



american cleaning institute®  
for better living

December 31, 2010

Mr. David DiFiore  
Design for the Environment Branch  
Economics, Exposure and Technology Division, Office of Pollution Prevention and Toxics  
1200 Pennsylvania, NW  
Washington, DC 20460-0001  
*Via electronic-mail*

Dear Mr. DiFiore:

The American Cleaning Institute® (“ACI,” formerly The Soap and Detergent Association) appreciates the opportunity to comment in response to the request from US Environmental Protection Agency’s (“EPA”) Design for the Environment (“DfE”) program in connection with review of its proposed enhancements to its Standard for Safer Cleaning Products (“Standard”).

## **Background**

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.

## **General Comments**

ACI supports EPA’s goal of enhancing the Standard to increase transparency and accessibility and appreciates the opportunity to participate in the stakeholder process. This section includes some general comments on the Globally Harmonized System of Classification (“GHS”) and animal testing. The following section includes specific comments on various sections of the proposal.

### GHS

Related to references in the proposed standard to use of GHS criteria, EPA should not incorporate any GHS criteria at this time. EPA should develop a stakeholder process for incorporating GHS into its programs that accounts for the specific needs of the chemical user community. Attempting to bring GHS criteria into EPA’s programs by incorporating it into this

specific program without a fully vetted consultation process would forego a necessary rigorous review and comment process on the merits and applicability of GHS to U.S. chemical users regulated by EPA. Further, EPA's DfE program is intended to apply to products which EPA has not regulated, namely workplace and consumer products. In essence, EPA is applying classification criteria to products that would be or could be addressed by regulations of other agencies, such as the Occupational Safety and Health Administration ("OSHA") and the Consumer Product Safety Commission ("CPSC"). One of these agencies, namely OSHA, is in the process of revising its regulations to adopt those portions of the GHS that are applicable to chemicals in uses over which it has authority. Since both agencies have yet to implement the GHS, ACI recommends that EPA defer consideration of GHS criteria throughout the proposed standard until OSHA and CPSC have implemented the GHS and the appropriate inter-agency consultations have occurred. Once that has been accomplished, ACI urges EPA to apply GHS criteria in this standard in a manner consistent with the criteria of other the Federal agencies.

Although ACI strongly urges EPA to withdraw GHS criteria from the proposed standard, under the specific comments that follow, ACI offers suggestions on the appropriate application of the GHS to finished products in the proposed standard for completeness.

#### Animal Testing

There are places in the proposed standard that could result in an applicant for DfE recognition performing animal tests as an alternative to using existing information and data (e.g., 4.5.2 pH; 4.5.4 Dermal absorption). EPA should clearly state a position on the application of new *in vivo* or alternatives to *in vivo* testing that could be done to satisfy the criteria presented in the proposed standard. Absent that context, ACI is concerned that EPA could be unintentionally encouraging unnecessary animal testing.

### **Specific Comments**

#### **Definitions: Section 2.1.9 Association of Occupational and Environmental Clinics (AOEC) list of occupational asthmagens**

Due to the lack of qualifications, the definition given for the "Association of Occupational and Environmental Clinics (AOEC) list of occupational asthmagens" implies the list is more definitive than it really is. As stated on the AOEC website, "The AOEC Exposure Code List includes substances that have been *reported* as asthmagens by experts in occupational asthma." [Emphasis added] It further states that ". . . not all of the substances reported to be asthmagens have yet been formally evaluated against the AOEC criteria . . ." <sup>1</sup> Though useful to occupational and environmental clinicians as a database for exploring causes for patient asthma, it is not a database of rigorously evaluated substances. ACI recommends that EPA modify the definition as follows to improve transparency and clarity for the reader:

**2.1.9 Association of Occupational and Environmental Clinics (AOEC) list of occupational asthmagens:** A list of respiratory substances reported to be sensitizers and irritants found in occupational settings, though not all have been formally evaluated. For more information, please see <http://www.aoec.org/>.

---

<sup>1</sup> <http://www.aoecdata.org/Default.aspx>

### 3.8 Ingredient Communication

ACI and its members fully support EPA's goal of transparency, as demonstrated by the strong participation by our member companies in the industry's Consumer Product Ingredient Communication Initiative ("Initiative"), which took effect in January 2010. The proposed enhancements capture the provisions included in the Initiative along with a few additions. We support section 3.8 as drafted with one important modification. EPA proposes that dyes and colorants be disclosed using a "chemical-descriptive name". However, there are many instances in which agreements between formulators and their dye and colorant suppliers preclude disclosure beyond the trade name. This is done primarily to protect proprietary information about the substance. ACI therefore, recommends a modification to the proposed enhancements to permit formulators to list dyes and colorants by their trade name. Absent allowing companies to list dyes and colorants by trade name, ACI seeks clarification as to what EPA means by the term "chemical-descriptive name."

#### 4.2.7.3 TRI

In its definition for TRI, EPA states: "DfE does not allow products containing chemicals included on EPA's Toxics Release Inventory chemical list." This is a misuse of the TRI list of chemicals. As stated by EPA, "[T]he goal of the Toxics Release Inventory program is to provide communities with information about toxic chemical releases and waste management activities and to support informed decision making at all levels by industry, government, non-governmental organizations, and the public."<sup>2</sup> Through its proposed standard, EPA is converting a communication program into a prohibition of chemicals that can be safely formulated in cleaning products. There should be a substantially higher standard for designating a substance for prohibition as opposed to communication. Therefore, while EPA could consider chemicals listed for TRI purposes to be candidates for restrictions, it should do so only after a case-by-case evaluation of each substance.

Further, should EPA rely on the TRI list for restrictions under its DfE program, it should recognize the qualifiers associated with each chemical in deciding whether or not to restrict a chemical. As stated by EPA: "[C]ertain EPCRA Section 313 chemicals listed in Table II have parenthetical 'qualifiers'. These qualifiers indicate that these EPCRA Section 313 chemicals are subject to the section 313 reporting requirements if manufactured, processed, or otherwise used in a specific form or when a certain activity is performed. The following chemicals are reportable only if they are manufactured, processed, or otherwise used in the specific form(s) listed . . ."<sup>3</sup> Some examples follow:

- 7647-01-0 Hydrochloric acid: "acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size"
- 67-63-0 Isopropyl alcohol: "only persons who manufacture by the strong acid process are subject, no supplier notification"

---

<sup>2</sup> <http://www.epa.gov/tri/index.htm>

<sup>3</sup> <http://www.epa.gov/tri/trichemicals/chemicallists/R2009ChemicalList.pdf>

- 7664-93-9 Sulfuric acid: “acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size”

In cases where a qualifier is associated with a chemical, EPA should only consider restrictions if the use of the chemical in a product meets the conditions of the qualifier.

Further, EPA has set *de minimus* levels for substances subject to TRI reporting which should be utilized in the DfE standard. Some examples follow:

- 500-00-00 Formaldehyde: 0.1%
- 7647-01-0 Hydrochloric acid: 1.0%
- 67-63-0 Isopropyl alcohol: 1.0%
- 7664-93-9 Sulfuric acid: 1.0%

In view of these considerations, ACI urges EPA to withdraw the proposed use of the TRI list of chemicals from the proposed standard.

#### **4.5.1 Non-irritants**

In this section EPA states that “[O]nly ingredients that are non-irritating to skin and eyes, as demonstrated by testing, clinical studies or consumer experience, will be acceptable. At a minimum, a product or its ingredients must not be categorized as an irritant under the EPA Office of Pesticide Program regulations (i.e., must not require a precautionary statement) or GHS criteria.” The prohibition of ingredients that are irritants is inappropriate. EPA should apply these criteria to the finished product.

Further, the mild skin irritant category under the GHS (category 3) should only be applied to pesticide products that are eligible to be considered under the proposed standard, since this GHS criteria was created to reflect the EPA category. It should not be applied to products regulated by CPSC or OSHA, which do not require hazard communication for products that meet the criteria for mild irritant. Similarly, EPA should not restrict products that classify as “mildly irritating to the eye” (category 2B) under the GHS.

#### **4.5.2 pH**

EPA states for this criterion: “[T]o further minimize the potential for dermal, eye or mucous membrane irritation, product pH must be greater than or equal to (>) 4 and less than or equal to (<) 9.5.” The requirement that the pH of a product must be greater than or equal to (>) 4 and less than or equal to (<) 9.5 appears to be arbitrary. EPA should justify this proposed criterion.

Further, ACI is concerned with EPA’s statement that “products with a pH outside this range may be considered for recognition if *in vivo* testing demonstrates they are non-irritating” could be

encouragement for companies that seek to gain DfE recognition for a product to conduct animal tests. EPA should adopt a tiered approach to assessing skin and eye irritancy that focuses on use of existing information and data on products and their ingredients and methods for further assessing these endpoints that utilize alternatives to animal testing. EPA should make it clear that it does not encourage or require animal testing to satisfy this criterion.

#### **4.5.3 Potential allergens and sensitizers**

In this section, EPA states: “[N]o ingredients classified under GHS as skin or respiratory sensitizers are permitted in labeled products.” No federal agency has adopted GHS criteria for skin or respiratory sensitizers. Therefore, EPA should not adopt these criteria for any of its programs until OSHA and CPSC have acted, let alone without a full stakeholder process.

Further, if EPA adopted these criteria, the prohibition of ingredients that are sensitizer is inappropriate. EPA should apply these criteria only to finished products. In addition, EPA should differentiate between category 1A and 1B sensitizers and only place restrictions in the DfE standard for products that are 1A sensitizers.

#### **4.5.4 Dermal absorption**

EPA states for this criterion: “[W]here an ingredient may be dermally absorbed, the applicant must provide data, for example, repeated dose toxicity testing via the dermal route of exposure, on potential effects; *these data must indicate that the ingredient presents a low hazard concern.*” [Emphasis added] This criterion inappropriately characterizes dermal adsorption as a hazard. Dermal adsorption is a factor in assessing exposure potential from the use of a chemical; it is not a hazard characteristic. In any event, as before, the suggestion that this criterion can only be satisfied by animal testing is inappropriate. ACI recommends that this criterion be deleted.

#### **4.5.9 Ingredients on prohibited lists**

This criterion prohibits ingredients on authoritative lists of chemicals prohibited or restricted for use in cosmetics. ACI recommends that such lists applicable to cosmetics should not be applied to other categories of products. Further, included among the lists noted in this proposed criteria are the European Union Cosmetic Directive (Annex II) and the Health Canada “Hotlist”. EPA’s reliance on the listing of substances on these two lists is inappropriate. The placement of substances on these lists was done according to EU and Canadian processes, respectively, which were not open to U.S. stakeholders so that they could provide their available data and information. Thus, U.S. stakeholders have no accessible records to document the data and decision making process actually used to make a determination to list each specific substance. As such, the completeness and reliability of the listings and their applicability to U.S. products cannot be judged due to the lack of transparency. Therefore, reference to non-U.S. lists should be deleted.

Further, the proposed criterion states that chemicals on the authoritative lists “...will not be acceptable in labeled products, *as confirmed by their toxicological hazard.*” [Emphasis added] it is unclear as to what is meant by the phrase “*as confirmed by their toxicological hazard.*”

## 5.11 Enzymes and Enzyme Stabilizers

ACI recommends that EPA elevate the importance of a safe work environment. All manufacturing operations should be held accountable for a safe workplace, and ACI believes that the protection of workers from exposures to all ingredients as well as physical hazards (noise, heat) should be addressed appropriately. We are concerned that language in this section stipulating needs for workplace and quality controls unfairly singles out enzymes as compared to other categories of ingredients which require similar levels of control. This undue emphasis may deter the use of enzymes, as it unnecessarily implies special manufacturing requirements and the public may then mistakenly view enzymes as undesirable in consumer products, even when used correctly. Further, moving this section under the General Requirements would also show EPA's commitment to worker safety. ACI suggests that Section 3 include language to ensure a safe working environment, and delete the specific requirements for enzymes from this section.

In addition, ACI would like to offer EPA the links to the enzyme safety publications for suppliers' and formulators' information. In some of the sections for the other ingredients, EPA refers to guidelines issued by other organizations. ACI's publications [Work Practices for Handling Enzymes in the Detergent Industry](#) and [Risk Assessment Guidance for Enzyme-Containing Products](#) are valued by our industry.

### Conclusion

ACI appreciates the effort EPA has devoted to making this standard more transparent, holistic, and user-friendly. ACI continues to support the DfE program, and offers its expertise to ensure the sustainability of the program.

Please contact me with any further questions.

Respectfully submitted,

*Kathleen Stanton*

Kathleen Stanton  
Associate Director, Scientific Affairs