Addressing Stakeholder Feedback in the Final Revisions to the Alternatives Analysis Guide

DTSC released Version 1.0 of the Safer Consumer Products Alternatives Analysis (AA) Guide in June 2017. Before releasing the AA Guide, the California Department of Toxic Substances Control (Department) solicited stakeholder feedback on its initial Draft AA Guide. Version 1.0 reflects changes made based on that feedback. A summary of the key feedback received and responses and improvements made to the Draft AA Guide follows.

- ***The AA Guide lacks sufficient clarity and details to conduct an AA that complies with the Safer Consumer Products (SCP) regulations.***

  Stakeholders requested specifics on what the Department considers an acceptable AA or what standards are to be met to be "in compliance" (e.g., what weighting factors to use). We did not change the discussions in the Draft AA Guide regarding these topics because the regulations allow flexibility for the responsible entity in conducting an AA. For instance, the Department will not prescribe arbitrary thresholds for AA decision-making processes. This burden lies with the responsible entity. Instead, we simply require that the responsible entity document the reasoning and assumptions used to arrive at decisions based on their own values and criteria.

- ***The scope of the AA Guide exceeds what was required in the SCP regulations. Approaches are burdensome.***

  The approaches, tools, and methods presented in the AA Guide are suggestions that responsible entities may use at their discretion. We have taken care to ensure that the Guide does not impose additional requirements nor create new legal obligations beyond the SCP regulations. Special care was taken in this final version to avoid using language which might be construed as prescriptive. All revisions have undergone legal review with these concerns in mind.

- ***The economic analysis requirement is burdensome.***

  The scope of the economic analysis requirements is consistent with that of the regulations. The Guide provides examples of ways to monetize and compare the health costs associated with products, yet does not require any particular methodology. Responsible entities may elect to follow other, more streamlined, approaches as long as they can evaluate, monetize, and compare the Priority Product and its alternatives, as required by the SCP regulations.

- ***AA estimates of public health costs using mortality and morbidity costs may be a roadmap for plaintiffs to sue the responsible entities for health costs attributed to the Priority Product.***

  We acknowledge this concern. Nevertheless, the regulations require as much quantification of impacts as possible. Note that the AA process emphasizes *comparative* analyses.

- ***Which non-profit organizations are covered in the regulations and require cost estimates?***

  The previous draft of the Guide implied that responsible entities need consider a wide range of non-profits. However, per 69505.6(a)(3)(A)(2) of the regulations only non-profit organizations that specifically manage wastes, oversee environmental cleanup and restoration efforts, or are charged with protecting natural resources because of an environmental regulatory mandate must be considered when estimating costs. Non-profit organizations that simply advocate for

environmental protection are not covered. We added a discussion and examples to clarify this issue.

- ***What constitutes a suitable data estimation justification (e.g., when using read-across, structure-activity relationships, etc.)?***

  Stakeholders recommended detailed references and guidance documents. We have incorporated these into the Guide. In addition to these changes, we also added cautionary statements regarding the limitations of data extrapolation and prediction. This will continue to be an area of discussion within the program and with our stakeholders. We will continue to develop expertise to support responsible entities and to evaluate such estimations in submitted Alternatives Analyses. Appropriate use of estimations may also be a topic for consideration by the Green Ribbon Science Panel.

- ***How will the Department handle confidential business information (CBI)?***

  We added a discussion on CBI. The electronic submission of AA reports via CalSAFER allows submission of a redacted and an unredacted version by the responsible entity. Substantiation of CBI claims must be submitted for review by the Department. In addition, DTSC is developing policies and procedures specific to the SCP regulations and consistent with other Department CBI provisions. We will continue to provide focused outreach and education on this important topic.

- ***Multiple stakeholders requested that the Department conduct an example AA.***

  It is currently beyond the scope of the AA Guide for the Department to conduct an AA. We have expanded on existing examples (e.g., Figure 6-1) to further demonstrate options on how to present AA information. The examples included in the AA Guide, however, are not templates. We will continue to improve the guide and other resources for stakeholders and will actively seek out examples to be used to illustrate best practices for developing AAs. We agree that published examples would be valuable so we will continue to partner with external entities that are developing alternatives assessments that may serve as examples – the Interstate Chemicals Clearinghouse, BizNGO, the state of Washington, and REACH-compliant Analyses of Alternatives posted by the European Chemical Agency. Additionally, by offering commentary/annotation on such examples we can illustrate the strengths and weaknesses of AA elements to stakeholders.

- ***Including sensitive population in exposure assessment is beyond the regulatory requirement.***

  Sensitive subpopulations are explicitly mentioned in section 69503.3(b)(4)(D) which was referenced in 69505.5(c)(3)(B) of the SCP regulations. We disagree with this comment.

- ***Mitigating factors should be considered in an exposure assessment.***

  Based on section 69503.3(b)(4)(G), mitigating factors such as administrative and engineering controls may be considered when evaluating exposure pathways. We added such a discussion to the revised AA Guide. However, we also included a clarifying note that the Department will give preference to the greatest level of inherent protection through redesign of a product or process, rather than through administrative or engineering controls.

The AA Guide will continue to evolve and additional tools will be developed to support entities falling under the regulations. Further feedback is welcome from stakeholders on an ongoing basis.