June 29, 2015

Stanley Barone
Risk Assessment Division (7403M)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460–0001
Submitted via www.regulations.gov
Docket No. EPA-HQ-OPPT-2015-0078

Re: ARASP Recommendations for the Work Plan Chemical Problem Formulation and Initial Assessment for 1,4-Dioxane

Dear Dr. Barone:

The Center for Advancing Risk Assessment Science and Policy (ARASP) is pleased to provide the following comments on the Environmental Protection Agency's (EPA) Work Plan Chemical Problem Formulation and Initial Assessment for 1,4-Dioxane.[1] ARASP is a coalition of twenty-two independent groups that have been actively engaged in working with federal agencies and other interested parties to promote consistent and transparent risk assessment approaches, science methodologies and policies that ensure the use of the best available and relevant science in chemical assessments.

We applaud EPA for providing the public with a problem formulation and initial assessment document before beginning a full risk assessment of 1,4-dioxane. Informing stakeholders of the intended uses that EPA plans to evaluate, the pathways of concern, and the datasets that will be evaluated is critically important to help inform the final assessment. In addition, planning and scoping is critical to ensuring that the EPA activities will contribute to a sound risk assessment that will indeed serve its intended purpose.

ARASP fully supports and endorses the detailed comments of the industry coalition, including the Adhesive and Sealant Council, the American Chemistry Council, the American Cleaning Institute, the American Coatings Association, the Consumer Specialty Products Association, and Waste Management, submitted to Docket No. EPA-HQ-OPPT-2015-0078, dated June 29, 2015 (attached).

We highlight below a few important points:

[1] Notice of Availability of Work Plan Chemical Problem Formulation and Initial Assessment for 1,4-Dioxane; Request for Public Comment, 80 Fed. Reg. 23545 (Apr. 28, 2015).

- It is critically important that future problem formulation documents are consistent with the recommendations set forth in the 2014 EPA Human Health Risk Assessment Framework (HHRA Framework).[2] Problem formulation documents must clearly articulate the potential policies and risk management options that may be informed by the work plan assessments.

- Based on the risk management options that may be considered, EPA should clearly articulate the type of risk assessment that will be conducted (i.e., screening level or robust assessment) and the plans for external peer review.

- Rigorous assessments that will be used to inform regulatory activities under TSCA Section 6 should be treated as Highly Influential Scientific Assessments and should undergo robust peer reviews consistent with Office of Management and Budget (OMB) guidance.[3]

- Consistent with multiple recommendations from the National Academies of Science (NAS), the Office of Pollution Prevention and Toxics (OPPT) must conduct a rigorous review of all the scientific literature to ensure that the best information is used to inform Section 6 rulemaking. This includes seeking sources in addition to Integrated Risk Information System (IRIS) assessments to ensure that the best available science is considered.

    - In its 2011 review of the draft assessment for formaldehyde, the NAS noted that:

> [t]he general problems that the committee identified are not unique to the draft IRIS assessment of formaldehyde. Committees of the Board on Environmental Studies and Toxicology (BEST) of the National Research Council (NRC) have reviewed a number of IRIS assessments in the last decade, including three . . . in the last 5 years. Some of the general problems identified by the present committee have been commented on by the other BEST committees. For example, the 2006 NRC report on dioxin and related compounds commented on the need for formal, evidence-based approaches for noncancer effects, the need for transparency and clarity in the selection of data sets for analysis, and the need for greater attention to uncertainty and variability. . . The 2010 NRC review of the draft IRIS assessment of tetrachloroethylene found similar problems and provided a chapter, "Moving Beyond the Current State of Practice," that addressed methodologic issues and the failure to establish clear and transparent methods for carrying out and presenting the assessment . . . That report also

[2] See US EPA (Environmental Protection Agency). 2014. *Framework for Human Health Risk Assessment to Inform Decision Making*. EPA/100/R-14/001. Office of the Science Advisor, Washington, DC. http://www2.epa.gov/sites/production/files/2014-12/documents/hhra-framework-final-2014.pdf

[3] See https://www.whitehouse.gov/sites/default/files/omb/assets/omb/fedreg/2005/011405_peer.pdf

provided a broad set of recommendations on characterization of uncertainty.[4]

- In its subsequent 2014 review of the IRIS program, the NAS concluded that "although EPA has identified and is assessing important characteristics of the quality of human and animal studies, it has not historically conducted the assessments in a consistent and standardized way for studies included in IRIS assessments."[5] The 2014 report noted that systematic review methodologies, including the process for evaluating individual studies, are well established in clinical medicine and concluded that "experience gained from randomized clinical trials in human and veterinary medicine suggests that systematic reviews that assess animal toxicology studies for quality and risk of bias would improve the quality of IRIS reviews." The report concluded that "there is no assessment of the risk of bias in the studies evaluated" in IRIS assessments nor do they include "a description of quality-assurance measures for the collection of assessment data."[6]

- Conduct of systematic review approaches to evaluate study quality is vital to generating high quality scientific assessments. The 2013 1,4-dioxane IRIS assessment was finalized without fully implementing standardized approaches for evaluating studies, as well as other important NAS recommendations.[7] As such the IRIS assessment for 1,4-dioxane should not be seen as representing the best available science.

Thank you in advance for your consideration of ARASP's comments. If you have any questions, or need clarification on any of our comments, please contact me at 202-249-6417 or nancy_beck@americanchemistry.com .

Sincerely,

Nancy B. Beck, PhD, DABT
American Chemistry Council (ACC)
Senior Director
Regulatory and Technical Affairs
On behalf of ARASP

[4] National Research Council (NRC). Review of Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. Washington, DC: The National Academies Press, 2011. http://www.nap.edu/catalog/13142/review-of-the-environmental-protection-agencys-draft-iris-assessment-of-formaldehyde

[5] National Research Council (NRC). Review of EPA's Integrated Risk Information System (IRIS) Process. Washington, DC: The National Academies Press, 2014. http://www.nap.edu/catalog/18764/review-of-epas-integrated-risk-information-system-iris-process

[6] Id., at 65.

[7] See EPA 1,4- Dioxane Toxicological Review, available at http://www.epa.gov/iris/toxreviews/0326tr.pdf. In particular, see Appendix I.

ARASP members:
Acrylonitrile Group
American Cleaning Institute
American Composite Manufacturers Association
American Forest and Paper Association
American Petroleum Institute
CropLife America
Halogenated Solvents Industry Alliance
Nickel Producers Environmental Research Association
Styrene Information and Research Center
Wood Preservative Science Council
ACC Chlorine Chemistry Division
ACC Ethylene Oxide Panel
ACC Formaldehyde Panel
ACC Hexavalent Chromium Panel
ACC High Phthalates Panel
ACC Hydrocarbon Solvents Panel
ACC Olefins Panel
ACC Oxo Process
ACC Propylene Oxide/Propylene Glycol Panel
ACC Health, Products, and Science Policy Committee
ACC Silicones Environmental, Health and Safety Center of North America
ACC Vinyl Chloride Health Committee

Attachment: Industry coalition comments, Docket No. EPA-HQ-OPPT-2015-0078