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## PERMANENT ADMINISTRATIVE ORDER

### PH 253-2018

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OREGON HEALTH AUTHORITY  
PUBLIC HEALTH DIVISION

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#### RULES:

333-016-2060, 333-016-2080, 333-016-2090

AMEND: 333-016-2060

RULE TITLE: Notification Requirements

NOTICE FILED DATE: 07/14/2018

RULE SUMMARY: OAR 333-016-2060 is being amended to clarify the need for only one report (biennial notification) of a specific children's product. Amendments are also made to establish a hierarchy of persons or entities the Authority will hold primarily responsible for reporting and with respect to enforcement, per OAR 333-016-2090, Enforcement and Civil Penalties. OAR 333-016-2060 is also being amended to align rule with existing statute to require that the number of children's products sold or offered for sale in Oregon that contain a HPCCCH must be part of a biennial notification.

#### RULE TEXT:

- (1) No later than January 1, 2018, and every other year thereafter, a manufacturer of a children's product sold or offered for sale in this state that contains a HPCCCH listed in OAR 333-016-2020 in an amount at or above a de minimis level must submit:
- (a) A notice to the Authority that contains all the information required in these rules, unless the manufacturer or product is exempt; and
  - (b) Any applicable fee in OAR 333-016-2080.
- (2) The first manufacturer's notice due on January 1, 2018, applies to children's products sold or offered for sale in this state between January 1, 2017 and December 31, 2017.
- (3) Future notices apply to children's products sold or offered for sale during the previous two year period. For example, for the reporting year 2020, a manufacturer must include children's products sold or offered for sale between January 1, 2018, and December 31, 2019, that contain a HPCCCH listed in OAR 333-016-2020.
- (4) The notice required in section (1) of this rule must include the following:
- (a) The name and Chemical Abstracts Service Registry Number of the chemical contained in the children's product;
  - (b) The product category of the children's product that contains the chemical;

- (c) A description of the function of the chemical in the children's product;
  - (d) The amount of the chemical used in each unit of the children's product reported as a range rather than an exact amount;
  - (e) The number of the children's product that contain the high priority chemical either sold or offered for sale in Oregon during the biennial notice period;
  - (f) The name and address of the manufacturer, and the name, address and telephone number of the contact person for the manufacturer; or
  - (g) The name, address and contact information for the trade association submitting the notification on behalf of the affected industry; and
  - (h) Any other information that the manufacturer deems relevant to the appropriate use of the children's product.
- (5) The second biennial notice will cover the period of January 1, 2018 through December 31, 2019.
- (6) If a manufacturer has included a children's product in a notice required under these rules, and determines that there is no change to the information submitted to the Authority in the previous notice, the manufacturer may, in lieu of including the children's product again in a subsequent notice, submit a written statement, or if available, an electronic notification indicating that the previous reported data is still valid for that children's product.
- (7) A trade association may provide the notice required in these rules on behalf of a member manufacturer.
- (8) A trade association who fulfills the notice or exemption requirements of these rules on behalf of a member manufacturer will not be held liable for a violation or penalty as a result of the member manufacturer's noncompliance with the requirements of these rules.
- (9) A manufacturer may, during the notification process, submit to the Authority recommendations regarding technical, financial or logistical support considered necessary for the implementation of innovation and green chemistry solutions related to HPCCCH used in children's products.
- (10) Only one person or entity that falls within the definition of manufacturer is required to report with respect to a particular children's product. The Authority will hold the following primarily responsible for ensuring that it receives a complete, accurate, and timely notice for the children's product, in the following order:
- (a) Any person or entity that manufactured the children's product, unless it has no presence in the United States.
  - (b) Any person or entity that distributed or made available for distribution the children's product, unless it has no presence in the United States.
  - (c) The importer or owner of the children's product in the United States.
- (11) The Authority will enforce the reporting requirements in this rule against a manufacturer in the same order as the priority order for reporting in section (10) of this rule.

STATUTORY/OTHER AUTHORITY: ORS 413.042, 431A.258

STATUTES/OTHER IMPLEMENTED: ORS 431A.258

AMEND: 333-016-2080

RULE TITLE: Fees

NOTICE FILED DATE: 07/14/2018

RULE SUMMARY: OAR 333-016-2080 is being amended due to the passage of HB 5027 (Oregon Laws 2017, chapter 546) in the 2017 legislative session. HB 5027 adopted in statute one fee relating to OAR 333-016-2060, Notification Requirements (\$250 per chemical), and enacted two fees relating to OAR 333-016-2070, Exemptions from Notice Requirement:

- A) A \$1,500 nonrefundable Exemption Request fee; and
- B) A \$200 per hour fee for review of these Exemption Requests submitted to the Authority.

Before HB 5027, OAR 333-016-2080, Fees required those seeking exemption from notice requirements to pay an initial fee of \$12,000 for review of a Manufacturing Control Program (MCP) submitted in support of an Exemption Request, and additional MCP review fees in increments of \$12,000, if needed. MCP reviews, set at \$200 per hour, were deducted from those \$12,000 increments with those fee increments refundable if unspent. HB 5027 allows the Authority to directly invoice those seeking an Exemption Request at \$200 per hour for MCP review. The intention of this rule change is to align the fee listed in rule with statute.

RULE TEXT:

The following fees are established:

- (1) Notification. A nonrefundable fee of \$250 for the notification of each HPCCCH reported to the Authority under OAR 333-016-2060(1).
- (2) Exemption request:
  - (a) A non-refundable fee of \$1,500; and
  - (b) The fee for review of a Manufacturing Control Program is \$200 per hour.
- (3) The Authority shall not review a Manufacturing Control Program unless the fees required under this rule are paid by the manufacturer and a request for exemption may be denied on the basis that the required fees were not paid.

STATUTORY/OTHER AUTHORITY: ORS 413.042, 431A.270

STATUTES/OTHER IMPLEMENTED: ORS 431A.270

AMEND: 333-016-2090

RULE TITLE: Enforcement and Civil Penalties

NOTICE FILED DATE: 07/14/2018

RULE SUMMARY: OAR 333-016-2090 is being amended to state that the Authority will use the same hierarchy adopted in OAR 333-016-2060, Notification Requirements, for enforcement purposes.

RULE TEXT:

(1) The Authority may impose a civil penalty on a manufacturer for a violation of any provision of ORS 431A.258 or these rules. A civil penalty may not exceed:

(a) \$2,500 for the first violation.

(b) \$5,000 for the second and each subsequent violation.

(2) For purposes of assessing civil penalties under these rules a violation consists of a single course of conduct with regard to an entire children's product line that is sold or offered for sale in this state.

(3)(a) If a manufacturer violates the notification requirement described in ORS 431A.258 the Authority shall provide the manufacturer with written notice informing the manufacturer of the violation and stating that the manufacturer may avoid a civil penalty for the violation by providing the proper notice required under ORS 431A.258 within 90 days.

(b) If the manufacturer fails to cure the violation within the first 90 days, the Authority may impose a civil penalty not to exceed \$2,500.

(c) For a continuing violation, each 90-day period that the violation continues after the preceding imposition of a civil penalty is considered a separate offense subject to a separate civil penalty not to exceed \$5,000. The Authority is not required to provide the manufacturer with an opportunity to cure the continuing violation before imposing the separate civil penalty.

(4) If the Authority has reason to believe that a children's product that contains a HPCCCH used in children's products is being sold or offered for sale in this state in violation of ORS 431A.258 the Authority may request that the manufacturer provide a statement of compliance on a form provided by the Authority. The manufacturer must submit the statement of compliance within 10 days after receipt of a request. To prove compliance with ORS 431A.258 the manufacturer must provide:

(a) Evidence that the children's product does not contain the HPCCCH used in children's products;

(b) Evidence that the manufacturer has previously provided the Authority with notice as required by ORS 431A.258 and these rules; or

(c) Provide the Authority with notice as required by ORS 431A.258 and OAR 333-016-2060.

(5) In imposing a penalty under these rules the Authority must consider the following factors:

(a) The past history of the manufacturer in taking all feasible steps or following all feasible procedures necessary or appropriate to correct any violation.

(b) Any prior violations of statutes, rules, orders or permits pertaining to HPCCCH used in children's products.

(c) The gravity and magnitude of the violation.

(d) Whether the violation was a sole event, repeated or continuous.

(e) Whether the violation was a result of an unavoidable accident, negligence or an intentional act.

(f) The violator's cooperativeness and efforts to correct the violation.

(g) The economic and financial conditions of the manufacturer incurring a penalty.

(h) The manufacturer's declaration that a HPCCCH used in a children's product is present only as a contaminant, and the manufacturer is able to provide evidence that a manufacturing control program for the contaminant that meets or exceeds the minimum requirements for a manufacturing control program in OAR 333-016-2070 was in place prior to the violation and that the manufacturer has exercised due diligence.

(6) Civil penalties will be imposed in the manner provided in ORS 183.745.

(7) The Authority will enforce the reporting requirements against a manufacturer in the same order as the priority order for reporting in OAR 333-016-2060(10).

STATUTORY/OTHER AUTHORITY: ORS 431A.275, ORS 413.042

STATUTES/OTHER IMPLEMENTED: ORS 431A.275