



September 22, 2009

John R. Williams, Jr.  
Department of Ecology  
PO Box 47600  
Olympia, WA 98504-7600

**RE: Final Issues Statements**

Dear Mr. Williams,

Per your request, please find below, the Toy Industry Association's final response to your request for issues statements regarding your department's ongoing advisory group efforts on the CSPA. Please feel free to contact me or Andy Hackman, TIA's Senior Director of State Government Affairs, [ahackman@toyassociation.org](mailto:ahackman@toyassociation.org), if you have questions or if you would like additional information on any issues below.

Sincerely,

Ed Desmond  
Executive Vice President, External Affairs  
Toy Industry Association

Enclosure

## **Washington CSPA Issues – TIA Comments (September 22, 2009)**

### **1) Issues associated with the ‘reporting list’ – the list of chemicals that triggers reporting by manufactures.**

#### a) How many chemicals should be on the reporting list?

**(NOTE: Memo from J. Williams June 17, 2009 where after due consideration, Ecology has reached the indicated decisions on the following issue)**

About fifty chemicals should be on the reporting list. The CSPA does not specify how many chemicals will be identified on the reporting list of chemicals of high concern for children. However, as stated by the Governor in her veto message, Ecology’s “fiscal analysis of the bill assumed no more than fifty chemicals would be identified, and the Legislature has funded their work accordingly.” Consistent with this assumption and funding, Ecology will identify about fifty chemicals for the list of reporting chemicals

Memo Addendum: Should lead, cadmium, and phthalates be included on the reporting list?

No, lead, cadmium, and phthalates should not be included on the reporting list. These chemicals are being addressed at the federal level by the Consumer Product Safety Commission, which regulates their presence in children’s products under the Consumer Product Safety Improvement Act of 2008.

#### **Comments**

The 17 June memo from Mr. Williams notes that a preliminary decision has been made by WA ECY to compile an initial ‘reporting list’ of about 50 substances, specifically excluding lead, cadmium and phthalates due to the fact that these are being addressed at the federal level by the CPSC. This is a reasonable and manageable number. With careful thought it could be large enough to capture the chemicals of legitimate potential health interest, while not being unnecessarily burdensome for use in this pilot rulemaking effort.

How should they be selected or prioritized?

#### **Comments:**

Selection or prioritization of the substances for inclusion can be informed by joint review of specific existing lists and input from industry on relevant manufacturing materials. The use of existing lists can be informative in determining a chemical’s hazard characteristics; as the Department looks to prioritize chemicals for selection under the CSPA. However, each list or prioritization effort should be evaluated for its application and validity and

proper risk assessment must be performed for each chemical that is selected under the CSPA.

Hazard-based assessment lists cannot be looked at in a vacuum, and degree or likelihood of exposure to a chemical that would be designated under the CSPA must be considered. A risk assessment approach must be used in the process of designating the 50 chemicals under the CSPA. This approach will ensure that the chemicals that have the most severe hazard characteristics and exposures that result in a likelihood of causing harm to human health are selected for the CSPA reporting list.

Should the selection process be specified in the rule?

**Comments:**

Yes, the chemical selection process and the actual chemicals that will be designated for reporting under the CSPA should be specified in the rule. Specifically, chemical selection criteria could be spelled out in the rule language, such as toxicity measures greater than an identified threshold (e.g., acute LD<sub>50</sub> <0.1 mg/kg, Class A carcinogen) should be included; as well as the initial list of 50-chemicals. Additions or deletions to the 50chemicals should also be designated by subsequent changes to the rule with relevant notice and comment periods.

Should there be allowance for chemical exemptions such as Generally Recognized As Safe (GRAS) chemicals? See <http://www.foodsafety.gov/~dms/eafus.html> for list of chemicals.

**Comments:**

Yes. The designation of a substance as GRAS by the USFDA is powerful evidence that the substance does not belong on a 'reporting list' of high priority chemicals. If it can be used for food products, certainly its presence in toys should not be of legitimate concern.

Specifically, U.S. FDA states on its website if a substance is GRAS, "... there must be evidence that the substance is safe under the conditions of its intended use. FDA has defined "safe" (21 CFR 170.3(i)) as a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use."<sup>1</sup> Therefore, chemicals that are on the GRAS list, when used as intended, should not be included in the CSPA reporting list. A GRAS chemical used in a way not approved by FDA under the GRAS program and above its specified GRAS use level might be considered for the CSPA reporting list if, obviously, it meets other relevant criteria of concern and is justified to

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<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm061846.htm#Q1>

be listed. If a chemical listed on the GRAS has new data that is published indicate a valid concern, the Department may consider this new data for designation as one of the 50-chemicals.

- b) Should chemicals that are not ordinarily used in consumer products be excluded? If so, how do we know what chemicals are not ordinarily used? For example in a recent study tetrachlorethylene and 4-nonylphenol were found in some children's products.

**Comments:**

There probably won't be an unambiguous solution to this dilemma. However, with only 50 slots available on a 'reporting list', some preferential identification process will be essential. This may be a place where industry knowledge will be especially valuable, i.e. the 'reporting list' should be constructed by considering the common components of children's products and work outward to the more uncommon substances.

A list of all chemicals used in the manufacture of products would be nearly impossible to create, given the vast scope of children's products that could be impacted by the CSPA list process and the sheer number of chemicals that could be involved. However, an informed discussion with product manufacturers could be helpful in suggesting chemicals that would not likely be contained in any children's products.

- c) For this list of issues 'de minimis' means the amount of a substance in a product which would trigger reporting. Should there be a 'de minimis' value for the chemicals on the reporting list?

**Comments:**

Yes. If a chemical is placed on the 'reporting list' a de minimis level must be defined and is should be specific to the extent the chemical is reasonably accessible to a child. Even if the level is a general value; such as 0.1% of a total product's composition that is accessible, this value will be essential to ensuring that the reporting list requirements are feasible to implement. Without this level being specified there would be extreme over-reporting to the Department and immense testing burdens for manufacturers.

If so, what should it be based on?

**Comments:**

The de minimis value must be a reasonable level that is based upon sound risk assessment of a chemical's hazard traits and likely exposure profiles.

Should United States National Toxicology Program (US NTP; See - <http://ntp.niehs.nih.gov/>) Consumer Product Safety Commission (CPSC; See- <http://www.cpsc.gov/>), and EPA exposure limits be used?

**Comments:**

A combination of available information from these sources could act as a good starting point. This also presumes that a mechanism can be established to resolve inconsistencies where they occur. It is likely that there also would need to be a set of conservative assumptions developed to guide the identification of a 'de minimis' level for other substances to the extent that they have not been considered already by these agencies.

Should the 'de minimis' level be based on something other than risk, such as detection limit?

**Comments:**

For practical purposes, the words 'zero' and 'none' do not have useful meanings in the context of this rule. Thus, the 'de minimis' levels based upon potential health considerations should take precedence. However, there almost certainly will be cases where analytical limits (i.e., detection limits) will be greater than a health-based limit. In those instances, it will be important to identify a consensus Practical Quantitation Limit (PQL) that would serve as the 'de minimis level'. Such a value could be modified to the extent that new information becomes available, but those adjustments should be considered on a schedule coincident with what is decided at timing of addition or deletion of chemicals from the WA CPSA 'reporting list'.

- d) If a reporting list is in the rule, should the list also include the 'de minimis' limit? If the 'de minimis' value is in the rule, how would we deal with situations where new information shows that it should be adjusted?

**Comments:**

Yes, any value denoting minimum acceptable exposure levels to a substance should be published with the 'reporting list' via the rule. New information to change the de minimis value should be subject to review and comment; as such, a new rule and comment process would be needed for changes to the de minimis levels.

- e) Can the public recommend that chemicals be removed or added to the reporting list?

**Comments:**

A process should be contemplated and developed by which nominations of either type from the public (i.e., addition or deletion) could be

considered and addressed by the agency in a technically defensible manner via a rulemaking process.

If so what should the process be?

**Comments:**

As stated above we believe the reporting list and associated exposure levels should be included in the rule, and that subsequent revisions to the list should also be designated via the rulemaking process that allows for due process to document nominations for addition or deletion to the list.

What criteria and timeline should the agency use to make a determination or decision to add or remove a chemical?

**Comments:**

The decision to add or delete a substance from the 'reporting list' would be dependent upon the quality and completeness of information package and technical documentation submitted by the nominating party. It may not be possible to establish explicit criteria, other than to state that the documentation must be technically persuasive, based upon review of "credible and reliable scientific data published by an authoritative body". It is also appropriate to define the procedure by which a nominating party may challenge an agency decision to deny a nomination.

Should these criteria be in the rule?

**Comments:**

The schedule by which the 'reporting list' may be amended or adjusted could be included in the rule, but it does not seem reasonable or necessary for the explicit technical criteria by which nominations would be evaluated to be propounded in the rule itself.

Should a reasonable toxicological risk assessment be mandated as a contingent requirement for adding or removing a chemical?

**Comments:**

Such an assessment would be a normal and reasonable element to include in a nomination package that supports addition or deletion of a specific substance. It is not clear how the agency would be able to make a defensible determination in the absence of such information. The degree of detail required would be commensurate with the obligation incumbent on a nominating party to present a technically defensible and persuasive case for addition or deletion.

Can we base such decisions on hazard assessment alone?

**Comments:**

In our view, that qualitative level of information would not satisfy the technical requirement to present a technically defensible and persuasive case for addition or deletion.

- f) Is there a need to benchmark Registration, Evaluation, Authorization and Restriction of Chemical substances (REACH; see [http://ec.europa.eu/environment/chemicals/reach/reach\\_intro.htm](http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm) or Restriction of the Use of Certain Hazardous Substances (RoHS Europe)) see - <http://www.rohs.gov.uk/> or similar regulated chemical listing process as to who can add or remove chemicals from the prioritized list?

**Comments:**

TIA provided REACH background information and cover letter highlighting aspects of REACH to be considered on August 17, 2009.

Specifically is there a need to review current REACH or/and ROHS chemical criteria and prioritization lists as well as chemicals assessment approach for hazards/risks/exposure to determine if there are any cross-over applicability?

**Comments:** See above response to previous question.

- g) What should be the process for triggering the modification of the list after comments from the public? How is this one different from e)?

**Comments:** Please see response to Question e above.

- h) What should be the frequency for modifying the reporting list?

**Comments:**

Approximately annually. More frequent re-visitation to the 'reporting list' beyond annual may be counterproductive, while less frequent than annual revisions are likely to be inadequate to incorporate improved knowledge or data as it becomes available.

- i) How should the reporting list of chemicals be prioritized? Should the chemicals on this list be prioritized by importance to be phased out/banned?

**Comments:**

Prioritization should be based on a risk assessment review to identify chemicals with the greatest hazard characteristics and likely exposure profiles. Under the CSPA, the Department of Ecology does not have the authority to ban or require the phase-out of a chemical.

Should prioritization be based upon a strict toxicity measure of a standard exposure level to a set number of children, and which ones cause the most harmful effects? Or upon which chemicals are the most prevalent among those children are exposed to? Or which toxic chemicals are found at the highest levels in which children's products? Or, which high priority chemicals are found in the most popular children's products?

**Comments:**

All of these possibilities readily could be incorporated as individual criteria during a selection and prioritization process for a 'reporting list'. Both the potential intensity of exposure under reasonable and conservative exposure conditions, as well as the frequency/likelihood of potential exposure in the population, would be of technical interest. It is likely that a series of criteria or toxicological endpoints would be valuable in guiding the selection and/or prioritization process for 'reporting list'.

- j) Should the sources for identifying high priority chemicals (EU, REACH, California, Canada, et al.) be included in the rule?

**Comments:**

Specifying in detail the source information may not be necessary or beneficial to the agency although important potential sources could be spelled out in the rule language such as those defined in the question.

If not, would it just be included in the final report and available on the DOE website?

**Comments:**

The entire selection process for compiling the 'reporting list' should be explicitly addressed in the Final Report and should also be made available on the DOE website or at other appropriate locations.

- k) Should there be some high priority chemicals for which there is no 'de minimis' value, i.e., zero amount can be intentionally added to the production of a children's product?

**Comments:**

As noted elsewhere, for practical purposes the words 'zero' and 'none' don't have useful meanings in the context of this rule. Thus, 'de minimis' values based upon potential health considerations should take precedence. However, there almost certainly will be cases where analytical limits (i.e., detection limits) will be greater than a health-based limit. In those instances, it will be important to identify a consensus Practical Quantitation Limit (PQL) that would serve as the 'de minimis' level. Such a value could be modified to the extent that new information

becomes available, but those adjustments should be considered on a schedule coincident with what is decided at timing of addition or deletion of chemicals from the WA CPSA 'reporting list'.

What would be the method to identify what is intentionally added? What about chemicals that are not intentionally added but are present in the product due to manufacturing processes or contamination?

**Comments:**

There probably won't be an unambiguous solution to this dilemma. However, with only 50 slots available on a 'reporting list', some preferential identification process will be essential. This may be a place where industry knowledge will be especially valuable, i.e. the 'reporting list' should be constructed by considering the common components of children's products and work outward to the more uncommon substances. While as noted above, providing a list of all substances in children's products is unfeasible, informed discussion with industry would help address issues of chemicals not intentionally added to products. Additionally, the setting of de minimis levels for chemicals will be crucial in addressing the complex issue of trace contaminants and making the reporting requirement feasible.

- l) How should Ecology/DOH weight the value of the REACH list compared to Canada or California's lists in coming up with our own list?

**Comments:**

We have provided REACH background information and a cover letter highlighting aspects of REACH to be considered. Each list from any source must be examined for its intended application, quality of data, and relevance to the CSPA's goals; then risk assessments must be made to consider the "children's product" focus of the CSPA.

- m) What do we mean by "children's products?"  
Should we more precisely/carefully/narrowly define the universe of children's products to be covered by reporting? It would be good to make sure we are all talking about the same products.

**Comments:**

The term 'children's product' means a consumer product designed or intended primarily for children 12 years of age or younger. In determining whether a consumer product is primarily intended for a child 12 years of age or younger, the following factors shall be considered:

- (A) A statement by a manufacturer about the intended use of such product, including a label on such product if such statement is reasonable.

(B) Whether the product is represented in its packaging, display, promotion, or advertising as appropriate for use by children 12 years of age or younger.

(C) Whether the product is commonly recognized by consumers as being intended for use by a child 12 years of age or younger.

(D) The Age Determination Guidelines issued by the Commission staff in September 2002, and any successor to such guidelines.

The definition above should be accompanied by the guidance on child care items given by the CPSC and published in the Federal Register (February 23, 2009 (Volume 74, Number 34)).

Are there some products that we are missing? See California's draft cosmetics reporting form to get an idea of how they have defined the universe of cosmetics products.

<http://www.cdph.ca.gov/programs/cosmetics/Pages/faq.aspx>.

Comment: Agree. It will not be reasonable to try to answer this question until a definition is crafted and agreed to regarding "children's product".

- n) Should reporting be limited to chemicals known to be used in manufacturing or should it also include chemicals known or likely to be present due to common contamination?

**Comments:**

This question is similar to Question b above. There probably will not be an unambiguous solution to this dilemma. However, with only 50 slots available on a 'reporting list', some preferential identification process will be essential. This may be a place where industry knowledge will be especially valuable. In our view, the 'reporting list' construction should start by considering the common components of children's products and work outward to the more uncommon substances.

**2) Issues associated with the reporting process**

- a) How should confidential business information be reasonably treated?

**Comments:**

Confidential, trade secret and proprietary information not generally available to third parties must be adequately safeguarded to avoid damage to reporting businesses and to provide the greatest incentives to reporting.

- b) What should be the timeline for reporting? (who should have to report on what, when?)

Should there be a phased-in approach? If so, what should it be based on?

How would it work? Which companies, for which materials or substances should be required to report first?

**Comments:**

A reasonable and practical reporting timeline must be considered. We would propose at least 36 months after the effective date of the pilot rulemaking to allow chemical and product manufacturers time to build the necessary infrastructure to collect the required data requirements. Once the reporting requirements are implemented, it should be updated at no less than 12 months intervals (annually).

Additionally, phase-in of reporting requirements should be based on exposure characteristics of a chemical. For example, products that are highly likely to result in exposure to a chemical would need to report first, products that might result in exposure to a chemical would report second in a later time period, and products with no exposure (i.e. the chemical is fully contained) to a chemical on the reporting list would not require reporting.

- c) What information and format must a report contain? Is there any reason to allow submittal of hard copy, rather than electronic, data?

**Comments:**

The format and information will need to be agreed upon by all stakeholders. Our preference is to use the electronic format or have the option to use hard or electronic copies of the report.

- d) Should there be a standardized mechanism for reporting (i.e. companies are required to fill out a standardized form for each chemical etc.)? This may help minimize time trying to translate information to the public.

**Comments:**

The standardized approach focused on chemical or material manufacturers is recommended for reporting. We would certainly want to understand the process for doing this.

- e) What should be done with the information reported to Ecology? Options range from releasing information upon request to actively putting it in the public eye – i.e. post it on a website, do press releases, etc.

Should the way the information will be handled be in the rule? Should information be provided in a manner that clearly communicates exposure risk or the lack thereof? Should these options be in the rule?

**Comments:**

To the extent any information is released, it should be provided in a manner that clearly communicates exposure risk or just as importantly, the lack thereof, in order to avoid misleading statements and public confusion.

- f) How can a chemical or material manufacturer determine if their product has a chemical from the reporting list? Testing, Self-certification or Self-declaration of conformity, documented oversight process to ensure none of the chemicals are used at any point in the production process, etc.

If we allow something other than testing results to be submitted, what information must be included in the report?

**Comments:**

There are significant challenges to testing a broad list of chemicals. Most of the current chemical testing protocols have a limited number of chemicals that are tested based on current applicable regulatory requirements. Adding another set of new chemicals to the testing protocols will overburden the already taxed chemical testing done by CPSC approved laboratories.

In place of chemical testing results, chemical or material self-declarations or self-certification for conformance or/and audits of quality management program oversight of manufacturing process will ensure none of the identified chemicals are used in the product supply chain. Effective certification programs for consumer products should comprehensively address the entire supply chain and be able to provide verifiable assurance at critical stages. Chemical composition and material management systems must anticipate reporting or registration requirements by stage by the chemical or material manufacturer.

**Downstream User/Supplier Information:** Within the scheme of self-declarations, it is essential that a product manufacturer be able to rely on data and material certifications provided from their upstream suppliers or data provided separately by such suppliers or their trade Associations. This data may then be provided to the Department of Ecology as a part of a self-declaration by a children's product manufacturer. Additionally, it may be more streamlined for a supplier or trade association to provide upstream component/ingredient data directly to the Department (when reporting is required). Individual product manufacturers in their declaration then may simply reference that they use a component/ingredient that has been reported upstream or need not report (per above) if the ingredient exposure level listed is not met or the ingredient itself is not intentionally used.

This would not remove the requirement that product manufacturers provide a declaration specific to their impacted product categories, but would

streamline the data workload for the Department and reporting companies.

- g) Is there a need to benchmark Registration, Evaluation, Authorization and Restriction of Chemical substances (REACH) see - [http://ec.europa.eu/environment/chemicals/reach/reach\\_intro.htm](http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm) or Restriction of the Use of Certain Hazardous Substances (RoHS (Europe)) see - <http://www.rohs.gov.uk/> or similar regulated reporting process?

Specifically is there a need to review current REACH or/and ROHS reporting process to determine if there are any cross-over applicability?

**Comments:**

TIA provided REACH background information and a cover letter highlighting aspects of REACH to be considered. Also note problems with REACH approaches as outlined in our previous submission and issues that may limit application via a parochial state versus National approach. To the extent information on high priority chemical listing is available under REACH, a “safe harbor” should be considered to reduce burdens imposed by duplicative inefficient reporting.

- h) How should Ecology summarize and analyze reported data that is submitted by manufacturers?

Should information be analyzed by products or types of products?

Should this work feed into revising the reporting list?

**Comments:**

Analyses of the reported data should be by product category (preferably defined as chemicals or substances) and can be used in the revision of the reporting list.

**3) Issues associated with enforcement of the CSPA**

- a) How should the reporting requirements established by the rule be enforced?

**Comment:**

Based upon limited Departmental resources enforcement could be accomplished by review of self-declarations, testing of a truly representative product sample, and ensuring that companies have quality control and production control procedures.

- b) What should trigger a penalty? Should the agency provide notice and opportunity to comment prior to issuing a penalty?

**Comment:**

A violation occurrence would be based on a product in question that was not reported, not based upon the number of units made, as each individual item or unit is not a separate violation of reporting. Since reporting is not required for each physical product unit, violations would also only be based on the product as a uniform composition. There also should be reasonable due process so that a company can appeal any violation or submit reasonable evidence about the alleged violation.

- c) Should the media be informed?

**Comment:**

As noted previously, there should be reasonable due process so that a company can appeal any violation or submit reasonable evidence about the alleged violation. The media should not be informed, if at all, until all due process appeals have been exhausted.

- d) Should Ecology independently test products to ensure compliance with the law?

**Comment:**

See answer to Question a).

- e) What methods (audits, inspections, objective evidence) should Ecology use to ensure that manufacturers are compliant with the reporting requirements of the CSPA?

**Comment:**

See answer to Question a).

- f) Should labeling be considered? For example: If a product contains one or more reporting chemical, it gets labeled in some way - such as some cautionary language a la Prop 65.

**(Note: Memo from J. Williams July 2, 2009 where after due consideration, Ecology has reached the indicated decisions on the following issue)**

Labeling can be considered in the context of a change to the current statute or a discussion of policy options. However, current CSPA language does not provide the authority for Ecology to issues rules requiring labeling. The only enforcement mechanism authorized by the CSPA is the civil penalty. A civil penalty of up to five thousand dollars may be imposed for each violation in the case of a first offense. Repeat violators are subject to a civil penalty not to exceed ten thousand dollars for each repeat offense.

**Comments:**

Fundamental Due process requirements afforded under Constitutional and Administrative law generally govern the process by which the process of

assessing penalties against an affected party under statute. The Department is bound by such process. In addition, the Department's jurisdiction may be only limited to entities conducting business within the State. Regardless of inspection and testing methodologies employed, as noted above, regulations are required to establish criteria for chemical listings and standards for exposure prior to the development of testing, audit or enforcement regulations or policies.

- 4) **The Issues listed below are being evaluated by our legal counsel. While you are welcome to provide your position on these issues, it is doubtful that Ecology will act against the advice provided by our legal counsel.**

**(NOTE: Memo from J. Williams June 17, 2009 where after due consideration, Ecology has reached the indicated decisions on the following issues)**

Should the reporting list be in the rule?

Yes, the reporting list of chemicals should be in the rule. The reporting list, as an essential component of the CSPA reporting requirement, constitutes a "rule" under the Washington Administrative Procedures Act (APA). The APA defines a "rule" in relevant part as an "agency order, directive, or regulation of general applicability" the violation of which "subjects a person to a penalty." RCW 34.05.010(16). The reporting list fits this definition: it identifies which chemicals all regulated manufacturers must report on, so it is agency action of general applicability; and failure to report regarding the identified chemicals can subject a violator to a penalty.

How can penalties be appealed or what Due Process should be incorporated? If a right to appeal a penalty is allowed, what grounds for appeal will there be that will prevent appeals that merely serve to delay the implementation of the rule and allow the continued use of a high priority chemical in children's products?

Penalties assessed under the CSPA and associated rule will be appealable to Washington's superior courts, pursuant to Washington's Administrative Procedure Act. RCW 34.05.514(1). On appeal, the penalized person may make various arguments, including that Ecology's action was unconstitutional, beyond Ecology's authority, or arbitrary or capricious. RCW 34.05.570(4). The most likely arguments are probably that the violations on which the penalty was based did not occur and/or that the penalty amount is unreasonable.

Appealing a penalty is not the same as a challenge to the implementation of the rule itself. Additionally, it is important to clarify that the rule will not

prevent the use of high priority chemicals in children's products. The rule will simply require reporting if identified chemicals are present.

Should other mechanisms besides penalties be used for multiple violations? If so, what?

The only enforcement mechanism authorized by the CSPA is the civil penalty. A civil penalty of up to five thousand dollars may be imposed for each violation in the case of a first offense. Repeat violators are subject to a civil penalty not to exceed ten thousand dollars for each repeat offense.