



Interstate Chemicals Clearinghouse

Alternatives Assessment Guide Response to Comments

December 2013

Comment Contents

General	1
Title Page	31
Definitions	32
Background	35
How to Implement	39
Initial Evaluation	42
Identification of Alternatives	51
Decision Making Module	59
Stakeholders Module	66
Performance Evaluation Module	72
Hazard Module	76
Cost and Availability Module	84
Exposure Assessment Module	89
Materials Management Module	93
Social Impact Module	98
Life Cycle Thinking Module	104
Webinar Questions and Responses	109
Scoping Input and Responses	130

General Comments

1. **A commenter stated ‘... the guidance (or reference document) should not be a guide for alternatives assessment and risk reduction. A key goal of alternatives assessment is to identify and evaluate less hazardous alternatives to chemicals of concern, hence reducing risk. Risk can also be reduced by reducing exposure but not hazard. If the goal is informed substitution and safer chemistry, then hazard reduction must be the first intention of an alternatives assessment process. This is consistent with the principles of green chemistry. Such a focus on hazard reduction is particularly important for chemicals in products where it is difficult, if not impossible to control exposure to single, let alone multiple, dispersive chemicals. Research indicates that product based exposures make a significant contribution to human chemical body burdens.’**

Response: The name of the document has been changed to “Interstate Chemicals Clearinghouse Alternatives Assessment Guide”. However, by stating that the alternatives assessment process reduces risk does not prevent there from being other methods to reduce risk as well including reducing exposure. Experience has shown that many exposure assessments have underestimated risk and attempts to control or reduce exposure have not always been successful across the life cycle of the chemical, product or process. By including reducing risk in the title, we are emphasizing that the alternatives assessment process is risk-based and unlike the risk assessment process concentrates on reducing risk rather than assessing risk.

2. **A commenter stated ‘... Ensuring a reduction in hazard as a key focus and outcome of the alternatives assessment process. Hazard reduction – and the focus on solutions – is what differentiates AA from risk assessment and life cycle assessment. Consideration of exposure is important in alternatives assessment processes but primarily as a tool for prioritization (for uses of a particular chemical), to identify alternatives with potential unintended consequences, and to reduce any residual exposures after a substitution decision-takes place (for example to process chemicals).**

Response: The importance of hazard in the assessment process is indicated by including it early in the assessment process. IC2 appreciates the clarification and support along with all comments provided by stakeholders during the creation and review process.

3. **Two comments were received indicating the Guide should not ‘... prioritize hazard over other considerations ...’ and should ‘... provide an explanation of the differences between IC2’s draft-Guidance and that of the EPA’s risk assessments already being used under current TSCA work plans.’**

Response: Risk assessments attempt to identify whether or not a chemical poses a risk based upon assumptions related to exposure. No attempt is made to select the chemical with lowest hazard, but rather the focus is to identify the hazard associated with a specific chemical, evaluate the potential for exposure and reach a conclusion about the risk posed based upon that information. The alternatives assessment process goal is not to assess risk but to reduce risk. It does this by evaluating all possible alternatives and selecting the alternative that has both the lowest hazard and exposure potential. The chemical that has the lowest risk based upon this evaluation is identified as the preferred alternative to continue with further evaluation. As the EPA risk assessment process has a different objective, it is not comparative to the alternative assessment process and is not germane to the Guide.

4. **Several comments stated that an alternatives assessment must use a ‘... risk-based approach to evaluate all relevant factors ...’ and ‘... evaluate whether the options exist to reduce exposure and thereby reduce risk to an acceptable level.’**

Response: The alternatives assessment guide is a risk-based approach that focuses on prevention. Unlike a traditional risk assessment which seeks identify risks based primarily upon exposure assumptions; the objective of an alternatives assessment is to reduce risk by selecting alternatives that have both lowest hazard and lowest exposure potential. This risk-based reduction process that emphasizes hazard reduction is fundamental to the alternatives assessment process. Therefore, IC2 considers that alternatives assessments are risk-based.

5. **A comment stated that the Guide should ‘...Keep the focus on assessing chemical hazards. We support the Guidance’s assertion that hazard determinations must be made first. The fundamental focus of an Alternatives Assessment must remain on hazard identification and minimization. This is the approach that many leading businesses have used to choose safer alternatives. It is cost-effective, efficient and leads to decisions that help companies avoid substitutes that are regrettable ...’ The same commenter cautioned about including ‘...the concept of risk time and again – repeating the word itself 103 times. Risk Assessments are a different tool that should not be confused with Alternatives Assessment.’**

Response: The authors agree that risk assessments should not be confused with alternatives assessments. However, a common misunderstanding is that alternatives assessment does not consider risk. Risk is a function of hazard and exposure. As an alternatives assessment considers both factors and tries to select the alternative that has the lowest hazard and exposure, it is by definition considering risk. The authors agree though that there is a definite difference between risk assessment and alternatives assessment. It is appropriate to discuss risk in the alternatives assessment guide. All uses of risk were clarified to emphasize that it is appropriate to the reducing risk concept and not assessing risk.

6. A comment was received that ‘Focus on lowest hazard AND lowest exposure is a show stopper-this proposal includes no rational consideration of risk or the safety of products.’

Response: Risk by definition is a function of hazard and exposure. Therefore, by definition the alternatives assessment process is based upon consideration of risk. Its objective is to reduce risk by emphasizing both components of the risk equation. This emphasis produces alternatives that pose the lowest risk by identifying alternatives optimized to have the lowest potential impact upon human health and the environment.

7. An extensive comment was received that supported the original assertion that ‘Established Approaches to Product Safety are Disregarded: Exposure Controls and De Minimis Concentration Thresholds for COCs: The Document does not recognize well-established international approaches to product safety that center on exposure concerns.’ The commenter also recommends the use of a de minimis level of 0.1% or 1,000 ppm.

Response: New tools are needed to deal with the challenges currently faced by the continued use of toxic chemicals. As identified by the National Academy of Sciences in a recent report on Sustainability, '4.6. Finding: Risk analysis as commonly applied to environmental issues often does not adequately account for the full range of human health and ecosystem risks, including cumulative risks, intergenerational considerations, and the distribution of risks among population groups. In addition, better methods are needed to support consideration of health and environmental effects for the green chemistry goal of safer products and more sustainable chemical usage (p.60).'

(http://www.nap.edu/catalog.php?record_id=13152).

Alternatives assessments address some of these concerns by including an emphasis on reducing hazard in the selection of chemicals used in products or processes. Ultimately, the goal of an alternatives assessment is to use chemicals that have minimal to no impact upon human health and the environment. Lastly, the use of a standard value such as 1,000 ppm (0.1%) may not consider the potential impact chemicals have upon human health and the environment. For example, 1,000 ppm may be adequate for some chemicals; however, for others such as endocrine disrupting chemicals, 1,000 ppm may be an unacceptable level of exposure. Therefore any level should be tied to the impact a chemical has and should consider the full life cycle impact of a chemical's use and not just its use in specific products or processes. This can be particularly true for PBT chemicals that will impact human health and the environment for decades to come.

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8. **One commenter stated that ‘As an overarching philosophical matter, there appears to be a great divide between what industry considers most important and the approach outlined in this Draft AA Guidance, specifically relating to a focus on hazard versus exposure. We acknowledge that a focus on inherent hazard traits is appropriate. However, it is critically important to prioritize our efforts based on the potential for exposure. It is for this reason, the potential for exposure across the entire lifecycle of the product should be considered upfront, and not merely as a criteria to compare alternatives later. We think an exposure assessment needs to enter into the AA approach at two points. It needs to be part of the threshold criteria on when to perform an AA; and, it needs to be part of the assessment of which alternatives are safer.’**

Response: Exposure should play an important role in selection of which chemicals should be subjected to the alternatives assessment process. However, it was identified early in the development of the guide that selection of chemicals for evaluation was outside the scope of this document. Language has been inserted into the guide making it clear that such discussions are not considered in the guide. Once the chemicals have been selected, however, it is appropriate to consider the hazard and exposure potential to identify the safest alternative by selecting those that pose the lowest risk by reducing both hazard and exposure. As identified by the National Academy of Sciences in a recent report on Sustainability, new tools are needed to address the problems caused by the continued use of toxic chemicals.

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9. **Several comments were provided indicating that the commenters did not believe that the stakeholder process was adequate. Commenters specifically stated that**

commenting ‘on the individual modules ... is impractical given the multi-step alternatives analysis process [and] ‘...stakeholders must be able to review the guidance as a comprehensive package.’ One commenter expressed concern that ‘... development ... was limited to members of the IC2... [and] ... should have included business/industry members in the ... Guidance Team.’ A third comment was that the IC2 should ‘... take a step back to allow for broad consensus that includes business/industry.’ In essence the comments reiterated the belief that industry should have been involved in the development of the guidance.

Response: Interested stakeholders including industry, environmental groups and individuals were provided the opportunity to comment at any time along the development process. The goal of the IC2 was to hear what stakeholders thought during the development process and therefore provided the opportunity for stakeholders to comment as modules were completed. Several individuals indicated they preferred to wait for the final document to provide comments. The IC2 Team provided for a 45-day public comment process that was extended to a 60 day period at the request of stakeholders. The authors provided enhanced stakeholder involvement beyond what is typically supported for the development of guidance. The authors encouraged interested stakeholders to provide input at any time during the document generation process, and provided three industry workshops, two stakeholder webinars and the 60-day public comment process. We also developed a public blog for the project. This was the first time for the IC2 to run a multi-state project and we appreciate the interest and feedback on the process which we can use in future efforts.

10. Two comments stated that because the IC2 did not involve business in the creation of the Guide, it was in violation of the National Technology Transfer Act.

Response: Public Law 104-113, the National Technology Transfer Act, does not apply in this instance according to an OMB circular on the implementation of Pub. L. 104-113. The "National Technology Transfer and Advancement Act of 1995" applies to federal agencies using standards. There is no indication that it applies to those receiving federal funds. (<http://www.whitehouse.gov/omb/circulars/a119#5>), CIRCULAR NO. A-119 Revised, February 10, 1998. Specifically, point #5 address the question of: ' 5. *Who Does This Policy Apply To? This Circular applies to all agencies and agency employees who use standards and participate in voluntary consensus standards activities, domestic and international, except for activities carried out pursuant to treaties. "Agency" means any executive department, independent commission, board, bureau, office, agency, Government-owned or controlled corporation or other establishment of the Federal Government. It also includes any regulatory commission or board, except for independent regulatory commissions insofar as they are subject to separate statutory requirements regarding the use of voluntary consensus standards.*

It does not include the legislative or judicial branches of the Federal Government.' This law is only for specific uses within the Federal Government and is not applicable to state use of Federal funds.

- 11. A comment stated that ‘The product optimization process is iterative, complex, and case-by-case. Thus, it is inherently difficult to comment on individual aspects of the multi-step alternatives analysis process. Industry representatives will continue to review the modules as they are posted, and we encourage you to continue your present approach to their release. However, we intend to comment on the entirety of the guidance package rather than commenting on individual modules.’**

Response: Accepted: Stakeholders were able to provide input at any time during the guidance development process; however, final sections including, “How to Implement the Guidance” that were not written until the end of the process are important for understanding how the Guide was to be used. It was for this reason that an additional 60-day comment process was provided to allow stakeholders to see the final document. The IC2 appreciates the input received.

- 12. One commenter stated that ‘...comprehensive comments could not be developed until such time as all the modules were released given the inherently interconnected nature of the modules in the alternatives assessment process.’**

Response: Stakeholder comments were very important throughout the development process; therefore stakeholders were provided the opportunity to comment as modules were completed. Comments received throughout the development process including input received during webinars are addressed in this document.

- 13. A commenter questioned ‘...why the alternatives assessment guidance is being developed under a grant to protect and restore the Puget Sound ...’ and ‘...any effort to protect and restore the Puget Sound must be coordinated with the Puget Sound Partnership (Partnership).’**

Response: Although EPA through the National Estuary Program provided \$150,000 seed funding for the development of the Guide, individual states provided significantly more in terms of staff involvement and support. In addition, the grant was reviewed and approved by EPA as part of their oversight of Ecology as a Lead Organization. The development of the

Guide was identified in the Puget Sound Partnership's Action Agenda as a Near-Term Action needed to protect and restore the Sound as required for any NEP grant funding. Both EPA and the Partnership were routinely informed of progress toward development of the Guide.

14. A commenter '...appreciate[d] the extra steps the Department is taking to receive feedback on the Alternatives Assessment.'

Response: Stakeholder involvement was very important at every step through development of the Guide. The IC2 appreciates the support along with all comments provided by stakeholders during the creation and review process.

15. Two comments were received concerning the contract with Clean Production Action, an environmental group, to provide technical support during the development process. Specific concern was raised that 'CPA also wants to promote its Green Screen© tool and its preferred approaches to the design and development of safer chemicals and products.'

Response: Ecology followed its contracting procedures to contract with Dr. Lauren Heine as a technical advisor during development of the Guide. Dr. Heine is a nationally recognized expert on alternatives assessments. She served as a member of the Green Ribbon Science Panel for the State of California and has functioned as a technical advisor to EPA's Design for the Environment Program. In addition, because of her involvement of the GreenScreen™, Dr. Heine recused herself from involvement in the Hazard Module. Other members of the Guidance Team wrote the Hazard Module and it was their decision to use the GreenScreen, not Dr. Heine or any other member of Clean Production Action. Lastly, Dr. Heine and representatives from EPA's Design for the Environment (DfE) program functioned solely as advisors and made no decisions during the development process. IC2 members are solely responsible for all decisions made in creation of the Guide. Therefore, there was no impropriety in Dr. Heine's function as a technical support to the Guidance Team.

16. Two related comments were received. The first stated that 'Global Automakers supports the collaborative approach that the eight participating states have adopted. A patchwork of AA programs will lead to confusion and regulatory instability ...' Both commenters recommend '...to work towards the development of one set of guidance for all states and in further developing this guidance, maximize the compatibility with existing mandatory AA processes including

those of other states as well as any federal or international schemes ...’ The second commenter expressed some concern about California developing its own guidance even though they were actively involved in the Guide.

Response: Accepted. The IC2 appreciates the support along with all comments provided by stakeholders during the creation and review process and will continue to coordinate as much as possible among IC2 member States. The IC2 is aware of the developments in California and, as the Department of Toxic Substance Control (DTSC) representatives have been involved in the development process, we are working to provide as much coordination possible between this document and future efforts in California.

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- 17. A comment expressed concern that ‘First, while this document is currently labeled as “guidance,” we are concerned Ecology will use its guidance to circumvent a formal rule-making process and require manufacturers to conduct alternatives assessments. This concern comes from Ecology’s continued support of attempts to expand the law to require manufacturers to conduct alternatives assessments. During the past legislative session, Ecology supported legislation to expand Washington’s Children’s Safe Products Act (CSPA). This legislation included, among other things, the requirement for manufacturers of children’s products to conduct alternatives assessments for certain chemicals. In 2011, similar legislation requiring alternatives assessments was brought to the Legislature as Ecology’s own request legislation. Ecology’s continued support of the CSPA legislation demonstrates Ecology’s main objective is to expand the current law to compel industry to conduct alternatives assessments. If Ecology’s intention is to require alternatives assessments, Ecology should not be developing guidance on this issue. Rather, Ecology should only go forward with a formal rule-making process under the Administrative Procedure Act (APA). A formal rule making would require Ecology to engage a wider group of stakeholders and would prevent Ecology from developing “guidance” that is later used as a de facto rule without having gone through the formal rule-making procedures required by the APA.’**

Response: Ecology and the Washington State Legislature have a long history of preferring that safer alternatives be identified before specific chemicals are banned (e.g. RCW 70.76-ban on PBDEs). Ecology has long supported policies that result in more informed choices - along with the development of new tools that facilitate these more informed choices. Ecology believes that alternatives assessment is a tool that will facilitate this goal.

If any legislation is passed in Washington that requires an alternatives assessments, the State's Administrative Procedures Act would likely require new rules be promulgated to implement it. As such, Ecology would follow the APA requirements. Ecology has stated repeatedly the reason for creating the Guide and has never indicated any intent of using it in lieu of a formal rule development process.

- 18. The comment was received 'Next, AWB is concerned with how the IC2 draft-Guidance document will be used and implemented, which is likely to result in state-by-state interpretation and cherry-picking. In Washington, industry stakeholders recently met with Department of Ecology (Ecology) staff to discuss the IC2 process and intended use of the draft-Guidance. During our meeting Ecology staff indicated they were likely to only use portions of the draft-Guidance document, noting the document as drafted was burdensome. Given that individual states will be gleaned their own alternative assessment process from the draft-Guidance, it is even more advantageous that industry experts should have been included in the proceeding process and development of the draft-Guidance. Industry has long preferred a regulatory approach that provides consistency. Any process that promotes state-by-state interpretation or implementation is problematic.'**

Response: The goal of the IC2 is to reduce duplication of effort among the states working on chemical management programs. The IC2 supports a collaborative approach among the states and industry working to advance alternatives assessment implementation. Industry experts were provided the opportunity to provide input throughout the Guide development process. This included soliciting input during the scoping process, conducting a series of three workshops and two webinars, releasing documents as they became finalized for review and comment and a final 60-day comment process. For this reason, we believe the level of stakeholder involvement was appropriate.

Concerning the issue of states 'cherry-picking' specific information from the Guide, the Guide was developed to provide sufficient flexibility to allow individual states to adapt their state-specific guidance to meet criteria unique to the state. For example, one state might have legislation that requires a life cycle approach to be used while others may opt for a simpler approach. The same flexibility that works for industry in terms of adapting an alternatives assessment approach to meet specific unique needs is also applicable to the states.

- 19. A comment stated that ‘...the hazard-based approach for reviewing chemicals in the draft-Guidance document differs from the TSCA work plan announced by the EPA which is relying on a risk-based approach. The apparent differences between IC2’s and the EPA’s approach is concerning ...’**

Response: There are multiple efforts currently being conducted with EPA. This includes both risk assessments and alternatives assessments. As the process used in the Guide is based upon the EPA Design for the Environment’s process, there is good agreement between EPA’s efforts and the IC2. In addition, EPA representatives served on the Guidance Team to provide coordination support when possible.

- 20. A comment was received that ‘...any changes or modifications to the underlying document should also go through a robust stakeholder and public comment process.’**

Response: The IC2 appreciates the commenter’s concerns and will consider the need for additional stakeholder involvement in future changes to the Guide.

- 21. A commenter recommended that ‘...the main audience for this document be regulators addressing specific public health issues, and to a lesser extent large businesses.’**

Response: The objective to create a Guide for a broad range of users is important. However, the document has been simplified and made clearer, so all users, including regulatory agencies, will find it useful.

- 22. A comment stated that the Guide ‘... does not address where the burden of an alternatives analysis and risk reduction (AA) responsibility falls nor does it reflect an understanding of these complex and sophisticated global supply chains. ... automakers have limited control over compliance with AA obligations. ... [and] ... the AA approach must respect and protect confidential business information and trade secret at all stages of the assessment ...’**

Response: The commenter’s concerns are outside the scope of the Guide. The Guide does not impose any additional obligations on manufacturers at any point in the supply chain. IC2 does assert that manufacturers have considerable authority to control the chemical content of components used in their products by establishing product requirements and non-disclosure agreements with suppliers to prevent the use of chemicals of concern. This is already taking

place in the marketplace and manufacturers of complex products such as computers, memory devices and major US retailers have established systems to eliminate chemicals of concern from their products by requiring parts of an alternatives assessment such as a Hazard Assessment to provide some level of security that toxic chemicals have been eliminated from the supply chain. In addition, the ultimate responsibility for an AA resides with product manufacturers; however, these responsibilities can be required throughout the supply chain as is currently happening in several industries.

Users of the Guide may choose to share information or not, as appropriate for their business. Since use of the Guide is voluntary there should be no CBI concerns. EPA's DfE program provides a good example of how to conduct an alternatives assessment while maintaining CBI. The end result of the process and particularly the hazard information is made public which is in agreement with international legislation such as the European Union's REACH requirements.

In addition, companies that conduct chemical hazard assessments can and have established non-disclosure agreements and conducted hazard assessments of chemicals and products.

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- 23. A comment was received stating that 'While it is unclear exactly how the IC2 AA Guidance will be used, TIA has concerns that as drafted it is inadequate to assist companies that are not already familiar with these types of assessments, and lacks the flexibility to address the practical, and frequently complex, situations our industry faces when conducting these types of assessments.'**

Response: Although the alternatives assessment process is not simple, this Guide provides a basic framework. If, in the future, alternatives assessments become a requirement, it is likely that individual states/companies would provide additional support in implementation of any AA requirements.

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- 24. Several comments were received that the title of the document should be changed and several recommendations were provided on potential names.**

Response: Accepted. The document's title has been changed to the Interstate Chemicals Clearinghouse Alternatives Assessment Guide.

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- 25. Several comments were received that the document was verbose, is in need of editing and needs to be simplified.**

Response: Accepted. The document has been simplified and submitted for editorial review to improve its quality and the ability of interested parties to understand the alternatives assessment process.

26. Several comments were received concerning the structure of the Guide, use of the term 'Scoping' and specific recommendations were provided on a new structure.

Response: Accepted. The Guide has been reorganized to approximate the recommendation where possible. Not all recommendations were accepted. For example, the 'Identify Chemicals of Concern' is outside the scope of this document. Language was added however to make this process clearer.

27. A comment was received on the question format used in the Guide. '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.'

Response: Accepted. The question-based format has been reviewed and, where appropriate, eliminated in certain modules as recommended.

28. One commenter noted 'The choice of this numbering scheme is not clear. There is no section 1.0.'

Response: Accepted. Renumbering of the document was included in the extensive edits.

29. A comment was received to '...include three additional topics, Consumer Acceptance; Manufacturability; and Regulatory.' Four comments were received that indicated the Guide must '...ensure consumer acceptance.'

Response: Consumers expect that products on the shelf are safe and assume that the government is taking actions to reach that goal. In a survey conducted in 2007 for the Department of Ecology, Washington residents:

- ‘... express strong support for government action to regulate toxic materials ... Nearly three-quarters (73%) reported that government bans on specific toxic chemicals are very or extremely important. Support for all other types of government actions was even higher....
- 75% of the respondents indicated that it was extremely or very important that Washington State government requires thorough testing for the toxicity of all ingredients used in products that are sold in Washington State.
- Eighty-five percent (85%) of respondents said that it was very or extremely important that the government requires manufacturers to label all of their products with a complete list of ingredients.

Once the products have been improved, consumer acceptance can be included in the stakeholder module. However, consumer acceptance alone should not justify the continued use of toxic chemicals and any stakeholder review must include a detailed discussion the relative toxicity of the alternatives and why others were removed from consideration because of toxicity concerns. Manufacturability is a component of performance and is already included in the Guide. A discussion on regulatory issues has been added to Identification of Alternatives portion of the Guide.

30. Two comments were received suggesting the addition of a new section titled ‘Approaches to Alternatives Assessment: Examples.’

Response: Accepted. This information has been added to the Guide.

31. Two comments requested that a new section, titled ‘Identify Chemicals of Concern,’ be added to the Guide.

Response: Although chemicals of concern are part of the alternatives assessment process, the identification of chemicals of concern is part of the AA process. Once the chemical has been identified, it is part of any AA; however, there are numerous ways in which a chemical can be selected and these processes are outside the scope of the guide. Language will be inserted into Background and Purpose section of the guide to address these issues.

32. A comment requested adding a section titled ‘Resources for Existing Alternatives Assessment.’

Response: Accepted. Information was added to the Hazard Assessment Module to direct potential assessors to hazard assessments that have already been completed. In addition, a new section was added identifying completed alternatives assessments.

33. A comment was received to ‘Add more reference materials, if the document is to become a reference document. A reference document should have links to tools, cases, and examples where the guide or similar documents have been applied.’

Response: Accepted. More reference materials have been added to the Guide.

34. A comment was received that ‘Since this document is being prepared for a variety of entities including small businesses, we recommend some discussion of available resources and links. Many states provide technical resources directly or through universities or other mechanisms to assist businesses including pollution prevention services. We note that in Section 5d stakeholders are discussed, although this appears to be for a different purpose. We recommend that somewhere early in the document the person considering an alternative assessment identify available resources, internal and external to whatever entity is involved.’

Response: Accepted. Resources to address these issues have been added to the appropriate modules.

35. A comment suggested that under ‘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.’

Response: The Guide is not intended to show how an alternatives assessment is completed but provides an assortment of different options. It is expected that individual users will take the Guide and select how they wish an AA to be done. Inclusion of the recommended information would increase the complexity of the Guide while decreasing ability to implement. As more people develop experience with using the Guide, we may find that we have sufficient information to develop specific recommendations for certain types of issues, for example how it is best to conduct an alternatives assessment for a personal care product versus what is needed for an electronic product.

36. **The comment was received that ‘The Draft AA Guidance does not identify criteria for judging what an acceptable alternative is. While this is understandably difficult and perhaps cannot be done at this stage where tools and ideas are merely being assembled, it is a key preliminary step to ensure fair and consistent comparisons across similarly situated products and industries. The Draft AA Guidance should acknowledge that the development of standards, criteria, and weighting will be essential to any governments wishing to impose an AA as a regulatory requirement.’**

Response: Criteria are included in many of the modules that address this concern. For example, the Hazard Module places chemicals into one of four bins regardless of which level you are using. This clearly translates into weighting. In some of the other modules, the assessor is expected to identify and justify the weighting used that separates a preferable alternative from other, less favorable. The document will, however, be reviewed and edited where possible to make this issue clearer.

37. **Numerous comments were received concerning confidential business information (CBI) and the need for the Guide to protect CBI, trade secrets and innovation.**

Response: IC2 appreciates the concern about CBI, however, it is a legal issue that is beyond the scope of this document. Some information, however, cannot be kept confidential, specifically the toxicity of the chemical, product or process and the impact it has upon human health and the environment. This is in agreement with national and international alternatives assessment efforts. EPA's Design for the Environment Program, for example, allows a CAS number to be considered CBI but posts all of the hazard information associated with the chemicals reviewed. This information must be provided in an AA and, given the importance of hazard in reducing risk within the AA, CBI alternatives can either be eliminated or moved through the process depending upon their hazard assessment.

38. **The following statement was made in one of the comment letters received ‘On behalf of the American Forest & Paper Association (AF&PA), we respectfully submit the following comments to the Interstate Chemical Clearinghouse regarding the proposed Guidance for Alternative Assessment and Risk Reduction draft regulations issued in March 2013.’**

Response: Although there is no comment included in the above, the term 'draft regulations' in this opening sentence needs clarification. The Guide is not a regulation nor is it associated with any regulation or rule. It was not created for a regulatory purpose but rather to increase uniformity among the states and to provide guidance to those interested in conducting an alternatives assessment on a voluntary basis. Only one IC2 member state serving on the

Guidance Team (California) has regulatory authority to require an alternatives assessment. The other seven states have no authority and are creating the document to be used among states and on a voluntary basis by interested industries.

39. The 'BizNGO commends the IC2 TAAG Team for pulling together a comprehensive resource on Alternatives Assessment (AA). We agree with TAAG Team's approach that Alternatives Assessment is a solutions-oriented approach to addressing chemicals of concern to human health or the environment. The strengths of the current IC2 Guidance document are the assessment modules and the comprehensiveness of material pulled together. In the spirit of creating a document that is usable to the broad community of practitioners intended as users of the document, here are our comments.'

Response: The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

40. The comment was received that 'Alternatives assessment is a critical tool to support the informed substitution of chemicals and materials of concern. It is a process to ensure a thoughtful transition to safer and more sustainable chemicals. I applaud the TAAG for its efforts to develop resources that can be used by a range of stakeholders to support informed decision-making. Given the increasing focus of governments and the marketplace on reducing chemicals of concern in products, the guidance can play an important and timely role in facilitating safer chemistry.'

Response: The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

41. One commenter thanked IC2 '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.'

Response: The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

42. **‘The Technical Affairs Committee of the Association of Global Automakers, Inc.1 (Global Automakers) appreciates the opportunity to provide comments to the Interstate Chemicals Clearinghouse (IC2) on the draft version of the “Guidance for Alternative Assessment and Risk Reduction” (Draft Guidance) released on March 5, 2013.’**

Response: The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

43. **‘On behalf of the National Wildlife Federation, I am submitting comments on the draft IC2 Guidance for Alternatives Assessment and Risk Reduction. We appreciate the efforts that have gone into the guidance, and the opportunity to comment. My comments are focused on the relationships between the modules involved in the alternatives assessment process.’**

Response: The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

44. **Several organizations thanked IC2 for ‘ the opportunity to comment on the draft Alternatives Assessment and Risk Reduction Guidance. We would like to note that it is unprecedented for the Interstate Chemicals Clearinghouse to conduct a formal public comment period for documents it produces. ‘**

Response: Although there is no regulatory requirement to conduct a 60-day public comment process on a guidance document, stakeholder input was important to the development process as demonstrated by all of the work done during development of the document including publishing all modules for review once completed, three industry workshops, two open webinars and the final comment process. The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

45. **One commenter stated that ‘We appreciate both the Washington Department of Ecology and the broader network of states in the Interstate Chemicals Clearinghouse prioritizing alternatives assessment (AA) as an integral tool for the identification of safer chemicals and processes.**

Response: The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

46. One comment stated ‘We sincerely hope that the completed guide will help a wide range of users engage in the Alternatives Assessment process.’

Response: The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

47. ‘We are very appreciative of the leadership and effort of the State of Washington and the Interstate Chemicals Clearinghouse (IC2) in compiling this draft guidance on how best to prepare an Alternatives Analysis (AA). We support the collaborative approach among the states, and the creation of a useful, consistent, science-based set of tools and approaches for performing AAs. In particular, we support the goals of the Draft AA Guidance: • To avoid duplication and enhance efficiency and effectiveness of agency initiatives on chemicals through collaboration and coordination; • To build governmental capacity to identify and promote safer chemicals and products; • And, to ensure agencies, businesses, and the public have ready access to high quality and authoritative chemicals data, information, and assessment methods.’

Response: The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

48. One comment stated: ‘To recap, we are very supportive of the work the State of Washington is doing and we support the IC2 in developing a collaborative process to help identify and assemble the best thinking on AA approaches. This is an excellent first step and a worthy effort. However, more work needs to be done before any government can adopt this as a guidance tool. We look forward to future opportunities to assist in this regard.’

Response: Accepted. The document has undergone extensive editing based upon input received and the IC2 appreciates all of the work done by stakeholders during the creation and review process.

49. One commenter offered ‘the following recommendations on how alternatives assessment should be conducted based on industry’s vast experience in designing, manufacturing and marketing tens of thousands of safe and successful products to billions of consumers around the world. Our organizations recognize the

importance of a pragmatic and science-based approach to alternatives assessment and offer the product development and improvement paradigm as the basis for an appropriate framework. As explained below, companies rely on a variety of disciplines and knowledge to successfully evaluate product development alternatives; which does not lend itself to the traditional command-and-control approach of typical regulatory policy.'

Response: Input from industry was important to the development of the Guide. We hope that this new tool will be one that industry and governments can use to avoid the need for traditional command-and-control approaches. It is worth noting that toxic chemicals continue to be used in manufacturing and in consumer products and that many adult and childhood diseases are alarmingly on the increase. Although it is often difficult to make a connection between diseases and specific chemicals, increasing consumer concern about toxic chemicals that continue to be used are driving the development of new techniques like alternatives assessment to identify safer alternatives to toxic chemicals and to reduce their use. Industry can take advantage of these new tools and support the development of alternatives assessments as markets become increasingly sustainable. The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

50. One commenter stated: 'We especially want to thank Alex Stone and the TAAG Team and technical advisors for all of their hard work on this document. This guidance is a very important endeavor in the pursuit of Safer Chemicals.'

Response: The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

51. 'We believe that the IC2 Draft Guidance reflects a good start at developing a science-based, comprehensive and flexible alternative assessment (AA) approach that if refined appropriately will meet the IC2's goals to avoid duplication, enhance efficiency and effectiveness of agency chemical initiatives, promote safer chemicals and products, and provide access to high quality chemicals information.'

Response: The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

52. Three comments were received that primarily expressed concern that the Guide '... overlooks existing regulatory compliance obligations (international, federal and state...'

Response: The Guide has been updated to include a review of regulatory requirements. If a chemical of concern must be used to meet regulatory requirements, language has been added to indicate an alternatives assessment may not be needed. If, however, using a chemical of concern is only one way of meeting a regulatory requirement, an alternatives assessment is still recommended so all methods can be reviewed to determine which alternative has the lowest impact upon human health and the environment while still meeting regulatory requirements. For example, if chemicals are added to meet flammability requirements, an alternatives assessment is still appropriate to determine if flammability requirements can be met without chemical addition or, if chemical addition is necessary, which of the added chemicals has the lowest impact upon human health and the environment.

53. Four comments were received that indicated the Guide must ‘...ensure consumer acceptance.’

Response: Consumers expect that products on the shelf are 'safe' and assumes that the government is taking actions to reach that goal. In addition, consumers are often unaware of the chemical content of products under review as manufacturers rarely identify the chemical content of products and the impact those chemicals may have upon human health and the environment. Consumers also often lack the technical expertise to understand these impacts and expect government to evaluate products for them to make sure they are 'safe.' Once the products have been improved, consumer acceptance can be included in the stakeholder module. However, consumer acceptance is not adequate for the continued use of toxic chemicals. Any stakeholder review should include a detailed discussion the relative toxicity of the alternatives and why others were removed from consideration because of toxicity concerns.

54. Two comments were received that alternatives assessment must ‘... allow for gradual and measured implementation.’

Response: The issue of ‘gradual and measured’ implementation of an alternatives assessment is an issue left for the individual users to decide how best to implement the Guide.

55. The comment stated that ‘Safety, leading to protection of public health and the environment, is the foundation of our industries, our member companies, and the products they produce. Alternatives analysis is a core element to the development of safe consumer products. The fundamentals of the process are routinely executed as part of industry’s ongoing research and development and product improvement. The key to innovation, and meeting consumer needs and preferences, is the ability

of manufacturers to draw on a variety of existing decision-making tools and approaches for developing products. As such, concepts that leverage existing practices in the product development paradigm should form the basis of an effective regulatory framework for alternatives analysis.'

Response: States as well as consumers are concerned that existing practices are not always adequate to address the issues faced by the continued use of toxic chemicals in products or processes. This point of view is in agreement with the National Academy of Sciences which indicated in a recent publication on sustainability that '4.6. Finding: Risk analysis as commonly applied to environmental issues often does not adequately account for the full range of human health and ecosystem risks, including cumulative risks, intergenerational considerations, and the distribution of risks among population groups. In addition, better methods are needed to support consideration of health and environmental effects for the green chemistry goal of safer products and more sustainable chemical usage.'

(http://www.nap.edu/catalog.php?record_id=13152) The alternatives assessment process is one of those new tools under development.

56. The comment stated that 'The IC2 Guidance document has many strengths, including the comprehensiveness of the material in the document, its parsing the alternatives assessment process over a series of modules, and the flexibility by which it can be used by a wide range of stakeholders in a variety of regulatory and non-regulatory situations.'

Response: The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

57. Two comments were received that expressed concerns about 'any mandatory assessment proposal and assert[s] that any "framework" for AAs needs to be flexible for different applications as well as disparate products/product categories...'

Response: The Guide does not create any mandatory requirements. It does address provide a wide range of flexibility for users. It does not recommend a single method for conducting an alternatives assessment but provides an assortment of different modules and decision methodologies that can be used to assess alternatives.

58. A comment raised a concern that the Guide '... emphasizes the assessment process rather than the outcome....'

Response: IC2 believes that the proposed process is inextricably linked to achieving the desired outcome of informed substitution. If applied as envisioned, the alternatives assessment process will result in selected alternatives will have a reduced impact upon human health and the environment.

59. A comment suggested that the Guide ‘... accept all appropriate and adequate alternatives’

Response: The goal of the AA process is to identify all appropriate and adequate alternatives to chemicals of concern. Such alternatives include chemicals, products or processes that are safer than the chemical of concern while still performing. Appropriate and adequate alternatives will support the objective of an alternatives assessment, i.e. the replacement of toxic chemicals with safer alternatives to protect human health and the environment.

60. A comment stated that ‘... AAs must: Be science-based, and have the flexibility to deal with complex and varying business models & products;’

Response: IC2 agrees and believes the proposed Guide meets both of these objectives.

61. ‘Global Automakers commented that ‘its members have consistently supported the development and use of safe chemicals and products available for use in the automotive industry. Through the application of green chemistry principles and sound scientific methods, Global Automakers believes that the design and development of new chemistries and technologies will continue to provide innovative solutions to current and emerging environmental challenges. We support the development of science based, balanced alternative assessment processes. Our goal is to ensure that our members have the opportunity to provide high quality, environmentally sound, safe products and services. With these goals in mind, we look for ways to provide tools to our members to facilitate continuous improvement and to ensure that wherever possible we assist them to not only meet but exceed safety and environmental standards.’

Response: The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

62. A comment stated that ‘We strongly support the flexibility that has been built into the process, most notably the ability of the user to select the modules and levels appropriate for the AA that needs to be performed.’

Response: The IC2 also appreciates the recognition that the alternatives assessment process contains a high degree of flexibility.

63. Global Automakers ‘believes that the IC2 Draft Guidance reflects a good start at developing a science-based, comprehensive AA approach that if refined appropriately will meet the goals that IC2 has set for this effort. Specifically, IC2 identifies the following goals (Draft Guidance, p. 16): • To avoid duplication and enhance efficiency and effectiveness of agency initiatives on chemicals through collaboration and coordination. • To build governmental capacity to identify and promote safer chemicals and products. • To ensure that agencies, businesses, and the public have ready access to high quality and authoritative chemicals data, information, and assessment methods.’

Response: The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

64. Two comments were recommended that the ‘...IC2 try to work with all states, federal agencies and international organizations to maximize consistency.’

Response: IC2 member states will continue to coordinate as much as possible.

65. A comment stated that ‘The objective of an alternatives assessment is to replace chemicals of concern in products or processes with inherently safer alternatives, or modify the production processes themselves or the exposure potential of the product, thereby protecting and enhancing human health and the environment. By including this additional phrase, IC2 will recognize a broader set of solutions than just chemical substitution.’

Response: The Guide addresses and supports many of the comments received with the major exception of the reference to ‘modify the ... exposure potential of the product.’ The objective of an alternatives assessment is to reduce risk by selecting alternatives that are significantly less hazardous than the chemical of concern. Assumptions about exposure potential have not always proven to be protective of human health and the environment and, as indicated by the National Academy of Sciences, which states that new tools are needed to address the issues of chemicals in

products. The alternatives assessment process is one of these new tools and it places emphasis on reducing hazard as the most positive way to reduce risk and to protect human health and the environment.

66. **One comment stated that ‘...The four scoping modules and seven assessment modules presented in the Draft Guidance are appropriate and will help the user to define the scope of the AA. We encourage IC2 to consider other modules as they are suggested by those who have had extensive experience with both developing and implementing AA processes.’**

Response: The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

67. **One commenter supported ‘the approach that if multiple alternatives are identified as favorable, selection of the alternative to replace the chemical of concern (COC) to employ is left to the user. Furthermore, it is important to note that even if a preferred alternative is identified in the AA process, it does not mean that the alternative will ultimately be the right choice for the product in which it will be used. Often, product design, testing, and validation is necessary to confirm that an alternative will be functionally-equivalent to the COC it is replacing.’**

Response: The alternatives assessment Performance Module includes consideration of product design, testing and validation.

68. **Global Automakers stated that they were ‘pleased to see the states working in a collaborative process towards standardized guidance for AAs. We believe standardization is important for consistency and certainty state-by-state, as well as for reducing duplication and burden. Our primary concern remains outside the scope of the text of the Draft Guidance, but in that the California DTSC’s SCP Program may use AA guidance separate from this document. The SCP Program must allow the use of this guidance for the benefits of standardization to be achieved, and we believe that this guidance would be appropriate for purposes of the SCP Program. Therefore, our primary recommendation is that the guidance be refined to ensure the California DTSC’s allowance of this process under its SCP Program.’**

Response: The use of this document by IC2 member states is the choice of the individual states and it is not appropriate to indicate how the Guide can be used. Any comments about use of the Guide should be directed to the specific state agencies involved.

69. One comment stated that the ‘...the IC2 Draft Guidance reflects a good start at developing a science-based, comprehensive AA approach if refined, and we strongly support the flexibility that has been built into the process. The Draft Guidance will benefit by addressing common industry issues, such as product cycles, de minimis levels, critical uses of chemicals, lack of alternatives, and trade secret information, to name a few, as well as more involvement from industry stakeholders.’

Response: These issues have been addressed in other comments within this document. The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

70. AF&PA ‘supports the efforts of the Technical Alternative Assessment Guidance Team in putting together the Guidance for Alternatives Assessment and Risk Reduction and working with industry, EPA and others to share best practices. AF&PA believes this guidance document could help businesses avoid the costly and time-consuming process of analyzing alternatives according to a wide variety of different state protocols.’

Response: The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

71. One comment stated that ‘... the majority of an alternatives assessment and its complexity relates to chemical substitutions, where information must be obtained and evaluated about possible safer alternatives, rather than committing effort, time and money that could be wasted if a poor decision is made and the wrong alternative chosen. However, some knowledge already exists about safer chemicals and processes and is readily available, which would preclude the need for an extensive alternatives assessment.’

Response: Accepted. The Guide has been updated to indicate sources of information that may be available and that could preclude the need for a detailed alternatives assessment.

72. Two comments were received recommending changes to the name of the Appendices and the alternatives assessment modules.

Response: The structure of the Guide has been altered based upon recommendations from this and other stakeholders.

73. A comment was received indicating concerns that the Guide ‘... could easily become unworkable for complex durable goods such as automobiles ...’ and offering to assist the Guidance Team to address these and other issues.

Response: Although the concern is recognized, well documented cases exist where other companies have shown the alternatives assessment process works even in complex and multi-component products. These manufacturers set clear objectives and product component requirements and worked closely with suppliers to make sure toxic chemicals were removed from components used in the final product. This process should be applicable to the automobile industry.

74. A comment expressed concern that ‘Variability in Assessment Approaches Provides Inconsistent Results ...’ and ‘... the responsible agency should ... have input with the state regulatory agency or responsible assessor concerning which modules are relevant and appropriate prior to the initiation of the AA.’

Response: The Guide is not a regulatory document. The goal is to assist states in providing greater uniformity when conducting alternatives assessments, and to help interested manufacturers on a voluntary basis. Most of the states working on the Guide do not have authority to require any alternatives assessment. The Guide provides some recommendations on what constitutes the minimum that level of information needed to have some confidence that the alternative is likely to be safer. IC2 recognizes that no alternatives assessment can guarantee complete certainty that an alternative does not have some undisclosed problem; however, there is a minimum data set that is needed to provide an acceptable level of confidence. This is the reasoning for establishing a minimum recommended data set for an alternatives assessment which cannot vary among alternatives assessments or the process fails. Individual states will make decisions on what parts of the Guide they will recommend or adopt.

75. The comment was made that ‘Some modules, notably the non-core modules as well as portions of the Cost and Availability Module, provide much less detail concerning

the assessment approach, while simultaneously requiring sophisticated cost-benefit analyses.'

Response: The Guide has been modified to address many of these concerns with an emphasis on providing tools to address specific issues within each module. In addition, the assessor has considerable influence regarding what level of assessment is done within the four recommended modules and which, if any, additional modules are included in any alternatives assessment. If the assessor believes some of the issues included in a module are not applicable, the assessor can conduct a simpler review by implementing one of the lower levels.

76. The comment was made that '...identification of alternatives should be limited to those that have a reasonable probability of being successful.'

Response: The Guide is intended to not only look at existing alternatives but to also encourage innovation and product development. Therefore the Identification of Alternatives Module, for example, casts a wide net for potential alternatives. These alternatives are subsequently evaluated through a series of modules that narrow down alternatives to those that are most viable. However, it is possible to conduct a screening analysis within the Identification of Alternatives Module that will select alternatives that are identified as most favorable after the screen. In line with the transparency requirements of an alternatives assessment, all alternatives that are removed need to be identified and their removal justified.

77. The comment was made that '... safety assessments and exposure evaluations must occur before an alternatives assessment for a particular chemical/product combination is pursued. This will help identify those chemical/product use pairs that result in exposures which may cause harm and for which an alternatives assessment will likely result in significant improvements to public health and/or the environment. The alternatives assessment should follow appropriate methodologies and be adaptable on a case-by-case basis for different product applications.'

Response: Safety assessments and exposure evaluations are built into the Guide Exposure Module. However, the recommendation that a 'safety assessment and exposure evaluation must occur before an alternatives assessment' is inconsistent with the objective of an alternatives assessment as defined. The AA process has been developed to identify safer alternatives to chemicals of concern and to prevent regrettable substitutions from occurring. This is particularly important as traditional safety assessments and exposure evaluations have not always proven to be protective of human health and the environment. This is in agreement with recommendations from the National Academy of Sciences that '4.6. Finding: Risk analysis as commonly applied to environmental issues often does not adequately account for the full range of human health and

ecosystem risks, including cumulative risks, intergenerational considerations, and the distribution of risks among population groups. In addition, better methods are needed to support consideration of health and environmental effects for the green chemistry goal of safer products and more sustainable chemical usage (p.60).’ (www.nap.edu/catalog.php?record_id=13152). It is for these reasons that an AA emphasizes a scientific, hazard based approach for the review of alternatives to chemicals of concern. The Guide is flexible and provides the ability to adjust the AA process for different chemicals, products or processes under evaluation.

78. The comment was made that ‘...The IC2 AA Guidance does not reflect the necessary flexibility to address the complexities of conducting an alternatives assessment in a practical manner. We do not think the IC2 AA Guidance is appropriate as a regulatory mandate. The guidance is not workable and we oppose any attempts, now or in the future, to attempt to develop a “checklist” compliance approach based on this guidance.’

Response: The IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process. Please note that the Guide was not developed as a regulatory framework or under any regulatory mandate . It was developed specifically to provide flexibility in the alternatives assessment process. It does provide some minimum expectations on what constitutes an adequate AA and individual users will decide how to use the Guide. As indicated in the Guide and at several presentations made, the Guide was created to provide greater consistency among state approaches and as a tool to work with companies on a voluntary basis.

79. The comment was made that ‘Decisions regarding which types of products meet consumer needs and expectations, and are commercially viable and sustainable from a business and safety perspective clearly do not lie within the government, but instead with the product development and product safety departments of product manufacturers.’

Response: Consumers expect that products on the shelf are safe and assume that the government is taking actions to reach that goal. The roles of government and industry are beyond the scope of this project. See Response to Issue no. 30.

80. The comment was made that ‘Alternatives assessment should be a flexible but rigorous process adapted from the product development and innovation process that considers all relevant design, performance, manufacturing, health and

environmental impacts, regulatory compliance and consumer acceptance factors in identifying and analyzing potential improvements to an existing product.'

Response: The Guide addresses all of the issues raised. In addition, the Guide includes a definition of the term 'alternatives assessment' and clearly lays out a detailed yet flexible process that allows manufacturers to evaluate the impact chemicals, products or processes have upon human health and the environment. The emphasis upon hazard and the identification of the chemicals with the lowest possible impact is the preferred pathway. If chemicals with the lowest possible hazard can be used while maintaining product performance, cost and availability, etc., the issue of exposure becomes much less important.

81. The comment was made that 'Alternatives assessment should reflect current industry practice in product design and the product development process.'

Response: The alternatives assessment process was developed specifically to reduce the continued reliance upon toxic chemicals. Existing product development and improvement processes sometimes use assumptions about exposure to justify the continued use of toxic chemicals. Many exposure assumptions have been proven to be inaccurate or incomplete. The reliance upon hazard and subsequent exposure potential allows for the replacement of chemicals of concern, except under very specific circumstances that are explained and justified. Chemicals chosen through an Alternatives Assessment have a lower impact upon human health and the environment.

82. Two comments were made that 'A sensible approach for conducting an alternatives assessment is flexible and modular (focusing on parameters relevant to the product being evaluated), provides comparable or improved product efficacy, values consumer acceptance, requires informed decision making, allows for gradual and measured implementation, and includes a feasibility check to make sure that the proposed alternative actually meets the goals set.'

Response: Many of the concerns raised in this comment are addressed in the Guide. The alternatives assessment process is science based, is 'flexible and modular', includes all relevant factors and ensures products have less of an impact upon human health and the environment. In addition, the Guide does not mandate any requirements, as most of the states involved in its creation do not have regulatory authority to require an alternatives assessment.

83. The comment was made that the Guide '... lacks critical flexibility.'

Response: The Guide was developed specifically to provide flexibility to evaluate a wide range of chemicals, products or processes. Assessors can decide what modules to use, what level within each module and what decision methodology to use and can optimize them for the particular chemical, product or process under review. The need for flexibility defined the approach. The Guide does include minimum recommendations on what constitutes a valid alternatives assessment but retains a high degree of flexibility above these minimum recommendations.

Title Page Comments

- 1. One comment was received concerning the disclaimer. Specifically ‘The beginning of the document contains disclaimer language (“... specific views do not necessarily reflect those of [participants] or agencies for whom they work. Participation does not necessarily imply endorsement...”). This makes clear that no one involved in the development of the IC2 AA Guidance owns or endorses the document or its usage. Given the implications for adoption by IC2 participating members and other states, we are stymied by the lack of recourse if the IC2 AA Guidance is adopted in whole or part by a state.’**

Response: The Guide was written and the results supported by the members of the Guidance Team. However, rather than seek approval from the management of all IC2 member states involved which was believed to be a long and complicated process, the decision was made to leave adoption of all or any portion of the Guide to the member states after completion. To support this aim, standard disclaimer language was placed at the beginning of the document.

Definitions Comments

1. **One comment advocated for flexibility within the alternatives assessment process as an ‘... AA has a multitude of additional applications or uses.’**

Response: The Guide is flexible and can be used by a wide range of users for a variety of chemicals, products or processes being evaluated. Any AA, however, must support the goal of replacing toxic chemicals with safer alternatives by selecting less hazardous options with the resultant impact of lowering risk. The current definition specifically defines these issues and is appropriate for the AA processes being described. No change will be made to the definition.

2. **Several comments were received concerning the definition of alternatives assessment. The comments expressed a belief that the definition was incomplete and suggested alternative definitions.**

Response: The IC2 supports the definition of alternatives assessment in the Guide. The Guide’s definition of alternatives assessment is sufficient, as it does not specify how the safer alternatives are selected. As an AA can include factors not mentioned including social impact, life cycle thinking, etc., the definition is left general to provide the flexibility needed to address the variety of chemicals, products or processes potentially subjected to an AA. The EPA Design for the Environment process, for example, does not include these issues and, for this reason, is too limited for use in the Guide. Many of the other issues are also covered in the Guide, including the extremely rare instances that a chemical of concern cannot be replaced. However, the objective of an AA is to eliminate the use of toxic chemicals and that should always remain an AA's priority.

3. **Several comments were concerned that the definition of ‘authoritative body’ does not include work conducted by potentially biased sources such as environmental groups and industry.**

Response: Although advocacy groups were not identified in the list of authoritative bodies in the definition, the wording has been changed as recommended to make the definition clearer. Other suggestions, however, were not adopted. For example, authoritative bodies provide a technical opinion based upon the knowledge and expertise of the participating scientists. These decisions are based upon the scientists' professional expertise and differing scientific opinions are resolved before a final decision is made. Stakeholder review and involvement in this purely scientific process is not appropriate as stakeholders are often biased and biases are not based upon scientific data.

4. **A comment raised concern that the definition of exposure pathway fails to recognize potentially natural sources of chemicals of concern.**

Response: Accepted. The definition was changed as recommended. Examples of naturally occurring sources include natural contamination found in groundwater such as higher than average levels of arsenic, dioxins from forest fires, etc. Naturally occurring sources do not include background levels as a result of human activities. For example, legacy concentrations of PCBs do not qualify as 'naturally occurring' as PCBs exist solely due to human efforts.

5. **A comment was received concerning the definition of 'inherently toxic'. The comment suggested that the term '... combines the concepts of both hazard and exposure' and '... both hazard and exposure need to be present before priority is placed on any chemical or product.'**

Response: This comment is related to the selection of chemicals of concern or products to be subjected to the alternatives assessment process. The selection of chemicals of concern is outside the scope of this document. The Guide concentrates on the process to use after a chemical of concern or product has been identified to be subjected to the alternatives assessment process. It is worthwhile, however, to note that the concept of risk is applied throughout the document. The AA attempts to select safer alternatives that pose the lowest risk to human health and the environment by first selecting chemicals with the lowest hazard and then reviewing exposure potential to identify alternatives that have the lowest hazard and exposure potential, thereby risk.

6. **A comment recommended that the definition of 'risk reduction' be modified to change the word 'low' in the definition to 'lower' as alternatives with the lowest hazard may not be favorable alternatives when other modules are considered.**

Response: The objective of an alternatives assessment is to identify alternatives with the lowest hazard and, from that pool, to identify the alternatives with the lowest exposure potential. The AA also allows incremental improvement when the most favorable alternatives has the lowest hazard but ends up not being favorable when other modules are considered. With this explanation in mind, the definition accurately represents the need for continual improvement by retaining the term 'low' in the definition.

7. **One comment was received that the term 'Process Flow Diagram' was used but not defined. The recommendation was made to add a definition for this term.**

Response: A definition for Process Flow Diagram has been added.

8. Several comments were received related to PBT (persistent, bioaccumulative and toxic) definitions. Recommendations were made to use more complex definitions defined in regulatory and other sources.

Response: The intent of the Guide is to provide a general definition of terms used within the document and not to include extremely detailed definition of terms. The Guide is intended for a wide range of users including those with limited technical knowledge and expertise. Adding more technical and occasionally regulatory defined definitions for some terms would make the document less useful to a wide range of users. Therefore the proposed definitions for these terms will be retained.

9. A comment was received concerning the definition of the term 'Exposure Pathway'. The major concern was that the definition states '...The use of a definition from an agency that deals primarily with hazardous waste facilities (i.e., ATSDR) is inappropriate for the purposes of this document. While the process may be very similar, the implication is unnecessarily derogatory towards products and their manufacturers.'

Response: There was no intent to imply any negative connotation to products or processes. The Guide is attempting to help manufacturers eliminate toxic chemicals from their products thereby making the products safer for consumers. As indicated in a previous comment, the Guide provides general definitions to enable it to be used by a wide range of potential users. The suggested language is only applicable for someone conducting a full exposure assessment as part of a risk assessment and would suggest a greater amount of detail than is used for the lower levels of the Exposure Assessment Module. The detail recommended is only applicable to the highest level in the module and therefore is not appropriate for a general, simple explanation of the term. No change will be made to the definition.

Background Comments

1. One comment compared the Guidance to current industry practice and found differences. “This (industry) coalition recognizes the importance of a pragmatic and science-based approach to alternatives assessment and offers the product development and improvement paradigm as the basis for an appropriate framework. Alternatives assessment (AA) is core to developing safe consumer products. The fundamentals of the process are routinely executed as part of industry's ongoing research and development and product improvement. The key to innovation, and better meeting consumer needs and preferences, is the ability of manufacturers to draw on a variety of existing evaluation and decision making tools and approaches for developing products. Safety—protecting public health and the environment—is a fundamental component of the product design process. The product improvement process is iterative, complex, and different on a product-by-product, company-by-company, and case-by-case basis. Additionally, two manufacturers performing an alternatives assessment on the same product will likely reach differing but equally valid conclusions owing to their innovative and technical skills. Concepts that leverage existing practices in the product development paradigm should form the basis of a practical and meaningful framework for alternatives assessment. A sensible approach for conducting an alternatives assessment is flexible, modular (focusing on relevant parameters), effective, ensures consumer acceptance, ensures informed decision-making, allows for gradual and measured implementation, and includes a feasibility check. While some of the underlying themes within the proposed AA guidance document are appropriate and appear to be consistent with the existing product development paradigm, there remain many challenges.”

Response: Many of the points raised in this comment are incorporated into the Guide as it currently stands. It contains sufficient flexibility to address many of the issues raised.. The alternatives assessment process emphasizes the need to find safer alternatives for toxic chemicals and the importance of lowering hazard with its resultant impact on risk.

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2. One comment stated that the scope of the Guidance was too broad and recommended focusing on the needs of public policy makers. “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. It effectively communicates a similarly complex and analogous topic to policymakers.”

Response: The recommendation was considered and, although it contains much value, IC2 decided to continue to try to provide the Guide to a broad range of users. The Guide has been substantially condensed and simplified which hopefully will make it more useful to the broad range of intended users.

- 3. One comment recommended developing a simplified companion document containing a streamlined, minimal, step-by-step implementation based on the practices within the document. “As written, this document would be overwhelming for most businesses to use effectively.”**

Response: A simplified companion document could be developed in the future. Although many of the issues raised are valid concerns, they are better addressed on a state-by-state basis rather than by the larger IC2 group. The recommendation will be made to the IC2 for future consideration.

- 4. One comment suggested editing and reorganization of the Background chapter.**

Response: The Guide has undergone substantial editing including a name change and condensing and reorganization of sections.

- 5. One comment recommended that supporting members of IC2 be mentioned.**

Response: Language was added identifying IC2 supporting members from industry and the environmental community.

- 6. One comment stated a need for increased confidential business information provisions in AAs.**

Response: Within supply chains, multiple mechanisms have been developed by business to protect confidential business information while still making CAS numbers and hazard information transparent. Some of these include non-disclosure agreements or the use of a third party reporting mechanisms. Transparency for toxicity information is required both nationally and internationally. For example, EPA when conducting alternatives assessments has kept the CAS number of certain chemicals confidential while publishing all toxicity information related to the chemical. The European Union REACH legislation also requires toxicity information to be transparent. When considering legal requirements for alternatives assessments, governments must decide at that point the level of confidential business information they will require or protect. This decision is best left to the appropriate governmental body and is outside the scope of this document.

7. **One comment thanked the Guidance Team for the opportunity to comment. “The Guidance clearly demonstrates the dedicated efforts of the IC2 Technical Alternatives Assessment Guidance Team over the past two years. The document is impressive and an excellent comprehensive resource for alternatives assessment (AA) practice. I agree with TAAG Team’s definition of alternatives assessment and its solutions-oriented approach that begins with a chemical of concern and a market or regulatory impetus to substitute that chemical with a safer alternative.”**

Response: IC2 appreciates all of the work done and comments provided by stakeholders during the creation and review process.

8. **One comment recommended ensuring the document does not lead to paralysis by analysis. “While the introduction makes it clear that the user can choose (beyond the four “minimum” modules) which to include in the analysis, as written the document could be construed to mean that an alternatives assessment is not thorough or comprehensive without including all of the modules. This is problematic. Few, if any, alternatives assessments include all of these components and, indeed, completing all of the analyses at the highest level could lead to high costs and paralysis by analysis, which is inconsistent with the goal of promoting the transition to safer chemicals. While our decisions to transition from chemicals of concern should be made using the best available information, experience has demonstrated that most firms will not have the resources to complete such data and analysis intensive assessments will can most agencies. The reference document adds many elements to alternatives assessment that have not been traditionally a formal part of the practice. While on its surface this is not a problem and may actually add to more thoughtful alternatives assessments, it is important not to let**

the perfect be the enemy of the good. The goal is to make the best substitution decisions using the best available information. While having good information to avoid unintended consequences is important, more detailed, quantitative information does not necessarily lead to better decisions. Expert evaluation and judgment may also play key role.”

Response: The Guide is intended to present all tools that might be used in an alternatives assessment, with multiple levels of complexity for each. Beyond the required modules, additional modules may be selected based on need and resources available. Language has been added to indicate that an AA consisting of the four modules recommended is an adequate AA.

9. Several comments recommended eliminating the Golden Rule, modifying it, or changing it altogether.

Response: The recommendations in this comment were discussed and the Golden Rule was retained because of its importance in identifying the objectives and concerns associated with an Alternatives Assessment. In addition, the language was not added to include exposure, which, although an important consideration as evidenced by its presence in the Exposure Module, exposure, alone, should not be used to justify the continued, used of toxic chemicals.

10. Several comments recommended eliminating the Principles, modifying them, or changing them altogether.

Response: This issue was discussed and it was decided to retain the principles. However, the wording has been altered to address one comment about emphasizing hazard. Otherwise, the Principles help in better defining the objectives of an alternatives assessment and are an important part of the overall Guide.

11. Two comments were received indicating that ‘...an alternatives assessment (AA) where there is no risk or low risk (i.e. a chemical is below a de minimis threshold) to human health or the environment from a chemical of concern in a product.’ And that exposure should play a larger role in the AA process.

Response: This issue has been discussed extensively in the Hazard Module and will be included in the responses in that section of the Guide.

How to Implement Comments

1. **A comment was provided to add more detail on how the modules in the Guide would be used ‘... to address specific types of public health or environmental issues faced by regulators. Not all issues require all modules.’**

Response: Although the suggestion is a good idea, how the Guide should be used on specific issues is a decision left to the individual states. In addition, there may be variety in how each issue would be addressed within specific states so it could prove difficult to reach agreement. Inclusion in the Guide might indicate requirements or recommendations best left to the state. Language has been added to the module to clarify that decisions such as these are best left to states.

2. **A comment was provided on the language addressing decision framework selection. It was recommended ‘...to choose critical points of influence (initial screen, final acceptance) and set constraints (hazard screening first, burden-shifting 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.’**

Response: Accepted. The Decision Module has been edited and this issue was addressed.

3. **A comment was provided supporting ‘...the IC2 approach of providing for a flexible AA guidance structure that is designed to meet the needs of the user while at the same time delivering solid, risk-based guidance. The guidance recognizes that different degrees of complexity must be matched up with the issue and decision that is needed and that “no AA is expected to encompass all the modules and frameworks”’.**

Response: The IC2 appreciates all comments provided by stakeholders during the creation and review process.

4. **A comment was made that ‘When a regulatory agency proposes a chemical or chemical/product combination for assessment, the process must be transparent and well documented as well [as an AA] and ... state and federal agencies need to apply as much rigor to their prioritization and selection process as they expect from the regulated community in conducting AA.’**

Response: The identification of what chemicals of concern will be subjected to the alternatives assessment process is outside the scope of the Guide. Language clarifying this issue has been added to the Guide.

5. A comment suggested that it might be appropriate to address the issue of Confidential Business Information (CBI) in this module.

Response: Although the IC2 appreciated the concern about CBI, it is a legal issue to be resolved outside the scope of this document. Some information, however, cannot be kept CBI, specifically the toxicity of the chemical, product or process upon human health and the environment. This is in agreement with national and international alternatives assessment efforts. EPA's Design for the Environment Program, for example, allows a CAS number to be kept CBI but posts all of the hazard information associated with the chemicals reviewed. This information should be provided in an AA and, given the importance of hazard in reducing risk within the AA, CBI alternatives can be eliminated or moved through the process depending upon their hazard assessment.

6. Several comments were received about the structure and figures within the modules. The figures did not provide sufficient information to instruct how the scoping and analysis modules related to each other and how some of the modules fit into the alternatives assessment process. In addition, one reviewer indicated that the introductory paragraphs were confusing and recommended the module be simplified and edited to increase clarity.

Response: The Guide has been extensively edited, the order of the modules has been changed and these issues were addressed in the edits.

7. A comment was received suggesting that the 'Summary or Introduction would be ideal following the Golden Rule or following the principles.'

Response: Although the idea has merit, the Guide was constructed with the intent of keeping it as short and pithy as possible. Repeating information that is included in other sections is contrary to this objective.

8. **A comment was received that suggested eliminating the How To Implement module and replacing it with a more simple graphical representation using the IC2 wiki as an example.**

Response: Although the decision was made to keep this module, the order of the modules has been extensively edited and the structure of the Guide substantially changed. A graphical representation was added to help clarify the alternatives assessment process.

9. **A comment was received related to the decision framework selection. The commenter indicated that a Hybrid approach is most commonly used and that much of the discussion on decision frameworks was unnecessary. The main point in the comment was that ‘Clarification of the audience would help determine the appropriate amount and detail of content.’**

Response: Although the hybrid approach might be most useful to the commenter, the Guide was written to provide guidance to a wide range of potential users including companies with limited knowledge, experience and resources. For small and medium size companies, the Sequential Framework might be the more applicable approach. The module, however, has been extensively edited and perhaps the new structure addresses some of the concerns raised. However, some of the issues of which framework is more appropriate is best left to the individual states/users who will decide what portion or portions of the Guide are most applicable.

Initial Evaluation Comments

1. **One comment stated: “Manufacturers should regularly evaluate the life cycle maturity of their products that may dictate the extent to which a product is re-engineered or redesigned. Principles of Green Chemistry and Green Engineering are good sources when evaluating product design and development.”**

Response: Agreed. The Guide supports the Green Chemistry principles and further emphasis is not warranted.

2. **One comment stated: “The example given (the sportswear manufacturer) is not particularly useful at the beginning of the discussion. ITI suggests including point-specific examples within each step of the document, or applying a “case study” where the example is referenced throughout the document. However, a single example is not likely to be applicable to the very broad scope of products that the AA looks to cover. For example, a formulated product such as a cleaner is much different from a complex article such as a toy or shoe. While in the initial parts of the assessment, the differences are not as likely to matter (e.g., “intentionally added” is the same no matter what you are working with), in later parts, these differences in product types are fundamental to how an assessment is performed.”**

Response: Although the stated limitations of a single example are valid; no single example can be relevant for every sector or circumstance. The intent of the example, however, was to show the type of evaluations that should be considered at this point. The questions should be adapted to fit a particular chemical, product or process under evaluation to determine if a chemical of concern can be eliminated without adversely affecting the quality of the product involved. This evaluation was intended as an important cost savings for manufacturers as, if the chemical can be eliminated, no alternatives assessment is necessary. It is the responsibility of individual companies doing alternative assessments for their own products to conduct the evaluations. Associations or manufacturers could develop examples relevant for their members.

3. **One comment stated: “It is not clear what 1.b means. Clearly, if a product is ready for its next iteration, the product will be re-designed. However, it’s not clear what the difference is between parts i and ii. The Alternative Assessment is part of the design and development of a new model of a product, and the AA process and the green chemistry principles are not mutually exclusive. It is not clear what purpose separating these out serves.”**

Response: If a company is phasing out a product, it's not necessary to do an alternatives assessment comparing the chemical-of-concern in the current product with alternatives. If the new product doesn't contain a chemical of concern, it won't be necessary to do an alternatives assessment for that product either. Where appropriate, companies might want to incorporate such comparative assessments into new product design.

4. **One comment stated: “The issue of concentration in the product must be expanded upon. If the chemical is only in trace amounts, it is possible that no assessment is necessary, since there is practically no chance of exposure. This does not, however, mean that there is not room for improvement in the design or manufacturing process for trace substances in a product.”**

Response: Whether a trace amount of a particular chemical creates a risk to human health depends on the chemical. Exposure considerations may need to consider aggregate exposure to the chemical in products, not just the single exposure.

5. **A comment was received that in essence indicated a concern with the term ‘function’. Specifically it was stated that ‘While another product may have the same function, it may not accomplish the function with the same speed, reliability, or efficiency as an original product.’**

Response: Performance is an important and integral part of the function of a product. Extremely generic definitions of "function" aren't useful. Bikes and cars both aid the generic function of mobility, but clearly don't have similar performance. However the issue of functionality can be addressed in the performance module if issues not listed in the module are identified, explained and justified to meet the need for transparency of decisions when conducting an alternatives assessment.

6. **Several comments were made concerning condensing and changing the position of the Performance Module in the overall structure of the Guide.**

Response: Accepted. The Guide has undergone substantial editing including recommending a screen of performance in the Identification of Alternatives Module to focus resources on those alternatives that function best, among other changes.

7. **One comment stated: “This module is based on the assumption that if a product contains a chemical of concern that chemical should be phased-out or eliminated without any consideration given to whether an exposure exists or the potential risk involved, and due to this shortcoming may encourage regrettable substitutions which can increase risk. This module provides a limited set of criteria to assist with the development of an evaluation process based on the presence of a chemical. Most, if not all, manufacturers already have processes in place which they regularly use to evaluate their products.”**

Response: The objective of an alternatives assessment is to eliminate the use of chemicals of concern and to replace them with safer alternatives. Assumptions about exposure used to justify the continued use of a chemical of concern are not supportive of this objective and therefore are not a part of the Guide. In addition risk is an important consideration in the alternatives assessment process as both hazard and exposure potential are optimized, leading to a lower aggregate risk.

8. **One comment stated: “The purpose of the Initial Evaluation module is to determine whether or not an AA is needed for a product or process containing a COC. If a product is ready to be phased out or if a COC can be eliminated from a product, an AA may not be needed. At this stage in the assessment it is also important to consider whether there is a need for the original chemical or product to remain available for certain uses such as replacement parts for durable goods.”**

Response: Whether or not an alternatives assessment is needed for replacement parts for a product that is being phased out will depend on the expected lifetime of the original product that needs replacement parts. The answer may be different for products with long life spans (e.g., washing machines) or products that become rapidly obsolete (e.g., some electronic products).

9. **One comment stated: “We support the concept that if a product is in the process of being phased out, then an AA may not be necessary. Important aspects of a product’s phase out are both the product cycle time and phase out schedules. Both of these considerations are best informed by the manufacturer or processor of the chemical or product in question. We encourage IC2 to add specific language that reflects both aspects, including the length of time a product is in the market, the time for research and development of alternatives, and the time to implement new alternatives (or phase out the old product). We also recommend that a good balance be struck between devoting resources to assessing older products being phased out versus investing in the design and development of greener products. It is more important**

to have a forward looking process that invests in the design and development of new technologies rather than investing research and development resources in older technologies that may be at the end of their production cycle.”

Response: Whether an alternatives assessment should be undertaken when a product is being phased out will depend on a variety of factors -- e.g., the potential impact of the chemicals of concern in the product, the volumes of product sales anticipated during the phase out period, and the anticipated timing of the phase out. A company should weigh these factors in determining whether an alternatives assessment is needed.

- 10. One comment stated: “We support IC2’s recognition that some chemicals are present unintentionally. We recommend that IC2 strengthen this section by including language on a de minimis level for chemicals in products, both intentionally-added and present as contaminants (or unintentionally-added). Specifically, on page 44, we would recommend elaborating on adequate levels of reduction, levels associated with exposure, and recognition that it is not always essential to get to zero. We encourage IC2 to consider a de minimis that is universally accepted, such as the commonly adopted 0.1% threshold.”**

Response: There are obvious products for which safety issues must be considered as part of product performance (e.g., critical airplane components). But this should not imply that no assessment of alternatives is appropriate. Brominated flame retardants in furniture and clothing were long justified on the basis of fire safety, but recognition of the health risks has led to the emergence of a variety of alternative approaches to meeting the fire safety goals. In addition, the issue of threshold values has been addressed in other response to comments. Although a threshold value may be appropriate for some chemicals, it would not be adequate for others. For example, endocrine disruptors present at 1,000 ppm (.1%) can constitute a serious threat to human health and the environment. Threshold values therefore should be appropriate for the hazard being evaluated and not restricted to an artificial value of 0.1% or other arbitrarily reached value.

- 11. One comment stated ‘We support IC2’s recognition that in some (albeit limited) cases there may not be a safer substitute... [and] ... consideration of tradeoffs between substitutes in the guidance is equally important.’**

Response: There are obvious products for which safety issues must be considered as part of product performance (e.g., critical airplane components). But this should not imply that no assessment of alternatives is appropriate. Brominated flame retardants in furniture and clothing were long justified on the basis of fire safety, but recognition of the health risks has led

to the emergence of a variety of alternative approaches to meeting the fire safety goals. Language has been added to the Guide indicating there may be some instances where regulations require the use of a specific chemical of concern (lead used as shielding in medical equipment, for example) but that if there are multiple ways to meet a requirement, an alternatives assessment is still possible.

- 12. One comment stated: “There is no mention in this section as to who should be responsible for preparing the AA. It may be that the responsible entity would be different depending on the chemical or product. It may be useful in this section to describe a number of options. These should include (1) the manufacturer or processor; (2) a consortium; (3) an independent group, (4) an industry/government partnership, etc.”**

Response: Accepted. Language has been added to the Background section to address this issue.

- 13. A comment suggested that eliminating consideration of an unintentional toxic chemical when it would not affect performance is not appropriate. The commenter suggests the product still be subjected to an alternatives assessment to ‘.... consider the pertinent issues such as what the potential risks of the chemical of concern in the products are, and what the costs of removal are.’**

Response: The objective of an alternatives assessment is to replace a chemical of concern with safer alternatives and to reduce risk by eliminating toxic chemicals from products or processes. It is not a risk assessment process but a risk reduction process. If a toxic chemical can be eliminated without affecting product performance, there is no reason to subject the product to the cost and effort associated with an alternatives assessment.

- 14. One commenter recommended that ‘... all processes involved in producing the product be identified in a process flow diagram. Some processes contribute to the presence and amount of the chemical of concern and therefore it is critical that they are identified at this stage.’**

Response: Accepted at least in part. Language has been added to the module suggesting that a process flow diagram might help with understanding how toxic chemicals ended up in the final product or process. Such detailed information might assist in eliminating the toxic chemical. However, because of concerns associated with making the process too complicated for many small businesses to use, the process flow diagram is presented as a suggestion and not a recommendation.

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15. **One comment stated: “The order provided in this section seems to be reversed-- where you first ask about whether it could be phased out and then why it is in the product in the first place. We recommend proceeding from why is the chemical of concern in the product? Does it have a useful purpose? How is it introduced into the product? at what point in the process? deliberately added or unintentional?, etc.”**

Response: It may be appropriate to consider the phase out of a specific chemical or class of chemicals based on peer reviewed science from an authoritative body. Identification of the chemical of concern would facilitate an inquiry if the chemical is currently contained in the product across the value chain. If the product will no longer be produced, or the chemical of concern is eliminated, then understanding how or why the chemical of concern was originally included in the product is of interest only to the extent that it helps facilitate the change.

16. **One comment stated: “We ... believe that at this Initial Evaluation, a business has some idea of its competition, market share and whether competitors are claiming to have a safer or greener product. This is useful information.”**

Response: Agreed. This information, however, is not outside the scope of the evaluation and can be included within an alternatives assessment as long the information continues to support the objective of an alternatives assessment, i.e. the replacement of a chemical, product or process of concern with a safer alternative. The information should not be used to justify the continued use of a chemical of concern.

17. **One comment stated: “We question the following statement: 'Many of these decisions are internal to organization. There are few tools available to help with these decisions.' We recommend discussing the fact that there may have been earlier evaluations of the production process either internally or externally by a consultant engineer, industrial hygienist, etc. New management personnel need to determine whether there are existing records that might be helpful or other personnel that have institutional memory. Chemical sampling results at different stages of the process may have been done. This is another place where outside technical resources could be discussed that may be available through states or universities. Green chemistry resources should be included and the IC2 . If a sector has been evaluated by EPA, thru DfE, or by states, such examples might be mentioned here.”**

Response: Companies should make use of any previous technical studies or assessments that have been done on the product or production processes, as well as relevant information available from external sources such as EPA DfE and state technical assistance programs. Examples of alternatives assessments that have been completed have been added to the Guide, which addresses some of these concerns.

18. One comment stated ‘Consideration is not given to whether the COC may be intentionally added for specific regulatory purpose.’

Response: Agreed. Language has been added to the Guide indicating that whether or not a chemical is required to be present must be considered in an alternatives assessment. The limitation is placed upon whether or not the regulation identifies that only a specific chemical can be, if a range of alternatives are available or if any alternative will work as long as it meets a specific requirement. If an addition of a chemical of concern is only one of a number of possible additions or if there are many ways to meet the regulatory requirement, an alternatives assessment is still necessary to determine which of the regulatory required options is most protective of human health and the environment. If a chemical of concern is specifically required, an alternatives assessment is not required.

19. One comment stated: “Consideration is not given to whether the COC presents no risk to human health or the environment due to lack of bioavailability.”

Response: Bioavailability is one of the important criteria considered in the Hazard Module. The emphasis is on prioritizing alternatives that have both the lowest hazard and the lowest exposure potential, thereby evaluating and reducing risk to human health and the environment. Both components of risk are addressed in individual module and assumptions about exposure are alone are not sufficient to justify the continued use of a toxic chemical.

20. One comment stated ‘Consideration is not given whether the COC is present in the product at levels that are below established de minimis value, as acceptable under well-established national and international regulation and guidance concerning public health and product safety.’

Response: Although a threshold value may be appropriate for some chemicals, it would not be adequate for others. For example, endocrine disruptors present at 1,000 ppm (.1%) can constitute a serious threat to human health and the environment. Threshold values therefore should be appropriate for the hazard being evaluated and not restricted to an artificial value of 0.1% or other arbitrarily established value.

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- 21. One comment stated: “While elimination of the COC may take place during the next innovation cycle, the replacement timeline is unknown. This is an important concern for where goods require a substantial lead-time for product development.”**

Response: Agreed. Product development timelines that incorporate alternatives assessment could be considered in the design and lifecycle of the product. Conducting an alternatives assessment is a recommended practice for the current product, and valuable for product development phase. The intent, however, of an alternatives assessment is to eliminate the use of chemicals of concern and could be considered as justification for an accelerated product replacement timeline.

- 22. One comment stated: “The directive to identify the universe of potential alternatives, including emerging technologies and novel chemistries, appears to be in conflict with the goals of other modules requiring prediction and quantification of social, health, and economic impacts. It does not seem likely that the deeper understanding required for completion of the higher levels of those modules would be possible for chemistries that have not been used in large scale implementation, and for which less is known.”**

Response: Agreed. These issues should be considered as part of the technical feasibility and market availability evaluation steps of the alternatives assessment with particular emphasis on supporting the aim of elimination of the chemical of concern from the product or process under evaluation.

- 23. One comment stated: “The discussion on impurity ‘removal’ is naïve and not connected to the practical world of manufacturing.”**

Response: Impurities present a challenge to continuous improvement in the world of manufacturing. The alternatives assessment requires the assessment of impurity removal, not necessarily the removal of an impurity if it is not technically feasible. One other possibility is to explore whether the process can be changed which could reduce or eliminate the impurities. All possible avenues should be explored. However, in support of the alternatives assessment process, inability to remove an impurity should be explained and justified in the final alternatives assessment report.

- 24. One comment stated: “Manufacturers should regularly evaluate their products, allowing for an iterative process and a determination as to when a product is re-engineered or redesigned.”**

Response: Agreed. However, the intent of an alternatives assessment process is to spur the removal of chemicals of concern in products and processes and their replacement with safer alternatives. The need for an alternatives assessment process may prioritize the need to re-engineer and redesign a product. Companies should be willing to evaluate the chemicals, products and processes once their use of a chemical of concern has been identified and make the commitment to improve their products, where feasible by implementing the alternatives assessment process.

- 25. One comment stated: “Principles of Green Chemistry and Green Engineering are good sources when evaluating product design and development.”**

Response: Agreed. The alternatives assessment guide has stated its support of the Green Chemistry principles.

- 26. One comment stated: “The term function should be defined. Many products will function without some ingredients, but their performance will be compromised. Some would view a poorly performing product as not having the same function.”**

Response: The function of a product is an important part of the life cycle analysis and is defined within that process. Consumers expect safe products and expect government to be evaluating chemicals, products and processes to guarantee they have as small an impact as possible upon human health and the environment. The market will determine the value of a poorly performing product if it cannot perform the intended function. This is an important objective of the alternatives assessment process. A consumer’s belief that a product functions 'better' if it contains a chemical of concern is not justification for the continued use of the chemical of concern. In many instances, consumers are not told what chemicals are in products and what impacts those chemicals have upon human health and the environment. Even when told, consumers may not have the scientific background to compare alternatives. Government is expected to work with manufacturers to guarantee that products are safe and don’t contain toxic chemicals.

- 27. One comment stated: “‘Maturity’ should be defined. A baseball is a mature product, but why would we sunset this product?”**

Response: The term 'maturity' is a commonly accepted term used in business to identify products that have reached an end to their usefulness and productivity.

28. One comment recommended that, for Question 1c. (p. 31), the criteria used to determine if a product should go through innovation should be defined.

Response: This is a decision that needs to be made internally by a company.

29. With regard to Question 2 (p. 32), one comment stated: “The history of how an ingredient got into a product is not necessarily important. The key is risk to consumers and the environment that may be exposed to the product or its ingredients. A better question is, ‘For the chemical of concern, is there a significant risk to individuals exposed to the product during consumer use or to the environment during use or disposal?’”

Response: The investigation of the reason why a chemical was or is added to a product is germane to the alternatives assessment process. The purpose of conducting an Alternatives Assessment is to identify less hazardous alternatives to facilitate eliminating chemicals of concern. Understanding why a chemical has been used can help the user identify possible substitutes. Assumptions on exposure are not sufficient to justify the continued use of a toxic chemical.

30. Three comment proposed the following revisions to questions a.i, a.ii, and c:

- **Question a.i. (p. 33). Rephrase to read: “If yes, would removal of the chemical with the impurity or generating the by-product affect product performance, cost, consumer acceptance, or manufacturability?”**
- **Question a. ii. (p. 33). Rewrite to ensure that costs, availability of supply, consumer acceptance, and manufacturability are included in the analysis.**
- **Question c (p. 35). Rewrite to: “Could the product formula be adjusted to eliminate the chemical without impacting cost, consumer acceptance, or manufacturability?”**

Response: The questions as they stands are appropriate to the objectives of an alternatives assessment, i.e. to replace a chemical of concern with a safer alternative. The proposed questions suggest that performance, cost, consumer acceptance or manufacturability could be used to support a decision to continue to use a chemical of concern even when a less hazardous alternative is available. This is contrary to the objective of an AA is not appropriate for the Guide.

Identification of Alternatives Comments

1. **Two comments were received that in essence recommended “There should be a recognition that alternatives need to be “technologically and commercially feasible.” Therefore, following brainstorming, there might be some initial judgments regarding whether an alternative warrants further investigation based on technological and commercial feasibility.’ The comment also expressed some concern about the alternatives assessment process inhibiting innovations.**

Response: Partially accepted. Language has been added to this module that suggests assessors may want to conduct an initial hazard and performance screen to concentrate potentially limited resources on the most favorable alternatives. Other issues such as cost are addressed in subsequent modules which provide a more detailed evaluation than provided in this module. In addition, the process of alternatives assessment spurs innovation as it focuses attention on the continued use of toxic chemicals and the need for new chemicals that, using the principles of green chemistry, can be used as safer alternatives to the chemical of concern.

2. **A comment was received that ‘1) Alternatives analyses should include an assessment of the existing alternative as well as any potential choices of substitute ... it is possible that in some cases, what is being used now is the best option. 2) Potential substitutes need to be evaluated against all relevant factors, not just functional equivalence. Factors to be considered include: * Health and environmental impact, * Availability, * Cost, * Performance and quality of product, * Reliability and safety issues, * Energy efficiency.’**

Response: Partially agreed. The alternatives assessment process includes an evaluation of the chemical of concern in order to provide a baseline for comparison. Any alternatives that are equivalent or greater toxicity concern, for example, should be set aside as less favorable alternatives if an initial screen for hazard and performance are done. The remaining factors are important and, for alternatives that pass the initial screen, will be evaluated in subsequent modules. The purpose of the alternatives assessment is to conduct this comparison to identify alternatives to toxic chemicals and eliminate them from products and processes. However, in those rare instances where no safer alternative exists, the AA directs the user to justify continued use while spurring innovation toward creating newer and safer alternatives using Green Chemistry principles.

3. **It was suggested that ‘This section could be condensed into a bulleted list of typical approaches for identifying alternatives, and potential information sources.’**

Response: Although the module uses a question format, it in effect does indicate a list of typical approaches.

4. **The comment was made that ‘... 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.**

Response: Accepted. Wording has been added to emphasize the importance of working with suppliers as an important source of information on alternatives. This was addressed by questions 2-5 and 2-6 although the term 'chemical provider' was used instead of supplier. New language also recommends that users work not only with suppliers but also with the supplier's competition to see if something else is available in the marketplace. To further clarify, the term 'supplier' was inserted within the section in place of 'chemical' provider' and additional language added for emphasis.

5. **A comment suggested that‘...examples and guidance are needed for cases where a replacement cannot be found.’**

Response: Accepted. The document was updated to include examples of where a replacement may not be possible.

6. **The comment was made that ‘This module establishes two key considerations for the potential alternatives: 1) functionally equivalent alternatives, and 2) the availability of alternatives in the marketplace. These criteria are useful in the development of a broad list of alternatives which require assessment of cost, availability of supply, performance, compatibility with manufacturing processes, consumer acceptance, regulatory compliance, etc.’**

Response: The IC2 appreciates all comments provided by stakeholders during the creation and review process.

7. **The comment was made that the Guide should include consideration of ‘... the ability to meet federal, state, local and industry specific regulatory standards and cost’ in the Guide.**

Response: Accepted: Language has been added to the Guide to address this issue. However, this issue is better addressed in the Initial Evaluation Module. Wording has been inserted in that section to address this issue. In addition, if a chemical of concern is only one of a variety of methods available to meet a regulatory requirement, an alternatives assessment process is appropriate to determine which of the variety of methods best protects human health and the environment.

8. **The comment was made ‘We support IC2’s recognition that there may be some instances where “functional equivalency can be achieved in reasonable time through design of new chemicals or materials applying green chemistry principles or product redesign” (Draft Guidance, p. 39). It would add to the clarity of this concept if IC2 would add language that recognizes that the “old” product may need to stay in commerce while this new approach is being pursued.’**

Response: Agreed. Time may be required for transition to a better alternative, but the time period should be as limited as possible. The point for addressing any necessary transition period for a specific alternative is at the conclusion of the alternatives assessment when the preferred alternative has been identified and the plans for implementing the transition are spelled out. Language has been added to the Guide to address this issue.

9. **The comment was made ‘It is important to recognize that much data on chemical use is proprietary and may not be available to help determine what substitutes a competitor is using and whether that substitute would be a viable replacement. It would be helpful to specifically recognize that in this section. Additionally, this section could highlight the benefits of working in a collaborative process to develop AAs to enhance data sharing and availability.’**

Response: There may be cases where alternatives available in the market are proprietary. In such cases, the assessor may have to adjust what information can and cannot be made available. The impacts a chemical, product or process has upon human health and the environment (Section 6 Hazard Module) is not proprietary and should be made available so consumers can better understand the impacts those proprietary chemicals, products or processes have upon human health and the environment. This disclosure requirement is in agreement with National and International regulatory requirements. EPA, for example, in its alternatives assessment process allows the Chemical Abstract Services (CAS) number to be kept confidential but documents the results of the hazard assessment for that proprietary item. Concerning the issue of data sharing and collaborative process, the Stakeholder Module specifically addresses this issue as it expects assessors to work collaboratively with interested parties and to involve them

to the degree possible in the decision making process within the AA. This issue is already addressed in this module and no additional wording is needed at this point.

- 10. The comment was made that consideration of the production process be added here. Alternatives may include chemical substitutions, the use of alternative materials, changes to the production process or product redesign to eliminate the need for a particular chemical in the first place.'**

Response: These issues are included in the Guide in the Initial Evaluation Module where decisions are made whether changes can be made to the process, use of alternative materials, etc. that would negate the necessity for conducting an alternatives assessment. However, the Initial Evaluation Module language has been reviewed to make sure these points are covered and clear.

- 11. The comment was made that the Guide should make clear '... who will carry the responsibility of identification of alternatives.'**

Response: Identifying the alternatives is the responsibility of the assessor carrying out the alternatives assessment, but it clearly would be beneficial for that organization to collaborate as broadly as possible with other businesses, associations, technical assistance groups or other organizations that could support or share in the alternatives assessment effort.

- 12. The comment was made that 'Alternatives must be feasible. It would streamline the process if those alternatives known to be unacceptable based on expert judgment could be excluded from consideration at this point in the AA. The group empowered with performing this expert judgment would need to be identified.'**

Response: Transparency is expected throughout the alternatives assessment process. The Guide does not put a restriction on eliminating alternatives based upon expert judgment; however, if an alternative is eliminated, the reason for its removal should be identified in the final AA. This includes the qualifications of the individual making the expert judgment.

- 13. The comment was made that 'The Document does not consider the restraints on products with dedicated purpose, such as a component which may be subject to multiple design restrictions as a part of a larger assembly. Redesign to eliminate a COC may require redesign of other components of the assembly which may or may**

not be produced by the same manufacturer. This may require substantial lead-time to accomplish.'

Response: Determining the full range of changes that would be required to eliminate a chemical of concern is part of the analysis required for an alternatives assessment. Issues such as these would be addressed in the final report. The AA process does not specifically put a timeframe on when the changes should be implemented. As these issues are beyond the scope of the Guide, they are not mentioned within the document.

14. The comment was made that 'A chemical may have multiple functions in a product and may require multiple changes in ingredients and manufacturing to adequately satisfy those functions.'

Response: Agreed. These issues should be addressed in the final alternatives assessment report.

15. The comment was made that '... alternatives need to be "technologically and commercially feasible" [and] "legal" in all the jurisdictions in which it is made and sold. This not only includes chemical regulations, drug regulations, cosmetic regulations, and food regulations, but also patent restrictions. Regardless of what the alternative is, if a patent or regulation prohibits its use it cannot be used. Therefore, following brainstorming, there might be some initial judgments regarding whether an alternative warrants further investigation based on technological and commercial feasibility and applicable law. Moreover, recognition must be given that in some cases (such as drug and pesticide products) alternatives may be extremely limited or subject to regulatory restrictions.'

Response: The issue of whether or not the use of a chemical of concern is regulatorily driven has been added to this section. The Guide does not state that all alternatives must be considered; however, transparency is fundamental to the AA process and, if an alternative cannot be used, the decision should be documented and justified in the final AA report.

16. The comment was made that 'Most manufacturing entities will be largely dependent upon material suppliers for information regarding potential alternatives to specific chemicals. This close relationship permits the product design process, something that is typically very sensitive within a company, to be conducted in a confidential fashion. Disclosure of this sensitive information to external entities would be inappropriate.'

Response: This document provides a guide for companies carrying out their own alternatives assessment; it does not include requirements for communication to external entities. The comment however appears to be concerned with confidential business information issues which have been addressed in other comments.

17. Two comments were made concerning other tools available for identifying potential alternatives and the need to foster and recognize that innovation might be another way that alternatives can be identified.

Response: The tools identified are for companies to use as appropriate while carrying out an alternatives assessment. Transparency is a vital component of any alternatives assessment and all decisions reached should be supportive of the objective of an AA, i.e. replacement of chemicals of concern in products and processes with safer alternatives and be documented and justified in the final AA report. The issue of CBI has been addressed in other comments.

18. The comment was made that ‘...an alternative approach that was not considered - namely redesign of the product to reduce exposure and thereby reduce risk to an acceptable level.’ In addition specific questions related to performance, cost, etc. were suggested for addition to this module.

Response: The objective of an alternative assessment is to reduce risk by identifying alternatives with both the lowest hazard and lowest exposure potential. Therefore the recommendation to allow redesign does not meet the objective of an AA as it assumes continued use toxic chemicals if steps are taken to reduce exposure. This is contrary to the objective of an alternatives assessment.

19. The recommendation was made that ‘...the term “similar or equivalent functional requirement” should be defined.’

Response: Generic definitions of "function" aren't useful. . Function, however, is an important component of a life-cycle assessment and the Guide uses this established definition to define function for an AA.

20. Two comments were received about the use of the term ‘reasonable time’ and one suggested that it be defined.

Response: What is a reasonable time for implementation of a particular alternative can only be determined once the alternative is selected and an implementation plan is developed. But the goal is clear, to eliminate the use of a chemical of concern as expeditiously as possible. The AA process does not specifically put a timeframe on when the changes should be implemented which are more likely to be addressed either in legislation or in rules that require the use of an alternatives assessment. As these issues are beyond the scope of the Guide, they are not mentioned within the document.

21. The concern was raised that ‘...the Draft AA Guidance is impossible to implement as the universe of alternatives is too vast and broad.’

Response: The Identification of Alternatives Module has been updated to include screening of alternatives using information in the Hazard and Performance Modules. The use of these screens will enable the assessor to focus limited resources on the most favorable alternatives. In addition, the current module also allows the alternatives to be narrowed based upon specific decisions. For example, Washington State Department of Ecology’s Assessment of Alternatives to Decabromodiphenyl ether, rejected all halogenated flame retardant alternatives because of PBT concerns related with these alternatives. This decision was documented and justified and had the impact of narrowing evaluation to those non-halogenated alternatives.

Decision Making Module Comments

- 1. Several comments were received that, in essence, stated that ‘The product development and improvement methodology has demonstrated success in industry ... It sharply contrasts with the command-and-control approach of typical regulatory policy.’**

Response: The Guide does not take a ‘command and control’ approach. It outlines a group of different ways in which an alternatives assessment can be done and leaves many of the decisions on what modules to include and the level of review within each module to the assessor. In addition, it should be pointed out that the alternatives assessments are in part being done to address increased consumer concerns about the continued use of toxic chemicals in products, something which the product development process can fail to address. Therefore, the Guide can enhance product development and improvement processes. The Guide was created to address the issue of eliminating the use of toxic chemicals from consumer products while maintaining product performance. The Guide provides flexibility to address many of the issues included in this comment while maintaining the overall objective of providing safer products and protecting human health and the environment through the elimination of toxic chemicals. No changes are proposed on the basis of this comment.

- 2. A comment was received that ‘...there is recognition of the diversity of approaches that can be used and the need for flexibility. Ultimately, the final decision rests with the company that intends to put a product on the market as long as that product is safe for use.’**

Response: The Guide was developed with the recognition that there are many different types of products or processes and one approach may not work for all. The Guide provides this flexibility. As to the second comment that ‘..the final decision rests with the company... as long as that product is safe for use’ is not in agreement with the objective of an alternatives assessment to replace toxic chemicals with safer alternatives. In addition, as stated in other comments, consumers are very concerned with the continued use of toxic chemicals and expects government to make sure the products they use are safe. Therefore, this is not solely a business decision but a societal decision which requires the involvement of all impacted parties. Lastly, impacts during product use are not the only consideration. It is important to consider life cycle impacts upon workers, transport, storage, use and disposal as expected in the alternatives assessment process. Consideration of impacts only during product use fails to consider long-term impacts.

3. **A comments was received that the Decision Module ‘...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.’**

Response: Response: Applicable decision methods depend on a practitioner's individual situation. The Decision Module intentionally incorporates flexibility to allow for individual circumstances. Although the Guide provides flexibility, it does include a minimum recommended process which addresses some of the concern identified in this comment.

4. **Several comments were received that suggested combining and reorganizing the module to increase clarity.**

Response: The Guide has undergone substantial edits and the specified sections have been merged into a single section titled "Decision Theory Frameworks". These changes address the recommendations made within these comments.

5. **A comment was received that the module adequately emphasizes that ‘Choosing the proper method for complex decisions, and having the flexibility to apply individual business and product considerations is critical.**

Response: The IC2 appreciates all comments provided by stakeholders during the creation and review process and believes the flexibility inherent in the Guide addresses this issue.

6. **A comment was received that ‘This module does place emphasis on the replacement of one chemical for another, when in practice a manufacturer will need to base decisions on the results of analyzing alternatives in the context of the product as a whole rather than a single ingredient. Additionally, most of the examples in this module focus on hazard. Decision methods should take a risk-based approach, considering both potential hazard and exposure.’**

Response: The processes included in the Guide are risk-based as this module considers both hazard and exposure. The Guide's objective is to reduce risk by using the lowest possible values for both parts of the risk equation (i.e. hazard and exposure). This process emphasizes reducing hazard as the logical place to begin this risk reduction process. These approaches emphasize flexibility and can be applied in the manner that suits an individual's circumstances. In addition, although the examples may relate to the replacement of a chemical in a product or process,

some of the modules take a more product specific orientation, for example the Materials Management Module. Consideration of changes of more than one component in a product is not outside the ability of the Guide to address. No change is proposed on the basis of this comment.

- 7. A comment was received that Assessors have the ability to weight individual criteria within the context of the objective of an AA” (Draft Guidance, p. 40). Any such weighting should, of course, follow the guidelines for transparency and documentation as noted in Section 4.’**

Response: Weighting of criteria is only applicable for the Simultaneous Framework and the portion of the Hybrid Framework that uses Simultaneous Framework. If the assessor is using the Sequential Framework, the weighting is implicit in the framework and no additional weighting is required by the assessor. Although the Simultaneous and part of the Hybrid Frameworks provide the flexibility of assigning weights, it is within the context of meeting the objective of an alternatives assessment, i.e. replacing toxic chemicals with safer alternatives. All weighting should support that objective.

- 8. A comment was received that ‘... support[s] IC2 in looking to streamline the AA process and make it as workable as possible. We appreciate and agree with IC2’s position that too many assessment criteria can make an AA process too complex and unwieldy. We agree with the establishment of a hierarchy among the relevant criteria and support the idea that if everything is a priority, then nothing is a priority.’**

Response: The IC2 appreciates the comments provided by stakeholders during the creation and review process. The Guide has undergone substantial editing and condensing.

- 9. A comment was received that ‘... The frameworks provided do not result in a robust assessment: different alternatives are expected to be identified by different assessors due to the ability for assessors to select differing modules and levels of implementation. AA efforts require a uniform approach for consistent and predictable decision criteria.’**

Response: Alternatives assessments are performed by different entities for different reasons. The criteria for evaluation will necessarily be different for different types of analysis, such as formulations vs. articles, design changes vs. chemical substitution, or large chemical manufacturer vs. small, discrete mid-chain part producer. The state of practice does not currently support uniform decision criteria in all cases. More uniform approaches may appear

as individual states take the Guide and create recommendations for alternatives assessment within specific states.

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- 10. A comment was received that information in the Guidance concerning which modules are preferred is conflicting and ‘... three decision frameworks give guidance that the four “core” modules (Performance, Hazard, Cost and Availability, Exposure) are preferred or specified for AAs. Conflicting information is also provided in the Document (Sequential Decision Framework flowchart) indicating that all modules are required. As stated before, this AA Document is likely to be used to meet regulatory obligations; therefore, it is imperative that the guidance provides enough specificity to allow a regulated entity to know what must be done in order to comply.**

Response: In the decision module, it is important to recognize that all acts of selection become part of the decision. Determining which factors to evaluate and in what order (or simultaneously) constitutes a hierarchy decision, particularly if alternatives are screened out of consideration after evaluation. The suggested procedures for the sequential and hybrid decision process are specified as they are consistent with the goals of this guidance. The decision module was not developed to comply with any specific regulatory framework. It is the responsibility of the assessor to ensure that the factors considered and criteria used for comparison are consistent with any applicable regulatory requirements. The diagrams referred to show what four modules are recommended as the minimum to consider in an alternatives assessment, not a requirement.

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- 11. A comment was received that ‘The decision module is unbalanced and seems to ignore consideration of cost, availability, regulatory compliance (international, federal and state), manufacturability, and consumer acceptance.’**

Response: The assessor should consider all factors relevant to its decision and many of these issues are addressed in specific modules, which provide the information used in the decision framework selected by the assessor. The wording in the module has been edited to clarify this point.

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- 12. A comment was received that ‘Alternatives assessment guidelines must provide adequate flexibility to accommodate business models of companies from individual start-ups to global operators. Decisions should be based on sound scientific risk assessment to protect human health and the environment, taking into consideration**

all of the life-cycle phases ... Final decisions should balance human health and environmental impacts and lifecycle impacts based on risk.'

Response: The flexibility described in this comment is consistent with the Decision Module. The Guide is based upon a sound risk-reduction approach and responses to comments received on Risk can be found in the sections dealing with General Comments and Hazard, among others. No change is proposed on the basis of this comment.

13. A comment was received that in essence stated 'There will not be a single best alternative that works for every manufacturer of a given product, and governments must not impose such requirements in recognition of manufacturers innovations, place in the marketplace and availability of alternatives.'

Response: Response: The flexibility described in this comment is consistent with the Decision Module. No change is proposed on the basis of this comment.

14. One comment stated '... the module proposes a set of rudimentary frameworks that are not particularly helpful to the skilled assessor or experienced companies We concur with the sentiment expressed in the module that the "list (of three) is not meant to be comprehensive or to identify any priority for which framework should be used ... and we oppose any checklist use of the guidance or any effort to require the use of the modules to define a prescriptive decision regime. Checklist approaches too often result in limitations rather than delivering effective alternatives.'

Response: We agree that skilled assessors and experienced companies will most likely have their own systems in place, and are less likely to require the Guide. However, the majority of small and medium businesses do not have these processes in place and do not have the resources and technical expertise to develop their own process. The Guide was developed to provide guidance to a wide range of users. The guidance is not designed for meeting compliance requirements of any specific regulatory approach.

15. Two comments were received that 'acknowledge the principles and resources identified within the Decision Module as highly useful and suggestive of a rigorous approach towards alternatives assessment ... a creative review of the consumer need and the way in which the product under consideration addresses that need can result in several novel solutions that leap the need for a detailed decision process [and] the decision module is unbalanced and seems to ignore consideration of cost,

availability, regulatory compliance (international, federal and state), manufacturability, and consumer acceptance – all critical considerations in decision making and ... The decision methods are useful and we applaud the IC2 TAAG Team for offering them as a suggestion. However, we object to using them as a prescription.'

Response: The Decision Module describes possible approaches to decision-making that can be applied flexibly. The Guide, however, does not describe what modules need to be considered and leaves many of these decisions to the assessor. In addition, the Guide is not being written to address any regulatory concern and, therefore, is not prescriptive. No change is proposed on the basis of these comments.

16. A summary comment was provided indicating '... an alternatives assessment should be science-based, evaluating all relevant factors when assessing viable alternatives to an existing product, and ensuring safety. No single factor can be evaluated in isolation from other relevant factors. A sensible approach for conducting alternatives assessment is one that is flexible, modular (focusing on relevant factors), effective, ensures consumer acceptance, ensures informed decision-making, allows for gradual and measured implementation, and includes a feasibility check.'

Response: The flexibility described in this comment is consistent with the Decision Module. Similar language used in this comment can be found within the Guide and the modular design and flexibility were based upon previous comments received from stakeholders.

17. Several comments were provided that disagreed with the Guide inclusion of any modules beyond hazard assessment. The comments also indicated anything beyond hazard should be left to the assessor to decide and no minimum recommendations of what modules comprise an alternatives assessment should be provided.

Response: The Guide has been edited to further emphasize hazard as the starting point for an alternatives assessment. However, to expect hazard to be the only factor to be considered in an alternatives assessment is too limiting. If one chemical can be replaced with another without affecting any other factor such as cost, performance, exposure, etc., no additional work would be needed except language to say that these other modules were considered and not found relevant. If it can be shown that there is no substantive difference between alternatives for the recommended modules, no further work is needed. The number of occasions where hazard is the only variable in a decision is expected to be few. In those instances where more than hazard needs to be evaluated, an alternative assessment should consider at least those modules that

have impact among the four recommended modules. All four recommended modules may not need to be considered if it can be shown there is no impact from the change. For example, if a less hazardous alternative is used in the same way, in the same amounts and has the same route of exposure, no further exposure evaluation is needed than to state that this was the result and the information used to reach this conclusion. No change is proposed to the Guide based on these comments.

18. A comment recommended adding a new section to the Guide named ‘Approaches to AA: Examples’. This new section would provide a very short summary of alternatives assessments that have been completed along with information where more details can be found. The intent was to show how some alternatives assessments have been done so an assessor may determine if some of these methods are applicable to their chemical, product or process under review.

Response: Accepted. A new section has been added to the Guide to address this comment.

19. A comment was received to simplify the Reference Guidance into three core steps.

Response: The Guide has been reorganized along this direction although a majority but not all suggestions have been implemented.

20. A comment was received that ‘... does not support the use of the Simultaneous Decision Framework.’

Response: As the Guide contains three decision frameworks that can be used as part of an alternatives assessments, IC2 believes that the simultaneous approach may be an appropriate protocol to use in certain instances to evaluate numerous alternatives and select the preferred. The decision of which framework to use will be left to the assess or individual states to decide. The reviewer may wish to keep abreast of state efforts on alternatives assessment and provide the same comment to any state that might decide to recommend the Simultaneous Framework. Inclusion of the Simultaneous Framework in the Guide however does not constitute a requirement for its use in any or all alternatives assessments.

Stakeholders Module Comments

1. **Several comments were raised that requested greater clarity concerning which level of stakeholder involvement was recommended for different types of alternatives assessment and that the Stakeholder Module was distinctly different from the other modules in the guidance and, therefore, should be separated into its own section.**

Response: Accepted: Examples were added to the Stakeholder Module to suggest possible users for each level. The first Level is expected to be primarily an internal business oriented review and Levels 2 and 3 reflect increasing level of involvement of external stakeholders. Language was added to the examples to make this distinction clearer. Additionally, the Guide has undergone substantial reorganization and the Stakeholder and Decision Modules have been separated into their own, distinct section. This section retains the Scoping name but clarifies that these steps are different from others taken in the AA process.

2. **A comment stated that ‘Policy incentives should be implemented that recognize companies who voluntarily seek “safer” alternatives, and should serve as the primary tool that states use in promoting safer alternatives or green chemistry innovation without the need for a third-party approach. When conducting alternatives assessments “commercial viability” of each alternative should be evaluated. This might incorporate components of regulatory compliance and manufacturing compatibility along with commercial availability and cost effectiveness, among other factors. For high profile alternatives assessments, external stakeholder involvement may be warranted to minimize miscommunications with the public. However, stakeholder involvement in internal business design decisions would likely be very rare. Environmental justice (EJ), occupational concerns and related social considerations should be integrated into many of the product development steps. A number of social, worker and EJ considerations may be aspirational that companies wish to address but are external to their business decisions. It may be more appropriate to tier AAs to encompass essential elements and aspirational elements, with those that are able to address the aspirational elements attaining higher classification (e.g., LEED-type ratings: Silver status vs. Gold status).’**

Response: Many of the points raised in this comment are already contained within the Guide. For example, the first Level of the Stakeholder Module is primarily an internal decision process with only minimal involvement from external stakeholders, environmental justice issues are included in the Social Impact Module, etc. The issue of 'commercial viability', however, is outside the scope of the AA. Commercial viability is primarily a business decision and should

take place prior to the AA process. Once the decision has been made, the AA process is appropriate to guarantee that the product which has been determined commercially viable does not contain any toxic chemicals and provides the highest degree of protection to human health and the environment. Commercial viability is not a decision that is part of the alternatives assessment process.

3. A comment suggested the removal of the ‘Discussion concerning the evaluation and decision making process utilizing this data...’

Response: The degree and type of stakeholder involvement is determined by the assessor conducting the alternatives assessment.

4. A comment was received ‘Appropriate stakeholder communication is critical and requires providing consumers with accurate and useful information. Published results should be contextualized and communicated appropriately. Industry practices include: posting information on a company’s websites; communicating via advertising; packaging; and, a variety of publication channels. It is critical that consumer research is used to understand needs and conveys the information in a manner that is understandable to the consumer/user. However, manufacturers should not be expected to subject their critical business decisions to external entities. Stakeholder involvement may include: (i) Stakeholders in Performance Assessment and (ii) Stakeholders in the AA process. (i) Stakeholders in Performance Assessment: Manufacturers ultimately perform market research to assess consumer preference. Second to that is consumer contact information (e.g., toll free numbers), which is meaningful in identifying critical flaws. Marketers communicate with consumers through a variety of media including websites and 1-800 numbers as well as social media platforms such as Facebook and Twitter. Communications channels provide an opportunity to engage directly with those using the products, give consumers a forum to ask questions about appropriate use, and provide comments on the products. (ii) Stakeholders in the AA process (including government, NGOs): The quality of stakeholder engagement and input, substantiated by valid scientific principles, is imperative to appropriate stakeholder communication/involvement.’

Response: The issues raised in this comment may be considered part of a stakeholder involvement in the alternatives assessment process. The Guide does not limit the breadth and level of stakeholder involvement but provides suggestions on what might be considered when involving stakeholders in the AA process. An important component, however, of an AA is transparency. The final AA report should document and explain what stakeholder involvement

was selected and why. In addition, stakeholders are rarely informed about the chemical content of products and what impacts those chemicals may have upon human health and the environment. The final report should include what information was presented to stakeholders in order to fully inform stakeholders of the impact of their decisions. Otherwise, many of these details, however, are left to the assessor to determine.

- 5. Several comments were received concerning the importance of stakeholder involvement in the alternatives assessment process. In addition, concerns were raised about the protection of confidential business information (CBI) and how stakeholder involvement can affect this process.**

Response: Stakeholder involvement in the alternatives assessment process is important as acknowledged in the comments. However, the degree, extent and scope of the stakeholder process is left to the assessor with the caveat that, because of the emphasis on transparency, the AA should document the decisions made and reasoning involved. The Stakeholder Module has been written to show the range of stakeholder involvement from primarily internal, business-centric process (Level 1) to a more open process where stakeholders have a more active involvement in the AA process (Level 3). Which level is appropriate for a particular chemical, product or process is left to the assessor. In addition, the Stakeholder Module does not rule out expansion of the stakeholder process or adapting the levels in the module to suit specific needs as long as the reasoning is explained and justified. Lastly, the issue of CBI has been addressed in other comments. Specifically to the stakeholder issue, however, there are models for comprehensive stakeholder involvement that still protect CBI issues. For example, EPA's Design for the Environment program conducts extensive stakeholder involvement in their alternatives assessment process while protecting CBI issues.

- 6. Several comments were raised about the applicability of the stakeholder module to alternatives assessments conducted by businesses. The suggestion was made that the module should restrict itself to '... to the methodology of soliciting and acquiring stakeholder input and allow the decision-maker to determine how best to utilize this information.' Concerns were also raised about the ... unwarranted cost, complication and time...'**

Response: The power to make a decision around alternatives rests with the business conducting the assessment. Stakeholder input enables businesses to make informed decisions that will minimize opposition and constitute a long-term solution. Although there are companies (B Corp) that allow stakeholders to inform business decisions, this is not typical for most businesses. The assessor makes the decision on what type and level of stakeholder involvement is appropriate for the chemical, product or process under review. Level 1 in the

Stakeholder Module, for example, is suggestive of primarily an internal process with limited input from external stakeholders. The other levels in the Module suggest increasing levels of stakeholder involvement under the control of the assessor. Although an earlier version included B Corps as a possible level of stakeholder involvement, this type of stakeholder involvement is sufficiently rare that it was ultimately removed as a suggested alternative. Language has been added to make it clear that the assessor decides the level, content and extent of stakeholder involvement.

- 7. Two comments raised concern that the module suggested that ‘... stakeholders themselves will determine how much involvement is necessary from their perspective and no attempt will be made to limit stakeholder involvement externally.’**

Response: Language has been added to the Module to make it clearer that the assessor sets the level, scope and extent of stakeholder engagement. Within that scope, stakeholders decide what input they would like to give and how to involve themselves in the alternatives assessment process. It should also be noted, however, that Level 1 of this module is primarily an internal business stakeholder process with limited to no input from external stakeholders. Level 1 alone does not agree with the comments made on this issue.

- 8. Two comments were made that the level and type of stakeholder involvement identified in the module ‘...creates serious and unnecessary antitrust concerns unique to the business community.’**

Response: The degree, extent and scope of the stakeholder process is left to the assessor with the caveat that, because of the emphasis on transparency, the AA should document the decisions made and reasoning involved. The Stakeholder Module has been written to show the range of stakeholder involvement from primarily internal, business-centric process (Level 1) to a more open process where stakeholders have a more active involvement in the AA process (Level 3). Which level is appropriate for a particular chemical, product or process is left to the assessor. In addition, the Stakeholder Module does not rule out expansion of the stakeholder process or adapting the levels in the module to suit specific needs as long as the reasoning is explained and justified. Soliciting input from stakeholders does not threaten potential exposure under Federal anti-trust laws as indicated with comments from other industries and associations responding to this document. Level 1 in the Stakeholder Module, for example, is primarily a business-centric process and suggests limited external stakeholder involvement. This level in particular is contrary to many of the points raised in this comment. In addition, EPA’s Design for the Environment Program has conducted several alternatives assessments over the past ten years with extensive stakeholder process and has not faced any antitrust issues. Lastly, as the

assessor determines the extent and scope of stakeholder input, it is up to the assessor to address these and any other pertinent issues.

9. **A comment was made that the ‘...stakeholder involvement has long been a critically important aspect of any effective product development and innovation process... however, as written, the Stakeholder Module is inappropriate for the targeted user groups and fails to properly reflect the very principles it advocates.’ No additional information was provided on the reasoning for these statements and what steps should be taken. Similarly, a second comment was received stating ‘The preparation of the Stakeholder Module document appears to have neglected the very intent of the Stakeholder Module as the authors failed to solicit and incorporate adequate stakeholder feedback from the business community and thus have created a document that is more appropriately constructed for the governmental/regulatory user.’**

Response: Stakeholder involvement in the creation of the Guide has been extensive, broad and open to any group interested in providing input. Although state representatives created the Guide, all parts of the Guide were released for stakeholder review and comment. In addition, extensive stakeholder outreach occurred including three industry workshops, two open webinars, innumerable presentations at business association meetings, etc. This level of stakeholder review and comment far exceeds standard state policy when creating guidance documents not required to meet legislative or regulatory requirements but to be used solely on a voluntary basis. In addition, Level 2 of the Guide was created to represent the type of stakeholder involvement used during creation of the Guide.

10. **Several comments were received that ‘Consumer acceptance is critical to any product change and must be part of the decision making process for selection of alternatives.’**

Response: Although consumer acceptance is important, it is not the most important consideration in the alternatives assessment process. The objective of an AA is to replace toxic chemicals with safer alternatives by emphasizing less hazardous alternatives. These decisions provide safer products, reduce risk to human health and the environment and satisfy consumer demands and expectations of government oversight of consumer products.

11. A comment was received that the Stakeholder Module should be separated into stakeholder involvement in 1) Performance Assessment and 2) AA Process. No further information was provided.

Response: Performance is a component of the alternatives assessment process and therefore IC2 sees no benefit to making the suggested separation.

12. One commenter stated that ‘The quality of stakeholder engagement and input, substantiated by valid scientific principles, is imperative to appropriate stakeholder communication/involvement.’

Response: The Guide is based upon valid scientific principles and the IC2 thanks you for your support.

13. The comment was received that the module ‘... could benefit from judicious editing.’

Response: Accepted. The document has been subjected to an editor's review.

14. The comment was received that ‘Stakeholder groups should be identified by the Assessor.’

Response: The assessor decides the level, extent and scope of stakeholder involvement and language has been added to the module to clarify this issue.

Performance Evaluation Module Comments

- 1. Issue:** Two comments stressed the importance of considering performance in an alternatives assessment: “.... Efficacy/functionality standards may either be prescribed for in regulations or desired by consumers, e.g., antimicrobial log reductions in FDA Over-the-Counter drug monographs v. hair colorant vibrancy and longevity attributes, respectively. Required performance levels may be stipulated in existing regulations, and must be recognized (e.g., drug actives, pesticide actives). Companies cannot simply substitute out of those ingredients. Similarly, companies must consider consumer habits and practices of a “performing” product, characterized in terms of exposure and safety to ensure that use instructions provided are followed accordingly.... A selected alternative must have acceptable or enhanced performance while reducing or eliminating the potential for harm, via reasonable and foreseeable routes of exposure from a product.”

Response: Performance and cost are key components of an alternatives assessment as witnessed by the two separate modules included in the Guide. These criteria alone do not provide sufficient information on the alternatives to assure that adoption of alternatives to toxic chemicals are in fact safer. Consumers expect consumer products to be safe to use and expect government to oversee chemicals in products.

Increased consumer awareness of and concern about the continued use of toxic chemicals in products combined with the realization that traditional risk assessment can fail to protect human health and the environment from toxic chemicals are primary drivers for development and interest in the alternatives assessment process. Numerous examples exist where one toxic chemical was replaced with another of equal or greater concern because the only factors considered in the replace process were criteria such as cost and performance. Workers have suffered serious health impacts from poor decisions such as these regrettable substitutions. Therefore state governments are increasingly expecting businesses to evaluate alternatives that have the lowest hazard with the resultant lowest risk to human health and the environment, and to justify, in a transparent process, if they determine that these safer alternatives will not provide adequate performance. The alternatives assessment process does not dictate what is used but makes transparent the business decisions that declare and justify the continued use of toxic chemicals.

2. A comment suggested combining sections 62 and 20a.

Response: Agreed. The Guide has undergone substantial editing and these two sections have been combined.

3. A comment stated that this module has ‘... nothing to add to current practice within industry... [and] ... recommend eliminating most of the content of this module and limiting the discussion to guidance on avoiding over-engineering specifications.’

Response: Most companies have adequate processes for assessing the performance of new options already in place. This Guide is intended to be applicable to the full range of sophistication in the process, therefore includes information on how to assess performance.

4. One comment was received that stated ‘This section should have some of the summary information and the kinds of questions that should be answered here-- not just refer the reader to the Decision module.’

Response: If only the Simultaneous Framework is used, the comment would be valid. However, if the assessor decides to use either the Sequential or Hybrid Frameworks, it is necessary to have information within the Performance Module that enables focusing of alternatives to the most favorable. In those instances, the details within the Performance Module are necessary and will be retained.

5. Several comments stated that performance evaluation varies across sectors and is more nuanced and detailed than the steps outlined in the Guidance. Comments also stated that industry should be consulted on how performance is evaluated.

Response: Performance is an important product criterion in the alternatives assessment process. Many of the specific performance criteria pointed out here are specific to only certain kinds of products. The module was intentionally written to illustrate that the details of a performance assessment, at any level, must be determined by the industry conducting the assessment, as they are unique to each assessor’s conditions and associated nuances. Patents and intellectual property issues would be part of an individual industry’s considerations as they evaluate alternatives. Continual improvement is a core principal of a well-conceived alternatives assessment and is currently included in the Guide which was written broadly enough that some of the points raised could be included in a Performance evaluation as long

as the decisions were explained and justified and the results meet the overall objective of an alternatives assessment, i.e. replacement of toxic chemicals with safer alternatives.

6. **One comment stated: “Performance Assessment is critical to the safety of products and the assessment of potential alternatives. Any alternative must maintain, if not improve, the level of performance of the product during reasonable and foreseeable use. Additionally, an alternative must be able to perform to meet all relevant regulatory requirements, and address all aspects of safety – mechanical/physical, electrical, thermal, flammability and chemical risks. Focusing on chemical safety alone may lead to regrettable substitutions where a material is replaced with another which creates poorer safety performance in one of these other aspects, thereby creating another type of hazard. The guidance provides a basic approach to performance assessment. We appreciate that it is expressly stated that, “the intent of this module is to provide sufficient flexibility that will allow a wide range of users to determine if performance characteristics are a barrier to the use of a safer alternative.” A one-size-fits-all approach is not feasible for performance assessment as evaluation practices vary by industry and criteria will differ based on products categories and individual products.”**

Response: The IC2 appreciates the input and positive feedback. Based upon other comments received, meeting regulatory requirements was added to the Guide. The Guide also indicates that a one-size-fits-all approach is not adequate, which is why the Guide includes a high degree of flexibility and defers largely to the individual assessors to determine the appropriate performance indicators for assessing the technical feasibility of alternatives.

7. **One comment stated: “The module is accessible, and leverages publicly available information at the lowest level of assessment, and technical expertise and quantitative testing at the highest level of assessment.... A further comment is made that ‘Evaluation is terminated for those alternatives that are not viable based on lack of appropriate performance’ and that ‘It is essential that Performance be considered a critical part of the AA’.**

Response: Agreed. The comments do not require changes to the Guide.

8. **Several comments were received providing additional detail on what should be considered during a performance evaluation.**

Response: The comments provided by stakeholders during the creation and review process are appreciated. As indicated, the Guide is intended for use in a wide range of applications and flexibility to address these problems were an important factor in the Guide's development. Many of these issues indicated in these comments can be included in a performance evaluation assuming 1) the decisions reached can be explained and justified meeting the transparency requirement of an AA and 2) it meets the objective of an AA, i.e. replacing toxic chemicals with safer alternatives.

Hazard Module Comments

1. Several comments were received about the quality of data used in a hazard assessment.

Response: Only data from scientifically valid sources are used in a hazard assessment. This requirement is fundamental to the hazard assessment which provides very detailed information on what data can be used and the quality of the data involved. For example, the hazard assessment identifies both authoritative lists and screening lists. The authoritative lists are from internationally recognized experts in the particular hazard being evaluated. Screening lists are typically also from authoritative bodies but because of issues related to the quality of the data involved or other technical issues, the data is not given the same emphasis within the methodology.

These criteria are in agreement with the OECD requirements referenced in some comments. In addition, however, the hazard module is not dependent solely upon lists but allows the inclusion of additional data sources (databases, risk assessment reports, Safety Information Data Sheets, etc.), and requires all information including professional judgment to be well documented. The hazard assessment also uses the weight of evidence approach that allows decisions to be made when conflicting data is available. This weight of evidence approach is most protective of human health and the environment. In addition, the hazard assessment no longer assumes that a chemical is safe if there is insufficient data but assumes that a chemical is a problem unless it is evaluated for many of the criteria of highest concern. These criteria of highest concern are coordinated with the European Union Substances of Very High Concern (SVHC) protocol and the Global Harmonization System requirements. Overall, the hazard assessment requires use of the highest quality data and transparency of all information used to reach a specific conclusion related to the specific hazard under evaluation while providing the highest level of protection to human health and the environment.

2. One comment supported the inclusion of the DfE approach in the Guidance. As a governmental program, it is accessible to all and has been open to public comment and review.

Response: Accepted. The hazard assessment approach in the Guide is based upon the DfE methodology, which is why it is emphasized within this document.

3. One comment objected to the statement on page 49, “Examples such as this have emphasized the need for methodologies to compare chemicals of concern with

potential alternatives to guarantee safer substitutions.” It is simply impossible to guarantee a safer substitution and the IC2 AA Guidance should not insinuate that such a guarantee is possible.

Response: Accepted. The following language was added to the document to address this concern: *'Although it is impossible to guarantee that any chemical is truly a safer alternative, examples such as the above demonstrate the need to evaluate data currently available in order to eliminate chemicals that should not be used as an alternative which was not done in the above example. By evaluating the data available on alternatives and selecting those with the least known impact upon human health and the environment, businesses substantially reduce the likelihood of selecting a regrettable substitution.'*

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- 4. One comment stated that no provision for protection of confidential business information or trade secrets is described where information is required to be validated by an outside party.**

Response: Several concerns including CBI are outside the scope of the Guide. Although no protections were placed upon CBI, no limitations were placed upon it either. A primary principle, however, of an alternatives assessment is transparency. Although some CBI issues may be appropriate, CBI is not appropriate for some aspects of an alternatives assessment especially for hazard information. This is in agreement with other efforts such as the alternatives assessments conducted by EPA's Design for the Environment Program and the EU REACH requires all hazard information to be public available but allows restrictions on the release of risk assessment reports.

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- 5. One comment stated that the Hazard module does not concern itself with exposure. Therefore the phrase “depending on the degree of exposure,” should be deleted from the statement: “Hazard is the set of inherent properties of a substance, mixture of substances or process that, under production, usage or disposal conditions, make it capable of causing adverse effects to humans, animals and the environment, depending on the degree of exposure.”**

Response: Accepted. The phrase was deleted.

6. **One comment stated that the start of the GreenScreen discussion should not appear at the bottom of an EPA chart. It should start a new page. We recommend GreenScreen Hazard Assessment Tool.**

Response: Accepted. The document was edited accordingly.

7. **One comment stated that, as the Guidance is advancing the use of the GreenScreen, the Guidance should state the history of the GreenScreen's use, its credibility and that this is what is being recommended for the Hazard Assessment.**

Response: Accepted. Although these issues are addressed in the current document, additional language was included to emphasize these issues.

8. **The comment was made that the answer to the question 'What resources and knowledge are required to use this tool?' was not good.**

Response: Accepted. The section was simplified and this language was eliminated.

9. **The comment was made that '... inclusion of the existing chemical is emphasized but the sample chart does not include it.'**

Response: Accepted. The following language was added to the first sentence of the section: '... other and to compare the chemical of concern with potential alternatives' and the chart was corrected.

10. **Two comments were received on the issue of the information on data gaps in the Guide.**

Response: Accepted. This issue is addressed in the simplified section which refers all details to the GreenScreen website. Data gaps are discussed in detail in the GreenScreen guidance. In addition, more information on data gaps and their importance to the assessment was included in the simplified section.

11. Several comments were received concerning using the GreenScreen™ as an important part of the hazard module. Concerns centered around 1) the GreenScreen was developed by an environmental group, Clean Production Action (CPA), 2) it is a proprietary tool that is controlled by CPA and 3) there is a charge for using the GreenScreen.

Response: Each concern will be addressed separately.

1) It is true that the GreenScreen® was developed by Clean Production Action. However, it is based upon the methodology developed by EPA's Design for the Environment Program and, therefore, the fundamentals of the hazard assessment tool was developed by EPA and not CPA. In addition, CPA has coordinated the GreenScreen with other national and international efforts. It was updated to reflect the changes DfE made to its methodology in 2011 and to coordinate with efforts such as the Global Harmonization System (GHS) and the European Union's REACH legislation. Lastly the methodologies used by these sources and incorporated into the GreenScreen are a science-based, detailed and thorough evaluation of potential hazards posed by specific alternatives to chemical of concern. Based upon this information, the GreenScreen was selected as an appropriate tool to use in its hazard assessment module.

2) GreenScreen® is ultimately controlled by CPA but is available for free to any interested user; however, CPA has taken detailed steps to reach consensus among users with each improvement and change. CPA formed a Technical Advisory Committee composed of scientists from industry, government, academia and environmental groups to discuss and approve any suggested change to the GreenScreen®. CPA also discusses any potential change with certified GreenScreen profilers who conduct GreenScreens for interested companies. As the GreenScreen is not changed without detailed discussion and consensus from these and other reviewers, CPA has taken steps to guarantee the continued quality of the GreenScreen.

3) There is no cost to the use of GreenScreen® as long as no attempt is made to use the GreenScreen benchmark to market any chemical, product or process. Many organizations have made use of the GreenScreen® including companies such as Hewlett Packard, associations between environmental groups such as the Green Chemistry and Commerce Council and BizNGO, and state governments such as Maine and Washington, among others. All of this work was done without any fee to CPA for the use of the GreenScreen®. CPA, however, has become concerned about possible misuse and abuse of the GreenScreen®. For example, an alternatives assessment was submitted to the State of Maine assigning a Benchmark 3 to Bisphenol A because there was no exposure. The GreenScreen® is a hazard assessment tool and does not include any consideration of exposure in assigning a benchmark to a chemical, product or process- a misuse of the GreenScreen® methodology. To address this concern, CPA took the action of trademarking the GreenScreen to prevent abusers from using it to sell chemicals, products or processes using an inappropriate benchmark score. If an assessor plans on using the marketing of a chemical, product or process using the

GreenScreen benchmark score, the assessor must subject the GreenScreen® assessment for an independent, third-party review to guarantee that the assessment was done correctly. There is a fee for this review. The Guide recognizes these concerns and included this level of review only in the highest level in the hazard module. Someone using the guidance likely would not select this highest level unless it is planning on using the GreenScreen benchmark to market its chemical, product or process. For these reasons, using the GreenScreen as one of the hazard assessment tools is appropriate.

12. A comment was received questioning why the Quick Chemical Assessment Tool (QCAT) developed by the Washington Department of Ecology was not discussed in the Hazard Module.

Response: Accepted: The QCAT was originally one of the three screening tools used in the hazard module. In the updated module, however, the QCAT has been used in the new Level 1 of the updated module.

13. Several comments were received suggesting that rather than hazard, the primary focus of the guidance and the hazard module should be risk. Several comments indicated that the hazard should be considered along with exposure as the hazard of a chemical, product or process is not a major concern if there is no exposure to the toxic chemical.

Response: The Guide emphasizes the differences between an Alternatives Assessment and a Risk Assessment. A Risk assessment attempts to determine if there is any risk from a chemical based upon assumptions about exposure. An Alternatives Assessment seeks not to assess risk but to reduce risk by selecting the alternative with both the lowest hazard and the lowest exposure potential. For this reason, the Guide concentrates on selecting those alternatives with the lowest hazard. The assessment includes other factors such as performance and cost and availability as hazard is not the only factor in whether or not an alternative can be used to a chemical of concern. Assumptions about exposure, however, can underestimate the risk associated with the continued use of toxic chemicals and as indicated by the National Science Foundation, new tools are needed to address the problems associated with chemicals of concern in products. An alternatives assessment is one of these new tools and should not be confused with a risk assessment. In addition, as the Guide considers both hazard and exposure in separate modules, it emphasizes risk and risk is an important component of any alternatives assessment. The emphasis though is upon selecting chemicals that pose the lowest possible risk to human health and the environment and not to justify the continued use of toxic chemicals.

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- 14. Two comments were received related to the complexity of the GreenScreen. One commenter, although supportive of the GreenScreen, suggested having a level below the GreenScreen to facilitate implementation of the hazard assessment. The second commenter suggested referring directly to the information on the GreenScreen website thereby reducing the amount of detail in the guidance.**

Response: Accepted. Changes have been made to include an assessment methodology developed with smaller businesses in mind. Although the protocol (the Quick Chemical Assessment Tool) is not as comprehensive as a Green Screen assessment, it does enable companies to identify whether or not a problem exists based upon a limited number of hazard criteria from a select number of data sources. The hazard module has also been changed to refer directly to the source material without copying portions into this guidance. This allows changes to the source material to be immediately available to guidance users.

- 15. One comment suggested merging sections 6b and 20b.**

Response: Accepted. All hazard information has been condensed into a single chapter.

- 16. Several comments suggest that the hazard module needed to be simplified and was overly emphasized compared with other modules in the guidance team.**

Response: Accepted. The hazard module has undergone extensive review and simplification. As indicated in the one specific comment, the module spanned 72 pages. The updated module consists of 18. In addition, concerns were raised that the GreenScreen might be beyond the capability of some smaller companies. As part of the simplification, the screening tools were condensed into one and a simpler evaluation tool was used as Level 1 in the updated module to address these comments.

- 17. A comment was received ‘Where a more extensive assessment is required by the GreenScreen tool, the approach used incorporates endpoints selected by the State of California. It is likely that other states may not be content to rely on this state-specific guidance, potentially resulting in a patchwork of AA approaches: the very situation this cooperative draft Document was intended to prevent.’**

Response: Individual states may select different ways of doing an alternative assessment. As indicated earlier in the Guide, it was not the intention of the Guide to provide only one way to do

an alternatives assessment. Different states may have different priorities and legislative requirements. Therefore, it was necessary to have sufficient flexibility within the Guide to address these issues. For this reason, there are three different decision methodologies and each module has several different levels. Individual states can select from this array to identify what is appropriate for their state. For example, the additional California hazard criteria are important for some members of the Team. However, as indicated in this comment, these added hazard criteria may be beyond what other states would include in an alternatives assessment. It was for this reason that they were included in the highest level leaving two other levels. One important distinction, however, is that the Guide provides recommendations on what comprises a minimal alternatives assessment and have established a foundation upon which the states might vary depending upon their concerns or legislative directive.

18. One commenter suggested changing the title of the module to ‘EPA Pioneered Hazard Assessments.’

Response: Declined: Information was added to the module stressing the origin of the hazard module is based upon EPA methodologies. However, the specific tools included are an adaptation of the EPA methodology and to place EPA in the title of the module may be misleading to some users.

19. Two comments were received about the importance of including worker health and safety issues in the Hazard Module. One stated that the hexane example supports the inclusion of consideration of workers in the Hazard or Exposure modules, not in the optional Social impact module. The second suggested that worker health and safety issues be included in the Hazard Module while the Social Impact Module ‘... consider broader community impacts and workers involved in other capacities.’

Response: Worker health and safety is included in the hazard criteria. One of the hazard criteria used to assess hazard in the module is acute mammalian toxicity and workers are often the individuals for which acute exposure is often of greatest concern. In addition, many of the chronic effects such as cancer, mutagenicity, systemic toxicity, etc. are applicable to worker health and safety issues. For this reason, worker health and safety is included in the hazard module. The Social Module includes further emphasis upon broader worker health and safety issues and should not be construed as a lack of emphasis in the hazard module. Lastly, concern has been expressed that worker health and safety is not sufficiently emphasized in the GreenScreen benchmarking process. Clean Production Action has indicated a willingness to work with the technical advisory committee to address this issue in future revisions of the GreenScreen.

20. Several comments were received from one reviewer concerning language used in the module, questions about meaning behind various phrases and details related to the information presented. The reviewer also provided suggested changes.

Response: Accepted. The hazard module has undergone extensive editing and simplification. The suggested changes are addressed in these edits.

21. A comment was received from one reviewer that ‘... wherever possible, experimental data is used to evaluate hazard.’

Response: The Hazard Module is based upon the process established by EPA's Design for the Environment (DfE) program and DfE establishes protocols that places emphasis on experimental data over modeled data or professional judgment. DfE establishes that non-experimental data are used only when scientifically valid, peer reviewed data is lacking. These protocols have also been adopted into the GreenScreen® and Quick Chemical Assessment Tool (QCAT) methodologies. Therefore, the Guide supports the use of scientifically valid, peer reviewed experimental data over other forms of data and no change to the module is needed.

Cost and Availability Module

1. **Several comments were received expressing concerns that the five levels of assessment are too complex, there is significant overlap between levels and recommended merging Sections 6c and 20c.**

Response: Accepted. The Guide has been extensively edited.

2. **One comment stated: “While the first two levels could be performed by an individual or small team, the higher levels would require significant time, resources and expertise that would rapidly exceed the capacity and needs of many companies. We recommend the IC2 AA Guidance explicitly indicate the indicated scope and target audience of each level. In addition, it would also be beneficial to include a decision tree to clearly indicate which levels are required, when they are required, the level of expected expertise, information requirements and level of effort.”**

Response: It is up to each assessor to decide the appropriate level of analysis for their alternatives analysis in this module as long as the decisions are described and justified and the decisions meet the objective of an alternatives assessment, i.e. the replacement of toxic chemicals with safer alternatives. In addition, the Guide is not a regulation but a flexible guide to be used by a wide range of users on a voluntary basis, there is not a "required" level.

3. **Two comments stated that Levels 2 – 5 were too complicated to be used by business and recommended that only a simplified version of Level 1 be included.**

Response: The Identification of Alternatives Modules establishes a broad universe of alternatives, but allows assessors to make some broad decisions about what can or cannot be evaluated. As long as the decisions can be explained and justified, it is possible to narrowly focus alternatives assessments to the most favorable alternatives. The apparel industry has undertaken an excellent collaborative effort that should greatly assist companies in the sector both in identifying potential hazards (and how to avoid them) and identifying viable alternatives - the AFIRM toolkit. Collaborative efforts of these kinds by industry associations can dramatically reduce the burdens on individual companies and point to reasonable low resource solutions.

4. **One comment was received that “consideration of product use and exposure potential is an essential factor for any chemical or product evaluation. The IC2 AA Guidance document segregates the assessment of exposure and hazard, even though it is common practice to consider both aspects when assessing the safety of a material or substance.”**

Response: These issues have been addressed in other comments and one is referred to comments on either the Hazard Module or General Comments sections for more information.

5. **The comment was received that ‘The purpose of this module is to evaluate the cost and availability of potential alternatives for consideration in the AA process. Many alternatives that appear feasible may either be cost prohibitive or not available in sufficient quantities to remain a viable alternative. Any alternative that cannot be found both in adequate quantities, with limited likelihood for an increase in production, should be identified and potentially eliminated from consideration as a viable alternative. We believe this section is comprehensive and addresses the key issues of cost and availability.’**

Response: The IC2 appreciates the input and positive feedback.

6. **Two comments noted the inclusion of both internal and external costs and life cycle thinking in the module and suggested adding definitions and explanations for these concepts.**

Response: Definitions of Externalities and Internalizing Costs will be added to the Glossary. Life cycle thinking is a key factor for any full alternatives assessment; while the document specifically lays out life cycle thinking in a separate module, it is a natural component of all the modules. In addition, life cycle costing and social life cycle considerations were included within the individual modules rather than putting it all in the Life Cycle Module. This decision was made because although the life cycle costing and social life cycle are important parts of life cycle thinking, they are important for consideration in case an assessor decided not to conduct a full life cycle assessment. Changes have been made to the Guide transferring these issues back to the LC Module.

7. **Two comments noted that environmental and human health costs can be difficult to quantify and suggested additional guidance be provided.**

Response: Extensive documentation on quantification methods for such cost/benefit analyses is provided in the references at the end of the Cost and Availability Levels section. For example, EPA's Guidelines for Preparing Economic Analyses includes extensive sections on analyzing costs, analyzing benefits, mortality risk valuation estimates, accounting for unemployed labor in benefit-cost analyses, etc. This level of analysis is not expected to be a common component of many alternative assessments, but the references and information are available for companies that wish to use it for their evaluations.

8. **The comment was received that ‘The Document states that concerns related to human health and environmental costs include information on potential costs of externalities associated with emissions from raw material extraction or processing, from the transport, storage, use and disposal of chemical or materials. The Document further directs the assessor that it is important assess how many people are exposed or if some groups of people are exposed more than others, or if certain environmental sectors are impacted more than others.’**

Response: The assessor may want to include comparative costs in their analyses.

9. **Several comments noted the difficulty and expense of generating macroeconomic data, as well as projected social and health costs.**

Response: Broader macroeconomic trends are certainly important for companies to consider as components of all of their business decisions and strategies, whether related to current products or any new product development or product modification -- and whether or not the impetus for development of a new product is outcome of an alternatives assessment. An assessor can choose whether or not to include this level of analysis in their cost assessment. It is unlikely, however, for this level of analysis to be appropriate or necessary as a cost component of an alternatives assessment and including this level of detail is contrary to the objective of providing Guide to a wide range of users with varying level of knowledge and expertise. The assessor has the ability to address these issues in an AA as long as the decisions are explained and justified and the decision supports the overall objective of an AA, i.e. the replacement of toxic chemicals with safer alternatives.

10. **Two comments noted that companies regularly incorporate disposal, recycling and reuse considerations into product design either through voluntary efforts or regulatory mandates. Existing efforts to address environmental aspects of a product and/or stewardship plans which are already in place need to be taken into account.**

Response: Many companies have made major strides in stewardship to ensure reduced end-of-life impacts from their products (e.g., recovery and reuse of materials, use of recyclables, takeback programs, etc.). But it is also the case that toxic chemicals continue to be used, large amounts of waste are generated and disposed of, and many companies have opportunities to reduce these impacts through product re-design and alternative materials. So this remains a valuable area for companies to consider as part of an alternatives assessment.

- 11. One comment stated: “We agree with the recommendation to include experts in the field of environmental and health economics to better distinguish between individual or societal costs. It should also be mentioned that many health costs are already accounted for under existing health care and insurance costs on a societal basis (smoking, seat belt use, broader actuarial estimates) and care must be taken to minimize duplication of efforts or overestimation of costs. It should also be considered that there may be tax incentives (or disincentives) and other governmental programs that can serve a market function and impact societal costs.”**

Response: Some of these factors, when appropriate and applicable, may be considered in a cost assessment; however, the assessor has the ability to decide the scope, level and issues addressed in a cost assessment and inclusion of these issues in the Guide might suggest that they need to be considered during all cost assessments. Therefore, the Guide will retain flexibility by allowing the assessor to determine the extent of the cost assessment that might be appropriate for the chemical, product or process under evaluation as long as all decisions are explained and justified and the ultimate goal of the AA is met, i.e. the decisions are explained and justified and toxic chemicals are replaced with safer alternatives.

- 12. One comment stated: “We are very concerned that Level 1: Basic Cost and Availability Assessment of Alternative Chemicals encourages users with limited knowledge and expertise to perform the assessment and appear to provide minimal benefit. Having someone with limited knowledge and expertise perform an inadequate evaluation opens the door to regrettable substitutions and/or significant redundant effort. For example, first-time and inexperienced users would benefit from a discussion of the implications of patent protected or otherwise unavailable chemicals. In some cases, an alternative may not be available because its use is protected by patent or other restriction on its use by the manufacturer. As noted in other modules, rarely do one-for-one alternatives exist and there are important considerations beyond cost and availability that must be considered concurrently to ensure that a potential alternative is compatible, efficacious and viable. This limitation should be explicitly stated. The**

module also relies on the implicit knowledge and expertise of the supplier which is a variable not considered within the evaluation.”

Response: Level 1 only calls on companies to consider the availability and cost of potential alternatives being used in the market, which should be well within the capabilities of most firms. In addition, the Guide was created to be applicable to a wide range of users including those with limited knowledge and expertise. Although there may be some legitimate concerns associated with issues identified in the comment, it is unlikely that most of these would be relevant for a basic cost and availability review. For example, if there are patent restrictions, these issues would be known to the suppliers upon whom the assessor would depend for relevant information. If the assessor believes a more detailed cost and availability assessment is necessary, it should be considered in the scoping of the AA. However, most businesses routinely consider cost and availability in their daily decisions and, if these issues do not currently pose a problem, they are unlikely to do so in any AA.

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- 13. Several comments stated that return on investment should be included as a consideration in the cost and availability module and that complex economic trade-offs should be considered. One comment objected to the inclusion of externalized costs as not typical of cost evaluations.**

Response: Companies may want to consider many of these factors, where appropriate, in their evaluation of the costs of an alternative. But, as the comment points out, the extent to which such analysis is needed will depend "on the size of the project and complexity of the product." Relatively few alternative assessments will require inclusion of costs for a Premanufacture Notice (PMN) under TSCA. It is up to the assessor to determine both the scope of what can reasonably be considered as a viable alternative and the level of cost analysis required. An assessor would, of course, always want to ensure that use of a possible alternative would not lead to a regulatory violation, and incorporate potential regulatory compliance costs, where applicable, into the cost analyses.

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- 14. A comment was received that ‘the inclusion of the cost and availability module in the AA guidance. Again, we recommend that the guidance consider evaluation of cost and volume available of potential alternatives as part or in conjunction with the identification of alternatives module..**

Response: The IC2 appreciates the input. Cost and availability is identified as one of the four modules recommended as minimum content of an alternatives assessment. The issue of volume is also included in the current module structure.

Exposure Assessment Module Comments

1. **Several comments were received that ‘... exposure potential is an essential factor for any chemical or product evaluation.’**

Response: Exposure plays a role in an alternatives assessment. An alternatives assessment, however, is not a risk assessment and does not attempt to duplicate that process. The alternatives assessment process does not assess risk as is done in the traditional risk assessment process. It attempts to reduce risk by emphasizing the importance of reducing hazard and is a new and novel approach to addressing consumer concerns with the continued use of toxic chemicals in consumer products. As identified by the National Academy of Sciences in a recent report on Sustainability, *'4.6. Finding: Risk analysis as commonly applied to environmental issues often does not adequately account for the full range of human health and ecosystem risks, including cumulative risks, intergenerational considerations, and the distribution of risks among population groups. In addition, better methods are needed to support consideration of health and environmental effects for the green chemistry goal of safer products and more sustainable chemical usage (p.60).'* (www.nap.edu/catalog.php?record_id=13152). Alternatives assessment is one of these new tools and is addressing toxic chemical concerns by emphasizing hazard and reducing hazard in the selection of alternatives to toxic chemicals used in products or processes .

2. **Several comments were received suggesting condensing the levels down to three, making changes and clarification to wording used and to merge two of the portions of the Guide related to exposure.**

Response: Accepted. The Exposure Module has been extensively edited. These issues were addressed in the edits.

3. **A comment was received that stated ‘Both near field (direct consumer) and far field (environmental) exposures are considered. Workers involved in production and workers using the product must be considered in the Near Field category here.’**

Response: Worker health and safety is an important component of exposure and it is valid to include it in an all exposure assessments; however, an exposure assessment should consider all aspects of a chemical, product or process including worker, transport, accidental release, use, and end of life. No component should be emphasized unless the decision is made and justified in an alternatives assessment why some route of exposure is not applicable. Some routes, however, such as worker, use and end of life are important for all chemicals, products or processes and constitute a minimum of what should be considered in an exposure assessment.

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4. **A comment stated ‘The Document does not recognize established principles of toxicology and public health when it fails to consider the concept of de minimis concentration of a COC in a product and whether this affects the need for an AA. A 0.1% de minimis threshold is consistent with REACH, as well as other significant national and international regulation concerning public health and product safety.’**

Response: The Guide does not establish a de minimus level. The use of any standard value such as 1,000 ppm (0.1%) does not consider the potential impact chemicals have upon human health and the environment. For example, 1,000 ppm may be adequate for some chemicals; however, for others such as endocrine disrupting chemicals, 1,000 ppm may be an unacceptable level of exposure. Therefore any level should be tied to the impact a chemical has and should consider the full life cycle impact of a chemicals use and not just its use in specific products or processes. This is particularly true for PBT chemicals that will impact human health and the environment for decades to come.

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5. **A comment stated ‘... exposure considerations and bioavailability are specifically NOT permissible as a means of allowing continued use of a COC. Sophisticated manufacture and recycling practices, for example, play a critical role in whether there is a potential for exposure (i.e., the chemical is actually available for exposure). This should definitely be taken into consideration earlier and throughout the assessment.’**

Response: Exposure considerations and bioavailability are both considered in the Guide in the exposure and hazard modules, respectively. Bioavailability is one of the factors used to identify preferred alternatives. However, alternatives assessment as described in this document is designed to reduce risk by reducing hazard. Exposure reduction should be used to reduce risk by improving a product only after selecting the least hazardous option(s). Exposure controls alone should not be used to justify the continued use of toxic chemicals as they do not consider the full life cycle exposure potential of the toxic chemical and can be inadequate in protecting human health and the environment from exposure to toxic chemicals.

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6. **Three comments were received indicating that exposure and hazard should be considered together and not separately as ‘Alternatives assessment must be risk-based, taking into account both hazard and exposure to ensure that products are safe. The IC2 AA Guidance fails to acknowledge this critical nexus, eliminating any value that the guidance might otherwise have.’**

Response: The alternatives assessment process does not assess risk as is done in the traditional risk assessment process. It attempts to reduce risk by emphasizing the importance of reducing hazard and is a new and novel approach to addressing consumer concerns with the continued use of toxic chemicals in consumer products. As identified by the National Academy of Sciences in a recent report on Sustainability, '4.6. *Finding: Risk analysis as commonly applied to environmental issues often does not adequately account for the full range of human health and ecosystem risks, including cumulative risks, intergenerational considerations, and the distribution of risks among population groups. In addition, better methods are needed to support consideration of health and environmental effects for the green chemistry goal of safer products and more sustainable chemical usage (p.60).*' (www.nap.edu/catalog.php?record_id=13152). Alternatives assessment is one of these new tools and is addressing toxic chemical concerns by emphasizing hazard and reducing hazard in the selection of alternatives to toxic chemicals used in products or processes.

- 7. Several comments were received related to 'Consumer Product Use-Phase Ingredient Exposure Assessment: Determining human exposure to an ingredient in a consumer product is a relatively straightforward exercise of determining exposure to the product and knowing the ingredient concentration.'**

Response: The information process described in these comments is part of the risk assessment process and is not applicable to an alternatives assessment. See earlier comments on hazard, exposure and risk.

- 8. A comment stated: 'A fundamental difference between the IC2 approach and the Industry approach to chemical assessment is that IC2 judges chemicals and Industry judges chemical uses. Since there are hazards associated with every chemical but risks can only be determined based on use, it is incumbent upon manufacturers to assess the risks associated with the use of any particular chemical.'**

Response: By emphasizing the use of the least hazardous alternatives, the alternatives assessment process limits the type and amount of exposure controls needed. The ultimate objective of an alternatives assessment is the selection of alternatives that pose the same level of risk as water, which does not cause cancer, birth defects, does not mutate cells, etc. By emphasizing the least hazardous alternatives, the number and scope of exposure controls are considerably reduced with a greater chance of success.

9. **A comment stated that ‘While biomonitoring data may be helpful as supplemental information, it is well-established that the presence of a chemical in biomonitoring studies does not necessarily indicate there is a likelihood of harm.’**

Response: The presence of a chemical found in biomonitoring studies does not necessarily indicate harm. However, presence does indicate exposure and, coupled with a hazard assessment, provides valuable information on alternatives to toxic chemicals that should not be considered. For example, if an alternative is found in the hazard assessment to be toxic and is found in biomonitoring studies, it is shown that people are exposed to toxic chemicals.

10. **A comment on Additional Exposure Considerations with Respect to Alternatives Assessment stated: ‘It is important to note that all factors, not limited to simply exposure, must be considered together. Intended use would identify relevant exposure pathways worth evaluating further for relevant human health and environmental impacts. Exposure is also considered throughout the lifecycle of the product, evaluating risk at each stage (e.g., occupational).’**

Response: The objective of an AA is to identify safer alternatives to toxic chemicals that have both lower hazard and lower exposure potential and thereby lowering risk to human health and the environment.

11. **Numerous comments were received about the use of specific wording in the module and recommended changes to clarify the intent of the module.**

Response: Accepted. The module has been extensively edited and the comments received were addressed in the edits.

Materials Management Module Comments

- 1. A comment stated: “...this module be eliminated completely. The key topics in the SMM module could be incorporated directly into the Life Cycle Thinking module...”**

Response: Top level elements of the Materials Management Module (M3) module were incorporated into the third level of the Life Cycle (LC) Module; lower levels were modified to discriminate between products only. Lastly, the Guide was written with the intent of being useful to a wide range of users including small and medium businesses that may not be familiar with Sustainable Materials Management (SMM) and other concepts. Therefore inclusion of SMM principles throughout the Guide would adversely impact its ability to be useful to a wide range of users. The M3 module is also not one of the four recommended as a minimum and may not be part of many simpler alternatives assessments.

- 2. A comment suggested merging sections 6e and 20e.**

Response: Accepted. The Guide has been extensively edited to address this issue and others received as comments.

- 3. A comment stated that ‘this module is too narrowly focused and should be more broadly constructed.’**

Response: The scope of this module has been more clearly defined. It is now applied to products and elements of materials management including SMM were incorporated into the third level of the LC Module.

- 4. A comment was received that ‘...this section be considered a work in progress and that companies, especially small and medium-sized companies, be advised that this is not an essential component of the current AA process.’**

Response: This module is optional and is not one of the four recommended as a minimum for an alternatives assessment. As an optional module, it is unlikely that small and medium businesses will use the higher levels if at all. The module was revised to clarify the conditions under which it is best used (i.e. for products and not necessarily at chemical substitution level).

5. **A comment was received that ‘...energy and climate change can be better addressed without overwhelming the fundamental purpose of AA.’**

Response: Agreed. The issues of energy, climate change, etc. are considered as part of the Life Cycle Module.

6. **A comment was received that ‘...The materials management module requires product stewardship of recycled materials.’**

Response: M3 does not require product stewardship but rather addresses how chemical material and product design choices affect natural capital and waste; product stewardship is a strategy that may or may not have material management benefits.

7. **A comment was received that ‘...Sustainable Materials Management (SMM) should look at more than end of life issues such as recycling or reuse... While recycling is certainly a desirable attribute, often source reduction aspects (light weighting, down gauging) in the front end of the design have a bigger impact on lowering solid waste impacts to the environmental than recycling.’**

Response: Agreed. Assessment should help determine benefits of different designs. In addition based upon other comments received, the Sustainable Materials Management (SMM) portion of the Materials Management Module (M3) was transferred to Level 3 of the Life Cycle Module as comments indicated a, more detailed evaluation is better conducted as part of a life cycle assessment.

8. **A comment stated that ‘...Materials Management Module (MMM) is too narrowly focused based on the idea that products can be only “designed with the end in mind” (i.e., end of life issues).’**

Response: The scope and intended use of the M3 has been revised to ensure that the narrow focus is applied when appropriate.

9. **A comment was received that ‘...SMM should take an integrated and systematic approach to evaluating material flows and the associated impacts.’**

Response: Agreed. Based upon this comment and others, Sustainable Materials Management (SMM) was transferred to level 3 of the Life Cycle Module and has been included in a life cycle assessment.

10. A comment was received that ‘...social equity principles, however, are not as well established with the same degree of scientific quantification as the life cycle environmental measurement approach.’

Response: Social equity can be addressed in the Preliminary LC module and in the Social Impact Module.

11. A comment was received that ‘...the life cycle approach should be applied for all impacts, including sustainable feedstocks.’

Response: Agreed. Based upon this comment and others, SMM was transferred to level 3 of the Life Cycle Module and will be included in a life cycle assessment.

12. A comment raised concerns that ‘...the focus of the MMM on feedstocks, dematerialization and design for value recovery is fairly narrow, and instead should be the result of the broader SMM and life cycle approach that analyzes these and measures any unintended consequences of focusing solely on feedstocks and “dematerialization” and design for recovery only.’

Response: The evaluation of impacts should help to clarify if there are benefits from recycling or design for degradation strategies. In addition, based upon this comment and others, SMM and more detailed evaluation of M3 issues were transferred to level 3 of the Life Cycle Module and will be included in a life cycle assessment.

13. A comment was received that [Sustainable Materials Management] ‘SMM...be covered under the application of Life Cycle Thinking module, which better reflects the concepts of SMM.’

Response: Significant changes have been made to the module that addresses this comment and others. The advanced level of M3 is now included as part of the LC Module.

- 14. A comment was received that ‘The SMM principles seem to better be covered under the application of Life Cycle Thinking module.’**

Response: M3 and life cycle are clearly closely related. The challenge is that life cycle impacts are so broad and can apply to materials, energy, social, impacts, costs, etc. It is difficult to tease out all of the potential overlap. Revisions to M3 should help clarify differences. In addition, based upon this comment and others, SMM was transferred to level 3 of the Life Cycle Module and will be included in a life cycle assessment.

- 15. A comment was received that ‘...the AA is a micro tool to examine a product-level problem. Whereas, the materials management approach is a macro approach to systems-level global supply chain, identifying and mapping all raw materials and wastes across the globe.’**

Response: Agreed. The module was revised to be more consistent in structure with the other modules and the scope of its intended use was revised.

- 16. A comment was received that ‘...The AA should not discourage beneficial recycling efforts. The Materials Management Module requires product stewardship of recycled materials... [and] ... product manufacturers do not have control over how free-enterprise recyclers operate and are not in a position to “police” them.’**

Response: Agreed. Assessment should help determine benefits of different material options and product design. Product manufacturers, however, do have control of how their products are created and what is used in their products. While making these decisions, it is important to consider M3 issues in order to make the final product more attractive to recyclers. The intent of the alternatives assessment is not to ‘...discourage beneficial recycling efforts...’ but to emphasize the importance of product decisions that can encourage recycling.

- 17. A comment was received that ‘...energy and climate change can be included without overwhelming the fundamental purpose of AA.’**

Response: Energy and climate change are included in the Guide and are part of the Life Cycle Module.

18. A comment was received that ‘...supports the inclusion of the Materials Management Module in the AA Guidance.’

Response: The IC2 appreciates the input and positive feedback. The M3 Module is an optional module and can be included in any alternatives assessment at the discretion of the assessor. However, as indicated in an earlier comment, there is concern that the issues described in the M3 are beyond the capability of small and medium businesses; therefore, it will be left as a recommended module in the Guide. Individual states, however, may decide to include the M3 as a required module and this decision will be left to individual states.

Social Impact Module Comments

1. **One comment stated: “Social Benefits and Consumer Acceptance Inherent in the demand for the products are social benefits. Delivering these social benefits are among the performance assessment requirements that must be included in the evaluation of any alternatives. The consumer expects the alternative product to meet real and perceived benefits. Environmental justice is a concern of the manufacturers of products that might be subject to alternatives assessment. Substantiation of an environmental justice benefit must be based on a comparison of any alternative against the base case product for any future manufacture and sale. Sourcing from a part of the world that may be flagged as “conflict materials” or experiencing a “civil war” – is a social justice concern. There are even some jurisdictions that do not invest in certain parts of the world. There are known and positive social values associated with products on the market. People are using these products for clear benefits; otherwise there would be no market for the products. Maintaining existing product benefits, for example public health benefits such as hygiene, are an important part of alternatives assessment. Diminishing the value of hygiene in cleaning products through substitution would be compromising public health and clearly unacceptable. The inherent benefits of a product must be carefully considered prior to embarking on an alternatives assessment. Focusing too narrowly on hazard, may pull in other real rather than theoretical concerns.”**

Response: The alternatives assessment process was developed primarily because of increased consumer concern with the use of toxic chemicals and the impact those toxic chemicals have upon human health and the environment. There have been numerous cases where toxic chemicals have been replaced with alternatives that are as or more toxic with the resultant negative effect upon human health and the environment. The primary reason for these regrettable substitutions is because manufacturers failed to investigate or were unaware of alternatives to consider hazard when replacing a toxic chemical in their products. The AA process has the expressed objective of replacing toxic chemicals with safer alternatives and the Guide provides several procedures that can be used to reach this goal. The Guide provides sufficient flexibility that many of the issues mentioned can be addressed while emphasizing the need for increased emphasis on hazard. The Guide is a useful tool for addressing the issue of eliminating toxic chemicals from products or processes.

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2. **Two comments were raised concerns that issues raised in this module are ‘...beyond the scope and control of individual companies.’ The recommendation was made to eliminate this module and incorporate it into the Life Cycle Module. If retained, it should be collapsed into two levels.**

Response: Many companies are currently working to address social & labor issues in product sourcing, manufacturing and/or use or end-of-life. The social impacts are an important component of the overall assessment. Although social impacts are an important part of any life cycle assessment, this module was created with the intent that businesses could consider social impact issues without the necessity of conducting a full social life cycle assessment (SLCA). Therefore the module creates two levels of assessment that are simpler than what is required for a full SLCA. In recognition of the importance of social issues in a life cycle assessment, the highest level consisting of an SLCA has been included in the Life Cycle Module. If a company wishes to conduct an SLCA, it is included in Level 3 of the Life Cycle Module and is not included as part of this module.

3. One comment recommended merging Sections 6f and 20f.

Response: Accepted. The Guide has been extensively edited to addresses this issue and others received as comments.

4. One comment stated: “Most alternative assessments are performed to provide benefits to the general population rather than to focus on subgroups. Therefore, the typical comparison will result in little or no change for social impacts. We agree that alternatives should be evaluated to assure there is not a disproportionately negative impact on a sub-population. However the availability of reliable data related to actual impacts on sub-population which can be used to conduct a social impact analysis presents a challenge, thus this module should not be a part of any mandatory process.”

Response: The Guide was not created as a result of any legislative or regulatory requirement and therefore is not mandatory. The Guide was developed be used on a voluntary basis with willing industries. However, while data is currently very uneven by product type, life cycle steps or regions, it is increasingly available (for example, in the Social Hotspot Database being developed as part of the social life cycle assessment project), and many companies have developed their own data during interaction with local communities and/or supply chains. In addition, there is often basic qualitative information available to companies about their supplies on obvious abuses with respect to working conditions or child/forced labor.

5. One comment stated: “We recommend Non-abusive working conditions (not just hours). Adequate training, particularly hazard communication training. Children should not be working in any situation where they are exposed to toxic chemicals.”

Response: Accepted. The recommended changes were made, with the exception that no wording was added concerning children being exposed to toxic chemicals. The Guide should not provide any implied approval of child labor by adding this language to the table.

6. **One comment stated: “The purpose of the Social Impact Module is to ensure that the AA process does not result in unduly shifting a burden from one community of people to another. It requires the evaluation of impacts of an alternative upon the workers, communities, and societies involved in its manufacture, transport, use, and disposal. Global Automakers supports the concepts in this module.”**

Response: The IC2 appreciates the comments and positive support provided.

7. **One comment stated: “The module contains worker, community, and global societal considerations that include, for example: quality of life including historical, cultural or religious priorities; quality of life including recreational activities; and corruption. Only assessment endpoints that can be quantified and supported should be used in an AA effort... Many of these concerns are outside the scope of research by product manufacturers (e.g., public health assessment). The assessment endpoints should be reasonable and within the ability of the manufacturer to evaluate.”**

Response: Access to relevant data will depend where a social issue arises. One of the central features of social thinking is the need for companies to be aware of critical issues (e.g., social, environmental, or human health) through all phases of the value chain -- whether or not the companies directly owns or manages the steps in which particular hotspots emerge. In addition, many companies have taken the initiative to review their supply chain and establish minimum requirements for companies producing their products. Considerable effort has been made by companies like Apple, Nike, etc. to evaluate the conditions under which their products are manufactured and to establish minimum social requirements. Although these efforts may be outside the capability of many small or medium companies, awareness of the issues have value.

8. **Two comments were received that ‘Many of these concerns [in the Social Impact Module] are outside the scope of product manufacturers...’ and ‘The direct manufacturer of the product is the entity that would have access to information concerning worker- or community-level quality-of-life details.’**

Response: Who is most likely to have access to the relevant data will depend where a social issue arises. But one of the central features of social thinking is the need for companies to become more aware of critical issues (e.g., social, environmental, or human health) through all

phases of the value chain -- whether or not the company directly owns or manages the steps in which particular hotspots emerge. In addition, many companies have taken the initiative to review their supply chain and establish minimum requirements for companies producing their products. Considerable effort has been made by companies like Apple, Nike, etc. to evaluate the conditions under which their products are manufactured and to establish minimum social requirements. Although these efforts may be outside the capability of many small or medium companies, awareness of the issues have value.

9. **One comment stated, “Most alternative assessments are performed to provide benefits to the general population rather than to focus on subgroups. Therefore, the typical comparison will result in little or no change for social impacts. We agree with the IC2 AA Guidance that worker, community and global societal issues are sufficiently addressed in other modules.”**

Response: The Social Impact Module states that "elements in the Social Impact Module may also be components of other modules...." But the Module goes on to say, "This module emphasizes [the] importance [of specific worker health and safety, community, and global society issues, including environmental justice concerns] in an AA and conducts an assessment beyond what might have been included in other modules."

10. **One comment stated: “This component of an impact assessment can be variously titled and vary somewhat in scope based on the product and its place in the marketplace. However, the fundamental intent is to assure that alternatives be evaluated to assure there is not a disproportionately negative impact on a sub-population. Considering such impacts during the evaluation of alternative formulas/products does require some expertise since the actual impacts from alternative exposures do demand actual alternative formulations in essentially finished form in order to conduct such a social impact assessment.”**

Response: One of the goals of the Guide is to ensure that a selected alternative does not have a disproportionately negative impact on a subpopulation and that the end result of an alternatives assessment would generate decisions with broad and more favorable impacts. Comparisons can be made between the social impacts of alternatives until all have been produced "in essentially finished form." Several companies have taken the initiative to investigate their supply chain and establish minimum expectations for companies producing their products. Although this may be beyond the capabilities of many small and medium companies, becoming familiar with the issues can have long-term positive impacts.

- 11. One comment stated: “Products that have uses with sensitive sub-populations or with differing usage patterns by some communities may signal additional concern in this area and should be addressed as part of the hazard and exposure assessments to ensure that products are safe when used as directed. However, there is an equivalent concern for products that have recognized benefit for the general population or for certain groups. Alternatives must be carefully formulated to maintain those specific benefits and there should be an opportunity to introduce cost/benefit assessments in to the selection process. We do express some concern for a “check box” approach to the lists included in this module and suggest a more qualitative approach than a detailed reporting requirement.”**

Response: A thoughtful qualitative or, where appropriate and feasible, quantitative assessment is far preferable to checkbox approach. The intent of the lists is to call attention to social issues that are consistently raised in authoritative international documents on these issues. These should be considered, as appropriate, during the assessment.

- 12. Several comments stated the importance of hazard safety and communication data sheets and compliance with OSHA regulations to mitigate worker exposure.**

Response: While hazard communication and safety data sheets play a useful role, they have limitations in the extent of the information they convey. They certainly are not designed to cover all of the issues relevant to this Module. Safety data sheets are intended primarily to address worker health and safety issues and do not include considerations of the full life cycle impacts of the continued use of toxic chemicals including transport, accidental release, disposal, etc. The data in safety data sheets and data provided to meet GHS requirements are incorporated in the Hazard Assessment and are used to identify the level of hazard associated with alternatives to toxic chemicals. Commendable though these issues are, they are often not applied in countries that manufacture many of the products currently available to consumers. The important issue, however, is to increase awareness of social impact issues and, where possible, to consider them during selection of an appropriate alternative to a chemical of concern.

- 13. One comment stated: “Social Benefits and Consumer Acceptance: Inherent in the demand for the products are social benefits. Delivering these social benefits is critical to achieving true sustainability. The consumer expects the alternative product to meet real and perceived benefits. Consideration of benefits and concerns related to social justice, environmental justice and/or other social benefits may be a factor that companies consider internally, it should not be reflected in regulations. Companies may wish to do this of their own volition internal to their processes, but it should not be part of any mandatory process.”**

Response: As noted previously, this document is not a regulation and therefore the consideration of social impacts is not required. In addition, this module is one of the three 'optional' modules and is not one of the four recommended modules that is the minimum for a quality alternatives assessment. Consideration of social impact issues however is something important for an assessor to consider during the alternatives assessment process.

- 14. One comment stated: “Social Benefits and Consumer Acceptance: There are known and positive social values associated with products on the market. People are using these products for clear benefits; otherwise there would be no market for the products. Maintaining existing product benefits, for example public health benefits such as hygiene, are an important part of alternatives assessment. Diminishing the value of hygiene in cleaning products through substitution would be compromising public health and clearly unacceptable. The inherent benefits of a product must be carefully considered prior to embarking on an alternatives assessment. Focusing too narrowly on hazard, may pull in other real rather than theoretical concerns.”**

Response: As discussed in the performance module, the goal of an alternatives assessment is to reduce product hazards without adversely impacting performance. This document certainly does not support producing 'cleaning products' that fail to clean as a desirable or acceptable outcome of an alternatives assessment.

- 15. One comment stated: “Throughout the Draft AA Guidance, the document consistently becomes more unwieldy when macro issues are introduced into the micro analysis. Nowhere is this more evident than in the Social Impacts Module which appears to want a product-level analysis to include broad studies in public health epidemiology, evolutionary anthropology, and socio-cultural trends.”**

Response: The goal of this module is to focus attention on significant issues that can be addressed in the specific context of an alternatives assessment. The assessor has the ability to define the level, intent and scope for any social impact evaluation. As the Social Impact Module is not one of the four recommended modules that the Guide indicates comprises a valid alternatives assessment, the assessor can decide, for example, that social impact issues are not applicable for the chemical, product or process under review.

Life cycle Thinking Module Comments

- 1. One comment stated that ‘Consideration of unintended impacts enables regulators and manufacturers, to have a comprehensive review of alternatives, without shifting to the unanticipated risk.’**

Response: Identifying unintended consequences should be an outcome of a life cycle evaluation allowing comparison of alternatives versus the base product. The assessor should look to emphasize impacts found in the standing narrative considering scale. Proper description of the functional unit should reflect different scales for alternatives, and result in the evaluation properly accounting for the resources and impacts upstream.

- 2. Several comments raised concerns over the lack of clarity in the module’s content. One commenter suggested collapsing the module into two levels. Another that the alternatives assessment should only evaluate those aspects directly affected by the alternative.**

Response: The Life Cycle Module contains an initial screening step that helps to evaluate what relevant factors are important for the chemical, product or process under evaluation and then provides two ways (i.e. levels) in which to address the relevant factors. The first step is intended for those companies who wish to consider life cycle impacts without conducting a full, ISO compliant LCA. The second step requires a more detailed, ISO-compliant LCA. The language, however, has been updated to provide more clarity. The intent of application of the modules is for entities to have established their decision protocol, and then to apply a rational approach for interpretation. One then digs as deep and quantifies as best as possible to the point of having confidence in the attributes being compared. The value system of the entity needs to be clearly stated and then applied for decision-making. The intent of the Guide was not to prescribe specific criteria to determine relevance or acceptable burden shifting levels as that will likely be different given the rang of actors conducting the assessment.

3. A comment suggested merging sections 6g and 20g.

Response: Accepted. The Guide has undergone extensive edits to address this and other, similar comments.

4. Several comments were received concerning the breadth of review and the relationship between life cycle thinking and material flow assessments. One commenter indicated that all decisions made should reflect a broad perspective of the full life cycle of the product. Several commenters stressed the importance of material flow assessments. One commenter indicated 'A material flow assessment approach to product development is the key to developing sustainable products.'

Response: These issues can be considered as part of a life cycle review. However, the Guide was constructed to give assessors the ability to address these specific issues outside of the more complicated life cycle review as identified in the Life Cycle Module. The Guide, however, has been edited to refer the more advanced review of some of these issues to the LCM.

5. Two related comments were received. The first was that any life cycle evaluation should be done at the end of an alternatives assessment and that the module as written is overly prescriptive and implies that every AA requires a life cycle assessment. The second was an AA should only evaluate those aspects directly affected by the alternatives.

Response: The Life Cycle Module was constructed to allow a more quantitative life cycle review (Level 1) than required by a more complete LCA (Level 2). In addition, the LCM includes a initial screening step that specifically concentrates subsequent reviews only on those '...aspects directly affected by the alternative.' Therefore the Guide currently addresses these comments.

6. A comment stated support for ' the concepts in this module but suggests that trade-offs found in the life cycle of a product may complicate the decision process unless guidance exists that addresses how to consider trade-offs.'

Response: The Decision module gives guidance for decision process including allowing the assessor to determine the weights to assign to all criteria including those identified in the LCM as long as the weighting supports the goal of an alternatives assessment, i.e. the replacement of toxic chemicals with safer alternatives. The assessor in the final assessment identifies what

decisions were made and justifies those decisions. Transparency is an important component of the alternatives assessment process.

7. **Two comments were received that, although supportive of the module approach, were concerned about cross over with other modules. One commenter stated ‘Substantial overlap with other modules exists (Cost and Availability, Social Impact or Materials Management Modules).’**

Response: In response to several comments received, the more complicated portion of modules such as cost and availability (cost benefit analysis), social impact (social life cycle assessment) and materials management (sustainable materials management) were removed from those modules and placed in Level 2 of the Life Cycle Module. Although this indicates that these issues (cost, social impact and materials management) are components of an LCA, they still retain some simplified components in their own modules for use by assessors who still wish to consider these issues without conducting any life cycle review.

8. **A comment was received that ‘Detail concerning boundaries on the assessment approach is needed. Endpoints for consideration are often qualitative and non-specific; only assessment endpoints that can be quantified and supported should be used in an AA effort. If these endpoints are to be given the same weight as other modules in the assessment framework, similar quality of effort should be expended to characterize the assessment approach.’**

Response: Boundaries should include what is relevant to the comparison. One should not remove unquantified aspects just because there is no data as this poses a serious risk to the quality of effort. This does not relate to weighting, but relates to uncertainty. Language has been added to the module to address these issues.

9. **Several comments were received suggesting that specific standards be added to the module, standards such as ISO 14040, life cycle costing ASTM, etc.**

Response: Accepted, where appropriate. Language has been added to provide more reference to ISO, ASTM and other appropriate methodologies. Additions were limited only to those methods that appropriate for the process included in this module.

- 10. Two related comments were received that ‘... LCA as defined under ISO is appropriate for this LCT module.’ and ‘... LCA reference to ISO 14040 is good.’**

Response: The IC2 appreciates all comments provided by stakeholders during the creation and review process.

- 11. One commenter ‘... agree[s] a natural progression for life cycle thinking would include scoping LCAs, all the way up to determining whether a full LCA is needed.’**

Response: The Guide was developed with the intent of providing guidance to a wide range of users including small and medium businesses. Therefore a concerted attempt was made to provide a range of alternatives with increasing complexity. The Life Cycle Module was created to provide the ability for assessors to consider the life cycle impacts without conducting a full LCA. Therefore the LCM structure allows life cycle issues to be considered (life cycle thinking) qualitatively without the need to conduct a full LCA. In addition, the LCM is not one of the recommended modules although there are benefits to a life cycle review. Therefore, it was not the intent to require a full LCA if an assessor is interested in life cycle impacts. The LCM was not written to determine whether a full LCA is needed but to further life cycle considerations without requiring a full LCA.

- 12. Two comments were received noting that a Social Life-cycle Assessment (SLCA) is outside the current scope of the ISO 14040 LCA standards.**

Response: Accepted. Language has been added note the SLCA reference and indicate it is separate from 14040; however, the Guide still recommend that assessors use that framework in conjunction with the ISO standard.

- 13. A comment was received that the three levels in the Life Cycle Thinking module could be simplified by referring to the different types of LCAs under ISO.**

Response: Although this language is appealing, the Life Cycle Module is attempting to allow a step even lower than what is indicated as a 'Scoping LCA'. Level 1 is intended to be a more quantitative, thought provoking process and requires little quantitative data. Language has been added to the Guide so assessors can better understand how these ISO breakdowns can be used in an alternatives assessment.

14. A comment was received that the ‘... glossary is good.’

Response: The IC2 appreciates all comments provided by stakeholders during the creation and review process.

15. A comment stated that ‘As a life cycle approach is used in the material flow assessment, the review of material flow must be adjusted to a performance equivalent basis.’

Response: This comment relates to the equivalent functional unit concept, which is included within the current Guide. No changes to the Guide are necessary.

16. Two related comments were received that emphasized the importance of life cycle assessment but expressed reservations that the ‘... Life cycle Thinking Module appears to be afterthought...’ the recommendation was to include life cycle considerations in the initial evaluation and scoping of an alternatives assessment and that many of the other modules can be captured in the larger LCA scope.

Response: One challenge related to the Guide was how to incorporate life cycle thinking into the alternatives assessment. Life cycle concepts can improve the quality of the decision made about alternatives to toxic chemicals but is still a developing technique and is not easy for many companies to consider. In addition, the alternatives assessment process is specifically created to help businesses identify safer alternatives to toxic chemicals. Therefore although a life cycle assessment may consider many of the criteria included in other modules, the other six modules have been kept separate to concentrate on the benefits each brings to the AA process. In addition, life cycle is applied in the Guide to support the overall objective of an alternatives assessment, i.e. find the safest alternative to and not to justify the continued use of toxic chemicals. These issues should be kept in mind while alternatives are assessed.

Webinar Questions and Responses

The following is a transcript of the questions and responses from two webinars conducted by the Technical Alternatives Assessment Guidance Team lead, Alex Stone. The webinars took place on August 15th and November 28th, 2012. The questions and responses are included here directly from the transcript without any edits or corrections.

Webinar #1:

Question 1: What are the main challenges that the group has encountered associated with the life cycle considerations module?

Response: The main challenges and I alluded to some extent; the life cycle assessment is still early on, so there's been a lot of work done, particularly in the European Union about it, but most of the guidance and if you look at the ISO 1440 Guidance as well, it's a very long and involved and complicated process. And I think the biggest challenge that we had was to try to establish some levels for smaller and medium sized businesses and people that perhaps not as familiar with the life cycle assessment prop as maybe people who were more heavily into it because then I think you saw in our golden objectives it's very important for us that we provide guidance that's flexible to meet need of a wide range of users and we did not want to have a life cycle module that then added a huge level of complexity upon the whole thing that eventually made the guidance unusable for a large number of our target audience. There is still a lot of documents that are floating out there; a lot of information. We actually use as a guidance document a couple of European documents from United Nations Environmental Program and then also The German Government had dumped some work on Life Cycle Assessments and both of those documents found very useful so we're basically, that's one of the questions that maybe companies, in particular small and medium companies could help us with in terms of the evaluating is that look at what we published and get an idea and help you understand Life Cycle Assessment and if not you know, what sort of further guidance or information do you feel you'd need or whatever sort of input would you like to have to make it more useful to you as a small or medium company.

Question 2: Did I miss what process is used to determine which chemicals are considered for review using this process? Additionally what determination/what constitutes a chemical of concern is not a part of the guidance? Will this be determined be a regulatory decision?

Response: Thank you and that's a very good question and that's something I forgot to add in the initial presentation and I will keep that in mind in future presentations, as well. One assumption though we worked on when we started this guidance document was that the identification of the

chemical of concern is outside the scope of this document. So, whatever process has been decided that it's a chemical of concern is external, whether that be regulatory or whether it's a company that established a restricted substances list; or for whatever reason a company has decided that this chemical they want to eliminate from their product, that decision is external to the guidance. And the reason why we did that was because that's a very difficult question to answer. There are so many reasons why a chemical could be identified as a chemical of concern. So, we've made it very clear that that was outside the scope and what the guidance was meant to do is that okay once you've identified the chemical this is where the guidance steps in and starts...so and thank you for mentioning that, and I'm glad that question came up.

Question 3: When the document is completed, will it be accessible to the public and to all eight (8) states or all other states as well?

Response: The intent is that the document will be made available. This is a guidance document; there is no regulatory driver behind it so that it is not being tied to any rules or regulations or anything like that. Our intent is to post it; it will be posted, at least we've talked with them and I assume that it is still the case; it's likely it will be posted on the Interstate Chemical Clearinghouse Website and I'm sure any other state that might want to make use of it as a guidance or recommendation. I suspect that Ecology, for example, will also post it on its website. Whether or not it's posted on the other states will be an individual state-to-state decision; I have not asked that question, but you know we do still have a lot of involvement from each state, so I suspect that to some degree they will be referencing or at least ___ to the ___ IC2 Website. So this document will be made available to the general public.

Question 4: Which level of assessment in each of the different stages is sufficient; how does one know this; how do you know that at the lower levels you haven't missed anything important? What or who determines what level of analysis to use in different modules?

Response: This is a good question. Thank you for asking. I did refer to it a little bit in the decision methodology module and haven't actually gotten to it yet. So, in that module and since we haven't discussed it the guidance team meeting yet, this is more Alex's opinion than the guidance team's opinion. I want to make that clear, because it could be that when the team gets together, we decide to go a very different direction; so don't hold me to this if it turns that the end product is different from what I say here. But it's my expectation that we will have various paths to follow, if you will; and it's true, and we will make it probably clear in this decision methodology and that's why I mentioned earlier when I talked about something, here's something for small business, here's something for medium businesses, here something that we think is the absolute minimum; and when I say minimum, we mean, here are the...which of the

12 modules will be included in that minimum, what is the order, and what levels is included for each module, so we will divided the guidance along the way and I expect there may even be another one above that which is the preferred, so that there may be either additional modules at higher levels or something like that involved in that and the ____-like version where you do a full hazard assessment or risk assessment ___, how much money, whatever you want to throw at this. But it is a very good point that whatever people do, they'll have to understand and we try to make it clear, for example, in the hazard module and it should be clear in the other modules, the lower you are down in the level, the greater the risk is you're not doing a completely good decision. So, if talking about a hazard assessment and you're only doing a list by comparing with list of lists, for example, if your only doing an evaluation on whether or not an alternative is on a list of lists, there could be lots of other hazard information that's out there and available that would cause it to be a chemical of concern. So, if you want to be absolutely certain your decision is the best decision, you have to do as much evaluation as you can do. But realize even at the very highest levels you're still going to have a certain amount of uncertainty, because even at the ____ using ____ level #5 where you have no data gaps and it's been validated by external experts, it could be that data comes up tomorrow which changes everything and there could be a lot more information, in particularly using modeling work, etc., that would be wrong, so there's always going to be a certain amount of uncertainty involved in any of these decisions and that's how, when we get to the decision modules, we may want to come up with, what we think, is the minimum requirement for alternative assessment, even though realizing that minimum might still have a certain amount of uncertainty involved in it; there's just no way of escaping it.

Question 5: California has the Green Chemistry Initiative. How does this Alternative Assessment Guidance ____ the California Initiative?

Response: I find that question baffling amusing because I've asked the California Representatives on the Guidance Team exactly that question last week. Because I know in October California is starting its Alternative Assessment Guidance Meetings and California has been working on the Guidance and they are actively involved in it. I don't know how, what they'll come up whether or not it will be different or substantially different or how it's going to impact what we're doing here. I was told that it's likely that they will use a lot of the information and expertise and work that we've done in this guidance and when they come up with their own, but it's very likely they will come up with their own guidance. I would hope that we can maximize crossover between the two, but that's something that unfortunately California has to decide. Again, California is very actively involved in this document and has been for the last year, so I hope that there's a lot of overlap but only time will tell.

Question 6: Have you studied the way the Natural Step A, B, C,D is working for planning toward sustainability? This is a great tool for dealing with conflicts issues.

Response: No, actually I'm not familiar with that; it may be that somebody else on the Guidance Team is available and if you would please e-mail me that information, we'd love to consider it. Do you have my e-mail address on the screen? _____ I'm not familiar with it, but it could be too that we do have lots of other experts in certain areas so, for example, my weakness is Lifecycle Assessment so I'm very weak on that, so we have other people on the Guidance Team that address it, so I don't know of it personally, but may be other people do but I'd love to consider it. Please send it along.

Question 7: Can you clarify: Does Department of Ecology have the authority to require producers to perform Alternative Assessments and if not, why is the Guidance being put through a formal comment period?

Response: We do not have the authority to require anything; so, this is just guidance and it will remain to be guidance until we took our told otherwise. The Agency is not putting anything Legislation requiring authority to do Alternative Assessments. I think though that, and I can't say that why we are doing a formal comment period if there is no Regulatory; it's not a bad question. I don't know if I can answer that, except that we thought that this issue was important enough, and we wanted to really have as much Stakeholder involvements process as possible, that we would follow it as if it was a Regulatory requirement and realize that in all the work that we're doing and publishing the Modules and seeking input , we've had lots of meetings with people and discussions, and things like that. It's above and beyond what we would have done, probably, in a Regulatory process as well; so I think it's just more that we want as much input as we can get, so we're doing everything we can, and exploring all avenues. There is not Regulatory Driver, so we don't have to do a formal comment period; we just think it's the right thing to do.

Question 8: Are you including hazardous toxic chemical by-products in your consideration of chemicals of concern, and if so, how are they being considered?

Response: Yes, we are including them. For example, a lot of the hazard assessments that are done consider not only the chemical of concern, but also potential degradation products, by-products, etc., that could be an issue. The example that I quite often use is if DDT itself is not very toxic, it is more the degradation product DBE that cause the huge amount of problems. So, if that the hazard assessments, for example, does include that. But that's also a good example of what we're thinking about in terms of the Lifecycle Thinking Module, as well, that you know, if it hasn't been considered in other modules that is the perfect place to start considering that. And we're also, in the Lifecycle Thinking Module, it could be that there are more hazardous chemical

or toxic chemicals that are involved. Say for example in the manufacturing process. The example that I know of that we're dealing with here a lot in Washington is that PCBs are quite often manufactured during the production of certain odd dyes and inks. It has nothing to do with the actual end product; it's just something that's produced during the manufacturing process. In terms of a Lifecycle consideration, that's something that we would want to bring into the module is concerns like that, that might have been missed by other modules; and that's why I made a point of saying that that's an important component of the Lifecycle Thinking Modules is to go beyond the actual chemical and maybe just the degradation products from the chemical, but look at the whole lifecycle and we've used examples, if you're mining for minerals and if you're doing one mining process and it half creates a lot more mine waste than another process for the same sort of thing or if you go to a different source and there's not contaminants along.. That's what the Lifecycle thing; we want you to think about the broader perspective and not just the actual chemical and chemical degradation products. The degradation product issues are very much covered in the hazard evaluation module.

Question 9: How do you anticipate or hope Government entities and businesses will integrate this alternative assessment guidance into their work and are there plans to facilitate this adoption (?) or use?

Response: Well, I can only speak for Washington State; that I know that one of the reasons that we're interested in it: We have a very large pollution prevention program. And one of the things we've been starting to do is to educate our pollution prevention staff on hazard assessments and alternative assessments and actually go to companies that are reporting to Washington State that their using chemicals of concern and actually are paying a fee to Washington State for their use of chemical concern. And talk to them about this being a potential tool that they might use to move away from the chemicals of concern, the toxic chemicals that they're currently using and seek safer alternatives. So at least in Washington State, there is hope that down the road we would be able to use this as a tool that we could bring to our own businesses here in Washington. I should comment that this is a voluntary effort; this is not in a regulatory requirement. So, if a company decides not to use the tools we have no regulatory authority to force business (?) to do it. We do see it used in that manner. California was brought up; I don't know what California is going to do and whether or not they will decide to use it. As far as I know, none of the other states that are working on this guidance have any authority to require Alternative Assessments. The only other state that I know that has that authority is Maine; and they're not currently a member of this activity. So, I just think that at least in Washington we hope to use it down the road and hope Washington businesses move away from toxic chemicals and provide this as a tool. Other states, it will be on a state-by-state basis, how they decide and if they decide to use it.

Question 10: Can you comment on the applicability of the method for assessing alternatives to metal surface treatments. In particular, Gab___ and hexavalent chromium?

Response: That's an interesting question and I know that we've been dealing a lot in the hazard assessment world, as well, because one of those draft (?) limitations of some of the tools that have been developed for hazard assessment is that they have been concentrated on organic chemicals so that a lot of the grouping that's done, a lot of the decisions that are made are based upon issues that are pertinent to organics. And when you get to inorganics, some of these things fall down. So for example, one of the components that people are working on, one of the 19 criteria's persistent and how do you deal with persistence of an element. Do you deal with the fact that it's always going to be here no matter what you do or are you concerned about the form that an element is, etc.? So, I think until some of the tools developed to address in organics; I know we are working on that, Design for the Environment is working on that; Reproduction Action is working on that; and I think within the near future we're probably, and I know some major manufactures, as well, who deal with, in organics constantly, will be, are concerned about this issue as well. So, I don't think that I have really discreet answer for you, but it would be interesting to see your perspective from a guidance just looking at it for that particular problem and to see if it would work for you or for specific challenges that means that the outlines that have been put out there would not work for you in that particular application, because it would be interesting to see; and if we have to make some limitations right up front that there are inorganic issues with this methodology, it would be good to know that as well.

Question 11: Has IC2 conducted a beta test on the return of assessment using methodologies of the guidance to determine if the guidance is usable by smaller companies? I tried to play around with an alternative assessment using just Level One, the lowest complexity approach and even that required and a ___ of technical expertise. Can smaller companies really practice ___ assessment as outlined in the guidance without outside help?

Response: We hope so (Laughter). I know Art and I know he works for IBM; so that's not exactly a small company. One limitation though and again this is just Alex talking. We listed 12 modules up there, and I don't think for a small company, we would ever expect them to do all 12 modules. So that's one way it would make more easily implemented. We've done alternative assessments up here in Washington where we've looked at things, like hazard, exposure, cost and availability performance. Those are what I consider, maybe the big four, if you will. So, I would that if we were able to limit it to just those considerations, and use some of the easier levels, that that might work for a small company. If it doesn't, than I would love to hear that and ___ would and would not work for ___. If you have input, what caused problems, what would you think caused problems for a small company, I'd love to hear that, as well. One other

comment, too, I would like to make, and it's sort of embedded in the question that Art had: One of the things that we have ____ for EPA Funding, as well, once the guidance is completed, we will have actual funding to actually do a Beta Testing on it, and in that instance, I would hope that we would do a Beta Testing. Can this work for a small company? Can this work for a medium company? Is our minimum enough? That sort of thing? It our expectation or at least in Washington (It may be a Washington only thing) will probably open it up to the other states to be involved in it, as well. Washington is actually applying the for the funding to actually Beta Test and we do think that Beta Testing is an important question, so no guidance is useful if after you get through with it nobody can use it. That is our intent to do a Beta Testing on it.

Question 12: Will this program provide alternative for me, or is it simply a method to find my own alternatives? For example, if I use formaldehyde will the program provide me a list of specific alternative chemicals or just a method or procedure for me to identify it myself?

Response: That's an interesting question. It's very unique. It is not our intent; this method is not meant to provide answers. It is intended to provide a method so you can research it and find your own answers. However, I should clarify: This is a little bit outside of the guidance, so I ____ have spent a lot of time on this, so if you'd like to give me a call or send me an e-mail, we can chat about it more. There are other things that we're working on, for example, that sort of helped this process. So one of the things we're working on in the IC2, the Interstate Chemical Clearinghouse, is actually taking green screen assessments that have been completed and post____ so that, for example, somebody had done green screen assessments on formaldehyde, that information would be posted and you would not have to go out and reinvent the wheel and do all that work, but you could just go and use that. One of the concerns we have are limitations on it; you know, legal liability; how much qualifications we have; and that's what we're sort of working on now. And we're going to be doing this; if it's under the IC2, that will be made available to anybody with access to a computer. So, we are working on, particularly the hazard and maybe some of the other information to make it more readily available to help companies with it. But it's pretty much true that the guidance is meant as a method for companies to implement. And so, and to be honest with you, I look at my long term objective for the State to get out of the Alternative Assessment Business. And more by assistance to businesses to get them to do it themselves, directly.

Question 13: Have you considered chemical groups, so that you don't risk _____, for example, by going from one _____ flame retardant to another?

Response: We haven't actually considered groups, because for the most part, it is a chemical-by-chemical comparison. I do know that in Washington State, for example, when we were

looking at alternatives to the flame retardant ____, we made a managerial decision that we would not review any halogenated flame retardants. And that was a managerial decision. It had to do, not only concerns about persistence of halogenated flame retardants, but also because of regulatory requirements up here in Washington State, we did not feel comfortable recommending a halogenated compound as an alternative when that halogenated compound would force the company to have to manufacture more state-only dangerous waste, or something like that. So, there were concerns beyond their persistence issue, etc. I will bring it up to the group; it's an interesting question. I don't think that, unless you make those sort of executive managerial decisions leading up to an Alternative Assessment, and remember that that was the identification of the chemicals and what sort of restraints we have on those, the chemical alternatives are being made before the guidance is brought in. So if you're going to make that sort of executive decision not to include any halogenated or ____ flame retardant or any specific class of chemicals, and it may be, if I can think of ____ that maybe that a company has decided they're not going to allow any NPEs as viable. And there are plenty of other groups in classes of chemicals. I should comment though that EPA is publishing a list of safe chemicals based on the work that they have done in their safer product certification program. And I was at a meeting with them on Monday and they commented they would have up to 500 chemicals. And they're going to post it in terms of, "Classes" so that if a chemical group ____ or been ____, you would list them in that class, so it does get a little bit towards, if you are looking for a chemical to fit that particular class, that might help. So there may be information out there that will help, but I don't think that in the guidance, per say, we're likely to treat it as a, "Group". I will bring that to the Group, the Team, though, and ask them what they think and see if my opinion or ideas are contrary to the group.

Question 14: Are there any plans to include discussion of data quality issues in conducting Alternatives Assessments? So, for example, can a single study or whatever quality, drive the assessment or does data quality come into play?

Response: Data quality always comes into play. In particular when you're dealing with hazard assessment. That's a definite component on the DFE Methodology, looking at it, using ____ weight of evidence or approach. You're never going to run into a situation where all of the data is 100% in one way or another. So, if you only have one study you may have to make a decision based on that one study. But you need to document the fact that you don't have a lot of confidence in that decision because the amount of data that is involved is very limited. But then there's a bit of a converse, too. You could have 100 studies and 80 of them say it's a problem and 20 of them it's not a problem. You don't want to go and evaluate a hundred studies, I would imagine. So, in that case maybe you would use more a weight of evidence approach saying that 80% was the reason that we decided it was an issue. But this gets into the certainty issue that we were talking about earlier. Any decision that we make is going to have a large amount of uncertainty in it. And, factors like that are going to have a major impact on the uncertainty of

your decision. We're expecting that if you're doing, for example, hazard assessments, and you have those issues, you have to document them. You either make the decision that if it's only one study, that toxicity criteria or hazard end point is a data gap, because we only have one study; there are problems with the study; we don't think that it's definitive enough; or it's just not enough information. You can put it into the data gap and that acknowledges the fact that you don't really have enough information on that hazard end point to make a decision. But the converse is true; if you have a study, and it's a good study, and it looks like the data reasonable, you could rank it based on that one study. But you still need to include in your write-up that this is based on very limited information. So, at least I would expect that, as a scientist, I would expect my assumptions and limitations of any decisions I have made to be documented in the information that I provide.

Question 15: Do you have any examples where these modules have been evaluated using chemicals of concern for a particular product? It would be great to see case studies.

Response: If you look at some of our modules, case studies is one of the things that we think are very important, and that's one of the issues that sort of held us up to life cycle assessment, as well, life cycle thinking module, because we didn't have a lot of ideas on good case studies for some of the lower level, the non-LCA examples. It is our intent that in the write-up we will include case studies, where possible, of how things have been implemented; and we do have, for hazard module, for example, and for exposure, and for some of the modules. I think we have plenty of case studies that we will include in guidance to help understanding of what we meant by limitation. Some of them like life cycle might a bit more of a challenge. Environmental ____ or some of those, but we do see the value of case studies, and we will try to implement them, as much as we can.

Question 16: How do you see the ways that the information on chemical content life cycle and biodegradability for a product could be made available to guide the consumer and user in purchasing safer products? Do you foresee a voluntary rating system, such as ____ environments or regulatory requirements for a manufacture to list chemical components in the same way that a list of ingredients is required for food packaging?

Response: I don't know, I haven't thought about that; I don't know if we've considered it at all. I do think, though, that there are efforts underway to make sort of a uniform, reporting system and that's the Global Harmonization System. A lot of our hazard evaluations, for example, have been changed to correlate very well with GHS. And in GHS, it sets very discrete ranges for things like biodegradability or persistence or many of the hazard end points that are used in a hazard assessment. And EPA's design for the environment has provided the ranking information, etc. But, I think the GHS required companies to report that information if it's a problem. I think

that's very, very useful. And I think that will be sort of the standard for the future. This is a personal, "Alex opinion": One limitation I think of the GHS is that it doesn't include the information that, yes, this was tested for, and not found to be a problem, it's sort of implied, because if you don't list it as a problem, it's sort of assumed that you tested it and it wasn't a problem, and I hear that the scientists would just like have further clarity, to say that, just want the company to say that, "Yes, I did the analyses for persistence and it's not a problem." And I would love if they could actually even report what numbers, what value they had, so that that information would be more readily available. So if I were thinking of making a change to make that information more available, I'd add that to like GHS, etc. In terms of individual products, themselves, I think that's sort of outside of my area of expertise and what I can address. That's more of a policy decision, but Linda might have something she wanted and give me a break from talking for a minute. Linda: There is a country over in Europe, it doesn't come to mind right now, that has done a list ingredients, carbon impact. Of the climate carbon impact produced and transport, and I think it's a year-long test that was being done over in the European Union, by one of those countries, and it is listed next to the ingredients on the packages in the consumer products. Alex : So, like an FDA Reporting, if you will? I don't know of any efforts along that way in the U.S. and does anybody else know of anything in the room? It's not something that we're, as a consumer, I'd love to see it; I'd love to have information to be able to make my decisions about products. But, I know of no State efforts. If it could happen, that would be great. But I think it's a little bit outside of what we're planning to do with the guidance document.

Question 17: Has the 8- State alternatives working group grappled with the issue of communication of alternative chemical information. Is the group familiar with ____ Will it affect ____ chemical and processing information standards issued just last year by American National Standards Institute that's NC 3552011. This standard looks at the whole universe of chemicals in use in a gate-to-gate manufacturing scenario and consider ____.

Response: No, I'm not familiar with that. It may be that somebody else in the guidance team is, or Lauren Heine or some of the other people. I would love to have that information. I'll definitely bring that back to the group and discuss it with them. If you can send me the link with the information, I'd appreciate that. ____ the associate chemical attributes towards their total environmental of human health and safety effects.

Question18: Isn't the, "EPA Designed For The Environment Safe Chemicals List "just for cleaning products?

Response: No, It's not; but again, I'm not a DFE, so don't hold me to this; I'm sure that I can get corrected by our DFE Partners when the next I talk to them. It's my understanding that they have over 2,700 products that are currently receiving the DFE Logo. The vast majority of them

are cleaning products, but I believe that there are products outside of cleaning. It might be though, that their initial list is just cleaning; I don't know that off the top of my head. It thing it is fair to say that probably a majority of chemicals, if not all, will be cleaning product related. I think that DFE has looked to expand beyond the cleaning products, and has done work on things beyond cleaning products. And I'm sure as that information becomes available, they'll probably include that into their list. You might be right that it's currently just going to be cleaning products; I wouldn't expect it to stay that way. I imagine it would go beyond. If you want, you can send me the question and I'll ask DFE get back to you with more details.

Question 19: I thought that Massachusetts under the Toxic Usage Reductions Act does require Alternatives Assessment. Do you know about this?

Response: I did not know about that. Massachusetts is involved; I'll ask them that question. I thought that Maine and California were the only states that had authority for Alternatives Assessment. If Massachusetts has it, it must have happened a long time ago. I know that TORA Legislation was passed about 20+ years ago, so they have may the very first out of the block with it. I'll ask; I did not know that. But Massachusetts is serving on our panel and is providing a lot of guidance and input into the development, as well. I'm sure that whatever we're doing will be consistent with what they're doing.

Question 20: Have you considered proximity to materials in the research, like focusing on the materials we are trapped in buildings with, as opposed to the chemicals on the building envelope that are more difficult to get out of the building industry?

Response: I think that's part of an exposure evaluation. Was it CR or formaldehyde that was in the trailers from the Katrina issues. It was used in building products and then ended up having a fairly serious impact on some people who were sensitive to formaldehyde, etc. I think that sort of issue would be included in the exposure evaluation; I'm not sure at what level we would getting into that sort of detailed evaluation, but at some point or another things like that would be included in the evaluation. For example, if you're comparing Alternatives to formaldehyde, I think that's one of the things that you may want to consider; if you're using one of the Alternative in construction, is there a exposure component that makes it equal to or more of a problem than formaldehyde that sort of eliminates it or puts some concerns on it as a potential alternative to formaldehyde. I think those sort of things would be included in the Guide.

Comment on previous question and answer: Yes, it did happen a long time ago and it's part of the tour of legislation.

Question 21: Are you going to be doing outreach to other states _____ and is this going to be a proactive effort with those states?

Response: What activities are going to be done in other states is really up to the individual states. I will bring that up to the group and say that that was some input that was received during this discussion. I'm sure that Washington would be willing to help them with that outreach; I'm sure that we can set up other webinars or something like that. I know that nothing is planned, currently, for other states. I will take that input back to the group and ask them if that's something that State Representatives would like to do. I do want to point out that all of these webinars and all of the comments that we receive and all of the information that we publish is not meant just for Washington State to be providing input. We will take input from all the states, not even just the eight (8) states that are involved in the guidance document. If there are state representatives that have some interest or input from other states and would potentially think about using this guidance in some way or another, or would like to see it address certain issues, we will accept input from anybody. We had over 200 people on this (webinar) and I'd assume they were spread out over many states, and it wasn't just Washington people that were involved. I think we have done some outreach to other states, but it has been limited and I will bring that back to the group.

Question 22: Is there a process for incorporating other methodologies for hazard or exposure assessments outside of green ____ and BSE?

Response: I would say that if you have inputs on other Alternatives that you think are viable, I'm sure that we'd be willing consider them. And that's sort of the input we would love to hear. I think, though, one of the reasons why we went with the DFE Methodology, which is basically what green screen is based upon, as well, is because it was the most comprehensive and it was the most scientifically defensible and detailed. So, most other methodologies, I have to admit and I'm a little out of date, but when I first took this job about five (5) years ago, I went out there and reviewed all the methodologies and the DFE Methodology was consistently better than any other methodology I reviewed at the time. If there are new and developing methodologies out there that might have the same function, I think that we're open to it and flexible enough to have other alternatives put in the guidance, as well. If you have that input, send it along; we'll be glad to review it.

Question 23: Is this used to compare several alternatives? Sounds like it's only looking at the alternative.

Response: O.k., thank you for that clarification and if I led you to believe that it was only looking at a single alternative, that was not correct. The intent is, and this is a little complex

because what you're really doing is comparing cost and availability for all the alternatives against the chemical that is currently being used. So you have to have something to compare it to so when I'm talking about a single chemical it's usually the toxic chemical that is currently being used that's looked at as an alternative, that you need to find an alternative and then you're looking at cost and availability of the alternative compared to that specific chemical. It's also probably a good idea though to look at them comparatively against each other as well so quite often what is done in these instances is that people will do matrixes and sort of try to figure out from the matrix which one looks like it has issues on cost and availability and which one's don't but the baseline is typically the cost and availability of the current chemical and then all of the alternatives, information collected on all the alternatives.

Question 24: Are there social life cycle assessment evaluation models that are published?

Response: Yeah, that's an interesting question. We're still trying to work with that a little bit. A lot of this stuff, particularly for the lower levels are not necessarily module based. It's more complicated. For the higher levels where you do need to get into modules or models and approximate based on module information what is available. We are creating a section that's called resources where we're going to try to include information on potential models or other sources of information that can be used to address concerns in every single one of the modules so I don't know off the top of my head and I think that's one of the advantages of working with a large group of people like this and having EPA as a technical resource. We quite often are able to draw upon people who know a lot more about this sort of thing than I do so I personally don't have much experience or information on social impact modeling but we are accessing people that do and I would also recommend that if you have recommendations or suggestions on module that you might want to propose that could be used in that resource section please send them along and provide it. There will have to be a caveat of course that none of the states can endorse any particular module or any particular company particularly if they're doing something for profit but we are willing to make the potential resources available to everybody. So I will take your question though back to the group and maybe we can come back with a little bit more formal response. But I think that's outside my level of expertise but I think that's the best I can do for that.

Question 25: Does the financial life cycle costing rank equally with the social life cycle assessment?

Response: One of the interesting components particularly for the multi-attribute approach is that you have to establish not only the criteria and the ranking, but you also have to establish the weighting. And that gets a little bit to where we and we're leaving as much of that open to the individuals doing the alternative assessment as we can with a caveat that as long as it meets the objective of the alternative assessment process, so one concern that we've had with the multi-

attribute approach for example is that if you decided to weigh carbon emissions or energy usage or whatever I know of several examples where if you weigh those very highly or very heavily, they tend to blow out everything off the chart including hazard exposure, cost and availability, etc., so you have to be careful at setting the criteria, the ranking, and then the weighting as well but that's why we're in the module and particularly for the multi-attribute. We're going to be providing some guidance on which things we think need to be weighted highly and which ones we're going to leave open to the assessor to do. The important and I didn't mention this as much perhaps in the webinar as I should have, although we're leaving that open to the assessor to do, we are also expecting it to be transparent and documented, so if you're weighting something highly, you just can't weight it because you want to, you have to provide a justification and reason for weighting it so that if for some reason you feel that social impact is very important for a particular alternative or process or something like that, you can weight it highly in the multi-attribute approach for example as long as the golden objectives of the alternative assessment process are met.

Question 26: Have previous inputs and changes made and posted in the updated modules yet?

Response: No they have not and we did not plan on doing that because it's sort of an iterative process, we are getting comments and input at any time so we did not want to have sort of a living document like that out there particularly since at times we have to wait or we have battling comments or dueling comments if you will so some people want something and other people don't want something and we have to pretty much decide how to go so we decided that we would accept all comments until all of the modules were released and then once all the modules were released we would concentrate on documenting or implementing all of the changes that we could to the module and then post it at that time. We are not going to be posting iterative documents during this time. Again, we're going to give everybody a 45 day public comment period so you can see where your comments have or have not been implemented. We have not addressed whether or not we are going to release the response to comments for that or whether we're going to wait until the final document but that's an interesting question I'll bring up with our management and with the team to see how they want to do that because I think it would be appropriate or at least reasonable that once we release the document if we've accepted certain changes or not that we should at least let people know where your changes have been implemented and where they haven't but it's a tossup, it's an awful lot of work so I don't know how we're going to address that but it's an interesting point and I will bring that back to the group to discuss but short answer to your question, we're not doing iterative releases, you'll see that when we issue the document for the final 45 day public comment process but not before.

Question 27: While assessing alternatives, is avoidance costs part of the analysis, which would include an assessment of current product use?

Response: I guess maybe I could talk to Jonathan about that offline but, I don't know, it's a little hard for me to know exactly what you mean by avoidance costs but I am willing to bring that back to the guidance team and talk to them about it but Jonathan what I would suggest is that you have my email address so maybe you could send me some more information about what you exactly you mean with that question and I could either bring it to the team or respond. What we are trying to do to some extent is to look at impact to society so that but it is very hard to quantify you know, particularly there's been a lot of documentation for example done on the use of cigarettes and how that impacts health costs because of people having to deal with cancer and emphysema and etc. and quite often those costs aren't included when you assess the cost of cigarette use but we are trying to include some of that costing in avoiding issues or problems into the cost and availability module so that if you are using a toxic chemical that may be carcinogenic or something like that or if you are going to an alternative that isn't carcinogenic or has no other major human health impact, it would be reasonable to call that out, one other additional advantage is that we're avoiding potential exposure to carcinogenic chemicals so maybe that would increase the viability of that alternative, so in terms of that avoidance cost, I think some of that is built in but if I'm not understanding that correctly or if you have more detailed perspective, I would suggest you just send me an email or whatever and we can talk about it in more detail. I'm perfectly willing to bring that question back to the team for further clarification and discussion.

Question 28: Do you anticipate some sort of pilot process to determine feasibility of the approach and an idea of cost?

Response: Yes, we do have planned that once the guidance is done, we are thinking of test driving it if you will and we haven't you know to be honest with you I'm concentrating on getting the bloody thing done and we haven't done a lot of discussion on how we would test drive and what we would test drive so don't hold me to any of this but off the top of my head what I would like to see if we're test driving it, I would like to see different complexities of alternative assessments done in the test drive. So to do something, and not only is it important to have a test drive but it would also be important as a model to provide to companies to say, for example, if you're a small company here the minimum alternative assessment that you might be able to do and how you might be able to do it and give them a model so that if they are required to do it in California or other places that it would give them something that they can build upon and copy, so, and I know that there is work being done on that on sort of similar, not on our guidance, the California Green Chemistry Legislation. I know that there are groups that are working on doing sort of a test drive of that as well to see if they could figure out what would be needed to meet those requirements but yes we are expecting to do the same sort of thing and

we'll probably have more information on what we expect or what we hope to do once the guidance is done. I'll probably start working on that once the public comment process starts because I'll probably have time to do that.

Question 29: A lot of SME's (small to medium size enterprises) don't have the skills needed to do these kinds of analysis. Does Ecology or IC2 anticipate providing detailed training on the AA process? (Alternative Assessment process?)

Response: We haven't discussed that but my is Safer Chemical Alternative Chemist so I would be very surprised if I was not required or expected to do training both on the guidance and to assist companies that might want to do an alternative assessment. I should comment though that Ecology currently has no regulatory authority to require any alternative assessment so the only states that have that authority are California and Maine, so I don't envision at least for the state of Washington unless something goes through our legislature because our legislature would have to grant us authority to do that, that we would be expecting people to do an alternative assessment. However, my job is still try to work with companies to implement alternative assessment and to identify safer alternatives to toxic chemicals so if a company wanted to do that ahead of time they would be more than willing to approach ecology and work with them on how to do it and how to make it work for their company product or process. So we haven't formalized it yet what our expectations are but I think that's sort of inherent in my job as well and I expect there will be more of it down the road once the guidance is complete.

Question 30: Does the (__) and definitions in the guidance documents near those as used in the CSPA and the CSPA Regulations?

Response: We are trying to coordinate as much of the guidance with everybody that we can think of. So for example, we are doing a lot of work of trying to coordinate with European reach requirements. They have an alternative assessment requirement, the Organization for Economic Cooperation and Development, an international organization if you're not familiar with the OECD. They're also working on alternative assessment guidance and we're trying to coordinate the wording as much as possible with them as well. We have not actually, I have not actually specifically looked at the Children's Safe Product Act but I can do so and I'll take that as input to do it but I don't see that there's any major deviation from the wording that we're using and what my familiarity is with the Children's Safe Product Act. I do admit that I'm more on the nerdish side of the Children's Safe Product Act so I don't have a detailed knowledge but I do have a guy in the room with me who does know all that and he's shaking his head, he doesn't think that there's any deviation but I will take that as input and double check to make sure that that is the issue or that is the case but I do want to emphasize we are doing an awful lot of effort to coordinate this amongst as many groups. We're trying to coordinate it with California; there are organizations like (Biz?)

NGO that are working on alternative assessment. We are trying to coordinate it so that if somebody does an alternative assessment it should meet more than just this guidance requirement but it can meet a broader audience as well requirement or expectation.

Question 31: The test drive is a great idea. Suggest leaving the potential to update guidance based on learning's from the test drive effort.

Response: Ok. Thank you. That's a very good comment and I appreciate that and I should have mentioned it. I don't consider this guidance to be set in stone, no pun intended there. It is a living document so I would like it to change and alter and improve based on experience and also it may be that other organizations like the OECD or the (?) Union, or the state of California etc.... might establish processes etc. so I would like it to be reactive and encompass those potential changes that are coming down the road as well, so thank you for that input and I do very much think of this as a living document and the advantage and I would just say this as a regulator, the advantage of doing guidance that's not actually required is that we can make changes whenever we think it's appropriate. If it were a part of an expectation in a rule or regulation or in something that was passed by the legislature I would be limited to a very structured formalized process to make changes to it but since we have no regulatory requirements for this guidance we can make changes pretty much on a daily basis if we want, not that I expect we'll do that but, so yeah we will make changes to it based on the experience from the dry run and from any other source that comes available.

Question 32: What input have you had so far from groups outside of government such as nonprofit health and environmental groups?

Response: All of the input that we have received is available on our website so any input that we get with some exception, I think I just this week received some input on the materials management module that has yet to be posted. So you can go and see all of the input as soon as we get any comments on any of the modules we typically make a PDF out of them and post them within a week or two or something like that so all of that information is available on the web. As an aside, we tend to get more input from businesses. We've gotten fairly limited input from NGO's and the environmental community. Most of the input that we received has been from businesses. I welcome input from NGO's and environmental communities, I welcome input from anybody and we have tried through the blog site to make it easier for people to look at things and provide input on a more informal basis if you want. So if you are interested in providing input please do so.

Question 33: When alternatives go into the bin due to failure module let's take the example of cost, are they out even if someone is willing to pay extra for it or if it fails the social module for ignoring Native American issues can that be ignored because a company cannot change a state or federal issue?" It's really two questions but it's really what you can do in terms of if you have a failure in a particular module.

Response: If you have a failure in a particular module and what we try to do in the modules is to set up a gradation so for example in the hazard module when you evaluate chemicals you can put them in four different benchmarks and the expectation is that the benchmark force would be the ones that would go on for further assessment but if they failed for whatever reason, say for example that they have some of the issues that you say, maybe they're cost availability or because of Native American issues or whatever, they're not viable you could circle back to a benchmark 3 group and then submit those to the process but the way it's set up though too particularly if you're doing the sequential you could just go back to those that were binned in the previous module and evaluate those because say for example if you're doing six modules and you get to the module number six and there's a problem pops up with all the alternatives so they all fail what you would do is go back to the previous module, module 5 and say ok, which one there didn't go forward for evaluation and are there mitigating steps that you could take that maybe if somebody, you can check to see if users were willing to pay more so that maybe it failed because of cost of availability because it was much more, it was more expensive than the alternatives that were identified as favorable then you could see the mitigation would allow that to be processed or to go on for further evaluation. The cost and availability one is more easier, is easier to respond to than the social impact one because it's hard for me working for the Department of Ecology to ever say that there are ways that we would condone or endorse a chemical that would have major impacts on a native population or something like that so that I think if you had an alternative that got to a certain point and failed for those criteria, I think I would consider that one to be eliminated from consideration period unless under very extreme circumstances so but those sorts of things you would have to look at in case by case basis and perhaps in that situation what I would do is go talk to the native population and bring them in as stakeholders and say, "We have this alternative, it looks extremely viable for all these reasons but then we have this concern when we get to it. What's your input and how do you feel about this? Is this something that we could make some mitigating steps or is there some way that we could prevent this from being an issue?" So, I would use that as an opportunity to bring in a stakeholder maybe that was not involved in the past. So think of this as, we're trying to be flexible so if issues pop up, we're not trying to limit you and to give you a discreet yes or no. We want to give you the inflexibility to say, "What can I do to look further into that and see if it really is an issue or not.

Question 34: When trying to compare alternatives, there's often the lack of data. How do your modules take into account lack of data and or filling data gaps especially in modules other than hazard?

Response: That's a very interesting question and I know that for us in hazard module, we've been dealing with the data gap issue for a number of months if not years now. My gut feeling, and this is my personal opinion, this is not necessarily the opinion of the team or what would be reflected in the guidance. If you're doing a module evaluation and an alternative has serious data gaps I would put that in an unfavorable benchmark, say, "we are making this decision based on information so if your alternative that looks very viable for many other reasons comes out as being a problem because it has data gaps then I think there's no alternative but then to put it as an unfavorable option." But what you may also want to do then is to say, "If you have serious data gaps, go back to manufacturers and users and seek, is there data that can be made available?" I know that EPA, I've used this example quite a bit, that when they did the high production volume challenge and went back to manufacturers and said, "We need to have these data gaps filled in". It was surprising to me at least how much data was actually there and available but nobody asked for it and it wasn't provided so it might be that your data gaps are, there are ways of getting data to address your data gaps and that's for any module not just hazard module but and this is where the transparency comes down, it may get to a point where you have no option but to choose between alternatives for which there are data gaps, so you look at the ones that have the fewest data gaps or something like that but I also think of the alternative assessment process that has an iterative approach and the way I use it in some presentations, you don't necessarily have to reach nirvana with the first step. If you can go from a toxic chemical to one that's less toxic while continuing to review and collect more information so that maybe down the road you can go to the next step etc.. I know many companies would like to be able to make a change once and never have to make it again but because of the data gap issue and the fact that we don't always have all of the information that we need to make a decision, we may be forced into making these incremental step improvements rather than reaching nirvana with one giant step. If we can do it great, more power to us, but I think we're going to need to rely on the more incremental approach. But, back to your original question, if there are data gaps, I think there is no other option but to say, "To identify the data gaps, see if you can work around it but then if you can't just eliminate that as a viable option."

Question 35: A number of alternative assessment guide documents are being developed. How will users be able to select one approach? Will guidance be given on the guidance documents?

Response: Well, I can't dictate on some of them. I know for example on the reach guidance document, they have regulatory authority that requires you to follow their approach. As I did mention though before, we are trying to coordinate and make it as uniform as possible so that if

you're doing an alternative assessment using the reach requirements that it would probably meet many of the requirements of an alternative assessment under this guidance and under other guidance documents as well. Unfortunately there is, this is just a very hot topic issue and there are a lot of people working on it from many different perspectives and I'm involved in many of them as well so I understand the complexity and the issues involved. I think though that some of the guidance's are going to be broad based and provide more tools and ways things can be done without having a more discreet pathway. I think our guidance might be a little bit more unique and more similar to the reach guidance in that it does provide expectations and suggested routes or pathways that you can use to get to an acceptable alternative assessment but I guess that'll be just one that'll have to work out, work its way through as the documents get finalized and are out there and being used. Remember again that except for California, none of the states that are working on this have any authority to require any alternative assessments. (Maine's not working on this, so Maine's not) Sorry, I had a comment from the peanut gallery here in the room, so this guidance is meant just to be that, it's meant to be guidance and you can use it or not as you choose. Unless it's decided that somebody makes the guidance required either under statute or rule then we probably would have to tighten it down a little bit and exactly what we would expect under certain applications because I think this guidance is very broad and very flexible and I think it would be very hard to use solely as a regulatory pathway without providing a bit more direction on exactly what is expected for a minimum requirement. At least that's my expectation working for a regulatory agency but yeah, I understand your pain and I think that's always an issue for a number of companies that there are many people working on this issue and there may be distinct differences between them and that can cause us lots of headaches down the road. My only response is we're trying to coordinate and make a uniform approach as much as possible so hopefully those headaches would be less than what we expect or what we might see. But again, this guidance is living too so if it turns out that something comes out that is better than slice bread we can go back and change those guidance to coordinate better as well.

Question 36: Has the group discussed how intellectual property issues might affect business? For example, one company may have a patent on the only 'Safe Alternative' effectively creating a monopoly. Should be a common hazardous chemical equipment be set for elimination?

Response: Interesting, I have never thought of that potential or that alternative so to have a single company monopoly. To be honest with you, I don't know of any instance or example where that would actually hold true so I guess we're sort of building the guidance on the assumption that that would not be the case. It might be that for a short period of time there may be a company that has a product or process that might be a preferred alternative, I know that there's a lot of work for example and I'm not making a case out of this but flame retardants. I know that there's a lot of work being done on creating plastics that don't require the additional

flame retardants that self char or something like that so there may be intellectual property for periods of time while these products are being developed but even in that instance I know of several companies that are working on similar types of products so I just don't see that as being a major issue probably down the road. If we do get to that point that will be sort of interesting and maybe that'll be something that'll have to be factored in to the alternative assessment process but it's not something the group has thought, I'm perfectly willing to bring it back to the group to see what they think and I'll take that action item to do that.

Question 37: Are you using the complete EPA current TRI toxic chemicals list that contains about 600 chemicals on it?

Response: It is not clear how the hazards will be assessed. There are many, often conflicting, hazard classification schemes available.

Scoping Comments

Prior to beginning the development process, several stakeholders were solicited for their input into framing the document. Specifically a proposed alternatives assessment continuum was offered for review and stakeholders were posed seven questions. The following summarizes the input received and how the input was factored into the final Guide.

Question 1: What are your three main observations with the proposed continuum process?

The following input was received:

- Consideration of risk factors associated with potential alternatives, such as cost, performance, commercial availability, etc.
- Consideration of Life-cycle analysis.
- Two comments that chemical management should be effected under modernization of TSCA and not conducted at the state level.
- Wise use of time and resources.
- The proposed transparency is exemplary.
- Strongly supports beginning the continuum process with hazard assessment and including exposure as a secondary tool.
- Agree that a hazard approach first is most effective in fundamentally reducing toxicity and other impact potential.
- Alternatives assessment as principally toxicity-focused. LCA has wider application than this and can extend to other categories ... significantly increase the complexity of the guidance document. I would suggest keeping the focus on environmental and human health toxicity concerns.
- Concern that “inherently less toxic” will be the main theme and other considerations may be applied as possible, but not integral to the process.
- Not clear why different processes would be necessary for small businesses vs. bigger businesses. The science will not change for a company simply because it has fewer employees.
- It is not clear how the continuum will be applied at different steps. Generally, guidance may offer different pathways for different levels of complexity and thoroughness, but choosing where to begin a process is not usually user-specific.
- Sounds great – especially like the notion of using the selective portions of the guidance applicable for specific user.
- These are important factors to consider, especially functional equivalence, and cost effectiveness.

- From a practical standpoint ... who the users are ... Not just be a great guidance document (the scope sounds like it will be!!!) that is only usable by the scientific/technical/toxicological community.
- Continuum process is an excellent idea.
- It would be best to develop a criterion-referenced process.
- Issues identified years ago that led to well-developed current improvement programs might not have addressed hazards that are now made visible by this approach.
- May already have multiple internal programs at several different steps of the continuum, and see how to integrate them and leverage what has been learned to move to the next level.
- Discover that extensive, possibly high-quality work that has been done to address a high-profile issue or product line might have overshadowed less apparent issues in that product line or in others.
- Chemical Hazard assessment is the foundation for any alternative assessment ... [and] ... the ability to automate the evaluation of the available data and the roll-up of the endpoints is essential.
- Full life cycle analysis can be cost prohibitive and impractical for a broad range of organizations and supply chains.
- While all steps of the continuum have value and are applicable to certain issues, presenting this guidance as a “big picture” that shows how the steps relate to each other will be a huge benefit.
- Statement of problems and goals. The guidance document should discuss the importance of describing the problems and the goals.
- It would be useful for the guidance document to recognize the likely differences between alternatives assessments conducted voluntarily and those conducted due to regulatory requirements.
- The term “continuum” in this context is confusing ... an alternatives assessment includes several distinct “modules” that are used to evaluate different, mostly unrelated issues associated with the potential alternatives. There might be a module for human health concerns, one for cost effectiveness, one for technical performance, one for environmental impact, and so on.
- The continuum proposed by Ecology may be too complicated. Alternatives assessments tools should focus on the following information: Hazard data, including information on toxicity, persistence, and potential for bioaccumulation; Performance of available alternatives and their cost...
- Companies need to have a way to put chemicals in certain categories to prioritize action. It is useful to put chemicals with certain characteristics into categories—from high to low...
- The scope does not adequately reflect how widely this tool is already being used by businesses—large and small.

Response: Some of the issues provided in these comments are beyond the scope of the Guide. For example, discussions of whether the alternatives assessment process should be pursued

or whether work should be placed on modernizing TSCA reform is a federal issue and it us up to Congress to address the overwhelming shortcomings of TSCA. However, based upon the comments above, several recommendations were used in generation of the Guide that led to a much improved document. Those inputs implemented include:

- Use of a modular approach.
- Establishment of levels from ‘high to low’ within each module in terms of level of complexity to provide opportunities for businesses of all size to be able to conduct an alternatives assessment.
- Identification of the most favorable alternatives from evaluations conducted in each module.
- Focus on the hazard approach.
- Inclusion of examples of completed alternatives assessments.
- Statement of goals and objectives.
- Inclusion of performance, cost, exposure, etc. in separate modules.

Question 2: Has Ecology omitted any technical concerns as important components of the guidance continuum?

The following input was received:

- No mention of quality of data used.
- The proposal appears to identify chemicals of concern simply on their hazard profile.
- See recommendations with perhaps a “step-by-step” process to conduct alternatives assessments
- Concerned that use and exposure considerations may be relegated to second-tier concerns when they are still critical factors, even in a hazard-based assessment. However, the Draft Scoping document is not detailed enough to provide robust technical feedback.
- The plan for completed assessment results done ... and if results will be publically available.
- The P2 hierarchy should always be to look for ways to AVOID/ELIMINATE the need for a chemical, THEN look into the substitution/reformulation, etc. If the group concurs ... [use] the word eliminate (or related term) up to the top of the list of ... components. (It is sort of implied in “manufacturing process redesign”, but not explicit).
- Whether the “alternative is commercially available” is redundant
- Endocrine disruption seems like a potentially valid criterion.
- While this guidance will unquestionably help, the biggest difficulty in hazard evaluation always comes back to the data.
- Finding available data.
- Selecting or ranking multiple data available for the sample endpoint-especially if they are not close in value.

- Determining the category of endpoints for which simple data is not usually found in tables.
- Applying 'professional judgment.'
- If no one can agree on what the hazards of a particular chemical are, the whole process lacks credibility.
- Creations of 'harmonized' data resources for endpoints being added for alternatives assessment. Creation of such resources for GHS endpoints... goes a VERY long way towards easing these issues.
- Appropriate available resources should be listed.
- Free programs for those with limited resources....
- Commercial packages with more features for larger companies.
- Services/consultants for those who want someone to do it for them.
- Vetting or registration of resources that the process could provide would be a huge assistance and an incentive to get started.
- Actual examples or links to them ... for a tangible sense of how this step worked for someone.
- This tool should primarily look at hazards of the chemicals. This is one of those tools that can help evaluate the hazard information that exists for the chemicals. It should not include all considerations that a manufacturer may take into account.

Response: Many of the issues provided in these comments were incorporated into the Guide. For example, endocrine disruption was included in the hazard module as one of the criteria used in a hazard evaluation. Examples were added to the Guide to help understand how an alternatives assessment has been done in the past including resources available for companies to use if needed. An Initial Evaluation module was created to address the issue of pollution prevention and evaluating chemical use to determine if simple elimination is possible. One of the few comments not addressed was the issue of defining or clarifying 'professional judgment.' Professional judgment is an issue well defined within the scientific community. In addition, the comment that the question of whether or not the alternative is commercially available was retained as it is an important consideration to show viability as to whether or not the chemical can perform as a favorable alternative to the chemical of concern.

Question 3: What are some of the positives this process might bring?

The following input was received:

- Reduction of COCs that pose hazards to human health or the environment.
- Two comments encouraging further opportunity for industry to provide input.
- Several comments on emphasis on flexibility
- Data bank of safer alternatives

- Provide a clear, robust, scientifically-justifiable approach that states, industry and NGOs can agree upon would be a positive step.
- Publication of AA results for others to use.
- Alternatives with a credible body behind it should be beneficial and serve as a standard approach.
- Database where one could search for alternatives to a current product would be very useful.
- Provides full spectrum of guidance on driving safer chemistry for companies small and large.
- Making the process less overwhelming.
- Encouraging those with existing processes to evaluate them-continuous improvement is necessary.
- Cost savings for businesses that substitute harmful chemicals for safer chemicals.
- Protections for public health, Puget Sound, and renewed consumer confidence in products.
- Reduced burden on government and the public for waste disposal, health care costs and cleanup.
- Greater availability of safe products for consumers.

Response: Many of the comments were incorporated into the Guide as they clarify the benefits to an alternatives assessment process. In addition, the request for additional industry involvement was emphasized with industry workshops, posting of modules for review and comment as they were completed and a final 60-day public comment process.

Question 4: Do you have any concerns with the proposed process?

The following input was received:

- Stakeholders need to be specifically defined.
- No mention that the removal of the COCs should be in concentrations that present exposure hazards.
- No language stating whether of concentrations considered are based on entire product or component.
- Industry wish to remain involved in the development process.
- The scale and breadth of the proposed process is extensive and it is very unclear how this will allow it to be flexible and adaptable to stakeholders.
- Lack of specificity.
- Not clear who the 'recognized experts' are or how they will be chosen.
- Not clear how hazards will be assessed as there are many, often conflicting methods.
- Not clear whether the guidance will list specific approaches, or how any approach could be updated if new science or assessment processes become available.

- Concern that local species are more sensitive than test species for specific contaminants of concern.
- What leverage and motivation is available for manufactures to remove toxic chemicals from products?
- How will alternatives assessments get promoted and marketed? Will a certification program be established?
- Will the alternatives assessment process be required for government purchasing decisions?
- Importance of dose-response data and exposure data.
- Timeline too long.
- Concern the end product will be too complicated.

Response: Many of the comments were incorporated into the Guide. For example, a stakeholder module was created that provides additional guidance on the type of stakeholder is important to the different levels within the module. Specific hazard methods were selected for inclusion and these methods are based upon sound scientific processes developed by EPA. Some of the issues could not be specifically addressed such as the issue of local species being more sensitive than target species. Data availability is always an issue and use of existing data allows short-term decisions to be made using existing data. The alternatives assessment process needs to be revisited periodically to see if new data affects the final decisions. As new data on sensitive species become available, it can be built into the process. In addition, the comments on exposure including dose-response curves have been addressed in other comments in this document. In summary, the alternatives assessment process does not assess risk as is done in the traditional risk assessment process. It attempts to reduce risk by emphasizing the importance of reducing hazard and is a new and novel approach to addressing consumer concerns with the continued use of toxic chemicals in consumer products. As identified by the National Academy of Sciences in a recent report on Sustainability, '4.6. *Finding: Risk analysis as commonly applied to environmental issues often does not adequately account for the full range of human health and ecosystem risks, including cumulative risks, intergenerational considerations, and the distribution of risks among population groups. In addition, better methods are needed to support consideration of health and environmental effects for the green chemistry goal of safer products and more sustainable chemical usage (p.60).*' (www.nap.edu/catalog.php?record_id=13152). Alternatives assessment is one of these new tools and is addressing toxic chemical concerns by emphasizing hazard and reducing hazard in the selection of alternatives to toxic chemicals used in products or processes.

Question 5: Do you agree that the continuum approach is the best way to approach the various needs of an alternatives assessment?

The following input was received:

- Three comments were received that not until more details are provided.
- A risk-based approach is a fundamental component and important to ground any chemicals management work.
- Identify stakeholders first and create a section for what information will be most useful to them to fulfill their roles.
- Yes.
- A better approach was unknown.
- Yes. There is no one right process or 'step' that covers all situations in all fields and products.

Response: Many of the comments were address by providing opportunity for stakeholders to provide input throughout the development process. This included three industry workshops, two public webinar, posting of modules as they were completed for review and comment and a final 60-day public comment process. In addition, a stakeholder module was created to help with stakeholder involvement in the alternatives assessment process. Lastly, the question became somewhat moot as identified previously, stakeholder input caused the Guide to be constructed using a modular approach. This is different from the continuum approach but is believed to provide a more valuable guide to the wide range of users interested in the alternatives assessment process.

Question 6: Given aggressive timeline, which of the components listed above are most important to be tackled first?

The following input was received:

- Ensuring that the assessment is based on sound data for COCs that are not only present in certain concentrations, but in those concentrations that actually pose a hazard.
- A risk-based approach is a fundamental component and important to ground any chemicals management work ... [and] a harmonized and sustainable approach to chemical management.
- Environmental and human health hazard data Exposure concerns Life cycle concerns Commercial constraints (economics, technical feasibility) Practical implementation of alternatives assessments (not listed).
- Garner meaningful stakeholder input ... clearly delineate the meaning of several terms in the scoping document, including "recognized expert" and "hazard assessment." Without understanding of what the core parts of the process are, the remainder of the process is rudderless.
- The overarching/outline/protocol/steps per 5th bullet, including the types of end users who might be using each requirement of the continuum.
- Support the use of the Green Screen as a part of the continuum.

- Make at least a first cut at outlining the continuum. Identify the bulk of the steps, and pull and distill available descriptions of them. ... Don't wait until it is completed to have it out there for feedback and input...
- Start building out the lowest level with some detail and resources
- Identify experts for the rest of it and start building it out. Consider a Wiki – type approach...
- Performance characteristics – are the alternatives suitable functional substitutes? Human health toxicity and exposure potential.

Response: Many of the comments were included in the Guide and through extensive stakeholder involvement throughout development of the document. The issue of a 'risk-based approach' has been answered in several places in this document. Although the Guide is based upon risk, it is a risk reduction approach and not to be confused with the risk assessment process. The two methods have different goals and objectives and the Guide makes clear the role it is playing in reducing risk by emphasizing reducing hazard, not through exposure assessments and controls.

Question 7: The stakeholder group will have opportunity to provide additional input once the draft guidance framework has been formed, midpoint and before the guidance is finalized. Do you have any additional input to provide before the states begin discussing the guidance document?

The following input was received:

- Three comments indicated no further input.
- Will the document rely, reference or otherwise use established federal or international chemical management processes.
- Whether industry analyzed alternatives assessments will be considered along with the business case as to why and when alternatives may be chosen.
- More clearly explain how the criteria for hazard assessment will be used in the alternatives assessment process to compare multiple alternatives to each other.
- Apply broader sustainability criteria when evaluating a particular chemical and its uses against alternative chemicals for each of the same uses.
- Looking forward to more information as the scope becomes more solidified.
- Exposure and probability (i.e., risk) is an important factor in assessing chemicals, and while risk does not need to be the starting point for an AA, it must be considered.
- Duplicative or contradictory to established federal or international processes.
- How the additional components will be incorporated into the guidance.
- The guidance not be overly prescriptive.
- Evaluations of products with chemicals that are relatively new to me require checking multiple resources (Prop 65, NTP, IARC, ISTAS, AOEC, etc.). It is time consuming. A database that could yield this data quickly with the input of a CAS number would be quite helpful.

Response: Many of the comments were addressed during the development process by attempting to coordinate the Guide with existing National and International efforts. For example, the alternatives assessment guidance issued by the European Union was reviewed and included in deliberations. The hazard module was based upon the method developed by EPA. Expansion or changes to that method, however, were outside the ability of the states involved and the method was adopted as it exists with changes to help with implementation. In addition, new resources were identified to help with implementation. For example, several new databases have been developed that help with identification of chemicals of concern using lists from several authoritative sources. These databases allow use of a CAS number to identify if a chemical is a chemical of concern without having to go directly to all the individual sources. Lastly, the IC2 is developing its database to provide completed hazard assessments. A company conducting an alternatives assessment can go to this source and see if a hazard assessment has already been completed. If so, it saves the assessor an appreciable amount of money.

General Input: Several stakeholders also provided comments that have been grouped under the category of ‘General Input.’

The following input was received:

- Several comments were received indicating an interest to be further involved in the development process.
- Support rational, scientific and effective risk- based approaches to chemicals management and assessment that foster the safe use of materials and chemicals in products. ... this risk-based approach needs to be achieved by a unified solution at the federal level. State-by-state chemical management programs and different data submission requirements only contribute to a patchwork of regulations and put a strain on limited resources within companies and governments. While, we understand that the department has an interest in looking into this issue specific to the State of Washington, we strongly encourage the department to find ways to work with the federal EPA for a nationally focused solution.
- Strongly supports alternative assessment as a comprehensive and science-based route towards the production of safer chemicals, safer products, healthier people and a healthier environment.
- The guidance needs to allow for flexibility, while ensuring that critical hazard, use and exposure criteria are considered.
- Recognize the unique factors that must be considered in hazard evaluations and risk assessments ... by referencing the U.S. Environmental Protection Agency’s (EPA) Framework for Metals Risk Assessment.
- It is inappropriate to evaluate metal substances using the general hazard evaluation principles applied to organic chemicals. The Guidance Document should reflect this fundamental point.

- Persistent, Bioaccumulative, and Toxic (PBT) Characteristics Are Not Appropriate As a Hazard Trait for Metals and Metal Substances.
- The use of bioconcentration factors and bioaccumulation factors when applied as generic threshold criteria for the hazard potential of metals.
- Persistence is problematic for metals because all metals and other elements on the periodic table are conserved and hence, persistent.
- The Guidance Document Should Address Economic Impact of Alternatives Substitution.
- The Guidance Document should clearly and explicitly consider the economic impact of substituting an alternative chemical, including cost-benefit factors.
- What is the intended objective for the Guidance? Who is the target audience?
- US Environmental Protection Agency (EPA) Funding was presumably in response to a WDOE grant application. Could you provide a reference to the funding request?
- Does Ecology intend the Guidance be referenced for use in implementing WAC 173-307 Pollution Prevention Plans, WAC 173-333 Persistent, Bioaccumulative Toxins, or other Ecology-administered regulation?
- Will the Guidance impart any regulatory requirements?
- Will the guidance be duplicative of EPA's effort?

Response: Many of the comments were answered directly to the commenter including requests about EPA funding. As indicated in other comments, the alternatives assessment was constructed to foster collaboration among states and to use on a voluntary basis with interested industry. Only one state involved in development of the Guide has any legal authority to require an alternatives assessment. The other seven states are only using it on a voluntary basis. The issue of TSCA reform, however, is outside the scope of this document and is not addressed as indicated in previous comments. In addition, the issue of persistence and metals is included in the Guide. For example, special consideration is made for metals when conducting a hazard assessment because, as indicated by the commenter, metals and other elements are by definition persistent. However, the EPA metals risk assessment was not used because, again as indicated in numerous other responses to comments, there is a marked difference in the objectives of an alternatives assessment and a risk assessment. The objective of an alternatives assessment is to search for replacement to toxic chemicals. This includes the elimination of toxic metals where possible. Lastly, the Guide does not address economic impact of alternatives assessments, primarily because it is impossible to quantify the full impact of toxic chemicals upon human health and the environment. This includes increased health costs, disposal costs, clean up costs, etc. that have traditionally not been included in a true cost assessment toxic chemicals have throughout their full life cycle and the general impact to human health and the environment.