



September 7, 2023

Docket ID No. EPA-HQ-OPP-2016-0723

Ms. Cindy Wheeler
Office of Pollution Prevention and Toxics (7404M)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Comments filed via www.regulations.gov

RE: Docket ID No. EPA-HQ-OPPT-2016-0723: 1,4-Dioxane; Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment

Dear Ms. Wheeler:

ISSA, the worldwide cleaning industry association, greatly appreciates this opportunity to comment on the Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination for 1,4-Dioxane.

ISSA is a nonprofit, voluntary trade association that represents the commercial and institutional cleaning industry. Our membership is comprised of over 10,500 member companies worldwide, including manufacturers, wholesalers, and distributors of cleaning products and equipment, as well as cleaning service providers who use and apply these products on a daily basis.

ISSA has significant concerns related to the process followed by EPA in issuing its revision to its 1,4-dioxane risk determination and the negative precedent this course of action will set for the future evaluation of chemicals under TSCA. ISSA therefore respectfully urges EPA to withdraw its revised risk determination for 1,4-dioxane for the reasons set forth below.

EPA's Use of New Methods and Novel Applications of Existing Methods. The primary concern of ISSA related to EPA's revised determination of unreasonable risk for 1,4-dioxane under TSCA relates to the "new methods and novel applications of existing methods" employed by EPA in this process.

Specific examples of such new methods and novel applications of existing methods include:

- EPA's decision to review 1,4 dioxane as a whole chemical substance;

- The Agency's corollary assumption that no personal protective equipment is used in an occupational setting; and
- EPA's use of the Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0.

These new methods and novel applications of existing methods employed by EPA have directly resulted in the Agency's revised determination of unreasonable risk for 1,4-dioxane. However, these "new methods and novel applications of existing methods" have not been peer reviewed; nor have they been subjected to the public comment process. Consequently, it is highly inappropriate for EPA to rely on these new methods/novel applications in its reevaluation of 1,4-dioxane.

As a general course of action, EPA typically seeks review of such proposed new methodologies or novel applications to existing methods to ensure that the methodologies in question are "fit-for-purpose" before employing such methods in a regulatory action, such as the present risk determination for 1,4-dioxane. However, these new methods and novel applications of existing methods used by EPA in its evaluation of 1,4-dioxane have neither been peer reviewed nor subjected to the public comment process. Therefore, ISSA urges EPA to abandon its reliance on these methodologies until such time as they are refined and validated through proper and established processes. It is both inappropriate and inconsistent with TSCA for EPA to use these new methods and novel applications of existing methods in the Agency's reevaluation of 1,4-dioxane that have not been peer reviewed, nor subjected to the public comment process.

Therefore, it is incumbent upon EPA to withdraw its revised unreasonable risk determination for 1,4-dioxane because it was issued prematurely based on new methods/novel applications that have not been validated or otherwise vetted through the public comment process to ensure that they are fit for their intended purpose of a TSCA risk evaluation. Moreover, EPA's reliance on these new methods/novel applications in this situation is inconsistent with Section 702.41 of EPA's Risk Evaluation framework rule to ensure "all supporting analyses and components of the risk evaluation are suitable for their intended purpose."

As a consequence, ISSA urges EPA to forestall its revised risk determination for 1,4-dioxane and provide additional time and the opportunity for the public, the regulated community and other stakeholders to review and comment on the new methods and novel applications to existing methods used by EPA prior to their use in EPA's reassessment of its risk determination for 1,4-dioxane.

Existing Studies and Data. Instead of its reliance on unvalidated test methodologies in evaluating 1,4-dioxane, ISSA urges EPA to take into consideration the existing studies and data on 1,4-dioxane related to environmental and other exposures, which are well documented. In fact, EPA has failed to provide a robust rebuttal or otherwise address the several evaluations of 1,4-dioxane issued by other competent authorities, including Health Canada, the European Union and the Commonwealth of Australia. These and other very carefully and scientifically defensible evaluations and assessments have been completed by competent authorities around the world coming to similar conclusions: that trace levels of 1,4 dioxane in certain consumer and commercial products do not pose a significant risk.

In fact, Section 26 of TSCA requires EPA to take such studies into account when conducting a risk evaluation under TSCA. Therefore, by failing to address these studies, EPA has not met its obligation under TSCA Section 26. Specifically, in ignoring the aforementioned evaluations of 1,4 dioxane by competent authorities, EPA fails to take into consideration the “best available science” and disregards “reasonably available information” on the threshold carcinogenic mode of action for 1,4-dioxane—all of which is required by TSCA Section 26 in making such risk determinations.

Instead of relying on such readily available and peer reviewed data as required by TSCA, EPA has erroneously chosen to rely upon the Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0 (“Draft Fenceline 1.0”) in conducting its risk reevaluation of 1,4-dioxane. However, this methodology has not yet been finalized and it is therefore premature to use the Draft Fenceline 1.0 approach for the purpose of revising and updating a risk evaluation. Rather the Draft Fenceline 1.0 approach should be restricted to that of a screening tool and not be used for risk evaluation, as it has been in the revision to EPA’s risk determination for 1,4-dioxane.

As a consequence, any risk determination made by EPA regarding 1,4-dioxane under these circumstances is flawed and should be withdrawn by the Agency.

ISSA appreciates this opportunity to comment on the proposed revisions to the Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination for 1,4-Dioxane. Please contact ISSA at the information below if there is the need for any clarification of our comments.

Respectfully Submitted,



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