

>> Toxic Free Kids Act

A Report to the Governor and the 80th Oregon
Legislative Assembly



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Executive summary

The Toxic-Free Kids Act (Senate Bill 478) 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 to report on the presence of those chemicals in products intended for children aged 12 and under. In addition, the law calls for the eventual phase out the use of these chemicals in a subset of children's products.

As required by Senate Bill 478, OHA makes biennial reports to the Legislature on the status of the statute's implementation. The 2017 report to the legislature described OHA's adoption in rule of the list of high priority chemicals of concern for children's health; described the rulemaking advisory committee and rulemakings needed to develop the program; discussed development of guidance for seeking an exemption from reporting requirements, and outlined reporting systems in development.

This 2019 biennial report summarizes the earlier work and presents program accomplishments in the two years since the last report, including: rulemaking to update the list of high priority chemicals of concern for children's health and to adopt enforcement procedures; processing manufacturer requests for exemptions from product reporting; implementing the interim reporting system; and developing a multistate reporting data system. OHA is currently developing rules for the removal or substitution of chemicals from certain children's products and the process for waiving the requirement to remove the chemicals. This is the third and final major phase of the Toxic Free Kids program development, and the most technically challenging. OHA continues to work with stakeholders to develop the procedures required to implement this phase of the Act effectively and efficiently.

Introduction

The Oregon Legislature passed the Toxic-Free Kids Act (“the Act” or TFK), during the 2015 legislative session. The Act, restated in Oregon Revised Statutes, 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 with another chemical to make the product less hazardous, or seek a waiver if the chemical is in a children’s product that is mouthable, a children’s cosmetic, or is made or marketed to children under 3 years of age. Products that fall under this law include products marketed to or intended for children 12 years of age 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.

Oregon Revised Statute (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 online reporting systems for the program.

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 rules advisory committee (RAC) and conducted a rulemaking process in spring 2018, and adopted rules effective January 1, 2019 adding five and removing three chemicals from the high priority chemical list contained in Oregon Administrative Rule (OAR) 333-016-2020, listed in Table 1.

Table 1

Chemicals Added	Chemicals Removed
1. Bisphenol S;	1. Phthalic anhydride
2. Triphenyl phosphate;	2. Octamethylcyclo-tetrasiloxane
3. Tris(1-chloro-2-propyl) phosphate;	3. Molybdenum and molybdenum compounds
4. 2-ethylhexyl-2,3,4,5-tetrabromobenzoate;	
5. Short-chain chlorinated paraffins.	

OHA originally adopted Washington’s Department of Ecology’s list of 66 chemicals of concern in 2015 as directed by the Act. In 2017, Washington added 22 chemicals to their list and removed the three listed above. The removals were based on Washington State’s reevaluation of the risks posed by the chemicals; OHA toxicologists reviewed and concurred with the Washington State analysis. In an effort to align with Washington, OHA removed the three chemicals that Washington removed, but was limited in the number of chemicals that could be added to the list. The law stipulates that OHA may add up to five chemicals to the list every three years (ORS 431A.255(4)). In selecting the five chemicals to add to Oregon’s list, OHA toxicology staff prioritized toxicity endpoints with a negative impact on growing bodies as well as potential for exposure. Those prioritized toxicity end points were: carcinogenicity, reproductive/developmental toxicity, and endocrine disruption. The prioritized exposure attributes were: chemicals likely in products intended for children younger than three years of age and 3-12 years-old; chemicals known to leave markers in children’s urine; those persisting in the environment; and those found in dust in locations frequented by children. This approach aligns with the approach used by Washington State in adopting its original and updated lists.

Summary of reporting to date

As of January 1, 2018, OHA received reports from 114 manufacturers that produce children's products containing a chemical of concern and were sold or offered for sale in Oregon in 2017. They reported 962 products in 221 different 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 trade name or brand.

The 962 product reports included information on 64 chemicals of concern (of 66 chemicals for which notification was required in 2017). To assist in future efforts to regulate such chemicals, manufacturers were required to report the function of the chemical and its location (as a component) in the product. As a result, manufacturers made 4,787 distinct reports of chemicals at the component level as well as their function in the product.

Based on information submitted to date, approximately 75% of reports are for products only subject to the reporting requirement, while the remaining approximately 25% of reports are for products requiring removal or waiver by January 2022 (products for children less than age three, intended to be mouthable and children's cosmetics).

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 chemical of concern used in children’s products. Among the 4,787 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.	Methyl ethyl ketone	78-93-3
2.	Antimony & Antimony compounds	7440-36-0
3.	Ethylene glycol	107-21-1
4.	Styrene	100-42-5
5.	Cobalt & Cobalt compounds	7440-48-4
6.	Toluene	108-88-3
7.	Ethylbenzene	100-41-4
8.	Molybdenum and molybdenum compounds	7439-98-7
9.	Formaldehyde	50-00-0
10.	Di-2-ethylhexyl phthalate	117-81-7

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 with the data submitted to date under the Act. The Act does not require manufacturers to report the exact amount of the chemical in the children's product. Instead, it requires reporting of the amounts of a chemical with a range of concentration. Information on exposure routes and use patterns are also currently not required to be reported. All of 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 mouthable, 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 allows OHA to evaluate potential chemical exposures from some children's products in Oregon. This phase of program development commenced May 2019 and will conclude in 2020, 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.

Formulation of recommendations for reducing exposure to chemicals of concern

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 does not support formulation of such recommendations. As noted above regarding evaluating 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.

Completed and current rulemakings

After the Act's passage in 2015 OHA convened the Toxic Free Kids RAC. The RAC allows the public and stakeholders, including affected companies, to give input and suggestions during the development of new rules, including on their fiscal impact. The RAC for the Toxic-Free Kids Act include 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.

OHA has completed the following rulemakings:

- **Phase 1** (September 2015 – December 2015)
 - » Adopted High Priority Chemicals of Concern for Children's Health list in rule effective December 29, 2015
 - » Adopted same list in effect under Washington State'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 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 rulemaking began in 2019 and is still in progress.

- **Phase 3 (May 2019 – ongoing)**
 - » Addresses removal, substitution, or waiver process for high priority chemicals from certain children's products (those intended for children younger than age three, intended to be mouthable, or children's cosmetics).
 - » Requires OHA to establish methods for evaluating the health protectiveness of manufacturers' proposals to substitute alternative chemicals
 - » Most technically challenging phase of program development, unique nationally.

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.

To date OHA has received nine exemption requests and approved seven of these; the remaining two were not approved for lack of sufficient information.

Online reporting systems

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 OHA, and called for a multistate reporting system that allows manufacturers to report once and satisfy 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.” IC2 has experience developing searchable reporting databases, such as the Interstate Mercury Education & Reduction Clearinghouse (IMERC) – a reporting database for eight states with mercury-in-products reporting requirements.

In September 2016, OHA was successful in securing a \$500,000 grant from the U.S. Environmental Protection Agency to contract with IC2 to fulfill this objective of the Act, and the multistate High Priority Chemical Data System, known formally as the Interstate Chemicals Clearinghouse (IC2) Data System, is scheduled to go live in November 2019. The system will include a public facing data portal to allow Oregonians to review data submitted by manufacturers.

Because the IC2 data system could not be completed in time for the Act's first biennial notice requirement (Jan. 1, 2018), OHA developed an interim online reporting system for manufacturers to meet their initial reporting obligations under Oregon's law. OHA provides data from the system upon request.

Conclusion

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. The priorities ahead include completing rules for the most technically challenging phase of program development – assessing removal, substitution, or waiver of removal of chemicals of concern – and ensuring robust compliance by manufacturers with the Act's requirements through expanded outreach to the regulated community.



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