March 6, 2017

Cindy Wheeler
Chemical Control Division (Mail Code 7405M)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
(*via* *www.regulations.gov*)

Re: Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act: 1,4-Dioxane, TSCA Review and Scoping; **Docket No. EPA-HQ-OPPT-2016-0723**

Dear Ms. Wheeler:

The American Cleaning Institute (ACI)[1] is pleased to provide the following comments and information related to the recent publication by EPA of the Preliminary Information on Manufacturing, Processing, Distribution, Use and Disposal of 1,4-Dioxane, and in response to the February 14, 2017 Public Meeting on Risk Evaluation Scoping Efforts under TSCA for Ten Chemical Substances including 1,4-dioxane. ACI has been closely following the Agency's activities on 1,4-dioxane under TSCA since the Work Plan Chemicals Methods Document was released in February of 2012.[2]

We note that the Agency's Preliminary Information document includes links to more than 200 documents, primarily safety data sheets, for a number of materials. As a result of this survey, EPA has concluded, "[i]t is unlikely that 1,4-dioxane is intentionally used in formulations of currently available commercial and consumer products…" We agree with this conclusion, and accordingly,

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[1] ACI is a trade association for the $30 billion U.S. cleaning products industry. 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.

[2] ACI has collaborated previously with several trade associations to provide comments to the Agency in the context of its review of 1,4-dioxane. For example, in May 2013, ACI, the Consumer Specialty Products Association (CSPA), and the Personal Care Products Council (PCPC) submitted comments on EPA's process to identify and prioritize chemicals for review under TSCA (Docket ID EPA-HQ-OPPT-2011-0516), and in June 2015, ACI, CSPA and PCPC submitted comments on EPA's TSCA Work Plan Chemical Problem Formulation Assessment for 1,4-Dioxane (CASRN 123-91-1; Docket ID EPA-HQ-OPPT-2015-0078). Rather than repeat those comments here, we incorporate them by reference:
https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0078-0006
https://www.regulations.gov/document?D=EPA-HQ-OPPT-2011-0516-0035

we ask that EPA update its websites[3] and associated documents to remove the unintentionally misleading statements that 1,4-dioxane is *used* in consumer products. 1,4-Dioxane is not used as a deliberately-added ingredient in consumer products and we believe that the Agency's misstatement is confusing to consumers and implies there are potential risks to consumers due to the potential presence of trace quantities of the substance that might be unintentionally present in certain products at extremely low levels.

More accurately, the Preliminary Information document concludes that "many commercial and consumer products … have been reported to contain 1,4-dioxane in small amounts." That restates the widely known phenomenon that unintentional and unavoidable residues of 1,4-dioxane may be present in formulated products as a result of the starting materials and manufacturing methods for certain surfactants and similar materials. The Agency's ability to readily locate, review, and cite to more than 200 safety data sheets it references in the Preliminary Information document reflect good product stewardship on the part of those material and product manufacturers in complying with the Regulatory Information section of the safety data sheet in detailing potential TRI reporting requirements and state right-to-know laws such as California's Proposition 65.

Given the extraordinarily low levels of 1,4-dioxane that might remain at trace quantities in certain materials and products, we question whether any further in-depth assessment of the unintentional presence of the substance must be undertaken and whether doing so represents a good use of the Agency's scarce resources. Thus, ACI recommends that the Agency exercise its discretion to determine that the presence of unintentionally present trace levels of 1,4-dioxane in consumer and similar commercial products is beyond the scope of the risk evaluation EPA will undertake for 1,4-dioxane. There are at least two bases for making such a determination:

First, the mere presence of trace quantities of unintended impurities or process residues in certain materials and products does not represent a "condition of *use*" of 1,4-dioxane. Therefore this phenomenon need not be considered to be within the scope of the risk evaluation the Agency will conduct on 1,4-dioxane. While we understand the Agency might consider the *presence* of the substance in these products at trace levels to be "reasonably foreseen", its presence is not due to the "use" of 1,4-dioxane. Its presence in such products is due to the *use* of another substance (i.e., one or more chemical precursor) in the manufacturing process.[4] Moreover, persons who acquire and use consumer products that unintentionally contain 1,4-dioxane, do not acquire the product for, the purpose of making *use* of the substance. The presence of 1,4-dioxane does not contribute to the performance of the finished consumer product nor does it impart attribute (such as an aroma or hue) that enhances the product user's experience. Many of EPA's TSCA regulations do not require reporting on the presence of an impurity, and there is no reason to conclude Congress

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[3] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/evaluating-risk-existing-chemicals-under-tsca

[4] Those precursor chemical substances that are used in synthesis processes that can result in the unintended presence of 1,4-dioxane in a consumer-use product are not, however, among the 10 substances EPA has identified as being the subject of the first 10 risk evaluations EPA intends to undertake under the amended law. Nevertheless, it is the conditions of use of *those* substance that properly are those which result in the presence of 1,4-dioxane in consumer products.

intended EPA to use risk evaluation resources to focus on impurities and unintended process residues of little consequence in a finished product.

Second, the presence of 1,4-dioxane in trace quantities in consumer products does not meet the statutory "may present an unreasonable risk" standard for conducting a risk evaluation under the amended law. Relying on readily available information and assessments already performed by other authoritative bodies, the Agency has sufficient information to determine the trace quantities do not (much less *may* not) present an unreasonable risk to human health or the environment. For example, an assessment conducted by California's Office of Environmental Health Hazard Assessment (OEHHA) determined that exposures of less than 30 µg/day present *no significant* risk to humans. Applying the same "may present" criteria Congress established for selecting chemical and use conditions to undergo risk evaluations under the amended TSCA, it is absolutely reasonable for the Agency to exclude such trace-quantity/low-exposure uses from the scope of the risk evaluation it intends to undertake for 1,4-dioxane. We believe it is within the Agency's authority to exclude such trace impurities and byproducts from the scope of the Agency's risk evaluation, and we believe it would be more useful for the Agency to focus its limited resources on intentional uses of chemicals being assessed.

In the case of 1,4- dioxane, a number of very careful and scientifically defensible assessments have been completed by competent authorities around the world coming to similar conclusions – specifically, that trace levels of 1,4-dioxane in certain consumer and commercial products do not pose a significant risk to the public. Perhaps most notable, recently the International Cooperation on Cosmetic Regulation which includes regulatory authorities from Canada, the European Union, Japan and the U.S. Food and Drug Administration approved their recommendations for acceptable trace 1,4-dioxane levels in cosmetic products at 25 parts per million moving to 10 parts per million after a suitable transition period.[5] Clearly cosmetics uses are outside the scope of TSCA, nevertheless this development is important because cosmetics and personal care products like hand soap, body wash and shampoo are assessed based on certain assumptions that are especially protective of product users due to the nature of the exposures that consumers are likely to encounter if they are experiencing dermal contact when applying such products (in certain cases directly to their bodies, and often multiple times per day). Moreover, manufacturers of personal care products have been taking steps to reduce trace levels of 1,4-dioxane in their products for years and that has impacts for supply chains leading to surfactant producers and other users of these surfactants including cleaning product manufacturers. Those levels of trace impurities and residues of 1,4-dioxane that are currently recognized as "safe" for direct exposure to personal care products by so many regulatory authorities around the world should reasonably be anticipated to pose even lesser risks for users of other formulated consumer products since their exposures are indirect. Thus, taking the "Safe Harbor" levels established by OEHHA (and in certain Proposition 65 litigations) as reasonable and prudent benchmarks, it has become common practice for cleaning product manufacturers to limit the presence of 1,4-dioxane in their products to levels that will not exceed established safe harbor levels. Thus making it reasonable for EPA to conclude that such

[5] http://www.iccrnet.org/files/2414/8717/1555/ICCR_14-Dioxane_Final_2017.pdf

levels are well below the "may present" standard for triggering a risk evaluation under the amended TSCA.

Moreover, it appears that the Agency has already made a safe use determination with respect to a number of the surfactants that could potentially contain 1,4-dioxane as a byproduct of manufacturing. In its May 2012 (Design for the Environment) DfE Alternatives Assessment for Nonylphenol Ethoxylates,[6] the Agency identifies a number of surfactants that meets DfE Criteria for Safer Surfactants including surfactants that would likely be among those containing residues of 1,4-dioxane. Additionally, the EPA SaferChoice Safer Chemicals Ingredient List (SCIL)[7] includes a number of surfactants that would likely contain residues of 1,4-dioxane. Therefore, EPA has implicitly concluded that a number of surfactants that might contain residues of 1,4-dioxane are in fact safer for human health and the environment. Furthermore, EPA has been encouraging manufacturers to produce those SCIL surfactants, formulators to make products containing them, and consumers and institutions, including many state and local governments, to acquire products containing them. The Agency in its recent proposed rule on Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act stated "…EPA believes that its Safety Chemicals Ingredient List will be a good starting point for identifying potential candidates for Low-Priority Substance Designations."[8] We agree with the Agency's proposal and by virtue of the evaluations conducted to which led to surfactants being included on the SCIL, the Agency should conclude that surfactants containing 1,4-dioxane as unintended residues and impurities of manufacturing processes that are *not likely to present an unreasonable risk of injury to health or the environment* and should not be considered to be within the scope of the risk evaluation the Agency will conduct on 1,4-dioxane.

ACI reiterates that, given the ambitious work load that has been imposed on the Agency for implementation of the Lautenberg Chemical Safety Act (LCSA), we believe EPA should focus its attention on significant exposures associated with intentional uses of the chemicals it is assessing and set aside further assessment of trace levels of 1,4-dioxane in materials and products.

We appreciate this opportunity to provide comments and information on 1,4-dioxane and look forward to further engagement with EPA on this and other related matters of LCSA implementation.

Sincerely,

Paul C. DeLeo
Associate Vice President, Environmental Safety

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[6] https://www.epa.gov/sites/production/files/2014-06/documents/npe_final.pdf

[7] https://www.epa.gov/saferchoice/safer-ingredients

[8] 82 FR 4825 at 4830.