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October 23, 2015

Barbara Lee, Director
California Department of Toxic Substances Control
1001 I Street
Sacramento, CA 95814
(via [California Safer Products Information Management System \(CalSAFER\)](#) and e-mail)

RE: ACI comments on DTSC Draft Stage 1 Alternatives Analysis Guide

Dear Ms. Lee:

The American Cleaning Institute (ACI) appreciates this opportunity to provide comments to the Department of Toxic Substances Control (DTSC) on its Safer Consumer Products (SCP) Draft Stage 1 Alternatives Analysis Guide released on September 23, 2015. The Guide is of particular interest to us because *cleaning products* have been identified as one of the product categories included in the 2015-2017 Three-Year Work Plan, and we are the trade association representing the \$30 billion U.S. cleaning products market with about \$3 billion associated with business in the California. ACI members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers. We are dedicated to improving health and the quality of life through sustainable cleaning products and practices. ACI's mission is to support the sustainability of the cleaning product and oleochemical industries through research, education, outreach and science-based advocacy.

The Cleaning Products Industry is a Leader in Product Stewardship.

We note that DTSC has stated that the Safer Consumer Products program is designed to encourage market shifts towards a green economy. We would like to highlight some of the accomplishments of our industry in recent decades in continually improving the sustainability profile of our products going beyond the focus on improved chemical safety to also include other life cycle aspects such as reduced energy consumption, reduced water usage and reduced waste. Cleaning products have been the focus of numerous environmental certification programs for decades and the cleaning products industry has responded to the demand of customers. One program, the US Environmental Protection Agency's SaferChoice program (formerly Design for the Environment (DfE)) Safer Product Labeling program, boasts more than 2,500 SaferChoice/DfE labeled products, most of which are cleaning products.¹ In addition, the SaferChoice Safer Chemical Ingredient List (SCIL) includes hundreds of ingredients used in ACI members' consumer and commercial cleaning products. At ACI, we have been engaged in measuring and improving the safety and sustainability

¹ <http://www.epa.gov/dfepubs/projects/formulat/saferproductlabeling.htm>

attributes of our members products for years. We recently published a scientific review article covering over 250 published and unpublished studies on the environmental safety of major, high-volume surfactant classes used in cleaning products.² ACI and its members have spent more than \$30 million on the assessment and reporting of the environmental safety of the major surfactants over the past five decades. Likewise, we recently completed our commitments under the USEPA and OECD High Production Volume Chemical Challenge programs which has resulted in hazard data sets (Screening Information Data Sets) for nearly 300 chemicals being made available to the public. By compiling both published and in-house company data, this effort by ACI has put a wealth of hazard and exposure data for cleaning product ingredients in the public domain while avoiding the unnecessary sacrifice of hundreds of thousands of additional laboratory animals and hundreds of millions of dollars in duplicative testing. Beginning in 2012, we have taken this approach one step further and applied it to all of the chemicals used in our members' consumer cleaning products. As part of our Cleaning Product Ingredient Safety Initiative,³ we surveyed our members' consumer cleaning products and identified 600 ingredients used in their formulation. These ingredients are listed in our Ingredient Inventory which is publicly available on the ACI website.⁴ Next, we consolidated in our Hazard Data Portal publicly available human health and environmental hazard data set(s) for the chemicals on the Ingredient Inventory.⁵ Most recently, we have released exposure information associated with the use of those ingredients in consumer cleaning products. Over the next year we plan to develop and report the screening level risk assessments for those chemicals on the Ingredient Inventory. Likewise, many of our member companies have their own transparency initiatives where ingredients in products may be readily determined by consumers at the point of sale on the product itself or by means of a smartphone application.

One advantage of our Ingredient Inventory is that we can use it as a tool to screen for chemicals that are being highlighted by regulators, retailers and consumer advocates. When we compared our Ingredient Inventory to the Safer Consumer Products list of Candidate Chemicals, we found very little cross-over, and when we did, it was for chemicals that were used in very few products. We believe this is the result of decades of innovation and continuous improvement by our members in the development of cleaning products. Moreover, our members have looked beyond chemical safety and have provided innovations which reduce water use, energy use and waste disposal associated with cleaning product use. We also have measured industry-wide improvements in those metrics at our members' facilities in recent years.⁶ ACI would be happy to share this information with DTSC as you move forward to consider the next rounds of Priority Products.

² Environmental Safety of the Use of Major Surfactant Classes in North America. 2014. Christina Cowan-Ellsberry, Scott Belanger, Philip Dorn, Scott Dyer, Drew McAvoy, Hans Sanderson, Donald Versteeg, Darci Ferrer, Kathleen Stanton. *Critical Reviews in Environmental Science and Technology*, vol. 44(17): 1893-1993.
<http://dx.doi.org/10.1080/10739149.2013.803777>.

³ <http://www.cleaninginstitute.org/CPIS/>

⁴ http://www.cleaninginstitute.org/science/ingredient_inventory.aspx

⁵ http://www.cleaninginstitute.org/hazard_data_portal/

⁶ <http://www.cleaninginstitute.org/sustainability2015/>

The Stage 1 Alternatives Analysis Guide is Advisory in Nature, Not a Regulation.

We appreciate the Department's continued clarification of the purpose of the AA Guide. As you note, the Guide is not a standard or regulation and it creates no new legal obligations. The Guide is advisory in nature, informational in content and intended to assist responsible entities who are conducting Alternatives Analysis (AA). The Guide does not alter or determine compliance responsibilities set forth in statutory and regulatory requirements. It is important to note that while the Guide may represent the Department's best current advice, there is flexibility for Responsible Entities in preparing their AA regarding the approach, tools and sequence of activities within the scope of the Safer Consumer Product regulations.

Likewise, though there are specific requirements that must be satisfied with respect to the Stage 1 AA, there are other aspects of the AA process that are required under Stage 2 such as the evaluation of performance and economic considerations. There is no prohibition against analyzing and providing Stage 2 information during the Stage 1 analysis and the Responsible Entity might find it advantageous to do so. We appreciate the Department's acknowledgement of such flexibility within the Guide.

Finally, we appreciate your acknowledgement of the Alternatives Analysis process recently described by the National Academy of Sciences and its emphasis of comparative exposure as a critical step in the assessment process.⁷

DTSC Should Clarify the Product Requirements and Make Certain They are Consistent with the Regulations.

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 that these be distinguished by using purpose in connection with products and function in connection with ingredients.

A detailed listing of Product Requirements (purpose, performance, legal, consumer/market expectations, characteristic, 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 on this question, but contain required information relevant to the chemical of concern (CoC) and its alternatives. 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 "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

⁷ <http://www.nap.edu/catalog/18872/a-framework-to-guide-selection-of-chemical-alternatives>

explain why these functional and performance requirements are required. The Guide should make clear that any explanation beyond what is required in the regulations is suggested by the Department as a means of providing understanding why the Responsible Entity is constrained in its decision-making regarding potential alternatives later in the AA process.

The Guide Requires Additional Detail Regarding Relevant Factors.

We strongly agree that an Alternative Analysis should focus on Relevant Factors and set aside irrelevant ones that will not have a significant and meaningful impact on the outcome. This is an important means to narrow 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 overwhelming number of combinations of factors (113), lifecycle segments (12) and exposure pathways (3) that must be considered. These are multiplicative, so in all there are 4,068 combinations to be considered. The guidance indicates that unless there is justification for eliminating a factor, it must be analyzed, which will result in an unmanageable level of analysis.

A product manufacturer will have solid information for the safety, performance, cost impacts and consumer acceptance related to the manufacture of products, their transportation, use and disposal. Upstream information will likely be limited. Depending on the number of steps in the upstream value chain, this could represent significant gaps in information for the analysis, particularly with regard to alternatives for which there is limited experience or different sourcing.

Given the scope of this challenge, the guidance is inadequate. At a minimum, the Department should include a broader range of examples (the more complete the better), which may provide the best way to illuminate this area. The CO₂ example on page 36 is useful, but many more are needed to cover the wide range of factors. Examples should point out both situations where a particular factor is relevant and those where it is not. This will also provide insights on the Department's expectations and how it will judge the responsible entity's justifications of relevance.

Under the SCP regulations (§69503.2 and §69503.3), the Department is required to analyze Product-Chemical Identification and Prioritization Factors and evaluate Adverse Impact and Exposure Factors. Then, in its Priority Product description, it must identify a list of relevant factors for the Priority Product and Chemical of Concern as noted in the guidance near the bottom of page 34. This is an important expectation for finalized Priority Product regulations and will provide a helpful initial focus for the responsible entity in conducting the AA.

The regulations are clearer on the requirements for Relevant Factors than the guidance and they should be fully quoted directly from the Regulations ((§69505.5(c)(1)); missing text underlined).

For example, the regulations indicate that a factor, in conjunction with its associated exposure pathways and life cycle segments, is relevant if:

- A. The factor makes a material contribution to one or more adverse public health impacts, adverse environmental impacts, adverse waste and end-of-life effects, and/or materials and resource consumption impacts associated with the Priority Product and/or one or more alternatives under consideration; and

- B. There is a material difference in the factor's contribution to such impact(s) between the Priority Product and one or more alternatives under consideration and/or between two or more alternatives.

The discussion of relevant exposure pathways on page 43 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/aging) and the method of disposal. These factors together with physical/chemical properties of ingredients can be useful in completing a holistic analysis of potential exposure. This information should also be included in the discussion of the NAS report on page 44 as it helps to expand that thinking to a more useful approach.

The considerations for "inferior alternatives" on page 59/60 are helpful, however the text appears to indicate that an alternative exhibiting any of the impacts automatically indicate an inferior alternative that should be eliminated. Reality is likely to not be so black-and white. In some cases there may be trade-offs to be considered with other alternatives rather than an automatic elimination, and while there may be a particular factor which does not compare favorably, on balance an alternative may prove to be superior to the others considered and thus warrant selection.

DTSC Should Provide More Guidance Regarding a Contaminant as Chemical of Concern.

There is some mention of a contaminant as a potential Chemical 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, especially on how to eliminate from the AA those sections which are likely to be extraneous.

DTSC should include broader stakeholder Principles for Alternative Assessment.

The Commons Principles for Alternatives Assessment, developed by environmental groups, are described and included on pages 11 and 12. While these provide information from that perspective, the Department should consider the perspectives of a broader representation of stakeholders. Those perspectives should be provided as part of the Guide to offer balanced views among all affected stakeholders. In February of 2014, eight trade associations representing a varied set of product sectors (including many of which are now identified in the 2015-2017 Three Year Work Plan) published "Principles of Alternative Assessment" and provided them to the Department (attached). As described in the document, manufacturers routinely practice alternatives assessment, as part of their process for developing new and improved products for the marketplace. Protecting and improving public health and the environment is a key component of the design process. We respectfully request that these principles be included in the Guide.

DTSC Should Clarify the Necessity to Comply with Sources Identified in the Appendixes.

Appendix 2 (Data Sources for Identification of Alternatives) and Appendix 4 (Tools and Methods for Chemical Hazard Assessment) of the Guide identify a massive level of resources for each of these areas. While it is appropriate and helpful for the Guide to provide a broad set of resources it leaves the implication that every resource must be scoured in detail for each Alternative Analysis. In fact on page 99 phrases such as "...collecting and evaluating ALL available information..."; "all relevant available information..."; and "all human and environmental..." go beyond just implying this thinking, but seem to prescriptively demand it. Programs such as U.S. and OECD HPV and REACH have been successful in collecting, evaluating, summarizing and publishing health and environmental information on over 10,000 substances. It would be inefficient to expect responsible entities to exhaustively review every resource noted in a checklist sort of way. The Guide should make clear that the expectation of Responsible Entities is to select among the resources noted and other sources as necessary to accomplish the intended goal of completing the AA.

In closing, we would like to restate our commitment to working with DTSC so that the Department better understands the best practices of the cleaning products industry. The Department has committed to engaging regulated industries impacted by the SCP regulations and we would like to initiate that engagement as an industry named in the 2015-2017 Three-Year Work Plan. We believe there would be tremendous benefit for both the Department and regulated industries to collaborate on to better understanding Priority Products and the process by which manufacturers make product design and improvement decisions as the Department prepares the AA Guides. We believe such collaboration will enhance public trust in the Safer Consumer Products program and in consumer products on the market in California.

We appreciate the opportunity to comment on the Stage 1 Alternatives Analysis Guide and hope you will find our comments useful. We look forward to working with you more closely in the future and wish you continued success with the Safer Consumer Product program.

Sincerely,

A handwritten signature in black ink that reads "Paul C. DeLeo". The signature is written in a cursive, flowing style.

Paul C. DeLeo, Ph.D.
Associate Vice President, Environmental Safety

cc: Dr. Meredith Williams, DTSC
Mr. Karl Palmer, DTSC

Attachment

Principles for Alternative Assessment

FINAL - 1/23/2014

Manufacturers routinely practice alternatives assessment (AA) as part of their R&D process to develop new and improved products for the marketplace. Protecting and improving public health and the environment is an inherent component of the product design process. As in the R&D process, an alternative should have not only an improved safety and environmental profile, but also should be technologically and commercially feasible; of comparable cost; maintain or improve product efficacy, performance, and usability; and result in consumer acceptance in the marketplace. The graphic below depicts how AA is integral to the typical product R&D process.

Product R&D Process – Continuous Improvement



As governments and others suggest alternatives to chemicals of concern, the product development process provides the most appropriate model to establish a practical and meaningful framework for AAs. Using best practices from the R&D process would achieve the objective while avoiding regulatory mandates that stifle innovation.

Principles – The product development and improvement process is iterative, complex, and different on a product-by-product, case-by-case basis. A sensible approach for conducting an AA should be built on the same approaches that underpin product R&D processes as follows:

- **Ensure Consumer Acceptance** – The alternative must be verified to provide the same or better performance and value as viewed by the consumer; i.e., the product must not simply have the desired function, but must be perceived by the consumer as comparable or superior to the existing version of the product. Consumer acceptance will drive the market success that allows the alternative to achieve the goal of making meaningful improvement to public health and/or environmental benefit.
- **Be Flexible** – Alternatives assessments may be undertaken by individual manufacturers, or by consortia representing an industry segment or an entire industry. However, each company's business model is different. Even for similar chemicals/products, the AA outcome may be different for different manufacturers due to manufacturing processes, design features or market niches, for example. Each manufacturer must be given the latitude and discretion to leverage existing tools and approaches to evaluate alternatives and make decisions for their products.

Principles for Alternative Assessment

FINAL - 1/23/2014

- **Be Modular** – The following evaluation topics with their corresponding list of key evaluation parameters are all considered in a multi-factorial matrix. Analysis of some parameters may not always be necessary in every AA, however, the most critical and relevant parameters for which there is a significant difference exhibited between the alternatives must be identified for in-depth alternative evaluation.
 - Safety (human and environmental) – Understanding chemical hazards and product use and exposure are essential to product safety via a comprehensive risk-based safety assessment of alternatives throughout the product lifecycle. Uncertainties and assumptions should be addressed.
 - Performance and Value – Beyond product safety, consumer acceptance is driven by a product's cost, performance and useful life and the alternative must not compromise these factors.
 - Lifecycle/Resource Utilization – Evaluation includes a number of parameters, especially resource consumption of materials, water and energy, during a product's manufacturing, use and disposal phases.
 - Other – The alternative must be available at reasonable cost and in sufficient quantity, and the revised product must be manufacturable with acceptable yield in view of costs associated with equipment and process changes. There must never be an adverse impact on compliance with regulatory, patent or safety-related requirements.
- **Be Effective** – The alternative must provide meaningful improvement that delivers a significant benefit to public health or the environment.
- **Protect Confidential Business Information** – Trade-offs in decision-making must be understood and considered to avoid unintended consequences. Where necessary, due to the competitive nature of business innovations and value judgments, decision criteria, weighting and certain other evaluation information must be preserved as trade secrets and not be publicly divulged.
- **Allow for Gradual and Measured Evaluation and Implementation of Suitable Alternatives** – Adequate time is necessary to introduce a new product into the marketplace due to complex and lengthy design considerations, development of supply chains, ensuring regulatory compliance, and verifying consumer acceptance.
- **Include a Feasibility Check** – An opportunity for reassessment must be provided if new information or subsequent assessments or in-market surveillance uncover previously unknown concerns with the alternative.
- **Avoid Duplicative Efforts** – Alternatives assessments are and will be performed by companies and industries around the world to comply with various regulatory requirements and as part of internal product safety commitments and continuous product improvement projects. AAs should be portable and readily accepted in various jurisdictions. Regulators should seek to harmonize requirements to internationally accepted best-practices in order to avoid unnecessary duplication.

Thus, a best practices alternatives assessment process follows the Product R&D paradigm – it is flexible and modular, focusing on parameters relevant to the product being evaluated. It should result in comparable or improved product safety, efficacy, value and consumer acceptance. It should include informed, risk-based decision making, protection of confidential business information, allowances for gradual and measured implementation, and feasibility checks to ensure that the proposed alternative actually meets the goal of the process – the design and manufacture of improved products that are safe and cost effective, desirable to consumers, and make measurable improvements to public health and/or environmental benefit.