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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2015-0078; FRL-9923-84]

Notice of Availability of Work Plan Chemical Problem Formulation and Initial Assessment for 1,4-Dioxane; Request for Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: With this notice, EPA is announcing that it will be publishing a problem formulation and initial assessment or data needs assessment document for each TSCA Work Plan Chemical prior to conducting further risk analysis. This notice is also announcing the availability of a problem formulation and initial assessment document for the Work Plan Chemical 1,4-Dioxane and opening the 60-day public comment period for the document. Based on experience in conducting TSCA Work Plan Chemical assessments to date and stakeholder feedback, starting in 2015 EPA will publish a problem formulation and initial assessment or data needs assessment for each TSCA Work Plan Chemical as a stand-alone document to facilitate public and stakeholder input prior to conducting further risk analysis. EPA believes publishing problem formulations and initial assessments for TSCA Work Plan Chemicals will increase transparency about EPA's thinking and analysis process, provide opportunity for the public and stakeholders to comment on EPA's approach and provide the opportunity to receive additional information/data to supplement or refine the assessment approach prior to EPA conducting detailed risk analysis and risk characterization.

DATES: Comments must be received on or before **[60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2015-0078, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Stanley Barone, Risk Assessment Division (7403M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-1169; email address: barone.stan@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including those interested in environmental and human health; the chemical industry; chemical users; consumer product companies and members of the public interested in the assessment of chemical risks. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. What Action is the Agency Taking?

EPA is announcing that it will be publishing a problem formulation and initial assessment or data needs assessment document for each TSCA Work Plan Chemical prior to conducting further risk analysis. Based on experience in conducting TSCA Work Plan Chemical assessments

to date and stakeholder feedback, starting in 2015 EPA will publish a problem formulation and initial assessment or data needs assessment document for each TSCA Work Plan Chemical as a stand-alone document. A problem formulation and initial assessment document will serve to inform the public and other interested stakeholders about EPA's initial scoping of findings and plan for any further risk assessment. Problem formulation and initial assessment is the analytical phase of the assessment in which the purpose for the assessment is articulated, the problem defined and a plan for analyzing and characterizing risk is determined.

Outcomes of a problem formulation and initial assessment are: (a) Conceptual Model – including a visual representation and written description of actual or predicted relationships between chemicals and human or wildlife; (b) Analysis Plan – describing the intentions regarding the technical aspects of the risk assessment. In some instances, as a result of problem formulation and initial assessment, EPA identifies data gaps (uses, exposure pathways, toxicity data) so significant as to prevent conducting a meaningful risk assessment. In these cases, EPA will publish a Data Needs Assessment document and provide opportunity for the public and stakeholders to comment, identify or provide data or information that may fill identified data gaps prior to EPA pursuing data collection via TSCA authorities.

To facilitate public and stakeholder input prior to conducting further risk analysis, EPA will open a public docket for receiving comments, data or information from interested stakeholders when it publishes each problem formulation and initial assessment or data needs assessment document. EPA believes publishing problem formulation and initial assessment documents for TSCA Work Plan Chemicals will increase transparency of EPA's thinking and analysis process, provide opportunity for the public and stakeholders to comment on EPA's approach and provide additional information or data to supplement or refine assessment approaches prior to EPA conducting detailed risk analysis and risk characterization. Following receipt of comments on the problem formulation and initial assessment document and consideration of any additional data or information received, EPA will initiate a risk assessment which is the process to estimate the nature and probability of adverse health and environmental effects in humans and ecological receptors from chemical contaminants that may be present in the environment.

EPA is also announcing the availability of the TSCA Work Plan Chemical Problem Formulation and Initial Assessment for 1,4-Dioxane for public comment. 1,4-Dioxane is the first chemical for which EPA is releasing a problem formulation and initial assessment document under the TSCA Work Plan Chemical Assessment Program. 1,4-Dioxane is a chemical that is used primarily as a solvent in the manufacture of other chemicals. 1,4-Dioxane is also found as an impurity in anti-freeze and aircraft deicing fluids and in some consumer products [deodorants, shampoos, and cosmetics] (ATSDR 2012; EPA 2006; Mohr 2001). During problem formulation and initial assessment, EPA reviewed previous assessments by EPA and other organizations and additional published studies on the exposure and hazard of 1,4-Dioxane. EPA examined likely exposure and hazard scenarios based on current production, use, and fate information to identify scenarios amenable to a risk analysis. The data available and scenarios evaluated for

conducting a risk assessment are provided in EPA's TSCA Work Plan Chemical Problem Formulation and Initial Assessment for 1,4-Dioxane. The conclusions of the problem formulation and initial assessment are: (a) EPA will further assess potential risks to workers exposed during product formulation and use as a cleaning agent; (b) EPA will further assess potential risks to workers and consumers exposed during the use of TSCA-use products that contain 1,4-Dioxane as a contaminant, such as paints, varnishes, adhesives, cleaners and detergents; (c) Risk to the general population through inhalation exposure to ambient air emissions is estimated to be low; (d) An assessment of risk from exposure through drinking water is not needed at this time because 1,4-Dioxane is currently being monitored and EPA will determine whether or not regulatory action is needed as part of its Regulatory Determination Process; (e) Based on the low hazard profile for 1,4-Dioxane to aquatic organisms, risks to these organisms are expected to be low. EPA does not have the hazard data needed to determine if there are risks to sediment and soil organisms. Therefore, further analysis of environmental risk is not planned. EPA plans to review and evaluate the results of previous exposure assessments and health benchmarks for this chemical. As a result, EPA/OPPT will develop margins of exposure and cancer risk estimates to evaluate the potential risks from worker and consumer exposure to 1,4-Dioxane. Use the docket ID number: EPA-HQ-OPPT-2015-0078 to locate a copy of the 1,4-Dioxane problem formulation and initial assessment document, as well as to submit comments via [http:// www.regulations.gov](http://www.regulations.gov).

Authority: 15 U.S.C. 2601 et. seq.

Dated: April 21, 2015.

Wendy C. Hemnett,

Director,

Office of Pollution Prevention and Toxics.

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