Oregon Toxic-Free Kids Act – ORS 431A.253
Guidance for Requesting Exemption from Notice Requirements

Under Oregon's Toxic-Free Kids Act (ORS 431A.250), beginning January 1, 2018, manufacturers[1] of children's products sold in Oregon must notify the Oregon Health Authority (Authority) of those products that contain one or more of 66 high priority chemicals of concern for children's health (HPCCCH) in an amount at or above a de minimis level.[2]

A manufacturer of children's products is responsible for knowing the amount of HPCCCHs in its children's products sold or offered for sale in Oregon. Although guidance on notification is forthcoming, all manufacturers (or trade associations in which they have membership), regardless of company size or product "tier" are required to notify the Oregon Health Authority (i.e. the Authority) of products as described above unless exempted.

Alternatively, a manufacturer or trade association may submit to the Authority a request for an exemption from these rules for any HPCCCH in a children's product that is present only as a contaminant at or above the de minimis level. This request for an exemption from notifying the Authority of a HPCCCH(s) is hereafter called a manufacturing control program or MCP.

In order for the Authority to approve it, the MCP must demonstrate, as determined by the Authority, that the contaminant or contaminants exempted are being effectively controlled. Contaminant is defined in ORS 431A.250 as follows:

[1] As defined in Oregon's Toxic-Free Kids statute (ORS 431A.253), "manufacturer" means any person that produces a children's product or an importer or domestic distributor of a children's product. This statute applies only to manufacturers with annual worldwide sales of $5 million or more. See statute for additional details on reporting.

[2] Per ORS 431A.253, "de minimis level" means: (a) for a chemical that is an intentionally added chemical, the practical quantification limit; or (b) for a chemical that is a contaminant, a concentration of 100 parts per million.

"Contaminant" means trace amounts of chemicals that are incidental to manufacturing. They serve no intended function in the product component. They can include, but are not limited to, unintended by-products of chemical reactions during the manufacture of the product component, trace impurities in feed-stock, incompletely reacted chemical mixtures, and degradation products.

A request to the Authority for exemption from notification rules (OAR 333-016-2060 - Notification Requirements) is only available for HPCCCH present as contaminant(s) at or above the de minimis level (100 parts per million, or 0.01% by weight).

Manufacturers must notify the Authority of HPCCCH that are *intentionally added* during a manufacturing process of a product, per ORS 431A.250.

The purpose of this guidance is to clarify the elements of an MCP the Authority will look for when evaluating an exemption request. This guidance expands on rules issued by the Authority on February 1, 2017. [See OAR 333-016-2070 - Exemptions from Notice Requirement.]

A single MCP may be submitted for multiple contaminants, if appropriate. If a single MCP is used for multiple contaminants, the MCP should specify how each contaminant is to be controlled.

Given the variability in products and manufacturing processes, there is no “one size fits all” example of a MCP. The Authority may, in the future, determine that additional elements need to be added to this Guidance to ensure that contaminants are being controlled. Similarly, some elements may need to be updated as new and improved methods are developed. Any changes to MCP requirements that are in rule would take place through a formal rule-making process.

Successful MCPs will include responses to the following items (in bold):

1. **Manufacturer Name, Mailing Address, Contact Information (email/direct phone)**

   If the MCP is being submitted by a trade association on behalf of a manufacturer, the name, address and contact information of the trade association needs to be included as part of the MCP.

   A list of manufacturers, on whose behalf the trade association is submitting the MCP, must be identified in the application. [The name and contact information of a representative of each manufacturer must be included as well.]

2. **Confidential Business Records and Trade Secrets**

   Does the manufacturer believe that any information being submitted in the MCP is a trade secret?

   If so, the initial occurrence of that information must be marked "confidential – trade secret." For information on how the Authority assesses such information, see OAR 333-016-2070.

3. **Specify the HPCCCHs covered by the MCP.**

   Specify one or more chemicals from OHA's HPCCCH list that are being covered by the MCP. Be sure to include both the chemical's name and CAS number.

   An MCP may cover multiple HPCCCH chemicals; however, each HPCCCH chemical addressed in the MCP must be identified by chemical name and CAS number.

4. **Provide a description of the product(s) covered by the MCP? Include a description of how and when in the process the HPCCCH(s) is generated.**

   The MCP must include the GS1 Brick level (i.e. Global Trade Item Number) designation of a product) in addition to providing sufficient detail to describe the final formulated product. Include, in detail, how and when in the manufacturing/formulation process the HPCCCH is generated.

   If the HPCCCH is generated during production of feedstock (i.e., any bulk raw material), the applicant may obtain a declaration or certificate of analysis from the feedstock supplier identifying the maximum concentration of the HPCCCH in the feedstock (see Section 6 for example calculations).

5. **As stated in OAR 333-016-2070, indicate which of the following categories the MCP is being structured around. [More than one may be chosen, if appropriate.]**

   (a) Manufacturing processes, e.g. polymerization of plastic resin, injection-molding of plastic, pad-transfer printing, silk screening;

   (b) Materials or group of materials, e.g. multiple styrenic plastics;

   (c) Component parts; or

   (d) Finished products, e.g., children's personal care product containing siloxanes, children's clothing with perfluorinated water repellent coating.

6. **Provide a description of the mechanisms (category, process, materials and control methods) covered by the MCP. If multiple categories, processes, material changes and/or methods are used to control a contaminant or multiple contaminants, describe each mechanism separately, identify the contaminant(s) being controlled by that mechanism, and quantify the degree of contaminant control.**

   Adequate substantiation should be provided to facilitate verification that contaminant control is taking place. Such substantiation can include the following:

   (a) Report from an accredited laboratory demonstrating that instituted control measures are able to reduce the contaminant to de minimis levels;

   (b) Supplier declaration confirming that a manufacturing process associated with contaminant generation is not being used;

   (c) Supplier's certificates of analysis documenting maximum levels of contaminant (note: if you have multiple suppliers, a declaration should be provided for each supplier).

<u>Example calculations appear below:</u>

200 ppm 1,4-Dioxane in surfactant feedstock (i.e., 0.02%) used in children's baby shampoo: 0.02% x 50% ethoxylated surfactant in shampoo = 0.01% 1,4-dioxane in shampoo (i.e., 100 ppm)

160 ppm Cadmium in metal component of a child's metal and plastic bracelet: 160 mg cadmium/kg metal component x 0.030 kg metal component/0.040 kg on bracelet = 120 mg cadmium/kg bracelet = 0.012% or 120 ppm

7. What generally recognized industry best manufacturing practice(s) and processes(s) for the control of a HPCCCH does the MCP meet?

At a minimum, a reasonable MCP includes those methods and procedures required to comply with federal regulations for children's products. This may include recognized industry best manufacturing practices, including (but not limited to):

- International Standards Organization (ISO) Requirements (Specify ISO number)

  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.

- American Society for Testing and Materials (ASTM) standards, or other widely established certification or standards programs;

- Established certification or standards for product manufacturing [Specify what programs are used and how they control the specific contaminant(s)]

  - Sony Corporations Green Partners Standards
  - European ROHS (Restriction of Hazardous Substances in Electronic Parts)
  - EN 71
  - FDA approved food contact material
  - Responsible Care Management System® and (RCMS®) and RC14001® Technical Specifications
  - Other – Identify the certification or standard and how it applies

Alternative Methodology

[Should be described in detail.] MCPs may include proven alternative methodologies. To be acceptable, alternate methodologies must allow the applicant to demonstrate BOTH of the following:

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

(b) The alternative methodology is as effective (or more effective) at controlling the contaminant(s) than the standards listed above.

> Note: Just stating that a particular process, practice or procedure is to be used is insufficient. Successful applications will show how the process or procedure listed controls a HPCCCH(s) present in the product as a contaminant at or above the de minimis level.

8. Document and describe whether the manufacturing control practices or processes provided in #7 (above) include any of the following:

- Procedures to ensure the quality and purity of feedstock, whether raw or recycled;

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

- Periodic[3] testing for the presence and amount of HPCCCHs in the finished children's product, including documentation of how tests were conducted and applicable lab results from an accredited third party laboratory;

- Procedures and approaches to audit the methods used by contractors or suppliers to control HPCCCPs present as contaminants in a children's product;

- 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.

Submitting Exemption Requests to the Authority & Subsequent Steps

- Information on fee payment and how to submit Exemption Requests is available at healthoregon.org/toxicfreekids. The submitting party (manufacturer or trade association) should be listed on each page of the MCP submitted.

- Per HB 5027 (signed into law on July 3, 2017), a non-refundable fee of $1,500 must be made to the Authority for each Exemption Request/MCP submitted. In addition, the cost to the submitting party for review of the MCP is $200 per hour.

- See Form and Procedure for Requesting Exemption from Notice Requirements at healthoregon.org/toxicfreekids (under 'Requirements for manufacturers') for additional details on submission and invoicing for review services.

[3] Here "periodic" is defined as any time when there is a question as to whether the contaminant(s) are present in a differing amount, or if the contaminant for which the MCP was submitted is still the same. Such testing may be appropriate, but shouldn't be limited to, occasions such as when feedstock or materials change, when a new supplier is contracted, or when a new batch of feedstock or materials is accepted.

- Amendments to MCPs made after January 1, 2018 can only be made by a manufacturer or trade association with an existing, approved MCP on file with OHA.

Next steps:

Upon receipt of the exemption request (i.e. MCP and application form) and correct fees, the Authority will date stamp the request and, within three business days, acknowledge receipt of exemption request to the contact email address.

The exemption request will not be considered complete and won't be date-stamped unless the Authority receives appropriate fees, as listed above.

As stated in OAR 333-016-2070 - Exemptions from Notice Requirement, once date stamped the Authority must approve or deny an exemption request within 180 calendar days.

- If the Authority does not approve or disapprove the exemption request within 180 days the MCP is deemed approved.

- If the Authority approves the MCP, the Authority will notify the manufacturer of the approval in writing.

- If an MCP is disapproved, the Authority will provide written notice to the manufacturer of the disapproval, and the reason for the disapproval.

- 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.

- 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.

- If the Authority has received an Exemption Request/MCP prior to the January 1, 2018 deadline, it will not enforce this notification deadline for HPCCCH included in that Exemption Request/MCP until the review process described in OAR 333-016-2070 is complete.

  This only applies to HPCCCH included in that Exemption Request/MCP. Any other HPCCCH for which no exemption request has been submitted must be reported by January 1, 2018.

- At any time, the Authority may request additional information from a manufacturer requesting an exemption.

Questions?

Please contact the Authority's Toxic-Free Kids Program at toxicfreekids.program@state.or.us or 971-673-0977.

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