

# D R A F T

## SUMMARY

Redefines “de minimis level” for purposes of Toxic-Free Kids Act.

Exempts from provisions of Act any component of children’s product that is inaccessible.

Specifies term and applicable fees for manufacturing control program exemption.

Requires Oregon Health Authority to analyze data related to each chemical that is present in all children’s products that are mouthable, children’s cosmetics or made for, marketed for use by or marketed to children under three years of age, for purpose of determining which chemicals should be subject to removal and substitution requirements of Act. Requires legislative ratification of chemicals that authority determines should be removed or substituted.

Becomes operative on January 1, 2018.

Takes effect 91st day following adjournment sine die.

## A BILL FOR AN ACT

1  
2 Relating to high priority chemicals of concern in children’s products; creat-  
3 ing new provisions; amending ORS 431A.253, 431A.258, 431A.260, 431A.268  
4 and 431A.270; and prescribing an effective date.

5 **Be It Enacted by the People of the State of Oregon:**

## DEFINITIONS

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9 **SECTION 1.** ORS 431A.253 is amended to read:

10 431A.253. As used in ORS 431A.253 to 431A.280:

11 (1) “Chemical” means:

12 (a) A substance with a distinct molecular composition and the breakdown  
13 products of the substance that form through decomposition, degradation or

**NOTE:** Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

1 metabolism.

2 (b) A group of structurally related substances and the breakdown products  
3 of the substances that form through decomposition, degradation or  
4 metabolism.

5 (2)(a) "Children's cosmetics" means products that are intended to be  
6 rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied  
7 to the human body or any part thereof for cleansing, moisturizing,  
8 beautifying, promoting attractiveness or altering the appearance.

9 (b) "Children's cosmetics" does not mean soap, dietary supplements or  
10 food and drugs approved by the United States Food and Drug Administration.

11 (3)(a) "Children's product" means:

12 (A) Any of the following products that are made for, marketed for use by  
13 or marketed to children under 12 years of age:

14 (i) A product designed or intended by the manufacturer to facilitate  
15 sucking, teething, sleep, relaxation, feeding or drinking.

16 (ii) Children's clothing and footwear.

17 (iii) Car seats.

18 (iv) Children's cosmetics.

19 (v) Children's jewelry.

20 (vi) Toys.

21 (B) Any component part of a product specified in subparagraph (A) of this  
22 paragraph.

23 (b) "Children's product" does not mean:

24 (A) Athletic shoes with cleats or spikes.

25 (B) Batteries.

26 (C) BB guns, pellet guns and air rifles.

27 (D) Bicycles and tricycles.

28 (E) Chemistry sets.

29 (F) Consumer electronic products, including personal computers, audio  
30 and video equipment, calculators, wireless telephones and game consoles,  
31 handheld devices that incorporate a video screen and are used to access

1 interactive software, and the associated peripherals.

2 (G) Interactive software intended for leisure and entertainment, such as  
3 computer games, and their storage media, such as compact discs.

4 (H) Model rockets.

5 (I) Pocketknives and multitools.

6 (J) Roller skates.

7 (K) Scooters.

8 (L) Sets of darts with metallic points.

9 (M) Slings and catapults.

10 (N) Snow sporting equipment, including skis, poles, boots, snowboards,  
11 sleds and bindings.

12 (O) Sporting equipment and accessories, including but not limited to bats,  
13 balls, gloves, sticks, pucks, pads, helmets and other protective equipment,  
14 weight training and exercise aids, protective eyewear, backpacks and tents,  
15 raingear, sport bags and luggage, and golf equipment.

16 (P) Video toys that can be connected to a video screen and are operated  
17 at a nominal voltage exceeding 24 volts.

18 (Q) Food and beverages and food and beverage packaging regulated by the  
19 United States Food and Drug Administration or the United States Depart-  
20 ment of Agriculture.

21 (4) "Contaminant" means trace amounts of chemicals that are incidental  
22 to manufacturing and that serve no intended function in the product com-  
23 ponent, including but not limited to:

24 (a) Unintended by-products of chemical reactions during the manufacture  
25 of the product component;

26 (b) Trace impurities in feedstock;

27 (c) Incompletely reacted chemical mixtures; and

28 (d) Degradation products.

29 (5) "De minimis level" means[:] **a concentration of 100 parts per**  
30 **million.**

31 *[(a) For a chemical that is an intentionally added chemical, the practical*

1 *quantification limit; or]*

2 *[(b) For a chemical that is a contaminant, a concentration of 100 parts per*  
3 *million.]*

4 *[(6) “Intentionally added chemical” means a chemical in a product that*  
5 *serves an intended function in the product component.]*

6 [(7)] (6) “Manufacturer” means any person that produces a children’s  
7 product or an importer or domestic distributor of a children’s product. For  
8 the purposes of this subsection, “importer” means the owner of the children’s  
9 product.

10 [(8)] (7) “Mouthable” means, in describing a children’s product or any  
11 part of a children’s product, that an intended use of the product or any part  
12 of the product includes being placed in the mouth for any purpose.

13 [(9)] (8) “Practical quantification limit” means the lowest concentration  
14 of a chemical that can be reliably measured within specified limits of preci-  
15 sion, accuracy, representativeness, completeness and comparability during  
16 routine laboratory operating conditions.

17 [(10)] (9) “Trade association” means a membership organization of persons  
18 engaging in the same or a similar or related line of commerce, organized to  
19 promote and improve business conditions in that line of commerce and not  
20 to engage in regular business activities that ordinarily are carried on for  
21 profit.

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23

## EXEMPTIONS

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25 **SECTION 2.** ORS 431A.268 is amended to read:

26 431A.268. **The requirements of ORS 431A.258, 431A.260, 431A.263 and**  
27 **431A.265 and section 6 of this 2017 Act do not apply to:**

28 (1) Manufacturers of children’s products with annual worldwide gross  
29 sales of less than \$5 million, as reported on the most recent tax return filed  
30 by the manufacturer before the notice required under ORS 431A.258[, *are*  
31 *exempt from the requirements of ORS 431A.258, 431A.260, 431A.263 and*

1 431A.265].

2 **(2) Any component of a children’s product that is inaccessible and**  
3 **that would not, during reasonably foreseeable use of the product or**  
4 **reasonably foreseeable abuse of the product, come into direct contact**  
5 **with the skin or mouth of a child under 12 years of age.**

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**MANUFACTURING CONTROL PROGRAMS**

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9 **SECTION 3.** ORS 431A.258 is amended to read:

10 431A.258. (1)(a) A manufacturer of a children’s product sold or offered for  
11 sale in this state that contains a chemical included on the list established  
12 and maintained under ORS 431A.255 in an amount at or above a de minimis  
13 level shall provide a biennial notice as described in subsection (2) of this  
14 section to the Oregon Health Authority by January 1 of each applicable no-  
15 tice year.

16 (b) The first biennial notice required under this section shall be submitted  
17 to the authority by January 1 of the year following the year that the chem-  
18 ical contained in the children’s product sold or offered for sale in this state  
19 is added to the list.

20 (2) The notice required by subsection (1) of this section must contain:

21 (a) The name and Chemical Abstracts Service Registry Number of the  
22 chemical contained in the children’s product;

23 (b) The product category of the children’s product that contains the  
24 chemical;

25 (c) A description of the function of the chemical in the children’s product;

26 (d) The amount of the chemical used in each unit of the children’s product  
27 reported as a range rather than an exact amount;

28 (e) The name and address of the manufacturer, and the name, address and  
29 telephone number of a contact person for the manufacturer; and

30 (f) Any other information that the manufacturer deems relevant to the  
31 appropriate use of the children’s product.

1 (3)(a) The authority may enter into reciprocal data sharing agreements  
2 with other states in which manufacturers of children's products are required  
3 to disclose information related to high priority chemicals of concern for  
4 children's health used in children's products. The authority must use the GS1  
5 Global Product Classification system to identify and specify product categories  
6 subject to the data sharing agreements. If the authority has entered into  
7 a data sharing agreement with another state, and a manufacturer has reported  
8 the information required in the notice described in subsection (2) of  
9 this section to that state, the manufacturer may request that the other state  
10 provide the authority with the information in lieu of the manufacturer's direct  
11 reporting of the information to the authority.

12 (b) A manufacturer fulfills the notice requirement of subsection (1) of this  
13 section when the authority receives the information from the other state and  
14 the authority determines that the information received satisfies the requirements  
15 for the notice specified in subsection (2) of this section.

16 (4) In lieu of the manufacturer's providing notice to the authority under  
17 subsection (1) or (3) of this section, the authority may require that the notice  
18 described in subsection (2) of this section be submitted to the Interstate  
19 Chemicals Clearinghouse. The authority by rule shall specify procedures for  
20 the provision of such notice by manufacturers to the Interstate Chemicals  
21 Clearinghouse.

22 (5)(a) The authority shall grant an exemption to a manufacturer of  
23 children's products that applies for an exemption from the notice requirements  
24 of this section if the application demonstrates that:

25 (A) The high priority chemical of concern for children's health used in  
26 children's products is present in the children's product otherwise subject to  
27 the notice requirements of this section only as a contaminant;

28 (B) The manufacturer conducts a manufacturing control program for the  
29 contaminant; and

30 (C) The manufacturing control program meets minimum standards for a  
31 manufacturing control program as set forth by the authority by rule.

1       **(b) For the purpose of applying for an exemption under paragraph**  
2 **(a) of this subsection, a manufacturer of children’s products may**  
3 **conduct a single manufacturing control program for multiple con-**  
4 **taminants.**

5       ~~[(b)]~~ **(c)** The authority shall approve or disapprove an exemption applica-  
6 tion within 180 days after its submittal. If the authority fails to act within  
7 180 days, the exemption application is deemed approved. If the authority  
8 disapproves an exemption application, the manufacturer may submit a re-  
9 vised exemption application for consideration within 180 days after the  
10 authority’s disapproval.

11       **(d) An exemption granted under this subsection is valid until a**  
12 **manufacturer of children’s products makes significant changes to the**  
13 **components of the children’s products or to the manufacturer’s man-**  
14 **ufacturing control program. If a manufacturer of children’s products**  
15 **makes significant changes to the components of the children’s pro-**  
16 **ducts or to the manufacturer’s manufacturing control program, the**  
17 **manufacturer may file an application in accordance with paragraphs**  
18 **(a) to (c) of this subsection to renew the exemption.**

19       (6) A trade association may provide required notices on behalf of its  
20 member manufacturers under the provisions of this section.

21       (7) When a manufacturer provides notice to the authority under the pro-  
22 visions of this section, the manufacturer may submit recommendations to the  
23 authority regarding technical, financial or logistical support deemed neces-  
24 sary for innovation and green chemistry solutions related to high priority  
25 chemicals of concern for children’s health used in children’s products.

26       **SECTION 4.** ORS 431A.270 is amended to read:

27       431A.270. (1) The Oregon Health Authority may conduct testing of  
28 children’s products sold or offered for sale in this state in order to determine  
29 compliance with ORS 431A.258, 431A.260 and 431A.263.

30       (2) The authority may establish by rule a schedule of fees for manufac-  
31 turers of children’s products that are based on the costs to the authority for

1 administering ORS 431A.253 to 431A.280. **The authority may not adopt**  
2 **fees in excess of the following amounts for exemption applications**  
3 **submitted under ORS 431A.258 (5):**

- 4 (a) **\$2,000 for an initial exemption application;**  
5 (b) **Except as provided in paragraph (d) of this subsection, \$2,000 for**  
6 **a renewal of an exemption application;**  
7 (c) **\$500 for a revised exemption application; and**  
8 (d) **\$250 for a renewal of an exemption application.**

9 (3) Fees collected by the authority under *[this]* subsection (2) of this  
10 **section** shall be deposited in the High Priority Chemicals of Concern for  
11 Children's Health Fund established under ORS 431A.278.

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13 **REPORT TO THE LEGISLATURE**

14

15 **SECTION 5. Section 6 of this 2017 Act is added to and made a part**  
16 **of ORS 431A.253 to 431A.280.**

17 **SECTION 6. (1) After the date on which manufacturers of children's**  
18 **products are required to submit the third biennial notice under ORS**  
19 **431A.258, the Oregon Health Authority shall analyze, for the purpose**  
20 **of determining which chemicals should be subject to the removal and**  
21 **substitution requirements set forth in ORS 431A.260 and 431A.263, data**  
22 **related to each chemical that is present in each children's product:**

- 23 (a) **Of which the authority received notice under ORS 431A.258; and**  
24 (b) **That is:**  
25 (A) **Mouthable;**  
26 (B) **A children's cosmetic; or**  
27 (C) **Made for, marketed for use by or marketed to children under**  
28 **three years of age.**

29 (2)(a) **An analysis conducted under subsection (1) of this section**  
30 **must:**

- 31 (A) **Be based on credible scientific evidence; and**



1       **(B) Quantify the risk that a chemical poses for a child on the basis**  
2 **of the amount of exposure to the chemical that a child is likely to have**  
3 **in consideration of the children’s product’s intended use or reasonably**  
4 **anticipated use.**

5       **(b)(A) After conducting an analysis under subsection (1) of this**  
6 **section, the authority shall determine which chemicals should be**  
7 **subject to the removal and substitution requirements set forth in ORS**  
8 **431A.260 and 431A.263. To determine that a chemical must be removed**  
9 **or substituted, the authority must find that the chemical poses an**  
10 **unreasonable risk to children.**

11       **(B) In making a determination under this paragraph, the authority**  
12 **shall determine whether the requirements of ORS 431A.260 and**  
13 **431A.263 with respect to each chemical are duplicative of a federal law**  
14 **or regulation, or whether a federal law or regulation establishes for a**  
15 **children’s product allowable amounts of the chemical. If the require-**  
16 **ments of ORS 431A.260 and 431A.263 with respect to a chemical are**  
17 **duplicative of a federal law or regulation, or if a federal law or regu-**  
18 **lation establishes for a children’s product allowable amounts of the**  
19 **chemical, then the chemical does not pose an unreasonable risk to**  
20 **children for purposes of this section.**

21       **(3) After determining which chemicals should be subject to the re-**  
22 **moval and substitution requirements set forth in ORS 431A.260 and**  
23 **431A.263, the authority shall prepare a report for the purpose of mak-**  
24 **ing recommendations for legislation. The report must include:**

25       **(a) A detailed description of the analysis of each chemical and de-**  
26 **termination as to whether the chemical should be subject to the re-**  
27 **moval and substitution requirements set forth in ORS 431A.260 and**  
28 **431A.263; and**

29       **(b) Citations to any peer reviewed article or other information that**  
30 **authority relied upon in its analyses and determinations.**

31       **(4) The authority shall submit the report prepared under subsection**

1 **(3) of this section to an interim committee of the Legislative Assembly**  
2 **related to health on or before September 1 of the even-numbered year**  
3 **immediately following the year in which manufacturers of children’s**  
4 **products are required to submit the third biennial notice required un-**  
5 **der ORS 431A.258. Upon receiving the report, the interim committee**  
6 **shall file a proposed legislative measure with Legislative Counsel re-**  
7 **questing a measure by which the Legislative Assembly and the Gov-**  
8 **ernor may ratify the authority’s determination as to which chemicals**  
9 **should be subject to the removal and substitution requirements set**  
10 **forth in ORS 431A.260 and 431A.263.**

11 **SECTION 7.** ORS 431A.260 is amended to read:

12 *431A.260. [(1) On or before the date on which a manufacturer of a children’s*  
13 *product submits the third biennial notice required under ORS 431A.258 for a*  
14 *chemical that is present in a children’s product, the manufacturer must remove*  
15 *or make a substitution for the chemical pursuant to ORS 431A.263, or seek a*  
16 *waiver under ORS 431A.265, if the chemical is present in a children’s product*  
17 *that is:]*

18 *[(a) Mouthable;]*

19 *[(b) A children’s cosmetic; or]*

20 *[(c) Made for, marketed for use by or marketed to children under three*  
21 *years of age.]*

22 **(1) On or before January 1 of any year immediately following the**  
23 **year in which a measure is enacted pursuant to section 6 of this 2017**  
24 **Act for the purpose of requiring a chemical to be removed from or**  
25 **substituted in a children’s product described in section 6 (1) of this 2017**  
26 **Act, a manufacturer of the children’s product must:**

27 **(a) Remove the chemical from the children’s product;**

28 **(b) Make a substitution pursuant to ORS 431A.263 for the chemical**  
29 **in the children’s product; or**

30 **(c) Seek a waiver under ORS 431A.265 for the chemical in the**  
31 **children’s product.**

1 (2) A manufacturer with 25 or fewer employees may apply for a two-year  
2 extension of the date specified in subsection (1) of this section to meet the  
3 requirements of this section.

4 (3) Manufacturers are exempt from meeting the requirements of this sec-  
5 tion for children's products described in [*subsection (1) of this section*] **sec-**  
6 **tion 6 (1) of this 2017 Act** that contain high priority chemicals of concern  
7 for children's health used in children's products at levels that are at or be-  
8 low allowable levels for children's products as established by the Consumer  
9 Product Safety Improvement Act of 2008, P.L. 110-314, 122 Stat. 3016, as in  
10 effect on July 27, 2015.

11 [(4)(a)] (4) The Oregon Health Authority shall adopt rules providing for  
12 additional exemptions from the requirements of this section.

13 [(b) *For purposes of this subsection, any consumer product safety standard*  
14 *adopted under federal law that establishes allowable levels for children's pro-*  
15 *ducts of a high priority chemical of concern for children's health used in*  
16 *children's products is presumed to establish the maximum allowable level of*  
17 *the chemical that may be used in children's products that are sold or offered*  
18 *for sale in this state. The authority may not require a manufacturer in com-*  
19 *pliance with the federal standard to also comply with the provisions of this*  
20 *section unless the authority establishes in the rulemaking process that a lower*  
21 *maximum allowable level for children's products of a high priority chemical*  
22 *of concern for children's health used in children's products than the allowable*  
23 *level set by the federal standard is necessary to protect human health and*  
24 *welfare.*]

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26

## MISCELLANEOUS

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28 **SECTION 8. (1) Section 6 of this 2017 Act and the amendments to**  
29 **ORS 431A.253, 431A.258, 431A.260, 431A.268 and 431A.270 by sections 1**  
30 **to 4 and 7 of this 2017 Act become operative on January 1, 2018.**

31 (2) The Oregon Health Authority may take any action before the

1 **operative date specified in subsection (1) of this section that is neces-**  
2 **sary to enable the authority to exercise, on and after the operative**  
3 **date specified in subsection (1) of this section, all the duties, powers**  
4 **and functions conferred on the authority by section 6 of this 2017 Act**  
5 **and the amendments to ORS 431A.253, 431A.258, 431A.260, 431A.268 and**  
6 **431A.270 by sections 1 to 4 and 7 of this 2017 Act.**

7 **SECTION 9. This 2017 Act takes effect on the 91st day after the date**  
8 **on which the 2017 regular session of the Seventy-ninth Legislative**  
9 **Assembly adjourns sine die.**

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