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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED

10/30/2023 9:16 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Toxic Free Kids Modernization Act (HB 3043) – Fall 2023

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/21/2023 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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Filed By:
Public Health Division
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 11/15/2023

TIME: 10:00 AM

OFFICER: Staff

HEARING LOCATION

ADDRESS: Remote hearing via Microsoft Teams, Video/Teleconference, Portland, OR 97232

REMOTE MEETING DETAILS

MEETING URL: [Click here to join the meeting](#)

PHONE NUMBER: 971-277-2343

CONFERENCE ID: 843807023

SPECIAL INSTRUCTIONS:

This hearing is being held remotely via Microsoft Teams. To provide oral testimony during this hearing, please contact publichealth.rules@odhsoha.oregon.gov to register and receive the link for the Microsoft Teams video conference via calendar appointment, or you may access the hearing using the meeting URL above. Alternatively, you may dial 971-277-2343, Phone Conference ID 843 807 023# for audio only.

The hearing will close no later than 11:00AM, but may close as early as 10:30AM if everyone who has signed up to testify has provided their testimony.

Accessibility Statement: For individuals with disabilities or individuals who speak a language other than English, OHA can provide free help. Some examples are: sign language and spoken language interpreters, real-time captioning, braille, large print, audio, and written materials in other languages. If you need help with these services, please contact the Public Health Division at 971-673-1222, 711 TTY or publichealth.rules@odhsoha.oregon.gov at least 48 hours before the meeting. All relay calls are accepted. To best ensure our ability to provide a modification please contact us if you are considering attending the meeting and require a modification. The earlier you make a request the more likely we can

meet the need.

NEED FOR THE RULE(S)

House Bill 3043 (Oregon Laws 2023, chapter 426) was passed by the Oregon Legislature during the 2023 legislative session and signed into law by Governor Tina Kotek. The law modifies existing statute (2015 Toxic Free Kids Act). This rulemaking implements certain provisions of HB 3043.

The modifications directly affect only manufacturers with annual worldwide gross sales of \$5 million or more that sell or offer for sale children's products in Oregon containing high priority chemicals of concern for children's health (HPCCCH) at de minimis. The Toxic Free Kids (TFK) Program's charge is to maintain a list of high priority chemicals of concern for children's health. Manufacturers of children's products containing those chemicals must report those products to Oregon Health Authority (OHA). Under the Act, manufacturers are required to remove or substitute such chemicals in certain product types after making three biennial notices/reports.

Proposed amendments to OAR chapter 333, division 16 include:

- A) Adding two terms ("class of chemicals" and "subclass of chemicals") and their definitions to OAR 333-016-2010 Definitions. The changes were taken verbatim from HB 3043, SECTION 1.
- B) Amending OAR 333-016-2030 Modifications to the List of High Priority Chemicals of Concern for Children's Health per HB 3043, SECTION 2. This change allows OHA, at its discretion, to add groups of chemicals, as classes or subclasses, to OAR 333-016-2020 Chemicals of High Concern to Children (the HPCCCH list) at future triennial reviews of the HPCCCH list as required by statute. The next such review is Fall 2024 for a January 1, 2025, effectiveness date. No chemicals are proposed to be added to the HPCCCH list during this 2023 rulemaking.
- C) Amending OAR 333-016-2060 Notification Requirements per HB 3043 (2023), SECTION 3. With this required change, manufacture reports are due January 31st of even-numbered years for the previous two-year biennial notice/reporting period instead of January 1st.
- D) Amending OAR 333-016-3050 Quantitative Exposure Assessment (QEA) per HB 3043, SECTION 6. This change adds inaccessible to this rule. For purposes of this rule, inaccessible is defined. A QEA must demonstrate that a HPCCCH in a children's product is inaccessible to the consumer or otherwise not reasonably anticipated to result in exposure to a child based on an analysis of the leachability and bioavailability of the HPCCCH. A QEA submitted by manufacturers in support of waiver request (OAR 333-016-3040 Waiver from Removal or Substitution Requirement). This request, if approved by OHA, waives the requirement that the manufacturer remove or substitute HPCCCH(s) in certain children's products after being reported three times.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

HB 3043 (Oregon Laws 2023, chapter 426):

<https://olis.oregonlegislature.gov/liz/2023R1/Downloads/MeasureDocument/HB3043/Enrolled>

Oregon Toxic Free Kids Act, ORS 431A.250 – 431A.280:

https://www.oregonlegislature.gov/bills_laws/ors/ors431a.html

OAR chapter 333, division 16: <https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=1231>

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

1) The amendments to OARs 333-016-2010 on their own will not affect racial equity.

2) The amendments to OARs 333-016-2030 will likely have an overall positive impact on low-income populations in Oregon, which may include members of BIPOC or other marginalized communities. Often by necessity, those in low-income households buy less-expensive toys, clothing and other products intended for infants and toddlers. Such products may have greater concentrations of low-cost HPCCCH than more expensive versions. Those amendments will address this by allowing OHA to add groups of chemicals as classes and subclasses to the HPCCCH list as opposed to one by one. This may reduce children's exposure to a greater number of hazardous chemicals present in children's products used in low-income communities.

3) The amendment to OAR 333-016-2060 Notification Requirements per HB 3043 (2023), SECTION 3 won't likely have any effect on low-income populations in Oregon, which may include members of BIPOC or other marginalized communities. This is because the change moves the due date for biennial notices/reports back 30 days, which only affects manufacturers of children's products.

4) The amendments to OAR 333-016-3050 may have a negative impact on low-income populations in Oregon, which may include members of BIPOC or other marginalized communities. HB 3043 requires OHA to add the term inaccessible to OAR 333-016-3050, thus broadening the criteria under which OHA must approve waiver request. This may lead to more children's products with HPCCCH remaining in the Oregon marketplace after being reported three times.

While this round of rulemaking indirectly affects low-income populations, the TFK Program believes low-income and members of other marginalized groups such as the BIPOC communities should be prioritized in inclusion in the Rules Advisory Committee (RAC). Inclusion of community members in the RAC will ensure community voices are elevated during this round of rulemaking and future efforts related to the community impact of the TFK Act. The TFK Program requested participation on the Rule Advisory Committee by members of these communities by listing the opportunity in the September 2023 edition of the Community Engagement Team (CET) Highlight Letter, sent to over 150 OHA grantees and community partners. At least one newsletter recipient, Beyond Toxics, which focuses on environmental justice in underserved communities in Oregon, joined the RAC meetings. The TFK Program intends to increase participation by representatives of marginalized communities on its RACs for future rulemakings.

FISCAL AND ECONOMIC IMPACT:

A) The two terms and definitions added to OAR 333-016-2010 Definitions are taken verbatim from HB 3043. They will not have an economic impact on manufacturers of children's products on their own.

B) Changes to OAR 333-016-2030 may have a negative impact on children's product manufacturers in Oregon. The impact of changes may be negative for manufacturers because there are multiple chemicals in each class or subclass. Manufacturers may have to report and/or remove/substitute more HPCCCH than before this rule was amended. Reporting children's products containing a HPCCCH requires a \$250 per-chemical fee.

C) Changes to OAR 333-016-2060 will have a positive impact on children's manufacturers. Currently, manufacturers' biennial notices/reports are due on January 1st immediately follows the busy holiday season. Moving this due date back 30 days gives manufacturers time to reconcile accounts and prepare biennial notices/reports for submission. This change aligns the due date of biennial notices/reports for the TFK Program with that of the Children's Safe Product Act, a similar law in Washington State.

D) Changes OAR 333-016-3050 may have a positive impact on manufacturers. In a QEA submitted in support of a waiver request, manufacturers may now demonstrate that a high priority chemical is inaccessible to a child under normal and reasonably foreseeable use and abuse of the product. This may allow more items in certain categories of children's products to stay in the Oregon marketplace after being reported three times.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) A) The modification of OAR 333-016-2010 Definitions is not expected to have any cost of compliance impact on local or state governments, or the public.

B) The modification of OAR 333-016-2030 Modifications to the List of High Priority Chemicals of Concern for Children's Health is not expected to have any cost of compliance impact on local or state governments, or the public.

C) The modification of OAR 333-016-2060 Notification Requirements is not expected to have any cost of compliance impact on local or state governments, or the public.

D) The modification of OAR 333-016-3050 Quantitative Exposure Assessment (QEA) is not expected to have any cost of compliance impact on local or state governments, or the public.

(2)(a) ORS 431A.255 List of high priority chemicals of concern in children's products, ORS 431A.258 Disclosure by manufacturers; notice requirement; exemption, and ORS 431.265 Process for waiving requirement to remove or substitute chemicals, which relate to the OARs being amended, only pertain to manufacturers that gross over \$5,000,000 in worldwide gross sales per year. ORS 431A.260 allows manufacturers with 25 or fewer employees to apply for a two-year extension before they're subject to the removal or substitution provisions of the Act and therefore, the waiver and QEA provisions. The term manufacturer under the Act includes an importer or domestic distributor. We are unable to estimate the number of manufacturers that would be considered a small business based on available information.

(b) ORS 431A.255 List of high priority chemicals of concern in children's products, ORS 431A.258 Disclosure by manufacturers; notice requirement; exemption, and ORS 431.265 Process for waiving requirement to remove or substitute chemicals, which relate to the OARs being amended, only pertain to manufacturers that gross over \$5,000,000 in worldwide gross sales per year. Per ORS 431A.253, the term manufacturer includes an importer or domestic distributor.

If a small business met these criteria, they would be responsible for complying with reporting chemicals added to the HPCCCH list in the future as a result of these rules, and any related recordkeeping. They would be responsible for subsequent and removal/substitution of such chemicals after three reports. They would be responsible for any professional services needed to prepare QEAs if they chose to apply for a waiver.

(c) Manufacturers of children's products containing chemicals added in the future to the HPCCCH list as a result of these rules, would be required to provide notice to OHA. This would include labor costs and the submission of a \$250 per chemicals notification fee to OHA.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small business representatives and trade associations were invited to participate as Rule Advisory Committee members.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

333-016-2010, 333-016-2030, 333-016-2060, 333-016-3050

AMEND: 333-016-2010

RULE SUMMARY: Amending OAR 333-016-2010 Definitions. Two terms ("class of chemicals" and "subclass of chemicals") and their definitions from HB 3043 (2023), SECTION 1 are proposed to be added verbatim to this rule.

CHANGES TO RULE:

333-016-2010

Definitions ¶¶

The following definitions apply to OAR 333-016-2001 to 333-016-3080.¶¶

- (1) "Alternatives Assessment" or "AA" as described in OAR 333-016-3060 means the evaluation of the possibility of replacing chemicals in products or processes with inherently safer alternatives in order to better protect human health.¶¶
- (2) "Analytical methods" means defined protocols for the analysis of the presence of a HPCCCH in a sample of a medium, including laboratory testing that can be described and is readily reproducible by another party.¶¶
- (3) "Bioavailability" means the extent to which a HPCCCH at or above the practical quantification limit for the chemical established in OAR 333-016-2035(2) Exhibit A in leachate or air may be absorbed by a child.¶¶
- (4) "Chemical" means:¶¶
 - (a) A substance with a distinct molecular composition and the breakdown products of the substance that form through decomposition, degradation or metabolism.¶¶
 - (b) A group of structurally related substances and the breakdown products of the substances that form through decomposition, degradation or metabolism.¶¶
- (5) "Chemical Abstracts Service Registry Number" means the number assigned for identification of a particular chemical by the Chemical Abstracts Service, a service of the American Chemical Society that indexes and compiles abstracts of worldwide chemical literature called Chemical Abstracts.-¶¶
- (6) "Child" means an individual under 12 years of age.¶¶
- (7)(a) "Children's cosmetics" means products that are intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, moisturizing, beautifying, promoting attractiveness or altering the appearance.¶¶
(b) "Children's cosmetics" does not mean soap, dietary supplements or food and drugs approved by the United States Food and Drug Administration.¶¶
- (8)(a) "Children's product" means:¶¶
 - (A) Any of the following products that are made for, marketed for use by or marketed to children under 12 years of age:¶¶
 - (i) A product designed or intended by the manufacturer to facilitate sucking, teething, sleep, relaxation, feeding or drinking.¶¶
 - (ii) Children's clothing and footwear.¶¶
 - (iii) Car seats.¶¶
 - (iv) Children's cosmetics.¶¶
 - (v) Children's jewelry.¶¶
 - (vi) Toys.¶¶
 - (B) Any component part of a product specified in paragraph (A) of this subsection.¶¶
- (b) "Children's product" does not mean:¶¶
 - (A) Athletic shoes with cleats or spikes.¶¶
 - (B) Batteries.¶¶
 - (C) BB guns, pellet guns and air rifles.¶¶
 - (D) Bicycles and tricycles.¶¶

- (E) Chemistry sets.¶
- (F) Consumer electronic products, including personal computers, audio and video equipment, calculators, wireless telephones and game consoles, handheld devices that incorporate a video screen and are used to access interactive software, and the associated peripherals.¶
- (G) Interactive software intended for leisure and entertainment, such as computer games, and their storage media, such as compact discs.¶
- (H) Model rockets.¶
- (I) Pocketknives and multitools.¶
- (J) Roller skates.¶
- (K) Scooters.¶
- (L) Sets of darts with metallic points.¶
- (M) Slings and catapults.¶
- (N) Snow sporting equipment, including skis, poles, boots, snowboards, sleds and bindings.¶
- (O) Sporting equipment and accessories, including but not limited to bats, balls, gloves, sticks, pucks, pads, helmets and other protective equipment, weight training and exercise aids, protective eyewear, backpacks and tents, raingear, sport bags and luggage, and golf equipment.¶
- (P) Video toys that can be connected to a video screen and are operated at a nominal voltage exceeding 24 volts.¶
- (Q) Food and beverages and food and beverage packaging regulated by the United States Food and Drug Administration or the United States Department of Agriculture.¶
- (9) "Class of chemicals" has the meaning given that term in ORS 431A.253.¶
- (10) "Component part" means a uniquely identifiable material or coating (including ink or dye) that is intended to be included as a part of a finished children's product, including, but not limited to:¶
- (a) Bio-based materials (animal or plant based);¶
- (b) Synthetic polymers (such as but not limited to synthetic rubber, plastics, and foams);¶
- (c) Metals (including alloys);¶
- (d) Glass, ceramic and siliceous material;¶
- (e) Surface coatings (such as but not limited to paints, plating, and waterproofing);¶
- (f) Homogenous mixtures (gels, creams, powders, liquids, adhesives, synthetic fragrances);¶
- (g) Inks/dyes/pigments; and¶
- (h) Textiles (synthetic fibers and blends).¶
- (101) "Contaminant" has the meaning given that term in ORS 431A.253.¶
- (112) "De minimis level" has the meaning given that term in ORS 431A.253.¶
- (123) "Essential use" means a function of a HPCCCH in a children's product considered critical for performance of a product.¶
- (134) "Exposure scenarios" means the mechanisms by which children may be exposed to HPCCCHs found in a children's product.¶
- (145) "Hazard Assessment" or "HA" as described in OAR 333-016-3030 means an evaluation of whether a chemical or chemicals substituted for a HPCCCH in a children's product make that product less hazardous than it was when it contained the HPCCCH.¶
- (156) "HPCCCH" means high priority chemicals of concern to children's health.¶
- (167) "High priority chemicals of concern list" means the high priority chemicals of concern for children's health identified by the Oregon Health Authority in OAR 333-016-2020.¶
- (178) "Intentionally added chemical" has the meaning given that term in ORS 431A.253.¶
- (189) "Leachability" means the extent to which a HPCCCH is reasonably anticipated to migrate from a children's product through normal and reasonably foreseeable use and abuse of such product determined by measuring a HPCCCH at or above the practical quantification limit for the chemical established in OAR 333-016-2035(2) Exhibit A in media during simulated exposure scenarios.¶
- (1920) "Manufacturer" has the meaning given that term in ORS 431A.253.¶
- (201) "Manufacturing control program" or "MCP" means a program implemented by the manufacturer or its suppliers to control the amount of a HPCCCH present as a contaminant at or above de minimis levels through the implementation of tools, processes and oversight that support effective chemicals management at all levels to include supply chain management, quality assurance and educational programs. Control includes the minimization, reduction or elimination of contaminants when possible.¶
- (212) "Mouthable" has the meaning given that term in ORS 431A.253.¶
- (223) "Non-essential use" means a function of a HPCCCH in a children's product that is not critical for the performance of a product but is included for other reasons such as market demand.¶
- (234) "Owner" for purposes of clarifying the definition of "manufacturer" means the person or entity, whether an importer or a distributor, that offers the children's product for sale in Oregon.¶
- (245) "Practical quantification limit" has the meaning given that term in ORS 431A.253.¶

(256) "Product category" means the "brick" level of the GS1 Global Product Classification (GPC) standard, which identifies products that serve a common purpose, are of a similar form and material, and share the same set of category attributes.¶

(267) "Quantitative Exposure Assessment" or "QEA" means an assessment as described in OAR 333-016-3050 of whether a HPCCCH used in children's products is or is not reasonably anticipated to result in exposure based upon an analysis of leachability and bioavailability of the HPCCCH used in children's products.¶

(278) "Reasonably foreseeable use and abuse" includes: non-incident skin contact; swallowing; mouthing; inhalation of gaseous products emitted by a children's product; the aging of a children's product; and may include breaking during typical and reasonable use by children or other situations of a similar nature.¶

(289) "Subclass of chemicals" has the meaning given that term in ORS 431A.253.¶

(30) "Substitutable role" means a role for or presence of a HPCCCH that might be regarded as essential but where alternatives to the HPCCCH have been identified that have comparable functionality and performance making the use of the HPCCCH no longer essential.¶

(2931) "These rules" means OAR 333-016-2001 to 333-016-3080.¶

(302) "Trade association" has the meaning given that term in ORS 431A.253.

Statutory/Other Authority: ORS 413.042, ORS 431A.253 - 431A.280

Statutes/Other Implemented: ORS 431A.253 - 431A.280

AMEND: 333-016-2030

RULE SUMMARY: Amending OAR 333-016-2030 Modifications to the List of High Priority Chemicals of Concern for Children's Health per HB 3043 (2023), SECTION 2. This change allows the Oregon Health Authority, at its discretion, to add groups of chemicals, as classes or subclasses, to OAR 333-016-2020 Chemicals of High Concern to Children (the HPCCCH list) at future triennial reviews of the HPCCCH list as required by statute.

CHANGES TO RULE:

333-016-2030

Modifications to the List of High Priority Chemicals of Concern for Children's Health ¶

(1) The Oregon Health Authority (Authority) shall consider adding a chemical to the list of high priority chemicals of concern for children's health in OAR 333-016-2020 if ~~that~~ the chemical:¶

(a) Has been added to any of the following:¶

(A) Washington's list of Chemicals of High Concern to Children (WAC 173-334-130);¶

(B) Maine's list of Chemicals of High Concern (Maine law 38 § 1693-A(2));¶

(C) Minnesota's list of Chemicals of High Concern (Minn. Stat. 2010 116.9401 - 116.9407);¶

(D) Vermont's list of Chemicals of high concern to children (18 V.S.A. chapter 38A § 1773);¶

(b) Is currently or subsequently identified by the United States Environmental Protection Agency (USEPA) as being "carcinogenic to humans", or "likely to be carcinogenic to humans" through USEPA's Integrated Risk Information System;¶

(c) Has been or is subsequently found to have a reference dose or reference concentration based on neurotoxicity through USEPA's Integrated Risk Information System;¶

(d) Is currently or subsequently identified in monographs on the Potential Human Reproductive and Developmental Effects, United States Office of Health and Human Services National Toxicology Program, Office of Health Assessment and Translation as a reproductive or developmental toxicant; or¶

(e) Is currently or subsequently identified by the Centers for Disease Control and Prevention in its National Report on Human Exposure to Environmental Chemicals.¶

(2) The Authority may, in its discretion, include a class of chemicals or subclass of chemicals on the list of high priority chemicals of concern for children's health, in accordance with ORS 431A.255(1)(b). In making a decision whether to include a class or subclass of chemicals in the list, the Authority will consider the provisions in section (1) of this rule.¶

(3) The Authority shall also consider adding a chemical to the list of HPCCCHs in OAR 333-016-2020 if that the chemical, on or after the effective date of these rules:¶

(a) Is found to have the potential, as demonstrated by credible, peer-reviewed scientific evidence to:¶

(A) Harm the normal development of a fetus or child or cause other developmental toxicity;¶

(B) Act as a carcinogen;¶

(C) Cause genetic damage or reproductive harm;¶

(D) Disrupt the endocrine system;¶

(E) Damage the nervous system, immune system or organs;¶

(F) Cause other systemic toxicity;¶

(G) Be a very persistent toxic substance by having a half-life greater than or equal to one of the following:¶

(i) A half-life in soil or sediment of greater than one hundred eighty days.¶

(ii) A half-life greater than or equal to sixty days in water or evidence of long-range transport; or¶

(H) Be a very bioaccumulative toxic substance by having a bioconcentration factor or bioaccumulation factor greater than or equal to five thousand, or if neither are available, having a log Kow greater than 5.0; and¶

(b) Has been found through:¶

(A) Biomonitoring to be present in human blood, umbilical cord blood, breast milk, urine or other bodily tissues or fluids;¶

(B) Sampling and analysis to be present in household dust, indoor air, drinking water or elsewhere in the home environment; or¶

(C) Monitoring to be present in fish, wildlife or the natural environment.¶

(34) ~~The Oregon Health Authority~~ may remove a chemical, class or subclass of chemicals from the list if the Authority determines that:¶

(a) The chemical, class or subclass of chemicals is no longer being used in children's products; or¶

(b) The chemical, class or subclass of chemicals has been removed from any of the lists identified in subsection

(1)(a) through (e) of this rule.¶

(45) The list of HPCCCHs in OAR 333-016-2020 may only be modified by following the Administrative

Procedures Act rulemaking process.

Statutory/Other Authority: ORS 413.042, ORS 431A.255

Statutes/Other Implemented: ORS 431A.255

AMEND: 333-016-2060

RULE SUMMARY: Amending OAR 333-016-2060 Notification Requirements per HB 3043 (2023), SECTION 3. With this required change, manufacture reports are due January 31st of even-numbered years for the previous two-year biennial notice/reporting period instead of January 1st.

CHANGES TO RULE:

333-016-2060

Notification Requirements ¶¶

- (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 as an individual chemical or a member of a class or subclass of chemicals, in an amount at or above a de minimis level must submit:¶¶
 - (a) A notice to the ~~Authority~~ Oregon Health Authority (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 For the reporting years 2018, 2020, and 2022, reports are due on January 1st.¶¶~~
(4) On and after January 1, 2024, manufacturer reports are due on January 31st 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

RULE SUMMARY: Amending OAR 333-016-3050 Quantitative Exposure Assessment per HB 3043 (2023), SECTION 6. This change adds inaccessible to this rule. For purposes of this rule, inaccessible is defined.

CHANGES TO RULE:

333-016-3050

Quantitative Exposure Assessment

(1) For purposes of this rule, "inaccessible" means a HPCCCH that cannot be absorbed, swallowed, mouthed, or inhaled through normal and reasonably foreseeable use and abuse of the product.

(2) A Quantitative Exposure Assessment (QEA) must demonstrate that a HPCCCH in a children's product is not reasonably anticipated to result in exposure to a child based on an analysis of the leachability and bioavailability of the HPCCCH.

(23) A QEA may be done in two steps, as follows:

(a) A description of exposure scenario(s) that demonstrate ~~how, if at all,~~ that a HPCCCH in the children's product is inaccessible to the consumer or otherwise could not reasonably be anticipated to be transferred to or into a child's body through a completed exposure pathway because of leachability and bioavailability of a HPCCCH from the children's product. Exposure scenarios must focus on the reasonably foreseeable use and abuse of the specified children's product.

(b) If the manufacturer determines that the exposure scenarios, through reasonably foreseeable use and abuse of the specified children's product, are reasonably anticipated to result in a completed exposure pathway to a child regardless of the amount of HPCCCH potentially transferred, the manufacturer shall submit information on the leachability and bioavailability of HPCCCH from a product, including measurements of the concentration of a HPCCCH in the simulated media such as saliva, sweat, or digestive fluid appropriate for the exposure scenarios, using analytical methods relevant to the chemical and the product. The manufacturer must also submit a copy of any analytical test results for the HPCCCH in each media tested that include:

(A) The specific analytical methods or source of information utilized to determine the concentration of the HPCCCH in media relevant for each exposure pathway.

(B) The detection limit for each HPCCCH for each analytical instrument used for the testing in each medium tested.

(c) If a manufacturer determines that, based on exposure scenarios, a HPCCCH is inaccessible or cannot reasonably be anticipated to be transferred to or into a child's body through a completed exposure pathway because of leachability and bioavailability and only conducts the first step of the QEA as described in ~~subsection~~ (23)(a) of this rule, the manufacturer shall provide a detailed report and analysis to the ~~Authority~~ Oregon Health Authority (Authority) that demonstrates to the Authority's satisfaction, that a child would not be exposed to a HPCCCH.

(34) A QEA must include citations from scientific literature for any assertion made.

(45) Laboratory analysis done for purposes of a QEA must be conducted by a laboratory accredited to ISO/IEC 17025 as described in OAR 333-016-2070(7)(a).

(56) To enable accurate identification of children's products on which a QEA is conducted, such products must be identified by manufacturers as specified in OAR 333-016-3010(3)(a) through (c).

(67) In order to be approved a QEA must demonstrate that HPCCCH concentrations measured in the media are less than or equal to the Practical Quantification Limit of the HPCCCH established in OAR 333-016-2035(2), Exhibit A, incorporated by reference.

(78) If the Authority determines that there are exposure scenarios for which a completed exposure pathway is possible through reasonably foreseeable use and abuse of the specified children's product, it will deny the QEA. The manufacturer may resubmit a revised request along with a completed QEA.

(89) A QEA approved by the Authority may be used to apply to a new product if the composition of the new product is substantially similar to those specified in an approved QEA and differ only in ways that do not affect the HPCCCH's behavior in the product. Differences may include, but are not limited to, packaging, size/volume, product name, and other minor aesthetic differences. The use of a QEA approved by the Authority in this manner is permitted if all of the following are demonstrated for the new product:

(a) The chemical composition of the new product is substantially similar to those in an approved QEA;

(b) There are not any HPCCCHs at or above de minimis in addition to those in the product specified in the approved QEA; and

(c) Neither the concentration of the HPCCCH nor its mobility from the product has increased from those in the referenced product.

(910) To substantiate a claim that a QEA approved by the Authority applies to a new product, manufacturers shall submit all of the following:

- (a) A copy of the referenced QEA approved by the Authority;¶
- (b) Documentation demonstrating compliance with section (82) of this rule, which must include the signature, on an application form provided by the Authority, of an authorized representative of the manufacturer bringing the product into Oregon, with the knowledge and authority to attest to the veracity of the information submitted under section (82) of this rule; and¶
- (c) Identification of new affected products as specified in section (56) of this rule.

Statutory/Other Authority: ORS 413.042, ORS 431A.265

Statutes/Other Implemented: ORS 431A.265