



Toy Industry Association
Key Pilot Rule Response Issues
Washington State – Children’s Safe Products Act
Draft Pilot Rule (January 28, 2010)

Toy Industry Association (TIA) Input Overview: The Toy Industry Association is please to be providing this first official response to the Department of Ecology’s Draft Pilot Rule, dated January 28, 2010; based upon the input of TIA’s membership.

TIA is a not-for-profit trade association composed of more than five hundred (500) members, both large and small in size, located throughout North America that manufacture or distribute toys. Our member’s products meet and/or exceed stringent U.S. toy safety and environmental requirements and are sold throughout the State of Washington.

TIA has engaged a taskforce of representative members to provide feedback on the pilot rule and who have contributed to these comments. Companies, of large, medium, and small size provided input on the following key issues; with regard to the Pilot Rule.

Exposure Determination:

- The purpose of the Children’s Safe Products Act is to address exposure to chemicals of concern, not to address environmental concerns or unilaterally mandate the use of safer alternatives based on mere presence.
- For products where there is no exposure to a listed chemical (e.g., demonstrated inaccessibility) there should not be a reporting requirement.
- The Pilot Rule must be amended to prevent unnecessary reporting when there is not exposure to a reporting chemical; and therefore no safety concern with a product.
- **Suggestion:** The Tier 4 products category (in the draft Rule line 236) should be specifically exempt from reporting, since in that case there is no exposure to a chemical on the reporting list and, thus, no impact on safety or children’s health.

Intentionally Added:

- The statute clearly implies that intent is an important element of the analysis – only chemicals of concern intentionally placed in a consumer product are covered by the notification requirements.
- In vetoing the first section of the Act, the Governor clearly stated that she did not want the Department to “create obligations that are beyond what state government can deliver.” Regulating incidental contaminants that may be present in a consumer product as a result of equipment or transport would be beyond the scope of the Department’s ability to assess and regulate, and clearly beyond the intent of the statute.

- Additionally, detection levels are not a reasonable method for evaluating intentionally-added chemicals or establishing reporting trigger levels.

Suggestion: The scope of the program must be confined to “intentionally added” product ingredients that serve a functional purpose. Unintentional “contaminants” cannot be included if this is to become a feasible program that will not result in excessive testing. The following definition is suggested for use throughout the Pilot Rule:

An “intentionally added ingredient” would be any “element, chemical compound organic or inorganic substance of a particular molecular identity, which is intentionally used by a product manufacturer or component supplier to impart a functional purpose on the final product; including (a) any combination of such substances used in whole or in part as a result of a chemical reaction or occurring in nature, and (b) any element or uncombined radical”. (Adapted from the definition of chemical substance from TSCA, 15 USC 2602.

Reporting Trigger Values:

- Trigger values are essential for determining the structure of this program and reporting. Without trigger level thresholds, a company will never be able to “prove a negative” given the fact that a number of the listed chemicals are naturally occurring, or are present at levels that are of no health significance, but can never be verifiably eliminated down to the last molecule.
- Trigger thresholds are essential to ensuring that this program is feasible and that the data are reliable. Without trigger levels set in advance, participants of the pilot program will set their own levels, which may be inconsistent and therefore impossible for the agency to evaluate for purposes of determining the cost and difficulties of complying with the rule in the pilot project.
- For many products a reasonable, appropriate, and presently used general trigger threshold would be when a concentration of the chemical is equal to 0.1% by weight in the consumer product. (See European REACH Legislation Article 7) This of course would be superseded when the listed substance is not intentionally-added or present in an inaccessible form. In addition to the consideration of 0.1% threshold, less restrictive thresholds may be proposed for several substances on the List which are of extremely limited toxicity.
- Setting different thresholds for product applications and hazard traits will be complex, but potentially necessary. Any such effort would have to be justified by sound risk assessment.
- **Suggestion:** TIA’s discussion and recommendation for trigger reporting levels will be provided in a subsequent submittal.

Concerns with the Reporting List of CHCC: There are serious concerns with the basis for inclusion of certain chemicals on the Reporting List for chemicals of high concern to children (CHCC) related to what we believe to be inconsistencies, errors, or failure to consider readily available physical/chemical and toxicological data. TIA is conducting a detailed analysis of the Reporting List and will provide a specific critique and suggestions for this list that will be provided in a subsequent submittal. Specifically, TIA will provide rationale and basis for why certain chemicals do not rise to the level of concern warranted under this Program. This detailed analysis will demonstrate why certain chemicals should be removed from the list.

Data and Reporting: The issues highlighted below address many of the data and information provision questions that are relevant to the Pilot Rule. This information represents a generic process that is likely to be used by many toy companies regardless of size. It is TIA's suggestion that these statements frame the data reliability needs for this program.

- Articles such as toys are very complex and can be made of hundreds of components. It is infeasible to rely on aggregate destructive testing to determine compliance for every component of a toy, especially given the wide range of chemicals on the Reporting List.
- Testing for the presence of 50-66 chemicals in a product would be cost prohibitive for a vast majority of products. Additionally, for some of the chemicals listed, analytical test methods for reliably determining the presence of a chemical do not exist or are not available in validated form.
- Under the Consumer Product Safety Improvement Act (CPISA) toy manufacturers must provide detailed testing data to assure that their products comply with various regulatory standards for a limited range of substances; including lead, phthalates, and other heavy metals. This type of testing data would be infeasible for 50-66 chemicals in all toys. Simply put, the testing costs would put small toy manufactures out of business if they must test every product for 50-66 chemicals to assure the Department of Ecology that there is no exposure or that there is no presence of chemicals above trigger levels.
- Additionally, under Proposition 65 in California, all consumer products must provide a label for products that contain chemicals "known to cause cancer, birth defects or other reproductive harm" that are contained in the products above a no significant risk level (NSRL) or maximum allowable dose level (MADL). Generally, toys do not contain Prop. 65 substances that would trigger this labeling. However, the Department should remain cognizant of this law, and work to prevent reporting requirements such as this.
- **Suggestions:**
 - Manufacturers will need to rely on certificates provided by suppliers of components, resins, and substances for the intentionally-added substances and chemicals that comprise these articles.
 - Trade association or direct supplier reporting for commonly used resins, components, and substances would be an appropriate mechanism to streamline delivery of common information. This information could be referenced for applicable end-product uses.
 - Under this supplier certificate process: (1) the supplier would report to a company, a trade association; or potentially even the Department (if they desired) the presence of an intentionally added reporting list chemical; that is in a component, resin, or substance above a trigger level. Then, (2) a product manufacturer could report the use of that component, resin, or substance to the department.

- Subsequently, (3) the Department would be able to trace the use of that component, resin, or substance that contains a reporting chemical to the end-product being sold in Washington State; for the purposes of this Program.

Quality Control Assurance: Under the Consumer Product Safety Improvement Act (CPISA) companies maintain extensive information about the components and substances that are used in their products from suppliers and via independent analysis. These certifications are validated by extensive quality assurance methodologies.

- **Suggestions:**

- If a company has an existing quality assurance program that flows through the supply chain, they are justified in relying on certificates provided by suppliers.
- It is not feasible to force the establishment of an extensive component testing program to validate what can reliably be gained from supplier certificates.
- If the Department has questions/concerns with regard to chemicals in specific components these questions should be addressed on a case-by-case basis with component suppliers and end product manufacturers.

Phase-in (Tiered) Reporting:

- The rule should be created to be equally applied to all companies, regardless of size.
- “Market-Share” is not an appropriate or relevant indicator for phase-in of the reporting requirements
 - Market-share does not equate to impacts on human health or safety
 - It is fundamentally inequitable for larger companies or market-share to be a determinant in what products report first
 - Market-share driven application of the reporting requirement to companies could be viewed as discriminatory and unconstitutional under the statute. This could result in legal challenges against the Department for unequal treatment under the law.
 - Regardless of market-size those individual products that result in exposures of greatest concern should report first. In some cases, smaller companies may have fewer resources to prevent exposure to chemicals.
- **Suggestions::**
 - Phase-in of reporting should be driven by chemicals with the highest “severity of hazard” traits and those products that result in reasonable expectation of exposure capable of causing harm.
 - A phased in approach based on the hazard of the chemical, intended exposure route and likelihood of exposure, would be within the statutory authority and is an appropriate application of the intent to focus on product safety and human health.

- **Specific Tier Suggestions:** (1) Products with known/likely exposure to chemicals of highest concern should report before (2) products where known exposure does not present a serious health hazard; and then (3) products where there is only a theoretical potential for exposure would report. Finally, per the statement above, (4) for products where exposure is completely contained/controlled (e.g., demonstrated inaccessibility) no reporting should be required.

Public Chemicals Nomination: At present, the public nomination process for chemicals for future listing or for deletion from the base chemicals list does not stipulate adherence to a verifiable weight-of-evidence analysis that must be submitted before the Department is required to review a petition.

- “Weight-of-evidence approach” traditionally means a transparent, criteria-based, methodological evaluation to review and interpret all available and relevant scientific research for a given issue.
- Barring some burden of proof and explicit process placed on the public nomination process, the Department will expend exponential amounts of resources reviewing a continuous string of submissions without the ability to objectively assess the merits of inclusion or deletion.
- **Suggestion:** If a public nomination does not rely on “weight-of-evidence” data to present a substantial conclusion; the Department should reserve the right to reject the petition without a full public comment process.

Confidential Business Information: TIA supports that the draft Rule provides the following:

“If a reporting party believes the information being provided is confidential business information, in whole or in part, it can request that the department treat the information as confidential business information as provided in RCW 43.21A.160.”

RCW 43.21A.160

Request for certification of records as confidential — Procedure.

Whenever any records or other information furnished under the authority of this chapter to the director, the department, or any division of the department, relate to the processes of production unique to the owner or operator thereof, or may affect adversely the competitive position of such owner or operator if released to the public or to a competitor, the owner or operator of such processes or production may so certify, and request that such information or records be made available only for the confidential use of the director, the department, or the appropriate division of the department. The director shall give consideration to the request, and if such action would not be detrimental to the public interest and is otherwise within accord with the policies and purposes of this chapter, may grant the same.

TIA believes that there may be instances when this information will be provided to the Department and there should be specific protocols for the management of this data.