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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED
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ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Amendment of Practical Quantification Limits for High Priority Chemicals of Concern for Children's Health

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/23/2018 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.

A public rulemaking hearing may be requested in writing by 10 or more people, or by a group with 10 or more members, within 21 days following the publication of the Notice of Proposed Rulemaking in the Oregon Bulletin or 28 days from the date the Notice was sent to people on the agency mailing list, whichever is later. If sufficient hearing requests are received, the notice of the date and time of the rulemaking hearing must be published in the Oregon Bulletin at least 14 days before the hearing.

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NEED FOR THE RULE(S):

SB 478 (Oregon Laws 2015, chapter 786) was passed by the Oregon Legislature during the 2015 legislative session. 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, and establish requirements for disclosure, which includes requiring practical quantification limits (PQLs) equal to or above which high priority chemicals of concern for children's health, if intentionally added, are to be disclosed.

OAR 333-016-2020, Chemicals of High Concern to Children was reviewed and revised by the Authority during 2018 rulemaking under provisions in ORS 431A.255 List of high priority chemicals of concern in children's products. ORS 431A.255 directs the Authority to review OAR 333-016-2020, Chemicals of High Concern to Children every three years from the date OAR 333-016-2020 became effective (January 1, 2016). As part of this review, the Authority is to consider adding or removing High Priority Chemicals of Concern for Children's Health (HPCCCH) that are added or removed from Washington State Department of Ecology's Reporting List of Chemicals of High Concern to Children (CHCC). Changes to Ecology's CHCC list were made through Washington Administrative Code rulemaking, effective October 2017.

Under a 2018 rulemaking, the Authority added (to OAR 333-016-2020) five of the 20 chemicals added to Ecology's list and removed three chemicals that Ecology removed from their list. After a rules advisory committee, a public hearing and public comment period, PH 252-2018 was filed with the Secretary of State & Legislative Counsel on September 11, 2018 and is effective January 1, 2019.

Proposed amendments to OAR chapter 333, division 16 include:

Amend OAR 333-016-2035 Manufacturer Disclosure of High Priority Chemicals of Concern for Children's Health Used in Children's Products: Practical Quantification Limits. The Authority proposes to add PQLs for the five HPCCCH added to OAR 333-016-2020 and remove PQLs for the three HPCCCH that were delisted. Communicating clear expectations to members of the regulated community and effective regulation requires that the PQLs listed in OAR 333-016-2035 should be the same for HPCCCH listed in OAR 333-016-2020, Chemicals of High Concern to Children, both effective January 1, 2019. As was true for PQLs for chemicals in the original OAR 333-016-2020, Chemicals of High Concern to Children, the five PQL's and the suggested testing methods are those determined through Washington Administrative Code rulemaking. Those five PQL's and their methods are those found in Washington's Children's Safe Products Reporting Rule: Manufacturer Reporting Guidance, (Publication 17-04-040), published February 2018.

Please see text for amendments to OAR 333-016-2035 Exhibit A: Projected PQLs for the 68 high priority chemicals of concern in children's products. This proposed permanent rulemaking seeks to amend Exhibit A referenced in OAR 333-016-2035 so that the list of HPCCCH and corresponding PQLs aligns with the list in OAR 333-016-2020 that was adopted through permanent rulemaking filed September 11, 2018 and effective January 1, 2019.

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>

Permanent Administrative Order PH 252-2018

(<https://www.oregon.gov/oha/PH/HEALTHYENVIRONMENTS/HEALTHYNEIGHBORHOODS/TOXICSUBSTANCES/Documents/2016-2020%20FINAL%20text.pdf>)

State of Washington, Department of Ecology, Children's Safe Products Act Reporting Rule and guidance documents. and <https://fortress.wa.gov/ecy/publications/documents/1704040.pdf> and <https://fortress.wa.gov/ecy/publications/documents/1704040.pdf>

FISCAL AND ECONOMIC IMPACT:

Changes to OAR 333-016-2035 Manufacturer Disclosure of High Priority Chemicals of Concern for Children's Health Used in Children's Products: Practical Quantification Limits is expected to have minimal fiscal impact to manufacturers in Oregon for the following reasons: 1) all the chemicals in OAR 333-016-2020, Chemicals of High Concern to Children are found on Ecology's Reporting List of Chemicals of High Concern to Children (CHCC); 2) any testing needed to determine the PQLs for the five added chemicals will likely have been done for reporting required for Ecology's Children's Safe Products Act.

Most manufacturers reporting for Ecology's program must report the same products under the TFK Act. It makes sense that the PQLs for intentionally-added chemicals for both programs be the same.

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) The modification of OAR 333-016-2035 Manufacturer Disclosure of High Priority Chemicals of Concern for Children's Health Used in Children's Products: Practical Quantification Limits will result in an addition of five PQLs and the removal of three. This change is not expected to have any cost of compliance impact on the public or local or state governments, as they are not required to provide notification to the Authority.

(2)(a) 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 distributor. We are unable to estimate the number of manufacturers that would be considered a small business based on available information.

(b) The modification of OAR 333-016-2035 Manufacturer Disclosure of High Priority Chemicals of Concern for Children's Health Used in Children's Products: Practical Quantification Limits will result in an addition of five PQLs and the removal of three. These changes are to ensure the HPCCCH and corresponding PQLs align with the list of HPCCCH in OAR 333-016-2020. The changes are not expected to have any cost of compliance in addition to that of OAR 333-016-2020 that was adopted through permanent rulemaking filed September 11, 2018 and effective January 1, 2019.

(c) The modification of OAR 333-016-2035 Manufacturer Disclosure of High Priority Chemicals of Concern for Children's Health Used in Children's Products: Practical Quantification Limits will result in an addition of five PQLs and the removal of three. These changes are to ensure that the HPCCCH and corresponding PQLs align with the list of HPCCCH in OAR 333-016-2035 align with the list in OAR 333-016-2020. The changes are not expected to have any cost of compliance in addition to that of OAR 333-016-2020 that was adopted through permanent rulemaking filed September 11, 2018 and effective January 1, 2019.

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

Small businesses were not involved in the development of this proposed rule change. Please see below for further explanation.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

The Toxic Free Kid Program (TFKP) held two RAC meetings (in April & May 2018) and a public hearing (August 16, 2018) for the five chemicals that were added to OAR 333-016-2020 Chemicals of High Concern to Children list (and three that were proposed to be removed). This is the rule that directly corresponds to OAR 333-016-2035 Manufacturer Disclosure of High Priority Chemicals of Concern for Children's Health Used in Children's Products: Practical Quantification Limits. Small businesses were invited to these RAC meetings.

These chemical changes were non-controversial, and no testimony was given at the public hearing. Three written comments were received from both industry and health advocates on the rule changes, and all supported/didn't oppose the chemical changes made. Consistency between the Oregon and Washington's programs has been an ongoing goal of manufacturers of children's products.

Consequently, the Toxic-Free Kids Program did not convene another RAC for the changes to OAR 333-016-2035 Exhibit A because the proposed changes to Exhibit A are to align the list of HPCCCH with changes previously adopted under permanent rulemaking filed September 11, 2018 and effective January 1, 2019, for which a RAC was consulted

AMEND: 333-016-2035

RULE SUMMARY: The Oregon Health Authority (Authority), Public Health Division, is proposing to amend Exhibit A referenced in OAR 333-016-2035 pertaining to practical quantification limits (PQLs) for high priority chemicals of concern for children's health (HPCCCH) used in children's products. The Authority proposes to add PQLs to Exhibit A that correspond to the five HPCCCH added to OAR 333-016-2020 in a permanent rulemaking filed with the Secretary of State and Legislative Counsel on September 11, 2018 and effective January 1, 2019 (PH 252-2018). In addition, the Authority proposes to remove PQLs for the three HPCCCH that were delisted in the permanent rulemaking referenced above.

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.¶

[ED. NOTE: Exhibit referenced is available from the agency]

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.

Exhibit A: Projected PQLs for the **686** 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	75-94-7	20.0	3540/GCMS
12	Bisphenol A	80-05-7	20.0	8720
13	Bisphenol S	80-09-1	1.0	1694
14	Diethyl phthalate	84-66-2	5.0	8720
15	DBP (Dibutyl phthalates); di-n-butyl phthalate	84-74-2	5.0	8720
16	Di-n-hexyl Phthalate	84-75-3	5.0	8720
16	Phthalic anhydride	85-44-9	100.0	8091
17	Butyl benzyl phthalate (BBP)	85-68-7	5.0	8720
18	N-Nitrosodiphenylamine	86-30-6	1.0	8720
19	Hexachlorobutadiene	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	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-NP and its isomer mixtures including CAS 84852-15-3 and CAS 25154-52-3	104-40-5	10.0	USGS 5-B2
29	para-Chloroaniline	106-47-8	60.0	8720
30	Acrylonitrile	107-13-1	1.0	8260
31	Ethylene glycol	107-21-1	<u>5.0</u>	8015

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32	Toluene	108-88-3	<u>1.0</u>	8260
33	Phenol	108-95-2	<u>60.0</u>	8270
34	2-Methoxyethanol	109-86-4	<u>10.0</u>	8015
35	Ethylene glycol monoethyl ester	110-80-5	10.0	8015
36	Triphenyl phosphate	115-86-6	50.0	8270
376	Tris(2-chloroethyl) phosphate	115-96-8	50.0	8270
387	Di-2-ethylhexyl phthalate	117-81-7	20.0	8270
398	Di-n-octyl phthalate (DnOP)	117-84-0	5.0	8270
4039	Hexachlorobenzene	118-74-1	30.0	8270
410	3,3'-Dimethylbenzidine & Dyes Metabolized to same	119-93-7	10.0	8270
421	Ethyl paraben	120-47-8	30.0	HPLC
432	1,4-Dioxane	123-91-1	1.0	8720/many
443	Perchloroethylene	127-18-4	0.5	8260/many
454	Benzophenone-2; 2,2',4,4'-Tetrahydroxybenzophenone	131-55-5	20.0	GC-FID
465	4-tert-Octylphenol	140-66-9	10.0	USGS 5-B2
476	Estragole	140-67-0	10.0	IFRA GCMS
487	2-Ethylhexanoic Acid	149-57-5	1.0	Not given
48	Octamethylcyclotetrasiloxane	556-67-2	10.0	8260/8015
49	Benzene, 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	Perfluorooctanyl sulphonic acid and its salts; PFOS	1763-23-1	1.0	EPA PFOA
54	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	Molybdenum & molybdenum compounds	7439-98-7	1.0	EPA³
578	Antimony & Antimony compounds	7440-36-0	1.0	EPA³
589	Arsenic & Arsenic compounds including arsenic trioxide (1327-53-3) and dimethyl arsenic (75-60-5)	7440-38-2	1.0	EPA³
5960	Cadmium & cadmium compounds	7440-43-9	1.0	EPA³
601	Cobalt & Cobalt compounds	7440-48-4	1.0	EPA³
61	Tris(1-chloro-2-propyl) phosphate	13674-84-5	50.0	8270
62	Tris(1,3-dichloro-2-propyl) phosphate	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

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65	Diisodecyl phthalate (DIDP)	26761-40-0	50.0	8270
66	Diisononyl phthalate (DINP)	28553-12-0	50.0	8270
<u>67</u>	<u>Short-chain chlorinated paraffins</u>	<u>85535-84-8</u>	<u>50.0</u>	<u>GCMS</u>
<u>68</u>	<u>2-ethylhexyl-2,3,4,5-tetrabromobenzoate</u>	<u>183658-27-7</u>	<u>50.0</u>	<u>8270</u>

Effective January 1, 2019