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June 30, 2014

Miriam B. Ingenito, Acting Director
California Department of Toxic Substances Control
1001 I Street
Sacramento, CA 95814
(*via e-mail*: SaferConsumerProducts@dtsc.ca.gov)

RE: Priority Product Draft Regulatory Concept

Dear Ms Ingenito:

The American Cleaning Institute (ACI)[1] appreciates this opportunity to provide comments to the Department on its Priority Products Draft Regulatory Concepts. ACI was among a group of industry trade associations that provided recent comments to DTSC on the Priority Product Selection Process[2] and their development of Alternatives Assessment guidance.[3] In addition, we were able to meet with you and your staff on June 27, 2014 to discuss many of the points contained in the two letters. We thank you for the opportunity to speak with you and wanted to encourage you to look closely at the points we discussed and found in the two letters rather than reiterating them here.

Likewise, our associates at the American Chemistry Council, the American Coatings Association and the Juvenile Products Manufacturers Association have provided more detailed comments to you, and we wanted to endorse the content of those letters.

Also, I wanted to share a few process recommendations based on observations of the release of the Priority Product Profiles and the associated workshops.

- It is clear that affected industries should be brought into the selection process earlier to avoid errors and eliminate missing relevant data from the Profiles. Additionally, this will help the Department better understand markets and supply chains for the particular product.

[1] ACI is the trade association representing the $30 billion U.S. cleaning products market, with about $3 billion associated with business in the State of California. ACI members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers. ACI and its members are dedicated to improving health and the quality of life through sustainable cleaning products and practices. ACI's mission is to support the sustainability of the cleaning product and oleochemical industries through research, education, outreach and science-based advocacy.

[2] April 24, 2014 letter to DTSC Director Raphael regarding Priority Product Selection Process (attached)

[3] October 30, 2013 letter to DTSC Director Raphael regarding Development of DTSC Alternatives Assessment Guidance (attached)

- The Profiles should be released as a draft document with the opportunity for a comment period to finalize it.

- While the Department is required to consider the existence of chemical alternatives for the Priority Product, it should not presume these alternatives are safer and without regrets, and it should not encourage their adoption in the absence of appropriate analysis indicating such. It is more desirable for the Department to have manufacturers participating in the Alternatives Analysis process rather than having manufacturers fleeing to alternatives for which the human or ecological risks may not be fully appreciated.

- Finally, rather than pushing the boundaries of the Safer Consumer Product program, we feel the program would be more effective if the Department focused on a making the program reliable and predictable. The Department is more likely to see its desired market changes if its signals to the market are predictable.

We look forward to working more closely in the future and wish you continued success with the Safer Consumer Product program.

Sincerely,

Paul C. DeLeo, Ph.D.
Associate Vice President, Environmental Safety

cc: Meridith Williams, DTSC
Karl Palmer, DTSC

April 24, 2014

Debbie Raphael, Director
California Department of Toxic Substances Control
1001 I Street
Sacramento, CA 95814

RE: Priority Product Selection Process

Dear Ms. Raphael:

On behalf of the above associations, we offer the following comments to the Department of Toxic Substances Control (DTSC) on the Priority Product selection process based on the March 13, 2014 release of the three Priority Products and the associated Priority Product Profiles. We offer these comments and questions as a first step prior to an in person discussion to be arranged in the near future. In addition, we hope these comments will assist in preparing for the upcoming stakeholder workshops.

PRIORITY PRODUCT SELECTION PROCESS

DTSC should provide more clarity on how the prioritization factors were applied in the selection process to arrive at the Priority Products and Chemicals that were selected. Additionally, DTSC should identify the entities with which it consulted – from both the public and private sectors – to inform the initial Priority Product recommendations. *What steps does DTSC intend to take in subsequent rounds to make the Priority Product selection process transparent and repeatable to instill confidence in the Department's decisions?*

PRIORITY PRODUCT PROFILES

Product profiles with citations are helpful in describing the information DTSC developed and considered in selecting the particular Priority Products. It appears DTSC did this research on

their own without the benefit of input from businesses, which may have relevant published and unpublished scientific and market information on these products, their uses and exposures. Updating the Product Profiles via engagement with expert sources would ensure that the product profiles contain accurate information and better achieve the human and environmental safety improvements envisioned in the program. Updating the product profiles, prior to holding the first workshop, can help ensure the sessions are more productive and time is not unnecessarily wasted with correcting inaccurate information. DTSC should qualify the Priority Product Profiles by acknowledging they are draft both within the profile and on their website. *Are the product profiles subject to update/finalization prior to the initiation of formal rulemaking based on stakeholder input?*

Ensuring the initial product profiles are accurate and complete is critical, especially since DTSC publishes these profiles for the public and relies on them as a basis for the final listings. *For product categories in future rounds, would it not be appropriate for DTSC to proactively include early stakeholder engagement in developing product profiles in its Three-Year Workplan?*

PRIORITY PRODUCT IDENTIFICATION

GS1 descriptions are crucial to manufacturers, retailers and other potentially regulated entities in order to be clear on what is in/out of a Priority Product designation. GS1 descriptions are used in some Product Profiles and are important to distinguish the Priority Products in the consumer and retail realm, but this was not done in all cases. *Why are GS1 descriptions not included as the basis for every priority product profile?*

DTSC has stated that regulations only cover the specific Priority Products, not the individual product of concern or chemical of concern. The Priority Product Identification and Profile should reflect this. In addition, it would be useful if the Department provided some of its thinking regarding the Alternatives Analysis Threshold as part of the Profile as well. DTSC should include an explanation for the basis of the categories that were excluded from the Product Profiles. *Why did DTSC not provide explicit rationale in excluding Consumer Product Safety Commission (CPSC)-regulated products (e.g., mattresses) from the children's foam-padded sleeping products category? It would also make sense for DTSC to include a disclaimer that the draft Priority Product is limited to the selected chemical/product combination and no inferences should be drawn about other products containing the chemical.*

PRIORITY PRODUCT EXPOSURE INFORMATION

The information presented spans a very wide range - from general market information, to circumstantial environmental presence information unrelated to the product, to unquantified "detection" observations, to quantified consumer exposure pathway information (e.g., product concentration data), direct ingestion/inhalation levels relevant to consumer exposure and ADI benchmarks from federal regulations. The last provides useful exposure information for substantiating the potential for harm for making priority product decisions; the former are often not related to the priority product and do not provide sufficient evidence for such decisions. *Does DTSC intend to provide an opportunity for stakeholders, particularly those who manufacture the priority products, to improve the exposure information in the product profiles? Does DTSC intend to provide updated versions of the Profile as new information is received?*

RESPONSIBLE ENTITY

The regulations suggest that there is a hierarchy of responsible entities – if the manufacturers of Priority Products do not submit a Priority Product Notification, then importers and ultimately Retailers would be responsible. There are potentially hundreds to thousands of responsible entities for each priority product and it may not be obvious to those entities. *What are DTSC's expectations regarding identification of specific responsible entities for these products? Will the Department solicit stakeholder input on this? It would also be helpful to include guidance on the appropriate time for responsibility to shift to importers and retailers.*

REGULATORY DUPLICATION

In its first round selections, DTSC has cited worker-related illness and injury statistics to justify priority product selection, however Cal/OSHA has authority for worker safety in these areas. DTSC should not consider occupational exposure to the Priority Product as this is duplicative. Further, there is a potential conflict, or at least significant overlap, with other Federal efforts (e.g. US EPA Action Plans and Work Plans) to assess and regulate the same chemical and product applications cited in two of the priority products. *What boundaries will be set in priority product regulations to operate within the statutory limit and not impinge on the regulatory authority of any other department or agency? Are products intended for industrial and occupational settings subject to alternatives analysis? How does DTSC distinguish consumer products from industrial and institutional products? Will DTSC explain why they believe these priority product selections do not constitute regulatory duplication?*

ALTERNATIVES

The Priority Product Profiles contain some DTSC-identified potential alternatives to the draft Priority Products. The alternatives suggested do not have fully detail safety, performance, consumer acceptance and other A-M criteria that might make them alternatives to the Priority Product. *Could a workshop discussion be included to understand DTSC's thinking in this area and appreciate stakeholder concerns that the Profiles should be clear to cautiously characterize any discussion of alternatives, e.g. as "limited information on potential alternatives"?*

The undersigned trade associations remain committed to contributing to the Safer Consumer Products regulatory implementation process and we are eager to see a credible and transparent Priority Product selection process. We would like to discuss this and other aspects of regulatory implementation, including the development of the Three-Year Work Plan and the alternatives assessment guidance. For purposes of communication, we ask that you use as a point of contact Gene Livingston of GreenbergTraurig (916-442-1111) in responding to this letter.

Respectfully Submitted,

Tim Shestek, Senior Director, State Affairs
Mike Levy, Senior Director, Life Cycle Issues, Plastics Division
Emily Tipaldo, Manager, Regulatory and Technical Affairs
American Chemistry Council

Paul DeLeo, Ph.D., Associate Vice President, Environmental Safety
American Cleaning Institute

Stephen Wieroniey, Specialist; Health, Safety and Environmental Affairs
American Coatings Association

Mark Collatz, Director of Regulatory Affairs
Adhesive and Sealant Council

Steven Bennett, Ph.D., Senior Director of Scientific Affairs and Sustainability
Kristin Power, Vice President, State Affairs
Consumer Specialty Products Association

Emilia C. Lonardo, Ph.D., Vice President, Consumer Product Safety & Science Policy
Adrienne Black, PhD, DABT, Senior Manager, Science Policy and Chemical Safety
Grocery Manufacturers Association

Suzanne Hartigan, Ph.D., Director, Regulatory Affairs & Science Policy
International Fragrance Association North America

Iain Davies, PhD., Senior Environmental Scientist
Personal Care Products Council

Jennifer Gibbons, Director of State Government Affairs
Toy Industry Association

cc: Meridith Williams, DTSC
Karl Palmer, DTSC

October 30, 2013

Debbie Raphael, Director
California Department of Toxic Substances Control
1001 I Street
Sacramento, CA 95814

RE: Development of DTSC Alternatives Assessment Guidance

Dear Ms. Raphael:

On behalf of the above associations, we offer the following comments as the Department of Toxic Substances Control (DTSC) engages in the development of guidance on alternatives assessments as required by AB 1879 (Chapter 559 – Statutes of 209). Throughout the development of the Safer Consumer Products (SCP) regulation, our association staffs and member companies have individually and collectively provided significant stakeholder input including participation in the DTSC alternatives assessment workshops. Specifically, DTSC hosted a symposium on Industry Practices in Alternatives Assessment[1] in September 2011 providing industry insights on such topics as product safety and raw material assessment and product R&D case studies.

[1] Alternative Analysis III: Industry Practices in Product Research and Development, an Alternative Analysis (Sept. 15, 2011): http://dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/GCSymposiumAAIII.cfm.

Most companies practice alternatives assessment routinely as part of the continuous improvement process incorporated into their on-going product development. Through an informed substitution process, an alternative should not only have an improved safety and environmental profile, but also should be technologically and commercially feasible; of comparable cost; maintain or improve product efficacy, performance, and usability; and result in consumer acceptance in the marketplace. The alternatives assessment process required by the SCP regulation should follow current best practices and be adaptable on a case-by-case basis for the different Priority Products that might be selected by the Department.

We understand DTSC intends to rely on the Interstate Chemicals Clearinghouse Guidance for Alternatives Assessment and Risk Reduction[2] (IC2 AA Guidance) as the basis for the SCP regulation alternatives assessment guidance. To be clear, the alternatives assessment process requires flexibility, and we object to any rigid or mandatory alternatives assessment proposals that would mandate the selection of certain decision "frameworks" or specify the order and "appropriate" levels of use of guidance modules and rigid decision frameworks. Instead, a flexible implementation of best practices would be more appropriate in order to avoid regulatory mandates that stifle innovations. The IC2 AA Guidance does **not** reflect the necessary flexibility to address the complexities of conducting an alternatives assessment in a practical manner.

We are very concerned about the use of the IC2 AA Guidance as a basis for DTSC guidance. In many cases, we think the IC2 AA Guidance is not workable and offered extensive comments, both in the guidance development phase and in response to the initial release of the IC2 guidance modules. We draw your attention to our general concerns outlined in this letter and more specific concerns detailed in Appendix 1.

- The IC2 AA Guidance does not include a comprehensive risk-based safety assessment of alternatives. Companies routinely evaluate all relevant factors to ensure risk reduction measures are employed in the manufacturing of safe, quality products that consumers desire.
- The IC2 AA Guidance does not acknowledge the protection of confidential business information/trade secret information.
- The IC2 AA Guidance ignores the critical importance of consumer acceptance of products in the marketplace. To ensure consumer acceptance, any alternative must provide the same or better performance and value as viewed by the consumer.
- The IC2 AA Guidance decision module is unbalanced and seems to ignore consideration of cost, availability, regulatory compliance (international, federal and state), manufacturability, and consumer acceptance.

The alternatives assessment process should be flexible and modular (focusing on parameters relevant to the product being evaluated). It should result in comparable or improved product efficacy, value consumer acceptance, include informed decision making, allow for gradual and

[2] IC2 Guidance for Alternatives Assessment and Risk Reduction - http://www.newmoa.org/prevention/ic2/aaguidance.cfm

measured implementation, and include a feasibility check to make sure that proposed alternatives actually meet goals set.

We, the undersigned trade associations remain committed to assisting DTSC in developing a credible, deliberate, and workable alternatives assessment guidance document. We request that DTSC staff review and incorporate our comments into the SCP regulation Alternatives Assessment Guidance, and encourage the staff to engage directly with industry stakeholders.

Respectfully Submitted,

Tim Shestek, Senior Director, State Affairs
Mike Levy, Senior Director, Life Cycle Issues, Plastics Division
Emily Tipaldo, Manager, Regulatory and Technical Affairs
American Chemistry Council

Paul DeLeo, Ph.D., Senior Director, Environmental Safety
American Cleaning Institute

Stephen Wieroniey, Specialist; Health, Safety and Environmental Affairs
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Steven Bennett, Ph.D., Senior Director of Scientific Affairs and Sustainability
Kristin Power, Director, State Affairs – West Region
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Iain Davies, PhD., Senior Environmental Scientist
Personal Care Products Council

Jennifer Gibbons, Director of State Government Affairs
Toy Industry Association

cc: Miriam Ingenito, DTSC
Karl Palmer, DTSC
Bob Boughton, DTSC

Appendix 1:
Specific Comments on the Interstate Chemicals Clearinghouse Draft "Guidance for Alternatives Assessment and Risk Reduction"

Golden Rule

Given the serious concerns with the approach taken in the IC2 AA Guidance, we recommend an alternative Golden Rule and Principles should be adopted as a point of departure for Alternatives Assessment.

Goal - "Alternatives Assessment" is a core continuous improvement process for developing innovative, safe and effective consumer products.

The fundamentals of the Alternatives Assessment process are routinely executed as part of industry's ongoing research and development programs and product improvement projects. The key to innovation, and meeting consumer needs and preferences, is the ability for manufacturers to draw on a variety of existing decision making tools and approaches for developing products. Safety - protecting public health and the environment, as well as those making, shipping, and selling the products - is an inherent component of the product design process. Concepts that leverage existing practices in the product development paradigm should form the basis of a practical and meaningful framework for alternatives assessment. Processes dictated from outside this paradigm which do not mesh well with it will of necessity impose unnecessary cost and time penalties on the entity conducting the alternatives assessment and will harm consumers through higher prices for desired products or the choice of fewer products, and could easily result in no product being available which meets the consumer's needs.

Principles - The product development/improvement process is iterative, complex, and different on a product-by-product, case-by-case basis. A sensible approach for conducting an AA should:

- **Ensure consumer acceptance** – The alternative must provide the same or better performance and value to the consumer; i.e., it must not simply have the desired function, but must do so at use levels and consumer cost comparable or superior to the present version of the product.
- **Be Flexible** - Each business model is different. Even for similar chemicals/products, the AA outcome may be different (due to, for example, innovative processes or design features). Each manufacturer must be given the latitude and discretion to leverage existing tools and approaches to evaluate alternative ingredients/components for their products as appropriate.
- **Be Modular** - Although all criteria are considered in a multi-factorial evaluation matrix, the most critical <u>and relevant</u> parameters are identified for further evaluation in each case.
    - Safety (human and environmental) – Product use and exposure in addition to chemical hazard considerations are paramount to ensure product safety. Uncertainties and assumptions should be addressed.
    - Performance and Value.
    - Lifecycle/Resource utilization.

- Other (e.g., Manufacturability, Availability, Capability, Regulatory Compliance - The alternative must be available at reasonable cost and in sufficient quantity, and the revised product must be manufacturable with acceptable yield in view of reasonably and easily-achieved process changes. There must never be an adverse impact on compliance with regulatory or safety-related requirements).

- **Be Effective** - An AA has to be practical and meaningful (not just paperwork) in which the change provides a significant benefit to public health or the environment.
- **Incorporate Informed Decision Making** – Trade-offs must be understood and considered to avoid unintended consequences. However, due to the competitive nature of business innovations and value judgments, decision criteria and weighting cannot be divulged.
- **Allow for a gradual and measured implementation of appropriate or suitable alternatives** - Adequate time is necessary to introduce a new product into the marketplace due to complex and lengthy design considerations, development of supply chains, ensuring regulatory compliance, and ensuring and verifying consumer acceptance.
- **Include a feasibility check** - Provide the opportunity for reassessment, if new data or subsequent assessments uncover previously unforeseen concerns with implementation.
- **Ensure that an alternative formulation is legal**, especially when considering patent issues and state and federal regulations.

Glossary

Authoritative body: *An organization independent of the manufacturer and not tied to industry funding in a way that could affect its independence. Authoritative bodies include state, federal and international government research organizations, independent research organizations conducting scientific studies, etc.*

The definition for "Authoritative Body" is poorly characterized. This definition, rather than a listing of examples of organizations, needs to include criteria for the acceptability of these organizations as “authoritative.” In identifying an “authoritative body”, IC2 should look to government agencies or formalized scientific organizations that satisfy all of the following requirements:

- It characterizes chemicals pursuant to an open, deliberative and transparent scientific process in which stakeholders are able to participate formally, communicating directly with the authoritative body through written and oral comments.
- It is widely perceived to be objective, scientifically based, and does not engage in advocacy.
- It bases its characterization of chemicals on a weight-of-evidence approach. To the extent available, it considers multiple reliable studies, conducted by different laboratories, at different times, and involving not only different strains but different species and gives full consideration to mode of action, confounding factors, maternal toxicity, historical controls and any other scientific information that may be relevant to understanding the potential effects of chemicals on health and the environment.

- It publishes its characterizations of chemicals through governmental regulations, periodic reports, monographs or similar publications.

Bio-accumulation: *Progressive increase in the amount of a substance in an organism or part of an organism which occurs because the rate of intake exceeds the organism's ability to remove the substance from the body. (IUPAC)*[3]

Recently, the Society of Environmental Toxicology and Chemistry (SETAC) conducted a Pellston workshop on Persistent Organic Pollutants (POPs) and Persistent, Bioaccumulative and Toxic chemicals (PBTs) that explored the current state of bioaccumulation science.[4,5] The SETAC workshop, with participants from governments, academia and businesses, developed the following definition for a bioaccumulative substance: "A substance is considered bioaccumulative if it biomagnifies in food chains." Standard criteria for reporting the extent to which a chemical may bioaccumulate were noted including trophic magnification factor (TMF), biomagnification factor (BMF, both laboratory and field), bioaccumulation factor (BAF), bioconcentration factor (BCF), octanol-water partition coefficient (KOW) and octanol-air partition coefficient (KOA). The workshop concluded that the most relevant bioaccumulation criterion is the trophic magnification factor (TMF; also referred to as a "food-web magnification factor"); in the absence of data on the TMF, the BMF (either derived in the laboratory or based on field data) is a reliable indicator. They also concluded that "[t]he BCF is no longer recognized to be a good descriptor of the biomagnification capacity of chemical substances" and "that the KOW is a highly useful chemical specific descriptor of the bioaccumulation potential of chemicals in fish and many other water breathing aquatic organisms." The IC2 AA Guidance document should use a similar definition of bioaccumulation and accommodate these five criteria (TMF, BMF, BAF, KOW, and KOA) as appropriate means of measuring bioaccumulation potential. In addition, clear criteria for what constitutes a bioaccumulative chemicals should be used consistent with the scientific consensus of the Pellston workshop (TMF > 1, BMF >1, BAF > 5,000, Log KOW > 4, Log KOA > 5) and in a tiered order of preference (TMF > BMF > BAF > KOW or KOA).

Exposure pathways: *The route a substance takes from its source (where it began) to its end point (where it ends), and how people can come into contact with (or get exposed to) it. An exposure pathway has five parts: a source of contamination (such as an abandoned business); an environmental media and transport mechanism (such as movement through groundwater); a point of exposure (such as a private well); a route of exposure (eating, drinking, breathing, or*

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[3] IUPAC: All definitions were taken from *IUPAC Glossary of Terms Used in Toxicology, 2nd Edition – IUPAC Recommendations 2007*, prepared for publication by John H. Duffus, Monica Nordberg & Douglas M. Templeton, available at: http://sis.nlm.nih.gov/enviro/iupacglossary/glossarye.html, accessed 2/2013.
[4] Gobas, F.A.P.C., W. de Wolf, L.P. Burkhard, E. Verbruggen and K. Plotzke. 2009. Revisiting bioaccumulation criteria for POPs and PBT assessment. *Integrated Environmental Assessment and Management*, 5(4):624-637.
[5] http://www.setac.org/resource/resmgr/publications_and_resources/pbtpopsexecutivesummary.pdf. Accessed on March 26, 2013.

touching), and a receptor population (people potentially or actually exposed). When all five parts are present, the exposure pathway is termed a completed exposure pathway.[6]

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. In fact, as currently defined, exposure pathways bring into question the scope and objective of the IC2 AA Guidance and overlooks completely consumer exposures to product use.

Inherently toxic*: Chemicals toxic to human and non-human species as defined by the Canadian Environmental Protection Act of 1999 (CEPA). "A substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that:*

1. *Have or may have an immediate or long-term harmful effect on the environment or its biological diversity;*
2. *Constitute or may constitute a danger to the environment on which life depends; or*
3. *Constitute or may constitute a danger in Canada to human life or health." (Section 64)."*[7]

While the definition of toxic present in the CEPA 1999 is useful for this guidance, the modifier "inherently" is not appropriate, since the definition of toxic under CEPA considers more than the inherent toxicity of a substance. We recommend the word "inherently" be deleted.

Persistent, bioaccumulative and toxic pollutants (PBTs)*: long-lasting substances that can build up in the food chain to levels that are harmful to human and ecosystem health. These contaminants can be transported long distances and move readily from land to air and water.*[8]

This definition would benefit from the addition of globally-accepted criteria to define a PBT substance like those defined in programs such as USEPA PBT, Canada Priority PBT, EU PBT, REACh SVHC candidates, POPs Treaty and the SETAC Pellston workshop on POPs and PBTs (described above):

- Persistence: Half-life ($t_{1/2}$) >6 months
- Bioaccumulation: BCF/BAF >5,000; TMF >1; BMF >1; Log K_{ow} > 4; Log K_{OA} > 5
- Toxicity: subchronic<10 mg/kg-bw/day, acute (aquatic) <1 mg/L, chronic (aquatic) <0.1 mg/L

Toxic substance*: Material causing injury to living organisms as a result of physicochemical interactions.*

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[6] Agency for Toxic Substances & Disease Registry (ATSDR), Glossary of Terms, available at: http://www.atsdr.cdc.gov/glossary.html#G-D-, accessed 2/2013.
[7] Environment Canada, accessed at: http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=EE479482-1&wsdoc=39C6A30B-E760-9B43-DCD7-A041AFF8E84B, accessed 2/2013.
[8] EPA PBT Chemical Program, available at: http://www.epa.gov/pbt/pubs/faq.htm, accessed 2/2013.

Very bioaccumulative and toxic (vBT)*: A substance that exhibits high levels of bioaccumulation AND is toxic to human health or the environment.*
Very persistent, very bioaccumulative*: A substance that exhibits high levels of both persistence AND bioaccumulation potential.*
Very persistent and toxic (vPT)*: A substance that exhibits high levels of persistence AND is toxic to human health or the environment.*

The series of definitions above (Toxic Substance, vBT, vPvB, vPT) are not particularly helpful since there are no criteria associated with them which allow the user to put context to the definition. Moreover, the definitions for vBT and vPT, while permutations of two-component combinations of P, B and T, are not widely accepted. Only vPvB has come into wider usage by virtue of its incorporation into the European REACH legislation.

Scoping Modules

Initial Evaluation

- Manufacturers should regularly evaluate their products, allowing for an iterative process and a determination as to when a product is re-engineered or redesigned.
- Principles of Green Chemistry and Green Engineering are good sources when evaluating product design and development.
    - http://pubs.acs.org/doi/pdf/10.1021/es032373g
    - http://www.epa.gov/oppt/greenengineering/pubs/basic_info.html

As the scope and intent of the IC2 AA Guidance is not perfectly apparent, the following comments are offered on the Initial Evaluation Module:

1. 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.
2. "Maturity" should be defined. A baseball is a mature product, but why would we sunset this product?
3. Question 1c. (p. 31). The criteria to be used to determine if a product should go through innovation should be defined.
4. Question 2 (p. 32). 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?"
5. 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?"
6. Question a. ii. (p. 33). Rewrite to ensure that costs, availability of supply, consumer acceptance, and manufacturability are included in the analysis.
7. Question c (p. 35). Rewrite to: "Could the product formula be adjusted to eliminate the chemical without impacting cost, consumer acceptance, or manufacturability?"

Identification of Alternatives

- A chemical may have multiple functions in a product and may require multiple changes in ingredients and manufacturing to adequately satisfy those functions.
- There should be a recognition that alternatives need to be "technologically and commercially feasible." It is important to recognize that an alternative must be "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.
- 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.
- For public alternative assessment exercises there are a number of "crowd-sourcing" tools already available to manufacturers to enable engagement of a larger community of experts and other stakeholders where appropriate:

    - The US government has a crowd-sourcing website (www.challenge.gov) where a problem is put out to the public for solutions. In addition, there are private firms in the business of facilitating crowd-sourced solutions such as IdeaScale (www.ideascale.com).
    - Another means of generating (new) alternatives is through the creation of a source of recognition of an innovation. However, recognition should not be an end in itself, but one means within a broader strategy for spurring change and to provide innovation support process. Among the kinds of recognitions that could be used are:
        - Exemplar prize (such as the Nobel Prize): defines excellence within an area.
        - Point solution prize: aims to reward and spur development of solutions for a particular, well-defined problem (NASA for example, for forecasting solar activity, keeping food fresh in space, and developing a compact aerobic device for astronauts); akin to the crowd-sourcing described above, and to include financial incentives to successful adoption of the solution.
        - Exposition prize: helps identify and promote a broad range of promising ideas and practices that may not otherwise attract attention.
        - Network prize: builds networks and strengthens communities by organizing winners into new problem-solving communities that can deliver more impact than individual efforts.

- Participation prize: creates value during and after the competition – not through conferral of the prize award itself but through their role in encouraging contestants to change their behavior or develop new skills that may have beneficial effects during and beyond the competition.
- Market stimulation prize: attempts to establish the viability of a market to address a potential market failure, mobilize additional human talent and financial capital to jumpstart development of a new industry, or change perceptions about what is possible.

The following comments are provided on the Identification of Alternatives Module:

1. This module asks two key questions: Does a functional equivalent exist; and do other manufacturers currently use an alternative or are there chemicals available that meet the functional requirement?
2. However, there is an alternative approach that was not considered - namely redesign of the product to reduce exposure and thereby reduce risk to an acceptable level. Additional questions (under both 1 and 2) which need to be asked include: Is there a sufficient supply of the alternative chemical? Has the alternative been fully vetted for impacts through its life cycle? Does the alternative perform the same function with the same efficiency as the current material? Is the alternative cost effective, compatible with existing manufacturing processes, and will it meet product requirement for stability, aesthetics, performance, cost, etc.?
3. In question 1 (p.38), the term "similar or equivalent functional requirement" should be defined.
4. In question 4 (p. 39), "reasonable time" should be defined. For example, registration of a new chemical under the Toxic Substances Control Act (TCSA) typically takes 5-7 years from the time of the material is identified as useful in product until EPA accepts the premanufacture notice (PMN). This time is used to collect appropriate data on safety, manufacture, and use and file a registration with EPA. It is not unusual for product development to take a decade or longer from inception to availability to consumers.

Decision

Flexibility rather than imposed command-and-control will result in successful outcomes. Manufacturers contract with society to develop products that meet demonstrated needs over time through iterative processes and consumers freely decide the value of the product and whether they are willing to pay the price to acquire it.

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. Decision principles must focus on whether alternatives are safer for human health and the environment, meet consumer needs, comply with all local, state and federal laws and regulations, and address significant lifecycle impacts. Final decisions should balance human health and environmental impacts and lifecycle impacts based on risk.

Unique business and market considerations, such as supply chain economics, corporate positioning and brand equity will impact each firms' decisions. 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.

Specifically**,** industry recognizes that some of the assessors who will be implementing the IC2 AA Guidance will need direction on the decision making process. However, the module proposes a set of rudimentary frameworks that are not particularly helpful to the skilled assessor or experienced companies since the problems are more complex and demand a more time and cost effective approach than a slavish adherence to the systems proposed. 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. Many valid decision methods may apply to a given situation and assessors should employ the approach that gives the most robust, dependable results with the information available." Therefore, 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.

We acknowledge the principles and resources identified within the Decision Module as highly useful and suggestive of a rigorous approach towards alternatives assessment. However, the possibility that each element of the tools might be considered a required "checkbox" for acceptance of an AA is a signal concern. Alternatives assessments require a significant degree of flexibility since the direct replacement of a "chemical of concern" by another "safer" substitute is rare. Instead 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. At the very least, we expect that the consideration of alternatives will engage the whole product rather than individual ingredients. Therefore, a checklist is often a limitation rather than and aid in delivering effective alternatives. Further, 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.

Our additional concern is that the Decision Module's suggested methods will describe boundaries of expected activities. As noted above, we would like to see a more expansive and creative approach encouraged. 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.

The product development and improvement methodology has demonstrated success in industry. This is a team approach that includes a variety of disciplines with weighted responsibilities in contributing to the overall success. It sharply contrasts with the command-and-control approach of typical regulatory policies.

Stakeholder Involvement

Stakeholder involvement has long been a critically important aspect of any effective product development and innovation process. The most successful companies and the most successful

products have been those that effectively and creatively considered and met the needs of stakeholders and society. So it is appropriate that stakeholder involvement should be included in an effective AA process. However, as written, the Stakeholder Module is inappropriate for the targeted user groups and fails to properly reflect the very principles it advocates.

Stakeholder involvement is a data gathering activity. Input is solicited from affected stakeholders to provide data points that can be used to improve the end result of the process; in this case the selection of the "best" alternative. The mechanisms that are used within a business to process, evaluate and utilize stakeholder or customer research data are as unique as the companies themselves. In fact it is the ability of a company to utilize this information in unique and creative ways to develop products and provide solutions that represents one of the greatest competitive advantages a company can have in the marketplace. Throughout history it has been one of the traits that has separated the most creative and successful companies from those that could not keep up. An AA process is in essence a product development/innovation process for the businesses involved. Therefore it is important for businesses involved within this AA process to protect the processes they use to incorporate stakeholder input and thereby protect their competitive advantage in the marketplace. On the other hand, regulatory and governmental agencies are required to operate with a high-level of transparency relative to their stakeholder input and decision making processes as they do not operate in a competitive marketplace.

The Stakeholder Module states: "*Expected users include small, medium and large businesses, regulatory agencies, non-governmental organizations, etc*." Based on this target user group, the Stakeholder Module and the level of transparency it advocates are inappropriate for this broad range of users. The following statements are contained within the Stakeholder Module.

- *Another important aspect of stakeholder involvement is transparency of the decision making process. The intent of this module is to provide information so other concerned parties can understand what decisions are being made, why these specific decisions were made and to provide opportunity to input into that process. Therefore, the stakeholder process emphasizes the transparency of the alternatives assessment process so even if agreement on the final decision is not possible, all parties can understand how the decision was reached.*

- *The stakeholders themselves will determine how much involvement is necessary from their perspective and no attempt will be made to limit stakeholder involvement externally.*

The level of transparency advocated by these statements, while possibly appropriate for governmental and regulatory agencies is clearly inappropriate for businesses in a competitive market. Additionally, as indicated previously, stakeholder involvement is a "data gathering process", not a "decision making process". This module should confine its discussion to the methodology of soliciting and acquiring stakeholder input and allow the decision-maker to determine how best to utilize this information. The "decision maker", if they are a business, must consider a multitude of factors that stakeholders will not have information about, be interested in or equipped to consider. Items such as market segment focus, financial and technical feasibility, functional performance and product liability, internal organizational

competencies and intellectual property are important considerations in business decisions that must be made within an organization, outside of the purview of the stakeholders.

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. The following statement is made on page 2 of the Stakeholder Module: "*Care needs to be taken that one stakeholder group does not assume a dominant role in the stakeholder process and bias the results in a particular direction*." That appears to be exactly what has taken place in this instance. The stakeholders from the non-business segments have clearly biased this module in a particular direction that is inappropriate and unworkable for the business community. The construction of this document as a "voluntary consensus standard" would have provided greater consideration of all stakeholder interests and produced a better and more universally supported document.

Finally, the Stakeholder Module suggestion that stakeholders be included in "all aspects of the alternatives assessment" coupled with the transparency of the process and reports creates serious and unnecessary antitrust concerns unique to the business community. Specifically, because an alternatives assessment process will likely contain economic, technical and functional data, including a review of the economic and technical feasibility and the functional acceptability of various considered alternatives, any public comment requirement essentially mandates the opening-up of competitively sensitive information to the horizontal competitors of the Regulated Entity. Such sharing of competitively sensitive information creates potential exposure under the federal antitrust laws, and that exposure cannot be eliminated or minimized on the grounds that the information sharing is mandated by state law. In fact, the federal antitrust law on this topic is quite clear that potentially anticompetitive behavior cannot be shielded by state law from antitrust scrutiny unless the anticompetitive behavior is "clearly articulated and affirmatively expressed" by the state law. At the very least, the anticompetitive behavior must be a "foreseeable result" of what the state has authorized. In this case, there is no underlying law; therefore the IC2 AA Guidance fails to meet any of these tests. We understand that the underlying grant used to develop the IC2 AA Guidance is focused on protection of the Puget Sound; there is no clearly expressed intent to displace commercial competition, and such displacement is not a foreseeable result of the Department of Ecology utilizing the EPA grant in this way. The Supreme Court has just recently reaffirmed all these federal antitrust law principles in the case of *Federal Trade Commission v. Phoebe Putney Health System, Inc.* (slip op. February 19, 2013) (holding that Georgia law creating local hospital authority did not express a state policy to displace competition through permitting potentially anticompetitive hospital mergers). Because the business community would remain exposed to potential federal antitrust liability for knowingly sharing commercially sensitive information with its competitors, the proposed IC2 AA Guidance Stakeholder Module is not a permissible or foreseeable form of such information sharing, and is generally contrary to federal antitrust law policy.

In summary, the following issues in the Stakeholder Module should be addressed:

- Stakeholder involvement is a data gathering exercise. Discussion within the module should be limited to processes and techniques that a user could employ to identify and

solicit stakeholder feedback. Discussion concerning the evaluation and decision making process utilizing this data should be removed.

- The level of transparency advocated should be appropriate for all target users groups. If a single version of the Stakeholder Module cannot serve all user groups, sub-module should be created to better tailor the Stakeholder Module document to particular user groups.
- Allowing the business community to target stakeholder engagement appropriately must be addressed to avoid competition law issues.

Appropriate stakeholder communication is critical and requires providing consumers with accurate and useful information and conducting research to ensure product acceptance. 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, ensure products will have consumer acceptance and conveys the information in a manner that is understandable to the consumer/user. However, manufacturers cannot and should not be expected to subject their critical business decisions to external entities. Most innovation processes already have a voice of the customer or other consumer feedback component. Consumer acceptance is critical to any product change and must be a part of the decision making process for selection of alternatives. This communication happens on a regular basis and there is no need for governments to mandate or interfere in this already functioning mechanism

Stakeholder involvement may include: (i) Stakeholders in Performance Assessment and (ii) Stakeholders in the AA process.

(i) <u>Stakeholders in Performance Assessment:</u>
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) <u>Stakeholders in the AA process (including government, NGOs):</u>
The quality of stakeholder engagement and input, substantiated by valid scientific principles, is imperative to appropriate stakeholder communication/involvement.

<u>Performance Evaluation</u>

Performance and how product performance relates to use patterns are key factors which must be considered when evaluating various alternatives. In fact, any alternative must maintain if not improve the level of performance of the product. Substitution of one material with another may have unintended consequences, such as replacing with a less effective chemical, thereby potentially creating a greater exposure despite having a lower hazard, while increasing the

overall likelihood of harm. Likewise, reduced performance could result in increased safety concerns from other hazards due to product failure. By focusing on chemical safety alone, one may be led to replace a material with another which has lower physical safety performance thereby creating another type of hazard, as is the case when substituting plastic containers with glass.

Performance criteria are necessary to ensure the level of efficacy/functionality built into the alternative product is met or exceeded. Alternatives assessment evaluators must consider the intended function of the final product. 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 versus 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 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. Use performance assessment, e.g., in-home use test, is critical to evaluating the effectiveness and commercial viability of a product. Cost plays a role in determining the effectiveness of a product as well. Cost-prohibitive materials may diminish the likelihood of finding a viable alternative.

Additionally, formulation requirements should be considered. Once an alternative is identified, the formulating company incorporates all the ingredients into a product formulation. This formulation must deliver the desired benefit to the consumer.

In formulating a product, however, additional concerns must be identified and overcome. These include:

- Product Stability: shelf lives of three years or longer are typical requirements for the product to deliver its benefits
- Microbiological Safety: during the shelf life and then after opening, formulators must ensure that the product does not develop harmful levels of microbes which can easily develop in many types of formulations.
- Packaging: the formulation must be compatible with the package, which has the role of safely providing the means to hold and transport the product to wherever the consumer uses it. The package is an integral part of the overall stability profile of the product and serves to keep microbes out of the product during much of its life expectancy.
- Processibility: the formulation identified may not be compatible with the equipment which the manufacturer has, meaning that capital expenditures will need to be made in order to produce the formulation. Occupational safety concerns also are critically important in evaluating this parameter.

To innovate one or more technically feasible and economically and functionally viable alternatives, a safety profile comparison of the base and alternative together with information on other relevant factors must be developed, and market research for consumer acceptance must be conducted. 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. Performance and acceptance must be confirmed via consumer research.

The IC2 AA Guidance presents a performance evaluation approach that allows performance to be evaluated across a basic, extended and comprehensive level. Within each level, a series of questions are presented to help obtain information that will help determine whether or not an alternative is viable. The approach is very basic and does not reflect the concept that performance evaluation practices vary by industry and must therefore be inherently flexible to accommodate the nuances associated with different businesses and product lines.

As discussed in the preceding section, the modules need to be more explicit in pointing out that performance is a key element of a holistic approach to safety and that proper exposure and risk assessments are essential tools for evaluating substitutes based on targeted or desired performance features. The modules also do not discuss the issues that need to be evaluated with regard to ingredient patents or intellectual property issues – things that need considered as they can impact the selection of viable alternatives.

The modules also fail to recognize the need for organizations and companies to develop specific organizational policies, practices and procedures for reviewing alternatives – Something that most companies have in order to ensure consistency, quality and accountability. The module should also recognize that companies do not always have to go outside of the organization to seek expertise as technical experts can usually be found in-house. Moreover, in larger organizations, the performance evaluation process usually involves the collaboration of various experts in numerous departments such as R&D, Regulatory, Legal, Safety, Product, Quality, Microbiology, and Analytical.

Moreover, it should also be recognized that different types of standardized tests can be used to evaluate performance (indeed, some are prescribed by regulations for certain product categories such as pesticides and drugs) and vary widely by product line and can range from stability studies to customer use and performance acceptance tests to clinical testing.

Importantly, the module needs to note that performance evaluation is something that should be done on a continuous basis. Consumer product markets are not static, but dynamic. New ingredients, process improvements and enhanced product safety and performance features are continuously being introduced and can quickly render existing products, innovations and technologies obsolete. For this reason, performance evaluation must not just be a onetime activity, but a continuous process which need to be revisited on a routine basis. By doing this products are continuously improved in terms both safety and performance.

Commercial availability and cost effectiveness

The product development process requires the expending of substantial resources, which hopefully results in a reasonable return on investment. Return on investment must be acknowledged as a critical component of the AA. Innovation requires resources (i.e., people, finances, and equipment) and time (anywhere from months to years) depending on the size of the

project and complexity of the product[9]. Feasibility of processing, compatibility and stability requirements, and scalability must be evaluated. Additional special testing for the substantiation of specific product claims or consumer tolerance in use may also extend the timeframe needed. Consumer and other testing are required to establish performance and warranty claims. In the case of some products, independent testing (e.g. UL seal) may be required. All of these take significant time and money to accomplish.

Not only are research and development necessary, but regulatory requirements must also be satisfied. It may be necessary to get a new chemical listed on the EPA Toxic Substances Control Act (TSCA) inventory, by submitting a Premanufacture Notification (PMN), in order for it to be manufactured in the U.S.

There are numerous economic trade-offs that must be weighed carefully before moving ahead with any particular alternative. Without careful consideration, one may inappropriately conflate direct experience of ingredient availability with reputation of the ingredient:

- The origination of raw materials may impact costs[10]. For example, due to biodiversity (e.g., plants, flora, fauna native to certain regions for esoteric oils/fragrances), commercial availability comes into question (e.g., fees paid to indigenous tribes to source the raw materials). There may be negative impacts on biodiversity (e.g., encouraging large-scale manufacturing of ingredient A may impede on or have negative impact on

[9] For example, for a "simple" substitution in formulated products, a company at a MINIMUM would need two months to get scientists & engineers coordinated and in the lab; one year of research to find a material that meets safety and economic requirements, supply, etc. ; three months of process lab testing; six months for testing at the manufacturing plant (to include scheduling for an experiment since plants typically run at capacity); three months of consumer testing (note that not all products are used every day, and some products must be used multiple times for the consumer to notice something negative). From the time one or a few materials are identified for further assessment, on the optimistic side, AT LEAST 26 months is necessary for R&D and this is ONLY IF an EPA Pre-Manufacturing Notification (PMN) is NOT required. Realistically, a responsible entity should be given 3 years, with the option to extend for another 2 years, plus an additional 1 year if a new chemical PMN is required (as the PMN work may sometimes be done with an R&D exemption).

However, in most cases, substitutions will be much more complex, and the product system may be more complex. Many substitutions will likely require multiple materials to be substituted for the one chemical of concern. A good example is the replacement of phosphate in auto dishwashing (ADW) products. While some companies continue to optimize the formula on phosphate replacement in ADW over the past 25 years, the initial replacement was accomplished in three years. Phosphate replacement required 4 to 5 different chemicals depending on the formulation, in which one of the materials required a PMN (and a New Substance Notification (NSN) in Canada), and another material an NSN. (Each PMN requires 2-5 years of testing, evaluation, report writing and submission. Examples of other PMNs include: DTDMAC to DEEDMAC in liquid softener replacement, DTDMAMS to ethanol, Quat in dryer sheet softener replacement, anionic surfactant LAS replaced with HSAS in coldwater detergent.)

[10] For example, the Lacey Act compliance with legal harvesting and endangered / threatened species laws, the conflict minerals provision of the Dodd Frank Act being implemented by the SEC, and California's "Transparency in Supply Chains Act of 2010" requires posting of a link to disclosure detailing how companies investigate and monitor slavery or human trafficking in their "direct" product supply chains.

native species - flora/fauna).[11] Compliance with the Lacey Act and California's Transparency of Supply Chains Act of 2010 requires additional effort to accomplish.

- UN Treaty on Biodiversity - Availability of material may be controlled by an originating country, which can be unpredictable.
- Economic trade-offs could arise when the raw material might have to be sourced from different regions of the world and fair trade practices need to be factored in.
- Pricing availability of indirect ingredients on ingredient of interest - diverting materials from one market to another can lead to an imbalance. For example, tallow may be used as a renewable feedstock for biodiesel fuel thus pulling tallow out of the consumer supply chain, thereby resulting in dislocation of glycerin pricing. It is important to recognize the potential dislocation on the larger market place.
- Production availability for substitutes beyond batch or consumer processing – i.e., capacity for substitution (cost-prohibitive), and quality of materials – should be understood and is an issue with new ingredients especially.

Hazard

Goal: Determine hazard concerns, if any, for the target chemical and potential alternatives. Module will include ways to compare chemicals with each other and to select those that are less hazardous to human health and the environment when compared to the chemical that is being evaluated.

- Chemical evaluations are conducted at various levels beginning at Level 1 up to Level 5.
- Initial levels (Levels 1 & 2) of modules are sufficient to identify chemicals that are hazardous and not considered to be "less hazardous" alternatives.
- Chemicals that fail evaluations at Levels 1 through 3, based on authoritative lists (as described in Table X of the module), are not considered to be safer alternatives based on hazard potential.
- If a chemical does not appear on the authoritative list in Levels 1-3, then further evaluation is required to identify concerns that are not documented by the authoritative lists. Levels 4 and 5 describe comprehensive evaluations required to determine if a chemical is truly a "safer alternative."
- The confidence of a chemical being "green" increases from Level 1 to Level 5 since the data requirements increase with each increasing level.
- Degree of complexity in terms of evaluation increases if a chemical cannot be evaluated by criteria set forth in Levels 1 & 2.

While the module provides detailed instructions on how evaluations can be conducted, the level of data analysis seems very intense and time consuming. Though it appears that an on-line assessment tool has been established some details regarding this tool need to be included in the module along with status of the tool. The effectiveness of this tool to enable quick analysis will be determined after running beta testing first followed by a general launch.

[11] Historical examples include the use of ambergris as a fixative in cosmetics, having a negative impact on sperm whale populations.

Overall, efforts by states to encourage improved product safety through greener chemicals are commendable and assessment levels outlined in the module are well laid out. However, until such time that all relevant databases required for a comprehensive assessment are easily accessible and perhaps sequentially linked if possible, the hazard assessment exercise will become resource intensive and costly in the long run. Moreover, it appears that the assessment is purely focused on hazard. This approach is a bit flawed since hazard should be linked with exposures to assess the true risk of a chemical-of-concern and a specific product in comparison with alternatives. The IC2 AA Guidance should make an attempt to tie in realistic exposures along with hazard to provide a way for a more holistic assessment that will truly address improvements to product safety. This assessment should be tied in with the tool that is currently available for hazard assessment alone.

Although hazard assessment of alternatives will be a fundamental component of an alternatives assessment, risk assessment is imperative to determine extent of exposure for given use scenarios, and level of concern, to help ensure safety. Any comparative assessment methodology that relies solely on hazard can be grossly misleading and may result in unintended consequences, including the potential that the alternative product identified could be more hazardous than the one it is supposed to replace. Comparative hazard assessment is but one factor in a multi-factorial evaluation.

The hazard assessment should focus on the collection of hazard information for the chemical(s) being evaluated and any potential alternatives. It may be possible to characterize an alternative based on the hazard information, but it is premature to eliminate an alternative solely on this basis without consideration of the use, exposure, performance, availability and other relevant factors.

Clear and consistent criteria should be established for the sources of data that will be collected and used. Information should meet specific data quality criteria for inclusion into the assessment. Hazard data is often binary (typically, inclusion, or not, on a list for a particular endpoint, for example, carcinogenicity) or a continuum (such as a particular toxicity value or bioaccumulation value). In either case, the quality of the data reported will dictate its utility. Furthermore, data quality can often be used as a discriminator for cases where there are multiple results available.

- Selection of data sources should be consistent with internationally recognized definitions for reliable information such as that from the Organization for Economic Cooperation and Development (OECD): "Reliable information" is from studies or data generated according to valid accepted testing protocols in which the test parameters documented are based on specific testing guidelines or in which all parameters described are comparable to a guideline method. Where such studies or data are not available, the results from accepted models and quantitative structure activity relationship ("QSAR") approaches validated in keeping with OECD principles of validation for regulatory purposes may be considered. The methodology used by OECD in Chapter 3 of the Manual for Investigation of HPV Chemicals (OECD Secretariat, July 2007) shall be used for the determination of reliable studies.

(http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html)

- Both the EU and U.S. EPA use procedures similar to those described by Klimisch (Klimisch, HJ, Andreae E, and Tillmann, U. 1997 in *A systematic approach for evaluating the quality of experimental and ectoxicological data,* Regulatory Toxicology and Pharmacology 25:1-5) to determine the robustness of safety studies. The lower the score the more reliable the information from the study.

- Inherent in the OECD definition of "reliable information" is the need for reproducible results.

There are a number of widely accepted tools for filling data needs including the use of molecular similarity, read across, and a number of computational methods. Adequately validated tools should be utilized during the hazard data gathering phase.

We object 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.

In addition, describing such tools may be useful in a guidance document however, we object to any mandatory requirement to use proprietary, third-party screening methodologies to conduct AAs.

Cost and Availability

While the module provides numerous levels for evaluating cost and availability, there is little guidance on determining which level is appropriate. This is compounded by the significant overlap between levels, which lends itself to potential duplication of efforts and minimal apparent benefit. We recommendation combining level 1 with level 2, and level 3 with level 4, or significantly improve the IC2 AA Guidance to clearly identify the target audience and scope of each level.

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.

We are concerned the statement that "products that become hazardous waste upon disposal incur costs to society (i.e., users or local governments) for proper hazardous waste disposal," fails to take into account product stewardship activities already in place. Companies regularly incorporate disposal, recycling and reuse considerations into product design either through voluntary efforts or regulatory direction.

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.

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.

Exposure

The IC2 AA Guidance document segregates the assessment of exposure and hazard. It is common practice by regulatory agencies and businesses to consider both aspects when assessing the safety of a candidate chemical. This can be observed in a wide range of chemical assessment frameworks, such as those prescribed by the Food and Drug Administration and Research Institute for Fragrance Materials (RIFM)[12] in the US and by agencies such European Medicines Agency (EMEA)[13] and European Commission Directorate General for Health and Consumers (SANCO)[14] in the Europe. Rather confusingly, the Exposure Module then talks about the how exposure data may be useful when the risk of a chemical has been shown, despite no guidance for risk assessment being offered. In addition, it appears that there is a desire to simplify the exposure assessment process and minimize burdens, yet the result is the opposite.

Further, we object to the approach taken in the IC2 AA Guidance because considering hazard and exposure separately would turn the practice of alternative assessment on its head. 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.

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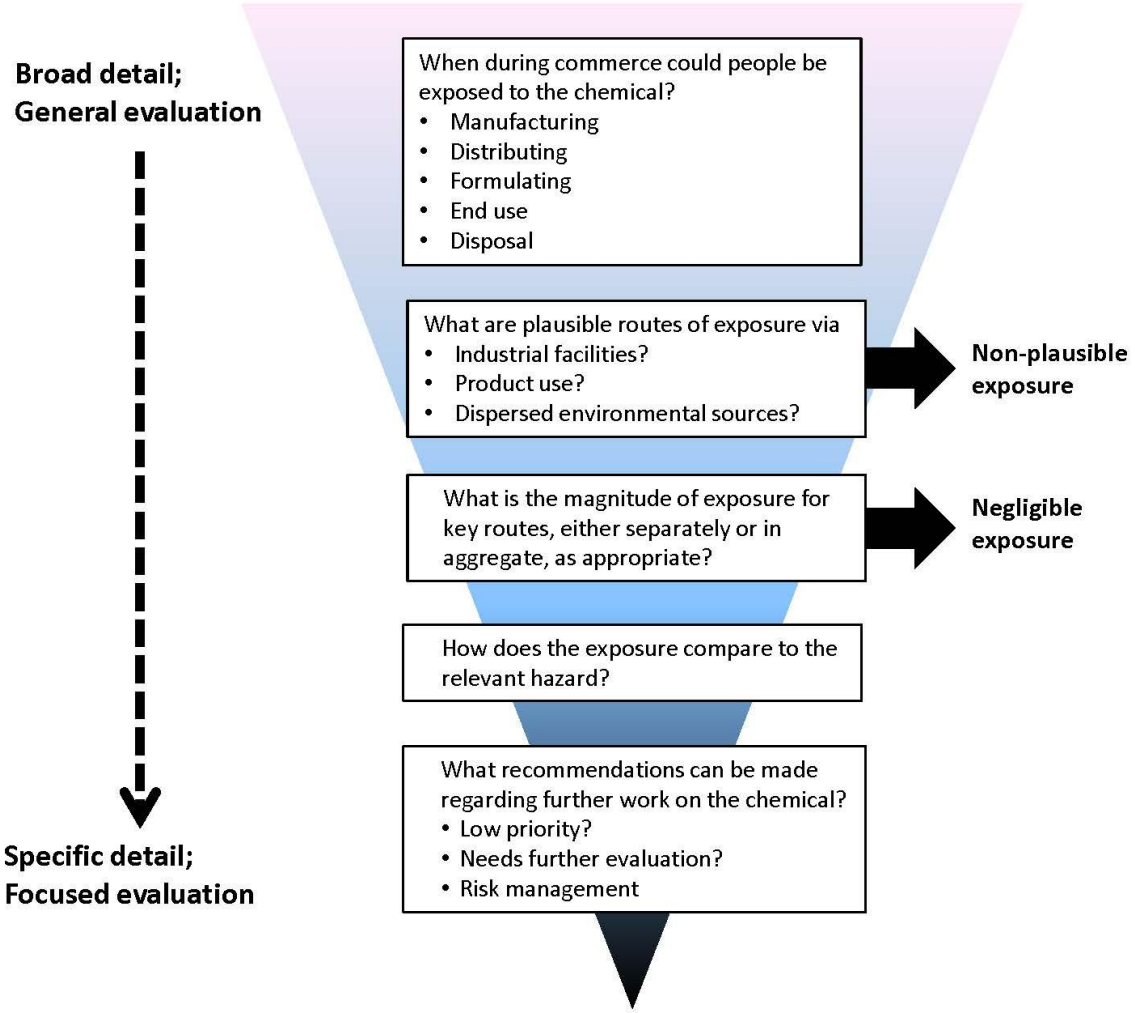
[12] Salvito, D.T., Senna, R.J., Federle, T.W. 2001. A framework for prioritizing fragrance materials for aquatic risk assessment. *Environmental Toxicology and Chemistry* 21 (6): 1301-1308

[13] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000400.jsp&mid=WC0b01ac0580029570

[14] http://ec.europa.eu/food/plant/pesticides/legislation/index_en.htm

The IC2 AA Guidance should contain a coherent process for conducting an exposure assessment in a logical manner following well founded scientific procedures such as those followed by a wide range of safety assessment frameworks within the US (e.g. RIFM). It is common practice to assess exposure for human health, occupational health and environmental health independently. Figure 1 provides a general illustration of a Generic Exposure Framework.



Because the approach described in the Exposure Module is rather disjointed, it does not lend itself to traditional exposure assessment in a logical and considered manner. For example, an environmental exposure assessment for a "down-the-drain" product would follow particular steps in the assessment to first examine removal efficiency of a chemical during wastewater treatment and subsequent releases into the aquatic environment via traces in the wastewater effluent. During this initial assessment, the physiochemical properties of the chemical would dictate whether there also may be terrestrial exposure from traces of the chemical present in wastewater biosolids which are then land applied. Although most considerations are mentioned at some point during the document it does not provide consideration in a logical step-wise fashion. As such, recommendations are provided on conducting an exposure assessment for the use phase of

the product first and some considerations of "far-field" exposures, followed by environmental exposure assessment following use.

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. A wide array of product-specific exposure assessment resources is available. In particular, we direct the reader to a compilation from the American Cleaning Institute (ACI) called *Consumer Product Ingredient Safety*[15] which focuses on human and environmental exposure and risk screening methods for formulated consumer products such as cosmetics, personal care products and cleaning products. It includes extensive citations of primary and secondary exposure models used in North America and Europe to assess dermal, oral and inhalation exposure scenarios for formulated consumer products. Moreover, habits and practices data for the use of those formulated products by consumers in North America and Europe also are provided. The U.S. EPA has also developed extensive resources related to exposure factors in their *Exposure Factors Handbook.*[16]

The European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) launched its Targeted Risk Assessment (TRA) tool in 2004.[17] The TRA consists of three separate models for estimating exposures to workers, consumers and the environment that arise during a series of events ('exposure scenarios'). The European Chemicals Agency (ECHA) has incorporated the ECETOC TRA as part of its Chemical Safety Assessment and Reporting (Chesar) tool for use in assessment of chemicals under REACH.[18] These tools assist in the development of exposure scenarios for workers, consumers and the environment as a part the assessment of a chemical (and its alternatives).

A number of other tools are available for conducting exposure estimates. The USEPA's E-FAST (Exposure and Fate Assessment Screening Tool)[19] will estimate general population and ecological exposure from industrial releases, consumer exposure from use of products, environmental exposure from down-the-drain disposal of formulated products, and downstream chemical concentrations from an industrial discharge. The U.S. EPA's Wall Paint Exposure Assessment Model (WPEM) estimates potential exposure of consumers and workers to chemicals emitted from wall paint.[20] In Europe, the ConsExpo[21] model from the Dutch National Institute for Public Health and the Environment (RIVM) is used for the estimation and assessment of exposure to substances from consumer products that are used indoor and their uptake by humans as a part of the assessment of general chemicals (under REACH) and biocides.

The "far-field" component of the Exposure Module also could benefit from utilizing the "tiered" approach that is currently widely used during (human) exposure assessment. When conducted

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[15] http://www.aciscience.org/docs/Consumer_Product_Ingredient_Safety_v2.0.pdf
[16] http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252
[17] http://www.ecetoc.org/tra
[18] http://chesar.echa.europa.eu/
[19] http://www.epa.gov/opptintr/exposure/pubs/efast.htm
[20] http://www.epa.gov/opptintr/exposure/pubs/wpem.htm
[21] http://www.rivm.nl/en/Topics/Topics/C/ConsExpo

according this approach the extent to which exposure may persist over space and time can be evaluated once an initial "near-field" (consumer use-phase and/or occupational) exposure assessment has been completed. The use of models such as RAIDAR[22] can incorporate potential incidental environmental exposures at a screening level. For the purposes of guidance to manufacturers, a screening-level assessment of "far-field" exposures is likely sufficient as higher level assessments can be quite complicated and well beyond the resources of most commercial organizations. Additional tools exist to examine the characteristics of a chemical to potentially contribute to "far-field" exposures. For example, the US EPA's PBT Profiler[23] can provide can provide an assessment of a chemicals persistence, bioaccumulation potential and toxicity.

With respect to environmental exposure assessment, there are existing approaches especially for formulated consumer products that are publicly available (e.g., ACI's *Consumer Product Ingredient Safety*[24] and the RIFM Framework for Conducting Environmental Risk Assessments[25]). These approaches focus primarily on estimation of exposure to the aquatic environment following "down-the-drain" disposal as this is a common scenario in the United States for these high volume formulated products. Potential removal by wastewater treatment processes (such as sorption to biosolids and biodegradation) is incorporated into the assessment to determine releases to the aquatic environment. When removal via sorption to biosolids is significant, terrestrial exposures via sludge application to land (in geographical areas where farming practices involve using wastewater treatment plant (WWTP) biosolids as fertilizer). A number of models are available to estimate environmental releases by WWTPs locally (e.g., SimpleTreat[26,27]), at the watershed scale (e.g, PhATE[28]) and at the national scale (e.g., iSTREEM[29]). In addition to releases to surface waters, models such as RAIDAR are capable of predicting atmospheric deposition of chemicals based on vapor pressure data. Estimation of the persistence or long-range transport of chemical that has a significant atmospheric release may be an important component of the environmental exposure assessment.

When an exposure assessment has been completed it generally yields an expected environmental concentration that is typically compared to a relevant hazard end-point, such as chronic toxicity (for humans) and ecotoxicity for relevant ecological species. Such a comparison results in determination of the margin of exposure (MOE) or a risk ratio. In either case, ideally the exposure level is much less than the hazard end-point that would cause adverse outcomes. In the cases where there is not a wide MOE or risk ratio, refinement of the exposure assessment or hazard characterization (a higher tier assessment) may be necessary, or risk mitigation/risk

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[22] http://www.arnotresearch.com/#!/page_RAIDAR_DLhttp://www.arnotresearch.com/#!/page_RAIDAR_DL
[23] http://www.pbtprofiler.net/
[24] http://www.aciscience.org/docs/Consumer_Product_Ingredient_Safety_v2.0.pdf
[25] http://www.rifm.org/rifm09/upload/SETAC%20LatAmer%20DSalvito%20102005.pdf
[26] Struijs, J. SimpleTreat 3.0: a model to predict the distribution and elimination of chemicals by sewage treatment plants. RIVM report no. 719101025. National Institute of Public Health and the Environment, Bilthoven, The Netherlands (available at: http://rivm.openrepository.com/rivm/handle/10029/257231)
[27] http://www.rivm.nl/en/Library/Scientific/Reports/2013/maart/Evaluation_of_the_model_Simple_Treat
[28] Cunningham, V.L, V.J. D'Aco, D. Pfeiffer, P.D. Anderson, M.E. Buzby, R.E. Hannah, J.Jahnke, and N.J. Parke. 2011. Predicting concentrations of trace organic compounds in municipal wastewater treatment plant sludge and biosolids using the PhATE™ model. *IEAM* 8(3): 530-542.
[29] http://www.aciscience.org/iSTREEM.aspx

management may be required including limiting the concentration level or use of the particular chemical.

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.

Additional Exposure Considerations with Respect to Alternatives Assessment
Consideration of product use and exposure potential is an essential factor for any chemical or product evaluation.

- First, there should be a reasonable or foreseeable route of exposure to the subject chemical before there is a need to conduct an alternatives assessment.

- Second, indicators of potential exposure may be useful in initial screening or prioritization efforts, but additional information such as use patterns, levels in products above an appropriate *de minimis*[30], and product forms should inform the exposure evaluation. Both chemical mass and corresponding physicochemical properties, as well as the route of exposure, are useful in assessing relative impact. This is also an opportunity to factor in sensitivities of unique subpopulations when performing the risk assessment.

- Third, potential for exposure will help identify and eliminate alternatives that may likely adversely contribute to significant exposure through use.

Prior to alternatives assessment, the source(s)/major contributor(s) to overall exposure would have to be identified. 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. As stated by the Center for Disease Control and Prevention (CDC), "The measurement of an environmental chemical in a person's blood or urine is an indication of exposure; it does not by itself mean that the chemical causes disease or an adverse effect." (http://www.cdc.gov/exposurereport/pdf/FourthReport.pdf) In an analogous manner, environmental monitoring may provide additional information to inform the risk assessment, but does not necessarily reflect levels of concern in an organism. There must be a realization that reliable methodologies will not necessarily be available to detect and measure certain chemicals in a particular human tissue matrix. Assuming measurement is possible, mere detection or even measurable levels may not contribute to an adverse impact. Lastly, biomonitoring reflects aggregate exposure to a particular compound at the time of analysis that may fluctuate depending on the toxicokinetic profile of the chemical.

[30] Whether a chemical is an intentionally-added ingredient or a trace contaminant may impact how a *de minimis* threshold is established.

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).

We object to the bias in the sentence on page 65, "Examples of administrative controls on a consumer product could include careful directions and/or warning for proper use such as use with ventilation, and PPE may be recommend for use with certain products." The basic goal of hazard communication is to ensure employers, employees and the public are provided with adequate, practical, reliable and comprehensible information on the hazards of chemicals, so that they can take effective preventive and protective measure for their health and safety. The use of the word "careful" in the sentence implies that manufacturers of consumer products are not using vigilance when developing use directions when in fact such directions are governed by a number of international and federal standards. We request the substitution of the more suitable term "appropriate" as reflective of existing standards and partnership with consumers to use the products in the manner in which they are intended to be used. We appreciate the acknowledgment on page 66 that manufacturers cannot prevent tampering with or inappropriate use of products.

Materials Management

High level Comments:

1. We agree Sustainable Materials Management (SMM) should look at more than end of life issues such as recycling or reuse – and include the entire life cycle analysis that examines impacts from various raw material inputs, energy, air and water emissions, as well as waste. 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.
2. We believe the 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).

Specific Comments:

1. We agree SMM should take an integrated and systematic approach to evaluating material flows and the associated impacts.
2. We generally subscribe to the EPA's SMM concept and the work of the Organisation for Economic Co-operation and Development (OECD) in establishing a set of Policy Principles for Sustainable Material Management. The social equity principles, however, are not as well established with the same degree of scientific quantification as the life cycle environmental measurement approach.
3. We believe the life cycle approach should be applied for all impacts, including sustainable feedstocks.
4. We believe 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. For instance, a life cycle approach of packaging products might show that a flexible multi-layer package has lower environmental, energy and footprint emissions compared to a

rigid package serving the same function. Even with no recycling of the flexible multi-layer package, a SMM or LCA approach and analysis would show that the flexible packaging is the more sustainable choice with lower overall emissions, including waste. The MMM focus on recovery only would miss this important distinction and possibly lead to incorrect choices or unintended consequences.

5. The level 1, level 2, and level 3 progression of the MMM seems to better be covered under the application of Life Cycle Thinking module, which better reflects the concepts of SMM.
6. From a policy perspective, sustainable materials management (SMM) is a process defined by the Organization for Economic Co-operation and Development (OECD) that is an approach to promote sustainable materials use, integrating actions targeted at reducing negative environmental impacts and preserving natural capital through the life cycle of materials, taking into account economic efficiency and social equity.
    a. The concept is this strategy would be an important shift of emphasis from waste management only and takes an integrated and systematic approach to evaluating material flows and the associated impacts.
    b. The SMM Policy Principles in this module (Preserve Natural Capital and Design and Management Materials, Products and Processes for Safety and Sustainability from a Life Cycle Perspective) is a principle industry generally subscribes to.
    c. The SMM principles seem to better be covered under the application of Life Cycle Thinking module.

Social Impact

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.

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.

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.

Hazard Communication and Safety Data Sheets

Manufacturers are developing and marketing products in the US that are safe for human health and the environment. Manufacturers are regularly applying green chemistry and green engineering principles in their operations. At the core of the consumer product industry practices is the essential premise that products, packaging and operations are safe for employees, consumers and the environment within the context of their intended use and good manufacturing practices. Manufacturers/marketers additionally recognize reasonably anticipated misuse. By implementing the principles of green chemistry, complying with applicable laws and regulations and continuing to innovate, critical environmental, social and worker justice issues would inevitably be addressed.

Manufacturers, distributors, retailers, employers and employees have shared responsibility for hazard communication, training, and appropriate handling of chemicals. It is important to acknowledge OSHA requirements (now aligned with the Globally Harmonized System for Classification and Labeling of Chemicals) to disclose health and physical hazards, as well as precautionary measures and first aid, on Safety Data Sheets (SDS). Safety Data Sheets are an important component of the Hazardous Communication Standard designed to communicate chemical hazards to promote worker safety. In addition, OSHA requires employee training that must be conducted at the time of initial assignment, and upon introduction of a new physical or health hazard in the environment.

Manufacturers/marketers also acknowledge that there is potential for worker exposure in industrial/institutional/commercial use of products. These uses expect a partnership between user businesses and the manufacturer. The manufacturer has the responsibility to provide adequate information and training for safe storage, handling and use of materials at their facilities. Because of the additional training and communication responsibilities of the user business, exposure mitigation strategies can be included in the strategy for acceptable use.

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.

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.

Life cycle Thinking

In a life cycle analysis, we think the AA should only evaluate those aspects directly affected by the alternative.

High level Comments:

1. We agree life cycle thinking goes into material flow assessment. Life cycle approach through first cut screening before going into a full blown ISO LCA as necessary.
2. Alternative assessments that examine impacts using a material flow assessment often give the most comprehensive look at the opportunities to identify multiple places to reduce energy, emissions and raw materials through the product development cycle
3. Manufacturers engage in continuous alternative assessment and product improvement. Recognizing the impacts this process may have throughout the whole value chain and life cycle of a product, from raw materials to use phase and final disposal - one important tool to assist in optimizing the tradeoffs of energy, raw materials and emissions before a product comes to market is life cycle assessment (LCA).
4. We believe this LCT module can be significantly streamlined by referring to the widely accepted ISO 14040 series of Life Cycle Assessment when the need to do any full LCA study is determined.
5. We like the glossary and reference to ISO LCA standards – there should also be a reference to accepted LCC ASTM standards as well for life cycle costing.
6. There are a number of life cycle approaches – scoping LCAs, attributional LCAs, consequential LCAs, and tools for communicating LCA results such as Environmental Product Declarations (EPDs) that also follow ISO standards and could be referenced.

Specific Comments:

1. We agree LCA as defined under ISO is appropriate for this LCT module.
2. This methodology not only provides a multi-parameter look at all the environmental, safety and health impacts of a product system from “cradle to grave”, but also provides a mechanism to identify product improvement – a “what if” analysis designed to maximize energy/emissions reduction and ability to lower overall footprint. The ISO standards for LCA, along with the development of commodity LCA databases for most processes and raw materials, make it viable for small, medium and large enterprises to perform screening versions of a full LCA, or if necessary – conduct a full life cycle study - to assist in the development of products with the least footprint. Common LCA impacts that are part of a full analysis may include ecotoxicity, human toxicity, change, acidification and eutrophication, to name a few.
3. If life cycle costing (LCC) is also going to be included, a reference to ASTM E917 Life-Cycle Costing standard should be included.
4. We agree a natural progression for life cycle thinking would include scoping LCAs, all the way up to determining whether a full LCA is needed for alternative assessment.
5. An LCA under ISO consists of 4 major stages: (a) goal and scope, (b) inventory analysis, (c) impact assessment, and (d) interpretation. Social impacts are an emerging part of life cycle thinking, and outside the current scope of the ISO 14040 LCA standards and should not be noted as such.

6. We suggest that the impacts associated with life-cycle costing section, which currently includes human health and environmental, economic, and social costs – be limited to the accepted ASTM #917 Life-cycle costing consensus standards used today.
7. The Level 1 and Level 2 and Level 3 screens could be simplified by referring to the different types of LCAs under ISO:
    a. a scoping LCA [for first timers to LCA and want get an idea of the key burdens (energy, air, water, solid waste) across the life cycle of your product system that might give you the best opportunity, both upstream and downstream, to make improvements and lower your product's footprint. A scoping study that examines the major inputs and outputs described in a life cycle inventory (LCI) can give you a benchmark snapshot picture from which you can proceed.]
    b. A comprehensive complete LCA [If you wish to not only quantify the energy, raw materials in and emissions (air, water, waste) through an LCI, but also perform a full impact analysis of the effects of those energy and material inputs and outputs, such as climate change, acidification, photochemical smog or fossil fuel depletion, you should consider conducting a full LCA compliant with ISO 14040 standards.]
8. Appendix A – glossary is good
9. Appendix ___ Life-Cycle Thinking
    a. LCA reference to ISO 14040 is good
    b. LCC reference should be to ASTM E917
    c. Social Life-cycle Assessment (SLCA) is a concept UNEP-SETAC Life Cycle Initiative is proposing, and is not currently part of the ISO 14040 LCA standards. There should be a notation that social LCA is an evolving concept that needs further development – and is not currently covered by ISO as part of the LCA standards.

Lifecycle thinking goes into the material flow assessment approach. A life cycle screening exercise can be used before going into a complete ISO-compliant life cycle assessment (LCA) as necessary.

Alternative assessments that examine impacts using a material flow assessment often give the most comprehensive look at the opportunities to identify areas of improvement: reducing energy; emissions; and/or raw materials throughout the product development cycle. Every product has different impacts along its life cycle phases – from raw material extraction, manufacturing production, distribution, transportation, use/operation and maintenance, recycling and final waste management after its useful life. This analysis, when combined with product development criteria like source reduction and cost reduction, is part of an iterative process of sustainable product design. A material flow assessment approach to product development is the key to developing sustainable products.

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. This will assure that maximum efficiency of material flow includes flexible alternatives for a holistic comparison of alternatives.

Manufacturers engage in continuous alternatives assessment and product improvement. Life

cycle assessment (LCA) is one important tool to assist in optimizing the trade-offs of energy, raw materials and emissions before a product comes to market. This methodology not only provides a multi-parameter look at all the environmental, safety and health impacts of a product system from "cradle to grave", but also provides a mechanism to identify product improvement – a "what if" analysis. The ISO 14040 standards for LCA, along with the development of commodity LCA databases for most processes and raw materials, make it viable for small, medium and large enterprises to perform screening versions of a LCA, or if necessary, conduct a full life cycle study. Common LCA impacts that are part of a full analysis may include ecotoxicity, human toxicity, acidification, eutrophication, energy use, water use, to name a few.

There should also be consideration of unintended impacts should resource volumes increase due to demand for a successful alternative. An example of this unintended effect is the environmental impact of palm oil cultivation on endangered species habitat due to the conversion from petroleum to "renewable" bio-based feedstocks such as palm oil. Consideration of unintended impacts enables regulators and manufacturers, to have a comprehensive review of alternatives, without shifting to the unanticipated risk.