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TEMPORARY ADMINISTRATIVE ORDER

INCLUDING STATEMENT OF NEED & JUSTIFICATION

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OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

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FILING CAPTION: Clarification related to the reporting of children's products under the Toxic Free Kids Act

EFFECTIVE DATE: 08/26/2021 THROUGH 02/21/2022

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NEED FOR THE RULE(S):

SB 478 (Oregon Laws 2015, chapter 786) was passed by the Oregon Legislature during the 2015 legislative session. This law, the Toxic Free Kids (TFK) Act, requires the Oregon Health Authority (Authority) to require manufacturers of children's products to disclose high priority chemicals of concern for children's health found at or above de minimis levels in children's products that are sold or offered for sale in Oregon. The law states that the Authority shall adopt a list of High Priority Chemicals of Concern for Children's Health (HPCCCH); establish requirements for disclosure; and establish a process for manufacturers to apply for an exemption from the disclosure requirements.

By January 1, 2022 (or when they have made three biennial notifications to the Authority of products containing HPCCCH at/above de minimis), manufacturers are to remove HPCCCH from product models in three subsets of children's products; or substitute them with a less-hazardous alternative; or have a waiver of this requirement approved by the Authority; or seek exemption from the removal/substitution requirement. [Specified in OAR 333-016-3010(1), those subsets are: products for children under three years-old; "mouthable" items, per ORS 431A.253(8); and children's cosmetics.] All elements above have been established through previous rulemaking.

Implementation of these central provisions of the TFK Act (biennial notifications and the removal/substitution requirements or their alternatives, if required) as stated in the law is contingent on manufacturer reporting of children's products on a consistent basis. Specifically, manufacturers must use the same method to determine the proportion of HPCCCH in each product component in which the HPCCCH is found to determine whether or not the products should be part of a biennial notification to the Authority using the multistate High Priority Chemical Data System (HPCDS).

After two biennial notification cycles (2018 and 2020), the Authority has determined that manufacturers of children's products sold or offered for sale in Oregon are likely using two different methods to determine the proportion of HPCCCH in each product. Some manufacturers are reporting the concentration of HPCCCH in the components of

products (expressed as “parts per million” or ppm as that is the standard calculation made by product testing laboratories: divide the mass of HPCCCH in each component of the product by the mass of the component). [For purposes of this discussion, this is termed the “component” method.] Others may be calculating HPCCCH levels by applying an adjustment factor to laboratory results such that the mass of HPCCCH in each component is divided by total mass of the product. [This is termed the “whole product” method]. This likely results in a concentration (in ppm) that is much smaller than that of the component method. That result may cause manufacturers to decide they don’t need to include those children’s products in biennial notifications to the Authority.

The Authority’s determination that manufacturers may be using different methods is based on two factors:

1) Recent Authority discussions with those affiliated with the toy industry indicated that an unknown proportion of toy manufacturers may be using the whole product method. Yet other manufacturers of children’s products reported to the Authority are using the component method. Similar children’s products laws of other states stipulate that the component method be used.

2) The Authority’s discussions with industry are corroborated by manufacturer reporting to the High Priority Chemical Data System (HPCCCH) for both Oregon and Washington. A preliminary comparison of the number of manufacturers of children’s products that reported to the Authority in 2018 with the number that reported under a similar law (Children’s Safe Products Act - CSPA) in the State of Washington indicates 36% of manufacturers reported for Washington but not Oregon vs. only 6% reporting to Oregon but not Washington. Washington requires that the component method be used to determine if a children’s product containing a high priority chemical is to be reported under CSPA because that is how component PPM is calculated by product testing laboratories.

Calculating the concentration of HPCCCH in the component using the whole product method rather than the standard component method will dramatically under-calculate the concentration of a HPCCCH in a product component. Using the whole product method results in a concentration that is very likely below the reporting limit (‘de minimis’ per ORS 431A.253) for HPCCCH. Authority staff estimate that the difference in concentration may be ten-fold or more for HPCCCHs in the components of some products.

ORS 431A.250 and OAR 333-016-2060 Notification Requirements stipulate that manufacturers are to report the “…amount of the chemical used in each unit of the children’s product…” that meets or exceeds a specific minimal level (de minimis) for that chemical, but the term “unit” is not defined in either ORS 431.250 or its implementing rule. This lack of specificity in rule may have led some manufacturers to believe that the whole product method is a permissible method of calculating the concentration of a HPCCCH in a product component and, consequently, not report the product to the Authority because the result was below de minimis for that HPCCCH.

The Authority proposes changes to OAR 333-016-2060 Notification Requirements that will remove this unintentional ambiguity. This change will apply to January 1, 2022 biennial notifications for products sold or offered for sale in Oregon in 2020 or 2021. The Authority will use its enforcement discretion and not require manufacturers who may have used the whole product method in the past, to submit those products for the 2018 and 2020 Biennial Notifications. The Authority intends to make this change permanent through a permanent rulemaking process in Fall 2021.

A uniform method for calculating a product's parts per million ensures both fair applicability of the law to all children's products and decreases the likelihood that specific product subsets (those for children under three years-old; "mouthable" items; and children's cosmetics) containing hazardous chemicals will be on the Oregon market without first having to comply with OAR 333-016-3010 Removal or Substitution of High Priority Chemicals or its alternatives.

JUSTIFICATION OF TEMPORARY FILING:

The Authority finds that failure to act promptly will result in serious prejudice to the public interest, the Authority, and children in Oregon, particularly those under three years of age. Without this clarification, children's products containing HPCCCH will continue to be on the Oregon market without notification to the public (per ORS 431A.250). In addition, without prompt action, products for children under three years of age; "mouthable" items, per ORS 431A.253(8); or children's cosmetics won't be subject to the HPCCCH removal or substitution requirements or their alternatives. Therefore, children in Oregon will potentially be exposed to hazardous chemicals from a greater number of children's products than they would without this temporary rule.

This rule clarification needs to be adopted promptly so manufacturers of children's products are able to review their product lines and test products, as needed, in time for the 2022 Biennial Notice due date of January 1, 2022 for children's products sold or offered for sale in Oregon in 2020 through 2021.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

High Priority Chemical Data System - https://hpcds.theic2.org/Search
Oregon Revised Statute 431A. 250 - https://www.oregonlegislature.gov/bills_laws/ors/ors431a.html
Oregon Administrative Rule 333-016-2010; 333-016-2060; 333-016-3010-
https://secure.sos.state.or.us/oard/displayDivisionRules.action;JSESSIONID_OARD=jr-rAldRGiW7tdiJiK_iPhhVt08t1WbVuPG-ACjaV5oJkPtbIgn_!1266747150?selectedDivision=1231
Washington Administrative Code 173-334-080 - https://app.leg.wa.gov/wac/default.aspx?cite=173-334-080
Vermont Statutes Online, Chapter 038A : Chemicals of High Concern To Children-
https://legislature.vermont.gov/statutes/section/18/038A/01775

AMEND: 333-016-2060

RULE TITLE: Notification Requirements

RULE SUMMARY: Amend OAR 333-016-2060: For purposes of biennial notices reporting HPCCCH in children's products, manufacturers must report a HPCCCH as its concentration of each component parts/units of the children's product in which it is found. For given component parts/units within each product category that containing multiple concentrations of a HPCCCH, the manufacturer must use the highest concentration for the purposes of a biennial notice.

RULE TEXT:
(1) For purposes of this rule, "unit" has the same meaning as "component part" as that is defined in OAR 333-016-2010.
(2) No later than January 1, 2018, and every other year thereafter, a manufacturer of a children's product sold or offered for sale in this state that contains a HPCCCH listed in OAR 333-016-2020 in an amount at or above a de minimis level must submit:
(a) A notice to the Authority that contains all the information required in these rules, unless the manufacturer or product is exempt; and

(b) A nonrefundable fee of $250 for the notification of each HPCCCH as specified in OAR 333-016-2080.
(3) The first manufacturer's notice due on January 1, 2018, applies to children's products sold or offered for sale in this state between January 1, 2017 and December 31, 2017.
(4) Subsequent manufacturer reports are due on January 1st of even numbered years for the previous two-year biennial notice period. For example, for the reporting year 2020, a manufacturer must include children's products sold or offered for sale between January 1, 2018, and December 31, 2019, that contain a HPCCCH listed in OAR 333-016-2020.
(5) The notice required in section (2) of this rule must include the following:
(a) The name and Chemical Abstracts Service Registry Number of the chemical contained in the children's product;
(b) The product category of the children's product that contains the chemical;
(c) A description of the function of the chemical in the children's product;
(d) The amount of the chemical used in each unit within each product category. The amount of the chemical used in each unit of the children's product is to be reported as a range rather than an exact amount. If there are multiple concentrations for a given unit in a particular product category, the manufacturer must use the highest concentration for reporting.
(e) The target age category for whom the children's product is intended, either ages 0-3, 3-12 or 0-12 years-old;
(f) The number of the children's product that contain the high priority chemical either sold or offered for sale in Oregon during the biennial notice period;
(g) The name and address of the manufacturer, and the name, address and telephone number of the contact person for the manufacturer;
(h) The name, address and contact information for the trade association submitting the notification on behalf of the affected industry; and
(i) Any other information that the manufacturer deems relevant to the appropriate use of the children's product.
(6) No later than January 1, 2020, and every other year thereafter, notices to the Authority shall be submitted utilizing the Interstate Chemicals Clearinghouse's High Priority Chemicals Data System (HPCDS) or alternate data system designated by the Authority. A link to the data system will be made available on the Toxic Free Kids Program website: www.healthoregon.org/toxicfreekids.
(7) If a manufacturer, required to report under ORS 431A.258, is acquired by another business entity, merges into another business entity or separates into distinct business entities, the new controlling entity must submit the required biennial notices to the Authority.
(8) If a manufacturer has included a children's product in a notice required under these rules, and determines that there is no change to the information for the product except the number of products sold or offered for sale submitted to the Authority in the previous notice, the manufacturer may, in lieu of including the children's product again in a subsequent notice, submit a written statement, or if available, an electronic notification indicating that the previous reported data is still valid for that children's product. The notification shall include the number of products sold or offered for sale during the biennial notice period.
(9) A trade association may provide the notice required in these rules on behalf of a member manufacturer. If a trade association reports on a member manufacturer's behalf, the trade association must specify which member or members the association is reporting on behalf of, including the name and contact information of a representative for each of those members, and must submit the fees for each member as required in OAR 333-016-2080.
(10) A trade association who fulfills the notice or exemption from notice requirements as well as waiver or hazard assessment requests in these rules on behalf of a member manufacturer will not be held liable for a violation or penalty as a result of the member manufacturer's noncompliance with the requirements of these rules.
(11) A manufacturer may, during the notification process, submit to the Authority recommendations regarding technical, financial or logistical support considered necessary for the implementation of innovation and green chemistry solutions related to HPCCCH used in children's products.
(12) Only one person or entity that falls within the definition of manufacturer is required to report with respect to a particular children's product. The Authority will hold the following primarily responsible for ensuring that it receives a

complete, accurate, and timely notice for the children's product, in the following order:
(a) Any person or entity that manufactured the children's product, unless it has no presence in the United States.
(b) Any person or entity that distributed or made available for distribution the children's product, unless it has no presence in the United States.
(c) The importer or owner of the children's product in the United States.
(13) The Authority will enforce the reporting requirements in this rule against a manufacturer in the same order as the priority order for reporting in section (12) of this rule.
(14) If a manufacturer has included a children's product in a notice required under these rules, and removes the HPCCCH from that children's product it shall, within 180 days of removal, submit a written statement, or if available, an electronic notification indicating the HPCCCH that was removed, whether another HPCCCH was substituted and the date the removal was effective, unless the Authority has already been notified under OAR 333-016-3010(1). Such notification will help the Authority avoid any unnecessary enforcement actions because of a failure to report or failure to comply with the other requirements of these rules.

STATUTORY/OTHER AUTHORITY: ORS 413.042, 431A.258

STATUTES/OTHER IMPLEMENTED: ORS 431A.258