

## Preliminary Action Plan Scope for Advisory Committee Review

### Overview: What this scope document contains

This document proposes topic areas that the Washington Departments of Ecology and Health Phthalates Action Plan team (“we”) will further investigate when developing the action plan. The document does not provide a complete outline of all sections that will be in the final action plan. It primarily focuses on the sources of phthalates that we prioritized during the scoping process. We constructed this scope document based in part on input we received during the Phthalates Action Plan advisory committee meetings held between February 17 and March 24, 2022. Including specific subjects in the scope does not necessarily imply we will include a recommendation in the final plan.<sup>1</sup>

If you have questions or concerns, please contact the Phthalates Action Plan team at [ChemActionPlans@ecy.wa.gov](mailto:ChemActionPlans@ecy.wa.gov).

### Next steps: How we will use this scope document

The scope identifies topic areas that we will further investigate and prioritize for recommendations as we develop the plan. Our action plan team will prioritize recommendations for action with a focus on **pollution prevention** and by considering the following:

- Feasibility (such as ease of implementation, availability of safer alternatives)
- Volume of phthalate use or release
- Potential for reducing human exposure
- Potential for reducing environmental contamination
- Potential for reducing disproportionate impacts
  - Sensitive populations
  - Sensitive species

We will investigate subjects included in the scope, using sources of information such as government reports and peer-reviewed literature—including those sources the advisory committee suggests. The quality of available information on each scope subject will help inform the recommendations for action. Below are examples of how information quality may inform how we develop recommendations.

For scope areas with **more comprehensive** information available, recommendations could include:

- Taking action under an existing program (like Safer Products for Washington or the Children’s Safe Products Act)
- Requesting additional funding for existing programs, or funding new projects or proposals
- Conducting outreach activities (such as providing information for voluntary use reduction)
- Taking no action

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<sup>1</sup> This project has been funded wholly or in part by the U.S. Environmental Protection Agency (EPA) under assistance agreement PC-01J18101 to the Washington Department of Ecology. The contents of this document do not necessarily reflect the views and policies of the EPA, nor does mention of trade names or commercial products constitute endorsement or recommendation for use.

For scope areas with **less comprehensive** information available, recommendations could include:

- Considering action under an existing program (like Safer Products for Washington or the Children’s Safe Products Act)
- Conducting outreach activities (such as providing information for voluntary use reduction)
- Gathering information to fill remaining data gaps (for example, through additional monitoring or product testing)

For scope areas with **limited** information available, but with significant interest from stakeholders, recommendations could include:

- Developing a plan to investigate
- Gathering information to fill remaining data gaps (for example, through additional monitoring or product testing)

## Phthalates Overview

The action plan will provide a general overview of the phthalates chemical class. A summary of the key uses and releases will highlight not only those that lead to potential human exposure and environmental contamination in Washington but also those that we prioritized during scoping discussions. Below are examples of the types of information we plan to include. We will expand these sections in the action plan.

We have two central goals for the action plan:

- Develop and make actionable recommendations that will **reduce human exposure** and **reduce environmental contamination**—focusing on **source reduction**.
- Focus on the potential for exposure in **sensitive and overburdened populations**, and the potential for exposure in **sensitive species and habitats**.

## General chemical information

Phthalates as a chemical class are defined as “synthetic esters of phthalic acid,” based on their chemical structure. The National Library of Medicine (NLM) defines phthalic acid as “benzenedicarboxylic acid consisting of two carboxy groups at **ortho-** positions.” Based on this definition, **the action plan will focus on ortho-phthalates**. Any subsequent references to “phthalates” refer specifically to ortho-phthalates. The action plan will not develop recommendations for benzenedicarboxylic acid derivatives with two carboxy groups in meta- or para- configurations (i.e., isophthalates or terephthalates).

## Production, uses, and releases

Phthalates have several functional uses. Manufacturers mainly use them as plasticizers and solvents, although these are not strict categories and uses continually change.

- Phthalates used as plasticizers add flexibility to plastics, predominantly in polyvinyl chloride or vinyl. The phthalates used as plasticizers tend to be less volatile and have a higher molecular weight. Some notable applications include children’s toys, medical supplies, packaging, and building materials.

- Phthalates are used as solvents in many products, ranging from fragrances in personal care and cleaning products, to use in adhesives and sealants. Phthalates in these solvent applications are generally lower molecular weight phthalates, which are relatively more volatile and water soluble.

When added to materials in manufacturing, phthalates do not form strong chemical bonds. These chemicals can be released during all stages of the product lifecycle—from manufacture to use and disposal. There are over 25 different phthalates that are used commercially. Annual global production was approximately eight million metric tons in 2015.

### Existing policies and regulations

The action plan will identify relevant regulations and policies that apply to phthalates. This includes key federal regulations under the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Consumer Products Safety Commission (CPSC), as well as regulations from other U.S. states. For example, in Washington, the Children’s Safe Product Act (CSPA) (Chapter [70A.430](#) Revised Code of Washington [RCW]<sup>2</sup>) restricts six phthalates in children’s products. Further, the Pollution Prevention for Healthy People and Puget Sound Act designates phthalates as a priority chemical class, and the Safer Products for Washington program is currently developing restrictions to reduce phthalates in vinyl flooring and fragrances in personal care products under that statute ([70A.350](#) RCW<sup>3</sup>).

## Human Health and Environmental Impacts

### Human health impacts

The action plan team will base the background section addressing health impacts on available government reports and peer-reviewed literature covering human exposure routes and potential health effects related to phthalates. Limited primary literature reviews will address areas of emerging science to update the conclusions of past reports. We will pay particular attention to reports that identify groups of people who may experience disproportionate effects of phthalates due to:

- Higher exposure levels
- Greater sensitivity to exposure

Examples of resources include reports from U.S. EPA, CPSC, Centers for Disease Control and Prevention, National Toxicology Program, European Union authorities, Health Canada, and other state government agencies.

### Exposure routes

People can be exposed to phthalates by ingesting food and beverages, as well as dusts, that contain phthalates. Some phthalates are detected in the air—in both gas and particle-bound form—and can be inhaled. Contact with phthalates can result in uptake through the skin. Specialty uses of phthalates in medical devices can lead to direct systemic exposures.

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<sup>2</sup> <https://app.leg.wa.gov/rcw/default.aspx?cite=70A.430>

<sup>3</sup> <https://app.leg.wa.gov/rcw/default.aspx?cite=70A.350>

### Health effects

Health concerns for phthalates stem mostly from disruption of endocrine processes. Exposure can disrupt developmental, reproductive, and metabolic tissues and processes. Some phthalates are also linked to cancer, inflammation, and asthma. The action plan may consider the potential for cumulative effects of multiple phthalate exposures, and where relevant, exposure to other endocrine disrupting chemicals.

### Sensitive and more highly exposed populations

When it comes to phthalate exposure, populations we are concerned about include:

- People of reproductive age
- Developing fetuses, infants, and children
- People who are more exposed from their workplace, medical procedures, or from using certain consumer products

By reviewing epidemiology studies and urinary metabolite data in the National Health and Nutrition Examination Surveys, our goal is to identify groups experiencing disproportionate exposure to phthalates.

### Environmental impacts

To evaluate potential environmental impacts, including in biota, we will consider information on the presence of phthalates in the environment and pathways leading to environmental contamination. Information sources we identified during scoping include: assessments by U.S. EPA, European Chemicals Agency (ECHA), Health Canada, the Washington Environmental Information Monitoring System (EIM) database, and past environmental monitoring reports from Ecology.

### Fate, transport, and distribution in the environment

The action plan will consider how phthalates move from their original production and use in manufactured products into environmental media. Physical chemical properties determine the fate and transport of different phthalates between media (air, water, soil, and biota). Studies detect phthalates in air and often associate them with particulate matter and atmospheric deposition. More water soluble phthalates can partition into waters, while less soluble phthalates tend to partition to sediment. As part of the action plan, we are completing a sampling study covering an expanded list of 15 phthalates in surface waters and sediments. We will use the results to inform recommendations. The advisory committee suggested which environmental media are of interest—including air, stormwater, surface waters, and sediment.

### Biota

The advisory committee raised several concerns relating to aquatic and terrestrial biota, but many data gaps remain in this area. We have not yet prioritized specific species or habitats for action plan recommendations. Some committee members noted challenges with analytical methods that created unreliable results in past studies. We will continue reviewing information sources the committee provides and reports from authoritative sources to address biota as appropriate in the action plan.

## Sources of Human Exposure and Environmental Contamination

The sections below identify the sources and systems the action plan recommendations will prioritize. Note that the topic areas are broad. We will further define and investigate specific subjects as we work to identify actionable recommendations.

### Primary sources

#### Household consumer products

Manufacturers broadly use phthalates in household consumer products. The action plan will focus on these uses because they can directly contribute to potential human exposure. Regulatory measures in Washington under CSPA focus on children's products. Reporting through the High Priority Chemicals Data System (HPCDS) is required for 13 phthalates, when the phthalates are used in children's products. The action plan will explore whether additional recommendations are warranted in this area.

Phthalates used as a component of fragrances in personal care and beauty products are being addressed through the Safer Products for Washington program. However, the action plan could make recommendations for other uses. Some packaging materials contain phthalates, and the action plan will consider these products. Further, when people use or dispose of consumer products containing phthalates, these products can contribute to downstream environmental contamination.

Product categories the advisory committee suggested for further investigation include:

- Cleaning products
- Personal care and beauty products
- Packaging (nonfood)
- Children's products
- Other vinyl furnishings and products (shower curtains, bath mats, garden hoses, apparel)

#### Building products

Building products are another source of phthalates we will consider in the action plan. Manufacturers use phthalates in a variety of building products. These chemicals can migrate out of materials over time. Once released, they can adhere to atmospheric particles and eventually deposit onto surfaces, where they can contaminate stormwater and other downstream matrices, such as sediment.

Building materials provide a potential opportunity to reduce phthalates entering the environment. Some information on these uses is captured in resources such as Declare labels, Health Product Declarations, and the Pharos database. The advisory committee suggested the following building products to investigate for potential recommendations:

- Roofing and waterproofing materials
- Adhesives and sealants
- Other building products (coated metal, wall base, wall coverings, flexible pipes, and water lines)

#### Exterior use products

Studies detect phthalates in a variety of exterior use products—including signage materials, vehicle wraps, and traffic control items such as cones and thermoplastic pavement markings. Exterior use products can contribute to environmental contamination. These products could present an opportunity

for the action plan to recommend pollution prevention actions. The advisory committee noted that the following exterior use products are particularly relevant:

- Vinyl coated metals (fencing, benches)
- Traffic control
- Exterior coverings (vehicle wraps, awnings)

### Food production, processing, packaging, and food service

Epidemiological studies and authoritative reports conclude that the main source of phthalate exposure for most people is diet. Producers do not add phthalates to foods or beverages intentionally, but food monitoring studies detect phthalates in a wide variety of foodstuffs. Phthalates can enter the food supply at many points from farm to table, including during food production, processing, packaging, and serving.

Federal rules (Title 21 CFR) govern the amount of specific phthalates that can be used in various food contact materials. Limited phthalate levels are allowed in materials used in food contact items (such as resins, coatings, polymers, lubricants, and packaging materials). During scoping, we prioritized food contact materials used in agricultural operations and in factory food processing for further consideration. We will also investigate some packaging items.

### Medical applications

A number of items the U.S. FDA lists as medical devices can contain phthalates. FDA allows phthalate plasticizers to confer softness and flexibility on medical devices, including:

- Tubing used in medical procedures
- Bags for intravenous administration of blood and other fluids
- Various catheters

Many hospital systems implement programs to reduce use of phthalate-containing items in neonatal intensive care units. However, our scoping process identified opportunities to further reduce uses. In addition, the FDA regulates certain intimate care products as medical devices. Studies detecting phthalates in tampons and sanitary pads are published in peer-reviewed literature. Given the widespread exposure to intimate care items in women of reproductive age, we will focus on these items when developing recommendations in the plan.

### Automotive applications

Manufacturers use phthalates in various automotive applications. The advisory committee suggested these products as an area to consider for recommendations. Examples of automotive products the committee raised for follow-up include:

- Interior materials (molded plastic, upholstery, floor mats)
- Vehicle care products (washes, waxes, tire dressings)
- Vehicle fluids (oils, lubricants, hydraulic fluids)

## Pass-through systems

In pass-through systems, the presence of phthalates is not intentional, and results from use in primary sources (including those we note above). Monitoring phthalates in pass-through systems may help us understand not only changes in usage upstream but also the potential for downstream environmental impacts.

## Wastewater treatment plants

Studies detect phthalates in influent and effluent of wastewater treatment facilities, and their removal rates can vary due to seasonality. In Washington, there are hundreds of treatment plants with varying secondary or tertiary treatment processes. The advisory committee noted it would be most pertinent to reduce sources of phthalates upstream to reduce levels entering influent wastewater. The committee also suggested monitoring influent and effluent as a useful way to measure progress over time.

## Biosolids

Biosolids are an end result of wastewater treatment systems that provide people clean water. Ecology established a program, as directed by the Legislature, to manage biosolids as a beneficial commodity. Studies detect phthalates in biosolids, but there are no established regulatory standards for phthalates in biosolids. Biosolids are tested and treated before they are applied to agricultural land, and must meet pollutant limits, pathogen reduction, and other requirements. The advisory committee expressed concerns about residual phthalates in land-applied biosolids. We will explore how a monitoring study may help us better understand levels of phthalates in biosolids in Washington.

## Landfills

Phthalate-containing products are widespread in landfills. Most products with phthalates end up in solid waste landfills. The advisory committee mentioned unlined landfills in Washington as a potential source of phthalates to groundwater. Landfill leachate could be concerning if it contributes to environmental contamination, but it is not routinely monitored for phthalates.

## Recycling

Phthalates can be carried through the recycling system via a few channels. Household waste plastics collected for recycling may contain phthalates. Phthalates may originate in the plastic container—either during the manufacture of the container or through the absorption of products placed within the container. As recycled content increasingly replaces virgin plastic, the chance of phthalate transmission from the recycled materials grows.

Phthalates are not removed during mechanical recycling processes, and may be carried into new products using recycled content. Molecular recycling technologies that may remove chemical hitchhikers are in development and not yet commonly available. Manufacturers who use recycled content often do not know the phthalate content of recyclable material. The advisory committee indicated the need to address these issues in the context of a circular economy. We also will explore the potential for worker exposure at material recovery facilities.