Guidance for Manufacturing Control Program per OAR 333-016-2070

Oregon Toxic-Free Kids Act – ORS 431A.250

Under Oregon's Toxic-Free Kids Act (ORS 431A.250) beginning January 1, 2018, manufacturers[1] of sold or offered for sale in Oregon must notify (report) the Oregon Health Authority (Authority) of those products that contain one or more of 68 High Priority Chemicals of Concern for Children's Health (HPCCCH) in an amount at or above the de minimis level [2]

Manufacturers of children's products sold or offered for sale in Oregon are responsible for knowing the amount of HPCCCHs in their children's products. Per OAR 333-016-2060, these manufacturers are required to notify the Authority of such products using the High Priority Chemicals Data System (HPCDS), unless exempted. Notification is required of all HPCCCHs at or above de minimis, regardless of location in a children's product.

Alternatively, a manufacturer or trade association ("manufacturer," hereafter) 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. Oregon Administrative Rule (OAR) 333-016-2010 - Definitions provides the definition of MCP the Authority uses.

In order for the Authority to approve it, the MCP must demonstrate that the contaminant or contaminants 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 and that 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 feedstock, 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. As defined in ORS 431A.253, de minimis for contaminants is 100 parts per million (ppm) or 0.01% by weight.

Manufacturers must notify the Authority of children's products containing an HPCCCH that is an *intentionally added chemical*, as defined in ORS 431A.253, and that is at or above de minimis.

OHA does not need to be notified of HPCCCH present as contaminants that are below 100 ppm.

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 March 1, 2021. [See OAR 333-016-2070 - Exemptions from Notice Requirement.]

A single MCP may be submitted for multiple contaminants in multiple 'product categories' (as defined by OAR 333-016-2010), if appropriate. If a single MCP is used for multiple contaminants, the MCP should specify how each contaminant is to be controlled in each product category, if appropriate.

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 first time that information appears should be marked "confidential – trade secret." For information on how the Authority assesses such information, see OAR 333-016-3070.

3. **Specify the HPCCCHs and product categories covered by the MCP.**

   Per OAR 333-016-2070(5), the MCP should specify one or more chemicals from OHA's HPCCCH list that the MCP is intended to address and the 'product categories' (as defined by OAR 333-016-2010) in which each is found. [See How Global Product Classification (GPC) works to understand the "brick" level specified in OAR 333-016-2010.]

   Be sure to include both the chemical's name and CAS number. An MCP may cover multiple HPCCCH chemicals; however, each HPCCCH addressed in the MCP must be identified by chemical name and CAS number.

   Trade associations submitting on behalf of members must specify, by member, this HPCCCH and product category combination.

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 provide 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.

5. **As stated in OAR 333-016-2070(4), the manufacturer should indicate the 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; or

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

   (c) Component parts; or

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

6. Per OAR 333-016-2070(6), what generally recognized industry best manufacturing practice(s) and processes(s) for the control of the 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. The cited practice should be relevant to the HPCCCH for which the exemption is requested. For example, while European Restriction of Hazardous Substances in Electronic Parts (ROHS) currently applies to six restricted substances, two are HPCCCH (cadmium and mercury). Therefore, ROHS may be used in a cadmium or mercury MCP, but not in a formaldehyde MCP.

Recognized industry best manufacturing practices, include (but are not limited to):

(a) International Standards Organization (ISO) Requirements (Specify ISO number);

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

(c) Established certification or standards for product manufacturing Specify what programs are used and how they control the specific contaminant(s). Programs include, but are not limited to:

- Sony Corporations Green Partners Standards
- European ROHS (Restriction of Hazardous Substances in Electronic Parts)
- EN 71
- Current American Society for Testing and Materials (ASTM) International standards that provide recommended industry standards for materials used or produced in the manufacturing process

Alternative Methodology

Per OAR 333-016-2070(6)(d), proven alternative methodologies may be utilized, but these must be described in detail. 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.

> 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.

7. Per OAR 333-016-2070(7), for category(ies) indicated in Section 5 of this document, the manufacturer must provide adequate evidence that the contaminant is being controlled. This should include, but is not limited to, the following:

(a) Periodic laboratory test reports from a third-party laboratory. The laboratory should be accredited as specified by OAR 333-016-2070(7)(a).

In addition, the laboratory must be accredited for the method used to conduct the testing. The test reports must show the presence, if quantifiable, and the amount of a HPCCCH, and include documentation that characterizes the test methodology.

(b) Supplier's certificates of analysis documenting maximum levels of contaminant (Note: if you have multiple suppliers, a declaration should be provided for each supplier). The certificate of analysis must include items listed in OAR 333-016-3070(7)(b)(A) through (H).

(c) Per OAR 333-016-3070(7)(c), documentation should be provided demonstrating that the instituted control measures are able to control the contaminant, as appropriate for category(ies) indicated in Section 5 of this document, including but not limited to, the quantification of the degree of contaminant control occurring because of contaminant control measures instituted.

> To provide adequate evidence that the contaminant is being "controlled" as specified in the definition of MCP in OAR 333-016-2010, a manufacturer must know or be able to estimate the contaminant level (parts per million) in the indicated category(ies) in Section 5 without the instituted control measures.
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> Then the manufacturer can quantify the effect of the controlling measures, and document how they specifically control the HPCCCH as a contaminant.

8. In addition to meeting at least one of the generally recognized best manufacturing practices in Section 6 of this document for HPCCCH and product category combinations listed, the manufacture should document and describe in its MCP whether the manufacturing control process for the manufacturer or the manufacturer's supplier includes any of following:

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

(b) 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;

(c) 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;

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

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

[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.

Submitting Exemption Requests to the Authority & Subsequent Steps

- Exemption Requests by any entity must be received by the Authority on or before the last day (**December 31st**) of the two-year biennial notice period for which the request is being made.

- Per OAR 333-016-2080(1), each manufacturer shall pay a non-refundable fee of $1,500 to the Authority for each Exemption Request submitted. In addition, this rule stipulates that the cost to the submitting party for review of the MCP is $200 per hour.

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

Next steps:

Upon receipt of the Exemption Request (i.e., MCP and application form) and correct fee, the Authority will date stamp the request. Within three business days, it will acknowledge receipt of the Exemption Request to the sender.

The exemption request will not be considered complete and won't be date-stamped unless the Authority receives the non-refundable fee, as listed in OAR 333-016-2080(1)(a)(A).

As stated in OAR 333-016-2070, 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 notice of disapproval to report product categories containing the HPCCCH in the denied MCP to the HPCDS. This is in accordance with OAR 333-016-2070(11).

"Pause" of Enforcement of Reporting Requirement

- If the Authority accepts an Exemption Request/MCP prior to the due date for which Biennial Notice of the product categories/HPCCCH(s) is required, it will pause enforcement of OAR 333-016-2060 for HPCCCH(s)/product categories specified in the MCP until review of the request, as specified in OAR 333-016-2070, is complete. [An exemption request approved by the Authority suspends enforcement.]

- This enforcement pause only applies to HPCCCH(s)/product categories included in the MCP submitted. HPCCCH(s)/product categories for which no exemption request has been submitted must be reported using the Hight Priority Chemical Data System by the Biennial Notice due date.

- While a manufacturer who has been denied an exemption request a second time must report product categories containing the HPCCCH in the denied MCP using the HPCDS, it may submit a new exemption request during future biennial notice periods.

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

> Manufacturers should be aware that under OAR 333-016-2070, the Authority will approve or disapprove the MCP in its entirety.
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> For MCPs with multiple HPCCCH and product category combinations, it will **not** approve some that meet criteria in rule but disapprove others that do not.
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> Therefore, manufacturers should be sure that all combinations adhere to criteria in rule.

Would you like to add product categories or trade association members, or update processes to MCPs previously approved by the Authority?

See OAR 333-016-2070(14) through (16).

Would you like to learn about the process the Authority will use when reviewing an MCP?

See OAR 333-016-2080(2) through (8).

Questions?

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

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