



DEPARTMENT OF
ECOLOGY
State of Washington

Concise Explanatory Statement
Chapter 173-334 WAC
Children's Safe Products – Reporting Rule

Summary of rule making and response to comments

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Concise Explanatory Statement

Chapter 173-334 WAC Children's Safe Products - Reporting Rule

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Introduction

The purpose of a Concise Explanatory Statement is to:

- Meet the Administrative Procedure Act (APA) requirements for agencies to prepare a Concise Explanatory Statement (RCW 34.05.325).
- Provide reasons for adopting the rule.
- Describe any differences between the proposed rule and the adopted rule.
- Provide Ecology's response to public comments.

This Concise Explanatory Statement provides information on The Washington State Department of Ecology's (Ecology) rule adoption for:

Title: Children's Safe Products – Reporting Act
WAC Chapter(s): 173-334
Adopted date: July 21st, 2011
Effective date: August 21st, 2011

To see more information related to this rule making or other Ecology rule makings please visit our web site: www.ecy.wa.gov/lawsandrules

Reasons for Adopting the Rule

The purpose of the proposed rule is to implement the reporting requirements of the Children's Safe Product Act (RCW 70.240).

The statutory authority for developing this rule is from the Children's Safe Products Act RCW 70.240. This law states that Ecology may adopt rules as necessary for the purpose of implementing, administering, and enforcing it. In addition, an assistant attorney general has reviewed the statute and concluded that there is sufficient ambiguity in the law to justify rule making.

The rule is designed to collect information that will help government and the public better understand the presence of chemicals in children's products. It requires manufacturers of children's products to report if their products contain certain chemicals.

Differences Between the Proposed Rule and Adopted Rule

RCW 34.05.325(6)(b)(ii) requires Ecology to describe the differences between the text of the proposed rule as published in the *Washington State Register* and the text of the rule as adopted, other than editing changes, stating the reasons for the differences.

There are some differences between the proposed rule filed on May 4, 2011 and the adopted rule filed on July 21, 2011. Ecology made these changes for all or some of the following reasons:

- In response to comments we received.
- To ensure clarity and consistency.
- To meet the intent of the authorizing statute.

No substantial changes were made to the proposed rule file on May 4, 2011. The sections listed below were changed. Below each section is an explanation of why the change was made. The wording also shows how the proposed rule filed on May 4, 2011 and the adopted rule differ. New text is underlined. Deleted text has a line through it. All other sections of the rule were not changed.

WAC 173-334-080 (1)b: The formatting of this section was changed for clarity.

(b) Each chemical on the CHCC list that is a contaminant present in a product component must be reported at any concentration above 100 ppm. A manufacturer need not file a notice with respect to any CHCC that occurs in a product component only as a contaminant if the manufacturer had in place a manufacturing control program and exercised due diligence to minimize the presence of the contaminant in the component.

~~— (c) A manufacturer need not file a notice with respect to any CHCC that occurs in a product component only as a contaminant if the manufacturer had in place a manufacturing control program and exercised due diligence to minimize the presence of the contaminant in the component.~~

WAC 173-334-090 (2)a: Reference to the entity that had the children's product "designed" was deleted to better correspond with the definitions in RCW 70.240.

(a) The person or entity that had the children's product ~~designed~~ ~~or~~ manufactured, unless it has no presence in the United States.

WAC 173-334-110: The wording of this section was changed for clarity and to remove the safer alternative option.

When must manufacturers begin to provide notice? (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 notice requirement will be phased in as provided in the schedule set out in subsection (2) of this section based on the manufacturer categories and children's product tiers established in subsections (3) and (4) of this section. ~~Manufacturers conducting safer alternative assessments for CHCCs may obtain an extension of the first notice date as provided in subsection (5) of this section.~~ After the first notice date, notice must be provided annually on the anniversary of the first notice.

(d) Tier 4 - children's product components that during ~~reasonable~~ reasonably foreseeable use and abuse of the product would not come into direct contact with the child's skin or mouth (e.g., inaccessible internal components for all children's products). ~~Any reporting~~ Reporting requirements for Tier 4 components will ~~not be based on a case by case~~ required, except by amendment of this rule, based on a case-by-case evaluation by the department. ~~evaluation by the department and may be required by amendment of these rules.~~

~~(5) If a manufacturer presents documentation to show that it is conducting safer alternative assessments for CHCCs contained in its children's products and that these assessments are intended to result in the elimination or significant reduction of CHCCs from the manufacturer's products, the department may extend by twelve months the reporting requirement for that manufacturer.~~

WAC 173-334-120 (1): A reference was changed in this section to correspond with the change to WAC 173-334-080 (1)b.

(1) 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 that the manufacturer either has not reported, or has reported at a lesser amount, the department will notify the manufacturer in writing. The department will then afford the manufacturer forty-five days from receipt of the department's notification to respond to the findings before the department takes further enforcement action.

In determining whether a violation of the CSPA or these rules has occurred, the department will consider the manufacturer's timely explanation as to why it did not report the presence or accurate amount of the CHCC in the product component. If the manufacturer asserts that the CHCC is present in the component only as a contaminant, and that the manufacturer did not report

the CHCC's presence based on WAC 173-334-080 (1)(~~e~~-b), then the manufacturer must present evidence that it conducted a reasonable manufacturing control program for the CHCC contaminant and exercised due diligence as described in subsections (2) and (3) of this section.

If the manufacturer contests the department's findings regarding the presence or amount of the CHCC in the product component, the manufacturer may further analyze the component in question for presence of CHCC and provide the department with a copy of its own laboratory findings for the component.

Response to Comments

The responses are organized by topic. Each response indicates how the final rule reflects agency consideration of the comments received.

Description of comments

Ecology has summarized and organized the comments by topic. If several comments made from multiple parties were related and on the same topic, one response was made. The index summarizes those issues each party commented on. Responses are directly below each comment.

All of the complete comments (and any attachments) in appendix A were received by the agency during the formal comment period, and have not been edited in any way. Appendix A contains the written comments and a transcript of the comments made during the public hearing. The index provided in Appendix A provides the specific page number in the appendix for each commenter. In the few cases where an individual submitted both written and verbal comments during the public hearing, two page numbers are provided. Those page numbers with the prefix “PH” reference the comments made during the public hearing. The entries in the index are sorted by the commenter’s last name.

Ecology also provided an opportunity for public comment on an earlier version of the proposed rule between October 22nd, 2010 and January 7th, 2011. The comments received on the first proposed rule are not responded to in this document. However, since many of the comments from this earlier period are still relevant these comments and our response to them are included in Appendix B.

Comments and Response by Topic

Ecology accepted comments on the supplemental proposed rule May 4, 2011 through June 15, 2011. If several comments made from multiple parties were related and on the same topic, one response was made. The summarized comments are organized by topic. (RCW 34.05.325(6)(a)(iii)). The next section provides summarized comments that we received during the public comment period and our responses. Additionally an index has been provided that shows which issue(s) each party commented on.

Children’s Safe Product Act – Reporting Rule: Summary and Response to Public Comment on Supplemental Rule Proposal

Below is a summary of the comments received on the supplemental proposed rule. Because many commenters had similar concerns about the rule, we’ve paraphrased the comments and listed who the specific commenter was in parentheses, followed by our response. A list of commenters and the associated abbreviation can be found in the index on page 24 of this document.

Appendix A has the original written comments and public hearing transcript from this comment period. Appendix B has both the written comments, the agency’s response and the public hearing transcript from the first public comment period (October 22, 2010 to January 7, 2011).

1) Reported information

Manufacturers should be required to report information on each individual product; the ‘brick’ approach does not provide specific enough detail so that consumers can tell which products contain chemicals of high concern for children. (WTC, EM, 37 PC, T-WTC, T-EM, T-PC, T-LWV)

Agency Response

Ecology understands the desire of consumers to know what is in the products they buy. However the sheer number of products and chemicals is such that consumers would have to search hundreds of thousands – even millions – of records in order to compare the ranges of chemicals present in products. Even then, they would not know which products are least harmful unless they also know what the potential for exposure is from each product. The proposed rule will instead provide new information that will help the agency focus our attention on those product categories or product components that are most likely to cause harm. For example, if a sippy cup contains a chemical of concern on the rim of the cup, the potential for exposure is much different than if the chemical was only present on the bottom of the cup. And if the chemical in the component used in the rim is replaced with a safer alternative, every other product made with that component will also pose less risk. Ecology considered both approaches and determined that it was not practical to require product specific reporting and that such an approach would preclude the opportunity to reach into the supply chain in order to impact many products at the same time. The data will be used to target product categories and components that use the most CHCCs.

The level of reporting was not changed in the current version of the rule.

2) Definition of “mouthable”

The scope of what is mouthable needs to be reduced. (AAFA)
Reporting on products for children three and under should not be limited to ‘mouthable’ products. (WTC, T-EM, T-WTC, T-PC, T-LWV, 37 PC)

Agency Response

The first version of the rule specified that all products for children 3 or under would fall into the tier 1 category, and therefore need to be reported on first. The purpose was to first collect information on products that that very young children will likely put in their mouths even if the product is not designed for that use.

The definition of mouthable was added to the second draft of the rule to clarify the agency's position on which products are included in tier 1. Our intent was to address those products that would have a greater potential for exposure through the mouth. The specific wording for this definition is as follows:

"Mouthable" means able to be brought to the mouth and kept in the mouth by a child so that it can be sucked and chewed. If the product can only be licked, it is not able to be placed in the mouth. If a product or part of a product in one dimension is smaller than five centimeters, it can be placed in the mouth.

Under this definition all products or products with a part that is less than five centimeters (about 2 inches) in any one dimension is mouthable and, as such, falls into the tier 1 product category. The following examples should clarify what this means in terms of reporting obligations.

Some products that would be mouthable by definition include:

- All clothing.
- All blankets, sheets, etc.
- A high chair where the legs are five centimeters (about 2 inches) or less in diameter.
- A car seat that has a buckle, strap, etc., which is five centimeters (about 2 inches) or less in any dimension.
- A swing set that includes chains that are five centimeters (about 2 inches) or less in any dimension.

An example of a product that would not be mouthable would be a 8 inch toy ball, because in the worst case, the most a child could do is lick it.

The "mouthable" criteria was not changed in the current version of the rule.

3) Reporting on the presence of contaminants

Remove the current option of not reporting contaminants in those cases where the manufacturer can prove to the agency that it both has and implements a manufacturing control program that keeps any contaminants as low as reasonably possible. (WTC, 37 PC, T-EM, T-LWV, T-WTC, T-PC)

Agency Response

The agency appreciates that when a child is exposed to a chemical of concern, the child's body does not distinguish between a chemical that was intentionally added and one that is present as a contaminant. However, in order to move away from using chemicals of concern it is critical to move toward chemicals that are less problematic. And central to assessing alternatives is understanding the function the chemical of concern has in the product. We assume that contaminants do not serve a function, per se, in the product and therefore are not amenable to a safer alternatives assessment. Therefore, we distinguish between those chemicals that serve a function and those that don't in order to encourage manufacturers to search for safer alternatives.

Also, it is the responsibility of manufacturers to keep the level of any contaminant present in a product as low as reasonably possible and some manufacturers have invested heavily in developing programs to do so. The current reporting triggers for contaminants are intended to encourage and even reward those companies who are taking the lead in having effective manufacturing control programs. In addition, if a manufacturer cites a “manufacturing control program” as the reason for not reporting a contaminant, they must provide Ecology adequate evidence that such a program existed and was being effectively implemented.

The contaminant reporting criteria was not changed in the current version of the rule.

4) Reporting List of chemicals of high concern for children

Chemicals need to be added to the list, specifically:

- Lead (T-KC).
- Tris(1,3-dichloroisopropyl) phosphate, also known as TDCPP or chlorinated Tris, CAS # 13674-87-8 (WTC, T-WTC).
- 2-ethylhexyl-2,3,4,5-tetrabromobenzoate, also known as TBPH, CAS #26040-51-7 (WTC).

Agency Response

The agency originally started with a list of thousands of potential chemicals for the reporting list. In consideration of the associated workload for the agency and the regulated community for each chemical on the list, the Governor directed the agency to identify “about 50” CHCCs for the rule . . . While we know that there are literally thousands of chemicals whose presence in products is unknown by the public, we also know that there is a limit to how many we can handle with our limited resources.

All of the chemicals on the reporting list meet both the hazard and potential for exposure criteria established in the law. The specific justifications for each chemical on the reporting list can be found [on the department’s website](#).

No additional chemicals were added to the reporting list of chemicals.

The list is way too long. (AWB)

Chemicals need to be removed from the list; specifically:

- Hexabromocyclododecane (EPS)
- Bisphenol A (ACC)
- Parabens (PCPC, AWB)
- Phthalates (ACC, TIA, TCC, CSPA FJATA, AEA, 1PC, WRA)
- Phenols (ACC)
- N-Butanol (ACC)
- Vinyl Chloride (ACC)
- Antimony (FJTA)
- Cadmium (FJTA)

Agency Response

The agency believes all of the chemicals on the reporting list meet both the hazard and potential for exposure criteria established in the law. The specific justifications for each chemical on the reporting list can be found [on the department's website](#).

Agency Response Regarding Hexabromocyclododecane (HBCD)

We understand that EPA has a chemical action plan for HBCD, and that as part of this plan a safer alternative assessment is being performed. However, the CSPA reporting requirement does not conflict with or duplicate this effort. Information on uses that could come from reports under the reporting rule could prove useful performing the alternative assessment.

No chemicals were removed from the reporting list of chemicals.

5) Products covered by the rule

To insure a level playing field the scope of products need to be very clear, the current guidance needs additional information. (P&G)

How will products sold from outside Washington State via mail order or the internet be handled? (AAFA)

Which tier do products fall into if they are 'mixed' i.e. if a costume has both face paint and a cape, does the face paint mean this product is a Tier 1 product? (WM)

Agency Response

Similar issues were raised during the first round of comments. In response, the agency drafted guidance to help clarify when and how manufacturers comply with the reporting requirements. This draft guidance includes a description and associated numeric code for all the product categories covered by the rule.

Based on the above additional comments we have added examples and clarifying language to the draft guidance. But, no change was made to the rule.

We continue to welcome specific suggestions on how to make the guidance clearer. ([see the department's website](#)).

Agency Response Regarding Cosmetics (CSPA)

The definition was established in the law.

6) Sharing the reported information with the public

Ecology needs to develop a plan of how it will make the reported information available to the public in an easy to use format. (WTC, 37 PC, T-PC, T-WTC, T-EM)

Agency Response

As stated in the rule any information submitted to the agency which is not CBI will be available to public. If the agency has the resources we will post the information on the

internet even if no one has specifically requested it. Our ability to do so depends on the resources available for database and web development.

The current reporting requirement was designed to help Ecology better understand where and how chemicals are used in children's products in order to focus our efforts. We recognize that in the short term, additional information may be desirable to consumers but we believe the proposed approach offers the best opportunity to broadly reduce the use of chemicals of concern in children's products. If resources allow, Ecology and DOH will work together to present the reported information in an easy to digest format. The level of information required by this rule should provide Ecology, the regulated community, and the public with the greatest opportunity to identify and address issues regarding chemicals in products.

No change was made to the rule.

7) Impact of chemicals of concern

Not all impacts from chemicals are the traditional end-points (e.g. cancer); often the effect can be preventing a child from reaching their full potential. (T- PC)

Agency Response

Thank you for your comment. The end-points used for the current list were based on professional advice provided by Catherine Karr, MD PhD MS, Director of the Pediatric Environmental Health Specialty Unit at the University of Washington. Within the requirements of the law, we will try to continue refine a list of chemicals that is both practical and relevant.

No change was made to the rule.

8) Mere reporting does not establish harm

We applaud the department for clarifying that this is a reporting law, and as such just reporting the presence of the chemical does not establish harm. We are still concerned that the public might not understand this concept. (TIA, ACC, AWB, AAFA, GMA)

Agency Response

We have tried to make it as clear as possible that the mere presence of one of the chemicals does not establish harm. The reporting party has the option to provide additional information when submitting a report; some may want to include clarifying information regarding this issue (e.g. risk assessments, toxicity studies, exposure assessments, etc.)

No change was made to the rule.

9) Definitions

Define "distributor," "produce," "producer," and "retailer." (WRA)

Agency Response

Most of these terms are already defined in the law. And based on this comment during the first round of public comments the rule language was adjusted to better describe the role of a party who is only a retailer. No further adjustment to the rule language was made.

No change was made to the rule.

Clarify the term “credible and peer-reviewed scientific information”. (ACC, AWB, TIA, GMA)

Agency Response

The law establishes the agency's authority to determine what it considers to be credible information. Our practice to date is to not base decisions solely upon either NGO or industry publications. In those cases where equally credible sources disagree (for example, if IARC and IRIS disagree) it is our policy to use the most protective determination.

No change was made to the rule.

Clarify the term “inaccessible parts”. (AAFA, GAP et al.)

Agency Response

Based on these comments we added clarifying language to the draft guidance. But, no change was made to the rule. We welcome additional specific suggestions on how to make the guidance clearer. ([see the department's website](#)).

10) Exemptions

Exempt all products already regulated by Washington State or Federal regulatory programs. (ACC, FJTA)

Exempt internal components. (AWB, ACC)

Exempt contaminants. (ACC)

Exempt jewelry. (FJATA)

Exempt trace amounts of all naturally occurring chemicals. (FJATA)

Exempt certain components, for example crystal. (FJATA)

Exempt degradation products. (CSPA)

Agency Response

The law is very specific regarding what products are and are not considered to be children's products. The law does not provide authority to Ecology to expand the list of exempted products through rulemaking.

No change was made to the rule.

Exempt importers from the obligations of a manufacturer if the importer:

- (a) obtained written assurances from the producer that the producer would comply with the notification requirements herein,
- (b) reasonably relied on those assurances,
- (c) promptly notified the State of producer's noncompliance after becoming aware of producer's noncompliance, and
- (d) reasonably cooperates with the State, including stopping sale of the product, as applicable. (WRA)

Agency Response

The law specifically includes importers in the definition of "manufacturer" and the notification requirements apply to manufacturers. The law does not allow for the commenter's suggestion.

No change was made to the rule.

11) Confidential Business Information (CBI)

We applaud the department's recognition of the need to have a process so that companies can request that certain information be treated as confidential business information (CBI). (AAFA, ACC, AWB, WRA, GMA)

Agency Response

Thank you for your comment. It is important to understand that merely requesting that information be treated as CBI does not mean that the agency will approve the request.

No change was made to the rule.

12) Providing notice on the presence of contaminants

Limit any reporting to intentionally added chemicals. (AWB, TIA,ACC)

Agency Response

The proposed rule is focused on intentionally added chemicals because these are the chemicals the manufacturer has the most control over and where the best opportunities are for improving the product (i.e. where the manufacturer has the most choice about providing the function of the chemical of concern in the product using safer alternatives). However, when a child is exposed to chemicals of concern it doesn't matter if the source is intentionally added or not, the potential for harm is still present. Therefore, consistent with the purpose of the law, we want to begin to collect information on the presence of contaminants as well.

No change was made to the rule.

13) Reporting schedule

The reporting requirement should not be phased-in. Reports for all products for all manufacturers should be reported "now." (T-EM)

Agency Response

Reporting the presence of chemicals is a new requirement for most product manufacturers. The universe of products and manufacturers covered by the CSPA and this rule is immense. For most products, certain routes of exposure (especially ingestion) are most important. And for many products, the few largest manufacturers account for the vast majority of sales. Ecology has only limited resources to use for this effort, and focusing on products with the greatest potential exposure for the most children makes sense.

Furthermore, agencies are directed by law to evaluate proposed rules to determine if there is a disproportionate impact on small business. We determined that this rule could have a disproportionate impact. By law when this occurs the agency is required to attempt to write a rule which mitigates as much of the impact to the smaller businesses.

The current phased-in approach was developed in an attempt to balance all these issues and requirements.

The phased-in approach was not changed in this version of the rule.

Product tiers are inconsistently applied and do not properly reflect actual exposure or routes of exposure. Ingested products should not be included in the same tier as skin care products that can be washed off. (PCPC)

Agency Response

The tiers were meant as an indication of exposure potential rather than a reflection of the actual exposure. As the commenter points out, routes of exposure can significantly impact the actual risk from the exposure and the agency appreciates the difference in the time a product would be in contact with the skin for 'wash-on/wash-off' as compared to lotions or ingested products. However, we also needed to come up with a relatively simple tiering structure to work for multiple product categories in a wide variety of situations. Creating tiers based on actual exposure for each chemical of concern and product category is beyond both the expertise and the resources of the agency.

The criteria for the product tiers was not changed.

If the reporting schedule is based on sales, it should be gross sales for children's products only. (CSPA, TIA, ACC)

Agency Response

The definitions and exemptions in the CSPA that define "children's product" would make it difficult for all parties to determine the gross sales of just children's products. Also, some manufacturers indicate that this type of detailed information should be considered CBI. Having two different tier systems for parties who want the information to be considered CBI and those who don't is not practical.

No change was made to the rule.

Eliminate the Tier 4 category. (AWB, ACC)

Agency Response

The proposed rule includes the Tier 4 category because experience shows that on occasion a material which the manufacturer thought would never come into contact with a consumer did end up coming into contact with them. But it should be noted that any reporting for Tier 4 products would require that the rule be amended, thus trigger all the opportunities for public comment established in the rule process.

No change was made to the rule.

Provide more guidance on the Tier 4 category, including what “case-by-case” means. (TIA, AAFA, SR)

Agency Response

Based on these comments we will be adding to the draft guidance and we welcome specific suggestions on how to make the guidance clearer. ([see the department’s website](#)).

Additionally, the wording in WAC 173-334-110 (4)d was clarified.

Describe the schedule for trade associations to follow if they aggregate reporting for manufacturers of different sizes. (AAFA)

Agency Response

The trade association would need to follow the reporting schedule established by the rule for the respective manufacturer categories and product tiers. For some trade associations this could mean they enter data into the system on different target dates.

Based on this comment we will be adding to the draft guidance and we welcome specific suggestions on how to make the guidance clearer. ([see the department’s website](#)).

No change was made to the rule.

Allow the RSL to substitute for reporting. (AAFA, GAP et al.)

Agency Response

The law requires that manufacturers provide the required information to Ecology. Many companies have restricted substances lists (RSLs) though some are not publically available and most do not include all the information that CSPA specifies.

No change was made to the rule.

Remove the hierarchy in the rule for who will be held responsible. (WRA)

Agency Response

The hierarchy in the rule is meant to make it clear that only one party has to report, and to make sure the various parties know when they will be held accountable.

No change was made to the rule.

14) Criteria for Identifying Chemicals of concern (TIA,ACC,WRA,AWB, PCPC, GMA)

We have concerns with the criteria the agency used to develop the list of reporting chemicals. It should be a more risk-based approach.

Agency Response

All of the chemicals on the reporting list meet both the hazard and potential for exposure criteria established in the law. We considered establishing the list of chemicals of concern using a risk-based approach but quickly determined that it was not practical - we do not have resources or expertise for to do this for every chemical and product nor do we have the necessary data.

No change was made to the rule.

Do not include a parent chemical on the list if the only justification is that it degrades to a chemical meeting the criteria used for creating the list unless the degradation occurs during 'reasonable and foreseeable use and abuse' of the children's product.

Agency Response

Experience has shown that many chemicals degrade and that degradation products can cause significant health concerns. The specific justifications for each chemical on the reporting list can be found [on the department's website](#).

No change was made to the rule.

Do not rely on the EU Endocrine Disruptor list to place chemicals on the reporting list. (PCPC, TIA)

Agency Response

The EU Endocrine Disruptor List as was only used as an initial screening tool in phase II. During phase III a more thorough review of each chemical was conducted. The results of this additional review are summarized for each chemical on the reporting list [on the department's website](#).

No change was made to the rule.

15) Reporting Trigger Values

The PQL is too low. The PQL threshold for reporting intentionally added chemicals is solely dependent on analytical techniques. Ecology should recognize that modern analytical techniques are extraordinarily sensitive. Quantitation limits in the parts per million level were generally surpassed long ago. Today, quantitation in the parts per billion level, parts per trillion level, or even parts per quadrillion level is now achievable for some chemicals. Such quantitation would require manufacturers to initiate scores of new tests, well beyond requirements for compliance with federal or state safety laws. The PQL

is not only an arbitrarily variable threshold, but it is also vastly over-inclusive. (ACC, TIA, PCPC, CSPA, GMA, Gap et al., WRA, AWB)

Agency Response

The agency understands this concern, indeed we have the same concern for the analysis we will need to perform during compliance assurance efforts. As a result we will be providing guidance on what PQL the agency will use. We encourage affected parties to submit specific suggestions regarding sensible PQLs for various chemicals in product categories and components. This guidance will be continually updated to reflect what is learned in the implementation of the rule.

No change was made to the rule.

The 100ppm value is too low for contaminants and should not be based on EPA's Design for the Environment (DfE) program since DfE does not require any reporting for contaminants. (ACC)

Agency Response

The DfE program does not require reporting for contaminants(residuals), but it does place restrictions on the presence of contaminants at the 100 ppm level.

The actual wording in DfE publication [EPA's DfE Standard for Safer Cleaning Products \(SSCP\)](#) is as follows:

“Residuals of concern shall be limited to less than 0.01% (by weight) or 100ppm in the formulation. For ingredients known to contain residuals of concern, DfE's goal will be to limit those residuals to the lowest practicable levels. Dilution will not be considered in calculating the percentage of residuals in concentrates. Formulators should understand that residuals may be present and should encourage chemical manufacturers to carefully monitor and control processes to limit residuals of concern. [Note: DfE is working to ascertain whether the state of green chemistry can support the restrictions imposed by this section.]”

In this same publication the following definitions are given:

“residual: *Trace amounts of chemicals that are incidental to manufacturing. Residuals are not part of the intended chemical product, but are present because of factors such as the nature of the synthesis and engineering pathways used to produce the chemical. Residuals include: unintended by-products of chemical reactions that occur in product formulation and chemical synthesis, impurities in an ingredient that may arise from starting materials, incompletely reacted components, and degradation products.*

residual of concern: *A residual that fails to meet the criteria in the General Standard for carcinogenicity, mutagenicity, reproductive toxicity and other human health effects, or fails to meet the criteria for persistence, bioaccumulation and toxicity, as defined by the Final PB&T Rule.”*

The wording in the rule for the reporting trigger for contaminants was not changed.

The reporting trigger value should be 1,000ppm. (GMA, AWB, Gap et al., ACC, PCPC, CSPA, FJTA)

Agency Response

We concluded that 1000 ppm does not reflect whether or not a chemical is intentionally used or whether the use of the chemical is safe. While this value is used by the European Union's Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH) program, the REACH program does not assert that this value is a health- or safety-based value, or that any product with a chemical below this level is safe. This value was selected to try to keep the initial reporting manageable because the REACH reporting requirements apply to an enormous universe of products and chemicals (all chemicals that are intended to be released from all products.) REACH has a much more comprehensive scope of chemicals, products, and potential restrictions than the CSPA. Furthermore, Governor Gregoire's veto message directed Ecology to "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." Both of these jurisdictions use many approaches to control the chemical content of products, many of which are more restrictive than the 1000 ppm threshold.

In the European Union:

- *Annex 17 of REACH*: Annex 17 of REACH does establish health-based restrictions. These values have been used to ban, limit the allowed concentration, or limit the allowed use of over 80 specific chemicals, as well as "any" substance which has similar characteristics to those we used in creating our list of chemicals. There are very few cases where the value of 1,000ppm is used for a limit. Often where the chemical could be used in a children's product (toys, clothing, personal care products, etc.) it is banned completely, restricted to very few uses, or only allowed at very low concentrations. The restrictions established in Annex 17 for some of the chemicals on the CSPA list are:
 - 75-01-4 Vinyl Chloride – banned from some products – aerosols
 - 71-43-2 Benzene – limited to 5ppm in its free state for toys
 - 7440-43-9 Cadmium – banned for many uses
- *Toy Directive (Directive 2009/48/EC)*: A total of 22 CSPA chemicals are also restricted by the EU Toy Safety Directives that enter into force in July 2013. Several are classified as carcinogenic, mutagenic, or toxic for reproduction (including vinyl chloride, benzene, several phthalates, perfluorooctanyl sulfonates or PFOS, and mercury) and therefore not permitted in "toys, in components of toys or in micro-structurally distinct parts of toys." Migration limit values that correspond to a concentration much less than 1000 ppm are established for several other metals (antimony, arsenic, cadmium, cobalt, and mercury) that are included on the CSPA list.
- *Cosmetics Directives (including Directive 76/768/EEC)*: There are many hundreds of chemicals which are banned from being part of the composition of cosmetic products, including some which are included on the CSPA list (e.g. antimony, benzene, cadmium, mercury, vinyl chloride, and dioxane.) Additionally, there are 64 other chemicals which are only authorized for use in certain concentrations. Including some which are on our reporting list, such as formaldehyde and phenol.

Manufacturers who sell toys or personal care products in Europe must comply (or will have to comply within the next couple of years) with standards limiting the use of many CSPA chemicals to values considerable lower than 1000 ppm.

In California:

- *Proposition 65*: Proposition 65 does not require reporting, but does require product labeling. There are currently more than 700 unique substances and classes of chemicals on the Prop 65 list, which was used as a source for identifying and prioritizing chemicals to be included on the CSPA reporting list. Businesses are responsible for determining whether their products contain a listed chemical at a level above a “safe harbor” limit. Businesses must affix a warning label on any product that contains one or more listed chemicals over safe harbor limits; labels do not necessarily specify which chemicals are present or at what levels. Manufacturers must determine what concentration in their product warrants including a Proposition 65 label on their product, and in many cases the product concentration would likely be well below 1000ppm.
- *Safe Cosmetics Act of 2005*: The California Safe Cosmetics Act requires that for all cosmetic products sold in California, the manufacturer, packer, and/or distributor named on the product label must provide the California Department of Public Health a list of all cosmetic products that contain any ingredients known or suspected to cause cancer, birth defects, or other reproductive harm. This law currently applies to over 700 chemicals. There is no reporting trigger in this law; any amount that is intentionally added must be reported.

Manufacturers who sell products in California already need to know if over 700 chemicals are present in their products.

Ecology determined that intentionally added chemicals (i.e. those that serve a function in the product) offer the best opportunity for substitution with a safer alternative and should be where we focus most of our attention. Finally, we recognized that contaminants (those chemicals that are present but do not serve a function in the product) could be a significant potential source to children and could not be ignored.

The rule (see **WAC 173-334-080**) reflects these changes. We are requiring separate reporting requirements for intentionally added chemicals and for contaminants. The approach closely mirrors the approach used by the US EPA’s Design for the Environment (DfE) program. Within the United States, the DfE program is considered a gold standard for government programs designed to address chemicals in products. This program is widely respected among both NGOs and business, and has been used to evaluate and certify over 2,500 products. It is primarily targeted to formulated products, including cleaners and detergents, but EPA staff indicate that it can be applied to fabricated products as well. Any amount of an intentionally added chemical (an ingredient in the formulation) must be reported as part of the process of certification under the DfE program. Historically the program has required reporting for any amount of a contaminant above 100ppm, but currently is investigating to see if this requirement should be made more stringent. If deemed feasible, the program may simply not allow contaminants to exceed 100ppm for products to obtain DfE certification.

The rule reflects the following approach:

- For intentionally added chemicals, the lower limit is established by analytical method and its associated PQL.

For contaminants, if the contaminant occurs in the product above 100 ppm it must be reported, unless it can be demonstrated that the company had in place a due diligence system to keep the concentration of contaminants as low as reasonably possible.

No change was made to the rule.

All contaminants above 100ppm should be reported irrespective of any control programs used by the manufacturer. (WTC, EM, 29PC)

Agency Response

The 100 ppm level is consistent with policies established in EPA's Design for the Environment program. The due diligence provision is provided to both encourage companies to minimize the presence of CHCCs in their products and to clarify how the agency will implement this approach. See **WAC 173-334-120**. Ecology will provide draft guidance on this issue as well ([see the department's website](#)).

No change was made to the rule.

16) Providing an extension for manufacturers who do an alternative assesement

This option should be removed from the rule. If it remains in the rule the agency must establish what exactly is meant by an adequate alternative assessment. (AAFA, PCPC, ACC, TIA)

Agency Response

The wording in the rule that allows for an extension for alternative assesments has been removed.

17) Implementation guidance

There needs to be an acknowledgement of the difference between the manufacturing control programs an importer can have as compared to manufacturer of a private brand. (WM)

The guidance needs to clarify who would be held responsible for promotional items 'given away' with a product. (GMA)

The guidance for components needs more clarification. (TIA)

The guidance for due diligence and manufacturing control program needs more clarification. (TIA, AAFA, FJTA)

The guidance for disquishing between intentionally added vs. contaminates needs more clarification. (TIA, AAFA, GAP et al.)

Agency Response

Based on these comments we will be adding to the draft guidance and we welcome continued specific suggestions on how to make the guidance clearer. ([see the department's website](#)).

No change was made to the rule.

18) Chemophobia threatens public health. (ACSH)

Agency Response

Thank you for your comment.

No change was made to the rule.

19) This rule is a waste of money, there is no goal, or sunset clause. (Silk Road)

Agency Response

Thank you for your comment.

No change was made to the rule.

20) Toxics in products should be addressed by one federal law, rather than on a state-by-state basis. (AAFA, WRA, ACC)

Agency Response

Thank you for your comment.

No change was made to the rule.

21) Violations

Violations should be by tied to the applicable product within a category subject to reporting. TIA is concerned that ambiguities in the enforcement section could result in numerous violations being assessed against a manufacturer for a single product. (TIA)

Agency Response

For reasons already stated, the proposed rule will require reporting by component and product category. Our compliance assurance effort will be based on components by product category.

No change was made to the rule.

22) Remove the word “designed” from section 173-334-090. (WRA)

Agency Response

The word “designed” was removed from the rule.

23) Ecology has designed the reporting process in a manner that is inconsistent with the statute. (WTC)

Agency Response

Washington Toxics Coalition (WTC), represented by Earth Justice, argues that Ecology has designed the reporting process in a manner that is inconsistent with the statute being implemented, and that it is intended to prevent the public from identifying the amount of chemicals in specific products. WTC’s analysis is incorrect.

Section 5 of the CSPA, RCW 70.240.040, allows the amount of chemicals of concern to be reported *either* by product, *or* by component. WTC would like the chemical concentrations to be reported by product.

While Ecology believes the WTC’s preferred product-by-product approach might be possible under the statute, Ecology has instead chosen to require manufacturers to report chemical concentrations by component. Ecology defines “component” as “a uniquely identifiable material or coating (including ink or dye) that is intended to be included as a part of a finished children’s product.” Ecology has not taken this approach for the purpose of obscuring information about the amount of chemicals in specific products, but because Ecology interprets the statute as requiring it to choose one or the other means of reporting (by product *or* by component), and Ecology has concluded that reporting by component is the better approach.

There a number of reasons for this choice. The first is that it is less meaningful to know the concentration of a chemical within a given product (i.e., on a product “unit” basis), where the concentration of that chemical, by weight, may be diluted among all of the components that make up product. This is especially troubling in the case of components used as surface coatings, which are most likely to come in contact with the child. The second reason is a matter of administrative feasibility. To require reporting at, for example, the stock keeping unit (SKU) level would result in a volume of data that would be impossible for Ecology to handle and exponentially more burdensome for industry to comply with. Finally, reporting by product component provides the best opportunity to reach into the supply chain and potentially impact many products at the same time.

Ecology believes that the fundamental purpose of the reporting requirement is to give policy makers, including consumer advocacy groups like WTC, insight into how chemicals of concern are getting into children’s products and as a means of gathering information for exposure and risk analysis. This information is useful to, among other things, identifying product components that may be candidates for substitution with a safer alternative.

Thus, Ecology has adopted a reasonable interpretation of the reporting requirement that aggressively requires notice of concentrations of chemicals of concern at the component level instead of allowing manufacturers to report concentrations at the potentially diluted

product "unit" level. In addition, the rule still requires manufacturers to describe the products in which the component is used at a somewhat aggregated "brick" level.

Another advantage of reporting by component and brick is that it may lessen the possibility of manufacturers asserting an exemption from public disclosure on the basis of proprietary information or trade secrets, which was a matter of concern in the governor's veto message.

No change was made to the rule.

Rebuttal of WTC's legal assertions

WTC's legal argument relies heavily on its interpretation of the purpose of RCW 70.240.040 (section 5 of the CSPA), insisting that one of the purposes of the notice provision is to "provid[e] consumers with information critical to making informed choices about products." In other words, WTC seems to envision consumers being able to search a database for information about the concentrations of the 66 listed chemicals in every individual children's product in the marketplace as a means of informing their purchasing decisions.

The evidence that WTC offers for its preferred interpretation of the purpose of the statute is unconvincing.

WTC first points to the fact that Ecology was required, under RCW 70.240.030(3), to include in its 2009 report to the legislature "recommendations for additional ways to inform consumers about toxic chemicals in products, such as labeling." This actually undercuts WTC's argument. WTC wants the section 5 notice requirement to serve as a kind of labeling law, when in fact it is simply a way of gathering data preliminary to recommending the adoption of such a law.

WTC also points to the fact that the legislature, in section 6 of the act, added to Department of Health's product safety education campaign responsibilities a new provision regarding products "that contain chemicals of high concern for children as identified under section 4 of this act." WTC believes this confirms that individual products must be identified under the notice required by section 5. Ecology disagrees with this analysis. Section 6 does not even specifically refer to Section 5, the annual notice provision. Instead it refers to section 4, the provision requiring Ecology and Health to identify chemicals of high concern for children and to report to the legislature by January 2009 on the chemicals and the "children's products or product categories" that may contain the chemicals. Health may certainly use the information it gains from the section 5 notices to inform consumers of products that contain chemicals of high concern for children, but if it is to provide meaningful exposure risk information to consumers, it will need to provide much more than the raw data contained in manufacturers reports. This would be the case even if the reports provided chemical concentrations on a product unit basis as WTC would prefer.

Fundamentally, if the legislature had intended to mandate reporting chemical concentrations by product unit, it would not have said "product *or* product component" in subsections (2) and (4) of section 5 of the act. RCW 70.240.040(2) and (4).

Ecology has concluded that it is unrealistic to expect that the information manufacturers are required to report under section 5 can provide consumers with product-specific information that will be useful in assessing risk of exposure as between one product and another. A more modest, but far more realistic objective of the notice requirement is to provide policy makers, including consumer advocacy groups like Washington Toxics Coalition, with a map of where the potential "hot spots" of toxic and bio-accumulative chemicals are in the vast marketplace of millions of products marketed for use by children. This is why the proposed rules indicate that their purpose is to fill a data gap for policy makers and consumers. Providing consumers with a tool for gauging risk of exposure, or potential harm on a product-by-product basis would require a different legal vehicle and far more resources than are available to Ecology to administer the present law.

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Appendix A: Comment Index, Written Comments with Attachments, and Public Hearing Transcript for Supplemental Proposed Rule

Appendix A can be found on the Department of Ecology's website at www.ecy.wa.gov/biblio/1107024a.html.

Appendix B: Comment Index, Written Comments with Attachments, Public Hearing Transcript, and Responses to Comments for Original Proposed Rule

Appendix B can be found on the Department of Ecology's website at www.ecy.wa.gov/biblio/1107024b.html.