Toy Industry Association, Inc.
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Department of Toxic Substances Control
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Subject: Comments on the California Department of Toxic Substances Control – Proposed Regulation: Safer Consumer Products

Dear Ms. Von Burg:

Below please find a summary and detailed discussion of key concerns from the Toy Industry Association (TIA) regarding the Department of Toxic Substances Control (DTSC or Department) Proposed Regulations for Safer Consumer Products (Proposed Regulations) under Assembly Bill 1879 and Senate Bill 509 (2008). We remain concerned about the current structure and requirements of this proposed regulation, and believe that without further changes many provisions will be unworkable and the regulation will not achieve its intended purpose.

TIA appreciates that the Department has made significant efforts to attempt to address concerns in some areas of the regulation, however other areas have been made more burdensome and/or complex, or remain flawed. Overall these regulations lack the transparency and predictability necessary to both operate and achieve the goals of a program of this magnitude. TIA strongly believes that through some additional changes and restructuring, it is possible for DTSC to create a regulatory proposal that protects human and environmental health, while minimizing negative effects on commerce and product innovation.

These comments are in addition to, and incorporate where relevant, previous comments submitted to the Department by TIA on July 20, 2010, November 1, 2010, December 3, 2010, December 30, 2011, May 30, 2012, and October 11, 2012. TIA continues to urge the Department to seriously consider compromise and progress toward reaching a workable solution that is consistent with existing requirements in other states. Considering the strigent regulations and burdens already imposed on our industry consistency between states on key issues is critical to workable Green Chemistry Regulations.

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. California is responsible for roughly 22.0% of the nation's total toy industry activity, more than any other

state. Additionally, Toy Industry Association members employ more than 32,000 employees in California with a direct economic impact of more than $6 billion to the state.

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.

Below are fundamental concerns with the proposed Regulations that TIA believes must be addressed before a workable regulation can be adopted.

Part of the Department's charge in crafting regulations is to take the most effective and least burdensome approach to meeting its statutory mandate. Additionally, it is a basic tenet of good regulation that those being regulated must understand what is being regulated and be able to predict the effect of that regulation on their products; in this the Department continues to be unsuccessful. Addressing the following issues would create a more effective and workable program, while minimizing the burden these regulations will place on the California and United States economies:

<u>Changes Necessary to Prioritization Factors</u>

1) **Inaccessible Components are Not an Exposure Concern [Sections §69501.1 & 69503.2]:** As DTSC acknowledges in their "Initial Statement of Reasons" (ISOR) [Section 69503.2], there is little to no exposure to a "Chemical of Concern" (CoC) from inaccessible components. TIA agrees with the Department's assessment on this issue; however the regulation only loosely addresses it as a factor for the Department to consider during prioritization.

   In order to provide appropriate focus to the prioritization process, there is a need to define "inaccessible components" and remove these components from prioritization. This approach is consistent with California's statute – § 25252(a) of the statute directs DTSC to consider potential exposure and exposure pathways which supports the exclusion of inaccessible components from coverage by the regulation. It is also consistent with similar laws regulating chemicals in children's products in Washington State and Maine, and on the federal level under the Federal Hazardous Substances Act and the Consumer Product Safety Improvement Act. Internationally, chemical regulation in Canada and the European Union also recognizes and exempts inaccessible components.

   Failure to remove inaccessible components from prioritization will result in costly and burdensome testing and analysis of components from which there is no exposure risk to the consumer. Additionally, the Department will waste valuable time and resources evaluating these components instead of focusing where there is potential for exposure.

TIA proposes adding new language in Section 69503.2 stating that ***"The Department shall not consider the presence of a chemical of high concern which is solely contained within inaccessible components as a basis for naming or selecting a priority product, unless the Department finds scientifically credible, peer-reviewed data indicating that significant adverse impacts to human health or the environment have resulted from exposure to inaccessible components at any time during the life cycle of the product."***

We further suggest that if a definition of "inaccessible" is deemed necessary and desirable, that the current standard in use by the United States Consumer Product Safety Commission, found at Title 16, Code of Federal Regulations, Parts 1500.48 and 1500.49 is appropriate for children's products up to age eight, and can potentially be modified for other types of products.

2) **Link Between Priority Products and Potential Exposure [Section §69503.2]:** Currently, the regulations outline specific factors DTSC will use to evaluate and prioritize Priority Products, which include "reliable information regarding exposures." What is glaringly absent is a requirement for DTSC to establish even the most tenuous connection between a specific product and the observed potential for exposure. TIA is interested to know on what basis DTSC determines that a specific product is a significant contributor to the pollution or bioburden, or even that it contributes at all? The current stance of the Department places the burden of proof (to prove a negative) on those being regulated, rather than the Department having a duty to establish with a reasonable degree of certainty that a specific product is a significant contributor to the exposure.

   In order for this regulation to be both workable and effective, when determining priority products DTSC must demonstrate:

   1) **That a priority chemical poses a significant hazard to human health and the environment;**
   2) **That a priority product may reasonably be expected to contain the priority chemical in a significant quantity;**
   3) **That a human and environmental exposure exists (of which the only acceptable evidence is consistent presence in air or water monitoring data or in biomonitoring data); AND**
   4) **That the priority product is a significant contributor to the observed exposure data.**

   Products that are a minimal contributor to exposure should not be listed as a "Priority Product."

3) **Definition of "Complex Durable Products" [Section §69503.5]:** TIA understands that the Department's intent in denoting a class of products which are "complex durable products" is to limit the number of components on which a manufacturer might otherwise be required to perform simultaneous alternatives assessments. TIA remains concerned that the scope of products in this category is both arbitrary and unduly limited. Products

with far fewer than 100 components may still be quite complex, and it is arbitrary and capricious to summarily discriminate against children's product makers by excluding them from the (albeit limited) protections of this section when manufacturers of other product classes are not. We request that the Department look to redefine this section with terminology and standards which would minimize the burden for manufacturers of assembled products with 50 or more components, including children's products manufacturers, who should not be put at a disadvantage compared to other manufacturers of assembled products which contain multiple components.

4) **Consider <u>All</u> Factors Related to Impact and Exposure [Section §69503.2]:** The Department's product-chemical identification and prioritization process in Section 69503.2 requires the department to consider "one or more" factors related to impact and "one or more" facts related to exposure. **The Department should be required to consider in <u>totality</u> "…all factors listed in § 69503.3 (a) or § 69503.3 (b) for which information is readily available…" TIA recommends the Department strike "one or more" where it is utilized in section § 69503.3 (a) and (b).**

<u>Alternatives Analysis Process Needs Restructuring</u>

1) **Alternatives Analysis (AA) Threshold/ De minimis:** TIA appreciates that the Department has recognized the distinction between "intentionally-added" ingredients and "contaminants" in this draft of the regulation. However, the regulation establishes that the AA threshold only applies to contaminants present below the Practical Quantification Limit (PQL). We are disappointed to see that DTSC has rejected the concept of a *de minimis* level, or a clear and predictable AA threshold level, being exempt. Additionally, TIA questions how DTSC expects entities to file an "AA Threshold Notification in Lieu of AA" stating with certainty that their priority product contains a priority chemical as a contaminant if it cannot be reliably measured.

   The regulation should exempt "contaminants" below a set de minimis level or where a manufacturer has a "due diligence" system – Manufacturing Control Program (MCP) – in place, as other states have done. We continue to recommend the following structure in order to focus Responsible Entity and Department time and resources where they will be most effective:

   A. For a chemical that is an intentionally added chemical in an accessible component of a product, the practical quantification limit; or
   B. For a Chemical of Concern Priority Product combination in which the chemical of concern is a contaminant present in an accessible component of a product, a concentration of 100 parts per million; or
   C. Any concentration in a product, if that chemical occurs only in an inaccessible component or occurs in a product only as a contaminant, as long as the manufacturer has in place a manufacturing control program and exercised due diligence to minimize the presence of the contaminant in the component.

2) **AA Threshold Notification in Lieu of AA [§69505.3]:** The overly cumbersome process for filing an alternatives assessment threshold exemption is counter to the spirit and intent of this provision – which intends to acknowledge that there is no concern with such extremely small levels of a chemical in a product. The Department and manufacturers will be overwhelmed by unnecessary paperwork under this provision, and consumers will be overwhelmed with information that is likely to be confusing and misleading. The process requires the release of proprietary data, which would be public when the Department posts the AA threshold exemptions on their website, for products that are not a priority and pose no human health or environmental concerns.

   TIA requests that the regulations strike the proposed exemption notification requirement and require only that a responsible entity notify the agency by letter within 60-days if it meets the requirements to notify (TIA has provided comments above regarding an appropriate structure for an AA Threshold). The Department could then request additional information if needed. Notifying entities should be allowed to assert a right to confidentiality of the chemical identity if such information could plausibly allow competitors to ascertain confidential business information regarding raw materials, manufacturing processes, or other pertinent information. This proposed change will allow the Department to carry out its mandate under the statute while minimizing administrative burdens for both reporting entities and DTSC.

3) **Alternatives Analysis Process [Article 5]:** TIA appreciates that the Department has removed the "certified assessor" requirement from the AA process. However, under the new structure, AAs (including preliminary and abridged AAs) would be subject to a public review and comment process. This provision is overly burdensome for the Responsibly Entity, and it is not clear what the Department hopes to achieve through this process given that public comments may or may not be based on reliable or credible information. TIA previously provided comments to resolve issues created with "certified assessors." If the Department has now rejected that concept, then we recommend that DTSC alone should review and approve AAs. Additionally, only Final AA Reports should be made public in order to protect Confidential Business Information (CBI). If a public comment process is established there should be requirements that comments be based on reliable and credible information.

   Additionally, alternatives assessment is core to developing safe consumer products and TIA supports a pragmatic and science-based approach. TIA believes the AA Industry Coalition's "Product development and improvement paradigm" (submitted to DTSC on October 8, 2012) is a solid basis for an appropriate framework. TIA shares the concerns noted in previous comments from the European Union (EU) that requirements in the draft Regulations for conducting an AA are highly complex, both technically/content-wise and administratively, and DTSC has not documented any feasibility analysis or "beta-testing" to examine whether the required work can be conducted at all, to estimate the costs and necessary timeframe for conducting an AA and whether these costs are proportionate.

Regulatory Response Clarification and Focus on Compliance Assistance Requested

1) **Focus on Compliance [Article 6]**: **S**ince this Regulatory Program is groundbreaking in terms of its expansive scope, and data submission and analysis requirements, TIA hopes it is the Department's intent to focus heavily on **compliance assistance** in the initial years of implementation, and to avoid unnecessary regulatory responses or penalties on Responsible entities that are working in good faith with the Department to comply with regulation.

2) **Listing of Information on the Department's Website [§69501.2, 69501.5, 69501.4 & 69507.1]:** The Department intends to post a Failure to Comply List, regulatory determinations and other information to their website. **It is imperative that any and all information posted to this list or other sections of the Department's website be done only after responsible entities are provided ample opportunity to object to the listing or posting of information, or remedy any compliance issues.**

3) **Product Information for Consumers [§69506.3]:** The regulation mandates information required to be made available to consumers prior to product purchase including "A list of any Chemicals of Concern and the known hazard traits." TIA is unclear on the Department's intent with this provision. If a CoC is determined through the AA process to be the safest, most effective material, will products still be required to list the CoC and all the hazard traits even though there is no safer alternative?

   Additionally, from a practical standpoint it would be impossible to get all of this information in multiple languages on product packaging or store signage. Having a website address on your package where the info could be found should be acceptable. If the Department intends for this provision to remain in the regulation, **TIA recommends that "Communication to Consumers" requirements be met by "either" website or point-of-sale information, rather than "both" to make this provision manageable for companies.**

Other Key Issues of Concern

1) Regulatory Duplication Applicability [Section §69501 & 69503.1]: Per the mandates of AB 1879, products where another federal or California State regulation addresses the same risk of injury or environmental threat that has resulted in DTSC prioritizing a chemical or product, must be excluded from further duplicative regulation. The revised regulations provide an exemption for products already regulated, however the Departments retains broad discretion over the determination over this applicability. TIA recommends that the Department strike the subjective language – "meaningfully enhance" – to provide clarity and a true applicability exemption for products already regulated by other laws. It is apparent that this last-minute addition creates a requirement which is beyond the scope of the department's mandate under the statute, and the language is just as clearly unconstitutionally vague.

2) **Trade Secrets Protection/CBI issues [Article 9]: S**ince this Regulatory Program is groundbreaking in terms of its expansive scope and data submission requirements, TIA asserts that trade secrets must be strongly protected (Article 10). The nature of the data required to be submitted - once a priority product and chemical concern combination have been designated, through alternatives assessment and regulatory response – is highly specific and unique. Therefore, unique provisions to protect trade secrets are warranted herein. **Moreover, Confidential Business Information, which may not fall within the definition of "trade secrets," should also be protected. Specifically, CBI should be protected during the Product Notification process, and not posted on the Department's website.**

3) **Department Responsibilities and Timelines [Articles 5, 6 & 7]:** This regulation imposes extensive and specified time restrictions on responsible entities, yet relieves the Department of the burden to appropriately respond to deadlines that it has created. This leaves responsible entities without the predictability they need for business plans, and without information they need to plan for investment, budgets, etc. For example, Section 69505.8 establishes that DTSC will review and issue a notice of compliance or disapproval, or ongoing review, within 60 days of receiving an AA. However, Section 69505.1 states that failure of the Department to make a determination for AA within the specified timeframe shall not cause an AA report to be deemed compliant.

   Similarly, Section 69505.1 requires responsible entities to file for an AA extension request at least 60 days before its original due date stating that the Department will respond within 30 days. Yet failure of the Department to issue a decision within 30 days does not constitute an approval of the extension request. Finally, in Sections 69507.4 & 69507.6, the regulation gives responsible entities a 30 day timeframe to file a Request for Review while establishing that the Department has 60 days to issue an order granting or denying the Request for Review, OR a notice of ongoing review which only provides an estimated date that the Department expects to issue an order. If a responsible entity has hired resources to assist them with the complex AA process and then they are left awaiting a determination for unspecified period of time this will create additional costs and complications. Additionally, leaving responsible entities with this uncertainty forces them to hold off on making important business decisions and plans which disrupts commerce.

   Given the expansive scope of this program, it is likely the Department will be overwhelmed with reports, complexity, questions, etc. By allowing the option to not respond in a timely manner, the regulations lay the groundwork for the Department's role in this process to become the bottleneck and raises issues of compliance. If a request for an extension is submitted 60 days out and the Department doesn't respond for an additional 60 days and denies the request, will this be deemed non-compliant? **TIA recommends that the regulations should specify that a responsible entity has met their filing deadlines, and the Department does not respond by its deadlines, all relevant timelines are put on hold until the Department responds.**

4) **Responsible Entities [Section §69501.1 & 69501.2]** – The regulation still includes "Retailers" as a "Responsible Entity" even though Retailers, have little, if any, part in the design or manufacturing of the products, and are therefore, unlikely to be able to influence the chemical composition of the product, or have the ability to conduct an AA of the product. Therefore, it is wholly inappropriate for them to share the regulatory burdens in the regulations, even if their responsibilities are the last step in the chain of responsibility after Manufacturers and the Importers.

In addition to the key issues noted above, we present in this letter a section-by-section analysis of specific elements within the Proposed Regulations that are problematic. TIA hopes that these comments are helpful to the DTSC as the regulations continue to be revised.

TIA Section Comments

Article 1: General

Section 69501 – Purpose and Applicability

"Potential": The Department has added the qualifier "potential" to "adverse impacts posed by" the chemicals of concern in the priority products. Adding "potential" as a qualifier will increase the scope of the regulations' impact. The regulations define "potential" to mean that the phenomenon described is reasonably foreseeable based on reliable information. What does "reasonably foreseeable" mean?

This term "potential" is too vague, even as defined ("reasonably foreseeable based on reliable information") and will encompass products that do not have any real risk of exposure. Reliable information is applied to the demonstration of "potential occurrence" of exposures to a chemical. Exposure information is scientifically available by peer-reviewed sources, but "potential" occurrence of exposure unnecessarily broadens the scope of exposure beyond what is scientifically acceptable and proven.

TIA recommends that term "potential" be deleted or appropriately defined.

Section 69501.1 Definitions

"Accessible Component" – For assembled products there is a need to define "accessible components"; which also should be referenced in several key places in the regulation to properly focus these regulations and resulting compliance requirements on those components for which there is a likelihood of exposure. Both the terms accessible and inaccessible component are critical to focusing these regulations on actual potential for exposure.

"Adverse Ecological Impact" – This definition contains several subjective terms that lack standards and clear definition for determining an actual adverse effects. Specifically, "Deterioration or loss of environmentally sensitive habitats" and "changes in ecological

communities" are terms that lack clear definition and exposition regarding how the DTSC will evaluate these impacts.

Alternatives Analysis Threshold": The regulation defines AA threshold as the PQL for a Chemical of Concern present solely as a contaminant present below the Practical Quantification Limit (PQL). We are disappointed to see that DTSC has rejected the concept of a *de minimis* level, or a clear and predictable AA threshold level, being exempt. Additionally, TIA questions how DTSC expects entities to file an "AA Threshold Notification in Lieu of AA" stating with certainty that their priority product contains a priority chemical as a contaminant if it cannot be reliably measured. TIA recommends for the following structure for an AA Threshold:

> ***A. For a chemical that is an intentionally added chemical in an accessible component of a product, the practical quantification limit; or***
> ***B. For a Chemical of Concern Priority Product combination in which the chemical of concern is a contaminant present in an accessible component of a product, a concentration of 100 parts per million; or***
> ***C. Any concentration in a product, if that chemical occurs only in an inaccessible component or occurs in a product only as a contaminant, as long as the manufacturer had in place a manufacturing control program and exercised due diligence to minimize the presence of the contaminant in the component.***

"Homogenous Material" – This term is difficult to define and has been problematic in the EU RoHS Directive. Therefore, we suggest removing the definition of "Homogenous Material" from the regulations. We agree that the Department needs the ability to set threshold levels at the material level, rather than the part or component level, but this can be addressed in the definitions of "component" and "consumer product." TIA recommends the following definitions:

> ***(21) "Component" means a uniquely identifiable part, piece, assembly, subassembly, or a material within a part, piece, assembly, subassembly, of a consumer product that:***
> ***(A) Is required to complete or finish an item***
> ***(B) Performs a distinctive or necessary function in the operation of a product or part of a product***
> ***(C) Is intended to be included as a part of a finished item***
> ***(22)(A) "Consumer product" or "Product" means any of the following:***
> ***1. A "consumer product" as defined in Health and Safety Code section 25251;***
> ***2. A component, or uniquely identifiable material within a component, that is identified under section 69503.4(a) (2) (B), as the minimum required focus of an AA.***

"Inaccessible component" – For assembled products there is a need to define "inaccessible components"; which also should be referenced in several key places in the regulation to prevent the regulations from overreaching and focusing on components

where there is no reasonable likelihood of exposure. We further suggest that if a definition of "inaccessible" is deemed necessary and desirable, that the current standard in use by the United States Consumer Product Safety Commission, found at Title 16, Code of Federal Regulations, Parts 1500.48 and 1500.49 be adopted.

"Responsible Entity" – Per above comments, **t**he regulation still includes "Retailers" as a "Responsible Entity" even though Retailers, have little, if any, part in the design or manufacturing of the products, and are therefore, unlikely to be able to influence the chemical composition of the product, or have the ability to conduct an AA of the product. Therefore, it is wholly inappropriate for them to share the regulatory burdens in the regulations, even if their responsibilities are the last step in the chain of responsibility after Manufacturers and the Importers.

Section 69501.2 – Duty to Comply and Consequences of Non-Compliance

Failure to Comply List: As discussed above, it is imperative that any and all information posted to this list or other sections of the Department's website be accomplished only after responsible entities are provided ample opportunity to object to the listing or remedy any compliance issues.

Section 69501.5 – Availability of Information on the Department's Website

Listing of Information on the Department's Website: It is imperative that any and all information posted to this list or other sections of the Department's website be done only after responsible entities are provided ample opportunity to object to the listing or posting of information, or remedy any compliance issues.

Article 2: Process for Identifying Candidate Chemicals

Section 69502.2 – Chemicals of Concern Identification

List of Chemicals: The inclusion of such a broad list of chemicals of concern (CoC), that is estimated to contain 1,200 chemicals, does not provide predictability and certainty to companies. There must be a clear risk & safety-based approach to prioritizing chemicals of concern within these regulations. This is the basis of international chemical regulations; such as the European Union REACH process and the Canadian Domestic Substances List program. Additionally, states like Maine and Washington State have adopted step-wise processes for prioritizing chemicals. While all stakeholders may not agree on the chemicals selected at each prioritization step, this process is necessary to providing predictability and direction to the market-place.

Finally, Alternative Assessments must not fall into the same trap, a rigid prohibition on replacing a CoC with anything on a list, but instead take a more holistic approach – i.e. any proposed alternative must on balance improve the safety and environmental profile of the product. This would not only fulfill the department's mandate and the intent of the statute, but recognize that improvements will often be incremental, multi-stage efforts.

Article 3: Process for Identifying and Prioritizing Product-Chemical Combinations

Section 69503.1 – Applicability

Regulatory Duplication: As discussed above, the regulations provide an exemption for products already regulated by another entity with respect to the same potential impacts, however the Departments retains broad discretion over the determination over this applicability. TIA recommends that the Department strike the subjective language – "meaningfully enhance" – to provide clarity and a true applicability exemption for products already regulated by other laws.

Section 69503.2 – Priority Product Prioritization

Prioritization Process: Per the comments above, the regulations outline specific factors DTSC will use to evaluate and prioritize Priority Products, which include "reliable information regarding exposures." What is glaringly absent is a requirement for DTSC to establish even the most tenuous connection between a specific product and the observed potential for exposure. **In order for this regulation to be both workable and effective, when determining priority products DTSC must demonstrate:**

A) **That a priority chemical poses a significant hazard to human health and the environment;**
B) **That a priority product may reasonably be expected to contain the priority chemical in a significant quantity;**
C) **That a human or environmental exposure exists (of which the only acceptable evidence is consistent presence in air or water monitoring data or in biomonitoring data); AND**
D) **That the priority product is a significant contributor to the observed exposure data.**

Products that are a minimal contributor to exposure should not be listed as a "Priority Product."

Additionally, reasonableness of exposure through normal use and foreseeable abuse is an essential principle of proper chemicals regulation and is recognized nationally and around the world. Assembled products that only contain CoCs in inaccessible components - for which there is no reasonable and foreseeable exposure pathway - should not be prioritized under this section. Only accessible components of assembled products should be the focus of these regulations, as they are the only components with the potential for reasonable and foreseeable exposure. The principle of applying chemical regulations only to accessible components of assembled products has been validated by the U.S. Consumer Product Safety Commission (CPSC), the Maine Department of Environmental Protection (DEP), and Washington State DoE under substantially similar laws. CPSC regulations – 16 CFR, Part 1500.48 and 1500.49 – can provide guidance for DTSC regarding specific technical requirements for determining accessibility

Section 69503.3 Adverse Impact and Exposure Factors

Use of "Potential": The regulations have been revised to consider "potential" impacts etc. Again, this qualifier will broaden the reach of the regulations to include Candidate Chemicals that may not actually have any impacts, based on the "potential" for impacts.

Additionally, (G) establishes as a factor**,** the "potential for the Candidate Chemical to degrade, form reaction products or metabolize into another Candidate Chemical" to be considered an Adverse Impact essentially allows any possible chemical reaction that could create a new Candidate Chemical to be considered as a factor. If Candidate Chemical A could potentially be reacted with any other chemical, to form reaction product Candidate Chemical B, Chemical A would be considered to have an adverse impact even if it was highly unlikely it would ever be combined with the other chemical to create the reaction product B. Anytime potentially is used as a condition, it simply opens the door to any interpretation. TIA suggests a more restrictive adjective such as 'likelihood' or 'probability" would be more appropriate for this provision.

Exemptions: The regulations no longer exempt from being named a Priority Product: (1) a product that is manufactured or stored in, or transported through, California solely for use outside of California; and (2) a product used in California solely for the manufacture of one or more of the products exempted from the definition of "consumer product". These conditions will be evaluated during the product prioritization process, during which DTSC will decide whether or not to include such products as Priority Products. This gives DTSC extraordinary discretion to include products that may never have any impact or effects in the State of California.

Workplace Exposures: The Department does not have regulatory authority under this statute over workplace exposures to CoCs; especially if those exposures occur beyond California's boundaries. Workplace exposures are the jurisdiction of U.S. OSHA and Cal OSHA. Thus these "manufacturing" exposure considerations should be removed from this Section.

Section 69503.4 Priority Product Work Plan

Work Plan: It is unclear from the regulations if the work plans are a pre-requisite to listing of a Priority Product. Will DTSC give 3 years notice via the work plan for future Priority Product listings? If so, then the second listing of Priority Products will be in 3 years, correct? TIA requests that the Department clarify that there will be no Priority Products listing annually until 3 years after the first work plan (the first three years there will only be the first 5 Priority Products). This would provide greater notice of possible product-chemical combination listings by requiring three-year advanced notice of work plan. No implementation or designation of Priority Products until after 3 years notice would allow product design time to eliminate telegraphed product-chemical combinations from products prior to the listing, which would serve the goals of the underlying statute and minimize the costs to the government.

Section 69503.5 Priority Products List

Complex Durable Products: Per comments above, TIA understands that the Department's intent in denoting a class of products which are "complex durable products" is to limit the number of components on which a manufacturer might otherwise be required to perform simultaneous alternatives assessments. TIA remains concerned that the scope of products in this category is both arbitrary and unduly limited. Products with far fewer than 100 components may still be quite complex, and it is ***arbitrary and capricious to summarily discriminate against children's product makers*** by excluding them from the (albeit limited) protections of this section when manufacturers of other product classes are not. We request that the Department look to redefine this section with terminology and standards which would minimize the burden for manufacturers of assembled products with 50 or more components, including children's products manufacturers, who should not be put at a disadvantage compared to other manufacturers of assembled products which contain multiple components.

Section 69503.6 – Initial Priority Products List

APA Process: It is unclear from the regulation where DTSC intends the Initial Priority Products List to be subject to the same Administrative Procedures Act (APA) process as future lists. This should be clarified as it is critical that the Initial Priority Products list be given the same review as future lists.

Article 4: Petition Process for Identification and Prioritization of Chemicals and Products

Section 69504 – Applicability and Petition Contents

Waiting Period: This section requires a 3 year waiting period before a petition can be filed to remove a list of chemicals, or a product-chemical combination. If there is evidence supporting removal of a list or product-chemical combination, petitions should be filed and reviewed immediately.

Article 5: Alternatives Analysis

Section 69505.1 – Alternatives Analysis General Provisions

Public Comment Process: As discussed above, AAs (including preliminary and abridged AAs) would be subject to a public review and comment process. TIA is concerned that as drafted DTSC would make the proprietary work and knowledge that a company must perform to complete an Alternative Assessment report publically available. We believe that by making a company's Alternative Assessment report, and their conclusions, public (even if the report is redacted) would jeopardize a company's ability to protect certain information as confidential business information (CBI).

Additionally, this provision is overly burdensome for the Responsibly Entity, and it is not clear what the Department hopes to achieve through this process given that public

comments may or may not be based on reliable or credible information. TIA previously provided comments to resolve issues created with "certified assessors." If the Department has now rejected that concept, then we recommend that DTSC alone should review and approve AAs. Additionally, only Final AA Reports should be made public in order to protect Confidential Business Information (CBI). If a public comment process is established there should be requirements that comments be based on reliable and credible information.

AA Process: The alternatives assessment process is essential for developing safe and innovative children's products. The fundamentals of the process are routinely executed as part of industry's ongoing research and development and product improvement. The key to innovation, and better meeting consumer needs, expectations, and preferences, is the ability for manufacturers to draw on a variety of existing evaluation and decision making tools and approaches for developing products. Safety—protecting public health and the environment—is an inherent component of the product design process. Concepts that leverage existing practices in the product development paradigm should form the basis of a practical and meaningful regulatory framework for alternatives assessment.

A rational, structured and predictable alternatives assessment process is essential from a business perspective and TIA supports the Green Chemistry AA Coalition's "Product development and improvement paradigm" as an appropriate framework.

Section 69505.3 – AA Threshold Notification in Lieu of AA

Notification Process: As discussed above, the overly cumbersome process for filing an alternatives assessment threshold exemption is counter to the spirit and intent of this provision – which intends to acknowledge that there is no concern with such extremely small levels of a chemical in a product. The Department and manufacturers will be overwhelmed by unnecessary paperwork under this provision, and consumers will be overwhelmed with information that is likely to be confusing and misleading. The process requires the release of proprietary data, which would be public when the Department posts the AA threshold exemptions on their website, for products that are not a priority and pose no human health or environmental concerns.

TIA requests that the regulations strike the proposed exemption notification requirement and require only that a responsible entity notify the agency by letter within 60-days if it meets the requirements to notify (TIA has provided comments above regarding an appropriate structure for an AA Threshold). The Department could then request additional information if needed. Notifying entities should be allowed to assert a right to confidentiality of the chemical identity if such information could plausibly allow competitors to ascertain confidential business information regarding raw materials, manufacturing processes, or other pertinent information. This proposed change will allow the Department to carry out its mandate under the statute while minimizing administrative burdens for both reporting entities and DTSC.

Additionally, TIA questions how DTSC expects entities to file an "AA Threshold Notification in Lieu of AA" stating with certainty that their priority product contains a priority chemical as a contaminant if it cannot be reliably measured.

Article 6: Regulatory Responses

Section 69506 – Regulatory Response Selection Principles

Focus on Compliance: As discussed above, **s**ince this Regulatory Program is groundbreaking in terms of its expansive scope, and data submission and analysis requirements, TIA hopes it is the Department's intent to focus heavily on **compliance assistance** in the initial years of implementation, and to avoid unnecessary regulatory responses or penalties on responsible entities that are working in good faith with the Department to comply with regulation.

Section 69506.3 – Product Information for Consumers

Communication to Consumers: Per above comments, the regulation mandates information required to be made available to consumers prior to product purchase including "A list of any Chemicals of Concern and the known hazard traits." TIA is unclear on the Department's intent with this provision. If a CoC is determined through the AA process to be the safest, most effective material, will products still be required to list the CoC and all the hazard traits even though there is no safer alternative?

Additionally, from a practical standpoint it would be impossible to get all of this information in multiple languages on product packaging or store signage. Having a website address on your package where the info could be found should be acceptable. If the Department intends for this provision to remain in the regulation, **TIA recommends that "Communication to Consumers" requirements be met by "either" website or point-of-sale information, rather than "both" to make this provision manageable for companies.**

Article 9: Trade Secret Protection

Section 69509 – Assertion of a Claim of Trade Secret Protection

CBI: Since this Regulatory Program is groundbreaking in terms of its expansive scope and data submission requirements, TIA asserts that trade secrets must be strongly protected. The nature of the data required to be submitted - once a priority product and chemical concern combination have been designated, through alternatives assessment and regulatory response – is highly specific and unique. Therefore, unique provisions to protect trade secrets are warranted herein. It is a major concern to TIA that Confidential Business Information (CBI), may not fall within the definition of "trade secrets." We recommend the following changes:

A. Add to definition section, Confidential Business Information: ***Any information in the custody of a business entity that the business entity reasonably expects to be preserved as confidential in order that the business may obtain or retain business advantage from its rights in the information.***

B. Add a section to the Trade Secrets Provision: ***In addition to trade secrets, a claim for Confidential Business Information will be reviewed by the Department to determine if disclosure of such information would cause substantial harmful effects to the claimant, including revealing capital and marketing costs, specialized technical expertise, unusual processes, or unique ingredients, or give competitors access to customers or information that may give them a competitive advantage. The claim shall include details of the substantial harmful effects to claimant, as well as a redacted form of the information.***

Chemical Identity: The trade secret protection provisions pertaining to hazard trait submissions have been revised to allow masking of precise chemical identify only for an alternate chemical being considered or proposed for which a patent application is pending. Masking will only be allowed until the patent application is granted or denied. This provision still does not take into account "recipes" which may not be subject to patent, but provide a competitive business advantage and therefore constitute "confidential business information."

Conclusion:

Product safety is a vital consideration for toy manufacturers. A core requirement of our industry is to perform rigorous testing to stringent federal requirements and in many cases stringent international environmental and safety regulations.

TIA appreciates the hard work that has gone into the development of these Proposed Regulations and attempts to balance many stakeholder interests. TIA asserts that significant revisions are nevertheless still needed before this regulation can be considered workable for industry and the Department.

Once again, TIA remains committed to working to ensure that these Regulations provide a workable solution to chemicals management issues in California that promote public and environmental health without placing undue and unnecessary burdens on business that is not commensurate with the benefit derived.

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
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