize them. We recommend that Ecology review each recommendation to ensure that all include priority actions to address environmental justice and equity concerns. Ecology should include a section on secondhand products in the consumer products section and a recommendation on how to address reducing exposures from secondhand products.

Ecology should better coordinate information provided about phthalates in Washington State. It would be helpful for Ecology to include contextual information about phthalates in Washington State either before or within the sections that outline the recommended actions. The recommended action sections are at times difficult to understand without the context about what is known or happening in Washington State. Much of this information is included in the appendices but requires the reader to flip between the general background, the recommendations, and the appendices to get the full picture. We recommend that each recommended action include: 1) the currently known status in WA, 2) what gaps exist, 3) what action is proposed, 4) why the action is needed, and 5) how it will be conducted.

Thank you again for the opportunity to comment on these important recommendations. Included below is a table with specific comments for the relevant sections and recommendations. Do not hesitate to reach out with questions.

Respectfully,

Shirles Tan

Shirlee Tan Phthalates Action Plan Advisory Committee Member Senior Toxicologist Environmental Health Services Public Health – Seattle & King County <u>Shirlee.tan@kingcounty.gov</u> 206-477-7978

Section	Comment	
Introduction and background sections		
Executive Summary and Introduction	 General readers will not know what this action plan is and how it differs from the Chemical Action Plan. In the first use of the term "Action Plan", please define what it is and how it differs from a Chemical Action Plan. Describe what an action plan is generally and why this was the approach here. 	
Executive Summary (Development)	 This document states that the final Phthalates AP was published in December 2023. Change to "anticipates publication in Dec 2023" 	
Phthalates Background information	 More information on the state of WA would be helpful for local jurisdictions to help us understand where we should focus and how we can help with actions in the AP Background information vs. information in the appendices should be more clearly organized and any information on what is known for Washington should be included sooner (either in background or in the information for each recommendation). 	
Background: Human exposures and health impacts	 The health section only briefly touches on the known impacts of phthalates, but then goes into more detail in the appendices. This is confusing and requires the reader to move around in the document to look for background information. It would be helpful to have related information on health, environment, etc., organized in one place. 	
Background: Populations and health impacts of concern	Please mention other racial groups that are disproportionately exposed to phthalates in personal care products.	
	Update draft with information about the cosmetics law and how this can now address phthalates	
	Provide citations for the statement on boys of color being potentially more exposed and impacted.	
Health and Environment sections	 It would be helpful for Ecology to provide a more organized overview of the known and suspected health impacts, populations of concern, and then any specifics known or suspected in WA. This could be organized in a table that would help highlight what is known relative to exposures of concern, impacts of concern, and populations of concern 	

PHSKC comments and recommendations

	Bring information from appendices to tie in with recommendations
	on what's known in the state of WA.
Regulations	A table of regulations would be helpful highlighting WA, national, other states. EU. Please Add table of relevant regulations
Products and materials	
sections	
	Include a discussion/recommendation on fragrance products that are not personal care products (e.g., air fresheners). Add to products section or justify why not included at this time.
Consumer products	
Background	In the discussion section, REACH, the State of Washington, and other testing of products is mentioned: Ecology should include here any information on regulatory or health action levels that indicate that exposures are problematic or not. It is hard for the reader to understand what 100ppm vs 100,000 ppm means, for example. It is only at the end that CPSA and its reporting limits are mentioned. Please define REACH and CPSA.
	For CSPA are there any conclusions for WA based on what manufacturers have been reporting? Is the reporting in children's products now less common or have manufacturers shifted to other phthalates that are not required to be reported?
Recommendation #1	 Page 34 – the statement about SPWA actions is not clear. It reads that they identified fragrances as a priority in the following products: personal care, beauty, and vinyl flooring. Please reword this for clarity. Add to the bulleted list – fragrance products such as air fresheners (exposures include from new clothing, in hotel rooms, in taxis and other car services, classrooms, etc.), considerations should be discussed especially for children, asthmatics, and workers that may be exposed all day (e.g., taxi drivers, hotel cleaning staff that spray them all day while cleaning hotels rooms).
Recommendation #2	 This is a good recommendation. The implementation should be more clearly laid out 1) how should the program be set up, 2) what is required, 3) how will products be prioritized?
Food Contact Articles	
Recommendation #1	 It is unfortunate that this is a recommendation to promote voluntary change to safer alternatives. Instead, it would be better if Ecology moved to require the move to safer alternatives by banning the most problematic food packaging items with phthalates. It would be helpful on this recommendation to understand what kind of manufacturers we have in WA and where the biggest impact would be – in this recommendation are you targeting food processing manufacturers, food packaging groups, or food packing production manufacturers? Describe where most of our processed food is coming from in WA?

	 The equity focus here is great, but please also include a discussion about children as a sensitive exposure group that should be prioritized, particularly when they are part of a vulnerable population.
Recommendation #2	 While this could fit under the activities of SPWA, the program is already very busy. Prioritize this exposure and identify ways expedite this work. SPWA is already on round 2 so adding this to their focus push action out for 5-10+ years. Additional resources should be requested - using PFAS as an example, the food packaging work conducted was not straightforward and takes time and resources on its own.
Daycares	
Background	 Check terminology that is preferred by state (day care vs child care), both are used here but it's not clear what the difference is. Page 43-44, add to the list of why kids are a sensitive population of concern that: because of their small size relative to body proportions, they have a large surface area and a much higher metabolism than adults, which also impacts exposure levels and metabolism of chemical exposures. In the daycare/childcare section discuss the various kinds of day cares that range from neighborhood family care to licensed facilities, and who is attending each of these facilities in WA. Neighborcare facilities are run by families in their own homes, likely leading to very different exposures to phthalates based on the kind/type of facility. Page 44 – define ECE. Check full document for acronyms that have not been spelled out or defined. Define CSPA. CPSC used earlier but defined here. Define CPSIA.
Recommendation #1	 I his is a good recommendation, additional ideas for inclusion: Projects focused on facility maintenance and environmental health are also occurring in local programs and could serve as partners to the state to incorporate this work. Justification makes it sound like Ecology's requirement for restriction of phthalates in vinyl flooring is already happening. More information should be provided about when this starts, how long it will take, etc. To prioritize facilities with the greatest needs, I would include small family friendly, neighborhood care facilities that are either unlicensed or licensed, especially in low income neighborhoods. These are likely the ones with the fewest resources and in the poorest facilities, often resident's homes.
Recommendation #2	 Consider addition the development of a co-op purchasing program for childcares that makes selecting phthalate free cleaning and other materials easy and less expensive. Providing education and information is more effective with assistance in providing safer products. Ecology should commit to finding funding that can help. It would be helpful here to

Health Care Background Recommendation #1	 understand what safer products exist and if swapping will be an prohibitive cost for facilities. Ecology should make all efforts to reach the facilities and communities most impacted and this would include the unlicensed, family neighborhood care. Clarify how the regulatory authority would be used here. Under Environmental Justice – translations "will" be required, not "may" be required. Discuss what is known about alternatives in DEHP free products. Again, this is an action that is ready to go. Pushing this action to
	SPWA will delay what can be done until the 3 rd round of SPWA at best, meaning another 5-10 years before it's addressed. This category should be addressed as soon as possible.
Recommendation #2	 Include patients in outreach when appropriate so they can advocate when they prefer phthalate free items.
Recommendation #3 and #4	 Ecology/DOH should target specific outreach to women, particularly of reproductive age, to raise awareness of this issue and allow them to understand approaches to reduce exposures.
Building Materials	
Background	 Include discussion and consideration of PVC decking in recommendations.
Recommendation #1	No comment. Good recommendation.
Recommendation #2	 Add county owned buildings to state owned buildings to ensure that public housing is included by the housing authorities that are managed by cities/counties.
Preferred purchasing	
Background	 No comments – PHSKC supports these recommendations. Please include in recommendations a statement that requires providing purchasing criteria to local governments for possible adoption.
Biosolids	 See King County Department of Natural Resources Division comments
Recommendation #1	 PHSKC supports recommendation. Please include compost related products (e.g., hydroseed matrix) to understand phthalates content.
Recommendation #1	 Discuss and include a recommendation focused on occupational and residential exposures from the recycling process itself and phthalates that are released into the environment: <u>The potential</u> for a plastic recycling facility to release microplastic pollution and possible filtration remediation effectiveness - ScienceDirect (this likely ties into the equity section as well).
Recommendation #2	 Rather than use state resources on a voluntary reporting and labeling protocol, Ecology/DOH staff time would be better spent working on establishing the information needed to ban packaging that has phthalates.

#2	voluntary testing and what those results look like, or what to expect from other testing that has been done elsewhere. Could jurisdictions that are
	other testing that has been done elsewhere. Could jurisdictions that are
	5
	doing voluntary testing be approached for a study with Ecology given the
	lack of funding? Same for gases? Include a recommendation to seek
	funding from/with air agencies in the state to do this work?
Drinking Water	
Background	PHSKC supports these recommendations
Aquatics: surface water,	
sediment, biota	
Background	Note which 6 phthalates have been monitored in Puget Sound
	sediments by Ecology since 1989 and whether trends in levels
	mirrors shifts seen in human biomonitoring from DEHP to DINP for
	example.
	 TSCA systematic review – TSCA tends to focus only on the
	data/exposures within their regulatory purview. Ecology should
	note whether this information referred to here includes non-TSCA
	literature/exposures/impacts (e.g., from FIFRA or other regulations
	like cleaning products and personal care product contributions to
	environmental concentrations).
	 Include/discuss data on phthalates in sediment/surface water/fish
	tissue from RI/FS studies from cleanup sites in WA.
Recommendation #1	Bullet #2: regarding, "Testing species and tissues that are most likely to be
	eaten by overburdened communities and sensitive populations." Please
	Add "or contribute to traditional practices or livelihood."
Outdoor air	No comments
3-year review	PHSKC supports evaluation and review at the three-year mark to ensure
	that proposed recommendations are on track and to determine what needs
	to change to make sure the actions move forward.
Appendix B: Health	Thank you for adding this information. It is very useful for context and
Chapter	understanding how to prioritize the proposed recommendations.
	Recommendations for this chapter include:
	• In the intro add a few sentenced about newer data on female
	reproduction, neurodevelopment, obesity and diabetes.
	 Add information from EPA proposed cumulative risk evaluation by their Science Advisory Constitutes on Changingle (CACC)
	their Science Advisory Committee on Chemicals (SACC).
	Dev lox - change pregnant women to pregnant people
	 Female reproductive toxicity – this section needs more information.
	Add Maffini paper and include Jodi Flaws papers.
	 Male reproductive toxicity – add any new relevant into from EPA
	proposed cumulative assessment of prinalates
	 Cumulative effects section – create as a standalone section as a sharter and undete with the recent review by SACC
	Chapter and update with the recent review by SACC.
numan exposure	Biomomitoring –
	Ine webs data seem like a significant piece to follow up on. Where are these elevated experime from 2 likely de elevated
	are these elevated exposures coming from? Include a
Human exposure	 Add Maffini paper and include Jodi Flaws papers. Male reproductive toxicity – add any new relevant info from EPA proposed cumulative assessment of phthalates Cumulative effects section – create as a standalone section as a chapter and update with the recent review by SACC. Biomonitoring – The WEBS data seem like a significant piece to follow up on Where

	 Mention the ECHO study and data from that on pregnant people's exposures and other phthalates of concern not included in NHANES. 	
	Occupational exposures –	
	 add workers in recycling facilities and transfer stations. 	
	Health equity considerations –	
	 Include discussion of exposures from second hand products. 	
	 Include a recommendation in earlier section on consumer products about secondhand exposures and actions to protect/remove toxic products from that market. 	
Appendix C	This appendix should be improved so that it contains more information and	
Phthalates in the	matches the scope and depth of the human health appendix.	
environment		
Appendix F	 Include in the introduction a description of what costs were considered. Are these sects to the state to manage each 	
	recommendation?	
	It would be helpful for stakeholders if Ecology could include health	
	cost calculations for each recommendation to demonstrate the	
	estimated benefit of each action.	
Logistical	 Check document for typos, grammar and acronyms that have not 	
	been written out with first use (e.g., CSPA)	
	 Format document with section listed on each page so that it is 	
	easier for the reader to scroll through the document and find	
	sections of interest.	

Seattle Public Utilities - Hazardous Waste Management Program

Ms. Grieves, Please find attached a comment letter on the Phthalates Action Plan from the Hazardous Waste Management Plan. I believe the comment period ended yesterday. Are you still able to accept this letter? Also, can you please confirm that you received this?

Thank you,

Ashley Evans



201 S. Jackson Street, Suite 5600, Seattle, WA 98104 www.kingcountyhazwastewa.gov

June 14, 2023

Kimberly Grieves Phthalates Action Plan Project Manager Washington State Department of Ecology <u>ChemActionPlans@ecy.wa.gov</u>

RE: Phthalates Action Plan Comments

Dear Ms. Grieves:

The Hazardous Waste Management Program in King County (Haz Waste Program) would like to thank the Washington State Department of Ecology (Ecology) and the Washington State Department of Health for the opportunity to comment on Phthalates Action Plan Preliminary Draft Recommendations.

The Haz Waste Program is a coalition of local governments comprised of King County, the City of Seattle, 37 other cities, and two tribes, all located in King County, Washington. Together the Program represents more than 2.3 million Washington state residents. The Haz Waste Program works to protect and enhance public health and environmental quality. We do this by reducing the threat posed by the production, use, storage, and disposal of hazardous materials, many of which are found in common household products and small businesses.

We support Ecology's work and recommendation in the Phthalates Action Plan. We particularly appreciate the phthalate background information and environmental justice emphasis, which will be a useful resource in our work. We do have a few comments, which we think would strengthen the action plan.

- Stronger recommendations to limit exposure to consumer products: The Haz Waste Program appreciates the recommendation that Safer Products for Washington (SPWA) consider and regulate additional consumer products as sources or uses of phthalates. As part of that work, we would like Ecology to examine the phthalates that are already banned in some products in Washington state and consider extending those bans to other products. The Public Health Seattle & King County letter, dated November 17, 2022, (enclosed) offers an example of certain phthalates being banned in children's products, but not for use in food contact.
- **Recommendations to limit exposure to materials in the second-hand market:** We are particularly concerned with the second-hand and reuse market. The Haz Waste Program requests that Ecology recommend ways to limit exposure to residents that receive or purchase

Kimberly Grieves June 14, 2023 Page 2

donated second-hand materials. Many overburdened populations purchase the least expensive materials they can afford or receive donated materials and are more likely to be exposed to phthalates through greater exposure to vinyl or plastic-based products. Populations included in the recommendations should include low income, immigrant and refugee renters, and homeowners.

- Recommend engaging with the U.S. Environmental Protection Agency (EPA) on the Toxic Substances Control Act (TSCA) evaluation of phthalates: The action plan mentions the fact that seven phthalates (DBP, BBP, DEHP, DIBP, DCHP, DIDP, and DINP) are currently undergoing TSCA risk evaluations by EPA, which will lead to federal regulations of those phthalates. The action plan does not recommend that Ecology engage with EPA on that process. TSCA regulations will preempt state regulations, so it is important to get the most protective regulations possible at the federal level. We ask that Ecology include a recommendation that it engage with TSCA on this regulatory process. We also recommend that Ecology continue to pursue Washington state regulations of phthalates simultaneously.
- Recommend increased discussion of cumulative impacts and actions to address them: National discussion is occurring on cumulative risk assessment and how best to act on potential impacts of multiple phthalates while also considering additional chemicals and stressors that make individuals more sensitive or vulnerable to phthalate exposures. We recommend that Ecology further explore how the action plan can account for cumulative impacts. Ecology should document and track the national discussion on possible cumulative exposures/impacts and work to identify similar trends within Washington state and propose actions to reduce those cumulative risks.

Thank you for the opportunity to comment on the draft Phthalates Action Plan. If you have any questions, please contact Ashley Evans at <u>ashley.evans@kingcounty.gov</u>.

Sincerely,

DocuSigned by:

Mayflia linhart D5213392EB3345B... Maythia Airhart

Hazardous Waste Management Program Director 206-263-9591 | mairhart@kingcounty.gov

Enclosure



Cheryl Niemi Department of Ecology Hazardous Waste & Toxics Reduction Program 360-338-2913 ChemActionPlans@ecy.wa.gov

November 17, 2022

Dear Ms. Niemi,

Public Health – Seattle & King County (PHSKC) thanks the WA State Department of Ecology (Ecology) and the WA State Department of Health (Health) for the opportunity to comment on the Phthalates Chemical Action Plan (CAP) Preliminary Draft Recommendations. As the most populous county in the state of WA, PHSKC represents a diversity of concerns around the use, release, exposure and elimination of phthalates. While we appreciate the extension to the comment period that was granted to interested parties and CAP advisory members, a longer timeline would have allowed for additional input from other King County departments. Ecology, Health and King County have a common goal of reducing harmful exposures to chemicals like phthalates, and PHSKC welcomes opportunities to participate in and support this important work in collaboration with state partners. Below we provide general comments as well as specific comments on the draft recommendations outlined by Ecology and Health.

General comments:

1) An abbreviated CAP will not provide a reference from which other agencies and organizations, local jurisdictions, community groups, individuals and policy makers can take action. WAC 173-333-400 defines a CAP as "a plan that identifies, characterizes and evaluates uses and releases of a specific PBT, a group of PBTs or metals of concern and recommends actions to protect human health or the environment." As defined, previous CAPs have described what is known about a chemical or chemical class in WA State and serves as point in time status of that chemical/chemical class in the state. It then highlights where there are concerns or knowledge gaps, and lays out recommendations for moving forward to reduce exposures to harmful chemicals in the environment and humans in WA State. Recommendations normally include both near and long term actions, including policy recommendations. Previous CAP recommendations spanned a wide variety of readiness, including immediately actionable to those where regulatory mechanisms would need to be developed to achieve them. For this phthalates CAP, Ecology is conducting an abbreviated process and will not be providing a robust "state of the state" for Phthalates in WA. As justification, Ecology has explained that they are under a limited timeline that is tied to grant funding. PHSKC is not clear on the difference between a CAP and what Ecology is calling an AP under the PBT rule and how funding for this works. While the current process seems to be tied to grant funding, Ecology has not explained why this effort is different from other CAP processes regarding funding and timeline (i.e., why Ecology chose to pursue a different approach for this CAP). Even with the current timeline, the



advisory group was convened for the first time in February 2022 and the deadline for a final plan is December 2023. With multiple staff working on this CAP we feel that there was sufficient time to develop a robust document. At present we have been informed that this document will contain limited background information centered only around the recommendations Ecology is providing, with little background information on how those recommendations were determined as priorities for the state. It is difficult to understand how robust recommendations that protect health and the environment can be devised without a detailed knowledge of the current status of phthalate use and release in the state.

PHSKC recommends that Ecology explore ways to extend the existing timeline so that a full CAP can be produced that includes the current state of phthalates in WA and action-oriented recommendations that are based the best available summary of phthalates use/release in WA state. If the timeline is not flexible, we recommend that Ecology expand the current effort to produce a CAP document that clearly lays out the state of phthalates in WA state. Such a document would better serve residents and local organizations than weak recommendations provided with no justification or background.

2) The preliminary draft recommendations reflect a rushed process and are not centered on prioritized actions.

All previous CAP documents produced by Ecology and Health continue to serve as important resources for everyone in WA state. They provide a historical reference point on any given chemical or chemical class, and have led to policy or other actions, even many years later. They also create policy goals towards which groups within the state can aim. The rushed nature of this CAP is reflected in the preliminary draft recommendations, which do not lay out what is known, where there are gaps, or justify the recommendations. The recommendations provided are weak, with little action, mostly focused on conducting more research rather than making the case for where and how actions are needed. Few recommendations currently proposed act to "protect human health or the environment."

PHSKC recommends that Ecology develop more robust action-oriented short and long term recommendations, including legislation or other policy that would reduce the exposures to harmful phthalates in WA state. Many actions could be proposed based on information that currently exists, and while more research is useful, concurrent short and long term actions should also be included in the recommendations provided.

3) The process to develop the preliminary draft recommendations did not effectively engage advisory members and the public.

Throughout the CAP development process, Ecology limited the time and information provided to advisory members and the public. Advisory meetings were conducted with no background materials provided ahead of time. As advisory members, it was difficult to provide information on the spot without any information on the status of what is known in WA state, nor were we



able to come to the meeting prepared to share relevant information that we could have gathered from our organizational partners. The process as designed was time intensive yet ineffective at gathering the in-depth information needed. Furthermore, it is difficult to determine how comments or suggestions by advisory members were incorporated in the preliminary draft recommendations - the broad preliminary draft recommendations provided only in slide presentations are not detailed, and the justification behind them is not provided. In other words, it's not clear if the advisory members suggestions were captured and considered in any documented or systematic way.

PHSKC recommends that Ecology revise their approach and re-focus current efforts on describing the state of phthalates in WA state so that actions can be developed by Ecology and Health and other interested parties based on clear and thorough information about phthalate production, use, release and exposure in WA. Furthermore, we recommend that Ecology leadership solicit feedback from the advisory committee members on how the current process needs to be improved for future CAPs.

4) The process to include environmental justice, cumulative and aggregate exposures considerations is not clear.

PHSKC is not sure how Ecology plans to address environmental exposures to mixtures and other stressors, specifically for communities that are overburdened by other chemical exposures and socioeconomic factors. We believe that Ecology has an obligation under the Heathy Environment for All (HEAL) Act of 2021 to explicitly target and reduce the disparate environmental impacts of PBTs, including phthalates, on vulnerable populations and overburdened communities. In advisory meetings, Ecology stated that there will be a "side section" that discusses this topic. We do not believe this is adequate or in the spirit of either the PBT Rule or the HEAL Act.

PHSKC recommends that Ecology ensure that environmental justice considerations are front and center in both the scope of recommendations and within each of the recommendations proposed. Ecology should develop the CAP to serve as a resource in communities experiencing injustices and disproportionate phthalate exposures to allow them to take local actions to reduce their phthalate exposure.

5) Petroleum trends and climate impacts

Because phthalates are made from petroleum products, PSHKC recommends that Ecology include a section it the CAP that discusses expected trends in the use of petroleum products and how that may impact exposures and health outcomes related to phthalates, especially in the context of climate change.

Public Health Seattle & King County

Comments on specific recommendations:

1) Environmental media and the scope of contamination:

PHSKC agrees that historical monitoring is not fully reliable, that trends in usage of certain phthalates has changed through time as well as lab methods for detection. However, environmental media sampling has been conducted for decades. To bolster that information there is information on human exposure through NHANES and studies like the NIH's ECHO research that indicate which phthalates are found in children and pregnant women, and how exposures trends have changed based on substitutions of certain compounds for others. There is a large amount of literature and monitoring within WA state that can be used now to identify possible hazards and provide interim proposed actions to reduce exposure risks. While continued research by Ecology is good, policy actions based on existing information should proceed as well. We recommend that the CAP include background information and findings from the 2007 EPA-sponsored Phthalates Work Group focused on source control and sediment (linked here and here).

The recommendations for air monitoring/action are very vague and propose potential sample collection and monitoring in WA State. Ecology does not distinguish how this would be done for indoor versus outdoor monitoring. There is information in the literature from other locations on this issue that should be tapped, including dust swipe studies in different types of facilities/businesses. Ecology should engage air agencies in WA state and determine actions as part of the CAP background rather than include that engagement as a recommended action. Furthermore, indoor air recommendations are possible at this time based on existing literature.

2) Biosolids, recycling, composting, and landfill recommendations:

For biosolids, recycling, composting and landfills, a large number of studies have been conducted and are reported in the literature. Biomonitoring has indicated which phthalates are detected in human blood and urine, and toxicity data exists for most compounds, including some mixtures information. Without being provided a summary of this literature by Ecology, it is difficult for the advisory committee to provide recommendations on priorities and how to proceed. Ecology should be providing a basis and justification for all CAP recommendations, and that should start with a status of what is known. The recommendations provided in these sections are very vague, and mainly propose more research and monitoring. They are not oriented toward identifying sources of phthalates that end up in our waste streams, nor focused on reducing any exposures that may result. While more monitoring and research are needed, PHSKC recommends that Ecology develop robust actions in the CAP along with the recommended research. Ecology could propose actions that help the state prioritize where actions are most needed through, for example, recommending development of regulatory or other mechanisms for required monitoring and reporting of biosolids, leachate, dust swipes, compost, etc. by businesses and utilities. **Environmental Health Services Division**

401 Fifth Avenue, Suite 1100 Seattle, WA 98104-1818 **206-263-9566** Fax 206-296-0189 TTY Relay: 711 www.kingcounty.gov/health

Public Health Seattle & King County

3) Consumer products

The phthalates CAP relies on Safer Products for WA to assess phthalates in consumer products in WA. While Safer Products for WA is an amazing legislation that allows WA to require safer chemicals be used in products within the state, PHSKC would like to see the CAP include specific actions that will help advance more timely policy action on phthalates. Safer Products for WA includes 5 chemical classes in any given cycle, so PHSKC would like the phthalates CAP to identify opportunities to expand and accelerate removal of known hazardous phthalate exposures in WA state and to accelerate hazard assessments for phthalates where information is less available. The CAP should lay out a plan to ensure that the work on phthalates proceeds at a pace that matches the health and environmental concerns (for example: Engle et al, 2021; Trasande et al, 2022), including strategies in addition to Safer Products for WA. Current recommendations for this category are limited and not proactive (e.g., voluntary transparency by industry and actions that may happen "if funding allows"). There are many actions that could be proposed and for which funding could be requested through the CAP. For example, there are currently 8 phthalates that are approved for food contact use by FDA (request for information is currently open in the Federal Register), however a number of these are banned or restricted by the Consumer Products Safety Commission or the WA State Children's Safe Products Act. PHSKC recommends that as part of the CAP, Ecology examine overlapping uses and differences in restrictions across routes of exposure that suggest the need for actions that to reduce cumulative exposure risks for sensitive populations like children. For example, banning or restricting the use of phthalates that are already banned or restricted in childrens' products may be a reasonable action to propose in the CAP. This would limit exposures to phthalates that are known to be harmful to children from multiple routes. Similar proposed actions could be developed in the CAP for phthalates that have multiple exposure routes of concern to sensitive and vulnerable populations.

4) Phthalates in Health Care

Ecology and Health proposed more research in the health care arena, which seems warranted. However, it is not clear what the timeline for this recommended research proposed by Ecology would be, how it will be shared with the public if not included as a "state of phthalates in WA" in the CAP, and what the proposed use of that information could be. Furthermore, non-medical products were flagged as an exposure concern (e.g., menstrual products, breast pump accessories, diapers, and incontinence products) with no actions proposed for WA, only a mention of legislation in NY state and a statement that additional product testing "may" be warranted. Again, PHSKC would like to see more action oriented recommendations included in the CAP. As in the consumer products section, exposures to women of child bearing age and children arean important focus for action with these products, especially in the context of phthalates already banned in children's products and routes of exposure not included for the phthalates in that ban.

5) Building Materials

The section on building materials does not discuss exposure concerns and estimate of health burdens on residents that receive or purchase donated or second-hand materials. PHSKC would like to see recommendations expanded beyond affordable housing projects. Many



overburdened populations purchase the cheapest materials they can afford or receive donated materials, and are more likely to be exposed to phthalates through greater exposure to vinyl or plastic-based products. Populations included in the recommendations should include low income, immigrant and refugee renters and home owners.

6) Preferred purchasing

PSHKC supports the recommendation by Ecology to work with state agencies to track purchasing metrics and incorporate guidance and amended contracts to reduce the number of phthalate purchased by state agencies. PHSKC encourages Ecology to use the metrics information to develop materials that help other agencies and businesses across the state to also reduce phthalate exposures in their purchasing practices. One action that could be recommended is for Ecology to facilitate purchasing cooperatives for different sectors state-wide that reduce costs through subsidies or large volume purchasing when they choose safer products.

7) Food contact

The recommendations around phthalates in food contact materials, while good activities for the state to engage on, should be more developed into actions. As mentioned above in the consumer product section, the overlap of phthalates that are restricted, banned or of concern in children's products should at the very least be prioritized for removal from food contact materials as well. Ecology should be recommending these types of actions in the CAP at this time to protect sensitive and vulnerable groups.

8) Drinking water

Ecology should explore whether use of PVC piping and other new plastics based tubing in housing contributes phthalates into drinking water at the tap, similar to how we approach understanding the relationship between older plumbing and lead exposure in the home. The CAP should also discuss what may be known about phthalates in bottled water.

9) Daycare and early childcare facilities

While the recommendation to provide outreach materials to day care and early learning center providers is helpful in raising awareness, relying on this as the main strategy proposed to reduced phthalate exposures to children in child care settings transfers the burden of reducing exposures to the child care providers themselves. Ecology and Health should work with the Department of Children, Youth and Families (DCYF) to develop other mechanisms that remove phthalates from products, facilitate exchange of products known to be high in phthalates for safer products, and consider holistically the various exposure paths that young children, low income children, and children of color experience.

10) Items missing from the recommendations:

a. Occupational Exposures

Occupational exposures were also not addressed in the CAP, and PHSKC would like to see some information from Ecology included for construction workers and other professions that may have higher exposures to phthalates through their work, including



a discussion of gaps in protections. "Take home" exposures, or chemical residues that can be transferred from the place of work to home via clothes, shoes or other means, should also be addressed (especially for children), for occupations where phthalate exposures can be high (e.g., construction, manufacturing).

b. Pathways analysis

PHSKC recommends that a comprehensive assessment of the major issues across different media and exposure routes be conducted to ensure staff working on specific issues are aware of potentially coninciding issues in other areas. The final plan should be able to bring together where pathways of exposure intersect as well as evaluate the major issues across areas so that the priorities for the state are clear and efficiencies are identified for addressing them.

Thank you again for the opportunity to comment. Do not hesitate to reach out to me with any questions.

Respectfully,

Shirles Tan

Shirlee Tan, PhD Senior Toxicologist Environmental Health Services Public Health – Seattle & King County Shirlee.tan@kingcounty.gov

American Chemistry Council

Please see the attached comments from the American Chemistry Council.



TO: Washington State Department of Ecology

RE: Washington State Draft Phthalates Action Plan

The Washington State Department of Ecology (Ecology) is soliciting comments on its Draft Phthalates Action Plan (May 2023). The American Chemistry Council (ACC) High Phthalates Panel¹ is pleased to provide comments relating to the ongoing Washington State Phthalates Action Plan process. Below we set forth our comments specific to 1) Ecology's decision to address orthophthalates as a chemical class; 2) phthalates in the environment; 3) phthalates in industry and manufacturing, and 4) phthalates in products.

General Concerns Related to Ecology's Failure to Address the Significant Differences in the Physical, Chemical and Biological Properties of Phthalates

As we have stated in previous comments on the Action Plan process, it is not clear what the main concern is for phthalates. None of the five Advisory Committee meetings provided any specific evidence that phthalates are a human or environmental health concern in food, drinking water, consumer articles, aquatic/terrestrial organisms or benthic sediments.

Virtually all the questions being asked have been answered in extensive, publicly available regulatory hazard/exposure/risk evaluations by regulatory agencies around the world. For instance, a multi-year evaluation of the human and environmental risk associated with 28 phthalates was completed in late 2020 by Canada. All but one phthalate were confirmed <u>not</u> to "*pose a risk to health or the environment at current levels of exposure.*"²

The US EPA has commenced thorough risk evaluations of the seven most consumed phthalates in the United States. The risk evaluations will encompass all possible routes of human exposure (occupational, consumer and fenceline communities) and environmental fate and effects from waste management and discharge. The evaluations will also cover all conditions of use, including manufacturing, imports, transportation, processing, conversion to final articles, end-of-life disposal and recycling. The work conducted by Ecology seems duplicative of the current ongoing work at EPA.

¹The American Chemistry Council (ACC) High Phthalates Panel is comprised of companies that manufacture, compound, convert, or import specific high molecular weight phthalates. These phthalates include di-isononyl phthalate (DINP) and di-isodecyl phthalate (DIDP), both of which are currently undergoing comprehensive manufacturer-requested risk evaluations under the EPA TSCA program.

² <u>Phthalates - Canada.ca</u>

While newer, highly sensitive analytical techniques now make it possible to measure parts per billion/trillion (ppb/ppt) levels of phthalates in water, soil, sludge etc., the presence of chemicals at such low levels are not, in isolation, indicative of concern.

Treating Ortho-phthalates as a Class is Not Scientifically Defensible

As Ecology states in the Draft Phthalates Action Plan, Ecology addresses ortho-phthalates as a chemical class, and does not examine or address each phthalate individually. Considering the clear and significant differences in the physical, chemical and biological properties of phthalates, recommendations for ortho-phthalates as a class likely cannot be done in a scientifically-defensible manner. Due to these distinctions, as well as use of phthalates in distinctly different applications, ACC continues to emphasize that phthalates should be treated as distinct categories based on toxicological similarity, specifically as low molecular weight (LMW) and high molecular weight (HMW) phthalates. The Draft Phthalates Action Plan acknowledges these differences on pg. 169 where Ecology makes a clear distinction for three different groupings of phthalates. Multiple groupings with recognized differences in physical-chemical properties and toxicities are appropriate.

1. Low molecular weight phthalates have a distinct hazard profile from high molecular weight phthalates.

LMW phthalates with 3 – 6 carbons in the straight chain backbones in the alkyl side chains have been shown to cause adverse reproductive effects in animal studies (Fabjan et al 2006). More specifically, toxicological effects observed in male rats after exposure to LMW phthalates during a critical window of male reproductive tract development include reproductive abnormalities characterized by malformations of the epididymis, vas deferens, seminal vesicles, prostate, external genitalia (hypospadias), cryptorchidism and testicular injury together with permanent changes (feminization) in the retention of nipples/areolae (sexually dimorphic structures in rodents) and demasculinization of the growth of the perineum resulting in a reduced anogenital distance (AGD) in adulthood (Gray and Foster, 2003; Foster, 2005; Foster, 2006). Four LMW phthalates have been classified for toxicity to reproduction in the EU based on these following effects (ie., cleft palate, neural tube defects, cryptorchidism, hypospadias, testicular tubular atrophy, complete ablation of spermatogenesis, fetal death).

These effects are <u>not</u> seen with HMW phthalates tested in similar study designs.

High molecular weight phthalates with the longest straight chain being 7 - 13 carbons in the alkyl side chains do not demonstrate adverse reproductive effects in animal studies (Boberg et al. 2011, Clewell et al., 2013a, Clewell et al., 2013b, Furr et al. 2014, Gray et al. 2016, Hannas et al. 2011, Hellwig et al 1997, Willoughby et al., 2000, Zirken et al. 1989). As an example, DINP has been
tested at doses above 1000 mg/kg/day (Waterman et al. 2000, Masutomi et al. 2003) with no induction of the adverse outcomes on development of the male reproductive tract that are observed with certain other phthalates (most notably DEHP and DBP). This clearly differentiates the DINP dataset from the LMW phthalates on the basis of toxicological profile.

2. When a weight of evidence approach is followed, no further action is necessary for HMW phthalates due to inadequate evidence of fertility or developmental effects.

The human health effects data reported in Appendix 2 follows a narrative approach and is focused primarily on studies which provide positive evidence of an association between exposure and a health effect. For example, the 2017 National Academies of Science, Engineering, and Medicine report entitled "Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals" is referenced on page 148 of the Draft Phthalates Action Plan to support the conclusion that six phthalates are presumed or suspected to pose a reproductive hazard to humans based on reduced fetal testosterone and reduction of anogenital distance in male offspring of exposed mothers (NAS 2017). However, Ecology fails to highlight that some associations were evaluated by NAS and found to be inadequate (e.g., inadequate evidence for an association between DINP exposure and change in anogenital distance).

To increase transparency and objectivity, a science-based evaluation of all available data on each phthalate should be conducted, and conclusions on the association between individual phthalate exposure and health effect should be based on the weight of the evidence. When a weight of the evidence approach was followed by Dekant and Bridges (2016), clear distinctions were found between the toxicological profiles for LMW and HMW phthalates, where developmental effects resulting in classification are observed after LMW exposure. There was no evidence supporting classification for high molecular weight phthalates such as DINP and DIDP.

Phthalates in the Environment

As we stated in previous comments, the environmental fate and disposition of phthalates is a prime example of why evaluation of phthalates as a broad class is not appropriate. As noted above, phthalates include a variety of chemicals with *distinct* toxicological, physical and chemical properties. HMW phthalates have considerably low vapor pressure and high solid-phase partition coefficients. These physico/chemical parameters are extremely important in understanding how these substances behave in the environment.

<u>Air</u>

While some phthalates are listed as hazardous air pollutants (HAPs), HMW phthalates like DINP (5.4 x 10⁻⁷ mm Hg at 25 °C) and DIDP are not. Due to their low vapor pressures, presence of these substances in ambient air is expected to be considerably low. For example, using ideal gas law, we

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Concern was raised during the Advisory Committee meetings regarding the potential presence of phthalates in particulates in air. Environment and Climate Change Canada (ECCC) published Level III fugacity models to predict environmental distribution of individual phthalates. For DINP⁴ and DIDP,⁵ the model predicts that >90% of plasticizer released to air will be sorbed to particulates in the air and subsequently deposited to soil, limiting potential for air transport. ECCC also noted that DINP degrades rapidly in air, with a half-life of <2 days.

Storm water and sediment

The ECCC fugacity model cited above also shows low partitioning of HMW phthalates to water. Less than 20% of plasticizer release to water remained in the water phase, with >75% partitioning to sediment. ECCC reported that DINP degrades rapidly in water, with a half-life of <6 months.

Soil

The ECCC fugacity model found that 100% of DINP released to soil remains in the soil compartment. Due to the high solid phase partition coefficient, the substance is expected to sorb to soil organic matter and is *unlikely to leach through soil into groundwater*.

As we noted previously, during the Action Plan process, Ecology cited its Cleanup Levels and Risk Calculation (CLARC) study from 2020.⁶ The study evaluated levels of certain phthalates in the marine environment of Puget Sound (WA). Frequency of detection for DINP was very low (10%), with an estimated concentration of 10-150 ng/L. The CLARC report identified a PNEC of 0.00051 μ g/L for DINP, which is considerably below the estimated concentration. As a result, the CLARC report concluded that these low levels of DINP reported posed a risk to the marine environment. This is not supported by other more exhaustive data-driven environmental risk evaluations. The CLARC study does not indicate how its PNEC (0.00051 μ g/L) is derived. The NORMAN database of ecotoxicology, cited as the source of this value, lists 21 freshwater acute and chronic studies in various organisms. No adverse effects were found in any of the studies and effect levels were well above water solubility.⁷ As a result, no PNEC can be derived. In its risk

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³ Pengelly, I., Johnson, P., Investigation of relationship between saturated vapour concentration and real exposure to vapour. Health and Safety Executive, 2012.

⁴ Environment and Climate Change Canada - State of the Science Report - Phthalate Substance Grouping - DINP

⁵ Environment and Climate Change Canada - State of the Science Report - Phthalates Substance Grouping - Longchain Phthalate Esters

⁶ Zhenyu Tian, Katherine T. Peter, Alex D. Gipe, Haoqi Zhao, Fan Hou, David A. Wark, Tarang Khangaonkar, Edward P. Kolodziej, and C. Andrew James. *Environmental Science & Technology* **2020** *54* (2), 889-901

⁷ According to the European Union Risk Evaluation of DINP, true water solubility of DINP is approximately 0.6 µg/L.

evaluation of DINP,⁸ the European Commission concluded that calculation of a PNEC_{sediment} was not possible because no aquatic PNEC could be derived "*due to the lack of identified adverse effects.*" The European Commission thus concluded that DINP "*has no adverse effects towards benthic organisms.*" The Canadian State of the Science report on DINP reached the same conclusions.⁹ Overall, the ECCC confirmed that "*tissue concentrations of DINP in sediment species are unlikely to reach levels predicted to result in acute or chronic effects due to baseline narcosis*". In line with the EU and Canadian evaluations, the true conclusion from the CLARC study should have been that DINP (as well as DIDP and DIUP) are found at a low frequency in marine sediments and do not pose a risk in these environments.

<u>Biota</u>

Ecology has indicated that it does not conduct routine biomonitoring studies on biota. There is no evidence that this is necessary for HMW phthalates. As noted, the European and Canadian risk assessment reports for DINP report no adverse effects related to exposure, either to fish, game or vegetation.¹⁰

Thus, the science supports the following conclusions concerning HMW phthalates:

- 1. Ambient air emissions and transport are negligible (due to low vapor pressures and rapid degradation in air).
- 2. HMW phthalates can be sorbed to air particulates, however these are deposited in soil and are not transported to any significant degree in air.
- 3. HMW phthalates released in water preferentially partition to sediments.
- 4. 100% of HMW phthalates deposited in soil strongly sorbs to organic matter, hence ability to leach into groundwater is negligible.

Specific Comments on Language from the Draft Action Plan:

- 1. p. 23 "Failure to reduce these constant sources of phthalate release has led to recontamination of sediments in the Puget Sound area following large-scale chemical remediation efforts (Ecology, 2009a)."
- p. 169 "Failure to reduce these constant sources of phthalate release has led to the recontamination of sediments in the Puget Sound area following large-scale chemical remediation efforts (Ecology, 2010)."

This sentence suggests that the presence of phthalates in sediments negated previous remediation efforts of sediments, which is unlikely to be the case. The suggestion that phthalates were a primary driver for previous remediation efforts is also questionable. Ecology Publication 11-03-008, titled "Control of Toxic Chemicals in Puget Sound, Characterization of Toxic Chemicals in Puget Sound

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⁸ <u>EU Risk Assessment Report (europa.eu)</u>

⁹ See footnote 3.

¹⁰ See footnotes 3, 4 & 7. Staples, C.A., Adams, W.J., Parkerton, T.F., Gorsuch, J.W., Biddinger, G.R. and Reinert, K.H. (1997), Aquatic toxicity of eighteen phthalate esters. Environmental Toxicology and Chemistry, 16: 875-891.

and Major Tributaries, 2009-10," for example, does not appear to highlight phthalates at all, despite being authored in the same time period as the two references provided.

2. P. 169 – "... the environmental fate of phthalates may differ based on molecular weight. For clarity, when discussing partitioning behavior, this section divides phthalates into three subgroups based on definitions laid out by Environment Canada and Health Canada (EC & HC, 2015a, 2015b, 2015c, 2015d). These categories are general groupings and may have some overlap within chemical properties and toxicities", "Low molecular weight or short-chain phthalates (containing sidechains of three carbons or fewer)...," "Short-chain phthalates also have high-water solubility compared to medium-chain (sidechains of three to seven carbons) and long-chain (sidechains of more than seven carbons) phthalates..."

It is interesting that Ecology makes a clear distinction here for three different groupings of phthalates, while grouping phthalates together in other contexts. Multiple groupings with recognized differences in physical-chemical properties and toxicities are appropriate.

- 3. P. 170 The extended discussion regarding algal degradation of phthalates and possible downstream impacts on the distribution of algal/toxins appears extremely speculative. It is not clear how this speculative discussion is appropriate here, particularly in the absence of discussion of other factors that could impact the algal community (e.g., nutrient loading).
- 4. P. 170 It may be helpful to recognize the statement that "...environmental concentrations of phthalates are unlikely to cause acute or chronic toxic effects in aquatic organisms (EC & HC, 2015a, 2015b, 2015c, 2015d)," which seems to address at least half of an earlier comment on p.169, "This leads to the potential for chronic exposure in aquatic and terrestrial systems, similar to that of persistent chemicals."
- 5. P. 144 "The FDA regulates phthalates in cosmetics, pharmaceuticals, medical devices, and food contact substances (US EPA, 2012). In May 2022, the FDA revoked authorizations for the food contact use of 23 phthalates, while eight phthalates remained authorized for use as plasticizers and one phthalate as a monomer in food contact uses."

This paragraph fails to provide the context that these authorizations were revoked because the specific uses were abandoned (87 Fed Reg. 31080). As written, it leaves the impression that these authorizations may have been revoked for other reasons.

Phthalates in Industry and Manufacturing

There are no known manufacturers of phthalate plasticizers in Washington, Oregon, or Idaho. The US Environmental Protection Agency is currently conducting a risk evaluation of seven phthalates, under the Toxic Substances Control Act (TSCA). These seven represent the majority of phthalates likely to be found in commerce. These risk evaluations are extensive and include examination of risks that could potentially arise from worker and environmental exposures, both from manufacturing, processing and final flexible vinyl article manufacturing sites across the United States. Any risk determination from these evaluations allows EPA to identify risk management measures to reduce exposure.

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We would recommend that Ecology wait until the EPA risk evaluations are completed, as these are more than likely to address the various exposure and risk concerns.

Phthalates in Products

Potential sources of information on phthalates in product use

As part of its ongoing TSCA risk evaluation of seven phthalates (including di-isononyl phthalate [DINP] and di-isodecyl phthalate [DIDP]), the US EPA has developed publicly available individual use reports, identifying examples of where these phthalates are used. For example, Table 2-5 in the DINP use report¹¹ identifies real world products, product manufacturer, and percent weight in product.

Food processing

The use of phthalates in food contact applications is strictly governed by federal law. Several phthalates are permitted for safe use by several food safety authorities across the globe. For example, high molecular weight (HMW) phthalates like DINP (FCM #728) and DIDP (FCM #729) are listed in the European Union (EU) positive list of plastic materials and articles intended to come into contact with non-fatty foods [Commission Regulation (EU) No 10/2011]. These listings are based on an extensive dietary risk evaluation that concluded that current exposure from food "*is not a concern for public health*".¹² Similar safe use conclusions have been reached (and published) by Canada,¹³ Australia,¹⁴ New Zealand,¹⁵ the United Kingdom,¹⁶ and the Republic of Ireland.¹⁷

In the US, only a limited number of phthalates are used in food contact applications and only in a narrow range of such applications.¹⁸ No phthalates were found to be used as primary plasticizers in PVC film for food service and commercial wraps (e.g. wrapping films for meat, vegetables or

¹¹ Final Use Report for Di-isononyl Phthalate (DINP) CASRN 28553-12-0 & 68515-48-0) (epa.gov)

¹² FAQ: phthalates in plastic food contact materials | EFSA (europa.eu)

¹³ Environment and Climate Change Canada. 2015a. State of the Science Report - Phthalate Substance Grouping - 1,2-Benzenedicarboxylic acid, diisononyl ester; 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich (Diisononyl Phthalate; DINP).

¹⁴ Food Standards Australia New Zealand. 2018. Survey of Plasticisers in Australian Foods: An Implementation Subcommittee for Food Regulation Coordinated Survey.

¹⁵ Pearson A, van den Beuken J. 2017. Occurrence and risk characterisation of migration of packaging chemicals in New Zealand foods. Wellington, New Zealand.

¹⁶ Bradley EL, Burden RA, Bentayeb K, Driffield M, Harmer N, Mortimer DN, Speck DR, Ticha J, Castle L. 2013. Exposure to phthalic acid, phthalate diesters and phthalate monoesters from foodstuffs: UK total diet study results. Food additives & contaminants Part A, Chemistry, analysis, control, exposure & risk assessment.30:735-742.

¹⁷ Food Safety Authority of Ireland. 2016. Report on a Total Diet Study carried out by the Food Safety Authority of Ireland in the period 2012 – 2014. Dublin, Ireland: FSAo Ireland.

¹⁸ Carlos KS, de Jager LS, Begley TH. 2018. Investigation of the primary plasticisers present in polyvinyl chloride (PVC) products currently authorised as food contact materials. Food additives & contaminants Part A, Chemistry, analysis, control, exposure & risk assessment. Jun; 35:1214-1222.

sandwiches at grocery stores and delis) or paper-based packaging for fast food.¹⁹ Similar to positive listings in the EU, these phthalates are federally regulated in the US via e.g. 21 C.F.R. § 178.3740 ("*Plasticizers in polymeric substances*"), 21 C.F.R. § 177.1210 ("*Closures with sealing gaskets for food containers*"), and 21 C.F.R. § 177.2600 ("*Rubber articles intended for repeated use*").

Building materials and consumer products

As noted previously, the ongoing US EPA risk evaluation of seven phthalates identifies uses in building materials as critical conditions of use to be evaluated. These will include potential for human and environmental exposures, through the lifecycle of these products (manufacturing to disposal or recycling). At present, there is minimal evidence that phthalate use in building materials is of any health and environmental concern. For example, extensive risk evaluations for DINP and DIDP continue to show no risk of exposure with consumer use.²⁰

¹⁹ Carlos KS, de Jager LS, Begley TH. 2021. Determination of phthalate concentrations in paper-based fast food packaging available on the U.S. market. Food Addit Contam Part A Chem Anal Control Expo Risk Assess. Mar; 38:501-512. Epub 20210125.

²⁰ European Chemicals Agency; Evaluation of new scientific evidence concerning DINP and DIDP In relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006. 2013.

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BASF Corporation

See attached document for comments.



June 14, 2023

Submitted online and via email: <u>ChemActionPlans@ecy.wa.gov</u>

Comments: Draft Phthalates Action Plan

BASF appreciates the opportunity to comment on the Draft Phthalates Action Plan (PAP).¹ The following comments are submitted to address information and recommendations presented in the draft PAP; complementary comments may be found in our substantive submissions from January 28, 2022, and February 3, 2003, on the Safer Products for Washington proposal. Our comments are not exhaustive, i.e., they have not necessarily addressed every point of concern; however, they are representative and focus on the following topics:

- Phthalates should not be regulated as a class owing to the differences in structure, physical properties, and toxicological behavior across the range of products.
- The recommendation to encourage the avoidance of ortho-phthalate-containing building materials is misinformed, owing to the low toxicity and strong performance properities of the higher molecular weight products typically used in these applications.
- The draft PAP relies heavily on epidemiological studies that show associations (or not) but no clear evidence of causation. We recommend again reviewing the EU SCENIR (2015) report on DEHP in medical devices; their conclusions on various epidemiological studies ranged from "no association" to "weak association" to :inconsistent evidence" hardly sufficient as a justification for regulatory action on specific ortho-phthalates or this whole class of chemicals.
- Some references report the detection of low levels (often described as "high") of orthophthalates in various consumer and other products. Any evaluation of these studies must also consider likely human exposure and potential risk relative to established NOAELs, TDIs, etc.
- The report also contains a number of errors such as incorrect citations, misrepresentation of the conclustions of some studies, and typographical errors.

Page 25: Black women: "... *phthalates that are used as fragrance in personal care products.*" Phthalates (e.g., DMP or DEP) are not used as fragrances; however, they may be used as a carrier for the fragrance.

¹ BASF manufactures a number of plasticizers including DOTP, DINCH, high molecular weight orthophthalates, adipates, and trimelliates. BASF Corporation is a subsidiary of BASF SE.



Page 26: Regulations – Washington State: The regulation in the link restricts ortho-phthalates, individually or in combination, to 0.1% or 1000 ppm and not 100 ppm (See RCW 70A.430.020(1)(c)).

p. 30 - Automotive products

Trim et al. (2017) presented testing results for a variety of automotive and other related products, which were described as "high" concentrations. Regrettably the values were reported in μ g/kg or ppb, giving the impression that high levels were found. Some brake pads had 17,000 – 22,000 μ g/kg, and serpentine belts had 950 – 1900 μ g/kg; in mg/kg or ppm, these values are 17 – 22 mg/kg and 0.95 – 1.9 mg/kg (or 0.0017 – 0.0022% and 0.000095 – 0.00019%). It is unlikely that the respective phthalates were present in these products and most of the others as functional ingredients (i.e., intentionally added). Why they were detected is unknown; however, they may have been impurities in some of the materials or were analytical artifacts (i.e., misidentified or were present in lab equipment or sample containers).

It is misinformed to simply equate detection of an ortho-phthalate in a product with potential risk without considering the likely exposure and relative hazard.

One major use of ortho-phthalates is in interior automotive materials such as trim, floormats, and seats. OEM materials are subject to low fogging requirements (SAE J1756); typically these are only met when using linear C9 and higher molecular weight ortho-phthalates (i.e., linear C9 and branched or linear C10 and higher; cf. Wickson, 1993). These products have lower toxicity concerns, and lower exposure is expected due to their low vapor pressures. After-market replacement parts may or may not meet the low fogging requirements.

p. 51 – Phthalates in medical products

"The use of DEHP in PVC blood bags is one medical application for which alternatives do not yet meet performance standards. DEHP has a stabilizing effect on red blood cells and allows for longer stable storage of blood products. This benefit is critical for maintaining adequate blood supplies, despite the risk of high exposure during transfusion procedures."

Non-DEHP medical products have been and are available for a variety of applications, including for storage of blood storage products. The European Pharmocopaoeia was updated to now include alternatives to DEHP – DINCH, DOTP/DEHT, TOTM, and BTHC:

https://www.edqm.eu/en/news/ph-eur-revised-its-general-chapters-plasticised-pvc-materials

In addition, please refer to the two publications, Lagerberg et al. (2015) and Prowse et al. (2014) for more detailed examples. More information on these applications can be provided if needed.



Page 59 – Building materials

Certain building materials are particularly important applications for high molecular weight orthophthalates, including specialty linear phthalates. For this reason, we disagree with the recommendations to support and encourage efforts to "avoid using phthalate-containing building materials," especially since the products most likely used have low toxicity and result in low exposure due to their low vapor pressure and water solubility.

For example, roofing membranes are an important market for plasticized vinyl. Owing to the need for low temperature flexibility and superior outdoor weather performance, specialty linear ortho-phthalates as well as DINP and DPHP are used. The following table shows some representative applications and the plasticizers typically used:²

Use	Plasticizers
Water-stop	DOTP, DINP
Caulks and sealants	Dibenzoates, DINP, DOTP, DINCH, DIDP
Pond and pool liners	DINP, DPHP, DIDP
Roofing membrane	DINP, DPHP, linear ortho-phthalates

Wire and Cable

Another key application for ortho-phthalates is for wire and cable insulation and jacketing. As noted in Godwin and Krauskopf (2008),³ general purpose plasticizers such as DEHP may be used to meet 60 °C UL-rated PVC formulations; however, DEHP is not widely used for these applications in North America. As discussed in Godwin and Krauskopf, "flexible PVC products rated for 75 – 80 °C performance require less-volatile plasticizers such as DINP, DIDP, DPHP, or 711P types. Performance ratings for even higher temperatures (i.e., 90 and 105 °C) require the low volatility higher-molecular-weight phthalates and/or trimellitates. In all cases, the optimum plasticizer choice is a function of wall thickness and other factors influencing oven aging . . ." The following table, which was adapted from Godwin and Krauskopf, shows examples of plasticizers that meet various oven aging tests and the corresponding UL temperature ratings.

² Godwin and Krauskopf, "Monomeric Plasticizers" in *Handbook of Vinyl Formulating*, 2nd ed., Grossman, R. F., Ed., Wiley: New Jersey, 2008.

³ Cf. Goodwin and Krauskopf.



Wall thickness (mil)	Test temperatures for 7-day aging, deg C				
	100 UL 60	113 UL 80, SAE-80	121 UL 90	136 UL 105	
8	DIDP, DPHP	DUP	DUP	TOTM, TINTM	
15	DIDP, DPHP	911P, DUP	DUP, DIDP/DTDP	DUP/TOTM	
30	DINP, DOTP, DIDP, DPHP	DIDP	DIDP	DTDP/TINTM	
60	DINP, DOTP, DIDP, DPHP	DIDP, DPHP	DIDP, DPHP	DUP, DTDP	

It is important to note that in the building materials segment, including wire and cable, specific high molecular weight ortho-phthalates are used owing to the performance requirements of the application; the important performance criteria are, for example, low temperature flexibility, heat stability, and outdoor weathering stability – higher molecular weight ortho-phthalates excel in these areas and are difficult to replace. In addition, flexible PVC usually provides the most cost-effective and best-performing option.

Page 138, physical-chemical properties: Delete "may"; ortho-phthalates have clearly defined and well-known structure activity relationships.

The water solubility is a function of chain length of the respective alcohols; i.e., longer chains are less water soluble and have lower vapor pressures.

Page 138, Table 6: This table appears to have come from the 2010 CPSC report, as referenced; however, some of the values appear to be incorrect and do not make sense. For example, the vapor pressure values of DEHP and DnOP in the table are lower than for DINP and DIDP (see Cousins, Mackay, and Parkerton, 2003, for leading references and more details).

The correct chemical name for DEHT is bis(2-ethylhexyl) terephthalate, although it is often described as diethylhexyl terephthalate or dioctyl terephthalate (i.e., DEHT and DOTP acronyms). NSF International has published an oral risk assessment on terephthalic acid and its esters (Ball et al., 2012), which provides details on the other esters.



Page 139: Engel et al. speculates about the potential for regrettable substitution and calls on government agencies to "eliminate phthalate use". As noted in previous comments, recommendations for restrictions on phthalates as a class is misinformed and does not consider the differences in structure between the various members of that class and the impact on physical properties and toxicological behavior.

Page 143. "Phthalates are regulated under several laws in Washington state. CSPA restricts the use of six phthalates in children's products at concentrations **greater than 100 ppm** individually or combined. CSPA also requires manufacturer reporting for six additional phthalates when used in children's products, for a total of 12 phthalates listed with a reporting requirement."

Please clarify what is the valid limit value?

RCW 70A.430.020 Prohibition on the manufacturing and sale of children's products containing lead, cadmium, **or phthalates.**

(c) Phthalates, individually or in combination, at more than 0.10 percent by weight (one thousand parts per million). → 1000 ppm, the limit in US CPSIA and CPSA limit cited on page 32 of pdf. Also see comment above.

Page 145:

"Phthalates as a chemical class can cause reproductive toxicity and developmental toxicity to the reproductive and nervous systems..."

Not all – only those in the active cluster; this sentence should read "some phthalates" ... (cf. Fabjan, 2006; CHAP, 2014)

"There is broad consensus that phthalates are endocrine disrupting chemicals..."

Disagree: not phthalates in general, but only specific ones.

"In studies of people, exposure to phthalates in the womb has been linked to brain and behavioral outcomes for children and respiratory symptoms after birth. When exposure occurs later in life, phthalates have adverse effects on semen quality and sperm count in men and on pregnancy outcomes in women. Risk and severity of uterine fibroids in women have been connected to phthalate exposure. Phthalates are also associated with metabolic effects like diabetes, gestational diabetes, insulin resistance, and obesity. In laboratory experiments in animals, phthalates cause liver and kidney toxicity."

This whole paragraph is dealing with epidemiologic associations where no causal relationship can be proven.



Page 146:

"U.S. EPA cited toxic effects on fetal development of the reproductive system as a critical health effect for the development of their 2012 action plan (US EPA, 2012)."

This sentence needs to be aligned with the EPA statement, which was more specific (EPA, 2012): "The most sensitive health outcomes following exposures of *some phthalates in animal studies* are the phthalate syndrome effects ..."

"The CHAP report focused on male developmental toxicity."

⇒ Male developmental **toxicity in animals**.

Canada:

"The key phthalate health hazards identified by ECCC are consistent with other studies: effects on the..."

Should be more specific, i.e. The key phthalate health hazards identified by ECCC are consistent with other **animal** studies: effects on the

Page 147:

"Authoritative reports identify phthalates as endocrine disruptors." This is too generic and should be more clear; i.e., identify **specific** phthalates

"Phthalates possess some limited estrogenic activity, and there is strong evidence that they act as antagonists of androgen receptors (Begum & Carpenter, 2021)." See correct reference to the final version:

Begum, T. F., & Carpenter, D. (2022). Health effects associated with phthalate activity on nuclear receptors. *Reviews on Environmental Health*, *37*(4), 567–583. <u>https://doi.org/10.1515/REVEH-2020-0162</u>

"Most of the phthalates with side chains *of 4 to 10 carbons* (e.g., DBP, DiBP, DEHP, BBP, DCHP, and DINP) that have been tested have anti-androgenic properties in laboratory animals, although the potency varies (Lioy et al., 2015; NAS, 2017)."

- ⇒ Disagree: it is only with alcohol side chains of 4-9 carbons or 3 6 carbon backbone (Fabjan 2006).
- ⇒ This is an error in both NAS 2017 and Lioy et al. (2015). NAS 2017 states that it is "ester side chains containing 4 10 carbon atoms," and Lioy et al. says that it is "three to eight



carbon atoms in the backbone of the alkyl side chain." NAS 2017 cited studies (Gray 2000 and Furr 2014) confirming anti-androgenic *activity* only for C4-C9 side chains.⁴

Page 149:

"*A review of epidemiological evidence concluded…*" What specific evidence? Epidemiology reports only associations with no causal relation and no evidence. There is a danger of random associations, and the scientific basis may be questionable.

"The human epidemiology evidence for effects on male reproduction is strongest for DEHP (Swan et al., 2015); however, DIDP has been linked to cryptorchidism and hypospadias, and DINP has effects on AGD and semen parameters, although results are inconsistent (Radke et al., 2018)."

"DIDP has been linked to cryptorchidism and hypospadias, ..."

Please add reference for this claim. Swan and Radke do not link DIDP with these effects.

Page 149:

"Three recent reviews conclude that phthalates have the potential to disrupt neurodevelopment and alter neurobehavior (Engel et al., 2021; Radke, 2020; Eales, 2022). Engel et al. (2021) concluded that the combined evidence from human and animal studies is sufficient to call for policy actions to reduce phthalate exposure to pregnant women and children and protect against harm to neurodevelopment and neurobehavior (Engel et al., 2021). "

Radke et al. (2020): "Conclusions and implications of key findings: Overall, there is not a clear pattern of association between prenatal phthalate exposures and neurodevelopment. There are several possible reasons for the observed null associations related to exposure misclassification, periods of heightened susceptibility, sex-specific effects, and the effects of phthalate mixtures. Until these limitations are adequately addressed in the epidemiology literature, these findings should not be interpreted as evidence that there are no neurodevelopmental effects of phthalate exposure."

"Another recent review of human health effects of phthalates concludes that there is robust evidence that phthalates can affect some neurodevelopmental outcomes but that there is a lack of clarity around susceptibility factors and the developmental stage when exposure has the greatest impact remains unclear (Eales et al., 2022)"

The publication by Eales et al., 2022, reports: The overview "**found robust evidence for an association** between phthalates/metabolites ..." This is different from the conclusion of robust evidence for neurodevelopmental outcomes. Further, results from environmental epidemiology

⁴ Furr et al. (2014) notes that "some C3 and C7 PEs reduce fetal T Prod and alter male rat reproductive development."



are not suitable to provide evidence for a causal relation. Recommend to carefully revisit Section 5.2 of Eales et al. on limitations.

Page 150:

"A third-party reviewed hazard assessment, Greenscreen, categorized DIDP as a high hazard for developmental toxicity." Add proper citation to enable the reader to understand the basis for this Greenscreen claim

DIDP is listed under CA Proposition 65 for potential developmental toxicity; however, it is not classified under EU REACH for any hazard end point, and US CPSC removed the restriction for use in children's products owing to the lack of anti-androgenic effects observed with certain other ortho-phthalates and since the Margin of Exposure (MOE) was sufficiently high when comparing the low exposures and critical NOAEL.

"In laboratory animal studies that exposed pregnant females to DINP during pregnancy and lactation, the most pronounced effects noted were skeletal malformations and kidney abnormalities in offspring (CRE & ACC, 2003)"

Disagree: This is a very selective reading and false citation of the letter by CRE & ACC to EPA; the effects in the Waterman studies do not support what is stated here. Please refer to US CPSC CHAP, which concluded that any developmental risk to humans from DINP is "extremely low or non-existent".

"Phthalates can affect reproductive health in both males and females. Authoritative bodies in the U.S. and other countries share a consensus that phthalates are reproductive toxicants based primarily on the toxicological effects in animals. There is also a body of supporting evidence for these effects in..."

⇒ Needs to be specified/corrected to "**some specific phthalates**" as structure activity relations are common knowledge and internationally accepted.

Female reproductive toxicity and preterm birth.

Care needs to be taken in evaluating these epidemiological studies that report associations but no causal relations – findings may be random. There are too many limitations to conclude anything meaningful.

Page 152:

"A systematic review of male reproductive outcomes for a subset of phthalates concluded that there is moderate to robust evidence of an association between DBP, BBP, DEHP, and DINP and adverse effects on semen quality parameters (Radke et al., 2018) and moderate evidence of DEHP, DINP and DIDP with reduced testosterone in adult men."

This is what Radke et al. (2019) stated in the abstract:



Conclusions and implications of key findings: Overall, despite some inconsistencies across phthalates in the specific outcomes associated with exposure, these results support that phthalate exposure at levels seen in human populations **may** have male reproductive effects, particularly DEHP and DBP. The relative strength of the evidence reflects differing levels of toxicity as well as differences in the range of exposures studied and the number of available studies.

Please note: associations need to be considered with some care and are not a proof for a causal link. The basic issue is that there is a lot of cross referencing and citing each other to get confirmation for own hypotheses – which is dangerous as there is a risk of bias.

In addition, neither Radke et al. (2018) nor Radke et al. (2019) appear to have discussed DIDP.

Page 152:

"DINP is listed as a carcinogen in California based on neoplastic lesions in liver and mononuclear cell leukemias observed in laboratory rodent studies. EPA recently stated that based on a technical review, the available literature provides evidence that DINP can be reasonably anticipated to cause cancer in humans (CRE & ACC, 2003)."

Correct, but it would be fair to present the complete content of the CRE & ACC document where the EPA ideas were challenged:

Kidney:

CPSC CHAP concluded that the kidney tumors occurred through a rodent-specific mechanism that is unlikely to have relevance to human risk. [CPSC 2001]

MNCL:

The CPSC CHAP concluded that **MNCL** was likely to be strain-specific to F-344 rats, with great variance in the rates of spontaneous occurrence in controls, and therefore was "of questionable relevance to humans." [CPSC 2001 at 122] Overall, the **CHAP** found that DINP is not plausibly associated with a significant increase in cancer risk in humans. [CPSC 2001]

Ahern (2019, 2022) \rightarrow associations, but no causal relations shown. And note, DBP is not genotoxic.

Page 153:

"Phthalates may increase the risk of type 2 diabetes, gestational diabetes, and insulin resistance in people. In laboratory animals some phthalates can alter glucose balance and impair glucose uptake. Phthalates are associated with glucose homeostasis disruption in people (T. Huang et al., 2014) and they can interact with receptors that may play a role in the development of type 2 diabetes and obesity (Begum & Carpenter, 2021)."



We create chemistry

- ⇒ The major source for human exposure to phthalates is food. Therefore, in case food intake is increased phthalate intake will be increased.
- \Rightarrow These associations may be a random finding.

The whole chapter "other health effects of concern" is populated with environmental epidemiology studies that report associations but no causal relations.

Page 157:

"Both the liver and kidney are targets of phthalate toxicity in rodents. EPA's 2022 Technical Review of DINP concluded that DINP produces chronic liver and kidney toxicity in rats. Thus, DINP can reasonably be anticipated to cause serious or irreversible chronic health effects in humans at moderately low to low doses. These include developmental effects, kidney toxicity, and liver toxicity (US EPA, 2022a)."

Reference? Shouldn't this be: <u>https://www.govinfo.gov/content/pkg/FR-2022-08-08/pdf/2022-16908.pdf#page=1</u>

Further, and again, the EPA proposal is based on historical EPA documents that have not been supported by others; i.e. CPSC CHAP.

Page 158:

Cumulative effects

Add reference: Cumulative Risk Assessment Under the Toxic Substances Control Act | US EPA

Assessment started some weeks ago

Page 163:

Is dust a relevant source of PAE exposure?

Please add the following references and use in the discussion:

Becker K et al. (2004). DEHP metabolites in urine of children and DEHP in house dust. International Journal of Hygiene and Environmental Health 207:409-417. DOI: <u>https://doi.org/10.1078/1438-4639-00309</u>.

Fromme H et al. (2013). Phthalates in German daycare centers: Occurrence in air and dust and the excretion of their metabolites by children (LUPE 3). *Environment international* **61**:64-72. DOI: <u>https://doi.org/10.1016/j.envint.2013.09.006</u>.



Additional References

Ball GL, McLellan CJ, Bhat VS. 2012. Toxicological review and oral risk assessment of terephthalic acid (TPA) and its esters: A category approach. Crit Rev Toxicol. 42(1): 28–67.

Cousins IT, Mackay D, Parkerton TF. 2003. Physical-chemical properties and evaluative fate modelling of phthalate esters, in Handb Environ Chem: Phthalate Esters, Staples CA, Ed. Springer: Berlin, pp. 57 – 85.

Lagerberg et al. 2015. In Vitro evaluation of the quality of red blood cells collected and stored in systems completely free of DEHP plasticized materials. Transfusion. 55, 522 - 531. <u>https://doi.org/10.1111/trf.12870</u>

Prowse et al. 2014. Commercially available blood storage containers. Int J of Transfusion Medicine (Vox Sanguinis). 106, 1 - 13. <u>https://doi.org/10.1111/vox.12084</u>

Wickson EJ, Ed. 1993. Handbook of PVC formulating. John Wiley & Sons: New York. See Wickson, EJ, Formulation development, pp. 1 - 7; and Krauskopf, LG, Monomeric plasticizers, pp. 212 - 216, for more details.

Patrick Harmon

Patrick Harmon Industry Manager Regulatory Affairs and Advocacy, Sustainability, Innovation BASF Corporation

Copies to:

Rainer Otter VP Regulatory Affairs and Advocacy BASF SE

John Erickson Associate General Counsel BASF Corporation

The Coalition for Clean Water

These comments are submitted on behalf of the Coalition for Clean Water. Our members provide wastewater treatment to many of Washington's citizens across the state. Member agencies include the cities of Bremerton, Everett, Seattle, Lynnwood, Tacoma, Vancouver, and Spokane; Pierce, King, and Spokane counties; and the Lakehaven Water and Sewer District in south King County, LOTT Clean Water Alliance (Thurston County), and the Discovery Clean Water Alliance (Clark County).

We thank the Departments of Ecology and Health, other state agencies, and members of the advisory committee for their efforts in producing the draft CAP. Developing a CAP is a challenging task. Many details will need to be worked out as individual recommendations are implemented.

The plan presents a clear picture:

- Phthalates are ubiquitous in the manufacturing of products, the environment, and our lives.
- The primary source of exposure for people is ingestion, mostly from food and water; house dust is an important pathway of exposure for children.
- Phthalates degrade relatively quickly in the environment and in our bodies but their broad presence in manufactured products means they are constantly released to the environment, and we are constantly exposed.

The plan anticipates that lead agencies will prioritize the implementation of recommendations with input from stakeholders. We support Safer Products for Washington and efforts to find alternative and less hazardous substitutes for phthalates and other substances that are determined to pose a risk to health or the environment. Wastewater treatment plants (and biosolids) are passive receivers of phthalates from other sources. We ask that Ecology focus its greatest effort on curtailing the true sources of phthalates by working with manufacturers to find better alternatives, and with consumers to change purchasing habits. If the use of phthalates is reduced, a corresponding reduction will be seen in biosolids and wastewater influent and effluent, as has been the case with other substances of concern.

The plan places biosolids and wastewater in the category of Solid Waste Media. Under state law in RCW 70A.226, biosolids are a valuable commodity and are explicitly not solid waste. We ask that you separate wastewater and biosolids from the management of solid wastes, which by law and rule appropriately include compost facilities, recycling products and packaging, and landfills.

The plan offers positive observations about biosolids, but also characterizes them as a source of phthalates and a threat, on some level, to human health and the environment. Perspective is important. Food contamination comes from many sources, the most significant of which have nothing to do with biosolids. Croplands treated with biosolids are less than 0.1 percent of Washington's total land area and perhaps 0.2 percent of agricultural land. Biosolids are used in many applications that do not include food crops, including the reclamation of disturbed and contaminated sites, growing timber, and the product of fiber for pulp. Most biosolids are not handled with bare hands (if at all), and plant uptake is only one component of many complex pathways involved in exposure and risk assessment. Biosolids permit criteria address surface water

and groundwater, as well as soil types, slopes, rainfall, method of application, and other considerations.

Ecology needs to expand the scope of its consideration for inputs of phthalates in agricultural settings. Other potential sources of phthalates include commercial fertilizers and pesticides, products designed to enhance soil water retention, and product packaging.

The first bullet under Recommendation 1 of the Solid Waste Media Recommendations section should include composting biosolids as a method of treatment to be assessed. In Recommendations 2 and 3, Ecology says it will need to work with farmers to plan and coordinate sampling efforts for crops/fodder grown on biosolid-amended soil. Biosolids generators have carefully cultivated working relationships with farmers and other users over many years and have a very large investment in those relationships. We ask that Ecology approach this as working with both users and producers.

We note that area universities are omitted as partners in research, yet both the University of Washington and Washington State University have done significant research on biosolids beneficial use and stormwater analysis. Ecology should take advantage of that expertise.

Thank you for taking the time to consider our comments and recommendations. Respectfully and on behalf of the members of the Coalition for Clean Water,

Kyle Dorsey Executive Director



June 13, 2023

Kimberly Grieves Phthalates Action Plan Project Manager Washington State Department of Ecology ChemActionPlans@ecy.wa.gov

RE: Phthalates Action Plan Comments

Dear Ms. Grieves:

The Discovery Clean Water Alliance (Alliance) thanks the Washington State Department of Ecology (Ecology) for the opportunity to comment on the Draft Phthalates Action Plan. The Alliance appreciates Ecology's efforts to address these ubiquitous and persistent chemicals to protect human health and the environment.

The Alliance is a partnership managed by the Clark Regional Wastewater District (District), along with Clark County, Washington, and the cities of Battle Ground and Ridgefield, Washington. The Alliance provides wastewater services to more than 125,000 people in Clark County (about 25% of the County's population). The Salmon Creek Treatment Plant (SCTP) is the primary wastewater treatment facility for the Alliance: SCTP produces approximately 10,000 tons of biosolids each year that is land applied as a beneficial soil amendment to agricultural sites within Washington's Cowlitz and Klickitat counties.

The Alliance wishes to make the following comments related to the Draft Phthalates Action Plan:

1. We support the plan's recommendations to identify and reduce upstream sources and uses of phthalates and believe that action will have the most meaningful impact on human health and the environment.

Wastewater facilities like those managed by the Alliance do not actively use or generate phthalates, they receive them in the waste streams from the homes and businesses that they serve. Thus, the Alliance strongly supports source control measures, like the Safer Products for Washington program, that aim to reduce the use of these chemicals in consumer products and will result in fewer phthalates in wastewater and biosolids. Wastewater treatment plants are not designed to treat or remove chemicals like phthalates and eliminating them at the source will be the most effective way to reduce their impacts on human health and prevalence in the environment without unfairly burdening ratepayers of public clean water agencies.

2. We suggest removing biosolids from the solid waste section of the plan, and more broadly addressing all agriculture-related exposure pathways for phthalates.

Laying the foundation for a vibrant economy and healthy environment Phthalates Action Plan Comments June 13, 2023 Page 2

The plan makes several recommendations related to biosolids under the "Solid Waste Media Recommendations" section. We think it is important to note that biosolids in Washington are not considered solid waste but rather required to be beneficially reused to the maximum extent possible under state regulations (Chapter 70A.226 RCW; Chapter 173-308 WAC). As noted in the plan, 85 percent of biosolids are beneficially used as soil amendments in Washington state. The beneficial reuse of biosolids replenishes nutrients in the soil, contributes to carbon sequestration, and provides a cost-effective fertilizer source for local farmers.

While the vast majority of biosolids are recycled, biosolids are only applied to a very small amount of Washington land – less than a quarter of one percent of agricultural acreage receives biosolids. Therefore, focusing on biosolids alone will not completely address phthalates contamination and exposure pathways in Washington's agricultural lands. Potential sources of phthalates in commercial fertilizers, pesticides, and other products will need to also be investigated to fully understand the extent of phthalates contamination in agricultural soil.

Addressing agriculture-related phthalates exposure in a broader context will keep in perspective the relatively small role that biosolids plays in statewide agricultural practices, while also acknowledging the importance of beneficial reuse as an environmentally sustainable, cost-effective means of managing this valuable resource.

3. We support further research and investigation as needed to develop science-based policies and regulations regarding phthalates.

We agree that more information is needed regarding phthalates in wastewater and biosolids, including the fate and transport of these chemicals through the treatment process, and the potential for crop uptake from contaminated soil. We support Ecology's efforts to investigate these topics and encourage the use of existing data and studies to inform future research, as well as partnering with academic institutions and other organizations who are also working to advance understanding of these issues. The Alliance is also willing to participate in Ecology studies to provide samples or data as needed to further these investigative efforts.

Thank you again for the opportunity to comment and for Ecology's leadership to address this important issue. As a public clean water utility, our goals are aligned with Ecology's to protect human and environmental health, and we support efforts aimed at reducing and restricting phthalate uses and sources in our state. If you have any questions regarding these comments, please contact me at jpeterson@crwwd.com or 360-993-8819.

Sincerely, John Peterson, P.E

Executive Director Discovery Clean Water Alliance

FOOD Northwest

June 13, 2023

Washington Department of Ecology Submitted online

RE: Draft Phthalates Action Plan

Food Northwest appreciates this opportunity to comment on the Draft Phthalates Action Plan. Established in 1914, Food Northwest is a trade association of food manufacturers in Washington, Oregon, and Idaho. Many of our members have facilities in Washington, and most of our members sell product in/into the state of Washington. We share the state's goal to protect and improve the environment and to reduce or eliminate exposures to scientifically demonstrated hazardous chemicals.

Food Northwest requests participation on the *Food Articles, Recommendation #1* workgroup charged with reducing the sources of phthalates in food and beverages and on the *Recycling Products and Packaging, Recommendation #2* workgroup that will establish voluntary reporting and labeling protocols.

The Action Plan proposes that a major source of human exposure to phthalates is dietary via migration to food from food contact articles such as processing equipment and packaging. The Food and Drug Administration regulates food contact articles, and the Action Plan recognizes that FDA is working to fill data gaps on the phthalates currently authorized for use. Food Northwest urges the departments of Ecology and Health to coordinate with the FDA as it assesses current food contact uses, use levels, dietary exposure, and safety levels.

Food Northwest looks forward to participating in Action Plan activities.

Thank you,

Pamela T. Barrow

Pamela Barrow Vice President



Friends of Miller Peninsula State Park/PO Box 2664/Sequim WA/98382

13 June 2023

Hazardous Waste and Toxics Reduction Program P.O. Box 47600 Olympia, WA 98504-7600 Phone: 360-407-6700

RE: Publication number 23-04-025

Friends of Miller Peninsula State Park, a federally recognized non-profit formed in 1990, submits the following comments.

We applaud the WA State Department of Ecology for moving forward on this very important matter. Sadly, like so many other chemicals, phthalates have been allowed to be marketed through so many products, including soaps, dryer sheets, perfumes, shampoos, hair dyes, perfumed packets inserted in hair dryers, air fresheners, surface cleaners, cleaning products, and PVC building products including vinyl flooring. These then have polluted air, soil, food, the marine ecosystem, impacting the health of humans and wildlife. Phthalates have rightly earned the nickname, the "everywhere contaminant."

We are pleased to see Ecology will approach phthalates by class, rather than individual chemicals. Your finely detailed document shows the ubiquity of this chemical, the cumulative impacts, the impossibility of the public to avoid exposure, leading to the conclusion that the timeline for regulations should be advanced. Indeed, it seems to us that the state should use its legal and regulatory powers to end the uses of phthalates where safer alternatives currently exist for consumer products.

Many of your report's recommendations address the hazard posed by phthalates in products and purchaser education or swapping out individual products. While important, these individual or "downstream" measures are burdensome and the least effective way to reduce people's exposure to toxic chemicals. Hence, in addition to ending unnecessary uses of phthalates, manufacturers must be required to label their products that have phthalates – a warning label that names this toxin *and* its health impacts.

The procurement measures outlined in the plan are an actionable step to shift market availability and build demand. Ecology should leverage existing resources that can facilitate the state purchasing of less-toxic building materials, including phthalate-free materials. Procurement guidelines should avoid other toxins like flame retardants, dioxins and formaldehyde.

We urge Ecology to commit to a more ambitious timeline to complete its work (sooner than three years) and put in place regulations that will more quickly advance the state's handling of this toxic contaminant.

Data collection - Ecology outlines many data collection steps to monitor phthalate levels in the environment. These studies should be designed to assess other hazardous chemicals at the same time, to build our understanding of people's exposures to a complex array of avoidable chemicals in air, water, soil and food crops.

Phthalate wastes – Like all persistent contaminants, phthalates pose a burden in the waste stream. A deep concern is the impacts of sewage disposal, including the sale of commercial compost derived from sludge that contains contaminants or pathogens. Without doubt, sewage residuals host toxic ingredients, including phthalates.

For a few years, Ecology has promised a map of locations where sewage wastes are spread. Supposedly a staff person was working on it. This information has not been forthcoming. It is important that the scientists, advocates and the public have this information to figure out if there are burdens to communities living near these disposal sites, including threats to drinking water.

We would encourage your citations to include those of Dr. Anne Steinemann. Dr. Steinemann, while at the University of Washington, helped to initiate research on phthalates. She has taught at several universities within the United States and in other countries, and the James Cook University, Australia. She now serves as Honorary Professor of Civil Engineering at both universities and serves as adviser to governments and industries around the world. She could advise on your agency's phthalates studies, if willing.

Her most current publications can be found here: <u>https://www.drsteinemann.com/publications.html</u>

Anne Steinemann's work

The fragranced products phenomenon: air quality and health, science and policy

- Open Access
- Published: 19 September 2020

The fragranced products phenomenon: air quality and health, science and policy

• <u>Anne Steinemann</u> <u>Air Quality, Atmosphere & Health</u> volume 14, pages 235–243 (2021

https://www.drsteinemann.com/publications.html

Fragranced Consumer Products: Emissions, Exposures, Effects

A collection of 17 sole-authored journal articles by Dr. Anne Steinemann

Please keep us informed as this plan moves forward.

Darlene Schanfald, Ph.D. Chair

Toxic-Free Future

No message. See attached letter.



June 15, 2023

Kimberly Grieves Department of Ecology Hazardous Waste & Toxics Reduction Program

Dear Kimberly:

Thank you for the opportunity to comment on the draft Phthalate Action Plan. The plan is states:

"We need to reduce sources and eliminate exposure pathways. To address this need, the Washington State Department of Ecology (Ecology) and Department of Health (Health) developed our first action plan (AP). The recommendations in this plan will help us strengthen our efforts to protect human health and the environment from the impacts of phthalates in Washington state."

We couldn't agree more that sources need to be reduced. The plan does an excellent job of documenting the scientific evidence on the serious health and environmental concerns posed by these chemicals widely used as plasticizers in PVC (vinyl) plastic and as solvents in fragrances and other products. The plan also does a good job at identifying major sources of phthalates. Unfortunately, the plan falls short on its recommendations to tackle the problem.

Phthalates in Products

The plan identified major product categories as sources of phthalates, including cleaning products, textiles and apparel, packaging, automotive products, building materials, medical devices, food contact materials, and other PVC products. A new law on cosmetics in personal care products has just been adopted to ban all phthalates in cosmetics and personal care products, so this category has been addressed.

Since phthalates are already listed as priority chemicals under Safer Products for Washington, Ecology and Health have tremendous opportunities to take action to address these product sources. The action plan should make clear recommendations on how these sources can be addressed using Safer Products for Washington.

For phthalates used as solvents, the plan should recommend that solvents be identified as a priority product for phthalates under Safer Products for Washington.



To address phthalates used as plasticizers, the plan should clearly recommend that Ecology address PVC under Safer Products for Washington. The program's draft list of priority chemicals for Cycle 2 includes brominated and/or chlorinated compounds, and the agency could identify PVC products as priority products in this cycle, addressing both phthalates and a highly problematic polymer. As exemplified by the toxic hazards released in February's train derailment in Ohio, PVC production and use creates unacceptable hazards in the production, use, and disposal phases of its life cycle. Our own research, detailed in Toxic-Free Future's April 2023 report, <u>PVC Poison Plastic</u>, found that 19 vinyl chloride and PVC plants currently operate in the United States and have reported yearly releases of the carcinogen vinyl chloride of more than 400,000 pounds. They have also reported transfer of tens of millions of pounds of chlorinated waste to incinerators and landfills. Some communities are bearing a larger portion of this toxic burden than others: these manufacturing facilities and disposal sites are located disproportionately in communities with higher percentages of low-income residents and people of color.

Once brominated and/or chlorinated compounds are listed as priority chemicals, the Safer Products for WA process should then identify certain building materials, packaging, textiles and apparel, food-contact materials, and other PVC products as priority products for bans and restrictions. With the vast quantities of PVC use going into building materials such as flooring, wall coverings, roofing membrane, windows, pipes and others, Ecology should place significant focus on this product category.

Swapping Out Phthalates in Durable Products

We were pleased to see the recommendation to use Ecology's Product Replacement Program to swap out durable products in childcare facilities that contain phthalates, such as vinyl flooring. This is a good way to reduce exposures for a vulnerable population, children. We have two suggestions related to this recommendation. One, the plan should clarify that a safer substitute for vinyl flooring will be used for these replacements. Two, the Product Replacement Program could have a large impact in affordable housing by providing funds to swap out vinyl flooring in existing buildings and/or provide financial assistance in the housing development phase to install safer alternatives to vinyl for flooring in new buildings.

Building Materials

There are other opportunities for the agency to address building materials, particularly in affordable housing. The Evergreen Sustainable Development Standard, which is a Dept. of Commerce standard for all affordable housing built with the state housing trust fund, is regularly updated. Ecology should work with Commerce to include a requirement for certain materials used in building projects to have a <u>Health Product Declaration</u>, which includes ingredient information and their associated hazards. Without information like this, contractors and builders cannot know if there are phthalates or other high priority chemicals in the



products they are using, such as sealants. In addition, Ecology should work with Commerce to update the standard to include mandatory requirements for eliminating use of other products that may contain phthalates.

Thank you for your work to reduce the sources of phthalate exposure and for considering our comments.

Sincerely,

Erika Schreder



Washington Association of Sewer & Water Districts

The Washington Association of Sewer and Water Districts (WASWD) appreciates the opportunity to comment on the proposed Phthalates Action Plan. WASWD represents more than 180 public sewer and water districts in the state, serving nearly 25% of our state's population. These districts provide cost-effective sewer and water services ranging from the state's largest population centers, to the smallest rural communities. Clean water is a major concern to both our membership and the clients they serve. The potential for contamination is always a concern, especially since, beyond our wellheads and collection points, we have no control over what is sprayed, injected, discharged or built proximal to our facilities.

In reviewing the plan, we are disturbed by some of the language contained in the Biosolids section. In this section, conclusive statements are shortly followed by statements about available science that casts uncertainty on preceding and subsequent conclusive statements. Starting on page 65, the first sentence states "Biosolids from composting and wastewater treatment plants (WWTPs) can serve as continued sources of phthalate emissions into the environment and pose a risk to human health." This very definitive statement is followed by another at the end of the same paragraph, stating "Scientists have not conducted studies characterizing the lifecycle of phthalates through the WWTP process, the land application of biosolids, uptake into crops, or composted biosolids in Washington state." This is followed by "However, it is possible that biosolids contain phthalates resulting from pre-WWTP sources (King County, 2021)." A little later in the section is the statement "Phthalates will biodegrade in WWTPs, and biodegradation rates are dependent on treatment conditions, such as oxygen levels, microorganisms, and temperature." These statements taken together (with emphasis added) really indicate that the state of the science and risk to human health from biosolids potentially containing phthalates is not well established. That renders the first sentence speculative and unsupported by facts, and it should be removed completely as it is alarmist and inaccurate.

In general, there is really no proper context for land application of biosolids presented in this document. There needs to be a lot more attention paid to the magnitude of the problem related to their manufacture. If there were less phthalates produced and used, there would be less in biosolids. Biosolids are applied to less than .01% of agricultural lands in any year, thus the magnitude of the problem of phthalates in biosolids is miniscule compared to exposure via everyday activities at work and in the home. The plan overall gives other sources of phthalates and needs to be sure that biosolids is presented in context, conveying the appropriate magnitude of the impact of phthalates from biosolids. In looking at the paragraph above, this section needs to be reworked, and alarmist language removed.

There is also a need to broaden the scope of phthalates as they may appear in agriculture, not just land-applied biosolids. The potential for phthalates to be associated with seeds, fertilizers, and pesticides are very real, depending on coatings, application methods and storage of these items. Irrigation water should also be examined. As with PFAS and PCB compounds, it has been surprising where these have been found once you look for them.

The proposed recommendations related to biosolids get down to the crux of the matter in calling for more studies on transport and breakdown, partitioning to water and soil, evaluating plant uptake, and evaluating fate of compounds in composted biosolids. We agree with these recommendations. More studies are needed before making the conclusive statements currently in the document.

The section on Drinking Water is a testament to the hard-working professionals in the water treatment business, with sampling for certain phthalates since 1993 indicating no confirmed MCL violations for phthalates in public drinking water sources. We agree with the recommendations to keep monitoring in compliance with EPA and DOH standards, and for education on proper sampling to avoid inadvertent contamination. We also agree with the three year review of recommendations and implementation. This can provide an update on necessary studies, and will provide feedback on the impact of programs like medical equipment change-out, personal care product formulation changes, food packaging changes and replacement of the myriad other products containing phthalates.

Thank you for your attention to these comments.



Washington Association of Sewer & Water Districts EDUCATE = ADVOCATE = COLLABORATE

June 14, 2023 Department of Ecology <u>Ecology's Phthalates Action Plan (commentinput.com)</u>

RE: Comments on Phthalates Action Plan

The Washington Association of Sewer and Water Districts (WASWD) appreciates the opportunity to comment on the proposed Phthalates Action Plan. WASWD represents more than 180 public sewer and water districts in the state, serving nearly 25% of our state's population. These districts provide cost-effective sewer and water services—ranging from the state's largest population centers, to the smallest rural communities. Clean water is a major concern to both our membership and the clients they serve. The potential for contamination is always a concern, especially since, beyond our wellheads and collection points, we have no control over what is sprayed, injected, discharged or built proximal to our facilities.

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June 14, 2023 Phtalates Action Plan Comments Page 2 of 2

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There is also a need to broaden the scope of phthalates as they may appear in agriculture, not just land-applied biosolids. The potential for phthalates to be associated with seeds, fertilizers, and pesticides are very real, depending on coatings, application methods and storage of these items. Irrigation water should also be examined. As with PFAS and PCB compounds, it has been surprising where these have been found once you look for them.

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Thank you for your attention to these comments.

Sincerely,

Judi Hadstone

Judi Gladstone Executive Director


WASHINGTON REFUSE & RECYCLING ASSOCIATION

June 14, 2023

Department of Ecology 300 Desmond Drive SE Lacey, WA 98503

To Whom it May Concern:

The Washington Refuse and Recycling Association (WRRA) is the oldest Solid Waste Trade Association operating on the West Coast of the United States, founded 76 years ago. WRRA represents the private sector solid waste and real recycling industry in Washington, from curbside collection service and state of the art recycling facilities to landfills. WRRA member companies and the solid waste industry serve a vital role in public health, safety, and environmental protection.

Our members provide essential services in their communities every day. Washington's solid waste system is a successful public-private partnership. Washington's regulated and municipal solid waste collection system provides for excellent service, has consistently beat the national recycling rate by double digits, and maintains family wage jobs in every community in which we operate— all at a transparent and affordable price. We have an obligation to serve and to provide universal service as directed by the state and local governments.

Thank you for the opportunity to comment on the Draft Phthalates Chemical Action Plan (CAP). WRRA is supportive of the department's efforts to measure and reduce phthalate exposure. WRRA members that own and operate recycling facilities, compost facilities, or landfills in Washington may also comment on the draft plan.

The Waste Industry Does Not Manufacture Phthalate Containing Products

WRRA members and their operations neither manufacture nor use phthalates or phthalate containing products. WRRA members receive waste containing phthalates from the communities and industries they serve. The most effective way to manage phthalates in the environment is to reduce the presence of phthalates in products in the first place. Upstream reductions targeted at the producers of phthalates containing products will always be the most effective means to reduce public exposure to phthalates.

Initiatives that help phthalate-intensive industries reduce use of these chemicals are the most effective means of reducing phthalates in the waste stream. Crucially, state policy must be grounded in an understanding that phthalates cannot be eliminated from the waste stream unless producers eliminate them from their products and packaging. Phthalates will persist in landfill leachate, recycled products, and compost as long as significant sources of phthalates are present in the waste stream, such as food packaging, construction materials, household products, manufacturing byproducts, and other goods.

Focus Upstream on Producers of Phthalates

Any plan for the management and reduction of phthalates must also address exposure to phthalates and management of phthalate containing waste. Landfills receive phthalates in various wastes, but this does not equate to public exposure. Members of the public are exposed to phthalates at a much higher frequency through the products they purchase. State of the art lined and heavily regulated landfills, like those operated by WRRA members, play a role in sequestering and limiting public exposure to phthalate containing products at their end of life. The waste disposal industry is an obvious partner in developing sound recommendations for the management of phthalates in the long-term.

Recycling facilities, or Material Recovery Facilities (MRFs) accept recyclable materials from curbside recycling programs across the state on a daily basis. At Washington's MRFs, those recyclables go through a process called mechanical recycling, which separates curbside recyclables into bales of individual commodity streams. Mechanical recycling does not change the chemical composition of materials and phthalates present in material entering a MRF will typically be present, unchanged, in bales that exit the MRF.

For Compost, WRRA supports the recommendation to develop and implement a plan to evaluate compostable containers and service wear for phthalates. Phthalates will always be present in any waste that contains phthalates containing products. The Department should look upstream to the producers of phthalate containing products to reduce the presence of these materials in the waste stream.

Conclusion

Thank you for the opportunity to comment on this important topic and developing the plan in conjunction with a stakeholder group that included representation from the solid waste industry. Please direct any questions or comments to Rod Whittaker at rod@wrra.org. Thank you for the opportunity to comment.

Respectfully submitted,

Bear R Lovers

Brad R. Lovaas Executive Director

Washington State Potato Commission

We are requesting representation on the workgroup charged with reducing the sources of phthalates in food and beverages through technical assistance, education, and voluntary actions in food production and food service in Washington (Food Contact Articles, Recommendation 1). We also request representation on the workgroup to establish voluntary reporting and labeling protocols to identify packaging that contain phthalates (Recycling Products and Packaging, Recommendation 2).

Zero Waste Washington

We are disappointed that all of the recommended actions are voluntary or research-orireinted. We would like to see some actions that would directly lead to restrictions, bans and other actions that would make meaningful reductions in phthalates use soon. There are enough studies already, as is shown in the summarized information in the action plan, that demonstrate that we need to eliminate phthalate exposures to human and wildlife now. Each action should have an action outcome, rather than a drawn-out study-oriented outcome. For example, labeling of products should be mandated, not through a voluntary workgroup process.

There are steps that Ecology and other state agencies can do now, such as update state procurement contracts to restrict the purchase of products with phthalates, not just provide guidance. This would serve as a model for other contracts and institutions. And state building projects (page 62) should be mandated to use phthalate-free products if they are available as alternatives as building and construction materials.

The action plan should include timelines. And also the plan should prioritize the recommendations in order of impact, i.e., starting with those which would make the biggest difference for human and wildlife health.

Thank you, Heather Trim Zero Waste Washington

CarolLee Braithwait

As a retired special education teacher, developmental difficulties are very real to me. I am aghast that no more progress has been made in getting this horrible compound out of our food supply. And by food supply, I mean anything that can conceivably end up inadvertently being consumed. If this stuff is "outgassing". from flooring, babies end up consuming it.

We've gotten lead out of paint; let's get phthalates out of our environment.

Wendy Ferrell

I am very concerned about the plastic gear used by aquaculture companies in Puget Sound. They cover the tideflats with gigantic sheets of netting, along with plastic bags, that show up on shorelines as debris. They also drill millions of PVC pipes into the substrate to protect their shellfish. Aquaculture does not need to use these new (plastic) methods right in our fragile waters and seabed. Degradation of this gear over time and the seeping of micro plastics into Puget Sound is shocking. They need to go back to the old ways and methods of aquaculture that were successful and kinder to the environment without all the modern gear and plastic.