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>> Toxic-Free Kids

A Report to the Governor and
the Oregon Legislature



Oregon
Health
Authority
PUBLIC HEALTH DIVISION

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Executive summary

The Toxic-Free Kids Act (Senate Bill 478; ORS 431A.250) 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, 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 high-priority chemicals of concern for children’s health
- Development of guidance for manufacturers seeking an exemption from reporting requirements, and
- Implementation of an interim reporting system.

This 2021 biennial report presents program accomplishments in the two years since the last report, 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 high-priority 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 continues to work with partners to develop the procedures required to implement this phase of the Act effectively and efficiently.

The Act also directs OHA to make recommendations for ways to further reduce children’s exposure to chemicals of concern. Recommendations 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.

Introduction

The Oregon Legislature passed the Toxic-Free Kids Act (“the Act” or TFK), during the 2015 legislative session. The Act, incorporated at Oregon Revised Statutes 431A.250, requires manufacturers of children’s products sold in Oregon to report products that contain one or more high-priority chemicals of concern for children’s health (chemicals of concern). In addition, manufacturers must ultimately remove these chemicals, replace them with another chemical to make the product less hazardous, or seek a waiver if the chemical is in a children’s product that is intended to go in the mouth, a children’s cosmetic, or is made or marketed to children under three years old. Products that fall under this law include products marketed to or intended for children 12 years old and under. 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 7,759 distinct reports of chemicals of concern in product components sold in the state from 2017 to 2019. Of these, 22 percent, or approximately 1,700 components, are subject to the requirement to remove or substitute chemicals or obtain a waiver by January 2022.
- Fewer manufacturers reported by the second biennial reporting date (January 1, 2020) than the law’s initial 2018 biennial reporting deadline. OHA undertook compliance efforts that increased reporting. However, COVID pandemic-related shutdowns and layoffs by manufacturers still affected compliance with reporting.

- So far, five manufacturers reported removal of chemicals of concern from previously reported children's products or from ceasing to sell such products in Oregon, with more anticipated by the January 1, 2022 deadline.

Updates to the chemicals list

ORS 431A.280(1) requires OHA to report on revisions to the list of high-priority chemicals of concern for children's health. OHA convened a rule advisory committee (RAC) in September 2021 and is currently conducting a rulemaking process with the adopted rules to be effective January 1, 2022. OHA is proposing to add five chemicals from the high-priority chemical list contained in Oregon Administrative Rule (OAR) 333-016-2020, listed in Table 1.

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 Washington's Department of Ecology's list of 66 chemicals of concern in 2015 as directed by the Act. The law 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. For the five chemicals currently proposed to be added to Oregon's list, 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 current 2021 proposed chemical additions, OHA reviewed manufacturers' reports of chemicals to the multistate reporting system used by both states, the High Priority Chemical Data System (HPCDS). OHA is proposing to add chemicals most frequently reported to HPCDS under Washington's law that is not on OHA's list that also meets the toxicity and exposure criteria above.

Summary of reporting to date

To date, OHA received reports from 161 manufacturers that produce children's products containing a chemical of concern and were sold or offered for sale in Oregon in 2017 through 2019. Manufacturers reported products in 244 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 require reporting by brand name, model, or style.

Manufacturers made 7,759¹ 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 76% of reports are for products only subject to the reporting requirement, while the remaining approximately 24% of reports are for products requiring removal or waiver by January 2022 (products for children less than age three, intended to go in the mouth and children's cosmetics).

Reporting for the January 1, 2020, due date was less than that received for the 2018 due date (3,032 for 2020 compared to 4,727 for 2018). OHA initiated compliance efforts in Spring and Summer 2020 to remind manufacturers of their obligation to report. Unfortunately, these efforts coincided with COVID pandemic-induced workplace shutdowns worldwide. Several manufacturers reported furloughs of the staff responsible for reporting. OHA's compliance efforts brought the proportion of component-level reports made for the 2020 due date to 61% of those reported for the initial one of January 2018.

As of September 30, 2021, five manufacturers reported either an across-the-board removal of high-priority chemicals from previously reported children's products or a cessation of selling such products in Oregon in 2018 and 2019. We anticipate these actions from other manufacturers that previously reported children's products containing chemicals of concern by the January 1, 2022 deadline.

¹ Included are 192 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.

Summary of chemicals reported

The Act requires OHA to report on the amounts of high-priority 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 7,759 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.	Methyl ethyl ketone	78-93-3
4.	Styrene	100-42-5
5.	Cobalt and cobalt compounds	7440-48-4
6.	Ethylbenzene	100-41-4
7.	Toluene	108-88-3
8.	Formaldehyde	50-00-0
9.	Di-2-ethylhexyl phthalate	117-81-7
10.	Arsenic and arsenic compounds	7440-38-2

Potential for children's exposure to chemicals of concern

The Act asks 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. Currently, OHA is not able to determine children's potential for exposure to chemicals of concern in these products because the Act does not require manufacturers to report the exact amount of the chemical in the children's product. Instead, it requires reporting the amounts of a chemical with a range of concentrations. Information on exposure routes and use patterns are also currently not required to be reported. All this information would be required to evaluate the potential for chemical exposure.

In the next phase of the program, manufacturers will be required to remove or substitute chemicals of concern from a subset of reported products (products that are intended to go in the mouth, children's cosmetics, or intended for children under three years of age). The assessments required in this phase of the program may yield data that allow OHA to evaluate potential chemical exposures from some children's products sold in Oregon. Rulemaking for this last phase of program development:

- Commenced in May 2019
- Concluded in Spring 2021, and
- Was in advance of a January 1, 2022 statutory deadline for manufacturers to substitute or remove the chemicals of concern from targeted products or obtain a waiver.

Recommendations for reducing exposure to chemicals of concern and compliance challenges

The Act calls on 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. Data submitted to date do not support the formulation of such recommendations. As noted above regarding evaluating the potential for children's exposure to chemicals of concern, information OHA receives in the next phase of program implementation (chemical removal, substitution, or waiver) may provide data to support the development of recommendations.

However, based on OHA's experience to date implementing the Toxic-Free Kids Act, OHA can recommend modifications to the Act to reconcile conflicting directives in the Act. The conflicts and recommended changes, which in two cases have the potential to reduce children's exposure to chemicals of concern, include:

- **Conflict:** The Act limits Oregon's ability to maintain consistency between OHA's list of chemicals of concern and Washington's list, thus limiting Oregon's ability to reduce or eliminate children's exposure to chemicals of concern and requires manufacturers selling products in both states to meet differing reporting requirements.
- **Recommendation:** Remove the limitation allowing OHA to add to the list of high-priority chemicals of concern for children's health by only five chemicals every three years; this change would permit 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 manufactures selling children's products in Oregon and Washington. Washington's list currently numbers [85] compared to Oregon's [68].
- **Conflict:** The Act limits OHA's ability to comply with the direction to make available data on children's products containing chemicals of concern that is searchable and accessible to the public.
- **Recommendation:** Amend the Act to require manufacturers to report children's products by brand name and product model rather than general product categories as the Act currently requires (e.g., "toy car, non-motorized"). This change would make it possible for a consumer to look up information about a specific product, including whether the product contains a high-priority chemical, make purchasing decisions that may reduce a child's exposure to the chemical, and allow OHA to ensure information is accessible to people with

a wider array of literacy levels and comprehension of chemical information. Manufacturers reporting to Vermont's Chemical Disclosure Program for Children's Products are currently required to provide this information. This would not increase costs to manufacturers reporting to Oregon, since reporting fees are levied per chemical, not per product.

- **Conflict:** The Act limits Oregon's ability to align the biennial reporting date with Washington's program.
- **Recommendation:** Change the Biennial Notice due date for reporting years from January 1 to January 31; this would align with the due date of annual reporting for Washington's Children's Safe Products Act and give manufacturers additional time needed to report after the busy holiday season.

Completed and current 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 or are in progress:

- **Phase 1** (September 2015 – December 2015)
 - » Adopted High Priority Chemicals of Concern for Children's Health 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 high-priority chemicals 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 high-priority chemicals.
 - » 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 high-priority chemicals for reports due on or after January 1, 2022.
 - » Aligns with Washington’s method.
- **Triennial Review of High Priority Chemical List and Biennial Notification Rule** (September 2021 – December 2021)
 - » Five additional chemicals added to High Priority Chemicals list.
 - » Permanent rulemaking for Temporary Rule for Biennial Notification adopted August 2021.
 - » Both became effective January 1, 2022.

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. 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 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 12 exemption requests and approved 10. The remaining two were not approved for lack of sufficient information provided by the requestors. OHA has received no further exemption requests.

Online reporting system

The Act 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 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>. The HPCDS is expected to add reports under similar laws of Vermont and New York in the future.

However, as noted above in the section discussing OHA’s recommendations for ways to limit, reduce or prevent exposure to chemicals of concern, while the HPCDS makes the raw data on chemicals in categories of products available to the public, under the Act’s current requirements, manufacturers are not required to include information on the product name and model associated with the categories of products reported. Aligning Oregon’s program with the requirements of Vermont’s and New York’s children’s products reporting laws would make information accessible to the public in a form they can use to inform decisions about purchases.

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:

- Concluding current rulemakings to clarify reporting requirements and carry out the triennial chemical list review required by the Act.
- Setting up procedures to review requests for the removal of high-priority chemicals from certain children's products (intended to go in the mouth, children's cosmetics, marketed for children under age 3) or their replacement with a less hazardous substitute.
- Conducting outreach and education and, when necessary, enforcement actions to achieve manufacturer compliance with program rules now that all major components of the Toxic-Free Kids Program have been adopted in rule.



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