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RE: Comments on the IC2 *Guidance for Alternatives Assessment and Risk Reduction*

Dear Dr. Stone:

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Thank you for the opportunity to review and comment on the proposed IC2 *Guidance for Alternatives Assessment and Risk Reduction*. HP appreciates the work that went into preparing this guidance, and we support the harmonization of AA requirements between different states. The following comments are offered to improve the content and structure of the document.

At a high level, there are many aspects of the proposed guidance that can be clarified and improved:

- We recommend that the main audience for this document be regulators addressing specific public health issues, and to a lesser extent large businesses.
- Although well-written, this document is often quite verbose. A professional editor might help focus the text, reduce repetitions, and shorten the overall document, which would make it much more effective.
- The question-based format used throughout the document is not appropriate for many topics and is being misapplied in addressing others. Questions should be used in cases where there is a specific calculation or action that results from an answer, but not in cases where an affirmative or negative answer merely results in progression to the next step. Flow charts or simple lists of activities are better ways to convey this type of guidance. If groups of questions are needed to gather information for the AA, the questions would more effectively be presented as bulleted items.

Detailed comments for individual sections and modules can be found below.

Section 3. Background and Purpose (p16)

Section 3 notes that the IC2 goal is to create a document "…[f]lexible enough to meet a wide range of user needs including small, medium and large businesses, local, state and federal governments and other interested parties."

While commendable in spirit, this scope is too broad. Different audiences need different information and guidance with respect to alternatives assessment. A single document cannot meet all of their needs.

We recommend that the main audience for this document be regulators addressing specific public health issues, and to a lesser extent large businesses. By focusing on the needs of public policymakers, it would help clarify the structure as well as the content of the document.

A good model for the structure of regulator-focused guidance is the European Chemicals Agency (ECHA) document entitled *Guidance on the preparation of socio-economic analysis as part of an application for authorization*[1]. It effectively communicates a similarly complex and analogous topic to policymakers.

The needs of small and medium businesses would be better addressed through a simplified companion document containing a streamlined, minimal, step-by-step implementation based on the practices within the document. Alternately, regulators could be advised to create such a document as part of their specific implementations of the general method. As written, this document would be overwhelming for most businesses to use effectively.

Also, the team may want to consider adopting the convention of the language of regulations and technical specifications where "shall" is a requirement, "should" is a recommendation, "may" is allowable, and anything else is merely a statement. This practice serves a valuable function in differentiating core requirements from advisory statements.

Section 4. How to Implement Guidance (p20)

Public policy guidance - A useful adjustment to this section would be to get more specific about how certain modules or approaches could be used to address specific types of public health or environmental issues faced by regulators. Not all issues require all modules.

Decision framework selection – We have observed that most AAs actually employ a hybrid model, so the extended discussion of decision frameworks may be unnecessary. It may be more helpful to choose critical points of influence (initial screen, final acceptance) and set constraints (hazard screening first, burden-shifting

[1] ECHA document entitled *Guidance on the preparation of socio-economic analysis as part of an application for authorization* Is located at http://echa.europa.eu/documents/10162/13643/sea_authorisation_en.pdf.

detection at the end) rather than have an extended theoretical discussion. Clarification of the audience would help determine the appropriate amount and detail of content.

Section 5a. Initial Evaluation (p31)

This section could be condensed into a bulleted list of cases where an AA might not be necessary. This list could address policy situations as well as private industry cases.

Section 5b. Identification of Alternatives (p38)

This section could be condensed into a bulleted list of typical approaches for identifying alternatives, and potential information sources.

Also, this section does not seem to reflect the perspective and experience of industry practitioners. For example, the primary method of identifying alternatives in most cases is to work with suppliers. This approach should be the first and most prominent approach described. We would be happy to have detailed discussions with the authors to revise this section.

Finally, examples and guidance are needed for cases where a replacement cannot be found.

Section 5c. Decision Module (p40, p94)

This section may be of limited use unless regulators intend to prescribe particular methods. It seems that practitioners could use any framework that suits them in most cases, so it may potentially be more useful to establish if there are sequences or frameworks that would be unacceptable.

Section 5d. Stakeholder Involvement Module (p43, p104)

While consulting external stakeholders on key issues is a growing trend in large corporations, it is not clear whether formal consultation with stakeholders is needed in most technical decisions. Consulting stakeholders seems most appropriate for regulators and policymakers as they select public health and environmental issues on which to focus and on specific substances for action.

If this section is retained, it could be clarified that, in general, one would expect:

- Level 1 to be most commonly used by businesses. Stakeholders could reasonably be limited to employees with different roles within the company (product design, procurement, etc.).
- Level 2 could be used in external industry groups, consortia, or other collaborations.
- Level 3 would usually be limited to regulators, policymakers, research organizations, and NGOs.

Also, the amount of content on this topic in both the primary text and the module is especially large and could benefit from judicious editing.

Section 6a. Performance Evaluation Module (p46, p118)

Although assessing the performance of alternatives is almost always a part of the AA process, it is not clear whether the authors have anything to add to current practice within industry. This area is well-addressed and understood by practitioners in most cases. We recommend eliminating most of the content of this module and limiting the discussion to guidance on avoiding over-engineering specifications because doing so can result in eliminating potentially acceptable safer alternatives.

Section 6b. Hazard Module (p56, p126)

We support the GreenScreen approach, but we also believe that it will be too much work for some companies, especially smaller businesses. It might make sense to retain a level below a full GreenScreen, such as a restricted substance list or R-phrase screening, to accommodate the needs of lay users, including those within the public policy community.

Also, where possible, we recommend that you refer directly to Clean Production Action's content and web site rather than replicating the information in this document. Doing so will ensure that the content is always current.

Section 6c. Cost and Availability Module (p61, p186)

Five levels of assessment are too complex, especially because industry is very familiar with direct material cost and availability issues. The cost and availability analysis could be collapsed into three levels:

- Level 1: Material cost increase only. Detailed discussion would not be required in this document because all businesses are familiar with this type of evaluation. Refer to other resources, if needed.
- Level 2: Overall cost to the business and volume availability. Traditional cost-benefit analysis and net present value calculations could be used. This document would not have to discuss these techniques in depth as there are many comprehensive sources available to reference.
- Level 3: Life cycle costing or other methods for considering externalized costs. This topic could warrant extended discussion because of the difficulty of the calculations, and also because some of these calculations will be required for complying with the California Safer Consumer Products regulations.

Another alternative would be to adapt the practices found in the ECHA document referenced above.

Section 6d. Exposure Assessment Module (p66, 201)

Five separate levels of assessment may not be needed. The exposure assessment module could be collapsed into three levels:

- Level 1: Qualitative assessment, based on a set of questions or a checklist.
- Level 2: Quantitative assessment, based on data and test results.
- Level 3: Complete assessment as required in a formal risk assessment.

Also, within the Initial Evaluation in the module itself, there is no concluding section to indicate what to do with the responses generated to the questions presented.

Section 6e. Materials Management Module (p67, p223)

Completing AAs to select lower impact alternatives is part of meeting the goals of Sustainable Materials Management (SMM), rather than the converse (SMM is not part of meeting the goals of an AA). SMM should be incorporated into the framework and modules themselves, similar to the Golden Rule and AA Principles, rather than being placed in a separate module. Also, SMM is not a comparative assessment tool on its own, making it less suitable for an AA process.

We recommend this module be eliminated completely. The key topics in the SMM module could be incorporated directly into the Life Cycle Thinking module as part of identifying burden-shifting, rather than through the reference at the beginning of Section 6g.

Section 6f. Social Impact Module (p70, p232)

Many of the topics in this module are more appropriately considered by policymakers and regulators than private industry because they are beyond the scope and control of individual companies. This module would be difficult for companies to complete in a meaningful way, and it also does not lend itself to comparative analysis.

We recommend this module be eliminated completely. Essential topics could potentially be incorporated directly into the Life Cycle Thinking module, rather than through the reference at the beginning of Section 6g. If retained, the social impact analysis could be collapsed into two levels:

- Level 1: Qualitative assessment, based on a set of questions or a checklist.
- Level 2: S-LCA or relevant portions of REACH SEA[2] reserved as an option for policymakers and regulators.

Section 6g. Life Cycle Thinking Module (p74, p243)

This section and module are improved over earlier revisions; however, the content is still not clear enough. Life cycle thinking, as an approach, is not familiar to many

[2] ECHA document entitled *Guidance on the preparation of socio-economic analysis as part of an application for authorization* Is located at http://echa.europa.eu/documents/10162/13643/sea_authorisation_en.pdf.

practitioners, and therefore may require more detailed, structured implementation steps.

Also, the general method described could potentially create large amounts of analysis in areas for which there is no substantial impact. For example, a change from one substance to another might increase the aquatic toxicity by a factor of two, but if the aquatic toxicity impact of that product (including production and disposal) is a very low impact area for the overall product impact, it might not be the best decision to eliminate that alternative if it can improve the main impact area. To address this concern, we recommend adopting the California approach of determining the relevant factors by two steps:

- Identify the major impact areas for the product class, based on LCA midpoints and other criteria (potentially incorporating the social and materials module content as noted above).
- For the major impact areas identified, assess whether there is a meaningful difference between the alternatives and the baseline in those areas.

The life cycle thinking module could be collapsed into two levels:

- Level 1: Qualitative, based on a set of questions or a checklist.
- Level 2: Qualitative, based on an existing LCA or a newly created flow diagram. (Note: Quantitative assessment is usually not possible in this type of assessment.)

Finally, once the major impact areas with high levels of differentiation between alternatives are identified, the module should be clear about what analysis would be required for those major impact areas, how to interpret and use the results of the analyses, and what would constitute unacceptable burden-shifting.

Thank you again for the opportunity to comment on this important document, and we look forward to working with you in the future.

Regards,

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