Toy Industry Association, Inc.
www.toyassociation.org

May 3, 2013

Interstate Chemicals Clearinghouse
c/o Dr. Alex Stone, Senior Chemist
Washington Department of Ecology
PO Box 47600
Olympia, WA 98504-7600

Subject: Interstate Chemicals Clearinghouse Draft "Guidance for Alternatives Assessment and Risk Reduction"

Dear Dr. Stone:

The Toy Industry Association (TIA) is pleased to provide comments regarding the Interstate Chemicals Clearinghouse draft "*Guidance for Alternatives Assessment and Risk Reduction"* (IC2 AA Guidance). In addition to the enclosed comments, TIA has worked as part of a coalition of trade associations to provide in depth, collective comments from industry stakeholders on both the process and content of the draft IC2 AA Guidance, as well as recommendations on how alternatives assessment should be conducted.

TIA is a not-for-profit trade association representing more than six-hundred (600) toy makers, marketers and distributors, large and small, located throughout North America.

TIA is founded on the mission of bringing fun and joy to children's lives. In that pursuit protecting the safety of our young consumers is our top priority, and TIA and our members have long been leaders in toy safety. In this role, we develop safety standards for toys, working with industry, government, consumer organizations, and medical experts. The U.S. risk-based standards are widely recognized and used as models around the globe. TIA regularly conducts education seminars on these industry standards, and to educate parents and caregivers on choosing appropriate toys and how to ensure safe play.

TIA acknowledges the value of Alternatives Assessments (AAs) in some circumstances, and appreciates the IC2 work on this draft guidance. However we strongly object to any mandatory assessment proposal and assert that any "framework" for AAs needs to be flexible for different applications as well as disparate products/product categories in order to be considered workable.

While it is unclear exactly how the IC2 AA Guidance will be used, TIA has concerns that as drafted it is inadequate to assist companies that are not already familiar with these types of assessments, and lacks the flexibility to address the practical, and frequently complex, situations our industry faces when conducting these types of assessments.

As stated in our Coalition comments, "Alternatives assessment should be a flexible but rigorous process adapted from the product development and innovation process that considers a number of design,

performance, manufacturing, health and environmental impacts, regulatory compliance and consumer acceptance factors in identifying and analyzing potential improvements to an existing product."

TIA has concerns that the overall framework and process provided in the IC2 AA Guidance:

- Prioritizes hazard over other considerations – exposure, risk, safety;
- Fails to adequately address protection of Trade Secrets and other Confidential Business Information;
- Overlooks existing regulatory compliance obligations (international, federal and state);
- Emphasizes the assessment process rather than the outcome, and;
- Does not acknowledge the critical importance of consumer acceptance of products in the marketplace.

In order to produce outcomes that can be used to potentially improve product safety and innovation, AAs must:

- Ensure product safety and regulatory compliance;
- Accept all appropriate and adequate alternatives;
- Be science-based, and have the flexibility to deal with complex and varying business models & products;
- Allow for gradual and measured implementation;
- Use a risk-based approach to evaluate all relevant factors, and;
- Ensure consumer acceptance.

Enclosed, we offer a summary of comments and concerns on each of the modules in the IC2 AA Guidance. We thank you for the opportunity to comment. Please feel free to contact TIA directly via Jennifer Gibbons at: jgibbons@toyassociation.org if you have any questions or concerns about these comments or would like to discuss in more detail.

Respectfully,

Jennifer Gibbons
Director of State Government Affairs

Toy Industry Association Comments on IC2 Draft "Guidance for Alternatives Assessment and Risk Reduction" Scoping & Assessment Modules

Scoping

Initial Evaluation Module

This module is based on the assumption that if a product contains a chemical of concern that chemical should be phased-out or eliminated without any consideration given to whether an exposure exists or the potential risk involved, and due to this shortcoming may encourage regrettable substitutions which can *increase* risk. This module provides a limited set of criteria to assist with the development of an evaluation process based on the presence of a chemical. Most, if not all, manufacturers already have processes in place which they regularly use to evaluate their products.

Evaluation of Alternatives Module

This module establishes two key considerations for the potential alternatives:

1) functionally equivalent alternatives, and
2) the availability of alternatives in the marketplace.

These criteria are useful in the development of a broad list of alternatives which require assessment of cost, availability of supply, performance, compatibility with manufacturing processes, consumer acceptance, regulatory compliance, etc.

It should also be noted (as an alternative approach) when considering and documenting potential changes to a manufacturing process or redesign of a product that one should evaluate whether the option exists to reduce exposure and thereby reduce risk to an acceptable level.

Decision Module

The three frameworks provided for implementing the Guidance modules are useful, and it is appropriately pointed out in this module that, "This list is not meant to be comprehensive or to identify any priority for which framework should be used. Many valid decision methods may apply to a given situation and assessors should employ the approach that gives the most robust, dependable results with the information available." Choosing the proper method for complex decisions, and having the flexibility to apply individual business and product considerations is critical.

This module does place emphasis on the replacement of one chemical for another, when in practice a manufacturer will need to base decisions on the results of analyzing alternatives in the context of the product as a whole rather than a single ingredient. Additionally, most of the examples in this module focus on hazard. Decision methods should take a risked-based approach, considering both potential hazard and exposure.

Stakeholder Module

Stakeholder involvement is appropriate and a benefit to the alternatives assessment process, however we have concerns with the process laid out in this module. Private sector and public sector entities

cannot conduct a stakeholder process in the same manner, nor include the same level of stakeholder involvement. Public entities are required to operate at the highest level of transparency, whereas private entities are operating in a competitive marketplace where trade secrets and other Confidential Business Information often need to be protected.

The module suggests that stakeholders should determine their level of involvement and not be limited externally. While it may be appropriate for public entities to the have stakeholder involved in their decision-making process, it is unreasonable to have stakeholders involved in the decision-making process for a private entity. Stakeholder involvement in a private entities' AA process should be for purposes of collecting data and input which manufacturers can use to inform their analysis and evaluation of alternatives.

Assessments

Performance Module

Perform Assessment is critical to the safety of products and the assessment of potential alternatives. Any alternative must maintain, if not improve, the level of performance of the product during reasonable and foreseeable use. Additionally, an alternative must be able to perform to meet all relevant regulatory requirements, and address all aspects of safety – mechanical/physical, electrical, thermal, flammability and chemical risks. Focusing on chemical safety alone may lead to regrettable substitutions where a material is replaced with another which has creates poorer safety performance in one of these other aspects, thereby creating another type of hazard.

The guidance provides a basic approach to performance assessment. We appreciate that it is expressly stated that, "the intent of this module is to provide sufficient flexibility that will allow a wide range of users to determine if performance characteristics are a barrier to the use of a safer alternative." A one-size-fits-all approach is not feasible for performance assessment as evaluation practices vary by industry and criteria will differ based on products categories and individual products.

Missing from this module is a proper emphasis on exposure and risk as essential elements for evaluating the performance of potential alternatives. This is particularly important for formulated components, as a substitution which provides lesser performance may encourage consumers to use more of the reformulated product, potentially *increasing* exposure and risk.

Hazard Module

It is clear that the IC2 AA Guidance prioritizes hazard assessment over all other assessment factors. This approach is flawed as exposure assessment is equally as important to the determination of potential risk of a material or substance.

While hazard assessment is an integral part of alternatives assessment, hazard comparison without appropriate consideration of risk and exposure can be grossly misleading and may result in unintended consequences or regrettable substations.

The hazard assessment should focus on the collection of hazard information for the chemical(s) being evaluated and any potential alternatives. It may be possible to characterize an alternative based on the

hazard information, but it is premature to eliminate an alternative solely on this basis without consideration of the use, exposure, performance, availability and other relevant factors.

Additionally, clear and consistent criteria must be established for the sources of data that will be collected and used. And only reliable information should be used in order produce consistent results.

Finally, this module details some of the available tools which can be used for conducting hazard assessment. Use of specific proprietary, third-party screening tools should not be required to conduct AAs.

Cost & Availability Module

As detailed in the Coalition comments, there is significant overlap between levels in this module which may lead to duplication of efforts and minimal apparent benefit. We support combining level 1 with level 2, and level 3 with level 4, or restructuring this module to clarify the target audience and scope of each level.

Additionally, the product development process requires the expending of substantial resources, which hopefully results in a reasonable return on investment. Return on investment must be acknowledged as a critical component of the AA.

It should also be noted that companies regularly incorporate disposal, recycling and reuse considerations into product design either through voluntary efforts or regulatory mandates. Existing efforts to address environmental aspects of a product and/or stewardship plans which are already in place need to be taken into account.

Exposure Module

As stated in previous modules, consideration of product use and exposure potential is an essential factor for any chemical or product evaluation. The IC2 AA Guidance document segregates the assessment of exposure and hazard, even though it is common practice to consider both aspects when assessing the safety of a material or substance.

Since there are hazards associated with every chemical but risks can only be determined based on use, it is incumbent upon manufacturers to assess the risks associated with the use of any particular chemical. We recommend the Guidance include a science-based, logical process for conducting an exposure assessment using procedures such as those followed by a wide range of safety assessment frameworks within the US. It is common practice to assess exposure as part of any assessment of impacts to human health, occupational health, and/or environmental health.

As described in the Coalition comments, any framework for exposure assessment should include:

- A reasonably likely or foreseeable route of exposure to the subject chemical before there is a need to conduct an alternatives assessment.

- Indicators of potential exposure may be useful in initial screening or prioritization efforts, but additional information such as use patterns, levels in products above an appropriate *de minimis*[1], and product forms should inform the exposure evaluation. Both chemical mass and corresponding physicochemical properties, as well as the route of exposure, are useful in assessing relative impact. This is also an opportunity to factor in sensitivities of unique subpopulations.

- Potential for exposure will help identify and eliminate alternatives that may likely adversely contribute to significant exposure through use.

Materials Management Module

Alternatives Assessments should include consideration of Sustainable Materials Management (SMM); however products cannot be designed solely with that in mind. As such, this module is too narrowly focused and should be more broadly constructed.

Social Impact Module

Most alternative assessments are performed to provide benefits to the general population rather than to focus on subgroups. Therefore, the typical comparison will result in little or no change for social impacts. We agree that alternatives should be evaluated to assure there is not a disproportionately negative impact on a sub-population. However the availability of reliable data related to actual impacts on sub-population which can be used to conduct a social impact analysis presents a challenge, thus this module should not be a part of any mandatory process.

Life-cycle Thinking Module

Manufacturers engage in continuous alternatives assessment and product improvement. Life cycle assessment (LCA) is one tool to assist in evaluating the trade-offs of energy, raw materials and emissions before a product comes to market. For purposes of the IC2 AA Guidance, AAs should only evaluate those aspects directly affected by the alternative.

[1] Whether a chemical is an intentionally-added ingredient or a trace contaminant may impact how a *de minimis* threshold is established.