Welcome to the Hearing for the Formaldehyde in Cosmetics Rulemaking Proposal

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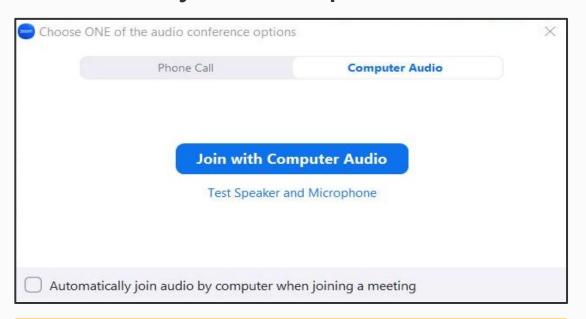
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Heather.Doran@ecy.wa.gov



Staff supporting this event

Rebecca Bohannan

Stacey Callaway

Heather Doran

Elinor Fanning

Shari Franjevic

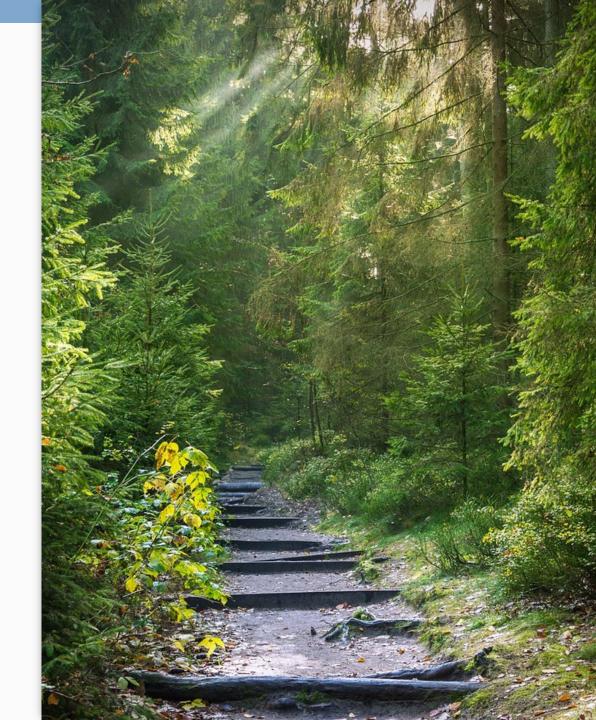
Roxanne Garcia

Cathy Hamilton-Wissmer

Adam Hayes

Fran Sant

Sean Zigah







Agenda

- 1. Info session
- 2. Questions and answers
- 3. Break
- 4. Public hearing
- 5. Next steps



Announcements and next steps

1. Online hearings

- March 31, 2025, at 10:00 AM
- April 1, 2025, at 5:30 PM
- 2. Comment period closes at 11:59 PM on April 11, 2025.
- 3. Decide on rule adoption by September 1, 2025.



Ground rules

- Use respectful language.
- Silence your cell phones.
- Limit background noise when speaking.
- Summarize lengthy questions and testimony.
- Speak in order called.





Info session

Law, rulemaking process, proposed rule, formaldehyde releasers, draft implementation plan



Other cosmetics rulemaking

Schedule

- Announced rulemaking in Dec. 2024
- Collect data until Fall 2025
- Workshops and preliminary draft in late 2025

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



Section 1. Toxic-Free Cosmetics Act





The law

- **1. Restriction:** Restricts the **manufacture**, **distribution**, and **sale** of cosmetic products that contain certain toxic chemicals.
- 2. Rulemaking: Gives us the authority to identify and restrict formaldehyde-releasing chemicals used in cosmetics and determine the lead limit.
- 3. Voluntary initiatives: Directs us to develop initiatives to support small businesses in transitioning to safer chemicals and products.

Restrictions on cosmetic products



Cosmetic products manufactured, sold, or distributed in Washington can't contain:

- Intentionally added restricted chemicals.
- Lead or lead compounds at or above 1 ppm.
 (Ecology issued an interim policy in Dec. 2024.)

Deadlines

- Jan. 1, 2025: Restrictions took effect.
- Dec. 31, 2025: Deadline for in-state retailers to sell existing stock.

Restricted chemicals and chemical classes

Chemicals

- 1. Formaldehyde (CAS 50-00-0)
- **2.** Methylene glycol (CAS 463-57-0)
- **3. Triclosan** (CAS 3380-34-5)
- 4. m-Phenylenediamine and its salts (CAS 108-45-2)
- **5.** o-Phenylenediamine and its salts (CAS 95-54-5)

Chemical classes

- **6. o-Phthalates** (several CAS)
- 7. PFAS (several CAS)
- 8. Mercury (CAS 7439-97-6) and mercury compounds
- 9. Lead (CAS 7439-92-1) and lead compounds

Rulemaking authority: formaldehyde releasers

Chapter 70A.560 RCW authorizes Ecology to conduct a rulemaking to:

- Identify chemicals used in cosmetic products that release formaldehyde (formaldehyde releasers).
- Adopt restrictions on the listed formaldehyde releasers.



Outreach efforts

- Connecting with industry and community-based organizations
- Updates to TFCA email list
- Postcards to businesses
- In-person events in Pacific Northwest
- Informational webinars
- Informal comment period
- News releases and media interviews
- Social media posts and webpages



Interested Parties

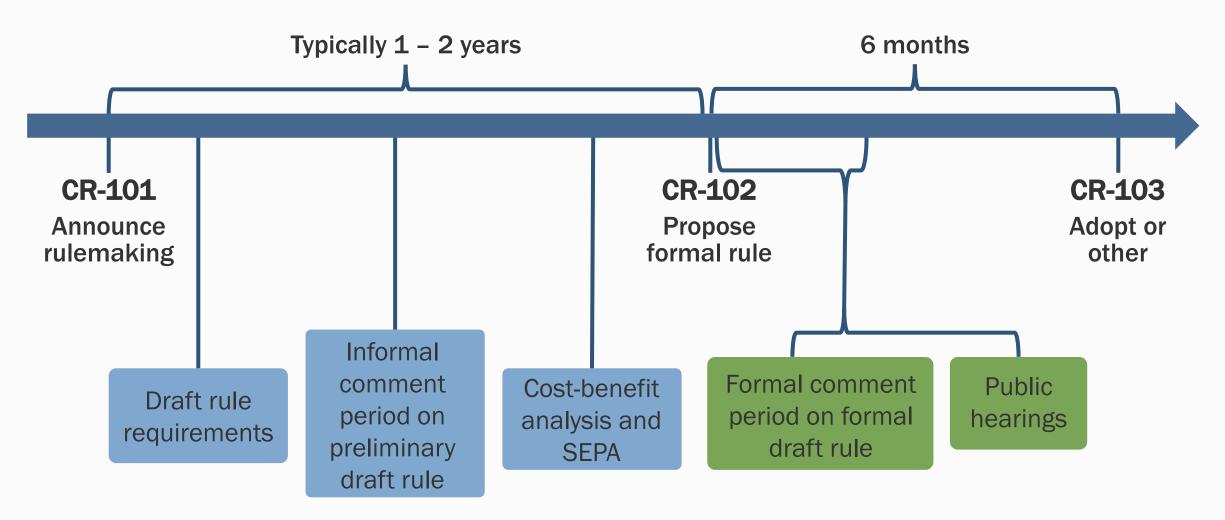
- Manufacturers, distributors, retailers
- Cosmetologists
- Community-based organizations
- Local health departments and government agencies
- Tribal organizations
- Environmental and community advocacy groups
- Media outlets
- Non-Washington State government agencies











See slide 55 for figure description.





CR-101INFORMAL comment period

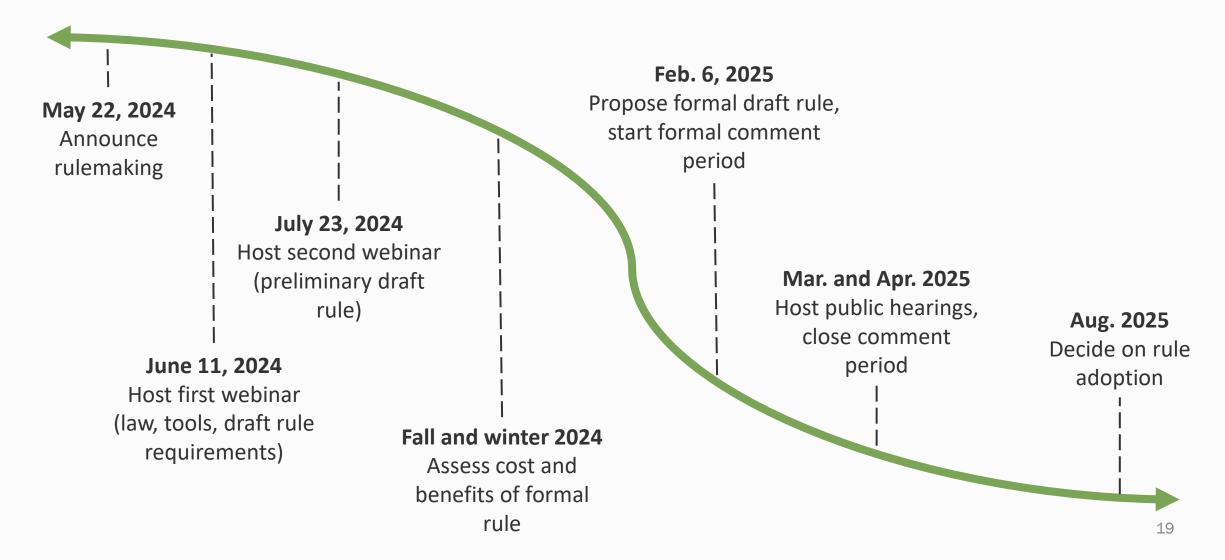
- Create draft rule requirements.
- Write preliminary draft rule.
- Provide INFORMAL public comment period.
- Significant changes are ok.

CR-102FORMAL comment period

- Release formal draft rule, costbenefit analysis, and SEPA.
- Provide FORMAL public comment period and hearings.
- Must refile the CR-102 form if significant changes to rule.

Formaldehyde in Cosmetics Rulemaking timeline





Rulemaking documents



- Available for comment
 - Proposed rule
 - Draft Cosmetics Implementation Plan
 - Preliminary Regulatory Analyses
 - SEPA analysis
- Supporting documents
 - Overview: Formaldehyde in Cosmetics Rulemaking
 - Formaldehyde releasers technical support



Preliminary Regulatory Analyses

Washington State

Cost: low	Cost: high	Benefit: low	Benefit: high
\$6 million	\$12 million	\$27 million	\$51 million







Part A: General

Authority and purpose

Applicability

Acronyms and definitions

Enforcement and penalties

Severability

035 Relation to other laws

and rules

Confidential business

information (CBI)

Part B: Chemicals in cosmetic products

Formaldehyde and formaldehyde releasers





This chapter applies to:

- Any person who manufactures, distributes, or sells or offers for sale a cosmetic product in or into Washington state.
- Cosmetic products, regardless of whether or **not** the product contains drug ingredients regulated by the U.S. Food and Drug Administration.
- Cosmetic products used in services, sold online, and sold in brickand-mortar stores.





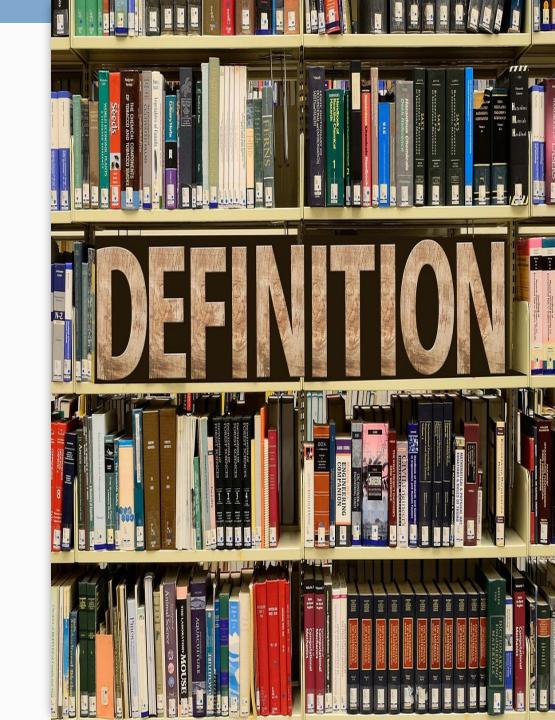
This chapter doesn't apply to:

- Cosmetic products transported or stored in Washington state solely for sale or distribution to consumers outside of Washington state.
- Drug ingredients regulated by the U.S. Food and Drug Administration.
- Prescription drugs approved by the U.S. Food and Drug Administration.
- The recycling or disposal of existing stock.

Acronyms and definitions (section 020)

Defined terms

- Cosmetic product
- Existing stock
- Formaldehyde
- Intentionally added chemical
- Manufacturer



Restriction on formaldehyde

- No person may manufacture, knowingly sell, offer for sale, or distribute a cosmetic product described in WAC 173-339-015(2) that contains intentionally added formaldehyde.
- Restriction took effect on Jan. 1, 2025.
- Notes
 - Established in RCW 70A.560.020.
 - Can't change in rule.

Restriction on formaldehyde releasers

- No person may manufacture, knowingly sell, offer for sale, or distribute a cosmetic product described in WAC 173-339-015(2) that contains the intentionally added formaldehyde releasers, including aliases of the chemical name or CAS RN, in the following table.
- Table includes 28 chemicals used in cosmetic products that release formaldehyde.

Compliance strategy

Ecology may infer from any of the following actions that a formaldehyde, a restricted formaldehyde releaser, or both were intentionally added by:

- Reviewing ingredients lists.
- Sampling for formaldehyde in cosmetic products.
- Considering other relevant information.

Compliance strategy (*cont.***)**

Manufacturers may rebut this inference by submitting a statement to Ecology that includes the following information.

- The name and address of the person submitting the statement.
- A statement that neither of the following were intentionally added.
 - Formaldehyde.
 - A chemical known to release formaldehyde.

Compliance strategy (cont.): example process

- Ecology tests regulated cosmetic products.
- Ecology detects formaldehyde in a regulated cosmetic product and notifies the manufacturer.
- Manufacturer may rebut the inference or work with Ecology to get to compliance.

Compliance schedules

- Restriction on formaldehyde releasers takes effect on Jan. 1, 2027.
- Definition of "intentionally added" takes effect on Jan. 1, 2027. Definition clarifies that formaldehyde is intentionally added when:
 - Formaldehyde is directly added to the cosmetic product.
 - A chemical selected to release formaldehyde to the product or ingredient over time is added to the cosmetic product.
- In-state retailers may exhaust existing stock until Jan. 1, 2028.



Statutory directive

- 1. Identify a list of formaldehyde releasers used in cosmetics consider:
 - Estimated prevalence of use
 - Potential to reduce disproportionate exposure.
 - Other relevant information.
- 2. Establish restrictions on formaldehyde releasers used in cosmetic products.



Formaldehyde releasers process





- 1. Compiled a list of 49 formaldehyde releasers.
 - Searched scientific literature and product databases.
 - Spoke with scientific experts and interested parties.



- 2. Narrowed our list to 28 formaldehyde releasers used in cosmetics.
 - Searched product databases.
 - Searched INCI database.



- **3. Prioritized our top ten formaldehyde releasers** and placed them as entries 1-10 in our list of 28 based on:
 - Prevalence of use.
 - Potential to reduce disproportionate exposure.

Prevalence of use



Table 1: List of formaldehyde releasers.

Item	Chemical name	Prevalence of use in U.S. products (%)
1	DMDM Hydantoin	43.59
2	Diazolidinyl Urea	32.27

Total number of cosmetic products in the US containing DMDM Hydantoin

Total number of cosmetic products in the US containing any formaldehyde releaser



% of cosmetic products in the US containing DMDM Hydantoin

Using Mintel's Global New Products Database

Potential to reduce disproportionate exposure

Products used more frequently by workers and women of color:

- Facial cleansers
- Hair straighteners and hair smoothers
- Intimate hygiene products
- Makeup
- Nail polish



Prioritized list





Chemical name	Prevalence in US products (%)	Used in products of concern
DMDMILL	A A	

99.0%

99.6%

Chemical name	Prevalence in US products (%)	Used in products of concern
DMDM Hydantoin	44	many
Diazolidinyl Urea	32	many
Imidazolidinyl Urea	14	many
Quaternium-15	3.6	many
Tosylamide/Formaldehyde Resin	2.2	one
2-Bromo-2-Nitropropane-1,3-Diol	1.8	many
Sodium Hydroxymethylglycinate	1.7	many
Polyoxymethylene Urea	0.4	some
Glyoxal	0.2	some
Polyoxymethylene Melamine	0.04	one





Draft implementation plan: purpose

This plan describes:

- How we intend to implement laws and rules related to reducing toxic chemicals in cosmetic products.
- Who may be affected by these laws and rules.
- How we intend to inform and engage interested parties.
- How we intend to support compliance with these laws and rules.



Draft implementation plan: structure

Part 1: Chapter 173-339 WAC: Cosmetic Products Restrictions

Focuses on the Formaldehyde in Cosmetics Rulemaking.

Part 2: Efforts to Reduce Toxic Chemicals in Cosmetic Products

Focuses on Ecology's many efforts (regulatory and voluntary) to reduce toxic chemicals in cosmetic products.



Draft implementation plan: highlights The HEALTH

- Formaldehyde in Cosmetics Rulemaking
- Other laws and rules related to reducing toxic chemicals in cosmetic products
- Supporting compliance
- Environmental Justice Assessment (HEAL Act)
- Informing and engaging
- Resources





- Suggest specific language.
- Use examples to illustrate concerns and explain feedback.
- Provide supplemental information.
- Offer solutions.

Your feedback helps us improve our efforts to reduce toxic chemicals in cosmetic products.



Questions and answers



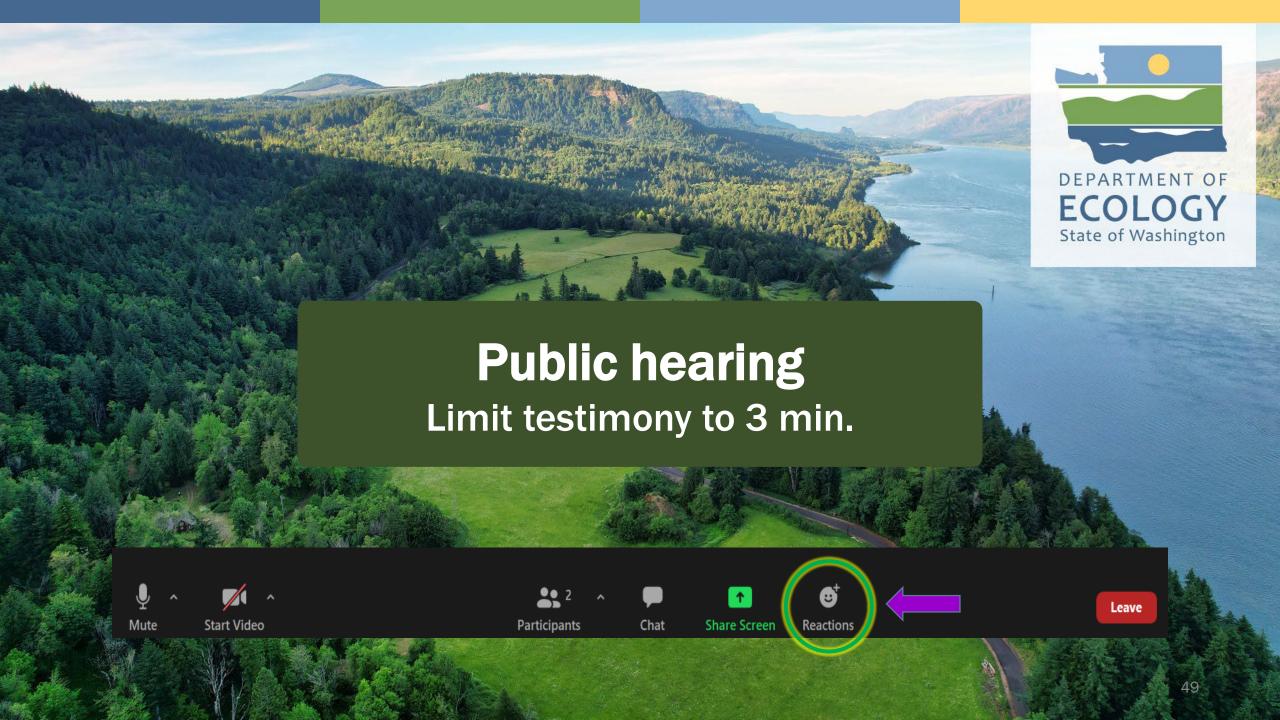


10 minute break





Public hearing







Comments due: April 11, 2025

Online

https://ecology.wa.gov/events/hwtr/tfca/formaldehyde-rule-public-comment

Email

ToxicFreeCosmetics@ecy.wa.gov

Mail

Stacey Callaway
WA Department of Ecology
P.O. Box 47600
Olympia, WA 98504-7600



Next steps





- Submit formal comments before April 11, 2025.
- We'll use the formal comments to create the final rule and finalize the supporting documents.
- Ecology's director will decide on rule adoption before September 1, 2025.





Email us at:

ToxicFreeCosmetics@ecy.wa.gov

Join our email list:

https://public.govdelivery.com/a ccounts/WAECY/signup/40162

Visit the TFCA webpage:

http://ecology.wa.gov/tfca

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Figure Description

• Slide 17: This slide shows the three milestones of the rulemaking process. We file the CR-101 form to announce the rulemaking, and this officially starts the rulemaking effort. This phase typically lasts one to two years and includes drafting the rule requirements, an informal comment period on the preliminary draft rule, a cost benefit analysis, and SEPA review. Then we file the CR-102 form and materials to propose the formal draft rule. This process lasts six months. During this time, we start the formal comment period (which typically lasts 30 – 45 days) and host formal hearings. If the Ecology director supports adopting the rule, then we file the CR-103 form and materials with the Code Reviser.