



DEPARTMENT OF
ECOLOGY
State of Washington

Preliminary Cost-Benefit and Least Burdensome Alternative Analyses

Chapter 173-334 WAC

Children's Safe Products - Reporting Rule

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**Preliminary Cost-Benefit and
Least Burdensome Alternative Analyses**
Chapter 173-334 WAC
Children's Safe Products - Reporting Rule

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Executive Summary

The Washington State Department of Ecology (Ecology) is proposing to adopt a new chapter called the Children’s Safe Products – Reporting Rule (Chapter 173-334 WAC). The Administrative Procedures Act (RCW 34.05.328(d)(e)) requires two types of analyses before adopting a significant legislative rule – a cost-benefit analysis and a least burdensome alternative analysis. This report provides the results of these analyses and shows the potential impacts associated with the proposed rule.

For Ecology’s proposed rule, *Chapter 173-334 WAC – Children’s Safe Products – Reporting Rule*, this means Ecology must estimate the impacts of the proposed rule on individuals, businesses and the public. Impacts are determined by comparing the expected regulatory environment in the absence of Ecology’s proposed rule, to the way CHCC content reporting will occur under Ecology’s proposed rule.

Ecology analyzed the impacts of the proposed rule relative to the current absence of a rule, with the exception of those elements of the rule that were dictated by law, and over which Ecology did not have discretion.

Ecology has analyzed the ranges of quantifiable impacts, as well as many likely qualitative impacts, relative to the baseline. Based on its analysis, Ecology has determined the likely benefits of the proposed rule exceed the likely costs, accounting for both quantified and qualitative impacts.

Costs and Benefits of Ecology’s Proposed Rule	
Annualized Costs millions of \$/year	Benefits
Testing costs: \$44.7 – 69.5 million	<ul style="list-style-type: none"> • Creation of a comprehensive database. • Public confidence and government transparency. • Credibility, consumer behavior, and investment. • Economies of scale in manufacturing. • Greater understanding of the distribution of CHCCs in Washington’s children’s products and economy. • Avoided children’s health. • Recall or litigation costs, related to \$100 thousand – \$15 million in costs per recall or lawsuit.

Chapter 1: Background and Scope

Background

Ecology is proposing the Children's Safe Products - Reporting Rule (Chapter 173-334 WAC) as part of the rulemaking it is allowed to perform by law in Chapter 70.240 RCW (Children's Safe Products Act; CSPA). This law was passed in 2008, and specifically allows Ecology to, "adopt rules as necessary for the purpose of implementing, administering, and enforcing this chapter."

The CSPA law requires Ecology to identify high priority chemicals that are of high concern for children. This includes chemicals that have been:

- Found through biomonitoring studies that demonstrate the presence of the chemical in human umbilical cord blood, human breast milk, human urine, or other bodily tissues or fluids.
- Found through sampling and analysis to be present in household dust, indoor air, drinking water, or elsewhere in the home environment.
- Added to or is present in a consumer product used or present in the home.

In July 2009, Ecology published a report (Ecology publication number 09-07-014) describing the work done by Ecology and the state Department of Health (DOH) to comply with CSPA requirements, address concerns raised by stakeholders, and implement direction from the Governor.¹ This included discussion of the process the agencies used to determine chemicals of concern that are being proposed as part of this rulemaking.

The majority of the CSPA law delineates requirements for manufacturers and sellers of children's products, including:

- Prohibition on the manufacturing and sale of children's products containing lead, cadmium, or phthalates above the limits established in the law. At this time the agency feels federal programs have substantially pre-empted our agency for the enforcement of these limits. So this rule only addresses the reporting requirement.
- Notification to Ecology that a children's product contains a high priority chemical.
- Actions that must be taken by – and penalties for – manufacturers in violation of the law.

Ecology conducted a stakeholder process and pilot rule phase to determine the content of the proposed rule. Both the pilot phase and the stakeholder process helped Ecology identify possible compliance difficulties for the regulated community without diminishing the effectiveness of the rule. These processes were also used to get other input from the public, business, environmental interests, and health interests might have toward rulemaking.

¹ The Governor expressed that Ecology and DOH should rely on safety testing conducted in the European Union and California, to the extent they provide a reasonable assurance of safety, in order to help establish a degree of consistency for the industry.

Pilot Phase

Ecology conducted a pilot rulemaking during the rule development process, to learn more about the effects of a CSPA rule as it applies to actual manufacturers subject to the rule. Pilot rules or pilot phases to rules allow Ecology to:

- Construct rules that minimize compliance difficulties for the regulated community.
- Effectively achieve the goals of the authorizing statutes, other law, and other existing Ecology goals and policies.

The pilot phase gave manufacturers a chance to test how the proposed rule may affect them. Pilot participants were expected to communicate any issues as they occur rather than waiting until the end of the pilot. Additionally, participants were strongly encouraged to submit a written final report indicating what worked and clarifying any unresolved issues. Ecology considered this input and our own experience with the pilot to draft the proposed rule.

Ecology gave participants the pilot rule language, including the list of reporting chemicals and the process we used to identify them. We encouraged participants to seriously evaluate how the implementation of the rule would affect them. Participants were asked to determine what they would need to do to comply with the rule for specific products or product categories, and to identify parts of the rule they thought needed clarification or modification.

Ecology gathered information during the pilot process to inform the stakeholder process and proposed rule. The information Ecology hoped to gather included, but was not limited to:

- Any data/suggestions which might help us determine the reporting trigger values. This could include risk assessments, 'safe harbor' values from other authoritative bodies, assumptions used to determine likely migration of chemicals, etc.
- Suggestions on which chemicals should be removed or added to the reporting list.
- Suggestions on how to improve the chemical selection process.
- Any data on chemicals likely to be in various children's products, or the raw material used to make children products.
- Information on analytical techniques for chemicals in different matrices (e.g. plastics, lotions, fabrics)
- Recommended layout for the reporting form to support one annual submittal for each manufacturer covering multiple products.
- Information on the time required to reformulate products.
- Information on the typical time frame for a product to go from the design phase to the shelf.
- Information on lead times needed to affect seasonal (Halloween, Thanksgiving, etc.) products including ordering and tracking and how compliance issues for these types of products might be different from products available year round.
- Recommendations on how to better phase in the reporting.

- Suggestions to improve the rule regarding the contaminant vs. intentionally added issue.
- Information about labs used to test products - locations, prices etc.
- Suggestions regarding any needed clarification of the confidential business information (CBI) requirements under Washington's public disclosure law.
- Information that would help us better understand the costs of complying with this law. This could include lab costs, third party monitoring, an audit system etc.
- Suggestions regarding safer alternative assessments including company specific mandates or use of third party systems.

Scope of Analysis

Ecology analyzed the impacts of Ecology's proposed rule in the following sections:

- **Chapter 2: Baseline and Exemptions**
This chapter explains the baseline concepts to which Ecology's proposed rule was compared in Ecology's analysis, as well as what was not analyzed, and how rule impacts were analyzed.
- **Chapter 3: Costs of the Proposed Rule**
This chapter explains the cost of the proposed rule.
- **Chapter 4: Benefits of the Proposed Rule**
This chapter explains the benefits of the proposed rule.
- **Chapter 5: Conclusions**
This chapter summarizes Ecology's results and includes comments on the analysis.
- **Chapter 6: Least Burdensome Alternative Analysis.**
This chapter explains Ecology's determination on whether the proposed rule places the least burden possible on those required to comply with it, while fulfilling the goals and objectives of the authorizing legislation.

Chapter 2: Baseline and Exemptions

Baseline

As there is no current state-level CSPA or similar rule, there is technically no baseline rule for comparison. There are no existing federal or Washington State requirements intended explicitly for children's products as under this rule. There are, however, a number of partially overlapping requirements and mitigating factors, including:²

- Washington's toxics in packaging law (Chapter 70.95G RCW – Toxics in Packaging) requires manufacturers to have practices that may include contract specifications, quality control mechanisms, and/or testing protocols to determine the amount of a chemical in product materials.
- Manufacturers must have procedures in place to test for lead under the federal Consumer Product Safety Improvement Act of 2008 (CPSIA). Some chemicals are restricted in cosmetic products under FDA regulations.
- Interstate toxics rules allowing manufacturers to employ economies of scale in producing a homogeneous product across multiple markets:
 - Manufacturers who sell children's products in Maine are subject to similar reporting requirements for priority chemicals (Me. Rev. Stat. Ann. tit. 38, §§ 1691-1699-B). The State of California has several reporting requirements applicable to manufacturers of children's products, including required reporting on use of specific ingredients in cosmetics (Cal. Health & Safety Code §§ 111791-111793.5).
 - Manufacturers who do business in California are also required to label products if exposure to certain chemicals from those products exceeds levels known to cause cancer or reproductive harm (California Proposition 65).
 - The European Union, for instance, enforces chemical limits in children's products through its Toy Directive (88/378/EEC) and Cosmetics Directive (76/768/EEC). Many companies have pre-existing restricted substance lists (RSLs) to describe and codify procedures to meet chemical limits in a variety of product lines for sale in various countries.

See Appendix B for a full listing of existing interstate and international rules that will likely mitigate the compliance costs created by the proposed rule.

These factors will likely mitigate some of the compliance costs for a subset of businesses covered by the proposed rule.

The baseline also includes the explicit provisions of the authorizing statute. These are excepted from this analysis. For further discussion, see Analytic Exceptions, below in this chapter.

² See Appendix B for a full listing of existing regulations that will likely mitigate the compliance costs created by the proposed rule.

Changes under Ecology's Proposed Rule

The proposed rule sets out requirements for:

- Annual notification of Ecology by manufacturers of children's products containing Chemicals of High Concern to Children (CHCCs), with pertinent firm, product, and CHCC quantity information as established by statute.
- Timing of first reporting is phased in according to the product tier and size of manufacturer. Product tiers (1 – 4) represent the level of contact with a child intended for types of products, based on levels of the GS1 Global Product Classification (GPC) standard. It is an industry standard for product classification.
- Enforcement priorities and penalties.

Analytic Exemptions

Ecology excluded from analysis the following elements, explicitly dictated or defined in the Children's Safe Products statute (Chapter 70.240 RCW):

- Definitions, including:
 - Children's cosmetics
 - Children's jewelry
 - Children's product
 - Cosmetics
 - High priority chemical
 - Manufacturer
 - Phthalates
 - Toy
 - Trade association
 - Very bioaccumulative
 - Very persistent
- Prohibition of the manufacturing and sale of children's products containing lead, cadmium, or phthalates.
- Explicit reporting requirements, including:
 - The name of the chemical used or produced and its chemical abstracts service registry number.
 - A brief description of the product or the product component containing the substance.
 - A description of the function of the chemical in the product.
 - The amount of the chemical used in each unit of the product or product component. The amount may be reported in ranges, rather than the exact amount.
 - The name and address of the manufacturer and the name, address, and phone number of a contact person for the manufacturer.
 - Any other information the manufacturer deems relevant to the appropriate use of the product.

- Notification of sellers and distributors
- Civil penalty

Analytic Approach

Ecology analyzed the costs and benefits of the proposed rule qualitatively, and quantified the impacts where possible. Ecology only analyzed those aspects of the proposed rule that were left to Ecology's discretion in the rulemaking process. In the case of the proposed rule, many of its elements were dictated explicitly by law, as is the general idea of manufacturer reporting.

One must keep in mind, however, that Ecology only had particular discretion on reporting ranges, and the phasing-in of first reporting time. Every chemical on the reporting list meets the standards set by the authorizing law. Ecology chose 59 chemicals from an initial list of two thousand prospective chemicals. Ecology believes the content of the list of CHCCs is sufficiently dictated by statute, so that the chemicals on the final list were not entirely left to Ecology's discretion. However, Ecology also believes it is to the public and state's advantage to present the estimated costs of testing and reporting, to provide additional information to manufacturers and the public regarding compliance with the authorizing statute.

Chapter 3: Costs of Proposed Rule

Ecology quantitatively assessed the likely costs of the proposed rule, and developed appropriate quantitative estimates of the value of those costs for which it was possible. Ecology expects the elements of the proposed rule over which Ecology had discretion to result in costs related to:

- The timing of first reporting.
- Reporting ranges of CHCC content.

The authorizing law allows Ecology to phase in first reporting, but it does not explicitly dictate the degree of phasing. Ecology's choice of the degree of phasing in the reporting schedule only acts to mitigate the costs of reporting on the initial date specified in the law (six months after the adoption date of a rule on this topic). Ecology, therefore, does not believe the choice of longer times before first reporting will impose additional costs.

Ecology determined the ranges of CHCC content that manufacturers must report into, either by reporting specific content inherently within a range, or by reporting that the content is between the endpoints of a range. Ecology expects the proposed ranges – and in particular the lower endpoint of the lowest range – to contribute to the likely costs of the proposed rule.

Quantified Costs of Ecology's Proposed Rule

Ecology estimated the quantitative costs of complying with the proposed rule, including those elements dictated by the authorizing law, based on:

- The number of businesses expected to comply.
- The number of chemicals that require testing or business practice or business chain knowledge.
- The estimated costs of testing or business practices and reporting.

These estimates are conservatively high, and do not account for economies of scale, non-reporters, or interstate/international regulatory consistency. Moreover, as a means of estimating CHCC content and reporting into a range, testing is not specifically required by the proposed rule or the law. Other options for gauging CHCC content include supply-chain knowledge and knowledge of the manufacturing process.

Ecology assumed that known businesses operating in Washington State manufacturing or importing toys and games, children's clothing, and baby supplies and accessories may have to comply with the law. These businesses fall into multiple NAICS³ categories, including:

- 3399 (Other Miscellaneous Manufacturing; includes toys, games, baby products)
- 4243 (Apparel, Piece Goods, and Notions Merchant Wholesalers; includes children's clothing)

³ North American Industry Classification System (see <http://www.census.gov/eos/www/naics/index.html>)

- 3256 (Soap, Cleaning Compound, and Toilet Preparation Manufacturing; includes baby care)
- 3371 (Household and Institutional Furniture and Kitchen Cabinet Manufacturing; includes baby furniture)

Based on WA Employment Security Department information, there are currently about 276 such businesses in the state. Ecology was also able to categorize most of these businesses roughly into size categories by employment and, to a lesser degree, annual earnings. Ecology believes these businesses represent the majority of the businesses that will need to comply with the proposed rule. Some retailers who act as importers or distributors for products made by companies with no presence in the United States may also need to report, but Ecology assumes this number will be minimal.

Ecology assumed that any given business would maintain at least existing business practices and standards, but Ecology assumed conservatively (attempting to overestimated costs, as to calculate a conservative net benefit of the proposed rule) that a business might choose to test for a maximum of ten CHCCs.

Based on surveys of current testing costs, Ecology estimated that this cost of knowing the level of CHCC content in children's products for some manufacturers would be in the range of approximately \$1 thousand – \$10 thousand per year for all the CHCCs in their products. This value was based on a range of existing, approved analytical methods. It is possible that new test methods could need to be developed. Ecology multiplied these values to calculate a total conservatively high⁴ testing cost of the proposed rule and CSPA law of \$2.8 million – \$27.6 million the first year, followed by \$2.8 million annually in subsequent years, when testing has been established.

The above calculations generated at total likely present value⁵ cost of compliance, over 20 years, with the combined CSPA rule and CSPA law, of \$44.7 million to \$69.5 million. Requirements set forward in the latter of these, the CSPA law, are exempt from inclusion in this analysis, but Ecology included this total cost in this analysis because the contribution of Ecology reducing the possible list of CHCCs (to only those meeting the requirements set forth in the authorizing law) was not separable from the overall impacts of the law .

⁴ Assuming all covered businesses must test to determine whether and what to report.

⁵ Accounting for expected inflation, using US Treasury I-Bonds (see http://www.treasurydirect.gov/indiv/research/indepth/ibonds/res_ibonds_iratesandterms.htm)

Chapter 4: Benefits of Proposed Rule

Ecology expects mandatory reporting of CHCC content to benefit the public in the short and long run through the information provided on potential hazards posed by children's products. Information on CHCC content may be used for consumer and government decision making, investment decisions, and industry understanding of CHCC content across the supply chain.

Ecology believes these benefits hold for both reporters and non-reporters (manufacturers of children's products that do not contain significant amounts of CHCCs). In particular, the status of being a non-reporting manufacturer, or having products that do not require notification of Ecology, communicates information about the qualities of a manufacturer's children's products to the consumer.

Creation of a comprehensive database

Ecology believes that notification of CHCC content for a comprehensive list of CHCCs, as defined in the law provides significant additional information for planning and implementing future product labeling or CHCC reduction goals. Compared to information collected under only federal regulations will likely result in a better understanding of the CHCC distribution in children's products sold in Washington. This can bring reductions in children's exposure to CHCCs more efficiently and with a greater degree of equity across the local economy Ecology believes this additional information will contribute to better policy decisions regarding CHCCs in future.

Public Confidence and Government Transparency

With a comprehensive CSPA reporting rule in place, understanding of CHCC content in children's products in Washington State is likely to hold more public confidence. This is probable not only for the CHCC tiers or values themselves, but for any future regulatory actions taken to reduce children's exposure to CHCCs. Increased public confidence in the quality and the scope of reported numbers increases the likelihood the public will more fully understand any specific regulatory actions, why they are taken, and how they affect the local economy, as well as be able to participate from a more informed standpoint in the process.

Credibility, Consumer Behavior, and Investment

Ecology expects the incremental information the actions prompted by the proposed rule to benefit consumers by allowing them to make more efficient consumption choices relative to their preferences. This reduces uncertainty for consumers that include childhood toxicity information in their purchasing decisions. The combination of increased knowledge about CHCC content in children's products, and increased confidence in the scope and accuracy of the information will benefit consumers' ability to behave in line with their full set of preferences. It is also likely to reduce the costs of misinformation or uncertainty related to the content of children's products, which may lead to a reduction in consumer search times, and a reduction in consumer avoidance of products that are not actually considered harmful in a CSPA context.

The CHCC content information may also benefit investors' ability to make financial decisions based on expected benefits and risks to manufacturers of children's products, depending on

CHCC content and other firm attributes, as relates to elements such as risk of liability and recalls.

Economies of Scale in Manufacturing

For those manufacturers operating in multiple markets – interstate or internationally – in addition to Washington State, the proposed rule may offer the benefit of economies of scale in production. This means, instead of producing children’s products to suit the regulations of multiple markets, a manufacturer may find it beneficial to use information discovered in the CHCC reporting process to produce a homogeneous good across all markets. This may reduce production costs for some manufacturers.

Greater understanding of distribution of CHCCs in Washington Children’s Products

Ecology expects the public, regulatory agencies, and business to benefit from a greater knowledge specifically of the local economy and its relationship to CHCC content in children’s products. For all three points of view – public, policy, and business – the proposed rule offers opportunity for Washington-specific improvements and efficiencies in:

- Policy planning and creation
- Public relations
- Consumer purchasing
- Investment behavior
- Children’s health
- Avoided litigation

Ecology expects the proposed rule to increase transparent, credible information in all of these interactions between the public, policy, and businesses – opening the possibility for benefits accruing to one or more of these groups, and benefiting Washington as a whole.

Avoided Litigation and Likelihood of Health Impacts

Ecology expects the proposed rule, through better manufacturer and importer understanding of product content, to reduce both the likelihood of health impacts from children’s products, and the likelihood of litigation resulting from harm to children. Ecology points out, however, that the presence of a chemical does not establish that there will be harm to a child, nor that the reporting ranges are indicative of prospective known harm or liability.

Ecology could not confidently estimate the degree to which these reductions might occur, due to the unknown degree to which products under current rule would cause harm to children, if any, and the associated lawsuits that might be expected. Ecology did, however, estimate the range of costs that might be avoided per lawsuit, to compare the range of reductions that would partially or fully mitigate estimated quantified costs.

Quantified Benefits of Ecology's Proposed Rule

In absence of a current rule, Ecology based conservatively low quantitative estimates of avoided costs of recall, litigation, or other violation of the proposed rule on the federal CPSIA rule's caps on civil damages for knowing violations.

Under the current federal rule, the caps are:

- \$100 thousand for knowing violations
- \$15 million for related series of violations

Ecology could not confidently estimate the degree to which these violations (possibly resulting in recalls, litigation, or children's health impacts under the baseline) would occur, and so compared the per-instance avoided costs to the total estimated costs of reporting under the proposed rule. Ecology calculated relative costs and benefits based on the midpoint value of this avoided cost range, of \$7.55 million per instance, as well. These values account for the loss of court cases, and do not include the inherent costs of litigation incurred regardless of outcome.

In relative terms, at the low end of the avoided costs range, it would take at least 4.5 thousand avoided cases of CHCC content resulting in recalls, litigation, or children's health impacts of a minor degree. This is over 20 years, or about 220 instances.

At the midpoint of the range, more likely accounting for both possibilities of litigation and the cost of unsold products, it would take at least 6 avoided cases of CHCC content resulting in recalls, litigation, or children's health impacts of a minor degree. Over 20 years, this is about a 33 percent reduction in the likelihood of any such case.

At the high end of the range of possible per-instance avoided costs (likely representing worst-case scenarios of large impact), it would take at least 3 avoided cases of CHCC content resulting in recalls, litigation, or children's health impacts of a minor degree. Over 20 years, this is about a 15 percent reduction in the likelihood of any such case.

Chapter 5: Conclusion

The Washington State Department of Ecology (Ecology) is proposing a rule to require reporting of CHCCs in children’s products sold in Washington State.

The Administrative Procedure Act (Chapter 34.05 RCW) requires that, before adopting a significant legislative rule, Ecology must, “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.” [RCW 34.05.328(1)(c)]

For Ecology’s proposed rule, *Chapter 173-334 WAC – Children’s Safe Products – Reporting Rule*, this means Ecology must estimate the impacts of the proposed rule on individuals, businesses and the public. Impacts are determined by comparing the expected regulatory environment in the absence of Ecology’s proposed rule, to the way CHCC content reporting will occur under the proposed rule.

Ecology analyzed the impacts of the proposed rule relative to the current absence of a rule, excepting from analysis those elements of the rule that were dictated by the law, and over which Ecology did not have discretion.

Ecology has analyzed the ranges of quantifiable impacts, as well as many likely qualitative impacts, relative to the baseline. Based on its analysis, Ecology has determined the likely benefits of the proposed rule exceed the likely costs, accounting for both quantified and qualitative impacts.

Costs and Benefits of Ecology’s Proposed Rule	
Annualized Costs millions of \$/year	Benefits
Testing costs: \$44.7 – 69.5 million	<ul style="list-style-type: none"> • Creation of a comprehensive database. • Public confidence and government transparency. • Credibility, consumer behavior, and investment. • Economies of scale in manufacturing. • Greater understanding of the distribution of CHCCs in Washington’s children’s products and economy. • Avoided children’s health impacts • Recall or litigation costs, related to \$100 thousand – \$15 million in costs per recall or lawsuit.

Chapter 6: Least Burdensome Alternative Analysis

Introduction

RCW 34.05.328(1)(e) requires Ecology to “determine, 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.”

Determination

Based on research and analysis required by RCW 34.05.328(1)(e) the Department of Ecology determines:

There is sufficient evidence the rule is the least burdensome version of the rule for those who are required to comply, given the goals and objectives of the law, for Ecology to propose the rule.

General Goals and Specific Objectives of the Authorizing Statutes

Ecology believes the authorizing law bears the general goal of understanding CHCC content in children’s products used in Washington State. A specific objective is the institution of a comprehensive reporting system of CHCC content in children’s products, that will inform not only current understanding of the presence of these chemicals, but also adequately inform future government or private sector action on addressing or reducing risks to children’s health. Other objectives include the inclusion of only CHCCs with specific characteristics delineated by statute, and

Alternative Rule Content Considered

Use detection limit as the reporting trigger value

Ecology expects this option to increase the frequency of testing, increase testing costs at lower levels, and increase the number of reporters. This option is not less burdensome than the content of the proposed rule.

Use a risk assessment to determine the trigger value

While the data collected by the reporting requirements will help inform which components and chemicals may need further attention, this law has always been a reporting law, not a certification of safety of a certain chemical in a particular product. Doing so would not meet a specific requirement in the authorizing statute.

Do not phase in the reporting requirement

Ecology expects this option to place a higher burden on entities required to comply with the proposed rule. This option is not less burdensome than the content of the proposed rule.

Require reporting on an individual SKU basis.

Ecology expects this option to place a higher reporting burden than the brick-level categorical reporting, as businesses would have to further subdivide their product lines to

determine the status and degree of compliance, and what to report. This option is not less burdensome than the content of the proposed rule.

Make the reporting list of chemicals longer.

A longer chemical list would increase the likelihood of more chemicals requiring monitoring, testing, or reporting by a representative business. This option is not less burdensome than the content of the proposed rule.

Make the reporting list of chemicals shorter.

All of the chemicals on the list of CHCCs in the proposed rule meet the criteria defined by the authorizing law. Reducing the list below these chemicals would not meet a specific requirement in the authorizing law.

Set a specific reporting date for chemicals in the internal components.

Some wanted a reporting schedule to be set in the rule for internal components, but it was determine that for internal components it made more sense to set the schedule on a product by product basis based on the likelihood of the child being able to access such components. Doing so would not meet a specific requirement in the authorizing statute.

Leave internal components out of the rule.

Some felt that internal components should be left out of the rule as the manufacturer never intended for the child to have access to such components. It was determine that in some cases the manufacture may not of taken adequate steps to prevent a child from accessing such components. Doing so would not meet a specific requirement in the authorizing statute.

Limit the list of reporting chemicals to those which have been proven to cause harm at the reporting concentrations.

All of the chemicals on the list of CHCCs in the proposed rule meet the criteria defined by the authorizing law. Reducing the list below these chemicals would not meet a specific requirement in the authorizing law.

Use leachable values not total for reporting chemicals.

Some felt that the total amount of the chemical would provide data that would not correlate with the possible impact the chemical could have. But as the law uses the term ‘presence’ in describing what needs to be reported the agency determined that the total amount needs to be reported. Doing so would not meet a specific requirement in the authorizing statute.

Include lead, and all the phthalates on the reporting list.

Lead and phthalate content is already restricted under the authorizing law. Ecology does not believe the additional burden of reporting for these chemicals generates information necessitated by the authorizing law. This option is not less burdensome than the content of the proposed rule.

Exempt those companies who already report to the FDA.

Some felt that as they are already regulated by the FDA they should not be subject to state specific requirements. Doing so would not meet a specific requirement in the authorizing statute.

Limit the list of reporting chemicals and the trigger amounts to those in the REACH program.

All of the chemicals on the list of CHCCs in the proposed rule meet the criteria defined by the authorizing law. Reducing the list below these chemicals would not meet a specific requirement in the authorizing law.

Limit the reporting ranges to existing health based numbers

While the data collected by the reporting requirements will help inform which components and chemicals may need further attention, this law has always been a reporting law, not a certification of safety of a certain chemical in a particular product. Doing so would not meet a specific requirement in the authorizing statute.

Put enforcement provisions for the limits on Lead, Cadmium, and Phthalates in the rule.

Lead and phthalate content is already restricted under the authorizing law. Ecology does not believe additional enforcement burden for these chemicals generates information required by the authorizing law. This option is not less burdensome than the content of the proposed rule.

Prove harmful exposure to establish what products and chemicals require reporting.

All of the chemicals on the list of CHCCs in the proposed rule meet the criteria defined by the authorizing law. Reducing the list below these chemicals would not meet a specific requirement in the authorizing law.

Provide a detail list of all the products the rule applies to.

Such a list would require difficult (or impossible) to comprehensively acquire, proprietary information. Developing such a list, and complying with it, would place additional burden on those entities providing this information. Ecology believes the authorizing law does not justify this additional burden and risk, and that the state can meet the goals of the law without the creation of such a list.

Provide a detail list of all the components the rule applies to.

Such a list would require difficult (or impossible) to comprehensively acquire, proprietary information. Developing such a list, and complying with it, would place additional burden on those entities providing this information. Ecology believes the authorizing law does not justify this additional burden and risk and that the state can meet the goals of the law without the creation of such a list.

Limit the list to chemicals which have been found in children's products.

The authorizing statute dictates that the list of CHCCs in the proposed rule include those:

- Found through biomonitoring studies that demonstrate the presence of the chemical in human umbilical cord blood, human breast milk, human urine, or other bodily tissues or fluids.
- Found through sampling and analysis to be present in household dust, indoor air, drinking water, or elsewhere in the home environment.
- Added to or is present in a consumer product used or present in the home.

All of the chemicals on the list of CHCCs in the proposed rule meet the criteria defined by the authorizing law. Reducing the list below these chemicals would not meet a specific requirement in the authorizing law.

Require that the report includes sales figures.

Ecology believes this additional reporting burden is not allowed by the authorizing law, and is not necessary to fulfill the statute's objective of comprehensive but appropriate reporting.

The number of reporting ranges should be increased.

Increasing the number of ranges would require smaller ranges, and thereby place additional burden on those required to comply with the proposed rule. Ecology believes this additional burden is not necessary to meet the goals and objectives of the authorizing law.

The number of reporting ranges should be reduced.

Reducing the number of reporting ranges would mean expanding the size of each range, or raising the lowest reporting quantity of CHCCs. The former option is not specific enough, and the latter option excludes too significant concentrations of CHCCs, to meet the goal of comprehensive and informative reporting.

Contamination should be exempt from consideration when reporting.

The issue at hand is the CHCC content of children's products, with the intent of collecting comprehensive and correct information on the quantity of CHCCs. The origin of such content is not relevant to meeting this goal, and exemption of some of this content would specifically fail to meet this goal.

Establish a more refined process on how chemicals will be added or removed from the reporting list.

The process in the rule follows those requirement established by the law so it was decided that there was no need to attempt to further clarify this process.

Establish de minimis values on a chemical by chemical basis.

While the data collected by the reporting requirements will help inform which components and chemicals may need further attention, this law has always been a reporting law, not a certification of safety of a certain chemical in a particular product. Doing so would not meet a specific requirement in the authorizing statute.

Put the process used to select the reporting list of chemicals in the rule.

The process used to select the reporting list under the authorizing law is immaterial to the proposed rule and procedures. The criteria for inclusion are also delineated by the authorizing law. A discussion of the CHCC selection process is available to the public in Ecology's report to the Legislature on that subject.⁶

Gross sales should not be used to establish a reporting schedule.

Gross sales are a proxy for both manufacturer or importer size, and the amount of CHCC-containing product produced by reporters. Ecology believes using an alternate measure of business size to determine the reporting schedule would place more burden on small businesses that are less likely to have mitigating cost factors. Ecology also understands the definitions to be broad enough that their reporting does not release a significant degree of business information (a degree that may affect business practices and competition).

The upstream supplier should be the one that has to report.

Reporting by the upstream supplier is both a shift of burden (reduction in one area, but increase in another), and logistically difficult to enforce for suppliers not selling or importing directly to Washington State.

Ecology would have difficulty receiving or enforcing requirements under the proposed rule on businesses that do not directly operate in the state. (This is especially true in the case of single suppliers supplying multiple manufacturers in multiple markets; they supply inputs, but do not necessarily know what the final products are.) This, in turn, would reduce the comprehensiveness of the reporting under the proposed rule, and may fail to meet the goal of the authorizing law to have a successful reporting system.

Those businesses covered by the proposed rule are welcome to measure and report the CHCC content of their products using supply-chain knowledge and relevant business practices. If it is available from the supplier, a manufacturer may use supplier-based CHCC content information in its report to Ecology.

If a chemical is on a product label it should not need to be reported to Ecology.

All of the chemicals on the list of CHCCs in the proposed rule meet the criteria defined by the authorizing law. Reducing the list below these chemicals would not meet a specific requirement in the authorizing law. Ecology does not have the authority to exclude chemicals from this list that meet the requirements of the authorizing law, regardless of where else they appear.

Initially use a higher reporting trigger, and lower this value over time.

Phasing in the reporting trigger would reduce burden on reporters in the short run, but would come with the additional costs of adjusting CHCC-measuring procedures or testing over time, as the reporting trigger fell. Ecology instead phased in the reporting schedule under the

⁶ Washington State Department of Ecology (2009). Children's Safe Product Act Report. Ecology publication number 09-07-014. <http://www.ecy.wa.gov/biblio/0907014.html>

proposed rule, allowing additional time for most businesses to report for the first time, without incurring the costly adjustment costs of changing measurement or testing procedures.

The report should have enough information so that the consumer can decide what to buy.

A level of information fully describing to a consumer what to buy and what not to buy, presumably based on health-risk preferences, is not authorized under the proposed rule. This option would also be more burdensome for those required to comply with it.

Penalties should be calculated on a unit by unit basis.

This option would place additional burden on those required to comply with the proposed rule.

Appendix A: Changes under the Proposed Rule

WAC 173-334 CSPA Reporting Rule	What the requirement means	Analysis
WAC 173-334-010 Introduction	-	none
WAC 173-334-020 What is the purpose of this chapter?	-	none
WAC 173-334-030 To whom does this chapter apply?	-	none
WAC 173-334-040 What definitions apply to terms used in this chapter?	-	none
WAC 173-334-050 What is the purpose of the CHCC list?	-	none
WAC 173-334-060 What schedule will the department follow to revise the CHCC list?	Applies to Ecology	none
WAC 173-334-070 How will the department identify chemicals for inclusion in the CHCC list?	Applies to Ecology	none
WAC 173-334-080 How will the department decide to remove a chemical from the reporting list?	Applies to Ecology	none
WAC 173-334-090 What must the manufacturer include in its notice to the department?		
(1) The notice required by RCW 70.240.040 must be filed annually with the department for each CHCC by product category and component. The notice must include all of the following information:		Explicitly dictated in authorizing statute
(a) The name of the CHCC and its chemical abstracts service registry number.		Explicitly dictated in authorizing statute
(b) The product category or categories in which it occurs.		Explicitly dictated in authorizing statute
(c) The product component or components within each product category in which it occurs.		
(d) A brief description of the function, if any, of the CHCC in each product component within each product category.		Explicitly dictated in authorizing statute

<p>(e) The total amount of the CHCC by weight contained in each product component within each product category. The amount may be reported in ranges, rather than the exact amount. If there are multiple CHCC values for a given component in a particular product category, the manufacturer must use the largest value for reporting.</p> <p>For the purpose of this rule, the reporting ranges are as follows:</p> <ul style="list-style-type: none"> (i) equal to or more than 40 ppm (0.004 %) but less than 200 ppm (0.02%), (ii) equal to or more than 200 ppm (0.02%) but less than 1000 ppm (0.1%), (iii) equal to or more than 1000 ppm (0.1) but less than 10,000 ppm (1.0%), (iv) equal to or more than 10,000 ppm (1.0%) but less than 100,000 ppm (10%), or (v) equal to or more than 100,000 ppm (10%). 	<p>This reporting is explicitly dictated in the authorizing statute (Chapter 70.240 RCW – Children’s Safe Products).</p> <p>The rule creates no specific requirements on how a manufacturer determines if they need to file a report. But normal manufacturing practices can include contract specifications, quality control mechanisms, and/or testing protocols to determine the amount of a chemical in product materials. These procedures are already necessary for manufacturers who must comply with Washington’s toxics in packaging law (Chapter 70.95G RCW – Toxics in Packaging).</p> <p>Manufacturers must have procedures in place in order to test for lead, cadmium, and several varieties of phthalates under the federal Consumer Product Safety Improvement Act of 2008 (CPSIA). Some chemicals are restricted in cosmetic products under FDA regulations.</p> <p>The new regulation will require companies to determine if they need to report on an expanded list of chemicals than currently required.</p>	
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<p>(e) The name and address of the reporting manufacturer or trade organization and the name, address and phone number of the contact person for the reporting manufacturer or trade organization. When a trade organization is the reporting party, the report must include a list of the manufacturers on whose behalf the trade organization is reporting, and all of the information that would otherwise be required of the individual manufacturers.</p>		<p>Explicitly dictated in authorizing statute</p>
<p>(f) Any other information the manufacturer deems relevant to the appropriate use of the product.</p>		<p>Explicitly dictated in authorizing statute</p>
<p>WAC 173-334-100 Who is required to provide notice to the department?</p>	<p>-</p>	<p>Explicitly dictated in authorizing statute</p>
<p>WAC 173-334-110 How often must notice be given?</p>		<p>Explicitly dictated in authorizing statute</p>
<p>WAC 173-334-120 When must manufacturers begin to provide notice?</p>		
<p>(1) This section establishes when manufacturers must first provide notice to the department if a children’s product contains a chemical on the CHCC list. The CSPA notice requirement will be phased-in as provided in the schedule set out in subsection (2) based on the manufacturer categories and children’s product tiers established in subsections (3) and (4). Manufacturers conducting safer alternative assessments for CHCCs may obtain an extension of the first notice date as provided in subsection (5). After the first notice date, notice must be provided annually on the anniversary of the first notice.</p>	<p>-</p>	

(2) The following table specifies when the first annual notice must be provided to the department in compliance with RCW 70.240.040. The due date will be determined by counting the number of months specified in the table, beginning with the first calendar month following the calendar month in which this rule goes into effect. The notice will be considered delinquent if not received by the department by the first day of the month indicated.

Notice due dates from adoption date of rule, values are in months.

Manufacturer categories	Product Tier 1	Product Tier 2	Product Tier 3	Product Tier 4
Largest	12	18	24	case by case
Larger	18	24	36	case by case
Middle	24	36	48	case by case
Smaller	36	48	60	case by case
Small	48	60	72	case by case
Tiny	60	72	84	case by case

A phased in approach is being used to both allow an efficient use of agency resources and to give businesses time to develop systems to lessen the burden of reporting. Larger companies with greatest pre-existing capacity to conduct activities necessary for reporting report earlier than smaller manufacturers.

WAC 173-334-130 How will this chapter be enforced?

(1) A manufacturer of children’s products is responsible for knowing the amount of CHCCs in its children’s products and their components. To control the amount of any chemical present in its final children’s product the manufacturer has a duty to establish and conduct a reasonable manufacturing control program. At a minimum, a reasonable manufacturing control program would include those methods and procedures established in federal regulations for children's products and recognized industry best manufacturing practices, e.g., compliance with relevant International Standards Organization (ISO) requirements, ASTM (American Society for Testing and Materials) standards, or other widely established certification or standards programs.

Manufacturers are expected to conduct a manufacturing control program that is equivalent to widely established certification or standards programs. Many manufacturers already comply with these programs.

<p>(2) In deciding whether to impose penalties for failure to provide appropriate notice as described in sections 9 through 12 of this regulation, the department may consider whether the manufacturer responsible for providing notice has exercised diligence to ensure it knows the amount of the CHCCs in its children's product components. Actions demonstrating diligence may include the use and enforcement of contract specifications, procedures to ensure the quality/purity of feedstock (whether raw or recycled), the use and enforcement of contract specifications for manufacturing process parameters (e.g., drying and curing times when relevant to the presence of high priority chemicals in the finished children's product components), periodic testing for the presence and amount of CHCCs, auditing of contractor or supplier manufacturing processes, and other practices reasonably designed to ensure the manufacturer's knowledge of the presence, use, and amount of CHCCs in its children's product components.</p>	<p>Manufacturers are expected to conduct a manufacturing control program that is equivalent to widely established certification or standards programs. Many manufacturers already comply with these programs.</p>	
<p>(3) A manufacturer of children's products in violation of this chapter is subject to a civil penalty not to exceed five thousand dollars for each violation in the case of a first offense. Manufacturers who are repeat violators are subject to a civil penalty not to exceed ten thousand dollars for each repeat offense. Penalties collected under this section must be deposited in the state toxics control account created in RCW 70.105D.070.</p>		<p>Explicitly dictated in authorizing statute</p>
<p>(4) The department may collect children's products subject to possible reporting, and analyze their components for the presence of CHCCs. If the department finds that a children's product component contains a chemical on the CHCC list in an amount above the amount reported by the manufacturer or that the manufacturer has otherwise failed to provide appropriate notice as described in sections 9 through 12 of this regulation, the department will inform the manufacturer in writing. The manufacturer shall have 45 days from receipt of the department's notification of potential violation to further analyze the components in question for presence of CHCCs or to provide an explanation for the omission. If the manufacturer fails to demonstrate that it exercised diligence to ensure it knowledge of the presence of the CHCC in its product, then the department may issue a penalty to the manufacturer, in accordance with RCW 43.21B.300.</p>	<p>Applies to Ecology</p>	

Appendix B: Interstate Children’s Products Regulations

State Chemical Reporting Requirements							
State	Statute / Regulation / Agreement	Chemical(s)	Product(s)	Who is Required to Report	Statutory/Regulatory Trigger for Reporting	Reporting Requirements/Data Expected	Ability to be Shared
California	Cal. Health & Safety Code § 25251-25257.1 (A.B. 1879)	?	?	?	?	Requires the Department of Toxic Substances Control (DTSC) to develop regulations, by January 1, 2011, that create a process for identifying chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern.	Department must maintain confidentiality of information identified as a trade secret at the time of submission. Does not prohibit the exchange of a trade secret between public agencies provided that confidentiality is maintained. Information not identified as a trade secret available to the public. Establishes a procedure for responding to requests for the release of information claimed as trade secret.

Cal. Health & Safety Code §§ 111791-111793.5	Chemicals known or suspected to cause cancer, birth defects, or other reproductive harm (list of 785 chemicals)	Cosmetics (as defined by US FDA)	Manufacturer, packer, and/or distributor named on label of product [for companies making ≥ \$1 million dollars in aggregate sales of cosmetic products within and outside of CA]	As of January 1, 2007, required to report if product contains any ingredient that is a chemical listed by CDPH.	<u>Chemical Use Reporting</u> Report list of cosmetic products containing a listed chemical.	Provides companies an opportunity to claim information as confidential. CDPH will not make confidential information available to the public unless the outcome of an official investigation deems the information is not confidential.
Information Sharing Agreement between Danish EPA and CalEPA	?	?	N/A	N/A	Areas of cooperation include exchange of information, experience, and best practices and the provision of technical support on chemical exposure from consumer articles (products).	CalEPA and the Danish EPA may invite additional organizations within their own jurisdictions to participate, at their own expense and subject to such terms and conditions as may be specified, in cooperative activities under the agreement.