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November 16, 2015

via CalSafer Web Portal

Ms. Barbara Lee, Director
Department of Toxic Substances Control
1001 I Street
Sacramento, CA 95814

Re: Safer Consumer Products Program Draft Stage 1 Alternatives Analysis Guidance Document

Dear Director Lee:

The Consumer Specialty Products Association (CSPA)¹ appreciates the opportunity to provide comments on the Draft Stage 1 Alternatives Analysis Guidance Document. CSPA and our member companies have participated throughout the years-long regulatory development process through submission of written comments and participation in public hearings and workshops/seminars. CSPA urges that DTSC carefully consider and adopt the recommendations of the National Academy of Sciences "A Framework to Guide Selection of Chemical Alternatives."

CSPA members are committed to manufacturing and marketing safe products that are protective of human health and the environment while providing essential benefits to consumers. As stated in previous submissions regarding the Safer Consumer Products Regulation, CSPA and our members support the broad goals of the Green Chemistry Initiative and will continue to work with the Department and other stakeholders in the state to help spur innovation and continue to ensure that products are safe. CSPA also supports the comments submitted by the Green Chemistry Alliance.

CSPA offers the following comments on the Draft Stage 1 Alternatives Analysis Guidance Document:

First, we note that this is but the first of two documents which DTSC will develop as part of its effort to provide guidance to responsible entities which will or might be required to conduct an

¹ The Consumer Specialty Products Association (CSPA) is the premier trade association representing the interests of companies engaged in the manufacture, formulation, distribution and sale of more than \$80 billion annually in the U.S. of familiar consumer products that help household and institutional customers create cleaner and healthier environments. CSPA member companies employ hundreds of thousands of people globally. Products CSPA represents include disinfectants that kill germs in homes, hospitals and restaurants; candles, and fragrances and air fresheners that eliminate odors; pest management products for home, garden and pets; cleaning products and polishes for use throughout the home and institutions; products used to protect and improve the performance and appearance of automobiles; aerosol products and a host of other products used every day. Through its product stewardship program, Product Care[®], and scientific and business-to-business endeavors, CSPA provides its members a platform to effectively address issues regarding the health, safety and sustainability of their products.

AA on a Priority Product. Consistent with the regulatory prioritization process, the Stage 1 guidance document describes an iterative screening process. We fully understand the nature of an iterative process aimed at reaching a decision regarding identification of alternatives to the chemical(s) of concern in the designated Priority Product which will be evaluated. However, we caution DTSC to make it clear to all who might refer to the guidance document that this iterative process is not intended to be an endless, circular and open-ended process. With this in mind, CSPA observes that the guidance document is robust on the factors to be considered but lacking clarity regarding its most basic processes for evaluating decisions made by a responsible entity.

In previous discussions and in comments submitted, CSPA has urged DTSC to embrace a flexible process which allows for customization for critical factors important to the responsible entity, including certain lifecycle and consumer acceptance criteria. While we appreciate the flexibility allowed for responsible entities conducting an AA, we note the tension between the need for and value of flexibility compared with a more definitive approach that provides clarity and certainty for compliance. Therein is the nerve-wracking tension whereby responsible entities had hoped the guidance would provide greater clarity in this space. At the end of the day, we appreciate the guidance and would suggest DTSC enhance the document with a more detailed description of DTSC perspectives and expectations in conducting AAs based on sound science, credible data and information that are in line with statutory and regulatory authority. Responsible entities must be assured that following the AA Guidance will result in an AA that is acceptable to the regulatory authority and meets statutory and regulatory requirements. We also urge DTSC to provide specific examples of AAs that meet DTSC's expectations, but as noted in later comments, the publically available AA examples must conform to the same rigor and quality standards as those required of responsible entities pursuant to California law.

As noted above, this draft Stage 1 AA Guide is but one of two to be developed by DTSC and hence at this time we are unable to comment on the entirety of the guidance. We look forward to an opportunity to comment on the guidance for the full AA process, therefore, wish to reserve the right to revise and extend our comments relative to Stage 1 upon thoroughly reviewing Stage 2 guidance at a later time and reflecting on the interplay between the two parts.

1. Definitions

- Exposure Factor – recommend inclusion of EPA Factors Handbook [U.S. EPA. Exposure Factors Handbook 2011 Edition (Final). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-09/052F, 2011.]
- Hazard Traits – recommend reference to Hazard Traits regulation which defines each of the hazard traits. The shortened definition presented here is potentially confusing and misleading, especially “exposure potential.”
- Monte Carlo Analysis – the definition is non-standard and makes little sense and we recommend revision. For example, "A problem solving technique used to approximate the probability of certain outcomes by running multiple trial runs, called simulations, using random variables."

- Transparency – the definition is a non-standard definition and we recommend revision. Generally the definition refers to openness and disclosure of information; including that the information be comprehensive and understandable is non-standard.

2. Background and Application of the Guide

While the focus of the guidance is on the “Is there a safer alternative?” question, the use of this guidance should help address the “Is this ingredient necessary?” question as well. A clear understanding of what purpose and function the ingredient serves in the product is fundamentally important. It is a significant concern that focusing on the second question implies that one can simply remove an ingredient without necessarily considering the impacts of its removal or replacement.

While the guide is described as “a resource not only for AA analysts, preparers, practitioners, and responsible entities, but also for the Department when it evaluates submitted AA Reports and supporting documentation,” in its current state it is unclear if the guide is sufficient to meet the needs of all of these interested parties due to the complexity and expansive scope of the regulation and guide. As noted previously, it is uncertain how DTSC would use this guide to evaluate an AA and more robust guidance would be helpful to all stakeholders and DTSC.

3. Chapter 1 – AA Framework

“Step 2: Identify Alternatives” currently states “Research and evaluate information that identifies possibly viable alternatives” which should be rewritten to “Research and evaluate information that identifies *possible* alternatives.” The viability of alternatives has not been evaluated at this point and it would be premature to eliminate alternatives without appropriate justification.

Under “Other Compliance Options,” a chart delineating the differences between the types of AAs would be helpful.

There appears to be little distinction between “Alternate Process AA” and “Previously completed AA” and it would make sense to simplify and combine into a single entity since both require DTSC approval already. In addition, would the timeframes differ? What criteria would the Department utilize to approve or disapprove an “Alternate Process AA” or “Previously Completed AA” Work Plans?

A “Previously Completed AA” by a consortia or private entity may not be completely within the control of the responsible entity and may have non-addressable transparency concerns.

Under “Regulatory Responses,” the guide notes an inconsistency between the regulations and guide that:

“When selecting and requiring regulatory responses, the Department *will* give preference to the following selection criteria:

- Alternatives of least concern when they are functionally acceptable, technically feasible, and economically feasible.
- Regulatory responses that provide inherent protection through redesign rather than administrative controls to limit exposure.
- The degree to which the regulatory responses address the adverse impacts, the cost of the regulatory response relative to other possible responses, and government interest in efficiency and cost containment.”

This provision effectively requires the Department to pick winners and losers in the marketplace, discourages innovation and runs counter to the intent of the regulation. In the authorizing regulation, the text indicates that “In selecting regulatory responses, the Department *shall seek to maximize* the use of alternatives of least concern when they are functionally acceptable, technically feasible, and economically feasible.” The shift from “shall seek to maximize” to “will” alters the intent of the regulation and will require a specific alternative rather than encourage many viable alternatives in the marketplace.

CSPA recommends that DTSC clarify when it is articulating a core legal requirement and when it is presenting non-binding suggestions and recommendations intended to assist a manufacturer in preparing an alternatives analysis.

4. Product Requirements.

The term “purpose” is associated with products in the guidance. The term “function” is associated with both products and ingredients. The difference between purpose and function as it applies to products is not clear. In addition, applying the term function to both products and ingredients is potentially confusing. We recommend inclusion of definitions for function and purpose and a clear delineation throughout the guidance.

A detailed listing of Product Requirements (purpose, performance, legal, consumer/market expectations, characteristic, and criteria) for any given product would cover a massive amount of information much of which may be irrelevant to the specific requirements surrounding a particular ingredient and its alternatives. We recommend that the guidance acknowledge that AA reports should not be exhaustive, but contain required information relevant to the chemical of concern (CoC) and its alternatives as identified in the Priority Product listing. Further, it should be acknowledged that some product requirement information will include very sensitive proprietary information which may be claimed as trade secret and not disclosed in documents intended for the public.

The Safer Consumer Product regulations require that “The responsible entity shall identify the functional, performance, and legal requirements of the Priority Product that must also be met by the alternatives under consideration” (§69505.5(a)(1)). While an enumeration of functional, performance and legal requirements is required, the Guide implies that the Responsible Entity must explain why these functional and performance requirements are required. The Guide should make clear that any explanation beyond what is required in the regulation is suggested by

the Department as a means of detailing why the Responsible Entity is constrained in its decision-making regarding potential alternatives later in the AA process.

The section below on educating consumers about potential alternative products and justification of selection (or non-selection) of an alternative poses a number of challenging questions:

During the AA, when evaluating potential alternatives, a responsible entity may consider if the product would remain marketable if its array of attributes or standards changes. Some responsible entities may elect to educate consumers about the benefits of any changes and as a result, consumers may accept such changes if they are aware of the value of a safer product. Although the Department acknowledges the importance of consumer acceptance, the Department will consider how a responsible entity justifies that a viable alternative was not selected because of consumer resistance by describing how it measured consumer acceptance. For example, the Department will be interested in the relevant questions that responsible entities ask consumers to determine acceptance.

For example, how would a responsible entity educate consumers about the changes made to a product that is not yet in the marketplace? The point in time when the guidance suggests this education occurs is prior to commencement of the AA and well before any determination of the viability of the alternative or regulatory decision. In addition, while we can see the relevance of questions ascertaining customer acceptance, it is unclear that the Department would have the appropriate expertise to evaluate these questions and responses. Accordingly, the basis for the market acceptance questions requires a thorough understanding of the customers and marketplace which likely involves very valuable and protected confidential business information outside the scope of the regulation. CSPA recommends a significant revision or removal of this section.

5. Relevant Factors.

We agree that an Alternative Analysis should focus on Relevant Factors and dismiss irrelevant ones that will not have a significant and meaningful impact on the outcome. This will allow narrowing the scope of the analysis based on similarities and differences in the alternatives. However, a major difficulty in conducting an AA for the SCP program is the sheer number of combinations of factors, lifecycle segments and exposure pathways that must be considered. The guidance indicates that unless there is justification for eliminating a factor, it must be analyzed, which will quickly result in an unmanageable level of factors under consideration. And the justification for elimination of a factor is important and should not be dismissed, as this narrow and possibly myopic view may miss important considerations initially dismissed as not relevant, opening up the very real possibility that this will lead to regrettable substitutions.

The Department, in its Priority Product description, must identify its list of relevant factors for the Priority Product and Chemical of Concern, which would provide a helpful initial focus for the responsible entity. This is indicated in the guidance² and would be an important expectation

² See bottom of page 34 of the AA Guide.

for finalized Priority Product regulations. This is also consistent with the NAS Framework guidelines in specifying the importance of the product scope.

A product manufacturer will have solid information for the safety, performance, cost impacts and consumer acceptance related to the manufacture of products; and their transportation, use and disposal. Upstream information will often be limited. Depending on how many steps are in the upstream supply chain, this could represent significant gaps in information available for the analysis, particularly with regard to alternatives for which there is limited or no experience and vastly different sourcing chains. CSPA urges DTSC to provide insight within the guidance document about any “new information” that may be required and to what extent such a requirement would be mandated or required during Stage 1 of the AA process.

Given the scope of this challenge, the guidance is inadequate. At a minimum, the Department should include a large number of examples, which may provide the best way to illuminate this area. The CO₂ example³ is useful, but many more are needed on a wide range of factors. Examples should point out both situations where it is relevant and where it is not relevant. This will also provide insights on the Department’s expectations and how it will judge the responsible entity’s justifications of relevance.

The discussion of relevant exposure pathways⁴ focuses primarily on the chemical of concern, versus the Priority Product/CoC combination in comparison with the alternatives. It is critical to note that it is the **Product** in combination with an **Ingredient** that drives the potential for the Ingredient’s exposure. Product-related exposure factors include: user profile, form and delivery type, frequency and duration of use, expected exposure routes, concentration of the ingredient, volume of ingredient use, the accessibility of the ingredient in the product, separation potential during product life (e.g., due to wear or aging) and the method of disposal. These factors together with physical/chemical properties of the ingredient can be very useful in completing a holistic analysis of potential exposure. This information should also be included in the discussion of the NAS report⁵ as it helps to expand that thinking to a more useful approach.

The considerations for “inferior alternatives”⁶ are helpful, however the text appears to indicate that any of the items automatically indicate an inferior alternative that should be eliminated. In some cases there may be trade-offs to be considered rather than an automatic elimination.

In addition, if data is missing or deemed not relevant, there is little incentive to subsequently develop data. Rather than driving toward new innovative chemistries, data gaps will likely push development toward existing alternatives.

³ See page 36 of the AA Guide.

⁴ See page 43 of the AA Guide.

⁵ See page 44 of the AA Guide.

⁶ See pages 59-60 of the AA Guide.

6. Contaminant as Chemical of Concern.

There is some mention of contaminants as potential chemicals of concern, however the discussion is limited. There would be a significant difference in an AA for an unintentional contaminant that has no function in the product, but is in the product due to air, water, raw material and/or processing related reasons. It almost seems as though there would be a different focus for such an AA, with a significant emphasis on reducing the contamination. More specific and elaborated guidance on this situation would be helpful.

In Chapter 4 on Impact Assessments, the AA guidance document addresses an important question that is likely to arise in many AAs – how to conduct scientifically sound risk and hazard assessments when there are significant data gaps on specific chemicals.⁷ The primary approach taken in this section is to identify a wide range of databases and tools that could be used to assist an evaluation. While this information is useful, DTSC should consider identifying principles that scientists typically use to identify sources of information that warrant greater weight in an evaluation. Not all information carries the same scientific standing, and that point should be recognized in the AA guidance document.

The guide affords larger, well-resourced entities the opportunity to utilize their internal resources, processes and expertise – something we appreciate and greatly value. However, we remain concerned about the ability for smaller responsible entities to undertake these requirements. And while we appreciate the resources suggested for responsible entities within the guidance document that begin to speak to resource issues particularly for those smaller entities, many of these resources have originated from chemical advocacy non-governmental organizations. This is concerning in that some, like the Scandinavian "SIN List," incorporate some exceptions in deference to public interest. This raises the question of whether such contract services or "publicly available" AAs will meet the same demands for rigor in documenting the specific judgments behind their conclusions and tools that other responsible entities will have to meet when submitting original supporting material.

It is clear that many smaller responsible entities and their contractors would welcome lists of supporting information and tools such as these lists. However, to the extent the organizations, their tools and services are outside the realm of recognized government agencies or authoritative bodies, the listings should simply be just that – lists – with no embellishment implying DTSC endorsement.

DTSC should also provide clarification regarding the level of rigor and documentation to which such contract services and publicly available AAs will be reviewed. A lack of consistency in rigor and documentation would inappropriately result in differential standards being used as a tool to achieve contracted AA as compared to an AA prepared in-house by a responsible entity.

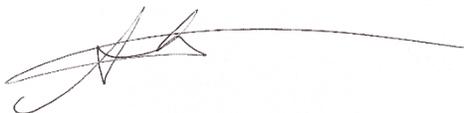
We urge DTSC to clarify the level of rigor in data and documentation for all entities – regardless of who generates the data and information. Responsible parties whether preparing AAs in-house

⁷ See pages 50-58 of the AA Guide.

or through contract services must meet the same requirements. Final AAs must not be allowed to be inappropriately leveraged in the market based on a regulatory response DTSC may impose that is disproportionate between a responsible entity's in-house AA and an AA developed by a contract services, or between two or more responsible entities regardless of who prepares the AA. Consistency and scientific rigor must be applied across all AAs.

We will continue to work with the Department to ensure that a workable AA guidance is developed but remained concerned that the complexity and scope of the guidance will discourage companies from entering into the AA process leading to a *de facto* product ban. We reiterate that DTSC carefully consider and adopt the recommendations of the National Academy of Sciences "A Framework to Guide Selection of Chemical Alternatives."

Respectfully submitted,

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Steven Bennett, Ph.D.
Senior Director, Scientific Affairs & Sustainability

A handwritten signature in black ink, appearing to read "Kristin Power", written in a cursive style.

Kristin Power
Vice President, State Affairs

cc: CSPA Scientific Affairs Committee Green Chemistry Task Force
CSPA State Government Affairs Advisory Committee
Nicole Quinonez, Randlett/Nelson/Madden