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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED
06/22/2020 12:57 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Toxic Free Kids Act - Phase 3 Rulemaking

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 07/23/2020 5:00 PM

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

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Filed By:
Brittany Hall
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HEARING(S)

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

DATE: 07/16/2020
TIME: 9:00 AM
OFFICER: Staff
ADDRESS: CALL-IN ONLY
Following direction from the Gov/CDC
public meetings are via conference call
Portland, OR 97232
SPECIAL INSTRUCTIONS:
Due to COVID-19 public meetings are being held via conference call. To provide oral testimony during this hearing, please dial 1877848-7030, access code: 2030826#

NEED FOR THE RULE(S):

SB 478 (Oregon Laws 2015, chapter 786) was passed by the Oregon Legislature during the 2015 legislative session. The law requires the Oregon Health Authority (Authority) to require manufacturers of children's products to disclose high priority chemicals of concern for children's health used in children's products that are sold or offered for sale in Oregon. The law states that the Authority shall adopt a list of High Priority Chemicals of Concern for Children's Health (HPCCCH); establish requirements for disclosure; and establish a process for manufacturers to apply for an exemption from the disclosure requirements, all of which have been established through past rulemaking. By January 1, 2022, manufacturers of three specific categories of children's products (those for children under three years-old; "mouthable" items, per ORS 431A.253(8); and children's cosmetics) are to remove HPCCCH from product models in these categories or substitute them with a less-hazardous alternative or have a waiver of this requirement approved by the Authority. This rulemaking establishes rules for these statutory requirements so manufacturers may comply with their

obligations under the law by the 2022 deadline. This rulemaking also modifies previously established rules to clarify them.

Proposed changes to OAR chapter 333, division 16 include:

A) Repeal OAR 333-016-2000 List of High Priority Chemicals of Concern for Children's Health When Used in Children's Products: Purpose, Scope, and Effective Date which contains language appropriate for the initial implementation of the 2015 Toxic Free Kids Act. Five years later, it has been replaced by OAR 333-016-2001 Toxic Free Kids Act Program; Effective Date with language reflecting the law's current implementation.

B) The amendment of OAR 333-016-2010 Definitions. Clarification of existing definitions and the establishment of new definitions to address the waiver application process.

C) The amendment of OAR 333-016-2020 Chemicals of High Concern to Children. Changes to spelling or chemical wording in any of the 68 HPCCCH in OAR 333-016-2020 is done only to harmonize them with that of their counterparts listed for Washington State's Children's Safe Products Act (CSPA). These amendments were done to assist those providing biennial notifications to the Authority, and to assist members of the public in their search for HPCCCH in children's products.

D) The amendment of OAR 333-016-2030 Modifications the List of High Priority Chemicals of Concern for Children's Health. In two places, the name High Priority Chemicals of Concern for Children's Health has been collapsed into acronym "HPCCCH."

E) The amendment of OAR 333-016-2035 Exhibit A. Changes to spelling or chemical wording in any of the 68 HPCCCH in OAR 333-016-2035 Exhibit A is done only to harmonize them with that of their counterparts in Washington's CSPA's list. These amendments were done to assist those providing biennial notifications to the Authority and to assist members of the public in their search for HPCCCH in children's products.

F) The repeal of OAR 333-016-2040 Purpose and Scope. Replaced by purpose and scope language in other sections of these rules.

G) The repeal of OAR 333-016-2050 Definitions. Replaced by 333-016-2010 Definitions.

H) The amendment of OAR 333-016-2060 Notification Requirements. Specifies the fee and clarifies the reporting deadlines for manufacturers to report products that contain High Priority Chemicals of Concern for Children's Health (HPCCCH) to the Authority. Adds a requirement for manufacturers to provide an intended age category for products sold in Oregon. Clarifies requirement that trade associations, if reporting on behalf of their members, must provide the name and contact information for a representative of that member. In addition, trade associations must provide the

specific product categories being reported for that member and pay the fees required for that member's report. Adds a requirement that manufacturers report to the Authority using the Interstate Chemicals Clearinghouse High Priority Chemicals Data System or alternate data system designated by the Authority.

I) The amendment of OAR 333-016-2070 Exemptions from Notification Requirements. Requires trade associations requesting an exemption from notification requirements on a manufacturer's behalf to provide the company name and contact information for the manufacturer. Clarifies the information needed by the Authority to evaluate whether or not the measures listed in the manufacturing control program will control the HPCCCH as a contaminant. Establishes a deadline for requesting an exemption for a particular reporting period. Specifies the information that must be submitted as part of an exemption request and specifies the process for making amendments to exemptions that have already been approved by the Authority.

J) The amendment of OAR 333-016-2080 Fees. Specifies the application fees for requesting a waiver from the requirement to remove or substitute a high priority chemical of concern for children's health. The fee for an exemption request is $1,500. There is also a $200 per hour fee for outside consultants to review the documents sent in support of the applications. [Both fees were approved by the Oregon Legislature as part of House Bill 5027 in 2017.] Establishes a process and timeline for the review of waiver applications, the approval/disapproval process and the process to provide a revised waiver request.

(K) The repeal of OAR 333-016-2090 Enforcement and Civil Penalties. Replaced by OAR 333-016-3080 Enforcement and Civil Penalties

Proposed additions to OAR chapter 333, division 16 include:

A) Adopt OAR 333-016-2001 Toxic Free Kids Act Program; Effective Date to state that the purpose of these rules is to implement the Toxic Free Kids Act established by the 2015 Oregon Legislature as well as the intention of the rules.

B) The adoption of OAR 333-016-2065 Formal Communications Regarding Toxic Free Kids. Requires that formal communication to/from manufacturers or trade associations and the Authority on requests in these rules use the Program email.

C) The adoption of OAR 333-016-3010 Removal or Substitution of High Priority Chemical. Specifies the three categories of children's products for which removal, substitution, or procurement of a waiver approved by the Authority is required, and respective due dates. Specifies the procedure that manufacturers must follow if removing a HPCCCH from a product or ceasing to manufacture the product (in lieu of substitution, waiver procurement). Specifies the process by which manufacturers with 25 or fewer employees may request a two-year extension of the date specified in ORS 431A.260(1) to meet the requirements of the rules.

D) The adoption of OAR 333-016-3015 Exemptions from Removal or Substitution Requirements. Specifies four

categories through which manufacturers can request an exemption from having to have a specific product comply with ORS 431A.260(1), and the process needed to apply for such exemptions.

E) The adoption of OAR 333-016-3020 Requirements for Chemical Substitution. Specifies the definition of children's product for this rule and that of OAR 333-016-3040. Specifies that a Hazard Assessment must be provided when substituting a less-hazardous chemical for a HPCCCH in a children's product. Provides the methods that should be used to identify children's products for which a Hazard Assessment is being done. Specifies the process and timelines by which the Authority and those requesting a Hazard Assessment must abide by for submitting and reviewing a Hazard Assessment.

F) The adoption of OAR 333-016-3030 Hazard Assessments for Substitute Chemicals. Specifies that manufacturers are to have their substitute chemicals assessed by a Licensed GreenScreen Profiler using GreenScreen® for Safer Chemicals Hazard Assessment Guidance. Details the standards under which the Authority will approve chemicals proposed to replace a HPCCCH. States the Authority's determination that GreenScreen Guidance is a scientifically-based, data-driven methodology. Provides the possibility of the use of an alternative methodology for a Hazard Assessment as wells as the criteria, process and timeline that should be used to submit the alternative process to the Authority for approval.

G) The adoption of OAR 333-016-3040 Waiver from Removal or Substitution Requirement. Specifies the application process and timelines by which the Authority and those requesting such a Waiver must abide by for submitting and reviewing Waiver documents. Specifies a manufacturer's responsibilities if the Authority disapproves a revised waiver request or an initial waiver (if the manufacturer does not submit a revised version).

H) The adoption of OAR 333-016-3050 Quantitative Exposure Assessment. Specifies the standards and required content of this type of document which may be submitted as part of a request that ORS 431A.260(1) and its rules be waived for specified children's product(s).

I) The adoption of OAR 333-016-3060 Alternatives Assessment. Specifies the standards and required content of this type of document which may be submitted as part of a request that ORS 431A.260(1) and its rules be waived for specified children's product(s).

J) The adoption of OAR 333-016-3070 Trade Secrets. Specifies what manufacturers must do if they believe the information they are submitting is a trade secret as well as what the Authority will do if it receives a public records request for such records.

K) The adoption of OAR 333-016-3080 Enforcement and Civil Penalties. Specifies the civil penalties for violations of the proposed rules, the process and timeline the Authority must follow to both determine and assess those penalties, and what manufacturers may do to remedy those violations.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

SB 478 (Oregon Law 2015, chapter 786):
https://olis.leg.state.or.us/liz/2015R1/Downloads/MeasureDocument/SB478/Enrolled

Oregon Toxic Free Kids Act, ORS 431A.250 – 431A.280: https://www.oregonlegislature.gov/bills_laws/ors/ors431a.html

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

State of Washington, Department of Ecology, Children's Safe Products Act Reporting Rule and guidance documents.
http://apps.leg.wa.gov/wac/default.aspx?cite=173-334-090 and
https://fortress.wa.gov/ecy/publications/documents/1704040.pdf
https://fortress.wa.gov/ecy/publications/documents/1704021.pdf

GreenScreen® for Safer Chemicals Hazard Assessment Guidance
https://www.greenscreenchemicals.org/images/ee_images/uploads/resources/GreenScreen_Guidance_v1_4_2018_01_Final.pdf

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FISCAL AND ECONOMIC IMPACT:

A) The adoption of OAR 333-016-2001 is not anticipated to have a fiscal impact on manufacturers or Oregon consumers.

B) The amendments to OAR 333-016-2010 Definitions are not anticipated to have a fiscal impact on manufacturers or Oregon consumers.

C) The amendments to OAR 333-016-2020 Chemicals of High Concern to Children s are not anticipated to have a fiscal impact on manufacturers or Oregon consumers.

D) The amendments to OAR 333-016-2035 Exhibit A are not anticipated to have a fiscal impact on manufacturers or Oregon consumers

E) The amendments to OAR 333-016-2060 Notification Requirements were made to clarify the reporting deadlines and specify what information is required to be submitted in the biennial notice required of manufacturers, and do not place additional
burdens on manufacturers. The information requested of manufacturers was previously part of reporting guidance issued by
the Authority. The changes are not anticipated to have a fiscal impact.

F) The amendments to OAR 333-016-2070 Exemptions from Notification Requirements clarify what information is required to be submitted to the Authority as part of an exemption request. These changes are not anticipated to have a fiscal impact.

G) The amendments to OAR 333-016-2080 Fees address the application and review fees for a waiver from the requirement to remove or substitute a HPCCCH from a product sold or offered for sale in Oregon. Fees are needed to review documents sent in support of requests for exemption from removal and substitution requirements. Manufacturers are not required to apply for a waiver or make a request for exemption, but those that do are required to pay these fees. A waiver request must include an Alternatives Assessment or a Quantitative Exposure Analysis, which will have associated cost to produce. It is not possible to estimate the cost of such an analysis due to the highly specific nature of each chemical and product. However, small businesses with 25 or fewer employees may apply for a two-year extension to meet the requirements of the removal or substitution requirements of OAR 333-016-3010. Manufacturers of children's products with annual worldwide gross sales of less than $5 million are exempt from these requirements.

H) The amendments to OAR 333-016-2090 Enforcement and Civil Penalties explains the enforcement process that the Authority will take when a manufacturer sells a product in Oregon that contains a chemical listed under OAR 333-016-2020 (Chemicals of High Concern to Children) and did not receive an exemption or waiver from the Authority. Manufacturers that do not follow the requirements of ORS 431A.250 through ORS 431A.280 may face a fiscal impact through the imposition of civil penalties.

I) The adoption of OAR 333-016-3010 Removal or Substitution of High Priority Chemical. Because the Authority is unaware of any efforts by other states or jurisdictions to implement similar statutory provisions requiring the substitution of a chemical with a less hazardous alternative, comparison costs are not available. Manufacturers that are required to remove or substitute a HPCCCH will experience a fiscal impact, as they will be required to reformulate children's products that contain the HPCCCH. It is not possible to estimate the cost of such a process due to both the lack of comparison costs and the highly specific nature of each chemical, the product model, and the chemical's role in that product.

J) The adoption of OAR 333-016-3015 Exemptions from Removal or Substitution Requirements. Specifies four categories through which manufacturers can request an exemption from having to have a specific product comply with ORS 431A.260(1). Manufacturers are not required to seek these exemptions. Manufacturers that produce children's products with HPCCCH that wish to seek an exemption from the removal or substitution requirements will bear the associated costs of producing the required reports and any associated fees. The application fee is $1,500 and the review fee is $200 per hour. It is not possible to estimate the cost of producing such an analysis due to the lack of comparison costs and highly specific nature of each chemical, the product model, and the chemical's role in that product.

K) The adoption of OAR 333-016-3020 Requirements for Chemical Substitution. Manufacturers that produce children's products with HPCCCH that wish to seek approval for a substitute chemical will bear the associated costs of producing the required reports and any associated fees. The application fee is $1,500 and the review fee is $200 per hour. Other than the estimate noted below for a GreenScreen assessment of a new chemical, it's not possible to estimate the cost of producing such reports due to the lack of comparison costs and the highly specific nature of each chemical, the product model, and the chemical's role in that product.

L) The adoption of OAR 333-016-3030 Hazard Assessments for Substitute Chemicals. Specifies that manufacturers are to have their substitute chemicals assessed by a Licensed GreenScreen Profiler using GreenScreen® for Safer Chemicals Hazard Assessment Guidance. There are both financial costs and benefits to this rule. At least 15% of HPCCCH's have a current GreenScreen assessment that is in the public domain. These may be used without cost to a manufacturer for these purposes. On average, GreenScreen assessments on new chemicals are estimated to range from $2,000 to $10,000. However, GreenScreen evaluations of potential substitute chemicals, if paid for by manufacturers, are the property of those manufacturers. GreenScreen evaluations may be used for commercial purposes, subject to the GreenScreen licensure agreement. Associated costs will be borne by manufacturers.

M) The adoption of OAR 333-016-3040 Waiver from Removal or Substitution Requirement. Manufacturer that produce children's products with HPCCCH that wish to seek a waiver from the removal or substitution requirements will bear the associated costs of producing the required reports and any associated fees. The application fee is $1,500 and the review fee is $200 per hour. It is not possible to estimate the cost of producing such reports due to due to the lack of comparison costs and the highly specific nature of each chemical, the product model, and the chemical's role in that product.

N) The adoption of OAR 333-016-3050 Quantitative Exposure Assessment. It is not possible to estimate the cost of producing a quantitative exposure assessment due to the lack of comparison costs and the highly specific nature of each chemical, the product model, and the chemical's role in that product. Manufacturers that request a waiver will be required to produce a quantitative exposure analysis, which will result in a cost to the manufacturer.

O) The adoption of OAR 333-016-3060 Alternatives Assessment. It is not possible to estimate the cost of an alternatives assessment due to the lack of comparison costs and the highly specific nature of each chemical, the product model, and the chemical's role in that product.

P) The adoption of OAR 333-016-3070 Trade Secrets. This is not expected to have a fiscal impact on manufacturers.

Q) The adoption of OAR 333-016-3080 Enforcement and Civil Penalties. Manufacturers found to be in violation of Oregon law may face civil penalties. These civil penalties may not exceed $2,500 for the first violation or $5,000 for the second and each subsequent violation. Those found in violation may avoid the penalties if they cure or address the violation within 90 days of the date of the notice of violation. There may be a fiscal impact to manufacturers who are unable to sell children's products found to be in violation by the Authority of ORS 431A.260 or 431A.263, or relevant OARs. Additional costs to manufacturers may result from efforts necessary to identify such products and communicate that they can't be sold in Oregon to business partners. It is not possible to estimate the total loss in profit for manufacturers of children's products that can no longer be sold in Oregon given the variety of products, prices and manufacturers.

COST OF COMPLIANCE:

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

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

B) The amendment of OAR 333-016-2060 Notification Requirements specifies the fees required for submitting an exemption request from the notification requirements of children's products sold or offered for sale in Oregon that contain a HPCCCH listed under OAR 333-016-2020. It also specifies what manufacturers need to provide to the Authority as part of that exemption request. These changes will not result in a compliance cost for state or local government or the public. Fees are collected by the Toxic Free Kids Program and utilized to support program efforts.

C) The amendment of OAR 333-016-2070 Exemptions from Notification Requirements clarifies what information is required to be submitted to the Authority as part of an exemption request. These changes will not result in a compliance cost for state or local government or the public.

D) The amendment of OAR 333-016-2080 Fees addresses the application and review fee for requesting a waiver from the requirement to remove or substitute a HPCCCH from a product sold or offered for sale in Oregon. Manufacturers that request a waiver are required to pay these fees. These changes will not result in a compliance cost for state or local government or the public. Fees are collected by the Toxic Free Kids Program and utilized to support program efforts.

E) The amendment of OAR 333-016-2090 Enforcement and Civil Penalties explains the enforcement process that the Authority will take when a manufacturer sells a product in Oregon that contains a HPCCCH listed under OAR 333-016-2020 and did not receive an exemption or waiver from the Authority. These changes will not result in a compliance cost for local government or the public. The state anticipates legal costs associated with the civil penalty process. These costs are offset by the collection of civil penalties.

F) The adoption of OAR 333-016-3010 Removal or Substitution of High Priority Chemical. This addition will not result in a compliance cost on state or local government or the public.

G) The adoption of OAR 333-016-3015 Exemptions from Removal or Substitution Requirements. This addition will not result in a compliance cost with state or local government or the public.

H) The adoption of OAR 333-016-3020 Requirements for Chemical Substitution. This addition will not result in a compliance cost on state or local government or the public.

I) The adoption of OAR 333-016-3030 Hazard Assessments for Substitute Chemicals. This addition will not result in compliance cost on state or local government or the public.

J) The adoption of OAR 333-016-3040 Waiver from Removal or Substitution Requirement This addition will not result in a compliance cost on state or local government or the public.

K) The adoption of OAR 333-016-3050 Quantitative Exposure Assessment. This addition will not result in a compliance cost on state or local government or the public.

L) The adoption of OAR 333-016-3060 Alternatives Assessment. This addition will not result in a compliance cost on state or local government or the public.

M) The adoption of OAR 333-016-3070 Trade Secrets. This addition will not result in a compliance cost on state or local government or the public.

N) The adoption of OAR 333-016-3080 Enforcement and Civil Penalties. This addition will not result in a compliance cost on state or local government or the public.

(2)(a) ORS 431A.258 Disclosure by manufacturers (OAR 333-016-2060 through 3080) only pertains to companies that gross over $5,000,000 in worldwide gross sales per year who manufacture children's products that contain HPCCCH. The term manufacturer includes an importer or domestic distributor. We are unable to estimate the number of manufacturers that would be considered a small business based on available information.

(b) ORS 431A.258 Disclosure by manufacturers only pertains to companies that gross over $5,000,000 in worldwide gross sales per year who manufacture children's products that contain HPCCCH. The term manufacturer includes an importer or domestic distributer. If a small business met these criteria, they would be responsible for providing notice, any associated fees and related recordkeeping to the Authority. There may be a fiscal impact to small business owners, as identified above, who are unable to sell, in Oregon, purchased children's products determined to be in violation by the Authority of ORS 431A.260 or 431A.263, or relevant OARs. Additional costs to manufacturers and retailers may result from efforts necessary to identify such products and communicate that they can't be sold in Oregon to business partners.

(c) ORS 431A.258 Disclosure by manufacturers only pertains to companies that gross over $5,000,000 in worldwide gross sales per year who manufacture children's products that contain HPCCCH. The term manufacturer includes an importer or domestic distributer. If a small business met these criteria and wanted to apply for a waiver from removing or substituting a HPCCCH in a children's product, they would be responsible for paying the application and review fees, as well as providing an Alternatives Assessment or Quantitative Exposure Analysis. It is assumed that this type of analysis would require labor, supplies and increased administration costs, and may also include equipment. We are unable to estimate the costs to comply with the waiver application process due to the lack of comparison costs and the highly specific nature of each chemical, the product model, and the chemical's role in that product.

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

Small business representatives and trade associations participated as Rule Advisory Committee members.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

333-016-2000, 333-016-2001, 333-016-2010, 333-016-2020, 333-016-2030, 333-016-2035, 333-016-2040, 333-016-2050, 333-016-2060, 333-016-2065, 333-016-2070, 333-016-2080, 333-016-2090, 333-016-3010, 333-016-3015, 333-016-3020, 333-016-3030, 333-016-3040, 333-016-3050, 333-016-3060, 333-016-3070, 333-016-3080

REPEAL: 333-016-2000

RULE SUMMARY: Repeal OAR 333-016-2000 List of High Priority Chemicals of Concern for Children's Health When Used in Children's Products: Purpose, Scope, and Effective Date, which contains language appropriate for the initial implementation of the 2015 Toxic Free Kids Act. Five years later, it has been replaced by adoption of OAR 333-016-2001 Toxic Free Kids Act Program; Effective Date with language reflecting the law's current implementation.

CHANGES TO RULE:

~~333-016-2000~~
~~List of High Priority Chemicals of Concern for Children's Health When Used in Children's Products: Purpose, Scope, and Effective Date~~
~~(1) These rules establish the initial list of high priority chemicals of concern for children's health when used in children's products. The presence of a high priority chemical of concern in a children's product does not necessarily mean that the product is harmful to human health or that there is any violation of existing safety standards or laws. The information required to be reported in these rules will help fill a data gap that exists for both consumers and agencies.¶~~
~~(2) A manufacturer of children's products sold or offered for sale in this state must provide biennial notice to the Oregon Health Authority, of all children's products that contain a high priority chemical listed in OAR 333-016-2020.¶~~
~~(3) A manufacturer's first report is due no later than January 1, 2018.~~
~~Statutory/Other Authority: OL 2015, ch. 786, sec. 3~~
~~Statutes/Other Implemented: OL 2015, ch. 786, sec. 3~~

ADOPT: 333-016-2001

RULE SUMMARY: Adopt OAR 333-016-2001 Toxic Free Kids Act Program; Effective Date to state that the purpose of these rules is to implement the Toxic Free Kids Act established by the 2015 Oregon Legislature as well as the intention of the rules.

CHANGES TO RULE:

333-016-2001
Toxic Free Kids Program; Effective Date
(1) OAR 333-016-2001 to 333-016-3080 implement the Toxic Free Kids Act established by the Legislature in ORS 431A.253 to 431A.280. The presence of a high priority chemical of concern in a children's product does not necessarily mean that the product is harmful to human health or that there is any violation of existing safety standards or laws. The information required to be reported in these rules will help fill a data gap that exists for both consumers and agencies.¶
(2) These rules apply to any children's product sold or offered for sale in Oregon by a manufacturer on or after January 1, 2017 that contains a high priority chemical listed in OAR 333-016-2020.
Statutory/Other Authority: ORS 431A.253 - 431A.280, ORS 413.042
Statutes/Other Implemented: ORS 431A.253 - 431A.280

AMEND: 333-016-2010

RULE SUMMARY: Amend OAR 333-016-2010 Definitions to clarify existing definitions and establish new definitions to address the waiver application process.

CHANGES TO RULE:

333-016-2010
Definitions ¶

~~(1) "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.¶~~
~~(2~~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) "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. "Children's cosmetics" does not mean soap, dietary supplements or food and drugs approved by the United States Food and Drug Administration.¶
(~~3~~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.¶
~~(4) "These rules" mean OAR 333-016-2000 through 333-016-2030~~9) "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) "Contaminant" has the meaning given that term in ORS 431A.253.¶
(11) "De minimis level" has the meaning given that term in ORS 431A.253.¶
(12) "Essential use" means a function of a HPCCCH in a children's product considered critical for performance of a product. ¶
(13) "Exposure scenarios" means the mechanisms by which children may be exposed to HPCCCHs found in a children's product.¶
(14) "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) "HPCCCH" means high priority chemicals of concern to children's health.¶
(16) "High priority chemicals of concern list" means the high priority chemicals of concern for children's health identified by the Authority in OAR 333-016-2020.¶
(17) "Intentionally added chemical" has the meaning given that term in ORS 431A.253.¶
(18) "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) "Manufacturer" has the meaning given that term in ORS 431A.253.¶

(20) "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) "Mouthable" has the meaning given that term in ORS 431A.253.¶
(22) "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) "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) "Practical quantification limit" has the meaning given that term in ORS 431A.253.¶
(25) "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) "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) "Reasonably foreseeable use and abuse" includes but is not limited to: 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 use by children. ¶
(28) "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) "These rules" means OAR 333-016-2001 to 333-016-3080.¶
(30) "Trade association" has the meaning given that term in ORS 431A.253.
Statutory/Other Authority: O~~L 2015, ch. 786, sec. 3~~RS 413.042, ORS 431A.253 - 431A.280
Statutes/Other Implemented: O~~L 2015, ch. 786, sec. 3~~RS 431A.253 - 431A.280

AMEND: 333-016-2020

RULE SUMMARY: Amend OAR 333-016-2020 Chemicals of High Concern to Children to harmonize spelling or chemical wording in several of the 68 HPCCCH in OAR 333-016-2020 with that of their counterparts listed for Washington State's Children's Safe Products Act (CSPA). These modifications are done to assist those providing biennial notifications to the Authority, and to assist members of the public in their search for HPCCCH in children's products.

CHANGES TO RULE:

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) Diethyl phthalate (DEP) (84-66-2).¶
(15) Di-n-butyl phthalate (DBP) (84-74-2).¶
(16) Di-n-hexyl phthalate (DnHP) (84-75-3).¶
(17) Butyl benzyl phthalate (BBP) (85-68-7).¶
(18) N-Nitrosodiphenylamine (86-30-6).¶
(19) Hexachlorobutadiene (HCDB) (87-68-3).¶
(20) Propyl paraben (94-13-3).¶
(21) Butyl paraben (94-26-8).¶
(22) 2-Aminotoluene (95-53-4).¶
(23) 2,4-Diaminotoluene (95-80-7).¶
(24) Methyl paraben (99-76-3).¶
(25) ~~p~~4-Hydroxybenzoic acid (99-96-7).¶
(26) Ethylbenzene (100-41-4).¶
(27) Styrene (100-42-5).¶
(28) 4-Nonylphenol (104-40-5)~~; 4-NP and its isomer mixtures including CAS 84852-15-3 and CAS 25154-52-3~~.¶
(29) ~~para~~4-Chloroaniline (106-47-8).¶
(30) Acrylonitrile (107-13-1).¶
(31) Ethylene glycol (107-21-1).¶
(32) Toluene (108-88-3).¶
(33) Phenol (108-95-2).¶
(34) 2-Methoxyethanol (109-86-4).¶
(35) Ethylene glycol monoethyl e~~st~~her (110-80-5).¶
(36) Triphenyl phosphate (TPP) (115-86-6).¶

(37) Tris(2-chloroethyl) phosphate (TCEP) (115-96-8).¶
(38) Di-2-ethylhexyl phthalate (DEHP) (117-81-7).¶
(39) Di-n-octyl phthalate (DnOP) (117-84-0).¶
(40) Hexachlorobenzene (118-74-1).¶
(41) 3,3'-Dimethylbenzidine and Dyes Metabolized to 3,3'-Dimethylbenzidine (119-93-7).¶
(42) Ethyl paraben (120-47-8).¶
(43) 1,4-Dioxane (123-91-1).¶
(44) ~~Per~~Tetrachloroeth~~yl~~ene (127-18-4).¶
(45) Benzophenone-2 (Bp-2)~~; 2,2',4,4'-Tetrahydroxybenzophenone (131-55-5).~~¶
~~(46) 4-tert-Octylphenol; 4(1,1,3,3-Tetramethylbutyl)~~ (131-55-5).¶
(46) 4-tert-Octylphenol (140-66-9).¶
(47) Estragole (140-67-0).¶
(48) 2-Ethylhexanoic acid (149-57-5).¶
(49) ~~Benzene,~~ Pentachlorobenzene (608-93-5).¶
(50) C.I. Solvent yellow 14 (842-07-9).¶
(51) N-Methylpyrrolidone (872-50-4).¶
(52) ~~2,2',3,3',4,4',5,5',6,6'-~~Decabromodiphenyl ether~~;~~ (BDE-209) (1163-19-5).¶
(53) Perfluorooctane sulfonic acid and its salts; PFOS (1763-23-1).¶
(54) ~~Phenol, 4-o~~Octylphenol (1806-26-4).¶
(55) 2-Ethyl-hexyl-4-methoxycinnamate (5466-77-3).¶
(56) Mercury (7439-97-6) and mercury compounds including methyl mercury (22967-92-6).¶
(57) Antimony and Antimony compounds (7440-36-0).¶
(58) Arsenic and Arsenic compounds (7440-38-2), including arsenic trioxide (1327-53-3) and dimethyl arsenic (75-60-5).¶
(59) Cadmium and cadmium compounds (7440-43-9).¶
(60) Cobalt and cobalt compounds (7440-48-4).¶
(61) Tris(1-chloro-2-propyl) phosphate (TCPP) (13674-84-5).¶
(62) Tris(1,3-dichloro-2-propyl) phosphate (TDCPP) (13674-87-8).¶
(63) Butylated hydroxyanisole~~;~~ (BHA) (25013-16-5).¶
(64) Hexabromocyclododecane (25637-99-4).¶
(65) Diisodecyl phthalate (DIDP) (26761-40-0).¶
(66) Diisononyl phthalate (unbranched) (DINP) (28553-12-0).¶
(67) Short-chain chlorinated paraffins (SCCP) (85535-84-8).¶
(68) 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

AMEND: 333-016-2030

RULE SUMMARY: Amend OAR 333-016-2030 Modifications to the List of High Priority Chemicals of Concern for Children's Health in two places where the name High Priority Chemicals of Concern for Children's Health is collapsed into acronym "HPCCCH."

CHANGES TO RULE:

333-016-2030
Modifications to the List of High Priority Chemicals of Concern for Childrens Health ¶

(1) The Oregon Health 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~~, on or after the effective date of these rules~~:¶
(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 shall also consider adding a chemical to the list of ~~high priority chemicals of concern for children's health~~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) The Oregon Health Authority may remove a chemical from the list if the Authority determines that:¶
(a) The chemical is no longer being used in children's products; or¶

(b) The chemical has been removed from any of the lists identified in subsection (1)(a) through (e) of this rule.¶
(4) The list of ~~high priority chemicals of concern for children's health~~HPCCCHs in OAR 333-016-2020 may only be modified by following the Administrative Procedures Act rulemaking process.
Statutory/Other Authority: O~~L 2015, ch. 786, sec. 3~~RS 413.042, ORS 431A.255
Statutes/Other Implemented: O~~L 2015, ch. 786, sec. 3~~RS 431A.255

AMEND: 333-016-2035

RULE SUMMARY: Amend OAR 333-016-2035 Exhibit A to harmonize spelling or chemical wording in several of the 68 HPCCCH in OAR 333-016-2035 Exhibit A with that of their counterparts listed for Washington State's Children's Safe Products Act (CSPA). These modifications are done to assist those providing biennial notifications to the Authority, and to assist members of the public in their search for HPCCCH in children's products.

CHANGES TO RULE:

333-016-2035
Manufacturer Disclosure of High Priority Chemicals of Concern for Childrens Health Used in Childrens 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.
Statutory/Other Authority: ORS 413.042
Statutes/Other Implemented: ORS 431A.253 - 431A.280

RULE ATTACHMENTS DO NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

Oregon Health Authority

OAR 333-016-2035

Exhibit A: Projected PQLs for the 68 high priority chemicals of concern in children's products

	Chemical	CAS	PQL (ppm)	Method
1	Formaldehyde	50-00-0	5.0	8315
2	Aniline	62-53-3	1.0	8270
3	N-Nitrosodimethylamine	62-75-9	1.0	8270
4	Benzene	71-43-2	1.0	8260
5	Vinyl chloride	75-01-4	1.0	8260
6	Acetaldehyde	75-07-0	1.0	8315
7	Methylene chloride	75-09-2	1.0	8260
8	Carbon disulfide	75-15-0	10.0	8260
9	Methyl ethyl ketone	78-93-3	1.0	8260
10	1,1,2,2-Tetrachloroethane	79-34-5	1.0	8260
11	Tetrabromobisphenol A (TBBPA)	795-94-7	20.0	3540/GCMS
12	Bisphenol A (BPA)	80-05-7	20.0	8720
13	Bisphenol S (BPS)	80-09-1	1.0	1694
14	Diethyl phthalate (DEP)	84-66-2	5.0	8720
15	Di-n-butyl phthalate (DBP) ~~Dibutyl phthalate~~	84-74-2	5.0	8720
16	Di-n-hexyl Phthalate (DnHP)	84-75-3	5.0	8720
17	Butyl benzyl phthalate (BBP)	85-68-7	5.0	8720
18	N-Nitrosodiphenylamine	86-30-6	1.0	8720
19	Hexachlorobutadiene (HCDB)	87-68-3	30.0	8720
20	Propyl paraben	94-13-3	30.0	HPLC
21	Butyl paraben	94-26-8	30.0	HPLC
22	2-Aminotoluene	95-53-4	1.0	8720
23	2,4-Diaminotoluene	95-80-7	10.0	GC/MS
24	Methyl paraben	99-76-3	30.0	HPLC
25	~~p-Hydroxybenzoic acid~~4-Hydroxybenzoic acid	99-96-7	10.0	HPLC
26	Ethylbenzene	100-41-4	1.0	8260
27	Styrene	100-42-5	1.0	8260
28	4-Nonylphenol~~4-Nonylphenol; 4-NP and its isomer mixtures including CAS 84852-15-3 and CAS 25154-52-3~~	104-40-5	10.0	USGS 5-B2
29	4-Chloroaniline~~para-Chloroaniline~~	106-47-8	60.0	8720
30	Acrylonitrile	107-13-1	1.0	8260
31	Ethylene glycol	107-21-1	5.0	8015
32	Toluene	108-88-3	1.0	8260
33	Phenol	108-95-2	60.0	8270
34	2-Methoxyethanol	109-86-4	10.0	8015
35	Ethylene glycol monoethyl ether	110-80-5	10.0	8015

Effective TBD per filing w/ SOS

	Chemical	CAS	PQL (ppm)	Method
36	Triphenyl phosphate (TPP)	115-86-6	50.0	8270
37	Tris(2-chloroethyl) phosphate (TCEP)	115-96-8	50.0	8270
38	Di-2-ethylhexyl phthalate (DEHP)	117-81-7	20.0	8270
39	Di-n-octyl phthalate (DnOP)	117-84-0	5.0	8270
40	Hexachlorobenzene	118-74-1	30.0	8270
41	~~3,3´-Dimethylbenzidine & Dyes Metabolized to same 3,3'-Dimethylbenzidine and Dyes Metabolized to 3,3'-Dimethylbenzidine~~3,3'-Dimethylbenzidine and Dyes Metabolized to 3,3'-Dimethylbenzidine	119-93-7	10.0	8270
42	Ethyl paraben	120-47-8	30.0	HPLC
43	1,4-Dioxane	123-91-1	1.0	8720/many
44	~~Perchloroethylene~~Tetrachloroethene	127-18-4	0.5	8260/many
45	Benzophenone-2~~; 2,2',4,4'-Tetrahydroxybenzophenone~~ (Bp-2)	131-55-5	20.0	GC-FID
46	4-tert-Octylphenol	140-66-9	10.0	USGS 5-B2
47	Estragole	140-67-0	10.0	IFRA GCMS
48	2-Ethylhexanoic Acid	149-57-5	1.0	Not given
49	~~Benzene, Pentachlorobenzene~~Pentachlorobenzene	608-93-5	1.0	8270
50	C.I. Solvent Yellow 14	842-07-9	1.0	LC/MS[1]
51	N-Methylpyrrolidone	872-50-4	50.0	8015/8270
52	~~2,2',3,3',4,4',5,5',6,6'-~~Decabromodiphenyl ether (BDE-209)	1163-19-5	10.0	8270
53	Perfluorooctane sulfonic acid and its salts~~Perfluorooctanyl sulphonic acid and its salts~~; PFOS	1763-23-1	1.0	EPA PFOA
54	4-Octylphenol ~~Phenol, 4-octyl phenol~~	1806-26-4	10.0	USGS 5-B2
55	2-Ethyl-hexyl-4-methoxycinnamate	5466-77-3	5.0	HPLC
56	Mercury (7439-97-6) & mercury compounds including methyl mercury	7439-97-6	0.5	EPA[2]
57	Antimony & Antimony compounds	7440-36-0	1.0	EPA[3]
58	Arsenic & Arsenic compounds including arsenic trioxide (1327-53-3) and dimethyl arsenic (75-60-5)	7440-38-2	1.0	EPA[3]
59	Cadmium & cadmium compounds	7440-43-9	1.0	EPA[3]
60	Cobalt & Cobalt compounds	7440-48-4	1.0	EPA[3]
61	Tris(1-chloro-2-propyl) phosphate (TCPP)	13674-84-5	50.0	8270
62	Tris(1,3-dichloro-2-propyl) phosphate (TDPP)	13674-87-8	50.0	8270
63	Butylated hydroxyanisole (BHA)	25013-16-5	10.0	USGS 5-B2
64	Hexabromocyclododecane	25637-99-4	10.0	3540/GCMS
65	Diisodecyl phthalate (DIDP)	26761-40-0	50.0	8270
66	Diisononyl phthalate (unbranched) (DINP)	28553-12-0	50.0	8270
67	Short-chain chlorinated paraffins	85535-84-8	50.0	GCMS

Effective TBD per filing w/ SOS

68	2-ethylhexyl-2,3,4,5-tetrabromobenzoate (TBB)	183658-27-7	50.0	8270

Effective TBD per filing w/ SOS

Effective TBD per filing w/ SOS

REPEAL: 333-016-2040

RULE SUMMARY: Repeal OAR 333-016-2040 Purpose and Scope. To be replaced in purpose and scope with similar language in other sections of these rules.

CHANGES TO RULE:

~~333-016-2040~~
~~Purpose and Scope~~
~~OAR 333-016-2035 through 333-016-2090:¶~~
~~(1) Require manufacturers of children's products to disclose high priority chemicals of concern for children's health used in children's products, unless the manufacturer is exempt;¶~~
~~(2) Establish requirements for disclosure;¶~~
~~(3) Establish a process for a manufacturer to apply for an exemption from the disclosure requirements;¶~~
~~(4) Establish a fee schedule; and¶~~
~~(5) Describe the Authority's civil penalty authority and enforcement process.~~
~~Statutory/Other Authority: ORS 413.042~~
~~Statutes/Other Implemented: ORS 431A.253-431A.280~~

REPEAL: 333-016-2050

RULE SUMMARY: Repeal OAR 333-016-2050 Definitions. That provision's terms and definitions are embedded in OAR 333-016-2010 Definitions.

CHANGES TO RULE:

~~333-016-2050~~
~~Definitions~~
~~(1) "Authority" means the Oregon Health Authority.¶~~
~~(2) "Chemical" has the meaning given that term in ORS 431A.253.¶~~
~~(3) "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.¶~~
~~(4) "Child" means an individual under 12 years of age.¶~~
~~(5) "Children's product" has the meaning given that term in ORS 431A.253.¶~~
~~(6) "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).¶~~
~~(7) "Contaminant" has the meaning given that term in ORS 431A.253.¶~~
~~(8) "De minimis level" has the meaning given that term in ORS 431A.253.¶~~
~~(9) "HPCCCH" means high priority chemicals of concern to children's health.¶~~
~~(10) "High priority chemicals of concern list" means the high priority chemicals of concern for children's health identified by the Authority in OAR 333-016-2020.¶~~
~~(11) "Intentionally added chemical" has the meaning given that term in ORS 431A.253.¶~~
~~(12) "Manufacturer" has the meaning given that term in ORS 431A.253¶~~
~~(13) "Manufacturing control program" means a program implemented by the manufacturer or its suppliers to control the amount of a high priority chemical of concern in children's products present as a contaminant at or above de minimis 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.¶~~
~~(14) "Mouthable" has the meaning given that term in ORS 431A.253.¶~~
~~(15) "Owner" for purposes of clarifying the definition of "manufacturer" means the first person or entity, whether an importer or a distributor, that first offers the children's product for sale in Oregon.¶~~
~~(16) "Practical quantification limit" has the meaning given that term in ORS 431A.253.¶~~
~~(17) "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.¶~~
~~(18) "These rules" means OAR 333-016-2040 to 333-016-2100.¶~~
~~(19) "Trade association" has the meaning given that term in ORS 431A.253.~~
~~Statutory/Other Authority: ORS 413.042~~
~~Statutes/Other Implemented: ORS 431A.253-431A.280~~

AMEND: 333-016-2060

RULE SUMMARY: Amend OAR 333-016-2060 Notification Requirements to specify the fees and clarify the reporting deadlines for manufacturers to report products that contain High Priority Chemicals of Concern for Children's Health (HPCCCH) to the Authority. Establishes the requirement for manufacturers to provide an intended age category for products sold or offered for sale in Oregon. Clarifies requirement that trade associations, if reporting on behalf of their members, must provide the name and contact information for a representative of that member. In addition, establishes the requirement that trade associations, when reporting for member(s), must provide specific product categories being reported for that member and pay notification fees associated with that member's report. Establishes that the number of products sold or offered for sale (reported as the number of units of such products) during a biennial notice period must be part of that manufacturer's biennial report. Establishes if a manufacturer has previously provided a biennial report to the Authority and only the number of products sold or offered for sale in Oregon has changed in the subsequent biennial notice period, that the manufacturer may inform the Authority, through email, that the previously reported data is still valid. They must still provide the number of products sold or offered for sale in the subsequent biennial notice period. Establishes the requirement that manufacturers reporting to the Authority must use the Interstate Chemicals Clearinghouse High Priority Chemicals Data System or alternate data system designated by the Authority.

CHANGES TO RULE:

333-016-2060
Notification Requirements ¶

(1) No later than January 1, 2018, and every other year thereafter, a manufacturer of a children's product sold or offered for sale in this state that contains a HPCCCH listed in OAR 333-016-2020 in an amount at or above a de minimis level must submit:¶
(a) A notice to the Authority that contains all the information required in these rules, unless the manufacturer or product is exempt; and¶
(b) A~~ny applicable fee~~ nonrefundable fee of $250 for the notification of each HPCCCH as specified in OAR 333-016-2080.¶
(2) 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.¶
(3) ~~Future notices apply to children's products sold or offered for sale during~~Subsequent manufacturer reports are due on January 1st of even numbered years for the previous two-year biennial notice period. For example, for the reporting year 2020, a manufacturer must include children's products sold or offered for sale between January 1, 2018, and December 31, 2019, that contain a HPCCCH listed in OAR 333-016-2020.¶
(4) The notice required in section (1) 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 of the children's product reported as a range rather than an exact amount;¶
(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; ¶
(~~f~~g) The name and address of the manufacturer, and the name, address and telephone number of the contact person for the manufacturer;~~ or~~¶
(~~g~~h) The name, address and contact information for the trade association submitting the notification on behalf of the affected industry; and¶

(~~h~~i) Any other information that the manufacturer deems relevant to the appropriate use of the children's product.¶
(5) ~~The second biennial notice will cover the period of January 1, 2018 through December 31, 2019~~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. ¶
(6) 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.¶
(~~6~~7) 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.¶
(~~7~~8) 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.¶
(~~8~~9) A trade association who fulfills the notice or exemption requirements of 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.¶
(~~9~~10) 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.¶
(1~~0~~1) 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.¶
(1~~1~~2) 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 (1~~0) of this rule~~1) of this rule. ¶
(13) 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 90 days of removal, submit a written statement, or if available, an electronic notification indicating the HPCCCH that was removed, whether another HPCCH 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

ADOPT: 333-016-2065

RULE SUMMARY: Adopt OAR 333-016-2065 Formal Communications Regarding Toxic Free Kid. Specifies the email address that the Authority and manufacturers/trade associations shall use for formal communications regarding waivers, chemical substitution, chemical removal, or exemption requests, and their fees.

CHANGES TO RULE:

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

AMEND: 333-016-2070

RULE SUMMARY: Amend OAR 333-016-2070 Exemptions from Notification Requirement to clarify the need for trade associations requesting an exemption from notification requirements on a manufacturer's behalf provide the company name and contact information for the manufacturer. Clarifies the information needed by the Authority to evaluate whether or not the measures listed in the manufacturing control program will control the HPCCCH as a contaminant. Establishes a deadline for requesting an exemption for a particular reporting period. Specifies the information that must be submitted as part of an exemption request and specifies the process for making amendments to exemptions that have already been approved by the Authority.

CHANGES TO RULE:

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 Authority a request for an exemption from these rules if the 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. ¶
(4a) ~~I~~An ~~order to meet the standards for an exemption a manufacturing control program~~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 before the last day (December 31st) of the 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 ~~manufacturing control program~~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 a ~~manufacturing control program~~n MCP meets the minimum standards for an exemption, the ~~manufacturing control program~~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) In addition to meeting one of the requirements of subsections (6)(a) through (dFor 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) Laboratory test reports from a third-party laboratory accredited to ISO 17025:2017 standards, and that is accredited for the method used to conduct the testing that shows 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 manufacture 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 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;¶
(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¶
(ed) 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.¶
(89) 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.¶
(~~9~~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.¶
(1~~0~~1) 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.¶
(11~~2~~) Resubmission of exemption requests in this rule is not allowed after the second disapproval.¶
(13) At any time the Authority may request additional information from a manufacturer requesting an exemption ~~.¶~~
~~(12) If a manufacturer submits information to the Authority as part of its request for an exemption under this rule that the manufacturer believes is a trade secret, the manufacturer must mark the information "confidential - trad~~, 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 use~~cret."~~d to control an HPCCCH. ¶
(a~~c~~) ~~If the Authority receives a publ~~The inclusion of additional members for specific product categories on an MCP approved by the Authority provided those members use all specific ~~r~~mec~~ords request for records related to a request for an exemption under this rule, 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(2).¶~~
~~(b) For purposes of this section "trade secret" has the meaning given that term in ORS 192.501(2)~~hanisms, 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 for an exemption must be accompanied by any applicable fees in OAR 333-016-2080. 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 manufacture 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

AMEND: 333-016-2080

RULE SUMMARY: Amend OAR 333-016-2080 Fees to specify the non-refundable application fees for requesting a waiver from the requirement to remove or substitute a high priority chemical of concern for children's health. Specifies that the non-refundable application fee for an exemption request is $1,500. There is also a $200 per hour fee for outside consultants to review the documents sent in support of the applications. Establishes a process and timeline for the payment of fees relating to waiver applications, hazard assessments, and exemption requests.

CHANGES TO RULE:

333-016-2080
Fees ¶

(1) The following fees are established:¶
(~~1~~a) Notification. A nonrefundable fee of $250 for the notification of each HPCCCH reported to the Authority under OAR 333-016-2060(1).¶
(~~2~~b) Exemption request made under OAR 333-016-2070(3) or (14):¶
(~~a~~A) A non-refundable fee of $1,500; and¶
(~~b~~B) ~~The fee for review of a Manufacturing Control Program is $200 per hour.¶~~
~~(3) The Authority shall not review a Manufacturing Control Program unless the fees required under this rule are pai~~$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(6).¶
(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) 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) 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 in a timely manner 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 subsection (4)(a) of this rule or if a new request is submitted under subsection (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 eithe~~r manufacturer and a request for exemption may be denied on the basis that the required fees were not paid~~r accepting or declining the estimate. If the estimate is declined, the Authority will consider the request for a waiver, chemical substitution, exemption, 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.' ¶

(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

REPEAL: 333-016-2090

RULE SUMMARY: Repeal OAR 333-016-2090 Enforcement and Civil Penalties. Replacing with OAR 333-016-3080 Enforcement and Civil Penalties.

CHANGES TO RULE:

~~333-016-2090~~
~~Enforcement and Civil Penalties ¶~~

~~(1) The Authority may impose a civil penalty on a manufacturer for a violation of any provision of ORS 431A.258 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 this state.¶~~
~~(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) If the Authority has reason to believe that a children's product that contains a HPCCCH used in children's products is being sold or offered for sale in this state in violation of ORS 431A.258 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 10 days after receipt of a request. To prove compliance with ORS 431A.258 the manufacturer must provide:¶~~
~~(a) Evidence that the children's product does not contain the HPCCCH used in children's products;¶~~
~~(b) Evidence that the manufacturer has previously provided the Authority with notice as required by ORS 431A.258 and these rules; or¶~~
~~(c) Provide the Authority with notice as required by ORS 431A.258 and OAR 333-016-2060.¶~~
~~(5) 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 was in place prior to the violation and that the manufacturer has exercised due diligence.¶~~
~~(6) Civil penalties will be imposed in the manner provided in ORS 183.745.¶~~
~~(7) 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(10).~~

~~Statutory/Other Authority: ORS 431A.275, ORS 413.042~~
~~Statutes/Other Implemented: ORS 431A.275~~

ADOPT: 333-016-3010

RULE SUMMARY: Adopt OAR 333-016-3010 Removal or Substitution of High Priority Chemical to specify the three categories of children's products for which removal, substitution, or procurement of a waiver approved by the Authority is required, and respective due dates. Specifies the procedure that manufacturers must follow if removing a HPCCCH from a product or ceasing to manufacture the product (in lieu of substitution, waiver procurement). Specifies the process by which manufacturers with 25 or fewer employees may request a two-year extension of the date specified in ORS 431A.260(1) to meet the requirements of the rules.

CHANGES TO RULE:

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 submits the third biennial notice required under OAR 333-016-2060 for a 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 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 no later than the last day (December 31st) of the third biennial notice period. 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. A manufacturer that intends to substitute a HPCCCH pursuant to ORS 431A.263 must comply with OAR 333-016-3030; 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.
Statutory/Other Authority: ORS 413.042, ORS 431A.260, ORS 431A.268
Statutes/Other Implemented: ORS 431A.260

ADOPT: 333-016-3015

RULE SUMMARY: Adopt OAR 333-016-3015 Exemptions from Removal or Substitution Requirements to specify four categories through which manufacturers can request an exemption from having to have a specific product comply with ORS 431A.260(1), and the process needed to apply for such exemptions.

CHANGES TO RULE:

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 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 with current accreditation to conduct such testing and found to be below the chemical migration limit of the EN-71 requirement for the HPCCCH for which exemption is requested.¶
(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 an exemption request and the fees specified in OAR 333-016-2080(1)(e) and provide to the Authority written supporting documentation, including a certificate of conformity, if available, that clearly establishes that the children's product meets the applicable standards described in the applicable 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, the technical dossier that a manufacturer is required to present to authorities enforcing the EN-71 standard that includes:¶
(A) A citation of the EN-71 standard(s), current as of December 31, 2019, that is applicable to the HPCCCH for which an exemption is being sought; and ¶
(B) A test report that identifies: ¶
(i) The children's products being tested, as identified by Universal Product Code or Stock Keeping Unit codes, style codes or other information sufficient to identify them;¶
(ii) The HPCCCH for which testing was conducted; and¶
(iii) That the HPCCCH found to be migrating from the product, if at all, is below the chemical migration limit of the EN-71 requirement applicable to the HPCCCH for which exemption is being requested.¶
(5) The specific children's products for which exemption is being sought under section (2) of this rule must be

identified by manufacturers as specified in OAR 333-016-3010(3)(a) through (c).¶
(6) This written documentation must be submitted in its entirely 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.¶
(7) 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.¶
(8) 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.
Statutory/Other Authority: ORS 413.042, ORS 431A.260
Statutes/Other Implemented: ORS 431A.260

ADOPT: 333-016-3020

RULE SUMMARY: Adopt 333-016-3020 Requirements for Chemical Substitution to specify the definition of children's product for this rule and that of OAR 333-016-3040. Specifies that a Hazard Assessment must be provided when substituting a less-hazardous chemical for a HPCCCH in a children's product. Provides the methods that should be used to identify children's products for which a hazard assessment is being done. Specifies the process and timelines by which the Authority and those requesting a Hazard Assessment must abide by for submitting and reviewing a Hazard Assessment.

CHANGES TO RULE:

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 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 Authority no later than the last day (December 31st) of the third biennial notice period for the product:¶
(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) If the Authority approves a HA it will provide written notice to the manufacturer of the disapproval and the basis for the disapproval. ¶
(7) 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. ¶
(8) 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. ¶
(9) 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).¶
(10) 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 is submitted to the Authority.
Statutory/Other Authority: ORS 413.042, ORS 431A.263
Statutes/Other Implemented: ORS 431A.263

ADOPT: 333-016-3030

RULE SUMMARY: Adopt 333-016-3030 Hazard Assessments for Substitute Chemicals to specify that manufacturers are to have their substitute chemicals assessed by a Licensed GreenScreen Profiler using GreenScreen® for Safer Chemicals Hazard Assessment Guidance. Details the standards under which the Authority will approve chemicals proposed to replace a HPCCCH. States the Authority's determination that GreenScreen Guidance is a scientifically-based, data-driven methodology. Provides the possibility of the use of an alternative methodology for a Hazard Assessment as wells as the criteria, process and timeline that should be used to submit the alternative process to the Authority for approval.

CHANGES TO RULE:

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 high hazard level 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 and is equivalent 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 30 business days before the date the manufacturer submits the Hazard Assessment.¶
(b) The Authority will review the request and within 30 business days respond in writing to the manufacturer either approving or denying the request. ¶
(6) The Authority will accept a HA that demonstrates through scientifically supported by 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.
Statutory/Other Authority: ORS 413.042, ORS 431A.263, ORS 431A.265
Statutes/Other Implemented: ORS 431A.263, ORS 431A.265

ADOPT: 333-016-3040

RULE SUMMARY: Adopt OAR 333-016-3040 Waiver from Removal or Substitution Requirement to specify the application process and timelines by which the Authority, and those requesting such a waiver must abide by for submitting and reviewing waiver documents. Specifies a manufacturer's responsibilities if the Authority disapproves a revised waiver request or an initial waiver (if the manufacturer does not submit a revised version).

CHANGES TO RULE:

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. 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 an initial or 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.

Statutory/Other Authority: ORS 413.042, ORS 431A.263, ORS 431A.265

Statutes/Other Implemented: ORS 431A.263, ORS 431A.265

ADOPT: 333-016-3050

RULE SUMMARY: Adopt OAR 333-016-3050 Quantitative Exposure Assessment to specify the standards and required content of this type of document which may be submitted as part of a request that ORS 431A.260(1) and its rules be waived for specified children's product(s).

CHANGES TO RULE:

333-016-3050
Quantitative Exposure Assessment
(1) 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) A QEA may be done in two steps, as follows:¶
(a) A description of exposure scenario(s) that demonstrate how, if at all, a HPCCCH in the children's product could 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 cannot reasonably be anticipated to be transferred to or into a child's body through a completed exposure pathway because of leachability and bioavailability and only conducts the first step of the QEA as described in subsection (2)(a) of this rule, the manufacturer shall provide a detailed report and analysis to the Authority that demonstrates to the Authority's satisfaction, that a child would not be exposed to a HPCCCH. ¶
(3) A QEA must include citations from scientific literature for any assertion made. ¶
(4) Laboratory analysis done for purposes of a QEA must be conducted by a laboratory accredited to ISO/IEC 17025:2017 standards and the tests used in the QEA must fall within the scope of the laboratory's accreditation.¶
(5) 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) 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) 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.
Statutory/Other Authority: ORS 413.042, ORS 431A.265
Statutes/Other Implemented: ORS 431A.265

ADOPT: 333-016-3060

RULE SUMMARY: Adopt OAR 333-016-3060 Alternatives Assessment to specify the standards and required content of this type of document which may be submitted as part of a request that ORS 431A.260(1) and its rules be waived for specified children's product(s).

CHANGES TO RULE:

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. For purposes of approving or disapproving a submitted AA, the Authority weighs the results of the modules, if needed, equally. ¶
(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 or essential;¶
(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 in the product for the reliability, quality, useful life and acceptability to consumers of the product; and¶
(d) After a HA 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.
Statutory/Other Authority: ORS 413.042, ORS 431A.263, ORS 431A.265
Statutes/Other Implemented: ORS 431A.263, ORS 431A.265

ADOPT: 333-016-3070

RULE SUMMARY: Adopt OAR 333-016-3070 Trade Secrets to specify what manufacturers must do if they believe the information they are submitting is a trade secret as well as what the Authority will do if it receives a public records request for such records.

CHANGES TO RULE:

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

ADOPT: 333-016-3080

RULE SUMMARY: Adopt OAR 333-016-3080 Enforcement and Civil Penalties to specify the civil penalties for violations of the proposed rules, the process and timeline the Authority must follow to both determine and assess those penalties, and what manufacturers may do to remedy those violations.

CHANGES TO RULE:

333-016-3080
Enforcement and Civil Penalties
(1) The 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 a pending or an 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 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