

Policy Statement: Interim Policy on Lead in Cosmetics

Program Name: Hazardous Waste and Toxics Reduction

Date Issued: December 19, 2024

Date(s) of Minor Revisions and Clarifications: January 15, 2025

Date(s) of Substantive Updates: Not applicable at this time

References: Toxic-Free Cosmetics Act (Chapter 70A.560 RCW)

Purpose

To provide cosmetic manufacturers with alternative paths to compliance for products that are unable to achieve lead concentrations below 1 part per million (ppm), while still requiring manufacturers to work toward the lowest lead levels possible in products.

Background

In 2023, the Washington State Legislature passed the <u>Toxic-Free Cosmetics Act</u>.¹ This law restricts the sale of cosmetic products containing certain chemicals, including lead and lead compounds. Makeup, shampoo, shaving cream, deodorant, and other personal care products are all covered by the new law. Effective January 1, 2025, these products must not include: (1) any lead that has been intentionally added to the product, nor (2) lead impurities over 1 ppm. The law also authorizes the Department of Ecology (Ecology) to conduct rulemaking to adopt a different limit on lead impurities.

In 2024, three separate but related petitions were filed with Ecology requesting the department use its rulemaking authority to change the lead contamination limit to match the federal recommendation of 10 ppm. Ecology declined to initiate rulemaking to adopt that rule; that decision was upheld on an appeal to the governor.

Situation

After meeting with many cosmetics manufacturers, Ecology learned that a strict 1 ppm limit can be difficult, if not impossible, to achieve in some products. The federal Food and Drug Administration (FDA) recommends cosmetic products and ingredients not exceed 10 ppm of lead impurities.

Lead is a naturally occurring metal that can be found in raw ingredients such as minerals and clay that are sometimes used in cosmetics. Ingredients used for pigments are a common source of lead impurities, but manufacturers have a limited number of

¹ Chapter 70A.560 RCW (https://app.leg.wa.gov/RCW/default.aspx?cite=70a.560)

FDA-approved pigments available to them. Concentrations of lead in these ingredients varies, which in turn affects lead concentrations in finished cosmetic products.

The variability of lead concentrations is problematic for manufacturers, because they are unable to guarantee consistently compliant levels of impurities across products. Although manufacturers report the majority of their products comply with the 1 ppm standard, they cannot guarantee every package of every product they produce does so.

Product testing data from Germany and the United Kingdom show that 90 percent of cosmetic products can achieve lead concentrations of 2 ppm for general cosmetics (such as lotion or cleansers) and 5 ppm for color cosmetics (such as blush or eye shadow). While there may be some variability in lead concentrations by geographic location, the data support the technical feasibility of lower concentrations. To protect human health and the environment, Washington's goal is to reduce lead in cosmetic products to the lowest level possible.

Interim Actions

More information is needed before Ecology can make a final determination about a feasible level for allowed lead impurities. Ecology also acknowledges the approaching January 1, 2025, compliance deadline. Our agency has committed to take the following interim actions by January 1, 2025:

1. Implement an interim policy.

This interim policy provides manufacturers with alternative paths to compliance for cosmetic products that are unable to achieve lead concentrations below 1 ppm, while still requiring manufacturers to work toward the lowest lead levels possible in products.

2. Open rulemaking on lead impurities in cosmetics in 2025.

This <u>rulemaking</u>² will be an open public process that will allow us to continue working with interested parties. To protect human health and the environment, Washington's goal is to reduce lead in cosmetic products to the lowest level possible.

While the department begins the lengthy process to better understand compliance challenges, these interim actions will provide regulatory flexibility and assurance to industry. This will allow companies to continue to manufacture, distribute, and sell products in Washington while taking steps to reduce lead impurities in products.

This interim policy is effective while Ecology gathers information for rulemaking about approaches to handling lead impurities in cosmetic products sold in Washington.

² https://ecology.wa.gov/regulations-permits/laws-rules-rulemaking/rulemaking /wac-173-339-lead-in-cosmetics

Interim Policy

As an exercise of enforcement discretion, Ecology will not enforce strict compliance with the 1 ppm limit on lead with respect to a cosmetic product for which the manufacturer has met the safe harbor provisions stated below.

The intent of this policy is to:

- Align enforcement with currently achievable limits to maintain product availability.
- Obtain product monitoring data from manufacturers to:
 - 1) Better understand the feasibility of a 1 ppm lead limit, and
 - Inform considerations for a feasible approach to regulating lead in cosmetics, including potentially changing the lead impurity limit to a new level between 1 and 10 ppm.

Interim safe harbor provisions for cosmetics exceeding 1 ppm lead impurity limit

Ecology will use its enforcement discretion for some cosmetic products with lead impurities exceeding 1 ppm.

While this policy remains in effect, Ecology will not enforce compliance with the 1 ppm limit on lead in cosmetic products under the following circumstances:

Option 1

The lead concentration is 2 ppm or below for general cosmetics or 5 ppm or below for color cosmetics or clay masks, *and* the manufacturer has notified Ecology of its decision³ to meet these limits for its products sold in Washington.

Option 2

The lead concentration of a color cosmetic or clay mask is above 5 ppm and below 10 ppm, *and* the manufacturer has notified Ecology of its decision³ to meet these limits for its products sold in Washington *and* is monitoring lead in each batch of the product and retaining lead concentration data and information. Submission of supporting data and information, including analytical methods, is not required unless requested by Ecology.

Additional requirements for option 2

Manufacturers may measure or estimate lead concentrations by testing raw ingredients, testing final products, or tracking lead concentrations in raw ingredients as reported by the certificates of analysis. If using certificates of analysis, the measured lead concentration must be reported. Any testing must be completed by a third-party laboratory. This policy does not specify or require specific analytical methods. Lead levels must be verified by measuring total lead (for example, using digestion), rather than

³ The word "decision" replaces the word "plan" in the original version of the policy. Submission of a written plan is not required.

leachate or bioavailable levels. The detection limit must be lower than the restriction level to provide reliable testing results.⁴

Manufacturers that are small businesses should demonstrate a good faith effort to monitor lead in products. Small businesses may rely on theoretical calculations from estimations in raw ingredients, composite testing, or exclude ingredients from their estimations if information is not available, so long as they have demonstrated a good faith effort to obtain data and information.

Additional requirements for all options

All manufacturers who use the safe harbor conditions described in this policy must notify Ecology of their decision⁵ to meet the conditions of this policy and provide contact information. This notice must be provided through Ecology's online submission form⁶ unless otherwise approved by Ecology staff.

Definitions of key terms

"Color cosmetic" means a cosmetic that contains pigments or colorants intended to beautify, promote attractiveness, or alter the appearance by adding color to skin, hair, eyelashes, or nails.

"**Cosmetic**"⁷ means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such article; except that such term shall not include soap.

"General cosmetic" means all cosmetics excluding color cosmetics and clay masks.

"Manufacturer"⁸ means any person, firm, association, partnership, corporation, governmental entity, organization, or joint venture that produces a product or is an importer or domestic distributor of a product sold or offered for sale in or into the state.

"Small business"⁹ means a business employing less than fifty people.

Confidential business information

Trade secrets may be eligible for protection from disclosure. On request and approval by Ecology, testing data and other sensitive information can be designated "confidential business information." Businesses wishing to obtain protection for such information must contact Ecology staff before submitting documentation to Ecology.

⁴ These two sentences with additional guidance on lead testing were added in this revised policy.

⁵ The word "decision" replaces the word "plan" in the original version of the policy. Submission of a written plan is not required.

⁶ https://forms.office.com/g/8aNzPabq83

⁷ RCW <u>69.04.011</u> (https://app.leg.wa.gov/RCW/default.aspx?cite=69.04.011)

⁸ RCW <u>70A.350.010</u> (https://app.leg.wa.gov/RCW/default.aspx?cite=70A.350.010)

⁹ RCW <u>70A.500.020</u> (https://app.leg.wa.gov/RCW/default.aspx?cite=70A.500.020)

Policy use and compliance

Distributors, retailers, and other sellers not covered by this policy may rely on it for compliance purposes. Cosmetic products purchased or received from manufacturers that notify Ecology of their intent to come within the conditions of this policy are considered compliant during the effective term of the policy.

Policy effective dates

This policy takes effect January 1, 2025. It will remain in effect until either a rule is adopted, the policy is repealed, or December 31, 2026, whichever occurs first. Ecology may extend the policy if it determines the policy is still needed after December 31, 2026.

Scope of Interim Policy

What does the interim policy cover?

The policy covers all cosmetic products as defined in <u>RCW 70A.560.010</u>.¹⁰ This is the same definition as <u>RCW 69.04.011¹¹</u> and as used by the FDA.

Who can use the interim policy?

Manufacturers of cosmetic products sold or manufactured in Washington.

Is my business required to follow the interim policy?

No. Manufacturers may elect to follow this policy but are not required to do so. Manufacturers who do not follow this policy must comply with the 1 ppm limit on lead in their cosmetic products.

Contact

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Webpage: <u>Toxic-Free Cosmetics Act</u>¹²

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¹⁰ https://app.leg.wa.gov/RCW/default.aspx?cite=70A.560.010

¹¹ https://app.leg.wa.gov/RCW/default.aspx?cite=69.04.011

¹² https://ecology.wa.gov/TFCA

¹³ https://ecology.wa.gov/accessibility