



Guidance for Quantitative Exposure Assessment per Oregon Administrative Rule (OAR) 333-016-3050 & 333-016-3060

Under Oregon's Toxic-Free Kids Act ([Oregon Revised Statute \(ORS\) 431A.250](#)) beginning January 1, 2018, manufacturers¹ of children's products sold or offered for sale in Oregon must notify the Oregon Health Authority (Authority) of products that contain one or more [High Priority Chemicals of Concern for Children's Health](#) (HPCCCH) in an amount at or above the de minimis level.² Per OAR [333-016-2060](#), this notification shall be made by 'product category' (GS1 'brick' level and completed using the [High Priority Chemicals Data System](#) (HPCDS)). Manufacturers are responsible for knowing the amounts of HPCCCHs in their children's products.

Per OAR [333-016-3010](#), 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](#), the manufacturer must remove or substitute HPCCCH(s) present from children's products that are:

- "Mouthable" per [ORS 431A.253](#);
- A children's cosmetic; or
- Made for, marketed for use by or marketed to children under three years of age.

Manufacturers that intend to substitute chemicals must comply with OAR [333-016-3020](#) prior to December 31st of the third biennial notice period. By this date, manufacturers who have removed the HPCCCH from products and do not substitute for it, or no longer manufacture the product, must notify the Authority per OAR [333-016-3010\(3\)](#). Within ninety days of the notice, manufacturer must comply with OAR [333-016-3010\(4\)](#).

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.

Alternatively, manufacturers of children’s products meeting one or more of the three definitions in OAR [333-016-3010](#) may submit to the Authority a request for a *Waiver from Removal or Substitution Requirement* per OAR [333-016-3040](#).

Waiver applications are to be accompanied by either a Quantitative Exposure Assessment (QEA) per OAR [333-016-3050](#) or an Alternatives Assessment (AA) per OAR [333-016-3060](#). Because a QEA is a required component of an AA, this QEA Guidance applies to both. [Stand-alone AA Guidance to be published soon.] Waiver applications must be received by the Authority by the last day (December 31st) of the third biennial notice period during which these products have been sold or offered for sale in Oregon.

In order for the Authority to approve a QEA, it 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 (OAR [333-016-3050\(1\)](#)). “Leachability” and “Bioavailability” are defined in OAR [333-016-2010](#).

Per OAR [333-016-3050\(6\)](#), 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](#).

A QEA may be submitted for an HPCCCH found either as a contaminant in a children’s product at or above 100 ppm or an intentionally-added chemical at or above *de minimis*. “Contaminant,” “Intentionally-added chemical” and *de minimis* are defined in ORS [431A.250](#). The TFK Act does not apply to HPCCCH found as contaminants in children’s products below 100ppm.

The purpose of this guidance is to clarify the elements the Authority will look for when evaluating a QEA sent in support of a Waiver Request. This guidance expands on several of the [Phase 3](#) rules issued by the Authority and effective March 1, 2021.

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

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

If the QEA 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 QEA.

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

2. Confidential Business Records and Trade Secrets

Does the manufacturer believe that any information being submitted in the QEA 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 [33-016-3070](#).

3. HPCCCH and specific brand name and product model/style sold or to be sold in Oregon.

Per OAR [333-016-3050](#), the QEA should specify the chemical from the Authority's [HPCCCH](#) list. Be sure to include both the chemical's name and CAS number. Manufacturers must describe the brand name and product model/style (BNPM) sufficient to identify the specific product on which they have conducted the QEA. Per OAR [333-016-3010\(3\)](#), this is to 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; and

(c) Universal Product Code (UPC) or Stock Keeping Unit (SKU) codes, style codes or other mechanisms sufficient to identify product models sold in Oregon, which have been assigned by the manufacture.

4. A QEA conducted for the Toxic Free Kids Act may be done in two steps per OAR [333-016-3050](#):

There are many ways a child may be exposed to a HPCCCH in a children's product and a large variety of children's products. Manufacturers should make a good-faith effort to briefly describe every exposure scenario that may result from the reasonably foreseeable use and abuse of a BNPM. Science-based claims made in these scenarios, and for other parts of the QEA, must include citations from the scientific literature.

Step A. The manufacturer should describe how, if at all, a HPCCCH in the children's product could reasonably be anticipated to enter a child's body through a completed exposure pathway. Manufacturers should specifically consider the leachability and bioavailability of a HPCCCH from the children's product per OAR [333-016-3050\(2\)\(a\)](#). Descriptions of exposure scenarios must focus on the 'reasonably foreseeable use and abuse,' per OAR [333-016-2010](#), of the specified children's product.

Step B

First Option (OAR [333-016-3050\(2\)\(b\)](#)):

If the manufacturer determines that the exposure scenarios 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. Information should include measurements of the concentration of a HPCCCH in the simulated media appropriate for that chemical and product, such as saliva, sweat, or digestive fluid. The manufacturer must also submit a copy of any analytical test results for the HPCCCH in each media tested for a BNPM. The analytical test results should include all items in OAR [333-016-3050\(2\)\(b\)](#) and be conducted in accordance with OAR [333-016-3050\(3\)](#) and [\(4\)](#).

Second Option (OAR [333-016-3050\(2\)\(c\)](#)):

If a manufacturer determines that a HPCCH cannot reasonably be anticipated to enter a child's body 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 that demonstrates to the Authority's satisfaction that a child would not be exposed to the HPCCH.

Potential Implications of Choosing Second Option for Step B:

In choosing the second option for Step B, manufacturers should consider the following:

OAR [333-016-3040](#) provides two opportunities for a Waiver Request to be approved. If the Authority disapproves a Waiver Request, it will identify deficiencies in its denial letter to the manufacturer. If the QEA-in question is part of the first attempt for a Waiver Request, the manufacturer may use that feedback for the second attempt.

Manufacturers who choose not to submit laboratory testing as part of their first attempt lose an opportunity to gain the Authority's feedback on the analytical methods used; sources of information used to determine the concentration of the HPCCH in relevant media; and/or the appropriateness of the analytical instruments used for testing.

Before deciding to submit only OAR [333-016-3050\(2\)\(a\)](#), manufacturers should clearly demonstrate that a HPCCH cannot be reasonably anticipated to enter a child's body, as described in OAR 333-016-3050(2)(a).

5. For BNPMs, manufacturers should provide the same information for the BNPM 'product category' at the GS1 'brick'-level that was reported in the most recent Biennial Notice Period to the High Priority Chemicals Data System

Per OAR [333-016-3040\(3\)](#), the manufacturer should provide the same information for the BNPM that corresponds to its GS1 'brick' reported to the IC2 [High Priority Chemicals Data System](#) (HPCDS).

6. Recommended format for a QEA with the same HPCCCH in multiple BNPM:

Given the variability in children's products and manufacturing processes, there is no "one size fits all" for a QEA. However, the Authority recommends the following format to shorten the length of the review:

For sufficiently similar BNPM containing the same HPCCCH(s) with concentrations (PPM) that do not vary by more than 10%, manufacturers may list the final results of Steps 3-5 of this Guidance in table format. Manufacturers should ensure that the underlying documentation for each BNPM is clearly labeled.

Manufacturers should not aggregate steps 3-5 for BNPM with different HPCCCHs, or with HPCCCH concentrations that vary by more than 10%. In this case, Steps 3-5 should be displayed for each individual BNPM.

Here are some examples of materials in multiple BNPMs that might be considered sufficiently similar for the BNPMs to be included in the same QEA:

Likely to be acceptable: same material, same exposure scenario:

- The same blue plastic is used to form the wheels on a toy car and the hat of non-powered doll that are both marketed to the same age of child and are of similar mouthable size.
- The same fabric is used for clothes for two-year old children and for clothes for a doll intended for two-year old children.
- The same rubber is used in a pacifier and in a teething ring.

Not likely to be acceptable: same material, different exposure scenario:

- Metal component in a sealed compartment of a powered toy car vs. the same metal component on an exterior metal casing of toy car.
- Plastic piece used inside sway mechanism of baby swing vs. the covering of the swing's seat made of the same plastic (that baby can lick).

Submitting Waiver Requests to the Authority & Subsequent Steps

- The Authority must receive Waiver Requests on or before the last day (December 31st) of the two-year biennial notice period for children's products for which the request is being made. This deadline is the same whether the Waiver Request is supported by an Alternatives Assessment per OAR [333-016-3060](#) or a QEA per OAR [333-016-3050](#).
- Trade associations may submit QEAs on behalf of specified members per [333-016-3040\(15\)](#).
- Per OAR [333-016-2080\(1\)](#), manufacturers shall pay a non-refundable fee of \$1,500 to the Authority for each Waiver Request submitted. This rule also stipulates that the cost to the submitting party for review of the QEA is \$200 per hour.
- 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, per OAR [333-016-3040\(4\)](#).
- Information on fee payment and how to submit Waiver Requests is available at healthoregon.org/toxicfreekids *****To Be Done***** . The submitting manufacturer or trade association should be listed on each page of the QEA submitted.

Next steps:

Upon receipt of the Waiver Request (*i.e.*, QEA and application form) and corresponding fee amount, the Authority will date stamp the request. Within three business days, it will acknowledge receipt of the Waiver 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\(1\)\(c\)](#).

As stated in OAR [333-016-3040](#), once date stamped the Authority must approve or deny a QEA submitted in support of a Waiver Request within 180 calendar days.

- If the Authority does not approve or disapprove the QEA within 180 days, the QEA is deemed approved.
- If the Authority approves the QEA, the Authority will notify the manufacturer of the approval in writing.
- If a QEA is disapproved, the Authority will provide written notice to the manufacturer of the disapproval, and the reason(s) for the disapproval.
- If the Authority disapproves a QEA, the manufacturer may submit a revised QEA for consideration within 180 days after the Authority's notice of disapproval.
- If the Authority disapproves a revised QEA, or the Authority disapproves an initial QEA and the manufacturer does not submit a revised QEA, the manufacturer has 90 calendar days to comply with OAR [333-016-3010\(4\) through \(6\)](#).

“Pause” of Enforcement of Removal/Substitution Requirement

- If the Authority accepts a Waiver Application/QEA prior to the third Biennial Notice due date for HPCCCH/product categories sold or offered for sale in Oregon, it will pause enforcement of OAR [333-016-3010](#) for products specified in the QEA, per OAR [333-016-3050\(5\)](#), until the review process described in OAR [333-016-3040](#), is complete. [A waiver request approved by the Authority suspends enforcement.]
- This enforcement pause applies only to HPCCCH(s)/products specified in the QEA submitted. Manufacturers of products for which a HPCCCH was required to be removed under OAR [333-016-3010](#), but were not specified in a pending QEA per OAR [333-016-3050\(5\)](#), must comply with OAR [333-016-3010](#) for these products or be subjected to enforcement action per OAR [333-016-3080](#).
- 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.
- For QEAs with more than one BNPM, manufacturers should be aware that under [OAR 333-016-3040\(16\)](#), the Authority may approve or disapprove the QEA in whole or in part. Submissions for individual BNPM may be approved or disapproved.

Would you like to learn about the process the Authority will use when reviewing a QEA? See [OAR 333-016-2080\(3\) through \(7\)](#).

Questions?

Please contact the Authority’s [Toxic-Free Kids Program](#) at toxicfreekids.program@state.or.us or 971-673-0977.