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November 16, 2015

Barbara A. Lee, Director
California Department of Toxic Substances Control
1001 I Street
P.O. Box 806
Sacramento, California 95812-0806

Sent Electronically to: CALSAFER.DTSC.CA.GOV

SUBJECT: Draft Stage 1 Alternatives Analysis Guide

Dear Director Lee:

We are writing on behalf of the members of the Alliance of Automobile Manufacturers (Alliance), a trade association comprised of BMW Group, FCA US, Ford Motor Company, General Motors Company, Jaguar Land Rover, Mazda, Mercedes-Benz USA, Mitsubishi Motors, Porsche Cars North America, Toyota, Volkswagen Group of America, and Volvo Cars of North America.¹ We welcome the opportunity to provide the following comments on the California Department of Toxic Substances Control's (DTSC) Draft Stage 1 Alternatives Analysis Guide (Draft AA Guide or Guide) for the Safer Consumer Products (SCP) program.

The Alliance appreciates that DTSC has undertaken the task of preparing this Draft AA Guide to help responsible entities conduct a first stage alternatives analysis (AA) that satisfies regulatory requirements. We also appreciate that the Guide's objective is to provide an advisory resource for a broad spectrum of manufacturers and varied product types, and therefore recognizes the need for flexibility. However, this Guide does not provide the informative AA guidance DTSC promised during the SCP rulemaking process, and that is needed by responsible entities in order to undertake quality alternatives analyses to ensure compliance with SCP regulations and to obtain DTSC approval.

While the regulated community was expecting a compliance guide that would add more certainty to the AA process, DTSC has provided an aspirational guide. DTSC has stated that this Guide is to help a responsible entity conduct an AA to meet regulatory requirements, yet that laudable and

¹ For additional information, please visit <http://www.autoalliance.org>.

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necessary goal seems to be hedged on by the prominent “Important Note” on the very first page which informs us that:

This Guide is not a standard or regulation and it creates no new legal obligation. The Guide is advisory in nature, informational in content, and intended to assist responsible entities who are conducting Alternatives Analysis. This Guide does not alter or determine compliance responsibilities set forth in statutory and regulatory requirements.

The Alliance is concerned that the overbroad guidance in the Draft AA Guide—foreshadowed by this note, combined with DTSC’s statements that the AA process is “iterative” will create an unworkable, unlimited data collection scheme that is unlikely to lead to improved decisions, or, perhaps, any decisions. The purpose of the Green Chemistry Law and the SCP Regulations is to find greener and safer alternatives to chemicals or chemical ingredients in consumer products that may be considered a chemical of concern. It is imperative that the Draft AA Guide set boundaries and clearly delineate the scope of an AA to further this purpose. The multiple rounds of data gathering, which DTSC appears to require, will frustrate this purpose by greatly increasing uncertainty, as well as costs for responsible entities.

The auto industry is committed to improving our products and has spent millions of dollars implementing groundbreaking processes such as the International Materials Data System (IMDS) to better track and manage substances of concern. While there is great value in continuing to invest financial and human resources in well-defined products and methodologies that will lead to improved/safer products for our customers, there is limited value in spending significant time, money and effort in a process which is poorly defined and with no discernable endpoint.

The Alliance is genuinely apprehensive regarding the ambiguity throughout the varying AA methodologies, and also regarding how conclusions will be considered by the DTSC. What appears to be an overbroad and iterative guidance leads us to conclude that DTSC does not yet have a clear vision or formal process for the evaluation of AAs, but that the agency somehow intuitively will “know a good AA when they see one.” On page 9 of the Draft AA Guide, DTSC states:

It is 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.

We are concerned that the Guide, through its application and its utilization by DTSC in evaluating AA Reports, is a “legislative rule” or “underground regulation” that runs afoul of the

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California Administrative Procedures Act (APA). A guide, such as the Draft AA Guide, is a regulation subject to the APA if it: 1) applies generally, rather than in a specific case; and 2) must “implement, interpret, or make specific the law enforced or administered by [the agency], or ... govern [the agency's] procedure.” Gov. Code, § 11342.600, *see also Tidewater Marine W., Inc. v. Bradshaw*, 14 Cal. 4th 557, 571 (1996), *Morning Star Co. v. State Bd. of Equalization*, 38 Cal. 4th 324, 333-34 (2006). The Draft AA Guide applies generally: it applies to all responsible entities required to perform an AA for a listed chemical of concern in a priority product. It interprets the AA regulatory requirement in the SCP regulations, provides specific details on how to carry out AAs under the SCP program and governs DTSC’s review of AAs.

The Draft AA Guide appears to be a rule, and the APA’s procedural requirements for rules are exacting. As summarized in *California Advocates for Nursing Home Reform v. Bonta*, “[t]he agency must give the public notice of its proposed regulatory action (id., §§ 11346.4, 11346.5); issue a complete text of the proposed regulation with a statement of the reasons for it (id., § 11346.2, subds. (a), (b)); give interested parties an opportunity to comment on the proposed regulation (id., § 11346.8); respond in writing to public comments (id., §§ 11346.8, subd. (a), 11346.9); and forward a file of all materials on which the agency relied in the regulatory process to the Office of Administrative Law (OAL) (id., § 11347.3, subd. (b)), which reviews the regulation for consistency with the law, clarity, and necessity. (Id., §§ 11349.1, 11349.3.)” 106 Cal.App.4th 498, 507 (2003).

We understand that a consequence of advocating for more clarity pushes the Draft AA Guide further into the realm of an underground regulation. However, it appears that the Guide has already crossed this line. We are concerned that the Guide in its current form—and also with the much needed additional certainty it should provide—may not withstand a judicial challenge. Any regulation that fails to comply with the APA requirements may be judicially declared invalid. Gov. Code § 11350. Should this occur, we will all be back at square one, without any certainty to the AA process. Therefore we respectfully request that DTSC not only incorporate the points of certainty raised in this letter, but that it undertake full notice and comment rulemaking under the APA for the Draft AA Guide. This will not only minimize the risk of judicial challenge, but also will provide the regulated community and other interested persons with the meaningful participation and analysis by DTSC, and the vetting by the OAL, to which they are entitled.

While we request that DTSC comply with APA requirements, we would like to stress that what the Alliance most needs is an AA process that gives manufacturers the certainty needed to be able to design, manufacture, distribute and sell products in a timely and efficient manner. In order to do this, DTSC must provide clear, understandable instruction regarding what is required for approval of an AA in order to keep costly and time-consuming adjustments to a

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minimum. DTSC approval of an alternatives analysis can be analogized as granting a permit for continued manufacture of a product. It is of extreme importance, especially in the case of a vehicle, that this process provide certainty around what will be required to ensure approval. The DTSC Draft AA Guide has failed to provide this certainty, as have other Draft AA Guides such as the one developed by the Interstate Chemicals Clearinghouse (IC2).

To test the achievability of performing an AA, members of the Auto Alliance explored the AA process under the IC2 framework, which included additional elements unique to the SCP regulations. Overall, this effort demonstrated that the AA process is of limited value because critical data are difficult or impossible to obtain. Data that were available on alternative performance, availability and cost were of questionable reliability and lead to uncertainties in the AA. Further, the AA was disproportionately time-consuming and costly given its limited utility in the process of identifying safer alternatives. Specific findings from our exploratory exercise are mentioned as appropriate in subsequent comments.

Necessary Changes to the Draft AA Guide

Notwithstanding our position that the Draft AA Guide may be invalidated for its failure to comply with the APA's procedural requirements, the Alliance requests that DTSC make the following necessary changes to the Guide.

- **Chapter 1 – AA Framework**

- Page 8 of the Draft AA Guide states:

The Department's 2008 California Green Chemistry Initiative outlined policy goals that expand the focus of impact evaluation to include additional stages like product design, product manufacturing, and the product's end-of-life management. By considering effects from a life cycle perspective, manufacturers can create products that are benign by design and that avoid unintended consequences from the outset.

Alliance members conduct in-depth design analyses of their products that address many environmental factors including end-of-life management. Alliance members strive to develop products that are "benign by design." However, DTSC should acknowledge that creating completely benign products may not always be possible. Further, product designs that are not completely benign by SCP standards may be necessary to meet other regulatory and customer standards for

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protecting human health and safety (*e.g.*, preservatives are critically important for human health but are by definition antimicrobial and therefore not benign).

Therefore, DTSC should change the statement:

By considering effects from a life cycle perspective, manufacturers can create products that are benign by design and that avoid unintended consequences from the outset.

to:

Considering effects from a life cycle perspective helps manufacturers to create products that are safer by design (to the extent possible for the product to perform the functions for which it is designed), and that avoid unintended consequences from the outset.

- Page 9 of the Draft AA Guide states:

To address the second question [Is there a safer alternative?], the regulations present a framework and steps for the alternatives analysis (AA) process to evaluate potential alternatives.

The statement that the "regulations present a framework and steps for the alternatives analysis" is misleading. The SCP regulations describe a broad, high-level approach to conducting the AA but do not give the details necessary to understand how it should actually be conducted. Commenters to the SCP regulations (including the Auto Alliance²) urged DTSC to provide more details regarding how AA's were to be conducted. DTSC instead finalized the regulations with a broad, high-level approach and deferred providing more detailed instructions to a later guidance document, which we presume is this Draft AA Guide.

- Pages 9 and 17 of the Draft AA Guide state that SCP program emphasizes life cycle thinking (LCT). DTSC should provide a discussion of the differences between LCT and life cycle analysis (LCA) and clarify that an LCA is not required to comply with the regulations.
- Page 9 of the Draft AA Guide states "[i]n particular, the Guide provides information about...approaches for identifying and collecting needed data." The

² Comments submitted to DTSC on February 28, 2013 and April 25, 2013.



Guide primarily provides information about chemical hazards and not about other necessary data (performance, cost, availability, feasibility, life cycle effects on natural resources, energy consumption, *etc.*). Obtaining this type of information will be a major difficulty in conducting the AA and we therefore request that DTSC recommend acceptable approaches for obtaining such data.

- Page 9 of the Draft AA Guide states:

It is 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.

A guidance that governs an agency's procedures is a "regulation," and is subject to notice-and-comment rulemaking under the APA, as discussed above. Responsible entities, analysts, preparers and practitioners are being deprived of their rights under the APA. DTSC cannot establish a regulation to govern its own procedures without OAL review and assessment.

If DTSC plans to use the Guide to evaluate AA reports, it should specify how the Guide will be used. DTSC states the document is not a checklist and that submitters have flexibility in devising their assessments. Further clarification is needed to understand how the Guide can be used to assess compliance, if flexibility from the Guide's recommendations is allowed. Manufacturers need clear instruction as to what is required for an AA to be approved.

- Page 10 of the Draft AA Guide states:

This Guide does not explicitly state how to meet the requirements, nor does it provide a single, specific approach for conducting an AA or its steps.

We appreciate that DTSC recognizes flexibility in conducting the AA is necessary. However, this leads to uncertainty about what DTSC will actually require. There is a sense of "we'll know what's acceptable when we see it." DTSC should provide examples of how certain AAs would and would not meet the SCP requirements. Without additional guidance, companies will be less likely to be creative and will follow the guidance rigidly in fear of having their AA report rejected.

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- Page 11 of the Draft AA Guide has a statement about consistency: “[o]bserve strict conformity within all steps of the AA to support internal consistency and comparability with similar analyses.” This statement indicates that the AA method should be consistent with other similar analyses. This statement contradicts previous statements DTSC has made in the Guide about flexibility. Flexibility is not truly allowed if companies should conform to a process used in similar AAs. DTSC should clarify what is meant by this statement, if it is not intended to limit flexibility.
- On page 11 of the Draft AA Guide and in several other places in the Guide, an iterative approach is described to improve accuracy “in all calculations, data management, and models used in the AA and in reporting of results.”

The discussion of an iterative approach comes up numerous times in the document, but the degree to which iteration is required is not clear. It seems clear that revisiting assumptions between Stages 1 and 2 is necessary for an AA to be approved. However, DTSC should specify how many times within a stage revisiting assumptions and relevant factors will be necessary. Again, the concern is that multiple rounds of iteration will prolong the analysis and add cost and uncertainty. This Guide does not improve decision-making or further the statute’s purpose if it is designed only to feed the department with paperwork to review, and not lead to decisions about alternatives. An AA is a decision-making tool; this Guide is not.

- Page 12 of the Draft AA Guide recommends that regulated entities should “[r]equire disclosure across the supply chain regarding key chemical and technical information.” This may not be feasible for manufacturers beyond information that is required by law (e.g. SDS information). Requiring disclosure across the supply chain becomes increasingly more complex when dealing with complex consumer goods, such as automobiles, with global supply chains sometimes six or seven layers deep. Because DTSC intends to use the Guide when reviewing AA reports, the Guide should be modified to provide leniency, so an AA is not rejected by DTSC on the basis that a supplier has not provided the information requested by the responsible entity.

Therefore, DTSC should change the statement “**REQUIRE DISCLOSURE AND TRANSPARENCY: Require disclosure across the supply chain regarding key chemical and technical information**” to “**REQUEST DISCLOSURE AND**

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TRANSPARENCY: Request disclosure and transparency across the supply chain regarding key chemical and technical information.”

- Page 15 of the Draft AA Guide states:

Although the AA framework specifies the particular elements that the responsible entity must include in the analysis and reports, the methods, approaches, and actions for completing those elements remain flexible.

DTSC states that there is flexibility in implementing the standard two-stage AA to account for the nature of different product types. We recommend that DTSC specifies that flexibility would not trigger an Alternate Process AA, unless the level of flexibility deviates from the required process in the SCP rule.

- Page 15 of the Draft AA Guide states:

During the first stage the responsible entity identifies the goal, scope, legal, functional, and performance requirements of the Priority Product and the Chemical of Concern, and uses this information to identify an array of alternatives to consider. The responsible entity also gathers information about relevant factors to compare the alternatives to the Priority Product, and may eliminate, or screen out, those alternatives that have greater adverse impacts or do not meet the legal, functional, or performance requirements of the Priority Product.

The Guide is inconsistent with respect to the degree that performance and function are considered as part of Phase I. In some locations it is clear they are part of the initial alternative screening process (see Table on p. 16, and Chapter 2 page 24-26), and in other locations they are relegated to Stage 2 (see Chapter 3 Table 3-1). Section §69505.5 of the proposed rule states that product requirements, such as functional, performance, and legal requirements should be identified in the first step of Stage 1 of the AA. Then, during the second step of Stage 1, alternatives should be selected that meet the priority product’s requirements, as identified in Step 1. More clarity is needed to understand how performance and function are considered as part of Stage I. Availability and performance are essential parts of the initial screening; an alternative that cannot perform adequately cannot be considered a true alternative. Stage 1 should

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consider availability and performance in a qualitative sense; Stage 2 should involve a deeper consideration of these factors.

We followed such an approach while exploring the AA process, and found it sufficient to identify relevant factors without being excessive. For example, Stage 1 could rely on readily available data (*e.g.*, prior AA reports for the product in question or other products from which inferences can be drawn, proceedings of conferences or workshops, opinions of technical experts working for or with the responsible entity). The information gathered at this stage would be qualitative. For example, is the alternative practically available (as opposed to conceptually possible)? In the opinion of the entity's technical experts, could the alternative plausibly perform the necessary function in the product? This can be useful to screen out alternatives that are implausible (the goal of Stage 1). The second stage would involve more in-depth research into the remaining alternatives. The information gathered would be used to compare among alternatives and the chemical of concern. For example, are any performance test data available for this or a similar chemical in the product or a similar product? How do the possible alternatives compare relative to one another? What do members of the supply chain say when asked about the possible performance of specific alternatives?

- Page 16 of the Draft AA Guide states:

Identify material contribution to one or more adverse impacts and a material difference in contribution to such impacts between the Priority Product and alternatives.

DTSC should provide guidance on what will constitute a "material contribution" that determines whether a factor is relevant or not. The term "material contribution" should be defined and examples provided.

- On page 17, the Summary Table describes the economic impacts that responding entities will have to analyze as part of Stage 2. While we realize that the chapters relating to the Stage 2 Guide have not been released, assessment of economic impacts may be the single most difficult part of the AA, a part that is inconsistent with all other AA frameworks we have seen. We do not believe reliable data needed to assess costs of different alternatives are readily available and it is unclear how private sector entities could obtain such information even if it did exist. DTSC should ensure that the Stage 2 Guide provides very clear

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descriptions and examples concerning the expectations for this part of the analysis.

- On Page 17, in the Stage 2 table, "*Support with Comparative Analysis*," is DTSC referring to the scenario analysis defined in the glossary? DTSC should provide clarification.
- Page 17 of the Draft AA Guide states:

After the responsible entity submits the Final AA Report, the Department will make it available for public review and collect public comment before making a determination about any applicable regulatory responses.

This highlights the need for DTSC to clearly define what requirements must be met for an AA to be approved. There must be a standard by which DTSC evaluates the comments that are received.

- Page 21 of the Draft AA Guide states:

The Department will give preference to...alternatives of least concern when they are functionally acceptable, technically feasible, and economically feasible.

The Department should defer to the judgment of the responsible entity concerning these factors.

- **Chapter 2 – Product Requirements and Alternatives**

The Alliance has reviewed this Chapter and provides the following comments and questions which are important because this guidance not only applies to the responsible entity searching for an alternative, but will also inform how the Alternative Analysis is reviewed by DTSC and the public during the public comment period.

- In general, Chapter 2 provides a number of product-specific examples that help to explain DTSC's ideas. This approach should be adopted elsewhere in the document.

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- The Alliance requests that DTSC uses more complex examples in the Guide. For instance, on page 24, the example of a beverage-packaging container is used. This is very straightforward, whereas identifying alternatives for complex durable goods with long and complicated supply chains is not as simple. For example, a typical automobile is comprised of tens of thousands of manufactured components. In many cases, product function and performance may not be so straightforward.

- Page 25 of the Draft AA Guide states:

Performance is one of the measures of how well a product carries out its functions. Performance requirements typically include criteria for the minimum acceptable performance of a product, and specify methods to assess these criteria, either qualitatively or quantitatively. A manufacturer may often establish performance criteria for a product by taking consumer demand and industry standards into account.

DTSC should specify what change in performance is considered significant enough to rule out an alternative. We understand that a single specific value may not be relevant to all cases, but it would be helpful if DTSC could provide acceptable examples of where such an approach could be taken. Responsible entities could then devise their own approach by analogy.

- Page 26 of the Draft AA Guide states:

A responsible entity may include any product characteristic, criterion, standard, or performance requirement in the description of its Priority Product, and seek alternatives that will also meet those characteristics, criteria, standards, or performance requirements.

We agree that responsible entities, who know the product and market best, are best suited to make these determinations. While the judgment of the responsible entity should be the controlling factor, DTSC should provide instruction as to what is required from the responsible entity in order to justify rejecting an alternative based on performance criteria.

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- Page 28 of the Draft AA Guide states that possible alternatives include “chemical substitution, alternatives currently available in the marketplace, and possible product or process redesign.” In the regulation, DTSC also states that reducing the concentration of the chemical of concern could be an acceptable alternative. This should be included in the list of possibilities on page 28. Furthermore, DTSC should define in the Guide how much of a reduction would be expected if the alternative chosen was reducing the chemical of concern rather than replacing it.
- Page 29 of the Draft AA Guide states:

The following questions...can help identify alternatives...Do chemical manufacturer(s) offer alternatives to the Chemical of Concern? Is an alternative listed on a manufacturer's website? Does the chemical supplier offer an alternative? Does the chemical supplier's competition offer an alternative?

Some of the methods DTSC recommends on page 29 of the Guide could be problematic for trade associations who must also comply with antitrust requirements. The Alliance cannot compromise compliance with antitrust laws and we therefore ask that DTSC recommend other sources of information for alternatives.³

Further, antitrust and confidentiality principles and law may make availability of data sought by DTSC, through the Draft AA Guide, impossible and illegal. This proved to be true in the Alliance’s exploratory exercise. Automotive parts have complex, multinational supply chains, and obtaining the detailed supplier data needed to attempt the exercise was quite difficult. In fact, many suppliers were disinclined to provide data or to disclose upstream elements of the supply chain, citing confidentiality and antitrust concerns. These concerns also were a barrier to cooperation among OEMs, yet cooperation seems necessary to maximize experience and technical understanding. The Draft AA Guide should be amended to enable compliance with antitrust and confidentiality laws, and to define compliance pathways, in the event of these legal barriers.

Furthermore, internet sources of information about alternatives may not be reliable. We urge that DTSC recommend these be used with caution.

³ The Alliance follows all United States Antitrust Laws and Regulations.

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- On page 29, DTSC should provide examples of the “technical resources that identify chemicals or materials or design changes with similar or equivalent functionality.”
- Page 29 of the Draft AA Guide recommends exploring whether “other AAs identified possible alternatives associated with similar use functions.” This condition will only be true for products already under study for replacement, which should not be the focus of this Guide. In exploring the AA process, we evaluated a chemical that is in a class that has been very well studied. We identified multiple AAs already available that could provide information on potential alternatives. However, even these provided fairly poor data on performance, cost and feasibility. Given the difficulty we encountered searching for alternatives in a chemical class that is relatively well studied, we have increased concern over the greater difficulty that would be encountered in identifying alternatives to more novel materials.
- DTSC should provide more specific guidance on how to identify possible alternatives. Page 29 of the Guide states that “[t]he Interstate Chemical Clearinghouse (IC2) Alternative Assessment Document and the European Chemical Agency’s Guidance for preparing an application for authorization also can help a responsible entity to identify alternatives.” These documents *do not* help to identify alternatives, but instead provide framework for evaluating alternatives once they have been identified.
- Page 30 of the Draft AA Guide states:

In addition to considering similar materials as replacements, a responsible entity may also consider dissimilar materials...If, however, the responsible entity primarily manufactures the container portion of the Priority Product, switching to a different container material may not be a feasible alternative to its manufacturing business model.

We agree with DTSC's contention that alternative selection should be constrained to alternatives compatible with the responding entity's business model. This has very significant implications for the breadth of an AA. It would be unreasonable for responsible entities to have to evaluate alternatives they would not ever produce and of which they have no technical knowledge. DTSC should specify in the Guide that businesses may, but are not required to evaluate alternatives outside of their business model.

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- Page 30 of the Draft AA Guide states that “[i]n addition, the responsible entity may consider materials or formulations currently used by others in the industry or other related industries.” Typically, information on the performance and content (and therefore hazard) of such alternatives is proprietary information which competitors will not provide. DTSC should specify in the Guide that competitor materials/formulations are typically unavailable, as this information could be considered proprietary.
 - Page 30 of the Draft AA Guide states that, “[a] responsible entity may consider redesigning the Priority Product to address potential exposures associated with the Chemical of Concern.” We appreciate that reduction of exposure is seen as an appropriate hazard mitigation step. Can DTSC provide guidance on how much of a reduction in exposure is sufficient to qualify a product as a true alternative?
 - Appendix 2 should be renamed “Data Sources for Conducting an AA” because not all of the data sources listed can be used to identify alternatives. For example, Pharos identifies health hazards but does not identify alternatives.
- **Chapter 3 – Relevant Factors**
 - It would be helpful to give product related examples as is done in Chapter 2.
 - Page 32 of the Draft AA Guide states:

Identifying relevant factors is part of the scoping process during the first and second stages of the AA and is an iterative process. Responsible entities will continually re-evaluate relevant factors throughout the AA.
- Responsible entities are required by the SCP regulation (Sections 69505.5-69505.6) to consider relevant factors in distinct steps through the AA process. They are not required to “continually re-evaluate relevant factors.” DTSC should rephrase this statement to accurately reflect the requirements. Per the SCP regulations, relevant factors should be considered in the following steps:
- Stage 1, Step 3: Relevant factors should be identified for comparison of alternatives.



- Stage 1, Step 4: Relevant factors should be considered in the initial evaluation and screening of alternative replacement chemicals.
- Stage 2, Step 1: Relevant factors should be identified for the purpose of comparing alternatives.
- Stage 2, Step 3: Responsible entities may, but are not required to, reconsider relevant factors.

Continual re-evaluation is impractical and prohibitively costly. Additionally, this process violates the statute and DTSC's regulation. The Guide must set boundaries on the scope of the analysis required to be in compliance. DTSC's principle task as a regulatory agency is to establish the rules of compliance.

- Page 32 of the Draft AA Guide states that “the factors that cannot be quantified by readily available information should not be overlooked; the regulations also allow the use of qualitative information.” Qualitative information could potentially be problematic, so DTSC should also include a statement about data quality in this section of the Guide. Qualitative information should be well supported by actual science. Data based on subjective opinion or hearsay should not be considered. DTSC should include a statement about necessary data quality. Data gaps should not be filled with poor data just for the sake of filling them. This will also be very important when addressing public comment which may introduce unsupported information. Responsible entities will need a standard by which to evaluate this input.
- Table 3-1 is titled “A summary of potential factors requiring consideration for a two-stage AA.” Per Section (c)(2) of the SCP regulation, the “Adverse Impacts Multimedia Life Cycle Impacts” require consideration “if applicable.” Because not all factors in this table are required, as the Table 3-1 title states, the table should indicate which factors are required to be considered and which are not. As written, this table is inconsistent with the regulation.
- In Table 3-1 of the Draft AA Guide, data on material and resource consumption impacts may be hard to obtain for specialty chemicals. Such information is available for major commodities like steel, glass and cement but may not exist for the smaller market chemicals that are typical of DTSC's chemicals of concern. Quantitative life cycle impact data for such low production volume chemicals are not readily available. If DTSC would like material and resource consumption

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impacts to be studied for specialty chemicals, DTSC should provide additional resources where this information could be obtained.

- In Table 3-1 of the Draft AA Guide, the LCT elements of the Stage 2 table should be considered as part of initial alternative screening in Stage 1. We recognize there was discussion of life cycle thinking being part of Stage 1 during the 2nd DTSC webinar, and if this is DTSC's intent, it should be made clearer in the Guide.
- In Table 3-1 of the Draft AA Guide, DTSC states that “internal cost impacts” should be considered. DTSC should specify that internal cost impact analyses can and should include the entire cost accompanying various alternative choices – including the purchase cost of one alternative versus another; costs of changes to manufacturing processes, costs of testing and validation, costs associated with other regulatory requirements, etc. Furthermore, DTSC should recognize that cost impact assessments can be difficult to perform, as we discovered while exploring the AA process, since much of the information is highly confidential. DTSC must provide additional guidance to businesses so they can efficiently complete the internal cost impact assessment.
- Page 35 of the Draft AA Guide states, “[i]n addition, during the second stage AA, the responsible entity will consider factors related to product function, performance and economic impacts.” This statement implies that function and performance are NOT considered during the first stage. This concept is not in line with statutory and regulatory requirements, so DTSC should fix the wording. Function and performance must be considered in both AA phases.
- Example 3-1 and Figure 3-2 of the Draft AA Guide and Figure 3-2 of the Guide are useful. Can DTSC explain where the data on CO₂ emissions could be obtained? We do not anticipate it being easy to obtain similar data for most products or chemicals of concern. It would be helpful if the tables in Appendix 3-3 gave more detail on the specific types of data (*i.e.*, energy use, water impacts, CO₂ emissions, *etc.*) responsible entities should address under the SCP regulation and which databases can provide them.
- Page 37 of the Draft AA Guide states:

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One of the key differences between the AA required by the SCP regulations and other assessments is the requirement to consider all relevant life cycle impacts.

The IC2 guidance *does* specify life cycle thinking as part of the assessment. DTSC needs to include more clarification regarding what aspects of LCT are required for an AA to be approved. Our understanding is that for SCP regulations, DTSC is not requiring a full life cycle analysis but statements such as this confuse the depth of analysis needed.

- Page 38 of the Draft AA Guide states:

Because the responsible entity evaluates only relevant life cycle segments—those where a material contribution and material difference occur—an in depth analysis is not likely to be needed for every life cycle segment.

How is the responsible entity supposed to know certain life cycle segments are not relevant unless they are first evaluated? This implies that all segments need to be looked at but only those that are considered relevant need to be discussed in the AA report. DTSC should clarify what is meant by this statement.

- Page 38 of the Draft AA Guide states:

If the alternative for a water bottle is a switch in raw materials between glass and plastic, most life cycle segments and associated impacts are likely to be relevant due to the differences in resource extraction, production, transportation, and end-of-life management between glass and plastic.

While the example given here is useful to some degree, it is fairly simplistic compared to some of the priority products that may be designated. More realistic examples would be helpful (*e.g.*, an antimicrobial additive in a cosmetic, a plasticizer in a plastic).

- The diagram on page 41 places too much emphasis on hazard. This simplified example misrepresents the level of analysis that DTSC is requiring. How would the decision process change if all of the other factors mentioned in the SCP regulations were included (*e.g.*, energy used, impacts on water quality, air quality,

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soil quality, etc.). Is the heavy use of examples focused on hazard because these are the only examples available? What does this suggest about the ability of responsible entities to obtain the data to carry out analyses under the SCP program?

- Page 42 of the Draft AA Guide states:

When developing the scope of relevant factors, the responsible entity must also consider the associated exposure pathways and consider how a sensitive subpopulation's potential use of, or exposure to, the product may be different from other, less sensitive populations.

DTSC should clarify that responsible entities must only consider exposure pathways under the normal conditions of use of a priority product. Responsible entities cannot control certain unintended uses of a priority product, so having to consider any possible outcome (for instance, if a material in a car was ingested), could make the exposure pathway analysis extensive and time consuming, and would pull focus away from the real exposure risks of a priority product.

- On page 43, the Draft AA Guide asks, “[w]here do these practices occur geographically?” What is the meaning of this sentence? Manufacturers will not have geographic information about the waste treatment or disposal of a product that is sold nation-wide. DTSC should provide clarification.
- Regarding the unlabeled figure on page 46, DTSC presents two alternatives, one of which is a neurotoxicant, a reproductive toxicant and a genotoxicant while the other is persistent and bioaccumulative. DTSC should provide clear guidance on how these different concerns should be compared. In Chapter 5, DTSC discusses the need to document trade-offs but gives little indication of how it views such tradeoffs. Are responding entities supposed to guess at DTSC's priorities? Might these vary by DTSC reviewer? This is a substantial issue with AAs that the Guide does little to address.
- Regarding Appendix 3-1, the Tables 3-2a and 3-2b "Checklists of Questions to Consider during Life Cycle Evaluation" are helpful. Will DTSC staff use these checklists to evaluate AAs? Is it advisable for responsible entities to fill these out and include them in the AA report? DTSC should provide additional clarification in the Guide.

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- Table 3-1 identifies 20 human health endpoints for consideration. Some of these endpoints (*e.g.* epigenetic effects, endocrine toxicity, etc.) lack standardized test methods, and consistent interpretation of experimental results will be challenging. Please advise what methods should be used to evaluate the human health endpoints.
- Regarding Appendix 3-3, the vast majority of information sources provided in Appendix 3-3 relate to hazard. Even some which are stated to relate to life cycle really provide information on environmental fate which is only a small portion of understanding a product life cycle. In many cases, the relevance of many of the data sources to life cycle, function and economic factors appears to be overstated. For example, the European Chemicals Agency (ECHA) and the US Environmental Protection Agency's Ecological Structure Activity Relationships Predictive Model (ECOSAR) provide information on environmental fate and persistence but cannot be said to provide data on the life cycle impacts of a given chemical. DTSC should correct this.
- **Chapter 4 – Impact Assessments**
 - On page 49 of the Draft AA Guide, clarification is needed as to how LCT fits into Stages 1 and 2. We recognize there was discussion of life cycle thinking being part of Stage 1 during the 2nd DTSC webinar, and if this is DTSC's intent, it should be made clearer in the Guide.
 - On page 50 of the Draft AA Guide, under “Data Gathering,” we suggest that DTSC recommend a Weight of Evidence (WOE) approach to determining hazard, particularly where data are limited or conflicting.
 - Page 51 of the Draft AA Guide states:

When experimental or measured data are not available for a particular chemical, responsible entities may elect to estimate data values using models or analog assumptions.

DTSC has not been clear regarding the need to address Data Gaps. On page 51, DTSC states that data gaps should be filled using models or analogue assumptions, while on page 56, DTSC states "the AA Report required by regulations does not require that data gaps be filled in this way." We do agree that attempts to address data gaps should be done cautiously and responsibly.

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entities should be very conscious of data quality. Use of surrogate and read-across approaches are increasingly common, but the level of rigor involved in doing such analyses varies considerably. Additional guidance on this point is needed.

- The Data Summaries discussion on page 53 is limited to health hazard. There is no discussion of other impacts or performance. While exploring the AA process, we found that data on other impacts or performance were not readily available. Therefore, DTSC should provide additional guidance on where such data can be found.
- Page 54 of the Draft AA Guide states:

Because different authoritative lists typically address different issues, some responsible entities may need to use several lists to gather a greater variety of information.

Regarding use of lists for hazard data, DTSC should recommend harmonized lists that gather data from multiple sources. For example, harmonized classification and labeling under EU regulations has the benefit of using risk phrases that are agreed on by a large number of entities, increasing confidence in the assignment. A Weight of Evidence analysis could be helpful here. The appearance of a chemical for the same concern on multiple independent lists provides stronger evidence of the hazard than evidence that appears contradictory or inconsistent.

- Regarding “Modeling Tools” on page 56, DTSC discusses modeling to predict hazard and possibly exposure but provides nothing about modeling to evaluate performance, cost or technical feasibility. Since performance, cost, and technical feasibility are also significant and challenging aspects of the AA, the DTSC should also discuss the use of modeling in these analyses as well. It would be helpful for DTSC to provide examples of the types of models and tools which can be used for these applications.
- Page 57 of the Draft AA Guide states:

In 2007, Clean Production Action created GreenScreen ®, one of the earliest comprehensive hazard comparison tools, providing training, a free translator tool, and inspiration for other comparison methods. Since that time, Clean Production Action has updated

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GreenScreen® and adapted it for a variety of specialized uses and applications, although it remains a technical tool requiring training for effective implementation.

The level of detail provided relative to other products makes it appear that GreenScreen® is DTSC's preferred alternative. The discussion of other products should be expanded, in order to not imply favoritism.

- Regarding Table 4-4 on page 58, some of the tools listed in Table 4-4 are less helpful than might initially appear. For example P2OASys provides a spreadsheet framework for gathering information on alternatives but does not provide the data that could be used as input to decision making. Cradle-to-Cradle is a proprietary for-hire tool for which little information is available. DTSC should expand the discussion about other products, as we recommended in the above comment. DTSC should include information on the capabilities of the products discussed.

- **Chapter 5 – Screening Alternatives**

- In general, the initial screening of alternatives is a critical step in the process, yet this chapter is quite short (just over 3 pages), generic and theoretical. The DTSC should provide more detailed instructions, including several examples of how the screening process should (or should not) be conducted.
- Page 59 of the Draft AA Guide states:

...the regulations indicate that the initial screen may eliminate those chemical alternatives that have the potential to pose greater impacts than the Chemical of Concern when considering the specified impact categories.

In the list of impact categories to consider, DTSC primarily provides the “relevant factors.” However, DTSC should also include “performance requirements,” “functional requirements,” and “legal requirements.” Identifying these factors is the first step of the AA because it is recognized that if the alternative does not meet these factors, it is not a true alternative. Like the other factors listed, these factors have a significant impact on whether an alternative is viable.

- Page 61 of the Draft AA Guide states:



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A hierarchy among the factors identifies which relevant factor the responsible entity determines to be the most important, followed by the next most important factor, and the next...

Due to unique perspectives, different entities may weigh relevant factors differently. Does DTSC have a preferred method for weighing relevant factors? DTSC should provide examples. DTSC should also specify how relevant factors should be weighted for non-sequential evaluations that consider all impacts simultaneously.

In conclusion, we would like to emphasize the need for more certainty in the process. We thank you for considering the arguments presented herein. Please do not hesitate to contact me with questions or if I may provide additional information. We look forward to working with DTSC as it moves forward.

Best Regards,

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