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Ms. Elizabeth Sommer
Design for the Environment Branch
Office of Pollution Prevention and Toxics
USEPA Headquarters
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(via e-mail: sommer.elizabeth@epa.gov)

Dear Ms. Sommer:

The American Cleaning Institute® (ACI) appreciates the opportunity to comment on the EPA's recently-released draft of the Design for the Environment (DfE) *Alternatives Assessment Criteria for Hazard Evaluation*. ACI is the trade association representing the \$30 billion U.S. cleaning products market. 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.

ACI and its members support the efforts of the agency, and the DfE Program in particular, to seek new and innovative ways to examine and reassess existing chemistries and certain uses of those chemistries in an effort to identify opportunities to shift toward the use of alternative chemicals and processes that might reduce risks to health and the environment. Following are comments concerning the process by which the *Criteria for Hazard Evaluation* is being developed and substantive aspects concerning certain criteria and the manner in which they might be applied in this context.

EPA should comply with the standards of the Administrative Procedure Act (APA) when seeking and considering public comment for the DfE *Alternatives Assessment Criteria for Hazard Evaluation* and the methods by which EPA intends to apply the Criteria both to specific substances and in agency decision making.

It is clear from recent EPA announcements issued in the context of certain "Action Plans" that the agency considers the chemical alternatives assessment process to be a critical component of its program for managing chemical risks for Action Plan Chemicals. Thus, the Criteria that are

being developed and will be applied as part of the *Alternatives Assessment Criteria for Hazard Evaluation* will have the effect of providing a basis for agency decisions to regulate or restrict the use of chemicals in the marketplace. Notwithstanding the “voluntary” nature of the DfE Alternatives Assessments Program, the tools and processes used by EPA, and the analytical outcomes that result will have the imprimatur of an EPA safety assessment and preferability of certain chemicals and products containing those chemicals. It is reasonable to conclude that the results of a DfE Alternatives Assessment ultimately will be used within EPA programs and by the states and localities wishing to articulate standards and requirements for the use of certain chemicals by the regulated community. Consequently, in developing procedures and standards for review of chemical substances, EPA should meet the standards for providing all members of the public with notice and the opportunity to provide comment on all aspects of both the development of the AA Criteria and the application of the criteria within the Alternatives Assessments Program as well as EPA’s risk-management decision making process. This should, at a minimum, include official notice in the Federal Register of the availability of the draft documents with appropriate comment periods, as well as the consideration of and a response to comments that are received.

EPA should more clearly explain how the Criteria for Hazard Assessment will be used in the Alternatives Assessment process to compare multiple alternatives to each other.

It is clear that the intent of the DfE Alternatives Assessment process is to utilize the AA Criteria to place individual chemicals on a continuum of relative hazard to inform decision-making and presumably alternatives selection. We understand the concept that for particular endpoints, substances will be categorized as either “High”, “Moderate”, or “Low” concern and, as a result, for any specific endpoint, one could place each substance on a continuum of relative hazard. However, the agency needs to clarify how one would utilize these categorization criteria to compile one continuum for a group of alternative materials being assessed against an existing material. It would seem that a key objective of the hazard evaluation process has not been addressed. It is important for all stakeholders to have the opportunity to comment on perhaps the most challenging, yet most important, aspect of the evaluation process.

EPA should apply broader sustainability criteria when evaluating a particular chemical and its uses against alternative chemicals for each of the same uses.

The *Alternatives Assessment Criteria for Hazard Evaluation* and the process discussed in the publication *Chemical Alternatives Assessment: Enabling Substitution to Safer Chemicals*¹ demonstrate that EPA intends to rely disproportionately on hazard-based criteria when evaluating the (safe) use of a chemical substance in a product, and when identifying potential alternatives. Such a limited approach can be flawed on several levels especially when hazard-based metrics are applied as the sole criteria for chemical selection. First, this approach presumes that most alternative chemicals are “drop-in” substitutes. However it is very rare that circumstances exist to allow for such seamless substitution. Moreover, an analysis based on hazard factors alone can ignore the effect that differences in physicochemical properties of chemicals can have upon exposures and environmental releases, even when drop-in substitution might be possible. Finding substitutes for established chemistries often requires that an

¹ Emma T. Lavoie, Lauren G. Heine, Helen Holder, Mark S. Rossi, Robert E. Lee II, Emily A. Connor, Melanie A. Vrabell, David M. DiFiore, Clive L. Davies. 2010. *Environmental Science & Technology*. 44 (24): 9244-9249.

alternative chemical be used at a different concentration than the material it replaces, or with multiple chemicals that are necessary to replace a single substance being de-selected. It is not clear that the DfE AA Criteria can take this into account and compare the relative hazards of one substance with the hazard associated with multiple chemicals or chemicals used in differing concentrations.

The hazard-evaluation-only approach proposed for the DfE AA Criteria also fails to consider other significant factors which influence the health and environmental impacts associated with a product. For many products, such as cleaning products, changes in certain components often can have significant impacts on the energy and water consumption characteristics associated with the use of the products. Therefore, for an alternatives assessment to effectively consider the potential human and environmental impacts of an alternative, consideration must be given to all phases of the product's lifecycle to significantly improve the sustainability profile of a particular product. Minor changes in the formulation of a high volume product can result in significant and unintended impacts on health and the environment. For example, efforts are being made to reduce the environmental impacts of laundering clothes and washing dishes, through the use of more water- and energy-efficient commercial equipment and consumer appliances. If an alternatives assessment fails to take into account non-hazard based factors, such as the compatibility of alternative ingredients for detergent formulations with the current and next-generation equipment that is designed to be less energy- and water-consumptive, then these hoped-for energy and water efficiency improvements might not be achieved due to low consumer acceptance. EPA's proposed hazard-evaluation-only approach for alternative assessment should be modified to more fully assess a product's entire lifecycle and consider the health and environmental impacts of substituting alternative chemistries across the entirety of the product's lifecycle.

The AA Criteria have been released with little context given to the broader Alternatives Assessment program or EPA's AA goal of *informed substitution*. In the past, EPA has stated that, in the context of *informed substitution*, "potential alternatives should exhibit as many of the following characteristics as possible: they should be technically feasible; deliver the same or better value in cost and performance; provide an improved profile for health and the environment; account for economic and social considerations; and have the potential to result in lasting change." None of these other characteristics have been given treatment similar to the AA Criteria for Hazard Evaluation and there is no indication that the agency will provide guidance to the public on how one might evaluate them as part of an alternatives assessment or that more comprehensive guidance on conducting an alternative assessment with the goal of informed substitution is forthcoming.

The agency's website on Alternative Assessments² includes a description of the key steps to conducting an alternatives assessment including Step 6, Apply Economic and Life Cycle Context. However, the description of Step 6 is quite broad in its coverage. The agency should prepare and communicate to the public a roadmap regarding its guidance on the alternatives assessment process so that no step is given disproportionate or undue weight and so that all characteristics of the goal of *informed substitution* may be satisfied.

² http://www.epa.gov/dfc/alternative_assessments.html

EPA should reconsider and enhance the criteria it has selected.

While the toxicological assessment criteria, and environmental toxicity and fate scoring parameters selected for use by EPA in its AA Criteria are familiar and accessible to many in the regulated community, there nevertheless are some important issues that should be taken into consideration with respect to the use of certain of the Criteria in the context of DfE Alternatives Assessments.

Anticipating Potential Changes to the GHS Criteria. EPA proposes to use criteria and endpoints derived from the United Nation's Globally Harmonized System for the Classification and Labeling of Chemicals (GHS). In the U.S., the Occupational Safety and Health Administration (OSHA) is responsible for implementing the GHS system for workplace use. However, OSHA has issued proposed regulations to modify its existing Hazard Communication Standard (HCS) to conform with the GHS [74 FR 50279; September 30, 2009]. The proposed modifications to the standard include revised criteria for classification of chemical hazards. The DfE AA Criteria document does not address whether and how the Criteria can be modified if and when OSHA adopts changes to the GHS. ACI recommends that DfE not adopt GHS criteria for workplace products, but instead wait for OSHA to complete its regulatory development process. Should EPA move ahead with adoption of some GHS components, any criteria that are inconsistent with OSHA final regulations should be revised in order to avoid manufacturers having to assess their products against two different systems.

Also, while the Consumer Product Safety Commission (CPSC) intends to adopt changes to its regulations to implement the GHS, it has not yet proposed those changes. Therefore, in order to avoid inconsistencies between its criteria and CPSC-regulated products, DfE should not implement any GHS-related criteria chemicals used for consumer products.

Consistent to the preceding comments, all references to characterizing chemicals and products according to GHS should be removed. Instead, EPA should refer to the hazard regulations of the respective agencies, which, as they adopt GHS under their respective review and comments procedures, would allow a DfE alternatives assessment program to remain consistent with those requirements.

In addition, EPA has started a public dialogue and record related to the agency's implementation of the GHS. In 2004, the agency received numerous comments on its document *The Globally Harmonized System of Classification and Labelling of Chemicals: Implementation Planning Issues for the Office of Pesticide Programs* (Environmental Protection Agency (EPA). Pesticides; Implementation of Globally Harmonized System; Notice of Availability, *Federal Register* / Vol. 69, No. 164 / Wednesday, August 25, 2004 [Docket number OPP-2004- 0205]). ACI (under its former name, The Soap and Detergent Association) submitted comments to this record. In addition, the Office of Pesticide Programs held a Public Stakeholder Meeting on the implementation of the GHS in 2006 (October 18-19, 2006), in which the agency received additional input. EPA should consider and respond to the comments it has already received on GHS implementation before proceeding with its proposal to include GHS elements in the Alternatives Assessment Criteria.

Identifying compounds of low hazard. The draft raises the potential for substantial confusion by designating substances where there are negative studies or test results, no structural alerts, etc. as “low” hazard. In such circumstances, the substance should be designated to not present the hazard.

Partial adoption of GHS elements. EPA should avoid incomplete adoption of criteria and approaches to classification presented in the GHS. For example, the proposed adoption of GHS criteria for Specific Target Organ Toxicity – Repeat Exposure (STOT-RE) for neurotoxicity lacks many of the critical elements of the classification criteria for this endpoint that are part of the GHS. EPA should compare the criteria for each endpoint from the GHS that it proposes to adopt against the criteria the agency currently uses, and present its rationale for the GHS elements it proposes to adopt and not adopt for each endpoint.

Use of Criteria from Other Countries Developed Without Opportunity to Provide Input in the U.S. The use of European Union criteria and authoritative lists in Section 4.1.2 and elsewhere in the document is inappropriate. U.S. stakeholders are not a party to the development of the EU lists and EU Risk Phrases. Therefore, unless EPA wishes to first solicit input and comment on the substantive aspects of the EU-based lists and criteria, those criteria should not be used to implement the DfE program in the U.S.

Use of Novel and Untested Criteria. The Endocrine Activity criterion described in the draft (Section 4.1.9) has not been used previously in government programs in the United States or elsewhere in the world. EPA’s new testing program for potential endocrine effects is itself in its infancy. By making use of this criterion now, as part of an assessment of alternative chemistries, DfE will be establishing a precedent that suggests the standards being used are considered to be generally acceptable and reliable in the scientific community. Until such time as there is general agreement in the scientific community on the appropriateness of using the method EPA proposes to comment on the potential endocrine effects of a substance, this criterion should be eliminated from the DfE Alternatives Assessment Criteria.

Order of data preference. EPA’s proposal states that data will be considered in a specific order of preference (“In general, DfE will use data in the following order of preference: 1) measured data on the chemical being evaluated, 2) measured data from a suitable analog, and 3) estimated data from appropriate models.”) and that “available human data will be considered.” ACI recommends that EPA clearly give preference to human data and experience, since such information is most relevant to exposures and effects that could occur in humans. Further, all other data should be considered in a *weight-of-evidence* evaluation.

Definition of “compound.” The term “compound” is used in the document, but is not defined. This could be confusing since terms such as “chemical” and “ingredient” are defined.

Use of Specific Criteria Which Are Inconsistent with Relevant Precedents.

4.1.1 – Acute Mammalian Toxicity: The Table 1. Acute Mammalian Toxicity Criteria for Hazard Designation are stated to have been derived from GHS criteria however these values are not consistent with those proposed by OSHA for the implementation of the GHS in the United States [74 FR 50279; 9/30/09]. We endorse the use of harmonized workplace GHS criteria in the U.S.

4.1.3 – Mutagenicity/Genotoxicity: We urge EPA to remove the Mutagenicity/Genotoxicity (M/G) criterion from its proposal. Hazard communication regulations of other agencies, such as OSHA, address mutagenicity/genotoxicity through the reproductive toxicity endpoint (see 29 CFR Parts 1910, 1915, and 1926 Hazard Communication; Proposed Rule; *Federal Register* (Vol. 74, No. 188, September 30, 2009), page 50388: “The GHS has a separate definition for germ cell mutagenicity, which is considered part of reproductive toxicity in the current HCS [Hazard Communication Standard].”) In the absence of results from higher-tier more sophisticated studies, the results from genotoxicity assays (i.e., mutagenicity tests) are used by most scientists to predict the potential carcinogenicity of a substance. A material that tests positive for mutagenicity either will be predicted to be a carcinogen or additional higher-tier tests may be undertaken to confirm or over-ride the concern. This is a conservative approach because there are mutagenicity screening tests that yield positive results for substances that are confirmed later not to be carcinogenic. Thus, since EPA proposes covering the Carcinogen and Reproductive toxicity hazard classes in the draft Alternative Assessment Criteria, implementation of M/G hazard would not improve the assessments.

Since the carcinogenicity and reproductive toxicity hazard classes are proposed for the alternatives assessment and they cover the adverse effects of M/G, and there would be a greater impact from the proposal due to the need to provide support applying the M/G criterion, the M/G hazard criterion should not be adopted.

Chronic or target-organ toxicities: For a number of the chronic or target-organ toxicity criteria, GHS hazard criteria for mixtures include both a dose-response value and a product concentration value in deriving the particular classification reflecting the risk-based nature of hazard communication labeling in the United States. If the DfE AA Criteria are going to be consistent with the GHS criteria, they should follow a similar risk-based approach.

4.2.2 Environmental Persistence: The 10-day window should not be incorporated into the criterion; or at least it should be mentioned that this criterion should be applied only for pure/discrete organic substances. Substances which are technical mixtures (e.g., surfactants, polyols, fatty acids and derivatives, etc.) should not be classified on basis of the 10-day window, as specifically stated in the OECD Guidelines.

The attributes that would be associated with a “degradation product of concern” should be stated. Otherwise, almost any degradation product could be of concern for one reason or another, by virtue of its formation.

It is unclear how a “qualitative assessment of atmospheric persistence” will be conducted. EPA should consider that other regulatory programs have employed an atmospheric half-life cut-off of 2 days; where substances which exceed this half-life are considered to have potential for long-range atmospheric transport. Also, the AOPWIN estimation tool should be mentioned as a reliable and semi-quantitative method for assessing atmospheric persistence.

4.2.3 Bioaccumulation: EPA should contemplate and incorporate other data relevant to bioaccumulation and “higher-tier” bioaccumulation studies where appropriate. For example, where measured in-vitro fish metabolism data are available, these data (and associated Km

value) could be used to categorize bioaccumulation potential or lack thereof. Similarly, EPA generally accepts that substances of high molecular weight are not accumulating; a cut-off value for molecular weight and/or diameter should be included. Finally, trophic magnification factors (TFM) are considered “gold standard” studies with regard to the potential for a compound to biomagnify up the food chain. Any assessment of a chemicals assessment to bioaccumulation should include the ability to incorporate such data.

* * *

ACI remains committed to working collaboratively with EPA to develop well recognized and reliable criteria for assessing chemicals-related risks and to identifying alternative chemistries which provide an effective means to reduce such risks. Please contact me by phone at 202-662-2516 or by e-mail at pdeleo@cleaninginstitute.org if you would like to discuss our comments and any improvement to the agency’s draft that you would like us to help you consider.

Sincerely,

A handwritten signature in black ink that reads "Paul C. DeLeo". The signature is written in a cursive, flowing style.

Paul C. DeLeo, Ph.D.
Senior Director, Environmental Safety