

WSR 25-05-003

PROPOSED RULES

DEPARTMENT OF ECOLOGY

[Order 24-01—Filed February 6, 2025, 7:53 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 24-11-148.

Title of Rule and Other Identifying Information: The Washington state department of ecology (ecology) proposes new chapter 173-339 WAC, Cosmetic products restrictions.

For more information on this rule making, visit <https://ecology.wa.gov/regulations-permits/laws-rules-rulemaking/rulemaking/wac-173-339>.

Hearing Location(s): On Monday, March 31, 2025, at 10:00 a.m. PDT, online hearing via Zoom. Register for the online hearing at <https://waecy-wa-gov.zoom.us/meeting/register/Gp62qlzTQgO6l0irK5RADg>; or to join via phone only, call 1-253-205-0468 and enter meeting ID 894 1263 4113. We're hosting this event online and will provide a presentation about the proposed rule, a question-and-answer session, and the formal hearing. You can attend this event from any device with internet access; and

On Tuesday, April 1, 2025, at 5:30 p.m. PDT, online hearing via Zoom. Register for the online hearing at <https://waecy-wa-gov.zoom.us/meeting/register/qebSZddERC6eka5tQfKStQ>; or to join via phone only, call 1-253-205-0468 and enter meeting ID 868 1327 1094. We're hosting this event online and will provide a presentation about the proposed rule, a question-and-answer session, and the formal hearing. You can attend this event from any device with internet access.

Date of Intended Adoption: August 1, 2025.

Submit Written Comments to: Stacey Callaway, Department of Ecology, Hazardous Waste and Toxics Reduction Program, P.O. Box 47600, Olympia, WA 98504-7600, email ToxicFreeCosmetics@ecy.wa.gov, online <https://ecology.wa.gov/events/hwtr/tfca/formaldehyde-rule-public-comment>, by 11:59 p.m. PDT on April 11, 2025. Information provided in a comment or attachment may be posted on the internet.

Assistance for Persons with Disabilities: Contact ecology ADA coordinator, phone 360-407-6831, Washington relay service or TTY call 711 or 877-833-6341, email ecyADAACoordinator@ecy.wa.gov, <https://ecology.wa.gov/accessibility>, by March 19, 2025.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The proposed rule:

- Identifies 28 chemicals used in cosmetic products that release formaldehyde, also called "formaldehyde releasers."
- Restricts formaldehyde and formaldehyde releasers intentionally added to cosmetic products.
- Defines the term "intentionally added" to clarify restrictions on toxic chemicals in the Toxic-Free Cosmetics Act (RCW 70A.560.020).

The restrictions in the proposed rule and in the Toxic-Free Cosmetics Act:

- Affect cosmetics manufacturers, distributors, retailers, and cosmetology businesses operating in Washington state.
- Apply to cosmetic products used in services, sold online, and sold in brick-and-mortar stores.

If adopted, the restrictions would take effect on January 1, 2027.

Formaldehyde releasers in the proposed rule:

Item	Chemical name	CAS RN
1	DMDM hydantoin	6440-58-0
2	Diazolidinyl urea	78491-02-8
3	Imidiazolidinyl urea	39236-46-9
4	Quaternium-15	4080-31-3; 51229-78-8
5	Tosylamide/formaldehyde resin (PTSAF)	25035-71-6
6	2-Bromo-2-Nitropropane-1,3-Diol (Bronopol)	52-51-7
7	Sodium hydroxymethyl-glycinate	70161-44-3
8	Polyoxymethylene urea	9011-05-6; 68611-64-3
9	Glyoxal	107-22-2
10	Polyoxymethylene melamine	9003-08-1
11	5-Bromo-5-Nitro-1,3-Dioxane (Bronidox)	30007-47-7
12	7-Ethylbicyclo-oxazolidine (Bioban CS1246)	7747-35-5
13	Benzylhemiformal	14548-60-8
14	Dimethylhydantoin formaldehyde (DMHF)	26811-08-5; 9065-13-8
15	Dimethylol glycol	3586-55-8
16	Dimethylol urea	140-95-4
17	Dimethyl oxazolidine	51200-87-4
18	Glyoxylic acid (when used in heat-activated hair straighteners)	298-12-4
19	Glyoxylol carbocysteine (when used in heat-activated hair straighteners)	1268868-51-4
20	MDM hydantoin	116-25-6; 27636-82-4; 16228-00-5
21	Methenamine	100-97-0
22	Methylal	109-87-5
23	Paraformaldehyde	30525-89-4
24	Polyoxymethylene	9002-81-7
25	Tetramethylol-glycoluril	5395-50-6
26	Timonacic (when used in heat-activated hair straighteners)	444-27-9
27	Tris (hydroxymethyl) nitromethane	126-11-4
28	Urea, polymer with formaldehyde, isobutylated	68002-18-6

Reasons Supporting Proposal: Cosmetic products such as makeup, perfume, shampoo, lotion, deodorant, shaving cream, and toothpaste can contain chemicals that are toxic to people and the environment. Some chemicals used in cosmetic products release formaldehyde, which exposes people to the chemical when they use the product. Formaldehyde can cause cancer, harm brain function, increase the risk of asthma, and irritate eyes and skin.

Statutory Authority for Adoption: Chapter 70A.560 RCW, Cosmetic products—Toxic chemical.

Statute Being Implemented: Chapter 70A.560 RCW, Cosmetic products—Toxic chemical.

Rule is not necessitated by federal law, federal or state court decision.

Agency Comments or Recommendations, if any, as to Statutory Language, Implementation, Enforcement, and Fiscal Matters: Ecology will extend an offer for government-to-government consultation with tribal governments during each phase of the rule making. Ecology will also

complete an environmental justice assessment in compliance with RCW 70A.02.06[0] as part of this rule making. For more information on this rule making, visit <https://ecology.wa.gov/regulations-permits/laws-rules-rulemaking/rulemaking/wac-173-339>. For more information on ecology's efforts to implement the Toxic-Free Cosmetics Act, visit <https://ecology.wa.gov/waste-toxics/reducing-toxic-chemicals/washingtons-toxics-in-products-laws/toxic-free-cosmetics-act>.

Name of Proponent: Department of ecology, governmental.

Name of Agency Personnel Responsible for Drafting: Stacey Callaway, Lacey, Washington, 360-584-5661; Implementation: Shari Franjevic, Shoreline, Washington, 360-338-2913; and Enforcement: Kimberly Grieves, Lacey, Washington, 360-522-2492.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Stacey Callaway, Department of Ecology, Hazardous Waste and Toxics Reduction Program, P.O. Box 47600, Olympia, WA 98504-7600, phone 360-584-5661, Washington relay service or TTY 711 or 877-833-6341, email ToxicFreeCosmetics@ecy.wa.gov.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(3) as the rule content is explicitly and specifically dictated by statute.

Scope of exemption for rule proposal:

Is partially exempt:

Explanation of partial exemptions: Ecology baselines are typically complex, consisting of multiple requirements fully or partially specified by existing rules, statutes, or federal laws. Where the proposed rule differs from this baseline of existing requirements, it is typically subject to (i.e., not exempt from) analysis required under the Regulatory Fairness Act (RFA), chapter 19.85 RCW, based on meeting criteria referenced in RCW 19.85.025(3) as defined by the Administrative Procedure Act in RCW 34.05.310. The small business economic impact statement (SBEIS) below includes a summary of the baseline for this rule making, and whether or how the proposed rule differs from the baseline.

The proposed rule does impose more-than-minor costs on businesses.

SBEIS

This SBEIS presents the:

- Compliance requirements of the proposed rule.
- Results of the analysis of relative compliance cost burden.
- Consideration of lost sales or revenue.
- Cost-mitigating action taken by ecology, if required.
- Small business and local government consultation.
- Industries likely impacted by the proposed rule.
- Expected net impact on jobs statewide.

A small business is defined by RFA as having 50 or fewer employees. Estimated costs are determined as compared to the existing regulatory environment, the regulations in the absence of the rule. The SBEIS only considers costs to "businesses in an industry" in Washing-

ton state. This means that impacts, for this document, are not evaluated for government agencies.

The existing regulatory environment is called the "baseline" in this document. It includes only existing laws and rules at federal and state levels.

This information is excerpted from ecology's complete set of regulatory analyses for this rule making. For complete discussion of the likely costs, benefits, minimum compliance burden, and relative burden on small businesses, see the associated regulatory analyses document (**ecology publication no. 25-04-009, January 2025**).

COMPLIANCE REQUIREMENTS OF THE PROPOSED RULE, INCLUDING PROFESSIONAL SERVICES:

Baseline: The baseline for our analyses generally consists of existing laws and rules. It allows us to make a consistent comparison between the state of the world with and without the proposed rule.

For this rule making, the baseline includes:

- Restrictions on chemicals in cosmetics under the Washington's Toxic-Free Cosmetics Act (chapter 70A.560 RCW);
- Restrictions on ortho-phthalates under the Washington's safer products restrictions and reporting rule (chapter 173-337 WAC);
- Federal cosmetic safety statutes and regulations, including:
 - o The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301-399).
 - o FDA Requirements for Specific Products (21 C.F.R. 700.11-35).
- Federal cosmetic labeling regulations (21 C.F.R. 701).

Proposed Rule:

- Identifies chemicals used in cosmetics that release formaldehyde;
- Establishes formaldehyde releaser restrictions and compliance schedule;
- Defines the term "intentionally added."

1. Identify chemicals used in cosmetics that release formaldehyde: Baseline: In addition to the chemicals and chemical classes restricted in the Toxic-Free Cosmetics Act, the statute also restricts chemicals determined by ecology to release formaldehyde. The statute does not list specific chemicals that release formaldehyde. Instead, RCW 70A.560.030 directs ecology to determine and adopt in rule a list of chemicals used in cosmetics that release formaldehyde.

Proposed: The proposed rule creates a list of chemical names and CAS numbers identified by ecology to release formaldehyde in cosmetics products, in accordance with RCW 70A.560.030.

Expected impact: Here we consider the list of formaldehyde-releasing chemicals in cosmetics separately from the restrictions on formaldehyde-releasing chemicals. Restrictions and the schedule for those restrictions are covered in section 2.3.2.

In isolation, we expect the list in the proposed rule to provide a benefit to potentially regulated entities by reducing compliance costs. The information contained in the list will reduce the costs for cosmetic ingredient suppliers, manufacturers, and retailers to identify chemicals that release formaldehyde in the cosmetics supply chain and choose alternatives. In addition, we expect the list in rule to reduce the costs of enforcement and to increase the timeliness of enforcement of the formaldehyde restriction. Most products that contain measurable formaldehyde list formaldehyde-releasing chemicals as product ingredients in compliance with federal cosmetic labeling requirements. Listing formaldehyde-releasing chemicals in rule enables ecolo-

gy to use an ingredients list as a resource to determine compliance. This reduces the cost of compliance and the time it takes ecology to identify noncompliant products. We expect this to increase compliance and benefit the public by removing noncompliant cosmetics from circulation more quickly, thereby reducing public exposure to formaldehyde.

2. Establish formaldehyde releaser restrictions and compliance

schedule: Baseline: The Washington Toxic-Free Cosmetics Act directs ecology to identify chemicals used in cosmetics that release formaldehyde and allows ecology to adopt restrictions on the identified chemicals. The statute specifies how soon the restrictions can take effect. In accordance with RCW 70A.560.030 (2)(b) and (c), restrictions on the first 10 chemicals cannot take effect before January 1, 2026, and restrictions on the remaining chemicals cannot take effect before January 1, 2027. Unlike the other chemicals restricted in RCW 70A.560.020, chemicals that release formaldehyde are not explicitly restricted in statute.

The baseline includes existing production practices, including the likely use of formaldehyde-releasing chemicals in the absence of the proposed rule. Based on data from Mintel Global New Products Database, a market intelligence database that catalogues products and information about those products, we find that formaldehyde-releasing chemicals are most prevalent in hair products, skin care products, and bath products, but this prevalence has declined substantially in the past ten years. Among products first recorded in Mintel in years 2014-2016, 20.9 percent of hair products, 18.4 percent of skin care products, and 12.1 percent of bath products contained an identified formaldehyde-releaser in their ingredient list. By 2021-2023, this rate had declined to 3.8 percent of hair products, 6.2 percent of skin care products, and 2.9 percent of bath products. This suggests that some cosmetic manufacturers may be voluntarily switching to alternative formulations that do not contain formaldehyde-releasing chemicals.

Proposed: Beginning on January 1, 2027, no person may manufacture, sell, offer for sale, or distribute a cosmetic product which contains an intentionally added formaldehyde releaser identified in WAC 173-339-110 (2)(b). In-state retailers may continue to sell existing stock until January 1, 2028.

Expected impact: The proposed rule establishes restrictions on intentionally added formaldehyde-releasing chemicals in cosmetic products and a date the restrictions take effect. For the purposes of analyzing the expected impact in this section, we consider a narrow baseline definition of intentionally added that includes any chemical added to a cosmetic product that has an intended function in that product. The term "intentionally added" is defined in the proposed rule, and we discuss the expected impact of the proposed definition in section 2.3.3. But this section only focuses on the compliance schedule for formaldehyde releasers in isolation and does not consider the definition of intentionally added.

The proposed rule restricts the manufacture of cosmetic products that contain formaldehyde releasers beginning on January 1, 2027. As a result, we expect cosmetic manufacturers who would otherwise include a formaldehyde-releasing chemical in their product to reformulate it before then. We expect this to increase health benefits to the general public, and to increase costs for cosmetic manufacturers and retailers.

We expect the proposed rule to provide a public health benefit to users of cosmetic products. Formaldehyde releasers are designed to re-

lease formaldehyde into the product over time. Small amounts of formaldehyde, especially from leave-on products such as lotions, can come into contact with skin, causing formaldehyde sensitization and contact dermatitis. Formaldehyde can also be released into the air and inhaled, especially indoors. There is evidence that inhaled formaldehyde can cause negative health impacts, including reproductive impacts, asthma, and cancers among others. A restriction on formaldehyde releasers in cosmetic products is expected to reduce these negative health impacts.

The proposed rule would place additional restrictions on manufacturers, generating higher costs. We expect these costs to be one-time costs associated with reformulating the product earlier than anticipated to replace the formaldehyde-releasing chemicals with alternatives. We expect any manufacturer who sells cosmetic products in the Washington market would either drop out of the market or reformulate their products before January 1, 2027, to comply with the proposed restrictions.

We expect the rule would cause a one-time cost for retailers that sell cosmetic products. They would be responsible for ensuring that none of their products include formaldehyde-releasing chemicals. This would include comparing the listed ingredients in their products to the list of known formaldehyde-releasing chemicals provided in the rule. Because we expect compliance among manufacturers, we do not expect retailers to need to take actions as a result of the proposed rule other than confirming that their store's products are in compliance.

Given that formaldehyde releasers are often used as preservatives, they have a role in maintaining product safety. Any new formulation would also be covered under the federal regulation, Modernization of Cosmetics Regulation Act of 2022 (MoCRA), which requires substantiation of product safety and a system for adverse event reporting for cosmetic products. A large and growing proportion of the market already uses preservative systems that do not include formaldehyde-releasing chemicals, which gives us confidence that cosmetic reformulations because of the rule can adequately maintain product safety.

While the rule would only directly impact cosmetics sold, distributed, or manufactured in Washington, personal communication with manufacturers suggests that at least some of them plan to change their formulations across the United States (U.S.) market rather than just for Washington. Manufacturers may incur lower costs through complete reformulation than if they stopped selling in Washington or created a separate supply line specifically for the state. However, the decision to remove formaldehyde releasers may not be based solely on cost considerations associated with the proposed rule. As we have noted, the use of formaldehyde releasers in cosmetic products has already declined over recent years. We assume the decision to remove formaldehyde releasers from cosmetic products is based not only on cost considerations, but also on other considerations, such as expectations that other states may enact similar laws or rules and the manufacturer's own goals of marketing the safest possible products to their customers.

Given these considerations, we present the direct benefits and costs for Washington residents and businesses as the main economic impact. For completeness, we also present the expected benefits and costs for the entire U.S. if the formaldehyde restrictions in the rule were to be adopted throughout the entire U.S. cosmetics market even

though the costs and benefits outside of Washington may not be necessarily attributable to the proposed rule.

3. Define the term "intentionally added": Baseline: The Toxic-Free Cosmetics Act restricts a person from manufacturing or selling cosmetic products that contain intentionally added chemicals and chemical classes beginning January 1, 2025: Ortho-phthalates; PFAS; formaldehyde (CAS 50-00-0) and chemicals determined by the department to release formaldehyde; methylene glycol (CAS 463-57-0); mercury and mercury compounds (CAS 7439-97-6); triclosan (CAS 3380-34-5); m-phenylenediamine and its salts (CAS 108-45-2); o-phenylenediamine and its salts (CAS 95-54-5); and lead or lead compounds.

The term "intentionally added" is not defined in the baseline Toxic-Free Cosmetics Act statute, nor is it defined explicitly or implicitly elsewhere in the baseline, creating uncertainty in how the statute may be implemented in the absence of a definition in rule. Some existing definitions of intentionally added may influence a manufacturer's choice of compliance strategy in the absence of a definition in the baseline. And any definition of intentionally added should meet the statutory intent, "to prohibit use of toxic chemicals found in cosmetic and personal care products and join other jurisdictions in creating a safer global standard for cosmetic products and bringing more sustainable, safer ingredients to the marketplace."

The FDA does not use the term "intentionally added" in regulating cosmetic products, though the baseline does include FDA rules concerning what ingredients are required to be listed on the product label. Labeling requirements exclude incidental ingredients, requiring only chemicals with a function in the final product to be listed. Incidental ingredients include anything that has a function in the raw material but not in the final product. For example, a fragrance may include a formaldehyde releaser as a preservative. After the fragrance is incorporated into a cosmetic formulation, the formaldehyde releaser would be considered an incidental ingredient in the final cosmetic formulation and would not be required to be listed as an ingredient in the final product even though it is still present and releasing formaldehyde.

Several states other than Washington have passed legislation designed to limit certain intentionally added chemicals in cosmetics and have defined the term "intentionally added ingredient" in the text of the legislation. In some state statutes, the definition of intentionally added excludes any chemical that would be considered an incidental ingredient by the FDA. California Assembly Bill 2762, which passed in 2020, bans many of the same cosmetic ingredients as the Washington Toxic-Free Cosmetics Act starting in January 2025. The definition of "ingredient" in the California statute explicitly excludes anything that would be considered an incidental ingredient under FDA labeling requirements. Maryland passed a similar bill with a similar definition of "ingredient" in 2021.

However, cosmetic restrictions in some states do extend to what the FDA would consider incidental ingredients. Oregon SB 546 signed into law in June 2023, bans the same chemical classes as the Washington Toxic-Free Cosmetic Act starting in January 2027. The bill defines an intentionally added ingredient as any ingredient that serves a function in the cosmetic product or component in the cosmetic product. The latter, an ingredient that serves a function in a component of the cosmetic product but not in the product itself, would be considered an incidental ingredient by the FDA. Act 131 in Vermont is similar legis-

lation that was signed into law in May 2024, and contains a similar definition of intentionally added.

The Washington safer products restrictions and reporting rule, chapter 173-337 WAC, restricts certain chemicals from select consumer products, including phthalates in cosmetic fragrances. It adopts virtually the same definition of an intentionally added chemical as the proposed rule, "a chemical that serves an intended function in the final product or in the manufacturing of the product or part of the product."

While any of the existing definitions of "intentionally added ingredient" with respect to cosmetics or Washington consumer products may inform the interpretation of the term in the absence of an explicit definition, none of the interpretations of intentionally added can be construed as clearly applying to the use of the term "intentionally added" within the Toxic-Free Cosmetics Act.

Without this definition, it is ambiguous as to how covered parties would comply with the statutory requirements. In the absence of an explicit definition, we expect that many businesses would have chosen to comply with a less restrictive definition of intentionally added, such as those that exclude incidental ingredients.

Proposed: The proposed rule defines the term "intentionally added" and applies that term to all the chemical classes in the Washington Toxic-Free Cosmetics Act beginning January 1, 2027.

The proposed definition of "intentionally added chemical" or "intentionally added" means a chemical that serves an intended function in the final product, the manufacturing of the product, or an ingredient in the final product. This definition would include chemicals that would be considered incidental by the FDA. This includes ingredients that the FDA would not require to be listed on the product's label, and would not be regulated by the California Toxic-Free Cosmetics Act.

Expected impact: The rule language defining "intentionally added" is intended to clarify the implementation of the Toxic-Free Cosmetics Act statute. In this respect, it provides benefits to regulated entities by providing greater regulatory certainty.

Under the baseline, we expect there may have been a variety of different interpretations of "intentionally added" by regulated entities. For the purposes of defining an expected impact and analyzing that impact in this section, we assume that, in the absence of a definition, regulated entities would generally not have interpreted ingredients that are considered incidental under FDA labeling requirements as qualifying as intentionally added under statute. The definition of "intentionally added" in the proposed rule makes compliance with statutory requirements explicit. We expect the definition would cause cosmetic manufacturers to change the ingredients they use or their manufacturing processes if they include chemicals that are listed in chapter 70A.560 RCW. We believe this would only impact cosmetics with ingredients that include formaldehyde releasers.

Methylene glycol, mercury and mercury compounds, m-phenylenediamine and its salts, and o-phenylenediamine and its salts have intended functions in the final product, which would be included in any reasonable definition of intentionally added. They are not thought to be present as incidental ingredients that would be covered by the proposed definition of intentionally added.

The Mintel consumer products database does not have a record of any cosmetic products that contain Triclosan currently on the U.S. market, and ecology believes it has been phased out of cosmetics products.

Ortho-phthalates have largely been phased out of cosmetic formulations, though they are still sometimes used as a fixative and solvent in fragrances. This use of ortho-phthalates is restricted in the baseline by chapter 173-337 WAC starting on January 1, 2025. Chapter 173-337 WAC uses the same definition of "intentionally added" as the proposed rule.

PFAS functions are generally not pertinent or useful within cosmetic ingredients, making the inclusion of PFAS in cosmetics intentionally added under any reasonable definition. Some studies have found detectable total fluorine in cosmetic products, suggesting the presence of PFAS, even when PFAS was not included in the label. PFAS are sometimes listed under trade names rather than under the chemical name, which may explain this discrepancy. It is possible that PFAS may also have a function in cosmetic ingredients or as a precursor or processing aid in the manufacturing process, which would be restricted under the definition of intentionally added proposed by the rule. Currently, we do not have evidence of this function in cosmetic manufacturing. PFAS may also be present in cosmetics as a contaminant from packaging or materials in the manufacturing process. However, this would not be considered intentionally added under the definition in the proposed rule.

Chemicals that release formaldehyde may serve a function within an ingredient of a cosmetic product, most often as a preservative and antimicrobial. The presence of the chemical in a cosmetic product due to its function in a product ingredient, but not in the final product itself, would be considered an incidental ingredient by the FDA. As an incidental ingredient, it would not be covered under some existing definitions of intentionally added. The proposed rule's definition of intentionally added would explicitly consider a formaldehyde releaser to be intentionally added if it was a component in a cosmetic ingredient. The definition of "intentionally added" in the proposed rule would restrict this use of formaldehyde and formaldehyde-releasing chemicals beginning on January 1, 2027.

We expect that this will create additional costs to comply with the rule for any manufacturers that need to change ingredient suppliers or purity grades to meet the requirements of the proposed rule. However, the start date of January 1, 2027, for this definition of "intentionally added" helps to offset much of the costs.

Each manufacturer would be expected to identify the cosmetic products that contain the restricted chemicals as an incidental ingredient. The costs of this should be minimal under federal MoCRA requirements that require adequate safety substantiation. Manufacturers would be expected to have access to information on all ingredients in their formulations, including the presence of any intentionally added chemicals. If a product is formulated with an ingredient that contains a restricted chemical, we expect some associated costs to identify an alternative supplier or product grade and to test the stability of the new ingredient in the formulation. In some cases, the product may need to be reformulated to maintain consistent product qualities.

We expect the benefits associated with the rule to be a reduction in formaldehyde exposure among the proportion of the public who uses cosmetic products or who is near enough to someone who uses the cosmetic product to inhale formaldehyde released by the cosmetic. The incidental formaldehyde releasers covered under this definition of intentionally added contribute a significantly lower amount of formaldehyde to cosmetic products on average than the amount covered under the restrictions described in section 2.3.2. However, exposure to small

amounts of formaldehyde is still expected to produce or worsen negative health effects, including sensitization and contact dermatitis, childhood asthma, and nasopharyngeal cancer, among others.

COSTS OF COMPLIANCE: EQUIPMENT AND SUPPLIES: Compliance with the proposed rule, compared to the baseline, is not likely to impose additional costs of equipment and supplies.

COSTS OF COMPLIANCE: LABOR: We expect Washington retailers to bear some cost associated with the rule. Retailers will have to coordinate with manufacturers and cosmetic brands to ensure that they do not include any of the identified formaldehyde-releasing ingredients in the cosmetic products sold by the retailer. We assume this can be handled mostly through standard contracts and by using databases of products and ingredients. Manufacturers are generally required to publish their ingredients list, which can then be compared to the list of chemicals published in the rule. We expect that existing resources can be used for this purpose with an additional cost of five to 10 hours of labor cost, on average, for each establishment that sells cosmetic products in Washington. We assume a cost of \$49.86 per hour for the business, which includes the median hourly wage rate for buyers and purchasing agents in Washington with an additional 30 percent expense for overhead. This cost is then discounted to mid-2027 to reflect compliance with the rule in the middle of the retailer stock sell-through period. According to the 2017 economic census, there are 2,448 retail sites with NAPCS codes associated with cosmetics sales in Washington that would be impacted by the rule. The estimated cost for retailers is between \$0.6 million and \$1.0 million.

We anticipate that manufacturers that include intentionally added formaldehyde releasers in their cosmetic products will reformulate those products before 2027 in order to comply with the proposed rule. Labor costs are a part of the overall reformulation costs, although ecology does not estimate labor costs specifically in the cost analysis. See "COSTS OF COMPLIANCE: OTHER" for additional detail.

COSTS OF COMPLIANCE: PROFESSIONAL SERVICES: We anticipate that manufacturers that include intentionally added formaldehyde releasers in their cosmetic products will reformulate those products before 2027 in order to comply with the proposed rule. Professional services are a part of the overall reformulation costs, although ecology does not estimate professional service costs specifically in the cost analysis. See "COSTS OF COMPLIANCE: OTHER" for additional detail.

COSTS OF COMPLIANCE: ADMINISTRATIVE COSTS: Where applicable, ecology estimates administrative costs (overhead) as part of the cost of labor and professional services, above.

COSTS OF COMPLIANCE: OTHER: We anticipate that manufacturers that include intentionally added formaldehyde releasers in their cosmetic products will reformulate those products before 2027 in order to comply with the proposed rule. Estimates of reformulation costs come from the FDA reformulation model for food and cosmetics, first developed in 2002 and revised in 2015. The model contains different ranges of estimated costs based on product complexity and the type of reformulation. Reformulations are broken out by product complexity, and we assume a low complexity given that formulations are generally shelf stable. Because formaldehyde-releasing chemicals often have a preservative or antimicrobial function in the product, the types of product reformulations that will occur as a result of this part of the rule are classified as a "substitution of a minor functional ingredient." After adjusting for changes in manufacturing cost using the producer price index, the FDA model provides mean expected costs of reformulation and ranges of ex-

pected costs of reformulation for small, medium, and large manufacturers. We use Dun and Bradstreet Market Insight data to estimate the number of cosmetic manufacturers at 44 large businesses, 609 medium, and 5,299 small businesses. Of these, 11 medium and 82 small manufacturers are located in Washington. See section 3.2.2 and table 1 in the preliminary regulatory analysis for additional details.

Using data from the Mintel Global New Products database, ecology estimates that 7.5 percent of cosmetic products currently on the market list an identified formaldehyde releaser as an ingredient in the cosmetic product. Under the rule, all of these would be reformulated before 2027. Because there has been a reduction in the use of formaldehyde releasers in recent years, we assume 27 percent of products that would be reformulated under the rule would also have been reformulated under the baseline. An additional 29 percent would be reformulated under the baseline after 2027. The cost to Washington cosmetic manufacturers is estimated to be \$4.6 million to \$10.0 million under the rule compared to the baseline. Scaling the rule impact to the entire U.S. cosmetic market, the cost to manufacturers would be an estimated \$334.9 million to \$639.9 million.

Ecology estimates that, under the rule's definition of "intentionally added," an additional five to 15 percent of cosmetic products include an intentionally added formaldehyde releaser despite not listing one among their ingredients. Under the rule, we assume manufacturers would identify alternative ingredients to comply with the proposed restriction before 2027. Additional stability testing or reformulation may also be required. The cost to Washington cosmetic manufacturers is estimated to be \$0.6 million to \$1.4 million. Scaling the rule impact to the entire U.S. cosmetic market, the cost to manufacturers would be an estimated \$40.5 million to \$88.8 million. See section 3.2.3 in the preliminary regulatory analysis for additional details.

COMPARISON OF COMPLIANCE COST FOR SMALL VERSUS LARGE BUSINESSES: We calculated the estimated per-business costs to comply with the proposed rule, based on the costs estimated in chapter 3 of this document. In this section, we estimate compliance costs per employee.

The average affected small business likely to be covered by the proposed rule employs about four people. The largest 10 percent of affected businesses employ an average of 3,771 people. However, businesses with as few as 17 employees are within the largest 10 percent of businesses. The cosmetic manufacturing industry has a few very large businesses and many relatively small businesses. Based on cost estimates in chapter 3, we estimated the following compliance costs per employee.

Table 1: Compliance Costs Per Employee

Employment or Cost	Small Businesses	Largest 10% of Businesses
Average employment	4	3,771
Compliance costs (low)	\$32,601	\$470,817
Compliance costs (high)	\$67,729	\$1,232,132
Cost per employee (low)	\$8,150	\$125
Cost per employee (high)	\$15,682	\$327

We conclude that the proposed rule is likely to have disproportionate impacts on small businesses, and therefore ecology must include elements in the proposed rule to mitigate this disproportion, as far as is legal and feasible.

MITIGATION OF DISPROPORTIONATE IMPACT: The RFA (RCW 19.85.030(2)) states that:

"Based upon the extent of disproportionate impact on small business identified in the statement prepared under RCW 19.85.040, the agency shall, where legal and feasible in meeting the stated objectives of the statutes upon which the rule is based, reduce the costs imposed by the rule on small businesses. The agency must consider, without limitation, each of the following methods of reducing the impact of the proposed rule on small businesses:

- (a) Reducing, modifying, or eliminating substantive regulatory requirements;
- (b) Simplifying, reducing, or eliminating recordkeeping and reporting requirements;
- (c) Reducing the frequency of inspections;
- (d) Delaying compliance timetables;
- (e) Reducing or modifying fine schedules for noncompliance; or
- (f) Any other mitigation techniques including those suggested by small businesses or small business advocates."

We considered all of the above options, the goals and objectives of the authorizing statutes (see chapter 6), and the scope of this rule making. We limited compliance cost-reduction methods to those that:

- Are legal and feasible.
- Meet the goals and objectives of the authorizing statute.
- Are within the scope of this rule making.

Modifying regulatory requirements, changing reporting requirements, reducing the frequency of inspections, and reducing the fine schedules for noncompliance would either not meet statutory requirements or would not be feasible in the proposed rule.

Reductions or modifications in the regulatory requirements would not have met the intents of chapter 70A.560 RCW, the purpose of which is to "ensure the safety of cosmetic products and protect Washington residents from toxic exposures." The rule does not include reporting requirements or inspections. The penalty for noncompliance is set in chapter 70A.560 RCW.

A delay in the compliance schedule in the proposed rule is designed to reduce costs to small businesses. The proposed rule delays the restriction on formaldehyde-releasing chemicals in cosmetics until January 1, 2027. It also delays the definition of "intentionally added" until January 1, 2027. This is a full year after the earliest date the restriction may be set under the statute. The primary reason for this delay is to allow small businesses more time to reformulate their cosmetic products and adjust production. Information from small businesses suggests they made need extra time in obtaining ingredients and other services, such as labeling, compared to larger manufacturers.

SMALL BUSINESS AND LOCAL GOVERNMENT CONSULTATION: We involved small businesses and local governments in the development of the proposed rule, using:

- Two rule-making webinars.
- Meetings with stakeholders, businesses, and local governments, including the organizations listed below.
 - o Seventeen small businesses or business trade groups, including product suppliers, cosmetic brands, cosmetologists, and ingredient tracking software companies.
 - o Eight nonprofit groups, including product safety, health, and product certification organizations.
 - o Three local governments or government associations.
 - o Three stakeholder or stakeholder groups.

- o Two professional organizations, representing cosmetologists and cosmetic chemists.
- Outreach at three community events.
- A presentation at a conference organized by the Independent Beauty Association, a trade association representing smaller businesses in the cosmetic supply chain.

NORTH AMERICAN INDUSTRY CLASSIFICATION SYSTEMS (NAICS) CODES OF INDUSTRIES IMPACTED BY THE PROPOSED RULE: The proposed rule likely impacts the following industries, with associated NAICS codes. NAICS definitions and industry hierarchies are discussed at <https://www.census.gov/naics/>.

- 325620 Toilet preparation manufacturing.
- 455XXX General merchandise retailers.
- 456120 Cosmetics, beauty supplies, and perfume retailers.

CONSIDERATION OF ECONOMIC OUTPUT AND IMPACT ON JOBS: We used the REMI E3+ model for Washington state to estimate the impact of the proposed rule on directly affected markets and direct market impacts, accounting for dynamic adjustments throughout the economy. The model accounts for variables including but not limited to: Interindustry impacts; price, wage, interstate and international trade, and population or labor market changes; and dynamic adjustment of all economic variables over time. Direct compliance costs were inputted in the following REMI categorized industries:

- Retail trade (excluding motor vehicle and parts dealers).
- Soap, cleaning compound, and toilet preparation manufacturing.

To partially account for economic impacts associated with childhood asthma, for each case of asthma avoided under the rule labor productivity is increased by 1.9 days of work evenly divided across all industries. There is also a reallocation of consumption from the pharmaceutical industry and physician services to other industries.

The results of the REMI E3+ model shows that the impact of the proposed rule will vary by industry (see table 2, below), costing the Washington economy an estimated \$9.4 million to \$17.4 million per year at the peak (total amount of goods and services produced by Washington businesses) across all sectors which is equivalent 0.002 percent of the state's gross domestic product.

Output losses are projected to be greatest in the years 2025 and 2026, the two years leading up to the rule implementation. This is caused by our assumption that manufacturers would reformulate prior to the formaldehyde releaser restriction that goes into effect in 2027. Peak loss occurs in 2026 at \$9.4 million and \$17.4 million per year in the low-cost and high-cost scenarios, respectively, which are almost 50 percent greater than the projected loss in 2025. After 2026, losses decline until the losses turn into small output gains around 2028, peaking between 2030 and 2031 before slowly approaching zero impact. These gains are caused by the rule changing the timing of cosmetic reformulations.

Table 2. Modeled Economic Output (\$ Millions)

Industry	2026 (Low)	2026 (High)	2030 (Low)	2030 (High)
Whole State	-9.4	-17.4	+2.1	+1.0
Construction	-2.2	-4.0	+0.8	+1.1
Toilet Preparation Manufacturing	-1.0	-3.3	+0.1	-0.8
Real Estate	-0.6	-1.5	+0.3	+0.2

Industry	2026 (Low)	2026 (High)	2030 (Low)	2030 (High)
Retail Trade	-0.7	-1.5	-0.2	-0.1
Wholesale Trade	-0.6	-0.9	+0.1	0.0

REMI results project a peak state-wide loss of 33 full-time equivalent positions (FTEs) under the low-cost scenario, and a loss of 60 FTEs under the high-cost scenario in the year 2026, which is over 40 percent greater than the loss in 2025. Losses decrease after 2027 until it becomes a small gain in 2028, peaking between 2030 and 2031 before slowly approaching a small consistent negative impact around 2035. Under the high-cost scenario, this is a projected state-wide job loss of less than 0.002 percent of state-wide FTEs at the peak loss in 2026.

Table 3. Modeled Impact on Jobs

Industry	2026 (Low)	2026 (High)	2030 (Low)	2030 (High)
Whole State	-33	-60	+7	+5
Construction	-10	-18	+4	+5
Retail Trade	-4	-7	0	0
Toilet Preparation Manufacturing	-2	-3	0	-1
Real Estate	-2	-2	0	0
Wholesale Trade	-1	-2	0	0

A copy of the statement may be obtained by contacting Stacey Callaway, Department of Ecology, Hazardous Waste and Toxics Reductions Program, P.O. Box 47600, Olympia, WA 98504-7600, phone 360-584-5661, Washington relay service or TTY 711 or 877-833-6341 (to request ADA accommodation for disabilities, or printed materials in a format for the visually impaired, call ecology at 360-407-7668 or visit <https://ecology.wa.gov/accessibility>), email ToxicFreeCosmetics@ecy.wa.gov. For more information on this rule making, visit <https://ecology.wa.gov/regulations-permits/laws-rules-rulemaking/rulemaking/wac-173-339>.

February 6, 2025
Heather R. Bartlett
Deputy Director

RDS-5886.6

**Chapter 173-339 WAC
COSMETIC PRODUCTS RESTRICTIONS**

PART A - GENERALNEW SECTION

WAC 173-339-010 Authority and purpose. (1) **Authority.** Chapter 70A.560 Revised Code of Washington (RCW) authorizes the Washington state department of ecology (ecology) to implement, administer, and enforce chapter 70A.560 RCW.

(2) **Purpose.** The goal of this chapter is to implement chapter 70A.560 RCW. This chapter ensures the safety of cosmetic products and protects Washington residents, particularly people with higher toxic exposures.

(a) This chapter implements chapter 70A.560 RCW by establishing:

(i) Definitions to supplement those in RCW 70A.560.010.

(ii) Ecology's determination of chemicals used in cosmetic products that release formaldehyde (formaldehyde releasers), which are additionally restricted in cosmetic products (RCW 70A.560.020 (1)(c) and 70A.560.030 (2)(b) and (c)).

(iii) Other generally applicable provisions pertaining to ecology's administration and enforcement of chapter 70A.560 RCW.

(b) This chapter implements chapter 70A.560 RCW by clarifying:

(i) The restrictions pertaining to cosmetic products that contain the chemicals or compounds specified in RCW 70A.560.020 (1)(a) through (h), and lead and lead compounds specified in RCW 70A.560.020(2).

(ii) How ecology will enforce the restriction on cosmetic products that contain intentionally added formaldehyde, which takes effect January 1, 2025.

NEW SECTION

WAC 173-339-015 Applicability. (1) This chapter applies to any person who manufactures, knowingly sells (including wholesale, online, or retail), offers for sale (including wholesale, online, or retail), or distributes (including distributing for sale and distributing for use) a cosmetic product in or into Washington state.

(2) Cosmetic products.

(a) This chapter applies to cosmetic products, regardless of whether or not the product contains drug ingredients regulated by the United States Food and Drug Administration (FDA).

(b) This chapter does **not** apply to:

(i) Cosmetic products excluded from chapter 70A.560 RCW.

(ii) Cosmetic products transported or stored in Washington state solely for sale or distribution to consumers outside of Washington state.

(iii) Drug ingredients regulated by the FDA.

(iv) Prescription drugs approved by the FDA.

(v) The recycling or disposal of existing stock.

NEW SECTION

WAC 173-339-020 Acronyms and definitions. Unless ecology determines the context requires otherwise, the following definitions apply for the purposes of this chapter.

"Alias" means a synonym for a chemical or chemical in a class listed in this chapter identified using a recognized authoritative source deemed appropriate by ecology.

"Chemical abstracts service registry number" or **"CAS RN"** means the number assigned to identify a particular chemical by the chemical abstracts service, a service of the American Chemical Society that indexes and compiles abstracts of worldwide chemical literature called *chemical abstracts*.

"Cosmetic product" has the same meaning as "cosmetic product" defined in RCW 70A.560.010 and "cosmetic" defined in RCW 69.04.011:

"The term "cosmetic" 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."

"Distributing" includes distributing for sale and distributing for use.

"Ecology" means the Washington state department of ecology.

"Existing stock" means cosmetic products possessed by an in-state retailer at the time a restriction takes effect.

"FDA" means the United States Food and Drug Administration.

"Formaldehyde" means formaldehyde (CAS RN 50-00-0).

"Intentionally added chemical" or **"intentionally added"** means a chemical that serves an intended function in:

- The final product.
- The manufacturing of the product.
- An ingredient in the final product.

This definition applies to the chemicals restricted in chapter 70A.560 RCW. This definition takes effect January 1, 2027.

"Manufacturer" has the same meaning as in RCW 70A.560.010:

"Manufacturer" 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."

"ppm" means parts per million.

"RCW" means Revised Code of Washington.

"Sell" or **"offering for sale"** includes wholesale, online, retail, and using in a service.

"WAC" means Washington Administrative Code.

NEW SECTION

WAC 173-339-025 Enforcement and penalties. (1) Any violation of chapter 70A.560 RCW or this chapter is subject to the enforcement and penalty sections of chapter 70A.560 RCW.

(2) In accordance with RCW 70A.560.030:

(a) A manufacturer that produces a product or imports or domestically distributes a product in or into Washington in violation of a requirement of chapter 70A.560 RCW or this chapter is subject to a

civil penalty **not** to exceed \$5,000 for each violation in the case of a first offense. Manufacturers who are repeat violators are subject to a civil penalty **not** to exceed \$10,000 for each repeat offense.

(b) A manufacturer may appeal any penalty provided for in this chapter to the pollution control hearings board.

(c) All penalties collected under this chapter shall be deposited in the model toxics control operating account created in RCW 70A.305.180.

NEW SECTION

WAC 173-339-030 Severability. If any provision of this chapter or its application to any person is held invalid, the remainder of this chapter or the application of the provision to other persons or circumstances is **not** affected.

NEW SECTION

WAC 173-339-035 Relation to other laws and rules. In addition to the requirements of this chapter and chapter 70A.560 RCW, other laws, rules, and ordinances may apply to cosmetic products containing restricted chemicals. Nothing in this chapter is intended to excuse persons regulated by this chapter from complying with other laws, rules, ordinances, procedures, restrictions, or limitations on regulated cosmetic products.

NEW SECTION

WAC 173-339-040 Confidential business information (CBI). A person who intends to submit information to ecology may request that ecology treat that information as confidential as provided in RCW 43.21A.160 by providing appropriate documentation supporting the request.

PART B - CHEMICALS IN COSMETIC PRODUCTS

NEW SECTION

WAC 173-339-110 Formaldehyde and formaldehyde releasers. (1) **Compliance schedule.**

(a) Formaldehyde.

(i) The restriction in subsection (2)(a) of this section takes effect January 1, 2025, in accordance with RCW 70A.560.020 (1)(c).

(ii) An in-state retailer in possession of cosmetic products on the date the restriction in subsection (2) (a) of this section takes effect may exhaust their existing stock through sales to the public until January 1, 2026, in accordance with RCW 70A.560.020(3).

(b) Formaldehyde releasers.

(i) The restriction in subsection (2) (b) of this section takes effect on January 1, 2027.

(ii) An in-state retailer in possession of cosmetic products on the date the restriction in subsection (2) (b) of this section takes effect may exhaust their existing stock through sales to the public until January 1, 2028.

(2) **Restriction.**

(a) Formaldehyde.

(i) 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, in accordance with RCW 70A.560.020 (1) (c).

(ii) Applying the definition of "intentionally added" in WAC 173-339-020 that takes effect on January 1, 2027:

Formaldehyde is intentionally added to a cosmetic product or ingredient when it functions as an antimicrobial, a preservative, a de-naturant, a cross linker, or serves another purpose. This includes the direct addition of formaldehyde, or the addition of a chemical selected to release formaldehyde, to the product or ingredient over time.

(b) 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 and aliases of the CAS RN, in the following table.

Table: Formaldehyde Releasers

Item	Chemical name	CAS RN
1	DMDM Hydantoin	6440-58-0
2	Diazolidinyl Urea	78491-02-8
3	Imidiazolidinyl Urea	39236-46-9
4	Quaternium-15	4080-31-3; 51229-78-8
5	Tosylamide/Formaldehyde Resin (PTSAF)	25035-71-6
6	2-Bromo-2-Nitropropane-1,3-Diol (Bronopol)	52-51-7
7	Sodium Hydroxymethyl-glycinate	70161-44-3
8	Polyoxymethylene Urea	9011-05-6; 68611-64-3
9	Glyoxal	107-22-2
10	Polyoxymethylene Melamine	9003-08-1
11	5-Bromo-5-Nitro-1,3-Dioxane (Bronidox)	30007-47-7
12	7-Ethylbicyclo-oxazolidine (Bioban CS1246)	7747-35-5
13	Benzylhemiformal	14548-60-8
14	Dimethylhydantoin formaldehyde (DMHF)	26811-08-5; 9065-13-8
15	Dimethylol Glycol	3586-55-8
16	Dimethylol Urea	140-95-4
17	Dimethyl Oxazolidine	51200-87-4
18	Glyoxylic Acid (when used in heat-activated hair straighteners)	298-12-4
19	Glyoxylol Carbocysteine (when used in heat-activated hair straighteners)	1268868-51-4

Item	Chemical name	CAS RN
20	MDM Hydantoin	116-25-6; 27636-82-4; 16228-00-5
21	Methenamine	100-97-0
22	Methylal	109-87-5
23	Paraformaldehyde	30525-89-4
24	Polyoxymethylene	9002-81-7
25	Tetramethylol-glycoluril	5395-50-6
26	Timonacic (when used in heat-activated hair straighteners)	444-27-9
27	Tris (hydroxymethyl) nitromethane	126-11-4
28	Urea, polymer with formaldehyde, isobutylated	68002-18-6

(c) Compliance.

(i) Ecology may infer from any of the following actions that a formaldehyde, a restricted formaldehyde releaser, or both were intentionally added.

(A) Reviewing ingredient lists.

(B) Sampling for formaldehyde in cosmetic products.

(C) Considering other relevant information.

(ii) Manufacturers may rebut this inference by submitting a statement to ecology that includes the following information.

(A) The name and address of the person submitting the statement.

(B) A statement that neither of the following were intentionally added to a cosmetic product or ingredient.

- Formaldehyde.

- A chemical known to release formaldehyde.

(C) Credible evidence supporting that statement. Include information, data, or sources relevant to substantiate that statement. Ecology determines what qualifies as "credible evidence" on a case-by-case basis.

(D) The following certification.

"I certify under penalty of perjury under the law of Washington that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry as the person or one of the persons who manage(s) the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete."