Preliminary Regulatory Analyses:

Including the:

- Preliminary Cost-Benefit Analysis
- Least-Burdensome Alternative Analysis
- Administrative Procedure Act Determinations
- Regulatory Fairness Act Compliance

Chapter 173-339 WAC

Cosmetic Products Restrictions

By

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For the

Hazardous Waste and Toxics Reduction Program

Washington State Department of Ecology

Olympia, Washington

February 2025, Publication 25-04-009

Publication Information

This document is available on the Department of Ecology's website at:
https://apps.ecology.wa.gov/publications/SummaryPages/2504009.html

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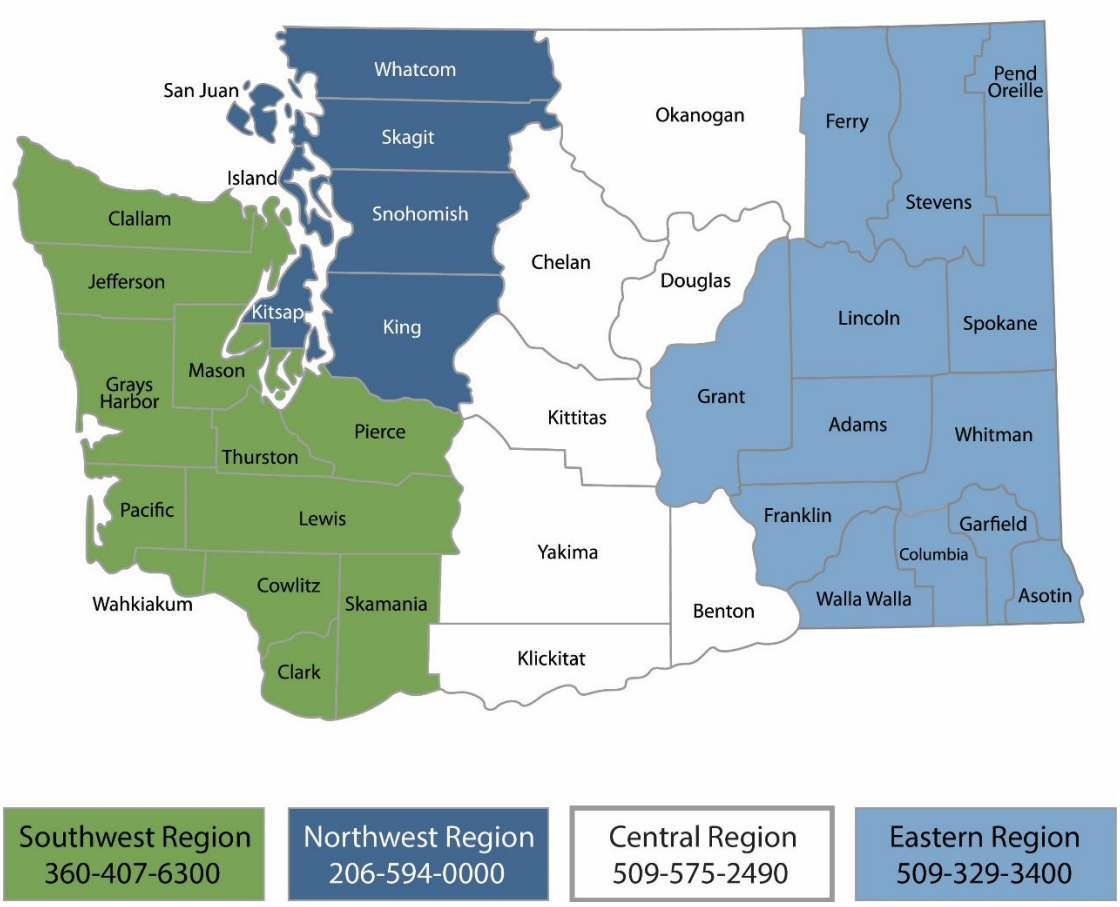

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Chapter 173-339 WAC, Cosmetic Products Restrictions

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DEPARTMENT OF
ECOLOGY
State of Washington

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Abbreviations and Acronyms

APA	Administrative Procedure Act
CAS	Chemical Abstract Service
CBA	Cost Benefit Analysis
CFR	Code of Federal Regulations
EPA	United States Environmental Protection Agency
FDA	United States Food and Drug Administration
FTE	Full-time equivalent
MoCRA	Modernization of Cosmetics Regulation Act
NAICS	North American Industry Classification System
NAPCS	North American Product Classification System
PFAS	Per- and polyfluoroalkyl substances
PPM	Parts per million
RCW	Revised Code of Washington
RFA	Regulatory Fairness Act
USC	United States Code
WAC	Washington Administrative Code

Executive Summary

Chapter 70A.560 RCW directs Ecology to identify formaldehyde-releasing chemicals and adopt restrictions on the identified formaldehyde releasers. The proposed rule will implement the statute by adopting a list of chemicals used in cosmetics that release formaldehyde, adopting restrictions on the listed formaldehyde releasers and a compliance schedule, and defining the term 'intentionally added.'

The proposed rule establishes a restriction on the manufacture and sales of cosmetic products that contain formaldehyde-releasing chemicals beginning on January 1, 2027. As a result, we expect manufacturers to reformulate any products that contain these chemicals prior to this date. While the rule would only directly impact cosmetics sold, distributed, or manufactured in Washington, it is possible that manufacturers whose products are distributed and sold outside of Washington may also choose to reformulate their products due to the proposed rule or other considerations such as similar future regulation in other states or product safety goals. We focus on cost-benefit impacts for Washington state but have also included estimates that extend the impacts of the rule to the entire United States to account for the broadest possible effect of the rule.

The underlying statute does not provide a definition of 'intentionally added' in reference to the chemicals it restricts. Without a definition, we can expect a variety of different interpretations of the term by regulated entities. We expect that manufacturers would generally not have considered an ingredient to be intentionally added under the statute if it falls under the FDA definition of 'incidental'. The definition of 'intentionally added' in the proposed rule would cause cosmetic manufacturers to change the ingredients they use or their manufacturing process if they include chemicals that are listed in Chapter 70A.560 RCW.

Chapter 3 estimates the costs associated with the proposed rule. The main drivers of costs are cosmetic reformulations. We anticipate that cosmetic products which include a formaldehyde releaser in the list of ingredients will be reformulated in order to comply with the proposed rule. In addition, we expect that some cosmetic products include components that do not appear on the list of ingredients and that would be restricted under the proposed definition of 'intentionally added'. These ingredients would need to be replaced, and the product may need to be reformulated. Estimates of reformulation costs come from the FDA reformulation model for food and cosmetics. Expected costs vary by size of the business as determined by total annual revenue as well as by the complexity of the reformulation.

The proposed rule is estimated to cost between **$6** and **$12 million** for manufacturers and retailers in the state of Washington. While our comparison of the costs and benefits of the rule focuses on Washington-specific impacts, if we extend estimated costs of cosmetic reformulations to manufacturers across the United States as a whole, the total cost would be between **$375** and **$729 million**. However, any reformulations outside of Washington will not necessarily be caused by the rule.

The benefits of the proposed rule are outlined in Chapter 4. The main benefit is improved public health for consumers of cosmetics and the public through reduced exposure to formaldehyde. We expect the public health impacts of the proposed rule would include:

- Reduction in skin sensitization and allergic dermatitis;
- Reduction in childhood asthma rates;
- Reduction in nasopharyngeal cancer rates;
- Reduction in myeloid leukemia and sinonasal cancer rates;
- Improved reproductive outcomes;
- Improved pulmonary function, including reduction in childhood and adult asthma severity and adult asthma incidence; and
- Reduction in acute sensory irritation.

We focus the quantitative economic impact estimates on the first three anticipated benefits related to formaldehyde exposure through personal cosmetic product use: reduction in skin sensitization and allergic dermatitis, reduction in childhood asthma incidence, and reduction in nasopharyngeal cancers. For the purposes of a quantitative economic analysis, these benefits are the most readily and precisely quantifiable at expected exposure levels. In addition to the benefits not quantified in this analysis, present value estimates of total quantified benefits of the proposed rule are between **$27** and **$51 million** for people in the state of Washington. While our comparison of the costs and benefits of the rule focuses on Washington-specific impacts, if we extend the estimated benefits to the population of the United States as a whole, the estimated benefit is between **$673** and **$1,367 million**, although much of this benefit would be attributable to cosmetic reformulations that may not be directly caused by the proposed rule.

Chapter 1: Background and Introduction

1.1 Introduction

This report presents the determinations made by the Washington State Department of Ecology as required under Chapters 34.05 RCW and 19.85 RCW, for the proposed Cosmetic Products Restrictions rule (Chapter 173-339 WAC; the "rule"). This includes the:

- Preliminary Cost-Benefit Analysis (CBA)
- Least-Burdensome Alternative Analysis (LBA)
- Administrative Procedure Act Determinations
- Regulatory Fairness Act Compliance

The Washington Administrative Procedure Act (APA; RCW 34.05.328(1)(d)) requires Ecology to evaluate significant legislative rules to "determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the law being implemented." Chapters 1 – 5 of this document describe that determination.

The APA also requires Ecology to "determine, after considering alternative versions of the rule…that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives" of the governing and authorizing statutes. Chapter 6 of this document describes that determination.

The APA also requires Ecology to make several other determinations (RCW 34.05.328(1)(a) – (c) and (f) – (h)) about the rule, including authorization, need, context, and coordination. Appendix A of this document provides the documentation for these determinations.

The Washington Regulatory Fairness Act (RFA; Chapter 19.85 RCW) requires Ecology to evaluate the relative impact of proposed rules that impose costs on businesses in an industry. It compares the relative compliance costs for small businesses to those of the largest businesses affected. Chapter 7 of this document documents that analysis, when applicable.

All determinations are based on the best available information at the time of publication. We encourage feedback (including specific data) that may improve the accuracy of this analysis.

1.1.1 Background

Steady exposure to chemicals contained in cosmetic products has the potential to harm the health of Washington residents. While color cosmetics, such as foundation, lipstick, and nail polish, are often thought of as synonymous with cosmetics, cosmetic products represent a wide array of products used daily by the vast majority of Washington residents. In addition to color cosmetics, lotions and other skin care products, shampoos and other hair care products, body washes and bath products, toothpaste and oral hygiene products, perfume and fragrances, deodorants, and shaving products are all considered cosmetic products. While exposure to

toxic chemicals from any single product and instance of use may be small, most individuals who use these products will use several of them on a consistent, daily basis. Any single exposure may have a negligible impact on an individual's health. However, small impacts can add up over time and at the population level. Frequent and pervasive exposures could carry health risks, particularly for cosmetologists and beauticians who are exposed to higher doses more frequently and with greater intensity due to the application method and types of products used.

Federal regulation of cosmetics takes place through the FDA, which has restricted a limited number of chemicals in cosmetics, and placed restrictions on products determined to be toxic. More recently, the FDA took additional steps to certify public safety under the Modernization of Cosmetics Regulation Act, passed in 2022, which sets new requirements for record keeping, facilities management, and ingredient disclosure, and requires the FDA to develop a report on PFAS in cosmetics.

In 2023, the Washington State Legislature passed the Toxic-Free Cosmetics Act, codified as Chapter 70A.560 RCW. This statute prohibits any person from manufacturing, selling, or distributing cosmetic products that contain more than 1 parts per million of lead, as well as the following intentionally added chemicals and chemical classes.

- Ortho-phthalates;
- Perfluoroalkyl and polyfluoroalkyl substances (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 (CAS 7439-92-1).

The Ecology legislative report, “Chemicals in Cosmetics Used by Washington Residents” outlines the health and environmental impacts of the chemicals and chemicals classes restricted by the statute.[3] Chemicals restricted by the Toxic-Free Cosmetics Act can cause endocrine disruption (ortho-phthalates), cancer (formaldehyde, methylene glycol, o-phenylenediamine, ortho-phthalates), developmental toxicity (mercury, PFAS), and aquatic toxicity (mercury, m-phenylenediamine, ortho-phthalates, o-phenylenediamine, triclosan), among others.

Beginning in 2025, California will also restrict the manufacture, distribution, and sale of cosmetics products that contain some of the same chemicals restricted in Washington, including quaternium-15 (which releases formaldehyde), mercury, o-phenylenediamine, PFAS, and select phthalates. Maryland, Oregon, and Vermont have passed bills to restrict similar chemical classes in cosmetics. The Modernization of Cosmetics Regulation Act (MoCRA)

[3] https://apps.ecology.wa.gov/publications/documents/2304007.pdf

requires the FDA to assess the safety of PFAS in cosmetics and publish a report by the end of 2025. The FDA also restricts mercury and triclosan in some cosmetic products.

1.2 Reasons for the proposed rule

While formaldehyde is explicitly restricted by Chapter 70A.560 RCW, many other chemicals (called “formaldehyde releasers”) release small amounts of formaldehyde slowly over time. The statute directs Ecology to identify formaldehyde-releasing chemicals and adopt restrictions on them. The main purpose of the proposed rule is to carry out this statutory direction.

The proposed rule also defines the term ‘intentionally added’ that will be applied to the restrictions in Chapter 70A.560 RCW. While Chapter 70A.560 RCW bans the manufacture, sale, and distribution of cosmetics in Washington if they include certain intentionally added chemicals, the statute does not define the term ‘intentionally added’. This definition is key to Ecology’s goal of implementing the statute using their rulemaking authority.

1.2 Summary of the proposed rule

The proposed rule would:

- Identify chemicals used in cosmetics that release formaldehyde;
- Establish formaldehyde releaser restrictions and compliance schedule; and
- Define “intentionally added.”

1.3 Document organization

The chapters of this document are organized as follows:

- **Chapter 2 - Baseline and the proposed rule:** Description and comparison of the baseline (what would occur in the absence of the proposed rule) and the proposed rule requirements.
- **Chapter 3 - Likely costs of the proposed rule:** Analysis of the types and sizes of costs we expect impacted entities to incur as a result of the proposed rule.
- **Chapter 4 - Likely benefits of the proposed rule:** Analysis of the types and sizes of benefits we expect to result from the proposed rule.
- **Chapter 5 - Cost-benefit comparison and conclusions:** Discussion of the complete implications of the CBA.
- **Chapter 6 - Least-Burdensome Alternative Analysis:** Analysis of considered alternatives to the contents of the proposed rule.
- **Chapter 7 - Regulatory Fairness Act Compliance:** When applicable. Comparison of compliance costs for small and large businesses; mitigation; impact on jobs.
- **Appendix A - APA Determinations:** RCW 34.05.328 determinations not discussed in chapters 5 and 6.

Chapter 2: Baseline and Proposed Rule

2.1 Introduction

We analyzed the impacts of the proposed rule within the context of all existing federal and state laws and rules. This context for comparison is called the baseline; it reflects the most likely regulatory circumstances that entities would face if Ecology does not adopt the proposed rule.

2.2 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 rulemaking, the baseline includes:

- Washington's Toxic-Free Cosmetics Act (Chapter 70A.560 RCW);
- Washington's Safer Products Restrictions and Reporting rule (Chapter 173-337 WAC);
- Federal Cosmetic Safety Statutes and Regulations, including:
    - The Federal Food, Drug, and Cosmetic Act (21 USC 301-399)
    - FDA Requirements for Specific Products (21 CFR 700.11-35)
- Federal Cosmetic Labeling Regulations (21 CFR 701)

2.2.1 Washington's Toxics-Free Cosmetics Act

The main purpose of Washington's Toxic-Free Cosmetics Act (Chapter 70A.560 RCW), is to ensure the safety of cosmetic products and to protect Washington residents from toxic exposure. The definition of 'cosmetic' in the statute is broad and is the same definition of 'cosmetic' as used in Chapter 69.04 RCW, namely,

> "(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."

RCW 70A.560.020 restricts the manufacture, distribution, and sale of cosmetic products that contain certain intentionally added chemicals or chemicals classes as of January 1, 2025. The statute also allows in-state retailers to exhaust their existing stock through sales to the public until January 1, 2026. The statute restricts the following intentionally added chemicals and chemical classes in cosmetics:

- 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.

RCW 70A.560.030 grants Ecology rulemaking authority to "adopt rules as necessary for the purpose of implementing, administering, and enforcing this chapter." It also requires Ecology to adopt by rule a list of chemicals used in cosmetics that release formaldehyde, taking into consideration estimated prevalence of use, potential to reduce disproportionate exposure, and other criteria as determined by Ecology. The statute specifies when the restrictions on the identified formaldehyde releasers may take effect:

> "(b) The department may identify for restriction an initial set of no more than 10 of the listed chemicals used in cosmetics that release formaldehyde. This restriction must take effect on or after January 1, 2026.
>
> (c) Restrictions on the remaining listed chemicals used in cosmetics that release formaldehyde may take effect on or after January 1, 2027."

2.2.2 Washington's Safer Products Restrictions and Reporting Rule

Washington's Safer Products Restrictions and Reporting rule (Chapter 173-337 WAC) also restricts intentionally added chemicals in cosmetic products. WAC 173-337-111(1) restricts intentionally added ortho-phthalates in fragrances in beauty products and personal care products starting on January 1, 2025.

From WAC 173-337-111(1):

Ortho-phthalates.

(1) **Fragrances in beauty products and personal care products.**

(a) **Applicability.**

(i) Priority consumer products. This subsection applies to:

(A) Fragrances sold separately, such as perfumes and colognes.

(B) Fragrances used in beauty products, regardless of whether the item contains drug ingredients regulated by the FDA.

(C) Fragrances used in personal care products, regardless of whether the item contains drug ingredients regulated by the FDA.

(ii) This subsection does **not** apply to:

(A) Ortho-phthalates used in beauty products or personal care products for purposes other than as a solvent or fixative for fragrances.

(B) Active ingredients in products regulated by the FDA as drugs.

(C) Consumer products regulated by the FDA as medical devices.

(b) **Compliance schedule.** The restriction in (c) of this subsection takes effect on January 1, 2025.

(c) **Restriction.**

(i) No person may manufacture, sell, or distribute a priority consumer product described in (a) of this subsection that contains an intentionally added ortho-phthalate used as a solvent or fixative for fragrance ingredients.

This does **not** apply to a priority consumer product described in (a) of this subsection manufactured before January 1, 2025.

Chapter 173-337 WAC defines "intentionally added" as **"**a chemical that serves an intended function in the final product or in the manufacturing of the product or part of the product. Chemicals present from the use of recycled materials are **not** considered 'intentionally added priority chemicals.'"

2.2.4 Federal Cosmetic Safety Statutes and Regulations

The Federal Food, Drug, and Cosmetic Act grants the FDA authority to oversee the safety of cosmetic products manufactured or distributed in the United States. Federal regulations require cosmetic products to be safe. However, except for color additives, cosmetic products and ingredients do not need to have FDA approval before they go on the market. The FDA considers a cosmetic product to be safe if it meets the requirements of 21 USC 364d.(c)

"**(1) Adequate substantiation of safety**

The term 'adequate substantiation of safety' means tests or studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe.

(2) Safe

The term "safe" means that the cosmetic product, including any ingredient thereof, is not injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual. The Secretary shall not consider a cosmetic ingredient or cosmetic product injurious to users solely because it can cause minor and transient reactions or minor and transient skin irritations in some users. In determining for purposes of this section whether a cosmetic product is safe, the Secretary may consider, as appropriate and available, the cumulative or other relevant exposure to the cosmetic product, including any ingredient thereof."

The presence of certain chemicals in cosmetic products listed in 21 CFR 700 causes the cosmetic to be considered "adulterated" and, therefore, prohibited from manufacture or sale under 21 USC 331. Mercury and mercury compounds are the only chemical class restricted by the Toxic-Free Cosmetic Act that is already restricted by the FDA. 21 CFR 700 allows mercury in eye makeup in concentrations of up to 65 ppm due to its effectiveness in preventing *Pseudomonas* contamination, which can cause potentially serious bacterial eye infections. However, it restricts the use of mercury as a skin-bleaching agent or preservative, allowing concentrations of less than 1 ppm.

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) requires cosmetic manufacturers and processors to register their facilities, products, and product ingredients with the FDA by July 2024. In addition, MoCRA makes regulatory changes to ensure product safety, including establishing an adverse events reporting system and increasing requirements for safety substantiation.

Under MoCRA the FDA has established draft guidelines for good manufacturing practice. Among them:

> "You should determine whether raw materials are identified, stored, examined, tested, inventoried, handled, and controlled to ensure they conform to appropriate standards and specifications. In particular, raw materials should be:
>
> - Stored and handled to prevent mistakes (i.e., mix-ups or selection errors), contamination with microorganisms or other chemicals, and degradation from exposure to excessive environmental conditions (e.g., heat, cold, sunlight, moisture, etc.);
> - Held in closed containers and stored off the floor;
> - Maintained in containers that are labeled with the identity, lot number, and control status (release or quarantine);
> - Sampled and tested for conformance with specifications and to ensure the absence of filth, microorganisms, and other adulterants prior to processing or usage (Animal and vegetable origin materials and those produced by cold processing methods should be reviewed for filth and/or microorganism contamination.); and
> - Properly identified and controlled to prevent the use of materials that fail to meet acceptance specifications."[4]

[4] Guidance for Industry: Cosmetic Good Manufacturing Practices Draft Guidance: https://www.fda.gov/media/86366/download?attachment

2.2.5 Federal Cosmetic Labeling Regulations

The FDA requires ingredients in the cosmetic product to be listed on the package label. 21 CFR 701.3(a) specifies:

> "The label on each package of a cosmetic shall bear a declaration of the name of each ingredient in descending order of predominance, except that fragrance or flavor may be listed as fragrance or flavor. An ingredient which is both fragrance and flavor shall be designated by each of the functions it performs unless such ingredient is identified by name. No ingredient may be designated as fragrance or flavor unless it is within the meaning of such term as commonly understood by consumers."

The FDA does not require manufacturers to list incidental ingredients on the label. 21 CFR 701.3(l) defines incidental ingredients:

> "(l) The provisions of this section do not require the declaration of incidental ingredients that are present in a cosmetic at insignificant levels and that have no technical or functional effect in the cosmetic. For the purpose of this paragraph, incidental ingredients are:
>
> (1) Substances that have no technical or functional effect in the cosmetic but are present by reason of having been incorporated into the cosmetic as an ingredient of another cosmetic ingredient.
>
> (2) Processing aids, which are as follows:
>
> (i) Substances that are added to a cosmetic during the processing of such cosmetic but are removed from the cosmetic in accordance with good manufacturing practices before it is packaged in its finished form.
>
> (ii) Substances that are added to a cosmetic during processing for their technical or functional effect in the processing, are converted to substances the same as constituents of declared ingredients, and do not significantly increase the concentration of those constituents.
>
> (iii) Substances that are added to a cosmetic during the processing of such cosmetic for their technical and functional effect in the processing but are present in the finished cosmetic at insignificant levels and do not have any technical or functional effect in that cosmetic."

2.3 Proposed rule

The proposed rule:

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

2.3.1 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 Ecology 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.

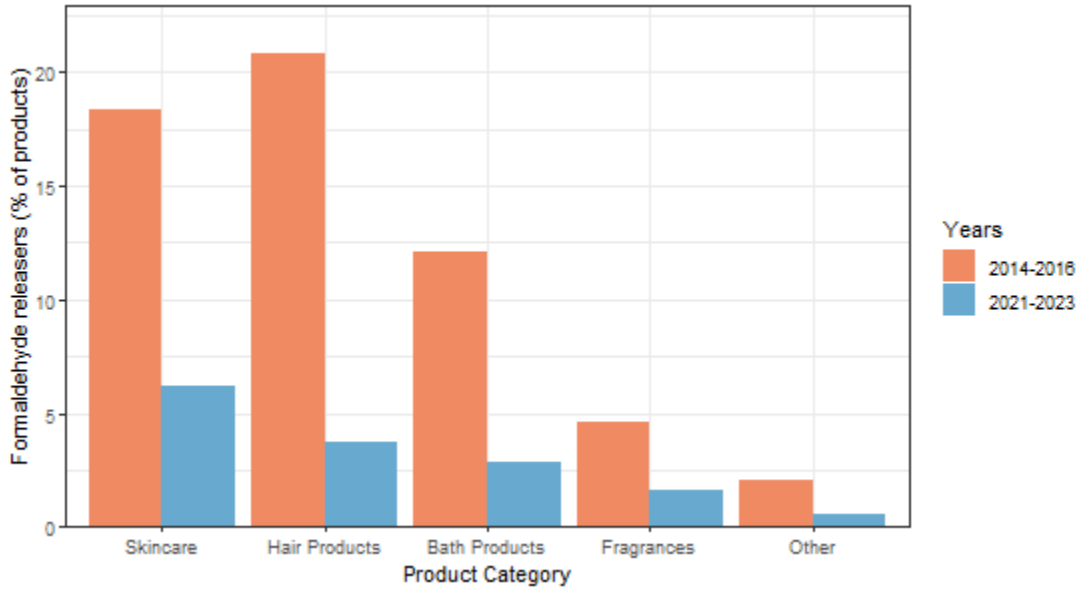
2.3.2 Establish formaldehyde releaser restrictions and compliance schedule

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 ten 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% of hair products, 18.4% of skin care products, and 12.1% of bath products contained an identified formaldehyde releaser in their ingredient list. By 2021-2023, this rate had declined to 3.8% of hair products, 6.2% of skin care products, and 2.9% of bath products. This suggests that some cosmetic manufacturers may be voluntarily switching to alternative formulations that do not contain formaldehyde-releasing chemicals.

Figure 1. Proportion of products with formaldehyde releasers on the ingredient label.



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 releases 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 release 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 includes 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, 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.

Potential for expanded impacts

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 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.

2.3.3 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.[5] The definition of 'ingredient' in the California statute explicitly excludes anything that would be considered an incidental ingredient under FDA labeling requirements.[6] Maryland passed a similar bill with a similar definition of 'ingredient' in 2021.[7]

However, cosmetic restrictions in some states do extend to what the FDA would consider incidental ingredients. Oregon Senate Bill 546 signed into law in June 2023, bans the same chemicals 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.[8] 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 legislation that was signed into law in May 2024, and contains a similar definition of intentionally added.[9]

Other restrictions on chemicals in cosmetics set a specific limit regardless of whether the chemical is an incidental ingredient. Many chemicals restricted by the FDA under 21 CFR 700 are prohibited regardless of how the ingredient came to be present in the final cosmetic product. FDA guidance recommends a lead limit of 10 ppm,[10] and the European Union requires a formaldehyde warning if the total amount of free formaldehyde in the final product exceeds 10 ppm.[11]

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

[5] https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200AB2762
[6] https://california.public.law/codes/ca_health_and_safety_code_section_111791.5
[7] https://mgaleg.maryland.gov/2021RS/bills/hb/hb0643T.pdf
[8] https://olis.oregonlegislature.gov/liz/2023R1/Downloads/MeasureDocument/SB546/Enrolled
[9] https://legislature.vermont.gov/Documents/2024/Docs/ACTS/ACT131/ACT131%20As%20Enacted.pdf
[10] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-lead-cosmetic-lip-products-and-externally-applied-cosmetics-recommended
[11] Commission Regulation (EU): https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32022R1181

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.
- 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. Drawing from examples in the FDA Cosmetic Labeling guide,[12] the proposed definition of intentionally added would include the following incidental ingredients:

- A substance added to a cosmetic during manufacture for its technical effect in processing and that is still present in the final product at a measurable level, but does not have any technical or functional effect in that cosmetic.
- A substance added to a cosmetic as a component of a cosmetic ingredient and having no technical or functional effect in the finished cosmetic. Example: Preservative of a raw material added to a cosmetic as an ingredient at a concentration which reduces the preservative to a level at which it is no longer effective.

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

[12] Food and Drug Administration: Cosmetic Labeling Guide: https://www.fda.gov/media/88234/download. Retrieved 2024-09-03.

'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 apply the expected impact of the definition of intentionally added to each chemical in the statute in turn.

Ortho-phthalates

Ortho-phthalates have largely been phased out of cosmetic formulations, though there is still sometimes used as a fixative and solvent in fragrances.[13] 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.

The proposed rule is not expected to have any impact on ortho-phthalates in cosmetics.

PFAS

PFASs are commonly utilized as emulsion stabilizers, bulking agents, and for their ability to repel oil and water, enabling the product to be more durable and resistant against weathering. They may also serve as skin conditioners or toners, allowing the skin to look brighter and in hair conditioning products as an accelerant for hair dyes. These 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.[14] PFAS are sometimes listed under trade names rather than under the chemical name, which may explain this discrepancy.[15] 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.

The proposed rule is not expected to have any impact on PFAS in cosmetics.

Formaldehyde and chemicals determined by the department to release formaldehyde

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,

[13] https://www.fda.gov/cosmetics/cosmetic-ingredients/phthalates-cosmetics
[14] Schultes, et al. (2018); Whitehead, et al. (2021)
[15] Whitehead, et al. (2021)

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 in order 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.

Methylene Glycol

In cosmetics, methylene glycol is most often used in hair-straightening formulas. It has an intended function in the final product, which would be included in any reasonable definition of intentionally added. It is not thought to be present as an incidental ingredient that would be covered by the proposed definition of intentionally added.

The proposed rule is not expected to have any impact on methylene glycol in cosmetics.

Mercury and Mercury Compounds

Under the baseline, mercury is allowed only in eye makeup in concentrations up to 65 ppm due to its effectiveness in preventing *Pseudomonas* contamination, which can cause potentially serious bacterial eye infection. It has an intended function in the final product, which would be included in any reasonable definition of intentionally added. It is not thought to be present as

an incidental ingredient that would be covered by the proposed definition of intentionally added.

The proposed rule is not expected to have any impact on mercury in cosmetics.

Triclosan

Triclosan has been used to prevent antibacterial contamination in some cosmetic products. Under the baseline it is not considered to be generally recognized as safe by the FDA in antiseptic washes.[16] The Mintel consumer products database does not have a record of any cosmetic products that contain Triclosan currently on the U.S. market. We expect that it has generally been removed from cosmetic products and their components.

The proposed rule is not expected to have any impact on triclosan in cosmetics.

m-phenylenediamine and its salts

m-phenylenediamine is generally used as a component in hair dyes. It has an intended function in the final product, which would be included in any reasonable definition of intentionally added. It is not thought to be present as an incidental ingredient that would be covered by the proposed definition of intentionally added.

The proposed rule is not expected to have any impact on m-phenylenediamine in cosmetics.

o-phenylenediamine and its salts

o-phenylenediamine is generally used as a component in hair dyes. It has an intended function in the final product, which would be included in any reasonable definition of intentionally added. It is not thought to be present as an incidental ingredient that would be covered by the proposed definition of intentionally added.

The proposed rule is not expected to have any impact on o-phenylenediamine in cosmetics.

[16] 21 CFR Part 310

Chapter 3: Likely Costs of the Proposed Rule

3.1 Introduction

We analyzed the likely costs associated with the proposed rule, as compared to the baseline. The proposed rule and the baseline are discussed in detail in Chapter 2 of this document.

We expect that cosmetic manufacturers in Washington will experience an increase in costs due to the rule as they will no longer be able to manufacture cosmetics that include formaldehyde-releasing ingredients in the state as of January 1, 2027.

Ecology estimates costs of rulemakings using a twenty-year time horizon. Industry costs in the future are discounted to the present value using a real annual discount rate of 5.3%. This means that a cost that occurs in one year will be worth 5.3% more than if it had occurred in the following year. This discount rate is determined by taking the EPA estimates of the corporate discount rate used in the economic benefit of non-compliance model[17] over the past 18 years, 7.9%, and subtracting the producer price index for manufacturing[18] over the same time period, 2.6%, to get a real corporate discount rate after adjusting for inflation.

Potential for expanded impacts

Manufacturers of products distributed and sold in other states may also choose to remove formaldehyde releasers from their products. This may be caused by the rule, which will restrict sales in Washington of any cosmetic product that contains formaldehyde-releasing chemicals in 2027. It may also be attributable to other considerations such as existing or anticipated laws and rules in other states, or commitments to product safety. We focus on expected rule costs for Washington state but have also included estimates that extend the costs of the rule to the entire United States to account for the broadest possible effect of the rule.

3.2 Cost analysis

The proposed rule would:

- Identify chemicals used in cosmetics that release formaldehyde.
- Establish formaldehyde releaser restrictions and compliance schedule.
- Define “intentionally added.”

3.2.1 Identify chemicals used in cosmetics that release formaldehyde

The identification of chemicals used in cosmetics that release formaldehyde in isolation from a compliance schedule is not expected to have any costs associated with it.

[17] We choose 18 years because this is the maximum allowable in the model. BEN 2024.0.0. https://www.epa.gov/enforcement/penalty-and-financial-models

[18] https://fred.stlouisfed.org/series/PCUOMFGOMFG

3.2.2 Establish formaldehyde releaser restrictions and compliance schedule

In conjunction with the list of identified chemicals that release formaldehyde in cosmetic products, we expect that manufacturers and retailers will bear costs associated with this aspect of the rule. We outline the anticipated manufacturer and retailer responses and estimate the associated costs in this section.

In addition to the costs we quantify in this section, there may be some additional costs associated with reduced consumer satisfaction. Formaldehyde releasers serve an important function in some cosmetic products. It is possible that an alternative formulation without formaldehyde releasers may not have the qualities that a consumer expects from the product. Given the observed reduction in the use of formaldehyde releasers in new cosmetic products, we expect this loss of consumer satisfaction is likely to be minimal, but it remains a possibility.

Manufacturer Response

We anticipate that cosmetic products which include an identified formaldehyde releaser with a function in the product will be reformulated before 2027 in order to comply with this aspect of the proposed rule. An alternative way that manufacturers could comply with this part of the rule is to cease production on formulations that would be restricted under the proposed rule. Given that businesses are expected to choose the compliance strategy that produces the greatest net revenues, we believe that removing, rather than reformulating, the product would only occur if the anticipated net revenues from the product would be less than the reformulation costs. In that case, the anticipated reformulation cost would be lower than the loss of market share among affected products. Reformulation costs can serve as an upper bound on the anticipated costs for manufacturers for this aspect of the rule. In conversations with industry, we believe it is also the compliance strategy that will generally be chosen. For that reason, our analysis of costs assumes that all affected products will be reformulated rather than removed from the market.

Reformulation Costs

Estimates of reformulation costs come from the FDA reformulation model for food and cosmetics, first developed in 2002[19] and revised in 2015.[20] While the 2015 version of the model is specifically updated to reflect food reformulations, the initial model is applicable to both food and cosmetic formulations. 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

[19] White, et al. (2002)
[20] Muth, et al. (2015)

changes in manufacturing cost using the producer price index, the FDA model provides mean expected costs of reformulation and ranges of expected costs of reformulation.

Reformulation costs vary by size of the business as determined by total annual revenue. We use the share of formulations in the market for each business size category implied by the 2015 version of the FDA model. Without data to consistently link cosmetic products to a particular manufacturer, we assume any reformulations that occur due to the proposed rule would be done by a business belonging to each size category in relative proportion to the number of that category's formulations on the market – e.g., 29% of formulations on the market are manufactured by small businesses, so we assume any given reformulation has a 29% probability of being done by a small business.

Data on the size and location of cosmetic manufacturers are obtained through Dun and Bradstreet Market Insight data. We limit the data to business sites with the NAICS code 325620, which comprises businesses that prepare, blend, compound, and package perfumes, shaving products, hair products, face creams, lotions, and other cosmetic preparations. We identify 5,952 businesses in the United States, of which 44 are large, 609 medium, and 5,299 small under the FDA reformulation model size definitions. Within Washington, there are 11 medium and 82 small businesses, and no large businesses.

Table 1. Mean reformulation costs by business size

Business Size	Annual Revenue per business	Mean reformulation cost	Range of reformulation costs	Share of formulations
Small	<$1.3 million	$23,892	$12,556-41,275	29%
Medium	$1.3-$651 million	$297,601	$137,915-544,395	65%
Large	>$651 million	$710,630	$331,813-1,282,757	6%

Reformulation Schedule

We estimate the proportion of products on the market that contain an identified formaldehyde-releaser using the previous ten years of product releases recorded in the Mintel database. This estimate is derived from two sources. First, the 2002 FDA reformulation cost model suggests that under normal business operations, a cosmetic product will be reformulated roughly every ten years.[21] Second, the FDA model estimates each formulation on the market is associated with $1.55 million in annual sales on average. The previous ten years of products on the Mintel database also gives an average of $1.55 million in annual sales per formulation after adjusting for inflation and changes in the size of the U.S. cosmetic market.

In more recent years, the use of formaldehyde-releasing chemicals in new products has decreased substantially in product categories where it is most commonly used. Between 2014 and 2017, 19.0% of hair products, 17.3% of skin care products, and 11.3% of soap and bath products contained at least one formaldehyde-releasing chemical as a listed ingredient. For

[21] White, et al. (2002)

products recorded in Mintel between 2021 and 2023, this proportion falls to 4.6% for hair products, 6.4% for skin care products, and 3.2% of soap and bath products.

The baseline includes current manufacturing practices. In the absence of any impact from the proposed rule, we assume that products would be reformulated every ten years, and that the proportion of new products in each cosmetic category that include any formaldehyde-releasing chemical in the formulation's listed ingredients would stay constant at the same proportion as the 2021-2023 period.

Under the proposed rule, we assume the baseline number of reformulations in 2024. Among the remaining products that include a listed formaldehyde-releasing chemical, we assume half of the products would be reformulated in 2025 and the other half in 2026. See Table 2 for a summary of reformulations that would occur under the baseline and under the proposed rule.

Table 2. Schedule of reformulations to remove formaldehyde-releasing chemicals as a listed ingredient under both the baseline and the proposed rule.

Product Category	Total Number of Formulations	Reformulations in Rule (2024-2026)	Reformulations in Baseline (2024-2026)	Reformulations in baseline (after 2026)
Skin Care	19080	2120	488	508
Hair Products	11519	1322	424	478
Color Cosmetics	10822	168	47	37
Bath Products	9254	657	209	197
Fragrances	2962	99	20	40
Oral Hygiene	2069	3	0	3
Deodorants	1527	4	1	1
Shaving	1223	25	7	11

Estimated Costs of the Rule

The estimated cost of the proposed rule for manufacturers is the cost associated with reformulating or the cost associated with reformulating earlier than under the baseline.

We generate a range of total cost estimates for the rule by first drawing a reformulation cost estimate for each business category based on the costs listed in table 1. The draw for each business category is from a triangular distribution with the minimum and maximum of the triangle defined by the reported cost range and the mean of the triangle set to the mean of the expected cost for each category. Each reformulation outlined in table 2 is then assigned to a single business size category in proportion to the share of that size category's formulations on the market in table 1. This process is repeated 10,000 times to generate a distribution of costs under the rule relative to the baseline. The cost estimates in table 3 reflect the 10^{th}, 50^{th}, and 90^{th} percentiles of the cost estimates under the rule as compared to the baseline, representing the low, expected, and high cost scenarios, respectively.

Table 3. Cost estimates of formaldehyde restrictions under the rule.

Manufacturers and Retailers	Expected Cost (in $millions)	Low Cost (in $millions)	High Cost (in $millions)	Expected Cost/business (in $thousands)
WA manufacturers	6.7	4.6	10.0	75.1
WA retailers	0.8	0.6	1.0	0.3
Washington Total	7.5	5.4	10.8	n/a
U.S. Total	454.9	334.9	639.9	n/a

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 5 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[22] with an additional 30% 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. This cost is included in Table 3.

3.2.3 Define ‘intentionally added’

We expect the proposed definition of intentionally added to have an additional cost for manufacturers. It would require each manufacturer to identify and remove any of the restricted chemicals listed in the Toxic-Free Cosmetics Act that were used in the manufacturing process or served as components in cosmetic ingredients, and that might be considered an incidental ingredient without this definition.

The costs of determining whether a restricted chemical is present in the cosmetic product ingredients should be minimal under federal MoCRA requirements that require adequate safety substantiation. Manufacturers would be expected to have access to information from suppliers on all ingredients that they use in cosmetic products, that includes any intentionally added chemicals within the ingredients. Costs to manufacturers would generally occur only if a restricted chemical was found to be included as a component of an ingredient used in the cosmetic product.

[22] https://www.bls.gov/oes/current/oes_wa.htm

Among the chemical classes in Chapter 70A.560 RCW, we expect that only formaldehyde-releasing ingredients would be present as incidental ingredients that would be newly restricted by the proposed definition of intentionally added. As outlined in section 2.3.3, apart from formaldehyde releasers, the chemicals and chemical classes listed in the Toxic-Free Cosmetics Act are expected only to be present as an ingredient with a function in the final product or as an unintended contaminant. Costs for manufacturers from the rule will depend on the prevalence of formaldehyde releasers within cosmetic product ingredients, and the costs associated with replacing these ingredients with alternatives that do not contain formaldehyde releasers.

Prevalence of intentionally added hidden formaldehyde

Information on the prevalence of formaldehyde-releasing chemicals in cosmetic ingredients is limited, although some studies look for 'hidden' formaldehyde in cosmetic products. In a study of 156 cosmetic products purchased in Denmark in 2021,[23] formaldehyde was found in 23 products that did not have formaldehyde-releasing chemicals listed in the product's ingredient list as compared to 14 products that did. However, this study appears to have oversampled self-tanners, and 14 of the 23 products that tested positive for hidden formaldehyde were self-tanners. A sample of 245 cosmetics used by patients at a dermatology clinic in Sweden between October 2012 and January 2013 were tested.[24] 58 products tested positive for formaldehyde. Among these, 26 products did not declare formaldehyde or a formaldehyde-releasing chemical among the product ingredients, representing 45% of the products that contained formaldehyde. A smaller study of 54 cosmetic products in Minnesota found 8 products with listed formaldehyde, and an additional 4 products with unlisted formaldehyde.[25]

Based on these three studies, we assume that the rate of unlisted formaldehyde that would be covered under the definition of intentionally added in the rule is between 5 and 15 percent of bath, skin care, and hair care products. This represents the proportion of cosmetic products we expect contain some level of formaldehyde due to the presence of a formaldehyde-releasing chemical as a component within an ingredient. In the absence of the rule, we assume this proportion of products that contain formaldehyde within their ingredients would persist indefinitely. Under the rule, we expect half of the formulations to substitute to alternative ingredients in 2025, and the remaining half in 2026.

Estimated Costs of the Rule

In cases where manufacturers are using ingredients that contain a formaldehyde-releasing chemical, we expect that each manufacturer will incur some cost in determining their response and finding an alternative supplier or alternative product grade. Given the preservative function that formaldehyde generally serves, the product may need some additional stability testing with the new ingredient to make sure it is still shelf stable over long periods. In some rare cases, the product may need to be reformulated altogether to maintain consistent product qualities.

[23] Søgaard, et al. (2024)
[24] Hauksson, et al. (2016)
[25] Nikle, et al. (2019)

Table 4. Expenses by business size and expense type.

Expense	Small Business	Medium Business	Large Business	Probability of Expense
Determine response and find alternative ingredient	$1,081 (437-2,110)	$5,785 (2,368-11,248)	$9,677 (4,097-18,264)	100%
Stability Testing	$923 ($328-1987)	$4,697 (2,079-8,981)	$9,993 (4,525-18,272)	50%
Full reformulation	$4,680 (2,143 – 8,581)	$66,593 (30,061-123,402)	$161,924 (73,993-297,377)	10-30%

If a manufacturer identifies an ingredient that contains formaldehyde, the cost estimates for each action a manufacturer may need to take in response is listed in table 4. For all formulations, businesses will have to determine a regulatory response and find an alternative product. Because the expected compliance response is to replace an ingredient with an alternative that does not contain a formaldehyde-releasing chemical, we believe that further action will be required only about half the time. In those cases, some additional stability testing may be required. If stability testing is necessary, there is a chance that a full reformulation would be required, which we assume to be between 20-60% of the cases that required stability testing. As in the preceding section, cost estimates are taken from the FDA reformulation model. In this case, it is the reformulation cost estimates for a substitution of a minor non-functional ingredient. Stability testing is not included as a cost estimate in the 2015 model, so we take these costs to be double the 'packaging assessment' costs associated with a reformulation. This estimate roughly matches the published cost estimates for stability testing as well as an earlier iteration of the FDA model that did include stability testing.

Cost estimates for each formulation that contains a formaldehyde-releasing ingredient covered under the rule's definition of intentionally added are generated for each business size category independently from a triangular distribution defined by the respective costs listed in table 5, with the minimum and maximum of the triangle defined by the reported cost range. Each response is then assigned to a single business size category in proportion to the share of that size category's formulations on the market determined in the preceding section. This process is repeated 10,000 times to generate a distribution of costs under the rule relative to the baseline. The cost estimates in table 4 reflect the 10^{th}, 50^{th}, and 90^{th} percentiles of the differences in cost estimates under the rule as compared to the baseline, representing the low, expected, and high cost scenarios, respectively.

Table 5. Cost estimates of 'intentionally added' definition

Washington and U.S. totals	Expected Cost ($millions)	Low Cost ($millions)	High Cost ($millions)	Expected Cost/manufacturer ($thousand)
Washington Total	0.9	0.6	1.4	10.0
U.S. Total	60.8	40.5	88.8	10.3

3.2.4 Distribution of costs[26]

We expect the cost impacts of the proposed rule to be minimal outside of the direct costs to industries outlined in the preceding sections. However, there is a possibility that the rule may further impact people of color, especially women of color. Formaldehyde, methylene glycol, and formaldehyde releasers are used more often in hair treatment products used to smooth textured hair. While formaldehyde and methylene glycol are restricted by statute, we expect the proposed rule would cause the reformulation of products that contain formaldehyde releasers. It is possible that an alternative formulation without formaldehyde releasers may be more expensive or less effective. We do not anticipate that any products will be removed rather than reformulated, but if a product were to be removed, that would restrict the choices of consumers of these products.

More generally, hair and nail salons employ mostly women.[27] A relatively large number of manicurists and pedicurists are women of color.[28] The rule may affect the products that they use. Any change in product cost or any removal of product from the market may cause additional costs in purchasing the product or identifying a replacement product.

While these are possible costs, we do not currently have any evidence that an alternative formulation without formaldehyde releasers would be more costly or less effective in hair smoothing treatments. On the contrary, Mintel product data suggests that prevalence of formaldehyde releasers in hair treatments that smooth or straighten hair has declined over the past ten years along with other product categories.

[26] Any input received from likely impacted communities, including input from overburdened communities and vulnerable populations, helped to inform the proposed rule amendments and our analysis of costs and benefits. See Chapter 6 for discussion of alternative rule content suggested during rule development that was not included in the proposed rule. Community engagement and input are documented in the Environmental Justice Assessment for this rulemaking, and included in the rule file, when a final rule is adopted.

[27] https://datausa.io/profile/soc/hairdressers-hairstylists-cosmetologists

[28] https://datausa.io/profile/soc/manicurists-and-pedicurists

Chapter 4: Likely Benefits of the Proposed Rule

4.1 Introduction

We analyzed the likely benefits associated with the proposed rule as compared to the baseline. The proposed rule and the baseline are discussed in detail in Chapter 2 of this document.

We expect the benefits from the proposed rule will be due to reduced formaldehyde exposure among the public. Cosmetic products that contain formaldehyde releasers can no longer be sold by retailers in the state of Washington starting January 1, 2028. At a minimum this will impact formaldehyde exposure among Washington residents, though it may extend beyond the state.

Ecology estimates benefits of rulemakings using a twenty-year time horizon. Benefits in the future are discounted to the present value using a real annual discount rate of 0.41%. This means that a benefit that occurs in one year will be worth 0.41% more than if it had occurred in the following year. This discount rate is determined by using the average return on U.S. Treasury I-Bonds[29] and subtracting changes in inflation measured by the consumer price index,[30] resulting in the real average annual return over the previous twenty years on an investment that can be considered essentially risk-free.

Potential for expanded impacts

As noted in Section 3.1, manufacturers of products distributed and sold in other states may also choose to remove formaldehyde releasers from their products. In that case, benefits of the rule would extend to the public outside of Washington state. However, manufacturer response outside of Washington may not be attributable to the rule. We focus on expected rule benefits for Washington state but have also included estimates that extend the benefits of the rule to the entire United States to account for the broadest possible effect of the rule.

4.2 Benefits analysis

The proposed rule:

- Identifies chemicals used in cosmetics that release formaldehyde.
- Establishes formaldehyde releaser restrictions and compliance schedule.
- Defines “intentionally added.”

4.2.1 Identify chemicals used in cosmetics that release formaldehyde

We expect some qualitative benefit associated with identifying and publishing chemicals used in cosmetic that release formaldehyde.

[29] https://www.treasurydirect.gov/savings-bonds/i-bonds/i-bonds-interest-rates/
[30] https://www.bls.gov/cpi/

This list helps to inform manufacturers, suppliers, and retailers of the common names and CAS registry numbers for formaldehyde-releasing chemicals used in cosmetics, thereby mitigating compliance costs associated with the rule. Most products that contain measurable formaldehyde list formaldehyde-releasing chemicals on the label. By comparing the labeled ingredients to the list of formaldehyde releasers published in the proposed rule, manufacturers and retailers will be able to more easily comply with the proposed restrictions.

Moreover, we expect it will increase the benefits of the proposed rule by allowing Ecology to use an ingredients list as a resource to determine compliance. This will reduce the time it takes Ecology to identify noncompliant products and help manufacturers and retailers remove products from the market more quickly, thereby reducing public exposure to formaldehyde. By publishing this list, consumers may also be able to take protective actions, proactively identifying cosmetic products with formaldehyde releasers and switching to alternatives. This would be particularly helpful if they have experienced symptoms that may be caused by formaldehyde releasers in cosmetic products, such as contact dermatitis.

4.2.2 Establish formaldehyde releaser restrictions and compliance schedule

Formaldehyde exposure is ubiquitous in indoor spaces. It is released from home building materials and furniture, tobacco smoke and other combustion sources, and a variety of consumer products, including many cosmetics. Some degree of formaldehyde exposure occurs across all homes, workplaces, and community spaces.

Health Impacts of Formaldehyde Exposure

Even small increases to the formaldehyde exposure levels that most people experience every day may carry small but significant risks. To reduce these risks, the use of formaldehyde and methylene glycol is restricted in cosmetics under Chapter 70A.560 RCW. However, formaldehyde exposure through cosmetic use is still possible if formaldehyde releasers are present in the product.

Formaldehyde is a carcinogen. Exposure to formaldehyde can increase the risk of myeloid leukemia, sinonasal cancer, and nasopharyngeal cancers.[31] The risk of nasopharyngeal cancers increases even for small amounts of inhaled formaldehyde.[32]

In addition to increasing cancer risk, there is evidence that formaldehyde is a reproductive and developmental toxicant. Research finds that formaldehyde exposure in women increases the risk of spontaneous abortion and results in other adverse birth outcomes.[33] Links between formaldehyde exposure and reproductive outcomes in men are less well-studied, but some research has found similar impacts.[34] Hair and nail salon workers, who are often exposed to

[31] EPA (2024)
[32] EPA (2024)
[33] Duong, et al. (2011)
[34] Wang, et al. (2012); Wang, et al. (2015)

formaldehyde in addition to many different volatile organic compounds, may be particularly at risk from reduced fertility but the evidence is mixed.[35]

Long-term formaldehyde exposure is associated with decreased lung function and with asthma, especially in children. Chronic bronchitis and asthma are more prevalent in children living in homes with a greater concentration of formaldehyde.[36] Meta-analyses have concluded that there is a relationship between inhaled formaldehyde and both asthma prevalence and severity among children at formaldehyde concentrations typically found in indoor spaces in Washington.[37] Formaldehyde may also increase asthma prevalence in adults, particularly among adults with higher exposure levels.[38]

At high concentrations, formaldehyde exposure causes eye and respiratory tract irritation that can be severe.[39] Less serious, but far more common, personal use of cosmetics that contain formaldehyde releasers is associated with allergic contact dermatitis among individuals with a formaldehyde allergy.[40]

In conjunction with the list of identified chemicals that release formaldehyde in cosmetic products, we expect that cosmetic users and anyone in close contact with cosmetic users will benefit from the proposed rule by reducing dermal and inhalation exposure to formaldehyde. We anticipate that cosmetic products which include an identified formaldehyde releaser with a function in the product will be reformulated before 2027 in order to comply with the formaldehyde restriction in the proposed rule. The reformulation schedule that we anticipate is outlined earlier in Section 3.2.2. We anticipate reductions in exposure as a result of the proposed rule will reduce the numerous negative health effects associated with formaldehyde.

In summary, we anticipate public health benefits due to the proposed rule:

- Reduction in skin sensitization and allergic dermatitis
- Reduction in childhood asthma rates
- Reduction in nasopharyngeal cancer rates
- Reduction in myeloid leukemia and sinonasal cancer rates
- Improved reproductive outcomes
- Reduction in childhood asthma severity and adult asthma incidence and severity
- Reduction in acute sensory irritation

We focus the quantitative economic impact estimates only on the first three anticipated benefits: reduction in skin sensitization and allergic dermatitis, reduction in childhood asthma incidence, and reduction in nasopharyngeal cancers. We chose these three health impacts

[35] Kim, et al. (2016); c.f. Peretz, et al. (2009)
[36] Krzyzanowski (1990)
[37] Lam, et al. (2021); Yu, et al. (2020)
[38] Lam, et al. (2021); Yu, et al. (2020)
[39] Green, et al. (1989)
[40] Hauksson, et al. (2016)

because their relationship to formaldehyde exposure has been quantified most precisely at exposure levels consistent with personal cosmetic product use. The benefits of the proposed rule are not limited to the benefits quantified in this section, they simply represent the benefits that are most readily and precisely quantifiable. Although we limit the benefits analysis to reductions in formaldehyde exposure from personal cosmetic use, some groups would be expected to see additional benefits: particularly, hair and nail salon workers and workers at cosmetic development and manufacturing facilities, who may be exposed to formaldehyde from cosmetic products more frequently and intensely.

Quantified benefits are broken up into the three benefit categories and analyzed separately within each category below.

Reduction in Skin Sensitization and Allergic Dermatitis

Skin can become sensitized to formaldehyde through repeated exposure, which can lead to ongoing allergic reactions. Skin sensitization to formaldehyde in North America has been found to be 7.8%. Sensitization rate to the formaldehyde releaser Quaternium-15 was similar to formaldehyde, while other formaldehyde-releasing chemicals had sensitization rates of 1.7-2.8%.[41] Contact dermatitis occurs or is worsened in a majority of sensitized individuals if they use a cosmetic product that includes a formaldehyde-releasing chemical as a preservative.[42] Restricting the use of chemicals that release formaldehyde in cosmetic products is expected to reduce both skin irritation and sensitization.

We monetize the benefits of reduced contact dermatitis by assuming the willingness to pay for this benefit is equal to or greater than price premium of a cosmetic product that is marketed as being dermatologist recommended among the segment of the market that would experience skin irritation from the product. One study reports the price for products advertised as dermatologist approved was 34% higher than the price for products without that claim.[43] We take this as the minimum price the affected population would be willing to pay to eliminate skin irritation. While this does not account for medical expenses, such as dermatology services, it does provide a value of avoiding potential skin reactions.

The segment of the affected market is the total market sales of cosmetics that would have contained formaldehyde in the absence of the proposed rule and that would have caused an allergic reaction. Based on skin sensitization studies and reports of irritation among sensitized individuals, we assume 1.5% of the public will have a formaldehyde-based skin irritation from a product that contains a formaldehyde-releasing chemical, with an estimated range of 1%-2.5%.

Retail sales of cosmetics and fragrances is classified under the North American Products Classification (NAPCS) Code 5001450000 and data for market activity broken out by NAPCS code is collected as part of the economic census. The most recent United States economic census, conducted in 2017, estimated total retail sales of cosmetics and fragrances at $61.63

[41] Atwater, et al. (2021)
[42] Hauksson, et al. (2016)
[43] Xu, et al. (2017)

billion.[44] To get the value for 2023, we scale it by a factor of 1.466, which is the growth in 'personal care' consumer spending between 2017 and 2023 according to the Bureau of Economic Analysis, producing an estimated retail sales for cosmetic products of $90.36 billion in 2023. A similar procedure for Washington state produces an estimate of $6.48 billion in retail cosmetic sales statewide in 2023. While this share of consumer spending has been increasing in recent years, for simplicity, we assume constant real spending on cosmetic products in future periods.

Total cosmetic product market revenue is broken up into product categories using the Mintel database to calculate average price by weight in each product category and the California Air Resources Board 2015 Consumer Spending Survey[45] as an estimate of relative weights of product categories purchased in the retail market. The estimated percent of revenue for each product category is the average price per ounce for that product category in the Mintel database multiplied by the total weight of retail sales in that category, and normalized so that the proportions of revenue equal one. See Table 6 for estimates of the sales revenue for each cosmetic product category.

Table 6. Washington and U.S. Sales by Product Category

Product Category	WA Sales Revenue ($millions)	U.S. Sales Revenue ($millions)
Skin Care	2,077	28,965
Hair Products	985	13,737
Color Cosmetics	1,520	21,193
Bath Products (excl. soap)	415	5,788
Fragrances	333	4,643
Oral Hygiene	1,015	14,155
Deodorants	103	1,433
Shaving	32	445

The economic value of reduced contact dermatitis each year is calculated as:

$$\sum_{k}\left(PctProd_{t,k,base} - PctProd_{t,k,rule}\right) \times PctACD \times MktRevenue_{k} \times SkinSafePremium.$$

The first term in parenthesis represents the difference in the proportion of products with formaldehyde in year *t* in product category *k* in the baseline as compared to the rule. This is multiplied by *PctACD*, representing the proportion of the population that would be expected to experience allergic contact dermatitis if a formaldehyde-releasing chemical is present in the cosmetic product. The third term, *MktRevenue*, represents the total annual retail market

[44] Economic Census 2017 Data, NAPCS Code 5001450000, https://data.census.gov/table?napcs=5001450000
[45] https://ww2.arb.ca.gov/our-work/programs/consumer-products-program/consumer-commercial-products-surveys

revenue for product category *k*. These first three terms together represent the change in total cosmetic market value impacted by formaldehyde-based skin irritation in the baseline but not in the rule for product category *k*. The value of this reduced skin irritation in the rule is multiplied by the final term, *SkinSafePremium*, which represents the expected willingness to pay among this segment of the market for reduced skin irritation, which we put at 34% to match the observed premium on the market for dermatologist-recommended products.

Table 7. Economic benefit of rule (reduced skin irritation)

Washington and U.S.	Middle ($millions)	Low ($millions)	High ($millions)
Washington	17.8	13.5	25.2
Entire U.S.	248.9	187.6	351.3

Reduction in Childhood Asthma Rates

There is strong evidence that, among other respiratory health effects, an increase in the amount of inhaled formaldehyde is associated with increased incidence of childhood asthma. For formaldehyde levels generally found in homes and schools, a 10 microgram/cubic meter average increase in formaldehyde concentration in the air is associated with a 10%[46] or 20%[47] increase in probability that a child under 15 years of age will be diagnosed with asthma.

Estimates of children's daily inhaled formaldehyde from cosmetics are derived from several different sources. Lefebvre, et al. (2012) reports changes in formaldehyde levels in indoor air for the hour after a cosmetic is used. The measured levels of formaldehyde in the products in the study are lower than the formaldehyde concentration in cosmetic products available in Washington[48], so we adjust for this by multiplying the formaldehyde exposure estimate by the ratio of formaldehyde concentrations in Washington products to the values of products in Lefebvre study to get a more realistic formaldehyde exposure level for Washington products. See Appendix B for additional details.

Table 8 reports the expected impact of using a cosmetic product on formaldehyde levels for the hour after it is used, though this is limited only to cosmetic products that contain formaldehyde releasers as a listed ingredient. We adjust formaldehyde exposure by the proportion of products in each category in the Mintel database that contain one of the formaldehyde releasers identified in the proposed rule. Our projected shares of products that contain formaldehyde-releasers on their ingredients list under the baseline and under the rule is the same as in section 3.2.2.

Information on the daily number of cosmetic products used comes from a 2023 survey conducted and reported by the Environmental Working Group in conjunction with Morning Consult[49]. We focus on bath products, hair care products, and skin care products as those were

[46] Yu, et al. (2020)
[47] Lam, et al. (2021)
[48] Ecology (2023)
[49] https://www.ewg.org/research/survey-finds-use-personal-care-products-2004-what-means-your-health

represented in Lefebvre, et al. (2012) and have the highest proportion of products with formaldehyde-releasing chemicals. Table 8 also reports the mean and ranges of daily product uses that we adopt for the analysis based on the reported survey results for the three key product categories. While we assume a child's formaldehyde exposure is based on a single person's cosmetic usage, this could under-represent exposure in a multi-person household where a child might inhale formaldehyde from cosmetics used by multiple family members.

Table 8. Cosmetic use and indoor formaldehyde concentration

Product Category	**1-hour formaldehyde impact per use in micrograms per cubic meter (range)**	**Mean daily uses per person (range)**
Bath Product	1.00 (0.00-3.39)	4 (2-6)
Hair Care	1.79 (0.79-3.32)	2 (1-3)
Skin Care	2.53 (0.11-3.93)	4 (2-6)

Estimates of the relationship between formaldehyde exposure and childhood asthma incidence typically measure average formaldehyde levels over the course of a day at home or at school, environments where a child would be expected to spend about 8-16 waking hours. We split the difference and use a 12-hour waking 'day' in estimating the impact of the rule on childhood asthma prevalence. The difference in a child's daily mean formaldehyde exposure, in micrograms per cubic meter, in the rule as compared to the baseline is calculated as:

$$DiffAirForm_t = \sum_k \left(PctProd_{t,k,base} - PctProd_{t,k,rule}\right) \times \left(\frac{AirForm_k}{12}\right) \times Uses_k.$$

The first term in parenthesis represents the difference in the proportion of products with formaldehyde in year *t* in product category *k* in the baseline as compared to the rule. This term is multiplied by the 1-hour impact of the cosmetic product in category *k* on indoor formaldehyde concentration in micrograms per cubic meter (*AirForm*) which is then divided by 12 to average the 1-hour impact over the entire 12-hour waking 'day'. This is multiplied by the final term (*Uses*), the number of uses of product category *k* per day. We add the product of these terms across the three cosmetic product categories to get the total daily impact of the rule on daily mean formaldehyde exposure.

Background indoor levels of formaldehyde in the United States have been measured between 12.5 and 32.5 micrograms per cubic meter with a mean of 21.7.[50] From the most recent national asthma data from the CDC, roughly 6.5% of children will be expected to have asthma at the mean formaldehyde concentration.[51] Taking the relationship between formaldehyde exposure and childhood asthma incidence from recent meta-reviews, we assume a 1 microgram per cubic meter increase in average daily formaldehyde exposure would cause a

[50] Liu, et al. (2006)

[51] https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm

1.5% increase (or, 0.0975 percentage point increase) in the incidence of childhood asthma, with a low estimate of 1% and a high estimate of 2%.

The expected difference in cases of asthma under the baseline compared to the rule are calculated as:

$$DiffCases_t = DiffAirForm_t \times AsthmaRate \times NumChild.$$

The first term, *DiffAirForm*, is the difference in average daily formaldehyde exposure in the baseline compared to the rule, as calculated previously. The *AsthmaRate* term represents the change in expected asthma rates for each microgram per cubic meter increase in daily formaldehyde exposure. The final term, *NumChild*, represents the total number of children ages 0-15 expected to be impacted by the rule. In Washington, this number is 1.4 million.[52] Across the entire United States, this number is 60.6 million.[53]

We use a published willingness to pay survey estimate to set the monetary value for reduction in childhood asthma risk. The survey was designed to elicit parents' preferences to pay slightly more for hypothetical asthma drug treatments that have slightly greater efficacy. This value is scaled up to 100% efficacy to put a value on an avoided case of asthma, but each respondent in the survey is valuing small changes in asthma severity. Results from the study estimate a value of $5,728 per year[54] to avoid an asthma case in children below the age of 15 with a maximum value of about $7,829.[55] These values serve as our middle and upper estimates for the value of an avoided asthma case in children and young adults. At a minimum, we expect the value of reductions in childhood asthma to exceed the average per-person medical costs associated with asthma. A published estimate for 2008–2013 medical expenses associated with asthma, including prescription drug costs, emergency visits, and in- and out-patient hospital visits puts this value at $4,677 per year on average across all expenses after adjusting for inflation.[56] This estimate serves as our low value for an avoided asthma case.

Table 9 reports the total estimated economic benefit of the rule in reducing childhood asthma and the average reduction in number of cases per year. As in sections 3.2.2 and 3.2.3, wherever we assume an expected value and a range, we estimate an economic benefit of the rule by drawing single values from triangular distributions where the range defines the minimum and maximum value of the triangle. We calculate a single economic benefit estimate based on these values. We then repeat this procedure 10,000 times to calculate a range of economic benefits,

[52] https://ofm.wa.gov/washington-data-research/statewide-data/washington-trends/population-changes/distribution-washington-population-age-and-gender
[53] https://www.census.gov/quickfacts/
[54] The values in the survey are translated from 2007 U.S. dollars to 2024 U.S. dollars using the consumer price index for medical care.
[55] Blomquist, et al. (2011)
[56] Nurmagambetov, et al. (2018)

and report the 10th, 50th, and 90th percentiles as the low, expected, and high values, respectively.

Table 9. Economic benefit of rule (reduced childhood asthma)

Washington and U.S.	Reduction in cases per year	Reduction in cases per year (range)	Economic benefit (in $millions)	Economic benefit (range, in $millions)
Washington	91	60-131	10.6	6.8-15.5
Entire U.S.	3,948	2,590-5,647	457.1	295.3-670.3

Reduction in Naso-pharyngeal cancers

A 2023 meta-review found that 9 of the 14 meta-analyses concluded that formaldehyde exposure was associated with an increased rate of nasopharyngeal cancer.[57] The EPA IRIS assessment of inhaled formaldehyde categorizes the evidence of this relationship as robust.[58] Based on the results of Beane Freeman, et al. (2013)[59] and reported in EPA (2024)[60] we assume a lifetime risk of nasopharyngeal cancer incidence increases by 1 chance in 135,000 for each 1 microgram per cubic meter increase in inhaled formaldehyde exposure. To translate the lifetime risk to the annual risk, we scale the assumed lifetime risk by a factor of 1/75, implying a life expectancy of 75 years. The expected daily reduction in formaldehyde concentration per cubic meter due to the rule is the same as calculated for childhood asthma, except we assume a 24-hour waking exposure period as our 'day' to match EPA model values for expected inhalation.

Due to the seriousness of cancer and the high degree of dread with which cancer is viewed, the economic value of reduced cancer cases is highly associated with a concept in economics called the value of statistical life. The value of statistical life is an estimate of the way people value very small changes in risks of mortality, often with changes in mortality on the order of 1 in a million or less. Estimates of values from these changes in mortality risk can then be scaled up to a single mortality event to give a single value of statistical life. Crucially, the value of statistical life is only applicable to relatively small changes in risk. The U.S. Department of Health and Human Services uses a value of statistical life of $13.1 million for regulatory analyses[61] with a low of $6.1 million and a high value of $19.7 million. We adopt their middle value in this analysis.

The economic value of an avoided cancer case has been estimated to be between 10% and 100% of the value of statistical life. One study of different cancers finds that the willingness to

[57] La Torre, et al. (2023)
[58] EPA (2024)
[59] Beane Freeman, et al. (2013)
[60] EPA (2024)
[61] Kearsley (2024)

pay to avoid a small change in a prostate or breast cancer diagnosis is roughly the same as the contemporaneous value of statistical life used by the EPA.[62] The same study estimated the willingness to pay to reduce the risk of colon cancer to be just over half of the value of statistical life. Another study of willingness to pay to avoid cancer risk near a contaminated industrial site in Italy found that the value of avoiding a cancer incident was just under half of the value of statistical life.[63] A study among four E.U. countries produced a lower value, estimating avoiding cancer risk to be as low as 10% of the value of statistical life, which the authors note is lower than most other estimates.[64] Given the latency period between formaldehyde exposure and the risk of nasopharyngeal cancers, the willingness to pay to avoid a case may be 60% lower than for shorter-term risks for people above the age of 40.[65]

In this analysis, we use a value of $4.6 million for each case of nasopharyngeal cancer that is reduced. This is calculated by valuing cancer risk at 50% of the value of statistical life in accordance with recent studies valuing avoided cancer cases discussed above, with a range of 10%-90% of the value of statistical life. Due to the latency in the relationship between small changes in formaldehyde inhalation and cancer, we reduce this value by 60% for the population above the age of 40. For simplicity we assume that the population above and below this 40-year threshold stays constant both in Washington and the United States. After adjusting for age bracket, the average value of reduced cancer risk from reduced inhaled formaldehyde is 35% of the value of statistical life per cancer case, with a range of 7%-63% of the value of statistical life ($0.92–$8.3 million).

Based on the expected change in daily formaldehyde exposure under the rule, Table 10 presents the expected reduction in cases of nasopharyngeal cancer per year and the associated economic benefit under the proposed rule compared to the baseline.

Table 10. Economic benefit of rule (reduced nasopharyngeal cancer)

Washington and U.S.	Reduction in cases per year (range)	Economic benefit (in $millions)	Economic benefit (range, in $millions)
Washington	0.027 (0.018-0.036)	2.3	1.2-3.7
Entire U.S.	1.1 (0.8-1.5)	95.8	50.1-157.8

4.2.3 Define the term ‘intentionally added’

We expect the definition of the term intentionally added will cause manufacturers to take steps to exclude ingredients that contain an identified formaldehyde-releasing chemical. The benefits of this rule depend on the formaldehyde exposure that results from the current inclusion of formaldehyde-releasing chemicals as a component in cosmetic ingredients, mainly as

[62] Cameron, et al. (2008)
[63] Tonin, et al. (2012)
[64] Alberini and Ščasný (2018)
[65] Alberini., et al. (2006)

preservatives. Regardless of any health benefits from the rule, defining the term intentionally added will have qualitative benefits for businesses who no longer face ambiguity in meeting the statutory requirements.

As in section 3.2.3, we assume that 5–15 percent of bath, skin care, and hair care products will contain some non-listed formaldehyde due to the presence of a formaldehyde-releaser in an ingredient that would be considered intentionally added under the definition of the term in rule. Under the rule, we expect this would be phased out in equal parts in 2025 and 2026. Under the baseline, we expect this use of formaldehyde-releasing chemicals in cosmetic ingredients to persist indefinitely.

The benefits of the rule would depend on the concentration of formaldehyde in the cosmetic product as well as the proportion of products that contain formaldehyde. One study of products in Minnesota noted that cosmetic products with hidden formaldehyde tended to test at much lower levels, but their testing method was not sufficiently precise to draw further conclusions.[66] A study of 156 cosmetic products purchased in Denmark in 2021,[67] measured the mean formaldehyde content of products with hidden formaldehyde as 30% of the formaldehyde content of products that did list a formaldehyde-releasing chemical, although the median level was just 7%. As noted in the previous section, this study oversampled self tanners which appear to have a much higher concentration of unlisted formaldehyde than other products. Based on this evidence, we assume formaldehyde concentration in products through their ingredients are, on average, 10% of the formaldehyde concentration of products that have a listed chemical that released formaldehyde.

Based on the concentration of unlisted formaldehyde levels compared to products with a listed formaldehyde releaser, we assume commensurate lower health impacts from this part of the rule. We assume reduction in skin irritation levels for products that have unlisted formaldehyde is about 10% of those that have listed formaldehyde. Likewise, inhaled formaldehyde released from the use of a cosmetic product that contains unlisted formaldehyde is about 10% of the amount inhaled from a product with a listed formaldehyde releaser. We quantify the same benefits for removal of formaldehyde-releasing chemicals from cosmetic product ingredients as we did in section 4.2.2 and tabulate them in table 11.

[66] Nikle, et al. (2019)
[67] Søgaard, et al. (2024)

Table 11 Economic benefit of 'intentionally added' definition (in $millions)

Health Impacts	Washington	Washington (range)	Entire U.S.	Entire U.S. (range)
Reduction in Skin Irritation	3.0	1.7-5.5	42.3	23.3-76.5
Reduction in Childhood Asthma	2.2	1.2-3.7	93.7	50.4-161.7
Reduction in Nasopharyngeal Cancers	0.5	0.2-0.8	19.3	9.5-33.9
Total	5.7	3.3-9.7	157.6	88.9-261.9

4.2.4 Distribution of benefits[68]

While everyone is exposed to some amount of formaldehyde—and so will benefit from the proposed rule—the distribution of benefits from the proposed rule may differ across communities. People of color and people with lower incomes are generally exposed to higher levels of formaldehyde from industrial sources, food cooking, cosmetic products, and cheaper building materials.[69-70] As noted above, hair and salon workers may be particularly at risk from formaldehyde exposure, and many of them are women of color. Restricting cosmetic products with formaldehyde-releasing chemicals, in conjunction with the restrictions that are already in statute, will help to reduce formaldehyde exposure most among the population with the highest exposure levels.

[68] Any input received from likely impacted communities, including input from overburdened communities and vulnerable populations, helped to inform the proposed rule amendments and our analysis of costs and benefits. See Chapter 6 for discussion of alternative rule content suggested during rule development that was not included in the proposed rule. Community engagement and input are documented in the Environmental Justice Assessment for this rulemaking, and included in the rule file, when a final rule is adopted.

[69] Johnson, et al. (2022); Li, et al. (2024)

[70] https://ww2.arb.ca.gov/resources/fact-sheets/formaldehyde

Chapter 5: Cost-Benefit Comparison and Conclusions

5.1 Summary of costs and benefits of the proposed rule

Summary of Costs

We expect the costs of the proposed rule are primarily reformulation costs. We expect that cosmetic manufacturers that include formaldehyde releasers in their products will generally reformulate them before the restriction takes effect on January 1, 2027. Costs are incurred from product reformulations that would either not have taken place without the rule or would have happened later. Expected costs and the range of expected costs are based on the FDA reformulation model. The present value of costs associated with the rule over a time horizon of twenty years as calculated in chapter 3 for the state of Washington are summarized in table 12.

Table 12. Summary of Washington Costs from Chapter 3

Proposed Rule Costs	Expected Cost (in $millions)	Low Cost (in $millions)	High Cost (in $millions)
Formaldehyde Releaser List	0	N/A	N/A
Formaldehyde Releaser Restrictions	7.5	5.4	10.8
Intentionally Added Definition	0.9	0.6	1.4
Total Washington Cost	**8.4**	**6.0**	**12.2**

Potential health costs are outlined in Section 3.2.4. Overall, we expect these costs to be minimal. It is possible, though not likely, that the rule may cause limitations on the availability or efficacy of cosmetic products that women of color use relatively more frequently.

Summary of Benefits

We expect the benefits of the proposed rule to primarily be health benefits due to a reduction in formaldehyde exposure, both to skin and through inhalation. There will also be some informational benefit associated with certain aspects of the rule. The expected benefits are outlined in Chapter 4, and include:

- Reduction in skin sensitization and allergic dermatitis
- Reduction in childhood asthma rates
- Reduction in nasopharyngeal cancer rates
- Reduction in myeloid leukemia and sinonasal cancer rates
- Improved reproductive outcomes
- Improved pulmonary function, including reduction in childhood and adult asthma severity and adult asthma incidence
- Reduction in acute sensory irritation
- Reduction in regulatory uncertainty with respect to the underlying statute

- Increased speed and ease in compliance with statute

We quantify the first three expected benefits: reduction in contact dermatitis, reduction in childhood asthma rates, and reduction in nasopharyngeal cancer rates associated with personal cosmetic use. We chose these three health impacts because their relationship to formaldehyde exposure has been quantified most precisely at exposure levels consistent with personal cosmetic product use. The benefits of the proposed rule are not limited to the benefits quantified in this section, they simply represent the benefits that are most readily and precisely quantifiable.

We generally rely on survey-based willingness to pay studies to estimate the economic benefit to reductions in childhood asthma and nasopharyngeal cancer rates. However, we base the lower-bound for reductions in childhood asthma on an estimate of average medical expenses associated with asthma, including hospital visits and medications. We estimate the economic benefit of reduction in allergic dermatitis by applying the price premium for dermatologist-recommended cosmetic products to the intersection of the market between consumers with a formaldehyde allergy and products that contain formaldehyde. While this does not account for medical expenses, such as dermatology services, it does provide a value for avoiding potential skin reactions.

Chapter 4 calculates the present values of the quantified benefits and the range of expected benefits for Washington over a time horizon of twenty years, which is also summarized in table 13.

Table 13. Summary of Washington Benefits from Chapter 4

Proposed Rule Benefits	**Economic benefit (in $millions)**	**Low benefit (in $millions)**	**High benefit (in $millions)**
Formaldehyde Releaser List	Qualitative	N/A	N/A
Formaldehyde Releaser Restrictions	31.2	23.5	41.6
Intentionally Added Definition	5.7	3.3	9.7
Total Washington Benefits	**36.9**	**26.8**	**51.3**

Compared to other professions, hair and salon workers have higher exposures to formaldehyde, as well as other volatile organic compounds, and may be at greater risk from formaldehyde exposure. More generally, people of color and people with lower incomes are exposed to higher levels of formaldehyde from a variety of sources. Restricting cosmetic products with formaldehyde-releasing chemicals is likely to reduce exposure more among this population.

5.1.1 Potential for expanded impacts

As noted in sections 3.1 and 4.1, it is uncertain to what extent manufacturers of products distributed and sold outside of Washington will be impacted by the rule. Removal of formaldehyde releasers from cosmetics may occur outside of Washington due to the rule, but also due to other factors such as existing or anticipated laws and statutes in other states or commitments to product safety. While we focus on Washington benefits and costs, we also

present the impacts for the entire United States to account for the broadest possible effect of the rule and summarize the costs and benefits in tables 14 and 15, respectively. However, even if all U.S. manufacturers were to remove formaldehyde releasers from their products, it would not necessarily be attributable to the rule.

Table 14. Summary of U.S. Costs from Chapter 3. This represents the broadest possible impact of the rule, not the expected rule costs.

Proposed Rule Costs	**Expected Cost (in $millions)**	**Low Cost (in $millions)**	**High Cost (in $millions)**
Formaldehyde Releaser List	0	N/A	N/A
Formaldehyde Releaser Restrictions	454.9	334.9	639.9
Intentionally Added Definition	60.8	40.5	88.8
Total U.S. Cost	515.7	375.4	728.7

Table 15. Summary of U.S. Benefits from Chapter 4. This represents the broadest possible impact of the rule, not the expected rule benefits.

Proposed Rule Benefits	**Economic benefit (in $millions)**	**Low benefit (in $millions)**	**High benefit (in $millions)**
Formaldehyde Releaser List	Qualitative	N/A	N/A
Formaldehyde Releaser Restrictions	814.2	584.3	1,105.2
Intentionally Added Definition	157.6	88.9	261.9
Total U.S. Benefits	971.8	673.2	1,367.1

5.2 Conclusion

We conclude, based on a reasonable understanding of the quantified and qualitative costs and benefits likely to arise from the proposed rule, as compared to the baseline, that the benefits of the proposed rule are greater than the costs.

Chapter 6: Least-Burdensome Alternative Analysis

6.1 Introduction

RCW 34.05.328(1)(c) requires Ecology to "…[d]etermine, after considering alternative versions of the rule and the analysis required under (b), (c), and (d) of this subsection, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated under (a) of this subsection." The referenced subsections are:

> (a) Clearly state in detail the general goals and specific objectives of the statute that the rule implements;
>
> (b) Determine that the rule is needed to achieve the general goals and specific objectives stated under (a) of this subsection, and analyze alternatives to rule making and the consequences of not adopting the rule;
>
> (c) Provide notification in the notice of proposed rulemaking under RCW 34.05.320 that a preliminary cost-benefit analysis is available. The preliminary cost-benefit analysis must fulfill the requirements of the cost-benefit analysis under (d) of this subsection. If the agency files a supplemental notice under RCW 34.05.340, the supplemental notice must include notification that a revised preliminary cost-benefit analysis is available. A final cost-benefit analysis must be available when the rule is adopted under RCW 34.05.360;
>
> (d) Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

In other words, to be able to adopt the rule, we must determine that the requirements of the rule are the least burdensome set of requirements that achieve the goals and objectives of the authorizing statute(s).

We assessed alternative proposed rule content, and determined whether they met the goals and objectives of the authorizing statute(s). Of those that would meet the goals and objectives, we determined whether those chosen for inclusion in the proposed rule were the least burdensome to those required to comply with them.

6.2 Goals and objectives of the authorizing statute

The authorizing statute for this rule is Chapter 70A.560 RCW, Cosmetic Products – Toxic Chemicals. Its goals and objectives are to:

- Ensure the safety of cosmetic products and protect Washington residents from toxic exposure.
- Create a safer global standard for cosmetic products and bring more sustainable and safer ingredients to the marketplace.

6.3 Alternatives considered and why they were excluded

We considered the following alternative rule requirements, and did not include them in the proposed rule. This list includes alternatives that were suggested by the public during development of the rule, with the intent of mitigating negative impacts and equitably distributing benefits. Each section below explains why we did not include these alternatives.

- Exclude incidental ingredients, as defined by FDA from the definition of "intentionally added"
- Raise the lead restriction level
- Earlier compliance dates

6.3.1 Exclude incidental ingredients, as defined by FDA from the definition of "intentionally added"

We considered excluding incidental ingredients from the definition of intentionally added. That would mean that the restrictions would not apply to chemicals added to raw materials or ingredients used in the final product. This would not meet the goal of protecting Washington residents from toxic exposure because products could still contain these chemicals if they were used in the ingredients.

Additionally, it would limit the restriction on formaldehyde to the direct addition of formaldehyde and exclude formaldehyde releasers. Formaldehyde is generally not added directly to cosmetics because it is a gas at room temperature. Instead, it is either mixed with other chemicals to stabilize it or released from other chemicals added to the product over time. Regardless of how the formaldehyde is added, it is serving a function in the product. By using the definition of "intentionally added" broadly, formaldehyde is restricted when it is serving a function in the product regardless of how it is added to the product.

6.3.2 Raise the lead restriction level

We considered raising the lead restriction. There are concerns from industry that 1 ppm is infeasible for certain types of cosmetic products. At the time of this rule proposal, Ecology does not have sufficient data to determine what restriction level would be feasible. Ecology concluded that raising the lead limit during this rulemaking may not effectively meet the goal of protecting Washington residents from lead exposure, and that more information would be necessary to make that determination. However, Ecology has announced a new rulemaking to identify a feasible approach to restricting lead in cosmetic products, including potentially adopting a different limit on lead impurities than the statutory limit of 1 ppm. Ecology has published an interim policy to provide compliance guidance to manufacturers while we conduct

the rulemaking. See Ecology's lead-in-cosmetics rulemaking webpage for additional information.[71]

6.3.3 Earlier compliance dates

We considered adopting earlier compliance dates for regulated entities. However, we determined that dates earlier than January 1, 2027, would be more burdensome for those required to comply with the rule. This date will allow regulated entities more time to prepare for the restriction.

6.4 Conclusion

After considering alternatives, within the context of the goals and objectives of the authorizing statute, we determined that the proposed rule represents the least-burdensome alternative of possible rule requirements meeting the goals and objectives.

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

Chapter 7: Regulatory Fairness Act Compliance

7.1 Introduction

The Regulatory Fairness Act (RFA; RCW 19.85.070) requires Ecology to perform a set of analyses and make certain determinations regarding the proposed rule. This chapter presents the:

- Analysis of relative compliance cost burden.
- Consideration of lost sales or revenue.
- Cost-mitigating elements of the rule, if required.
- Small business and local government consultation.
- Industries likely impacted by the proposed rule.
- Expected impact on jobs.

A small business is defined by the RFA as having 50 or fewer employees, at the highest ownership and operator level. This is different than the definition of small manufacturer used in Chapter 3 when estimating costs. The RFA definition of small business includes some manufacturers that were classified as medium sized in Chapter 3. Estimated compliance costs are determined as compared to the baseline (the regulatory environment in the absence of the proposed rule, limited to existing federal and state requirements). Analyses under the RFA only apply to costs to "businesses in an industry" in Washington State. This means the impacts, for this part of our analyses, are not evaluated for government agencies.

7.2 Analysis of relative compliance cost burden

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 4 people. The largest ten percent of affected businesses employ an average of 3,771 people. However, businesses with as few as 17 employees are within the largest 10% 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 16: 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.

7.3 Action taken to reduce small business impacts

The RFA (19.85.030(2) RCW) 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 rulemaking. 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 rulemaking.

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 the 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.

7.4 Small business and government involvement

We involved small businesses and local governments in its development of the proposed rule, using:

- Two rulemaking webinars.
- Meetings with stakeholders, businesses, and local governments, including the organizations listed below.
    - 17 small businesses or business trade groups, including product suppliers, cosmetic brands, cosmetologists, and ingredient tracking software companies.
    - 8 non-profit groups, including product safety, health, and product certification organizations.
    - 3 local governments or government associations.
    - 3 stakeholder or stakeholder groups.
    - 2 professional organizations, representing cosmetologists and cosmetic chemists.
- Outreach at community events, including:
    - Duwamish River Festival.
    - Mosaic River Festival.
    - Yakima Pride Festival.
- A presentation at a conference organized by the Independent Beauty Association, a trade association representing smaller businesses in the cosmetic supply chain.

7.5 North American Industry Classification System (NAICS) codes of impacted industries

The proposed rule likely impacts the following industries, with associated NAICS codes. NAICS definitions and industry hierarchies are discussed at www.census.gov/naics.

- 325620 Toilet Preparation Manufacturing
- 455 General Merchandise Retailers
- 456120 Cosmetics, Beauty Supplies, and Perfume Retailers

7.6 Loss of sales or revenue and impacts on jobs

Businesses that would incur costs could experience reduced sales or revenues if the proposed rule significantly affect the prices of the goods they sell. The degree to which this could happen is strongly related to each business's production and pricing model (whether additional lump-sum costs would significantly affect marginal costs), as well as the specific attributes of the markets in which they sell goods, including the degree of influence each firm has on market prices, as well as the relative responsiveness of market demand to price changes. Finally, overall shifts in economic activity in the state, including competition within markets and attributes of the labor market simultaneously adjust in response to changes in compliance costs.

Similarly, employment within directly impacted industries, other industries in Washington, the labor market within and outside of the state, and in the state as a whole will also adjust in response to a change in costs.

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: inter-industry 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[72]

[72] This is based on the assumption that a missed day of school would also cause a missed day of work. Johnson, et al. (2019) estimates days of school missed for children with an asthma diagnosis.

- Pharmaceutical industry consumption of $2,621 is reallocated across all other industries[73]
- Physician services consumption of $2,056 is reallocated across all other industries[74]

The results of the REMI E3+ model shows that the impact of the proposed rule will vary by industry (see table 15, 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. In the second quarter of 2024, Washington state's annual GDP was estimated at $840 billion.[75] $17.4 million is equivalent 0.002 percent of the state's GDP. We expect the proposed rule to have additional economic impacts. For example, the rule may decrease days of work missed due to reductions in adult asthma. Or there may be additional economic redistribution from medical expenses to other consumer spending due to improved reproductive outcomes. But because these were not quantified in Chapter 4, they were not included in the REMI simulation even though it may be expected to increase the state economic output. This means the negative economic outputs in table 15 are likely overestimated.

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% 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. Under the baseline, cosmetic reformulations to remove formaldehyde releasers are assumed to continue over the next ten years. By contrast, under the rule, all cosmetic reformulations from the rule occur before January 1, 2027. The proposed rule causes manufacturing costs in the short-term but removes a cost in later years.

Construction is impacted most among all industries. While it does not incur direct compliance costs, it is not unusual for the construction industry to have high projected impacts from a rule as the construction industry tends to be indirectly sensitive to any changes in the market in REMI models. Soap, cleaning compound, and toilet preparation manufacturing is the second most highly impacted industry, which includes cosmetic manufacturers.

[73] Nurmagambetov, et al. (2018)
[74] Nurmagambetov, et al. (2018)
[75] https://www.bea.gov/data/gdp/gdp-state

Table 17. 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
Retail Trade	-0.7	-1.5	-0.2	-0.1
Wholesale Trade	-0.6	-0.9	+0.1	0.0

The rule will result in transfers of money within and between industries, as compared to the baseline. The modeled impacts on employment are the result of these transfers and the way in which REMI projects these transfers to be utilized within the broader economy as well as changes to prices and other economic variables across all industries in the state. 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% 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.[76]

As with economic output, the construction sector is projected to be the most heavily impacted industry in terms of employment, accounting for around 30 percent of the state-wide job loss at the peak in 2026. Industries that are most heavily impacted are listed in table 16. Toilet preparation manufacturing is less labor intensive than some other sectors, so it is expected to be less heavily impacted in terms of employment relative to the expected impact on the industry's economic output.

Table 18. 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

[76] Assuming unchanged total employment from May 2023. https://www.bls.gov/oes/current/oes_wa.htm

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Appendix A: Administrative Procedure Act (RCW 34.05.328) Determinations

A. RCW 34.05.328(1)(a) – Clearly state in detail the general goals and specific objectives of the statute that this rule implements.

See Chapter 6.

B. RCW 34.05.328(1)(b) –

1. Determine that the rule is needed to achieve the general goals and specific objectives of the statute.

See chapters 1 and 2.

2. Analyze alternatives to rulemaking and the consequences of not adopting this rule.

Chapter 70A.560 RCW: Toxic-Free Cosmetics Act directs Ecology to develop a rule that identifies a list of chemicals used in cosmetics that release formaldehyde and restricts the intentional addition of the identified formaldehyde releasers. Identifying chemicals used in cosmetic products that release formaldehyde provides transparency to regulated entities. Compliance efforts may be easier because they can read ingredients labels to see if the restricted chemicals are in their products. This may also reduce compliance costs because they can rely on the ingredients label instead of testing their products.

The proposed rule also defines the term "intentionally added." Chapter 70A.560 RCW restricts certain intentionally added chemicals in cosmetic products. Defining "intentionally added" will provide clarity on how we will implement the restrictions in the law and proposed rule.

Please see the Least Burdensome Alternative Analysis, Chapter 6 of this document, for discussion of alternative rule content considered.

C. RCW 34.05.328(1)(c) - A preliminary cost-benefit analysis was made available.

When filing a rule proposal (CR-102) under RCW 34.05.320, Ecology provides notice that a preliminary cost-benefit analysis is available. At adoption (CR-103 filing) under RCW 34.05.360, Ecology provides notice of the availability of the final cost-benefit analysis.

D. RCW 34.05.328(1)(d) – Determine that probable benefits of this rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

See Chapters 1 – 5.

E. RCW 34.05.328 (1)(e) - Determine, after considering alternative versions of the analysis required under RCW 34.05.328 (b), (c) and (d) that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated in Chapter 6.

Please see Chapter 6.

F. RCW 34.05.328(1)(f) - Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

To the best of our knowledge, the proposed rule does not require those to whom it applies to take an action that violates requirements of a federal or state regulation. Ecology examined applicable federal and state regulations related to the regulation of formaldehyde releasers in cosmetic products.

G. RCW 34.05.328 (1)(g) - Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

To the best of our knowledge, the proposed rule does not impose more stringent performance requirements on private entities than on public entities.

H. RCW 34.05.328 (1)(h) Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter.

No. The federal Toxic Substances Control Act regulates chemicals but does not regulate formaldehyde releasers in cosmetics.

In Washington State, Chapter 70A.560 RCW restricts certain chemicals in cosmetics. The proposed rule compliments the restrictions in Chapter 70A.560 RCW and adds more clarity about those restrictions.

- If **yes**, the difference is justified because of the following:

  ☐ (i) A state statute explicitly allows Ecology to differ from federal standards.

  ☐ (ii) Substantial evidence that the difference is necessary to achieve the general goals and specific objectives stated in Chapter 6.

I. RCW 34.05.328 (1)(i) – Coordinate the rule, to the maximum extent practicable, with other federal, state, and local laws applicable to the same subject matter.

Ecology examined applicable federal and state regulations related to the regulation of formaldehyde releasers in cosmetic products. Where possible, the requirements in the proposed rule match similar requirements of other authorities including other US state and other nations.

Appendix B: Cosmetic use and indoor formaldehyde concentration

Number of Product Uses

The average number of uses for each product category are based on the reported results of the Environmental Working Group survey, administered by Morning Consult.[77] Their reported 'body care' product category most closely corresponds to our 'bath and soap' category, but is somewhat broader. For that reason, we scale the mean number of uses down by one-third. The survey reports the number of products used per day, but not necessarily the number of uses. Skin care products, especially, we expect to be used multiple times throughout the day, so we scale this number up by two. In all cases, we introduce uncertainty in the estimates, allowing all products to be used 50% more or less than our expectation.

Impact on inhaled formaldehyde

Lefebvre, et al. (2012) reports indoor formaldehyde concentrations from the use of personal cosmetic products. All the products in the study contain a formaldehyde releaser and the study reports the measured concentration of formaldehyde in the product. The study measures the formaldehyde levels in the air before the use of each cosmetic product category and for the hour after and reports the mean and confidence interval of each. To translate that into a formaldehyde exposure range for Washington residents, we first simulate draws from a multivariate normal distribution defined by the means (**μ**) and variances (**σ**) of the formaldehyde concentrations before the cosmetic is applied (indexed as 0) and the average for the hour after application (indexed as 1).

$$\boldsymbol{\mu} = \begin{pmatrix} \mu_0 \\ \mu_1 \end{pmatrix}, \boldsymbol{\Sigma} = \begin{pmatrix} \sigma_0 & \sqrt{\sigma_0 \sigma_1} \\ \sqrt{\sigma_0 \sigma_1} & \sigma_1 \end{pmatrix}$$

$$\mathbf{X} \sim N(\boldsymbol{\mu}, \boldsymbol{\Sigma})$$

The matrix **X** contains the simulated data for both the formaldehyde concentration before the use of the cosmetic and for the average concentration in the hour after its use. The difference between these represents the cosmetic's estimated impact on formaldehyde concentrations in the air. We define the expected impact in the analysis in Chapter 4 based on the interquartile range of this difference, assuming a triangular distribution with the minimum and maximum of the triangle equal to the 25th and 75th percentiles of the simulated change in formaldehyde for each product in the Lefebvre study. This range is reported in table 8.

We assign the products in the Lefebvre study into the corresponding product categories that we use in the analysis. Deodorant, face cream, and lotion are assigned to the skin care

[77] https://www.ewg.org/research/survey-finds-use-personal-care-products-2004-what-means-your-health

product category, shower gel is in the soap and bath product category, and hair gel, and shampoo, and conditioner are in the hair care product category.

In general, the formaldehyde concentration in the products used in the Lefebvre study are lower than the formaldehyde concentrations measured by Ecology in Washington cosmetic products. We scale each cosmetic product's estimated impact on formaldehyde concentrations in the air by the ratio of formaldehyde concentration in Washington products as reported in Ecology (2023) to the formaldehyde concentration of products used in Lefebvre, et al. (2012). Ecology (2023) does not measure each of the product types used in the study, so we use the ratios that are available that match the product type most closely. Skin care products are scaled by the ratio of formaldehyde measured in lotions. Shower gel, hair gel, and shampoos are scaled by the ratio of formaldehyde measured in hair gel.