Current Oregon Administrative Rules (OARs) for Oregon's Toxic Free Kids Act

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 high priority chemical of concern to children's health (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).

(11) "Contaminant" has the meaning given that term in ORS 431A.253.

(12) "De minimis level" has the meaning given that term in ORS 431A.253.

(13) "Essential use" means a function of a HPCCCH in a children’s product considered critical for performance of a product.

(14) "Exposure scenarios" means the mechanisms by which children may be exposed to HPCCCHs found in a children’s product.

(15) "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.

(16) "HPCCCH" means high priority chemicals of concern to children’s health.

(17) "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.

(18) "Intentionally added chemical" has the meaning given that term in ORS 431A.253.

(19) "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.

(20) "Manufacturer" has the meaning given that term in ORS 431A.253.

(21) "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.

(22) "Mouthable" has the meaning given that term in ORS 431A.253.

(23) "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.

(24) "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.

(25) "Practical quantification limit" has the meaning given that term in ORS 431A.253.

(26) "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.

(27) “Product model” means the specific product name used by the manufacturer to place the product into the stream of commerce.

(28) "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.

(29) "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.

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

(31) "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.

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

(33) "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
History:
PH 119-2024, amend filed 12/22/2024, effective 01/01/2025
PH 56-2023, amend filed 12/15/2023, effective 01/01/2024
PH 9-2021, amend filed 02/28/2021, effective 03/01/2021
PH 29-2015, f. 12-29-15, cert. ef. 1-1-16

333-016-2020
Chemicals of High Concern to Children

The following chemicals are designated as high priority chemicals of concern for children's health when used in children's products:

(1) Formaldehyde (50-00-0).

(2) Aniline (62-53-3).

(3) N-Nitrosodimethylamine (62-75-9).

(4) Benzene (71-43-2).

(5) Vinyl chloride (75-01-4).

(6) Acetaldehyde (75-07-0).

(7) Methylene chloride (75-09-2).

(8) Carbon disulfide (75-15-0).

(9) Methyl ethyl ketone (78-93-3).

(10) 1,1,2,2-Tetrachloroethane (79-34-5).

(11) Tetrabromobisphenol A (TBBPA) (79-94-7).

(12) Bisphenol A (BPA) (80-05-7).

(13) Bisphenol S (BPS) (80-09-1).

(14) Dicyclohexyl phthalate (DCHP) (84-61-7).

(15) Diethyl phthalate (DEP) (84-66-2).

(16) Diisobutyl phthalate (DIBP) (84-69-5).

(17) Di-n-butyl phthalate (DBP) (84-74-2).

(18) Di-n-hexyl phthalate (DnHP) (84-75-3).

(19) Butyl benzyl phthalate (BBP) (85-68-7).

(20) N-Nitrosodiphenylamine (86-30-6).

(21) Hexachlorobutadiene (HCDB) (87-68-3).

(22) Propyl paraben (94-13-3).

(23) Butyl paraben (94-26-8).

(24) 2-Aminotoluene (95-53-4).

(25) 2,4-Diaminotoluene (95-80-7).

(26) Methyl paraben (99-76-3).

(27) 4-Hydroxybenzoic acid (99-96-7).

(28) Ethylbenzene (100-41-4).

(29) Styrene (100-42-5).

(30) 4-Nonylphenol (104-40-5); 4-NP and its isomer mixtures including CAS 84852-15-3 and CAS 25154-52-3.

(31) 4-Chloroaniline (106-47-8).

(32) Acrylonitrile (107-13-1).

(33) Ethylene glycol (107-21-1).

(34) Toluene (108-88-3).

(35) Phenol (108-95-2).

(36) 2-Methoxyethanol (109-86-4).

(37) Ethylene glycol monoethyl ether (110-80-5).

(38) Triphenyl phosphate (TPP) (115-86-6).

(39) Tris(2-chloroethyl) phosphate (TCEP) (115-96-8).

(40) Di-2-ethylhexyl phthalate (DEHP) (117-81-7).

(41) Di-(2-methoxyethyl) phthalate (DMEP) (117-82-8).

(42) Di-n-octyl phthalate (DnOP) (117-84-0).

(43) Hexachlorobenzene (118-74-1).

(44) 3,3’-Dimethylbenzidine and Dyes Metabolized to 3,3’-Dimethylbenzidine (119-93-7).

(45) Ethyl paraben (120-47-8).

(46) 1,4-Dioxane (123-91-1).

(47) Tris (2,3-dibromopropyl) phosphate (TDBPP) (126-72-7).

(48) Tri-n-butyl phosphate (126-73-8) (TNBP).

(49) Tetrachloroethene (127-18-4).

(50) Dipentyl phthalate (131-18-0) (DPP)

(51) Benzophenone-2 (Bp-2) (131-55-5)

(52) 4-tert-Octylphenol (140-66-9).

(53) Estragole (140-67-0).

(54) 2-Ethylhexanoic acid (149-57-5).

(55) Perfluorooctanoic acid and related substances (PFOA) (335-67-1).

(56) Pentachlorobenzene (608-93-5).

(57) Bisphenol F (BPF) (620-92-8).

(58) C.I. Solvent yellow 14 (842-07-9).

(59) N-Methylpyrrolidone (872-50-4).

(60) Tricresyl phosphate (TCP) (1330-78-5).

(61) Decabromodiphenyl ether (BDE-209) (1163-19-5).

(62) Ethylhexyl diphenyl phosphate (EHDPP) (1241-94-7).

(63) Perfluorooctane sulfonic acid and its salts; PFOS (1763-23-1).

(64) 4-Octylphenol (1806-26-4).

(65) 2-Ethyl-hexyl-4-methoxycinnamate (5466-77-3).

(66) Mercury & mercury compounds (7439-97-6).

(67) Antimony and Antimony compounds (7440-36-0).

(68) Arsenic and Arsenic compounds (7440-38-2), including arsenic trioxide (1327-53-3) and dimethyl arsenic (75-60-5).

(69) Cadmium and cadmium compounds (7440-43-9).

(70) Cobalt and cobalt compounds (7440-48-4).

(71) Tris(1-chloro-2-propyl) phosphate (TCPP) (13674-84-5).

(72) Tris(1,3-dichloro-2-propyl) phosphate (TDCPP) (13674-87-8).

(73) Butylated hydroxyanisole (BHA) (25013-16-5).

(74) Hexabromocyclododecane (HBCD) (25637-99-4).

(75) Bis (2-ethylhexyl) tetrabromophthalate (TBPH) (26040-51-7)

(76) Diisodecyl phthalate (DIDP) (26761-40-0).

(77) Diisononyl phthalate (unbranched) (DINP) (28553-12-0).

(78) Bis(chloromethyl)propane-1,3-diyl tetrakis-(2-chloroethyl) bis(phosphate) (V6) (38051-10-4).

(79) Isopropylated triphenyl phosphate (IPTPP) (68937-41-7).

(80) Decabromodiphenyl ethane (DBDPE) (84852-53-9).

(81) Short-chain chlorinated paraffins (SCCP) (85535-84-8).

(82) Chlorinated paraffins (108171-26-2).

(83) 2-ethylhexyl-2,3,4,5-tetrabromobenzoate (TBB) (183658-27-7).

Statutory/Other Authority: ORS 413.042 & ORS 431A.255
Statutes/Other Implemented: ORS 431A.255
History:
PH 119-2024, amend filed 12/22/2024, effective 01/01/2025
PH 91-2021, amend filed 12/29/2021, effective 01/01/2022
PH 9-2021, amend filed 02/28/2021, effective 03/01/2021
PH 252-2018, amend filed 09/11/2018, effective 01/01/2019
PH 29-2015, f. 12-29-15, cert. ef. 1-1-16

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 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.

(4) The 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.

(5) 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
History:
PH 56-2023, amend filed 12/15/2023, effective 01/01/2024
PH 9-2021, amend filed 02/28/2021, effective 03/01/2021
PH 29-2015, f. 12-29-15, cert. ef. 1-1-16

333-016-2035
Manufacturer Disclosure of High Priority Chemicals of Concern for Children's Health Used in Children's Products: Practical Quantification Limits

(1) The practical quantification limit for a chemical that is a contaminant is 100 parts per million.

(2) The practical quantification limits for intentionally added chemicals are the limits established in Exhibit A, incorporated by reference.

[ED. NOTE: To view attachments referenced in rule text, click here to view rule.]

Statutory/Other Authority: ORS 413.042
Statutes/Other Implemented: ORS 431A.253 – 431A.280
History:
PH 119-2024, amend filed 12/22/2024, effective 01/01/2025
PH 91-2021, amend filed 12/29/2021, effective 01/01/2022
PH 9-2021, amend filed 02/28/2021, effective 03/01/2021
PH 280-2018, amend filed 12/10/2018, effective 01/01/2019
PH 10-2017, minor correction filed 10/12/2017, effective 10/12/2017
PH 34-2016, f. & cert. ef. 12-1-16

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) A manufacturer of a children's product sold or offered for sale in this state that contains a high priority chemical of concern to children's health (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 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. 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 2024, a manufacturer must include children's products sold or offered for sale between January 1, 2022, and December 31, 2023, 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) The brand name and product model;

(d) A description of the function of the chemical in the children's product;

(e) The amount of the chemical used in each unit. 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;

(f) The target age category for whom the children's product is intended, either ages 0-3, 3-12 or 0-12 years-old;

(g) 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;

(h) The name and address of the manufacturer, and the name, address and telephone number of the contact person for the manufacturer;

(i) The name, address and contact information for the trade association submitting the notification on behalf of the affected industry; and

(j) 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

History:
PH 119-2024, amend filed 12/22/2024, effective 01/01/2025
PH 56-2023, amend filed 12/15/2023, effective 01/01/2024
PH 91-2021, amend filed 12/29/2021, effective 01/01/2022
PH 40-2021, temporary amend filed 08/26/2021, effective 08/26/2021 through 02/21/2022
PH 9-2021, amend filed 02/28/2021, effective 03/01/2021
PH 253-2018, amend filed 09/11/2018, effective 10/01/2018
PH 5-2017, f. 1-31-17, cert. ef. 2-1-17
PH 34-2016, f. & cert. ef. 12-1-16

333-016-2065
Formal Communications Regarding Toxic Free Kids

Formal communication between manufacturers or trade associations and the Authority relating to waiver, chemical substitution, chemical removal, or exemption requests, and their fees, shall be to and from ToxicFreeKids.Program@dhsoha.state.or.us.

Statutory/Other Authority: ORS 413.042 & ORS 431A.258
Statutes/Other Implemented: ORS 431A.258
History:
PH 9-2021, adopt filed 02/28/2021, effective 03/01/2021

333-016-2070
Exemptions from Notice Requirement

(1) A manufacturer of children's products with annual worldwide gross sales of less than $5 million, as reported on the most recent tax return filed by the manufacturer before the notification required under OAR 333-016-2060, is exempt from all the requirements of these rules.

(2) If, following the filing of the most recent tax return, a manufacturer's annual worldwide gross sales are $5 million or more, the manufacturer must submit a notice as required under OAR 333-016-2060. The notice must be submitted during the next applicable reporting period or within 180 days of the filing, whichever is later.

(3) A manufacturer or trade association may submit to the Oregon Health Authority (Authority) a request for an exemption from these rules if the high priority chemical of concern to children's health (HPCCCH) in a children's product is present only as a contaminant at or above the de minimis level, and a manufacturing control program (MCP) is in place. A request for an exemption must be accompanied by any applicable fees in OAR 333-016-2080.

(a) An exemption request submitted by a trade association on behalf of its members must identify each member for which the exemption is being requested, including the name and contact information of a representative for each of those members.

(b) A request for an exemption from these rules by any entity must be received by the Authority on or before January 31st of even numbered years for the previous two-year biennial notice period.

(4) In order to meet the standards for an exemption an MCP must be structured using at least one of the following categories:

(a) Manufacturing processes, for example polymerization of plastic resin, injection-molding of plastic, pad-transfer printing, silk screening;

(b) Materials or group of materials, for example multiple styrenic plastics;

(c) Component parts;

(d) A HPCCCH present as a contaminant at or above the de minimis level; or

(e) Finished products.

(5) In addition to the information provided in section (4) of this rule a manufacturer or a trade association must document in its exemption request the specific HPCCCH present as a contaminant at or above the de minimis level that the MCP is intended to address and the product categories where the HPCCCH are found. MCPs submitted in support of an exemption request by a trade association on behalf of a member or members must include the product categories for which each member is seeking an exemption.

(6) In order for the manufacturer to demonstrate that an MCP meets the minimum standards for an exemption, the MCP must meet generally-recognized industry best manufacturing practices and processes for the control of a HPCCCH, such as but not limited to**:**

(a) The most current and appropriate International Standards Organization (ISO) requirements for a specific manufacturing process or facility. The manufacturer must demonstrate how the ISO certification held by the manufacturer or supplier is controlling the contaminant in a component part or in the finished children’s product**.**

(b) Another established certification or standards manufacturing control program such as, but not limited to, Sony Corporations Green Partners Standards, the European ROHS (Restriction of Hazardous Substances in Electronic Parts), and EN-71.

(c) The most current American Society for Testing and Materials (ASTM) International standards that provide the recommended industry standards for materials used or produced in the manufacturing process;

(d) Any proven alternative methodology that will enable the manufacturer to demonstrate:

(A) That the methodology controls the contaminant to the lowest practicable levels in the finished children's product; and

(B) That the alternative methodology is as or more effective at controlling the contaminant than the standards in subsections (a) through (c) of this section.

(7) For any category described in section (4) of this rule a manufacturer must provide adequate evidence that the contaminant is being controlled, including but not limited to:

(a) Periodic laboratory test reports from a third-party laboratory accredited to the current ISO/IEC 17025 standards by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) mutual recognition arrangement. The laboratory must be accredited for the method used to conduct the testing. The testing must show the presence, if quantifiable, and the amount of a HPCCCH, including documentation that characterizes the test methodology.

(b) A supplier's certificate of analysis documenting the maximum levels of contaminant in any category described in section (4) of this rule for which the exemption is being requested. A certificate of analysis must include:

(A) The name and address of the laboratory that performed the tests;

(B) The name and description of the product or material being tested, including, if known, the batch number used by the original manufacturer;

(C) The date of the batch's manufacture;

(D) A description of methodology employed to take samples from the batch to ensure that samples are representative of the product or material being tested;

(E) A reference to the analytical laboratory test method used, including the data quality assurance criteria and reporting limits;

(F) The results of all analytical laboratory tests performed on the batch for which the certificate is issued (in numerical form, where applicable) and a comparison with the established acceptance criteria (limits);

(G) The date or dates on which the test or tests were performed; and

(H) The signature of an authorized representative of the laboratory, and the contact information for that individual.

(c) Documentation demonstrating that the instituted control measures are able to control the contaminant, as appropriate for the category described in section (4) of this rule, including but not limited to, the quantification of the degree of contaminant control occurring because of contaminant control measures instituted.

(8) In addition to meeting one of the requirements of section (6) of this rule a manufacturer must document and describe, in its exemption request, whether the manufacturer's or the manufacturer's supplier's manufacturing control process, include any of the following**:**

(a) Procedures to ensure the quality and purity of feedstock, whether raw or recycled;

(b) Contract specifications for manufacturing process parameters, for example material purity, drying and curing times when relevant to the presence of high priority chemicals in the finished children's product components;

(c) Periodic testing that is for the presence and amount of HPCCCH in the finished children's product, including documentation of how tests were conducted and applicable lab results from an accredited third-party laboratory that meets the standards in subsection (7)(a) of this rule;

(d) Procedures and approaches to audit the methods used by contractors or suppliers to control a HPCCCP present as a contaminant in a children's product; and

(e) Education and outreach to members of a supply chain about the importance to the manufacturer of controlling the amount of HPCCCH in supplied materials through activities such as discussions with suppliers, oral presentations, written materials or webinars.

(9) The Authority, upon receipt of an exemption request will date stamp the document. Once date stamped the Authority must approve or deny an exemption request within 180 days.

(a) If the Authority does not approve or disapprove the exemption request within 180 days the manufacturing control program exemption is deemed approved.

(b) If the Authority approves the exemption the Authority will notify the manufacturer of the approval, in writing.

(c) If an exemption request is disapproved, the Authority will provide written notice to the manufacturer of the disapproval and the reason for the disapproval.

(10) If the Authority disapproves an exemption request, the manufacturer may submit a revised exemption request for consideration within 180 days after the Authority's notice of disapproval.

(11) If the exemption request is denied a second time, the manufacturer will have 90 days from the date of the written notification of disapproval to submit a notification in accordance with OAR 333-016-2060.

(12) A manufacturer who has been denied an exemption request a second time may submit a new exemption request under section (3) of this rule during future biennial notice periods.

(13) At any time the Authority may request additional information from a manufacturer requesting an exemption, and may specify the time period by which the manufacturer must provide the requested information

(14) A manufacturer or trade association may request an amendment of an MCP previously approved by the Authority. A request must be made at least 30 days before the next biennial notice period. Such amendments are limited to the following:

(a) The addition of product categories to an MCP provided that the HPCCCH in the manufacturing of products in these added categories is monitored and controlled, at all stages, with the specific mechanisms, tests and processes itemized in the approved MCP.

(b) Changes in the specific mechanisms, tests and processes identified in an approved MCP that are used to control an HPCCCH.

(c) The inclusion of additional members for specific product categories on an MCP approved by the Authority provided those members use all specific mechanisms, tests and processes itemized on the approved MCP for those product categories.

(15) The Authority may impose an MCP review fee under OAR 333-016-2080(1)(b)(B) for review of a request to amend an approved MCP.

(16) Within 90 days the Authority will inform the holder of the approved exemption request if the proposed amendment to the MCP still meets the standards for exemption as described in these rules.

(17) Trade associations seeking to include additional members on an MCP approved by the Authority in accordance with subsection (14)(c) of this rule shall submit a new exemption request as specified in section (3) of this rule. A request to add a member manufacturer to an approved MCP must include the product categories for which each member manufacturer is seeking exemption from these rules.

(18) A trade association must notify the Authority within 90 days of the date it determines a manufacturer member listed on an approved MCP is no longer party to an approved MCP.

(19) An approved MCP is only valid for the manufacturer that submitted it for approval. If a manufacturer with an approved MCP merges with or is acquired by another business entity the new controlling entity must send a notice to the Authority within 90 days confirming that the specific mechanisms, tests and processes itemized in the previously approved MCP will continue to be utilized, or the exemption will be considered by the Authority to be invalid.

Statutory/Other Authority: ORS 413.042, 431A.258 & 431A.268
Statutes/Other Implemented: ORS 431A.258 & 431A.268
History:

PH 119-2024, amend filed 12/22/2024, effective 01/01/2025
PH 9-2021, amend filed 02/28/2021, effective 03/01/2021
PH 5-2017, f. 1-31-17, cert. ef. 2-1-17
PH 34-2016, f. & cert. ef. 12-1-16

333-016-2080
Fees

(1) The following fees are established:

(a) Notification. A nonrefundable fee of $250 for the notification of each HPCCCH reported to the Authority under OAR 333-016-2060(1).

(b) Exemption request made under OAR 333-016-2070(3) or an amendment to an exemption request under OAR 333-016-2070(14)(b):

(A) A non-refundable fee of $1,500; and

(B) $200 per hour for review of an MCP.

(c) Request for waiving requirement to remove or substitute chemicals:

(A) A non-refundable fee of $1,500; and

(B) $200 per hour for review of an Alternatives Assessment or a Quantitative Exposure Assessment.

(d) Request to substitute chemicals:

(A) A non-refundable fee of $1,500; and

(B) $200 per hour for review of a Hazard Assessment conducted with an alternative methodology under OAR 333-016-3030(4).

(e) A non-refundable fee of $1,500 for a request to be exempt from removal or substitution requirements under OAR 333-016-3015.

(2) The Authority will not accept an exemption request per OAR 333-016-2070(3) and (14)(b) or OAR 333-016-3015; a waiver to remove or substitute chemicals; a request to substitute chemicals; or a request to be exempt from removal or substitution requirements under OAR 333-016-3015 unless the non-refundable fee under this rule is submitted along with the request.

(3) Prior to reviewing a request for a waiver, chemical substitution, exemption OAR 333-016-2070 and (14)(b) or a Hazard Assessment conducted with an alternative methodology under OAR 333-016-3030(4), the Authority will send the applicant an estimate for the cost of the review. Unless the applicant informs the Authority in writing within seven business days of the date the fee estimate was sent, objecting to the estimate, the Authority will consider the

estimate to be acceptable and will send an invoice to the applicant once the review of complete.

(4) If an applicant objects to the estimate within seven business days the Authority will not review the request and the applicant may do one of the following:

(a) Submit a second version of the initial request within 30 calendar days of the date the applicant submitted its objection to the Authority, in which case no additional application fee is required; or

(b) Submit a new request and $1,500 non-refundable fee, if more than 30 days has passed since the applicant submitted its objection to the Authority; or

(c) Comply with OAR 333-016-3010(3) or 333-016-2060.

(5) If a second version of the initial request is submitted under section (4)(a) of this rule or if a new request is submitted under (4)(b) of this rule, the Authority will provide a new estimate of the cost of the review. The Applicant will have seven calendar days to respond by either accepting or declining the estimate. If the estimate is declined or a response is not received within seven business days, the Authority will consider the request for a waiver, chemical substitution, exemption under OAR 333-016-2070(3) and (14)(b), or Hazard Assessment conducted with an alternative methodology under OAR 333-016-3030(4) to be incomplete and the request will not be reviewed. The Authority will not accept a third version of the initial request or another 'new request' and the manufacturer of the children's products for which the exemption, waiver or substitution request was made must comply with the applicable Oregon Administrative Rules.

(6) If in the course of its review the Authority expects the actual number of hours to exceed the estimate by more than 15 percent the Authority will stop the review and send a new estimate to the applicant. Within seven business days from the date the new estimate was sent the applicant must do one of the following:

(a) Accept the revised estimate by agreeing to pay for the new estimated amount; or

(b) Decline the new estimate and the Authority will consider the request for a waiver, chemical substitution, or exemption incomplete, and the request will not be reviewed. The Authority will invoice the Applicant for the actual hours spent on the review.

(7) The process delineated in Sections 3 through 6 of this rule also applies to revised requests for a waiver, chemical substitution, an exemption under OAR 333-016-2070(3) and (14), or a Hazard Assessment conducted with an alternative methodology under OAR 333-016-3030(4) .

(8) An applicant must pay its review fees within 30 days of receipt of the invoice.

Statutory/Other Authority: ORS 413.042 & 431A.270
Statutes/Other Implemented: ORS 431A.270
History:
PH 9-2021, amend filed 02/28/2021, effective 03/01/2021
PH 253-2018, amend filed 09/11/2018, effective 10/01/2018
PH 5-2017, f. 1-31-17, cert. ef. 2-1-17

333-016-3010
Removal or Substitution of High Priority Chemicals

(1) On or before the date on which a manufacturer of a children's product must submit the third biennial notice required under OAR 333-016-2060 for a high priority chemical of concern to children's health (HPCCCH) that is present in a children's product, the manufacturer must remove or make a substitution, or seek a waiver under OAR 333-016-3040 if the HPCCCH is present in a children's product that is:

(a) Mouthable;

(b) A children's cosmetic; or

(c) Made for, marketed for use by or marketed to children under three years of age.

(2) A manufacturer with 25 or fewer employees may apply for a two-year extension of the date specified in ORS 431A.260 to meet the requirements of these rules. To apply for an extension a manufacturer must submit a request for an extension. A request for an extension must:

(a) Be received by the Oregon Health Authority (Authority) on or before the date on which the manufacturer of a children's product is obligated to submit the third biennial notice required under ORS 431A.260.

(b) Include documentation that the manufacturer had an average of 25 or fewer employees on its payroll during the third biennial notice period and the number of employees currently employed by the manufacturer.

(3) A manufacturer that has previously reported a HPCCCH to the Authority and later removes the HPCCCH from a children's product sold or offered for sale in Oregon and does not substitute another chemical or is no longer manufacturing such a product, must submit notice to the Authority that the manufacturer is no longer using the chemical or a substitute chemical or manufacturing the product. The notice must be submitted on or before the date (January 31st) on which the requirement to remove or substitute a HPCCCH from a children's product is triggered under ORS 431A.260. The notice shall include

(a) The product category of the children's product;

(b) The brand names under which it is sold in Oregon and the model numbers of the children's product associated with those brand names; and

(c) Universal Product Code or Stock Keeping Unit codes, style codes or other mechanisms sufficient to identify product models sold in Oregon, which have been assigned by the manufacturer.

(4) From the date that the notice under section (3) of this rule is submitted, the manufacturer has 90 calendar days to:

(a) Cease selling or offering for sale in Oregon the children's product; and

(b) Provide notice to all known distributers and retailers to whom the product was distributed that the product may no longer be sold or offered for sale in Oregon. To identify affected units of such children's products, the notice shall include Universal Product Code, Stock Keeping Unit codes, style codes or other mechanisms sufficient to identify the affected product models.

(5) Units identified in this rule may no longer be sold or offered for sale in Oregon.

(6) Manufacturers shall provide the Authority with the notice in subsection (4)(b) of this rule and a list of known distributers and retailers to whom notice was given.

(7) A manufacturer that intends to substitute a HPCCCH pursuant to ORS 431A.263 must comply with OAR 333-016-3030.

Statutory/Other Authority: ORS 413.042, ORS 431A.260 & ORS 431A.268
Statutes/Other Implemented: ORS 431A.260
History:
PH 119-2024, amend filed 12/22/2024, effective 01/01/2025
PH 9-2021, adopt filed 02/28/2021, effective 03/01/2021

333-016-3015
Exemptions from Removal or Substitution Requirements

(1) For purposes of this rule "children's product" is a children's product as defined in ORS 431A.253 that is:

(a) Mouthable;

(b) A children's cosmetic; or

(c) Made for, marketed for use by or marketed to children under three years of age.

(2) A manufacturer is exempt from meeting the requirement of removal or substitution of a high priority chemical of concern to children's health (HPCCCH) in a children’s product under ORS 431A.260 if one or more of the following is met:

(a) The children’s product contains a HPCCCH used in children’s products at levels that are at or below allowable levels for children’s products as established by the Consumer Product Safety Improvement Act of 2008, P.L. 110-314, 122 Stat. 3016, as in effect on July 27, 2015.

(b) A manufacturer is in compliance with a federal consumer product safety standard adopted under federal law that establishes allowable levels for children’s products of a high priority chemical of concern for children’s health used in children’s products.

(c) The State of Washington has granted an exemption for the removal or substitution of a HPCCCH in the same children’s product model for which the exemption is requested under OAR 333-016-3015.

(d) A children’s product has been tested under applicable EN-71 standards, by a laboratory that is accredited to conduct such testing under the current edition of ISO/IEC 17025 by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation mutual recognition arrangement.

(3) More than one product model may be submitted in a single exemption request.

(4) In order to be exempt under one or more of the categories in section (2) of this rule a manufacturer must submit:

(a) An exemption request on a form prescribed by the Oregon Health Authority (Authority);

(b) The fees specified in OAR 333-016-2080(1)(e);

(c) The information required in OAR 333-016-3010(3)(a) through (c), for the product models as they are sold in Oregon for which exemption is being requested; and

(d) Written documentation supporting the exemption request, including but not limited to an electronic copy of the certificate of conformity issued by the applicable authority or an authorized designate, if available, and evidence that the children’s product meets the standards described in the applicable exemption category including:

(A) For an exemption request under subsection (2)(a) of this rule, the citation for the section of the Consumer Product Safety Improvement Act of 2008, P.L. 110-314, 122 Stat. 3016, in effect on July 27, 2015, naming the HPCCCH.

(B) For an exemption request under subsection (2)(b) of this rule, a citation to the federal consumer product safety standard adopted under federal law that

establishes an allowable level of a HPCCCH in children's products, specific to allowable levels of the HPCCCH in children's products.

(C) For an exemption request under subsection (2)(c) of this rule, a copy of the manufacturer's request for exemption under the applicable State of Washington law and the exemption approval from that state.

(D) For an exemption request under subsection (2)(d) of this rule, an electronic copy of an actual European Community/European Union Declaration of Conformity issued for the product or products for which exemption is being requested, establishing that the product or products meets current EN-71 standards applicable to the HPCCCH and product type for which an exemption is being sought.

(5) This written documentation must be submitted in its entirety to the Authority on or before the date on which the manufacturer is required to submit the third biennial notice under ORS 431A.258 and OAR 333-016-2060.

(6) The Authority will approve or disapprove an exemption request made under section (2) of this rule in writing within 180 days from receipt of all of the documentation required in the rule, explaining the basis of the approval or denial.

(a) If the Authority does not approve or disapprove the exemption request made under section (2) of this rule within 180 days of its submission, the exemption is deemed approved.

(b) If disapproved, a manufacturer may not resubmit an exemption request.

(7) If a manufacturer is granted an exemption under subsection (2)(c) of this rule and subsequently the State of Washington withdraws the approval for the exemption, the manufacturer must immediately notify the Authority and come into compliance with ORS 431A.260 and these rules.

(8) A manufacturer may request to add additional children's products to an approved list of exempted products if the following apply:

(a) The chemical composition of the new product is uniform in composition and chemically identical to those specified in the approved request and differ only in ways that do not affect the HPCCCH's behavior in the product;

(b) There are not any HPCCCHs at or above de minimis in the new product in addition to those in the approved list of exempted product(s); and

(c) Neither the concentration of the HPCCCH nor its mobility from the product has increased from those products in the approved list of exempted product(s).

(9) To request an addition to an approved list of exempted products, manufacturers shall submit the following to the Authority:

(a) A copy of the current Oregon Health Authority approved list of exempted products;

(b) An application form, provided by the Authority, with the signature of an authorized representative of the manufacturer, with the knowledge and authority to attest to the veracity of the information submitted under section (9) of this rule; and

(c) Identification of products proposed to be added, consistent with section (4)(c) of this rule

Statutory/Other Authority: ORS 413.042 & ORS 431A.260
Statutes/Other Implemented: ORS 431A.260
History:
PH 119-2024, amend filed 12/22/2024, effective 01/01/2025
PH 9-2021, adopt filed 02/28/2021, effective 03/01/2021

333-016-3020
Requirements for Chemical Substitution

(1) For purposes of this rule a "children's product" is a children's product as defined in OAR 333-016-3015(1) that is:

(a) Mouthable;

(b) A children's cosmetic; or

(c) Made for, marketed for use by or marketed to children under three years of age.

(2) When a manufacturer of a children's product that is sold or offered for sale in Oregon removes a high priority chemical of concern to children's health (HPCCCH) as required in ORS 431.260 and intends to sell the product in Oregon with a substitute chemical, the manufacturer must provide or submit to the Oregon Health Authority (Authority) no later than the date (January 31st) on which the requirement to remove or substitute a HPCCCH from a children's product is triggered under ORS 431A.260:

(a) A Hazard Assessment (HA) that meets the requirements in OAR 333-016-3030; and

(b) The fees specified in OAR 333-016-2080.;

(3) The Authority must either approve or disapprove a HA within 180 days of the receipt of a HA and the information and fees required in section (2) of this rule.

(4) During its review of the HA the Authority may request additional information from the manufacturer at any time and must specify the time period by which the manufacturer must provide the requested information.

(5) If the Authority does not approve or disapprove the HA within 180 days from receipt of all of the information and fees required in section (2) of this rule the HA is deemed approved and the manufacturer may continue to sell or offer for sale in Oregon the children's product for which the manufacturer submitted a HA.

(6) A HA approved or deemed approved under this rule is valid for a period of three years after the date of submittal of the HA. A manufacturer must resubmit a HA at the end of the three-year period. Any report upon which the resubmitted HA is based must contain a statement that evidence is of such a nature that it can be relied upon, based on current and credible scientific evidence, as specified by the entity conducting the HA, and that the evidence is of such a nature that it can be relied upon for a minimum of three years from the date the report was issued. A HA that has been approved or deemed approved for the same substitute chemical for a total of six years does not need to be submitted a third time.

(7) If the Authority approves the HA it will notify the manufacturer of the approval, in writing.

(8) If the Authority disapproves a HA it will provide written notice to the manufacturer of the disapproval and the basis for the disapproval.

(9) If the Authority disapproves a HA the manufacturer may submit a revised HA within 180 days after the date of the Authority's notice of disapproval that meets the requirements of this rule. The payment of non-refundable fees in OAR 333-016-2080 is not required for a resubmitted HA.

(10) A revised HA is subject to the same requirements as an initial HA under this rule and the Authority will review and approve or disapprove a revised HA in the same manner as an initial HA.

(11) If the Authority disapproves an initial HA and no revised HA is submitted, the manufacturer has 90 calendar days to comply with OAR 333-016-3010(4) through (6).

(12) The Authority will not consider any additional information it did not request that has been provided by a manufacturer and received by the Authority more than seven business days after the revised HA conducted with an alternative hazard assessment methodology (OAR 333-016-3030(4)) is submitted to the Authority.

(13) A manufacturer may request a HA for one or more product models or styles.

(14) If a manufacturer requests a HA for more than one product model or style, the Authority may approve or disapprove a request in whole or in part, based on criteria established in these rules.

(15) Trade associations may submit a HA on behalf of specified member manufacturers if the following conditions are met for each HA submitted:

(a) The HA meets the requirements in OAR 333-016-3030;

(b) The fees are paid as specified in OAR 333-016-2080; and

(c) The products are identified on which a HA has been conducted for each participating manufacturer as specified in OAR 333-016-3010(3)(a) through (c). This list of identified products shall include the name and contact information of a representative for each specified member manufacturer.

(16) It is a violation of this rule to continue to sell or offer for sale in Oregon a children's product with a substitute chemical without an approved or deemed approved HA.

Statutory/Other Authority: ORS 413.042 & ORS 431A.263
Statutes/Other Implemented: ORS 431A.263
History:
PH 119-2024, amend filed 12/22/2024, effective 01/01/2025
PH 9-2021, adopt filed 02/28/2021, effective 03/01/2021

333-016-3030
Hazard Assessment for Substitute Chemicals

(1) A manufacturer must conduct a Hazard Assessment (HA) of the substitute chemical that includes:

(a) A report:

(A) By a Licensed GreenScreen Profiler using GreenScreen® for Safer Chemicals Hazard Assessment Guidance (GreenScreen methodology) that assesses the hazard level of the substitute chemical or chemicals; or

(B) Using an Authority approved methodology as described in section (4) of this rule.

(b) Information about each product model containing the HPCCCH and each final product model containing the substitute chemical that will enable the Authority to determine if the final children's product is inherently less hazardous than before. The information provided shall include but is not limited to:

(A) A high-resolution image of the product model in JPEG or PDF form.

(B) Identification of products on which a HA is conducted by manufacturers as specified in OAR 333-016-3010(3)(a) through (c).

(C) A complete list of the product model's components containing a HPCCCH at or above de minimis levels. For each component, the amount of HPCCCH in the component should be expressed as parts per million. The substitute chemical in

each component of final product model should be expressed as parts per million. The HPCCCH and substitute chemical(s) shall be listed with their Chemical Abstract Numbers.

(2) The Authority will not approve a HA for a substitute chemical that has a hazard level score of 'high' or greater as determined by the GreenScreen methodology or Authority approved methodology for any of the following human health endpoints:

(a) Reproductive toxicity;

(b) Developmental toxicity;

(c) Endocrine activity; or

(d) Skin sensitization.

(3) For a HA submitted with an assessment from a Licensed GreenScreen Profiler:

(a) A HPCCCH is considered by the Authority to be comparable to a chemical that has a GreenScreen Benchmark score of 1.

(b) A substitute chemical is considered to be inherently less hazardous if it is assigned a GreenScreen Benchmark score of 2, 3 or 4, and is in compliance with section (2) of this rule.

(4) A manufacturer may request that the Authority approve an alternative methodology for conducting a HA that exists in the public domain, is hazard-focused, considers the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) categorization method of health hazard, and is comparable to the GreenScreen Guidance methodology of this rule, including having an equivalent or stricter health hazard criteria for the human health endpoints described below:

(a) Carcinogenicity;

(b) Genotoxicity and mutagenicity;

(c) Reproductive toxicity;

(d) Developmental toxicity;

(e) Endocrine activity;

(f) Acute toxicity;

(g) Systemic toxicity;

(h) Neurotoxicity;

(i) Skin sensitization;

(j) Respiratory sensitization;

(k) Skin irritation; or

(l) Eye irritation.

(5) Prior to conducting a HA using a methodology other than the GreenScreen methodology a manufacturer must submit detailed information about the methodology it proposes to use and a detailed analysis comparing the methodology to the GreenScreen Guidance methodology.

(a) Requests to use a HA methodology other than the GreenScreen methodology must be made at least 90 business days before the date the manufacturer submits the Hazard Assessment.

(b) The Authority will review the request and within 60 business days respond in writing to the manufacturer either approving or denying the request.

(6) The Authority will accept a HA that demonstrates with scientifically supported objective data that the children’s product and any substituted chemical is inherently less hazardous than before the substitution was made.

(7) For purposes of this rule and OAR 333-016-3060, the Authority:

(a) Finds that the GreenScreen methodology is scientifically supported by objective data;

(b) Finds that an assessment by a licensed GreenScreen Profiler contains sufficient protocols and safeguards to ensure that the assessment is reliable; and

(c) Will consider an assessment conducted by a licensed GreenScreen Profiler using the GreenScreen methodology that shows a children’s product and any substitute chemical is inherently less hazardous than before the substitution was made, to be sufficient to approve a HA, assuming all other provisions of this rule and OAR 333-016-3030 have been met.

(8) A HA approved by the Authority may be used to apply to a new product if the composition of the new product is substantially similar to that specified in an approved HA and differs 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, and 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 HA;

(b) There are not any HPCCCHs at or above de minimis levels in addition to those in a product that has an approved HA; and

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

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

(a) A copy of the reference HA approved by the Authority;

(b) Documentation demonstrating compliance with section (8) of this rule, which must include the signature, on an application form provided by the Authority, of an authorized representative of the manufacturer bringing products into Oregon, with knowledge and authority to attest to the veracity of the information submitted under section (8) of this rule; and

(c) Identification of new affected products as specified in subsection (1)(b) of this rule.

Statutory/Other Authority: ORS 413.042, ORS 431A.263 & ORS 431A.265
Statutes/Other Implemented: ORS 431A.263 & ORS 431A.265
History:
PH 9-2021, adopt filed 02/28/2021, effective 03/01/2021

333-016-3040
Waiver from Removal or Substitution Requirement

(1) For purposes of applying for a waiver from the removal or substitution requirement in ORS 431A.260 "children's product" is a children's product that is:

(a) Mouthable;

(b) A children's cosmetic; or

(c) Made for, marketed for use by or marketed to children under three years of age.

(2) A manufacturer may request a waiver from the requirement to remove or substitute a chemical under ORS 431A.260 for one or more product models or styles. An application for a waiver must include:

(a) A Quantitative Exposure Assessment (QEA) that meets the requirements of OAR 333-016-3050; or

(b) An Alternatives Assessment (AA) that meets the requirements of OAR 333-016-3060.

(3) An application for a waiver under this rule must be accompanied by the fees specified in OAR 333-016-2080 and the following information:

(a) The name, address, telephone number and other contact information for the manufacturer; and

(b) The information required in OAR 333-016-2060(4)(a) through (i) for each children's product category or children's cosmetics for which a waiver is being requested, based on the information reported in the most recent Biennial Notice Period.

(4) The Authority will not consider any additional information from the manufacturer it did not request, that is received by the Authority more than seven business days after a manufacturer submits a QEA, AA or an HA to the Authority.

(5) The Authority must either approve or disapprove a waiver request within 180 days of the receipt of a request and the fees required in sections (2) and (3) of this rule.

(6) During its review of the waiver request the Authority may request additional information from the manufacturer that submitted the request at any time and must specify the time period by which the manufacturer must provide the requested information.

(7) If the Authority does not approve or disapprove the waiver request within 180 days from receipt of the information and fees required in sections (2) and (3) of this rule the request is deemed approved and the manufacturer may continue to sell or offer for sale in Oregon the children's product for which the manufacturer submitted an AA or QEA.

(8) If the Authority approves a waiver request the Authority will notify the manufacturer of the approval, in writing.

(9) If the Authority disapproves a waiver request it will provide written notice to the manufacturer of the disapproval and the basis for the disapproval.

(10) If the Authority disapproves a waiver request the manufacturer may submit a revised waiver request that meets the requirements of this rule within 180 days after the date of the Authority's notice of disapproval. The payment of non-refundable fees in OAR 333-016-2080 is not required for a resubmitted waiver request.

(11) A revised waiver request is subject to the same requirements as an initial waiver request under this rule and the Authority will review and approve or disapprove a revised waiver request in the same manner as an initial request.

(12) If the Authority disapproves a revised waiver request, or the Authority disapproves an initial request and the manufacturer does not submit a revised waiver request, the manufacturer has 90 calendar days to comply with OAR 333-016-3010(4) through (6).

(13) A manufacturer who has had an initial or revised waiver request disapproved who intends to remove the chemical or substitute a chemical may do so in compliance with these rules but may not sell or offer to sell the children's products unless and until the HPCCCH that is the subject of a the notice requirement in ORS

431A.258 is removed and notice is given to the Authority or the Hazard Assessment for a substitute chemical has been approved by the Authority.

(14) The Authority will disapprove any waiver request from a manufacturer that submits fraudulent information.

(15) Trade associations may submit an application for a waiver on behalf of specified member manufacturers if the following conditions are met for each waiver submitted:

(a) The waiver application follows the requirements of section (2) of this rule.

(b) The fees are submitted as specified in OAR 333-016-2080.

(c) The products are identified on which a QEA or AA has been conducted for each participating manufacturer as specified in OAR 333-016-3010(3)(a) through (c). This list of identified products shall be listed by manufacturer and shall include the name and contact information of a representative for each specified member manufacturer.

(16) If a manufacturer requests a waiver for more than one product model or style, the Authority may approve or disapprove a request in whole or in part, based on criteria established in these rules.

Statutory/Other Authority: ORS 413.042, ORS 431A.263 & ORS 431A.265
Statutes/Other Implemented: ORS 431A.263 & ORS 431A.265
History:
PH 9-2021, adopt filed 02/28/2021, effective 03/01/2021

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.

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

(a) A description of exposure scenario(s) that demonstrates that a HPCCCH in 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 section (3)(a) of this rule, the manufacturer shall provide a detailed report and analysis to the Oregon Health Authority (Authority) that demonstrates to the Authority's satisfaction, that a child would not be exposed to a HPCCCH.

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

(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).

(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).

(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.

(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.

(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.

(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 (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 (9) of this rule; and

(c) Identification of new affected products as specified in section (6) of this rule.

Statutory/Other Authority: ORS 413.042 & ORS 431A.265
Statutes/Other Implemented: ORS 431A.265
History:
PH 56-2023, amend filed 12/15/2023, effective 01/01/2024
PH 9-2021, adopt filed 02/28/2021, effective 03/01/2021

333-016-3060
Alternatives Assessment

(1) An Alternatives Assessment (AA) must evaluate the possibility of replacing chemicals in products or processes with an inherently safer alternative, in order to better protect and enhance human health.

(2) A manufacturer must conduct an AA by doing a Hazard Assessment (HA), Quantitative Exposure Assessment (QEA), technical feasibility assessment, and financial feasibility assessment, starting with an HA, except as specified in section (3) of this rule. The three remaining assessments may be conducted in any order.

(3) If, after HA and technical feasibility assessments are conducted, an alternate chemical substitute or substitutes is not found to be technically feasible, the financial feasibility assessment is not required.

(4) The HA for purposes of an AA must be conducted in accordance with OAR 333-016-3030.

(5) The QEA for purposes of an AA must be conducted in accordance with OAR 333-016-3050.

(6) To substantiate a claim that removal of a HPCCCH or substitution of a HPCCCH in a children's product with a less hazardous chemical is not technically feasible, a manufacturer must provide to the Authority the following for each HPCCCH in a children's product:

(a) A detailed analysis of the role of each HPCCCH in the product specified by function, its application in the product (in a material, component, or manufacturing process) and whether the HPCCCH or function is non-essential, substitutable, essential, or a contaminant;

(b) For HPCCCH roles labeled as substitutable or non-essential, an explanation with supporting evidence shall be provided that justifies retaining the HPCCCH in the children's product;

(c) A detailed analysis of the role played by each HPCCCH if labeled as non-essential, substitutable, or essential in the product for the reliability, quality, useful life and acceptability to consumers of the product; and

(d) After an AA is conducted, a detailed explanation of why it not technically feasible for any identified alternate chemical substitutes to fulfill the roles specified in subsections (a) through (c) of this section.

(7) To substantiate a claim that removal or substitution of a HPCCCH is not financially feasible, a manufacturer must provide to the Authority a price comparison of the cost to produce the children's product with an alternative chemical to the current cost to produce the product. The comparison must include:

(a) Direct costs along the value-chain, such as product reformulation;

(b) Retooling;

(c) Research or other capital investment costs;

(d) An evaluation of adequate supply to meet demand; and

(e) An evaluation of the potential reduction in price of the alternative chemical if the volume of the alternative chemical being purchased increases.

(8) An AA 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 AA 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 an

AA 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 AA;

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

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

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

(a) A copy of the referenced AA approved by the Authority;

(b) Documentation demonstrating compliance with section (8) 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) of this rule; and

(c) Identification of the new affected products as specified in OAR 333-016-3010(3)(a) through (c).

Statutory/Other Authority: ORS 413.042, ORS 431A.263 & ORS 431A.265
Statutes/Other Implemented: ORS 431A.263 & ORS 431A.265
History:
PH 9-2021, adopt filed 02/28/2021, effective 03/01/2021

333-016-3070
Trade Secrets

(1) If a manufacturer submits information to the Authority in order to comply with these rules that the manufacturer believes is a trade secret, the manufacturer must mark the information "confidential – trade secret."

(2) If the Authority receives a public records request for information submitted by a manufacturer, it will review all documents submitted by the manufacturer to determine whether the documents contain trade secrets that would be exempt from disclosure under Oregon's Public Records Act, ORS 192.501.

(3) For purposes of this rule "trade secret" has the meaning given that term in ORS 192.501.

Statutory/Other Authority: ORS 192.501, ORS 413.042 & ORS 431A.253 - 431A.280
Statutes/Other Implemented: ORS 431A.253 - 431A.280

History:
PH 9-2021, adopt filed 02/28/2021, effective 03/01/2021

333-016-3080
Enforcement and Civil Penalties

(1) The Oregon Health Authority (Authority) may impose a civil penalty on a manufacturer for a violation of any provision of ORS 431A.258, 431A.260 or 431A.263, or these rules. A civil penalty may not exceed:

(a) $2,500 for the first violation.

(b) $5,000 for the second and each subsequent violation.

(2) For purposes of assessing civil penalties under these rules a violation consists of a single course of conduct with regard to an entire children's product line that is sold or offered for sale in Oregon.

(3)(a) If a manufacturer violates the notification requirement described in ORS 431A.258 the Authority shall provide the manufacturer with written notice informing the manufacturer of the violation and stating that the manufacturer may avoid a civil penalty for the violation by providing the proper notice required under ORS 431A.258 within 90 days.

(b) If the manufacturer fails to cure the violation within the first 90 days, the Authority may impose a civil penalty not to exceed $2,500.

(c) For a continuing violation, each 90-day period that the violation continues after the preceding imposition of a civil penalty is considered a separate offense subject to a separate civil penalty not to exceed $5,000. The Authority is not required to provide the manufacturer with an opportunity to cure the continuing violation before imposing the separate civil penalty.

(4)(a) If a manufacturer continues to sell or offers for sale a product for which a chemical was required to be removed under ORS 431A.260, and the manufacturer does not have an approved, or deemed approved waiver or hazard assessment request, the Authority shall provide the manufacturer with written notice informing the manufacturer of the violation. The notice shall state that the manufacturer may avoid a civil penalty by:

(A) Ceasing to sell or offer the product for sale; and

(B) Contacting any known entities who are distributing or selling the product in Oregon, advising them that the product can no longer be sold in Oregon, and providing documentation of those notifications to the Authority in accordance with OAR 333-016-3010(4) through (6); or

(C) Submitting proof to the Authority that it is not in violation as alleged in the notice.

(b) If the manufacturer does not submit proof that it is in compliance or fails to cure the violation within 90 days, the Authority may impose a civil penalty not to exceed $2,500.

(c) For a continuing violation, each day that the violation continues after the preceding imposition of a civil penalty is considered a separate offense subject to a civil penalty not to exceed $5,000. The Authority is not required to provide the manufacturer with an opportunity to cure the continuing violation before imposing the separate civil penalty.

(5) If the Authority has reason to believe that a children's product that contains a high priority chemical of concern to children's health (HPCCCH) used in children's products is being sold or offered for sale in Oregon in violation of ORS 431A.258, 431A.260 or 431A.263 the Authority may request that the manufacturer provide a statement of compliance on a form provided by the Authority. The manufacturer must submit the statement of compliance within 30 days after receipt of a request. To prove compliance with ORS 431A.258, 431A.260 and 431A.263, the manufacturer must provide the Authority with proof that:

(a) The children's product does not contain the HPCCCH at or above de minimis levels; or

(b) The manufacturer has previously provided the Authority with notice as required by ORS 431A.258; or

(c) The manufacturer is providing notice as required by ORS 431A.258; or

(d) The manufacturer or trade association has provided the Authority with an exemption request approved by the Authority under ORS 431A.260; or

(e) The manufacturer possesses a hazard assessment for a substitution approved by the Authority for the HPCCCH and products in question under ORS 431A.263; or

(f) The manufacturer possesses a waiver for the HPCCCH and products in question approved by the Authority under ORS 431A.265.

(6) Providing a notice under subsection (5)(c) of this rule does not exempt the manufacturer from compliance with the timelines for removal or substitution under ORS 431A.260, OAR 333-016-3015, ORS 431A.263, or OAR 333-016-3030.

(7) In imposing a penalty under these rules the Authority must consider the following factors:

(a) The past history of the manufacturer in taking all feasible steps or following all feasible procedures necessary or appropriate to correct any violation.

(b) Any prior violations of statutes, rules, orders or permits pertaining to HPCCCH used in children's products.

(c) The gravity and magnitude of the violation.

(d) Whether the violation was a sole event, repeated or continuous.

(e) Whether the violation was a result of an unavoidable accident, negligence or an intentional act.

(f) The violator's cooperativeness and efforts to correct the violation.

(g) The economic and financial conditions of the manufacturer incurring a penalty.

(h) The manufacturer's declaration that a HPCCCH used in a children's product is present only as a contaminant, and the manufacturer is able to provide evidence that a manufacturing control program for the contaminant that meets or exceeds the minimum requirements for a manufacturing control program in OAR 333-016-2070, which was approved by the Authority, was in place prior to the violation and that the manufacturer has exercised due diligence.

(i) Civil penalties will be imposed in the manner provided in ORS 183.745.

(8) The Authority will enforce the reporting requirements against a manufacturer in the same order as the priority order for reporting in OAR 333-016-2060(11).

Statutory/Other Authority: ORS 413.042 & ORS 431A.275
Statutes/Other Implemented: ORS 431A.275
History:
PH 119-2024, amend filed 12/22/2024, effective 01/01/2025
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