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SUBJECT: Comments on the Draft Stage 1 Alternatives Analysis Guide

The Department of Toxic Substances Control (DTSC) Human and Ecological Risk Office (HERO) has reviewed the Draft Stage 1 Alternatives Analysis Guide (the Guide). The scope of our review focuses primarily on aspects related to toxicology and hazard analysis, but we have also commented on information delivery.

The Safer Consumer Product (SCP) Regulations outline various Alternatives Analysis (AA) options including a default Two-Stage AA. The Two-Stage AA process includes a Stage 1 AA, a Preliminary AA Report, a Stage 2 AA, and a Final AA Report. The Guide provides recommendations and reference materials for a responsible entity on how to develop a Stage 1 AA and produce a Preliminary AA Report. Since the intent was to only provide information on performing a Stage 1 AA, the Guide does not provide information for the Stage 2 AA or the subsequent Final AA Report because the latter chapters are still in development. Therefore, the Guide is incomplete and does not provide the responsible entity with a complete AA guidance outlining the information and reference materials necessary to undergo both Stage 1 and Stage 2 AA. Prior to initiating the Stage 1 AA, the responsible entity should understand what is expected of them throughout the entire AA process. That being said, HERO has the following comments concerning the Guide as it stands now.

Regulatory Requirements – Even though the Guide is meant to be a “menu of options” rather than a regulatory checklist, the requirements for the Preliminary AA Report and the Final AA Report listed in the SCP Regulations should be clearly defined in the beginning of the main text. HERO found that the appendices provided concise and precise information for the AA process. Appendix 1 (Required Information for AA

Reports) is the backbone for the entire AA process. HERO recommends rearranging the document to have the information from Appendix 1 in the first part of the main text so responsible entities know what has to be in their AA Reports. From there, the guide can support each facet of those requirements. This will also make the message more succinct.

General Report Format – Since the responsible entity is tasked with producing all the components of the AA, it is also up to them to “decide which approaches, assumptions, tools, methodologies, data, and decision framework” will work best for evaluating potential alternatives to their particular priority product. HERO agrees that the responsible entity would be the most knowledgeable party to assess their priority product, but the lack of a general procedure for information delivery will result in a variety of formats and selected data sources. Since DTSC’s SCP Program is the reviewer of the AA reports, this may result in different treatment of different principal responsible entities. HERO recommends establishing a set reporting format, regardless of the AA methodology/procedures used to produce an AA. Responsible entities should be able to use the various models and references recommended in the Guide, but still deliver the information in a standard format prescribed by DTSC.

Exposure Assessment – Figure 1-2 illustrates whether chapters are to be used in either Stage 1 or Stage 2, or both. HERO notes that Exposure Assessment (Chapter 6, in development) is only prescribed for Stage 2 even though Chapter 3 (Relevant Factors) discusses ‘Incorporating Exposure Pathways’ (page 42). In this discussion, the incorporation of exposure pathways are to “capture trade-offs among alternatives and the Priority Product for risk reduction, using simplified exposure estimates when considering potential impacts” since the AA emphasizes “hazard reduction.” It is difficult to determine how to evaluate “hazard reduction” without an estimate of the amount of a replacement chemical required to produce a viable product which can be translated into estimates of near-field and far-field exposure for human and ecological receptors. If the Guide means to propose that a simple reduction in the number of hazard traits linked to the replacement chemical, as compared to the original chemical, will be the “hazard reduction” criterion it should be clearly stated. HERO does not believe the simple reduction in the number of associated hazard traits would be commonly understood as “hazard reduction”. Since preliminary exposure assessment is discussed in this iteration of the Guide, we recommend that the Exposure Assessment chapter be developed for Stage 1. HERO would also like to note that even though the SCP regulations do not require a traditional risk assessment, the DTSC reviewers may actually have to review at least some components of a traditional risk assessment.

Data Quality Requirements – Chapter 4 (Impact Assessments) of the Guide discusses how “the responsible entity must gather and evaluate information about the human health, ecological, and environmental effects associated with a Priority Product and its alternatives to assess and establish the impacts associated with those endpoints.” Under “Gather Data,” approaches for the general gathering of hazard and exposure data are discussed, but there are no defined requirements for data quality. Reference

volumes, data summaries, literature sources, proprietary research, and model tools are listed as data gathering sources, but the subsequent explanations mainly encompass the pros and cons of use. HERO does not consider all physical characteristic and toxicity information available to be equal in quality. HERO recommends that the text in this section provide specific details on what types of information are acceptable as per the SCP Regulations. For example, the SCP Regulations in §69501.1(a)(57) defines “reliable information.” Also, HERO recommends clearly stating the hierarchy of acceptable data (i.e. empirical data, then models and analog assumptions) as stated in SCP Regulations §69505.5(c)(2) “The responsible entity shall use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools...”.

Screening Alternatives – Chapter 5 discusses the considerations for screening out inferior alternatives to the Priority Product. The Guide, as specified in the SCP Regulations, lists impact categories, including the entire toxicological hazard trait list. It is up to the responsible entity to determine which alternatives have greater adverse impacts, without direction from the DTSC. HERO has two concerns with this approach:

- 1) Since all of the toxicological hazard traits as defined by the Green Chemistry Regulations are listed, HERO is concerned with the lack of ranking within this list. SCP may want to consider hazards traits such as carcinogenicity, mutagenicity, and reproductive toxicity (CMRs) or persistence, bioaccumulative, or toxic to the environment (PBTs) of higher importance than other hazard traits.
- 2) Given the timelines allocated to the responsible entity to develop an AA and the time DTSC has to review the resulting phased AA reports, HERO is concerned with screening either inferior or superior alternatives based on science (emerging hazard endpoints, toxicity testing techniques and/or hazard ranking methodologies) that may change over this timeline. HERO highly recommends inclusion of an iterative process mechanism to deal with the possible and likely emergence of new scientific data or methodology.

Example AAs – The examples provided throughout the Guide are generic in nature and are focused on specific portions of the AA process pertinent to the portion of the AA process being outlined. It may be more helpful to use the same chemical product combination (i.e., a ‘Priority Product’ previously assessed publicly by a different agency) throughout the Guide. This real life example with predetermined conclusions (recommended alternatives) would provide both the responsible entity and the SCP AA reviewers greater insight into the required AA process. Considering that “the Department shall post on its website examples of AAs that are available in the public domain at no cost” (SCP Regulations §69505(b)), the example chemical of concern (COC) in this example AA may be a possible example to be used in the Guide.

Specific Recommendations –

1. Page 8, paragraph 1: Provide a hyperlink to the SCP Regulations.

2. Re-check the hyperlinks; the U.S. Environmental Protection Agency's (EPA) websites recently underwent an Agency-wide update and upgrade and therefore many of the EPA hyperlinks are broken.
3. Page 15, paragraph 2: states "The first stage of the AA establishes *boundaries* of the analysis...". 'Boundaries' do not accurately describe what the Stage 1 AA entails. HERO recommends removing the sentence and proceeding directly to the third paragraph.
4. Please include an Acronyms list and a complete Glossary.
5. For tables, rather than referring to "the following table," please add a table number. Also, within the text, the referenced table number should link directly to the table indicated.
6. The highlighted blue boxes should have box numbers for reference rather than referring to "the box below." Please incorporate the box number within the text.
7. Page 29-30: Under the subheading "Removing a Chemical of Concern," it states "If a manufacturer removes the Chemical of Concern entirely, or substitutes a chemical that is not defined in the SCP regulations as a candidate chemical, the manufacturer *may be exempt* from the AA requirement, or subject only to limited notifications." It should be noted within the text that hazard identification is still needed prior to an AA requirement exemption.
8. Page 33, bullets: Two criteria are defined for a potential factor to become relevant. The bullets are copied verbatim from the SCP Regulations and include the terms "material contribution" and "material difference." These terms, while highlighted, are vague. HERO recommends that the Guide define these terms.
9. When referring to "chemicals of concern" and their "alternatives," please be aware of when the COC is an ingredient or contaminant, and whether the alternative is referring to COC elimination, reduction, or substitution. Discerning these differences will help with making the Guide more precise.
10. Page 43: For the text in the blue box, HERO recommends the title be "What are associated relevant exposure *factors*?" rather than "what are associated relevant exposure *pathways*?"

HERO appreciates the opportunity to provide review and comment on this important guidance document. Please contact Lynn Nakayama Wong at 916-255-6563 if you wish to discuss any of these comments.