

October 2023

» Toxic-Free Kids

A Report to the Governor and the Oregon Legislature



Oregon
Health
Authority

PUBLIC HEALTH DIVISION

Contents

» Executive summary	3
» Introduction	5
» Updates to the chemicals list	6
» Summary of reporting to date	8
» Summary of chemicals reported	10
» Potential for children's exposure to chemicals of concern	11
» Statutory changes from the 2023 Legislature	12
» Recommendations for reducing exposure to chemicals of concern and compliance challenges.....	14
» Completed and future rulemakings.....	15
» Exemptions from reporting requirements.....	17
» Waivers and Exemptions from Removal or Substitution Requirements.....	18
» Online reporting system	19
» Conclusion and future priorities.....	20

Executive summary

The Toxic-Free Kids Act (ORS 431A.250-431A.280) became law during the 2015 legislative session. This law directs the Oregon Health Authority (OHA) to:

- Keep a list of high-priority chemicals of concern for children's health (chemicals of concern), and
- Report on the presence of those chemicals in products intended for children aged 12 and under based on reports required from manufacturers of those products.

The law applies only to manufacturers with annual worldwide gross sales of \$5 million or more. In addition, the law calls for the eventual phase-out of the use of these chemicals in a subset of children's products.

As required by Senate Bill 478, OHA provides biennial reports to the Legislature on the status of the statute's implementation. The 2019 report to the legislature described OHA's:

- Adoption in the rule of additional chemicals of concern,
- Development of guidance for manufacturers seeking an exemption from reporting requirements, and
- Implementation of an interim reporting system.

The 2021 biennial report presented program accomplishments in the subsequent two years, including:

- 2019 establishment of a multistate reporting data system allowing manufacturers to satisfy reporting requirements of multiple state programs beginning with the January 2020 biennial reporting period,
- March 2021 rules for the removal or substitution of chemicals from certain children's products including a process for waiving the requirement to remove the chemicals, and
- Rulemaking in Fall 2021 resulted in a second update since the law's passage of the list of chemicals of concern for children's health. This became effective on January 1, 2022.

Development of the chemical removal or substitution rules was the third and final major phase of the Toxic-Free Kids program development, and the most technically challenging. OHA has implemented all procedures needed for manufacturers to comply with technical requirements of chemical removal and substitution.

This 2023 biennial report summarizes activities accomplished since the last report, which include:

- Establishment of the September 2021 temporary rule clarifying how concentrations of chemicals of concern are to be calculated for Biennial Notices, which was made permanent in January 2022,

- Development of enforcement protocols and procedures,
- Expansion of [Frequently Asked Questions \(FAQ\) section](#) on TFK's webpages, which was in response to questions from manufacturers around the world, and
- Review of waiver and exemption requests from notice requirement from manufacturers prior to the January 1, 2022 Biennial Notice due date.

The Act also directs OHA to make recommendations for ways to further reduce children's exposure to chemicals of concern. Recommendations made in 2021 include:

- Amending the law to allow Oregon to align its chemical list with Washington's, and
- The requirement of reporting using product names consumers see on store shelves.

HB 3043, which passed the 2023 Legislature, implements these recommendations. The statute also requires the following additional changes:

- OHA now has the authority to add classes and subclasses of chemicals of concern
- Hazard assessments approved for substitute chemicals or waivers are valid for three years, after which they must be resubmitted
- The Biennial Notice due date is now aligned with that of Washington's program, and
- Manufacturers submitting Quantitative Exposure Assessments sent in support of waiver requests may now demonstrate that chemicals of concern are inaccessible..

OHA's actions to date have focused on developing the foundational program elements to implement the Toxic-Free Kids Act, and the agency has met all statutory deadlines with robust participation by partners. The program's priorities ahead include:

- Focus on compliance and enforcement, both for reporting and to ensure manufacturers who have made three reports for products requiring removal or substitution (and don't have approved waivers or exemption requests) are no longer selling such children's products with reported chemicals of concern in Oregon
- Through rulemaking and outreach, incorporate changes required by HB 3043 into the program

Those changes will allow:

- » Consumers to be able to look up a child's product by product model and brand name and make informed purchasing decisions about children's products containing chemicals of concern
- » Manufacturers to have additional time after the busy holiday season to report their children's products to the program, which were sold or offered for sale in Oregon during the two-year reporting period
- » Alignment between the chemicals of concern lists for the Toxic Free Kids Act and Washington's Children's Safe Products Act (CSPA). This uniformity will reduce children's exposure to hazardous chemicals.

Introduction

The Oregon Legislature passed the Toxic-Free Kids Act (“the Act” or TFK), during the 2015 legislative session. The Act, codified in Oregon Revised Statutes 431A.250 - 431A.280, requires manufacturers of children’s products sold in Oregon to report products that contain one or more chemicals of concern for children’s health (chemicals of concern). Products that fall under this law include products marketed to or intended for children 12 years old and under. In addition, manufacturers must ultimately remove these chemicals, replace them with another chemical to make the product less hazardous, or seek a waiver from the removal requirement for a subset of reported products. The products subject to this additional requirement are: a children’s product intended to go in the mouth, a children’s cosmetic, or a product made or marketed to children under three years old. The Public Health Division of the Oregon Health Authority (OHA) manages the Toxic-Free Kids Program with one full-time staff and support from agency toxicologists and a manager.

ORS 431A.280 requires OHA to provide a biennial report to the Legislative Assembly in September of each odd-numbered year regarding revisions to the list of chemicals of concern for children’s health, the number of manufacturers in compliance with notice requirements, and the presence of chemicals in reported products. The Act also calls for information on the potential for exposure to the chemicals of concern in children’s products based on the number of children’s products sold or offered for sale, likely exposure routes and typical use patterns as well as recommendations to limit, reduce or prevent exposure to chemicals

of concern based on an analysis of the data collected. This report provides information on each of these elements. It also summarizes completed and current rulemakings, the reporting exemption process and the multistate reporting system for the program.

Additional key aspects of the TFK Program to report include:

- Manufacturers made 12,366 distinct reports of chemicals of concern in product components for the 2022 Biennial Notice Period. These components were reported as being in children’s products sold or offered for the sale in the state from 2020 through 2021. This is the most recent two-year period for which reporting is required. Of these, up to 30 percent, or approximately 3,800 reports, are subject to the requirement to remove or substitute chemicals or obtain a waiver by the third report for a product.
- So far, six manufacturers reported removal of chemicals of concern from previously reported children’s products or that they ceased to sell such products in Oregon after December 31, 2021, the last day of their third biennial notice period. As discussed in more detail below, OHA anticipates additional reports of chemical removal or cessation of sale in Oregon by the January 1, 2024 deadline.

Updates to the chemicals list

ORS 431A.280(1) requires OHA to report on revisions to the list of chemicals of concern for children's health. OHA convened a rule advisory committee (RAC) and conducted a rulemaking process in September 2021. The new rules, which took effect January 1, 2022, added five chemicals to the chemicals of concern list contained in Oregon Administrative Rule (OAR) 333-016-2020, listed in Table 1. Manufacturers are to report children's products that contain these chemicals of concern, which were sold or offered for sale in 2022 or 2023, on January 1, 2024.

Table 1

Chemicals currently proposed to be added	
1.	Dicyclohexyl phthalate
2.	Diisobutyl phthalate
3.	Ethylhexyl diphenyl phosphate
4.	Bisphenol F
5.	Chlorinated paraffins

OHA originally adopted the Washington's Department of Ecology's list of 66 chemicals of concern in 2015 as directed by the Act. The law as originally enacted stipulates that OHA may add up to five chemicals to the list every three years (ORS 431A.255(4)).

Washington does not have a similar restriction and has added many more chemicals to its list. As a result Washington currently includes 15 chemicals that are not on OHA's list. HB 3043 (2023), which was signed into law by Governor Tina Kotek, removes the limit on the number of chemicals OHA can add every three years. OHA will work to align its list with Washington's in the next review of Oregon's chemical of concern list in the Fall of 2024. The list is to be effective January 1, 2025.

For the five chemicals added to Oregon's list in 2022, OHA toxicologists used the same prioritized toxicity endpoints and exposure attributes as they did when adding chemicals in 2018. The prioritized toxicity endpoints are:

- Carcinogenicity
- Reproductive or developmental toxicity, and
- Endocrine disruption.

The prioritized exposure attributes are:

- Chemicals likely in products intended for children younger than three years old and three to 12 years old
- Chemicals known to leave markers in children's urine
- Chemicals persisting in the environment, and
- Chemicals found in dust in locations frequented by children.

This approach aligns with the approach used by Washington in adopting its original and updated lists. In addition to these criteria, for the chemical additions made in 2022, OHA reviewed manufacturers' reports of chemicals to the multistate reporting system used by both states, the High Priority Chemical Data System (HPCDS). This was done to ensure that the chemicals added, which meet the toxicity and exposure criteria above, are the chemicals of concern most frequently found in children's products. This allows alignment between similar state laws in the Northwest.

Summary of reporting to date

To date, OHA received reports from 192 manufacturers that produce children's products containing a chemical of concern and were sold or offered for sale in Oregon between 2017 and 2021. Manufacturers reported products in 277 product categories. A "product category" identifies items that serve a common purpose, are of a similar form and material and share the same set of attributes such as "toy truck, non-powered." The Act does not currently require reporting by brand name, model, or style. Starting January 31, 2026, manufacturers will be required to report at this level of detail as required by HB 3043 (2023).

Manufacturers made 12,366¹ distinct reports of chemicals in product components. The reports included:

- Type of product component
- The name of the chemical of concern in the component
- The function of the chemical in the final product
- The age group of a child for which the product is intended (0-3; 3-12; 0-12 years-old), and
- One of five categories of the chemical's concentration in the component.

Based on information submitted to date, approximately 70% of reports are for products only subject to the reporting requirement, while the remaining approximately 30% of reports are for products that may require removal or waiver after three Reporting Periods. Those are: products for children less than age three, intended to go in the mouth and children's cosmetics. This remaining proportion includes categories of products intended for children from birth to age twelve. Under provisions of the Act and rules currently in effect, OHA is unable to determine which portion of the 30% are actually intended for children ages 0-3. Starting in 2026, HB 3043 requires that children's products to be reported as they can be identified at a place of purchase. The capacity to identify product models intended for children ages 0-3 will allow OHA to address this data gap.

¹ Included are 198 component-level reports made by seven manufacturers directly to OHA per OAR 333-016-2060(8). These reports are not included in the HPCDS. OAR 333-016-2060(8) allows manufacturers who have previously reported categories of children's products, but have not made any changes to the reported chemical makeup of such products, to report directly to OHA.

Reporting for the January 1, 2022, due date was slightly less than what was reported for the 2018 reporting period (4,488 for 2022 compared to 4,731 for 2018), but significantly more than what was received for the 2020 reporting period (3,147). OHA initiated limited compliance efforts in 2022 to remind manufacturers of their obligation to report. With the majority of program development and rule adoption completed, OHA will have capacity to focus on compliance and enforcement. This will improve reporting in the coming biennium.

Six manufacturers reported either an across-the-board removal of chemicals of concern from previously reported children's products or a cessation of selling such products in Oregon. OHA is planning to engage in compliance efforts with remaining manufacturers who have made three reports for products requiring removal or substitution, and do not have waiver or exemption from removal/substitution requests approved by OHA. This is to ensure they are no longer selling such children's products with chemicals of concern in Oregon.

Summary of chemicals reported

OAR 431A.258 requires OHA to report on the amounts of chemicals of concern for children's health used in children's products, by product category, and the total number of and most frequently disclosed chemicals of concern used in children's products. Among the 12,366 component-level reports submitted, Table 2 displays the ten most frequently reported chemicals of concern.

Table 2

Rank	Chemical of Concern	Chemical Abstract Service No.
1.	Antimony and antimony compounds	7440-36-0
2.	Ethylene glycol	107-21-1
3.	Styrene	100-42-5
4.	Methyl ethyl ketone	78-93-3
5.	Cobalt and cobalt compounds	7440-48-4
6.	Toluene	108-88-3
7.	Ethylbenzene	100-41-4
8.	Di-2-ethylhexyl phthalate	117-8101
9.	Arsenic and arsenic compounds	7440-382
10.	Formaldehyde	50-00-0

Potential for children's exposure to chemicals of concern

ORS 431A.280 requires OHA to report on the potential for exposure to chemicals of concern in children's products based on the number of children's products sold or offered for sale, likely chemical exposure routes, and typical product use patterns.

Routes of potential exposure vary by product type, and likely include swallowing or mouthing; breathing in; or passage through the skin. Product use patterns vary greatly by product type. Although OHA is not able to report on exposure from any individual products, the changes implemented by HB 3043 (2023) to require reporting by brand name and product model will provide additional clarity on how many children's products that contain chemicals of concern are sold or offered for sale in Oregon. Together with the program's increased focus on compliance going forward as noted elsewhere in this report, we anticipate being able to identify the scale of how many of these products are in use in Oregon, and therefore the potential for children to be exposed to chemicals of concern in the future.

Statutory changes from the 2023 Legislature

OHA's 2022 Legislative Report recommended modifications to the Act to reconcile conflicting directives in the statute. HB 3043 (2023) modified the existing statute to address several of OHA's recommendations. Those are:

- **Conflict:** The 2015 Act allowed OHA to add five chemicals to the chemical of concern list every three years. This limited Oregon's ability to maintain consistency between OHA's list of chemicals of concern and Washington's list. This inconsistency requires manufacturers selling products in both states to meet differing reporting requirements. More importantly, this prevented the public from having access to information about chemicals of concern in children's products.
HB 3043's Resolution: Effective January 1, 2025, the limitation of adding only five chemicals of concern at a time will be removed. This will allow OHA to align its list with Washington's longer list, reduce children's exposures to a greater number of chemicals of concern, and set consistent reporting requirements for manufacturers selling children's products in Oregon and Washington.
- **Conflict:** The Act limits OHA's ability to make data on children's products containing chemicals of concern available and accessible to the public. Under current reporting requirements, consumers are unable to look up information about a specific product, including whether the product contains a chemical of concern, and make purchasing decisions that may reduce a child's exposure to the chemical. Under current rules, OHA cannot ensure information is accessible to people with a wider array of literacy levels and comprehension of chemical information.
HB 3043's Resolution: The bill requires manufacturers to report children's products containing chemicals of concern by brand name, product model and product category. The change allows consumers to identify children's products containing chemicals of concern at a place of purchase. This requirement applies to reports made on the January 2026 Biennial Notice due date and after.
- **Conflict:** The Act requires reporting in Oregon to occur every two years on January 1. This limits Oregon's ability to align the biennial reporting date with Washington's CSPA program of January 31st.
HB 3043's Resolution: The bill changes the Biennial Notice due date to January 31st of the year following the two-year Biennial Notice period, thus aligning it with the due date of annual reporting for Washington's CSPA. The change gives manufacturers additional time to report after the busy holiday season. This change is to be applicable to the January 2026 Biennial Notice due date and after.

In addition to program changes described above, HB 3043 (2023) made the following modifications to the Toxic Free Kids Program:

- Gives OHA the authority to add classes and subclasses of chemicals of concern.
- Establishes a three-year validity period for hazard assessments approved for substitute chemicals or waivers from the date of submission to OHA, after which they must be resubmitted.
- Allows manufacturers to demonstrate that chemicals of concern are inaccessible when submitting Quantitative Exposure Assessments sent in support of waiver requests.

Recommendations for reducing exposure to chemicals of concern and compliance challenges

ORS 431A.280 requires OHA to provide recommendations for ways to limit, reduce or prevent exposure to chemicals of concern based on an analysis of the data collected under the program. In this legislative report, OHA does not have new recommendations. The changes required by House Bill 3043 will address concerns presented to the Oregon Legislature in the 2021 report, but will take time to be implemented and have impact. Future legislative reports will discuss the effectiveness of the measures in HB 3043 (2023).

Completed and future rulemakings

Since the Act's passage in 2015 OHA has convened several Toxic-Free Kids rulemaking advisory committees (RACs). Each RAC allows the public and partners, including affected companies, to give input and suggestions during the development of new rules, including on their fiscal impact.

The RACs for the Toxic-Free Kids Act have included representatives from several large national and Oregon-based manufacturers and retailers of children's products, trade associations, advocates for child-toxics reduction, and representatives from state and local government agencies concerned with toxics reduction.

The following rulemakings have been completed:

- **Phase 1** (September 2015 – December 2015)
 - » Adopted High Priority Chemicals of Concern for Children's Health (chemicals of concern) list in rule effective December 29, 2015
 - » Adopted the same list in effect under Washington's similar law, as directed by statute
 - » Set forth criteria for updating the list
- **Phase 2** (April 2016 – December 2018)
 - » Established January 1, 2018 reporting deadline, information required for reporting and exemption requests, and penalties for noncompliance with the reporting requirement
 - » Adopted reporting requirements and exemption process in rules effective December 1, 2016 and February 1, 2017
 - » Updated list of chemicals of concern and clarified enforcement procedures effective January 1, 2019
- **Phase 3** (May 2019 – March 2021)
 - » Detailed requirements for removal, substitution, or waiver process for chemicals of concern from certain children's products (those intended for children younger than age three, intended to go in the mouth, or children's cosmetics) by January 1, 2022. Provides criteria and process for requesting exemption from removal or substitution of chemicals of concern.
 - » Modified previously established rules to clarify them.
 - » Most technically challenging phase of program development, unique nationally.
 - » COVID pandemic caused extended timeline for rule development and adoption.

- **Temporary Rule for Biennial Notifications** (August 2021)
 - » Makes clear how manufacturers calculate and report concentrations of chemicals of concern for reports due on or after January 1, 2022.
 - » Aligns with Washington's method.
- **Triennial Review of Chemicals of Concern List and Biennial Notification Rule** (September 2021 – December 2021)
 - » Five additional chemicals added to chemicals of concern list.
 - » Permanent rulemaking for Temporary Rule for Biennial Notification adopted August 2021.
 - » Both became effective January 1, 2022.

The following are known future rulemakings, including rules required to implement HB 3043. The timelines for rulemaking are tentative:

- **Phase 4** (October 2023 – January 2024)
 - » Revise rules for the triennial review of the Chemicals of Concern List per HB 3043.
 - » Limit duration of validity for hazard assessments to three years.
 - » Incorporate HPCCCH inaccessibility into Quantitative Exposure Assessment rules.
- **Phase 5** (September 2024 – January 2025)
 - » Triennial Review of Chemicals of Concern List.
 - » Incorporate Brand Name, Product Model criteria into Biennial Notification rules.
 - » Revise due date for biennial notices to January 31st of each applicable notice year.

Exemptions from reporting requirements

Certain children's products regulated by the Act may have one or more chemicals of concern present as a contaminant that is a byproduct of the manufacturing process, not because it was intentionally added. In such cases, the Act allows a manufacturer or trade association to seek an exemption from the Act's notice requirements per ORS 431A.258. Such exemption requests must be accompanied by a written manufacturing control plan (MCP) that describes how the manufacturer will minimize the contaminant in the product. If an exemption request is not approved for failure to meet the criteria in rule, a manufacturer may resubmit the request one time without paying an application fee (fees paid to technical consultants for review still apply). OHA developed a guidance document for the exemption process and MCPs with input from RAC members and states with established programs (Washington and Vermont).

House Bill 5027 (2017) authorized OHA to charge a fee for exemption requests, as well as a \$200/hour consultant fee paid to environmental engineering experts to perform technical evaluations of exemption requests.

Since the Program's inception, OHA received 15 exemption requests and approved 12. The remaining three requests were not approved for lack of sufficient information provided by the requestors. OHA has received no further exemption requests.

Waivers and Exemptions from Removal or Substitution Requirements

The Act requires that chemicals of concern in one or more subsets of children's products – those made for children under three years-old, intended to be mouthed or are children's cosmetics – be removed or substituted after three biennial notice periods.

ORS 431A.260 states that removal or substitution of chemicals of concern in these product types is not required if one or both of the following is approved by OHA:

- A waiver supported by an assessment conducted according to standards in rule that demonstrates a child will not be exposed to the chemical of concern, or
- An exemption from removal or substitution requirements request that is supported by documentation demonstrating that the product already meets criteria for one or more governmental or industry standard in rule.

Over the past two years, the Program has developed guidance documents to assist manufacturers in the preparation of these requests. Contracts with outside consultants to review these requests as permitted by the Act have been executed.

Going forward, the Program will prioritize enforcement of the removal or substitution of chemicals of concern requirement for products in one or more of the subsets above, which have been reported three times, but do not have an approved waiver or exemption from removal or substitution requirements request.

Online reporting system

ORS 431A,258 states that manufacturers (or trade associations working on their behalf) must provide biennial notice of regulated children's products containing chemicals of concern to OHA and that the resulting data must be searchable and accessible to the public. The Act did not set a deadline or provide funding for this system, but it did allow for biennial notices to the Interstate Chemicals Clearinghouse (IC2), instead of directly to OHA, and called for a multistate reporting system that allows manufacturers to report once and satisfy the requirements of multiple states with similar programs. IC2 is an association of 15 state and local government agencies that "promote a clean environment, healthy communities and a vital economy by use of safer chemicals and products."

In 2016, OHA secured an Environmental Protection Agency grant allowing OHA to contract with IC2 to develop the High Priority Chemicals Data System (HPCDS), which went live in early December 2019 and in time for the January 1, 2020, reporting due date. HPCDS includes a public-facing data portal to allow Oregonians to review data submitted by manufacturers. The multistate HPCDS is used by manufacturers to report children's products under Oregon's law, and Washington's Children's Safe Products Act. Reported data for both states may be reviewed at <https://hpcds.theic2.org/Search>. At OHA's request and with input of its staff, IC2 made available in 2022 an [HPCDS Search Guide](#) to assist Oregonians in searching reported data. The HPCDS is still expected to add reports under similar laws of Vermont and New York in the future. It appears likely that New York state and/or Vermont will contract with IC2 for database changes to implement their laws, including reporting by brand and model, in advance of Oregon's deadline for manufacturers to report brand and model information in January 2026. If for some reason those states do not move forward, OHA has time and fee revenue available to contract for that change independently.

Conclusion and future priorities

OHA's actions to date have focused on developing the foundational program elements to implement the Toxic-Free Kids Act, and the agency has met all statutory deadlines with robust participation by partners. The program's priorities ahead include:

- Focus on compliance and enforcement, both for reporting and to ensure manufacturers who have made three reports for products requiring removal or substitution and don't have approved waivers or exemption requests, are no longer selling such children's products with reported chemicals of concern in Oregon.
- Incorporate changes required by HB 3043 (2023) into the program through rulemaking and outreach.

Those changes will allow:

- » Consumers to be able to look up a child's product by product model and brand name and make informed purchasing decisions about children's products containing chemicals of concern;
- » Manufacturers to have additional time after the busy holiday season to report their children's products to the program, which were sold or offered for sale in Oregon during the two-year reporting period; and
- » Alignment between the chemicals of concern lists for the Toxic Free Kids Act and Washington's Children's Safe Products Act.



PUBLIC HEALTH DIVISION

Phone: 971-673-1222

Fax: 971-673-1299

You can get this document in other languages, large print, braille or a format you prefer free of charge. Contact the Toxic Free Kids Program at 971-673-0440 or toxicfreetoekids.program@odhs.oregon.gov. We accept all relay calls.