OFFICE OF THE SECRETARY OF STATE
LAVONNE GRIFFIN-VALADE
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE
AND TRIBAL LIAISON

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

PERMANENT ADMINISTRATIVE ORDER

FILED
12/15/2023 1:16 PM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

PH 56-2023
CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

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

EFFECTIVE DATE: 01/01/2024

AGENCY APPROVED DATE: 12/15/2023

CONTACT: Justin Waltz
971-673-1217
publichealth.rules@odhsoha.oregon.gov

800 NE Oregon St.
Portland,OR 97232

Filed By:
Public Health Division
Rules Coordinator

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

AMEND: 333-016-2010

NOTICE FILED DATE: 10/30/2023

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 being 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).¶
(10~~1~~) "Contaminant" has the meaning given that term in ORS 431A.253.¶
(11~~2~~) "De minimis level" has the meaning given that term in ORS 431A.253.¶
(12~~3~~) "Essential use" means a function of a HPCCCH in a children's product considered critical for performance of a product.¶
(13~~4~~) "Exposure scenarios" means the mechanisms by which children may be exposed to HPCCCHs found in a children's product.¶
(14~~5~~) "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.¶
(15~~6~~) "HPCCCH" means high priority chemicals of concern to children's health.¶

(16~~7~~) "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.¶
(17~~8~~) "Intentionally added chemical" has the meaning given that term in ORS 431A.253.¶
(18~~9~~) "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.¶
(~~19~~20) "Manufacturer" has the meaning given that term in ORS 431A.253.¶
(20~~1~~) "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.¶
(21~~2~~) "Mouthable" has the meaning given that term in ORS 431A.253.¶
(22~~3~~) "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.¶
(23~~4~~) "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.¶
(24~~5~~) "Practical quantification limit" has the meaning given that term in ORS 431A.253.¶
(25~~6~~) "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.¶
(26~~7~~) "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.¶
(27~~8~~) "Reasonably foreseeable use and abuse" includes: non-incidental 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.¶
(28~~9~~) "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.¶
(~~29~~31) "These rules" means OAR 333-016-2001 to 333-016-3080.¶
(30~~2~~) "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

NOTICE FILED DATE: 10/30/2023

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 Childrens 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.¶
(~~3~~4) 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

NOTICE FILED DATE: 10/30/2023

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~~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 202~~0~~4, a manufacturer must include children's products sold or offered for sale between January 1, 20~~18~~22, and December 31, 20~~19~~23, 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

AMEND: 333-016-3050

NOTICE FILED DATE: 10/30/2023

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.¶
(~~2~~3) A QEA may be done in two steps, as follows:¶
(a) A description of exposure scenario(s) that demonstrate ~~how, if at all,~~s that a HPCCCH in ~~the~~a 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 ~~sub~~section (~~2~~3)(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.¶
(~~3~~4) A QEA must include citations from scientific literature for any assertion made.¶
(~~4~~5) 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).¶
(~~5~~6) 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).¶
(~~6~~7) 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.¶
(~~7~~8) 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.¶
(~~8~~9) 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.¶

(~~9~~10) 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 (~~8~~9) 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 (~~8~~9) of this rule; and¶
(c) Identification of new affected products as specified in section (~~5~~6) of this rule.
Statutory/Other Authority: ORS 413.042, ORS 431A.265
Statutes/Other Implemented: ORS 431A.265