



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 23 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Stephen P. Risotto
Senior Director, Chemical Products and Technology Division
American Chemistry Council
700 Second St., N.E.
Washington, DC 20002

Dear Mr. Risotto:

This letter is the response to the Request for Correction received by the U.S. Environmental Protection Agency on June 12, 2015, which was assigned RFC #15003 for tracking purposes. In the RFC, the ACC's Phthalic Anhydride Producers Panel challenges the "objectivity" of several statements related to potential exposure to phthalic anhydride found in the documents developed for the Office of Pollution Prevention and Toxic's "TSCA Work Plan for Chemicals Assessments" (2014 Update and the TSCA Work Plan Chemicals Methods Document (2012)). The Panel alleges these statements are not consistent with the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*¹. To address its information quality concerns, the Panel asks that the EPA revise its conclusions about the potential exposure to phthalic anhydride and reconsider its planned review of this chemical as part of the agency's chemical assessment efforts under the TSCA Work Plan.

The EPA, after reviewing the Panel's RFC package, has concluded that the underlying information and conclusions related to phthalic anhydride that are presented in the TSCA Work Plan are consistent with the EPA's Information Quality Guidelines.

Originally released in March 2012, the EPA's TSCA Work Plan for Chemical Assessments helps focus and direct the activities of its existing chemicals program. The agency, based on input gathered from stakeholders, developed the criteria it used for identifying chemicals for further assessment. The criteria focused on chemicals that meet one or more of the following factors:

- Potentially of concern to children's health (for example, because of reproductive or developmental effects);
- Neurotoxic effects;
- Persistent, Bioaccumulative, and Toxic;
- Probable or known carcinogens;
- Used in children's products; and
- Detected in biomonitoring programs.

¹ 67 FR 63657 (October 15, 2002).

http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

Internet Address (URL) • <http://www.epa.gov>

After considering stakeholder input on the methodology document issued in August 2011, the EPA issued a detailed explanation of the approach the agency would use to identify the chemicals in the TSCA Work Plan for Chemical Assessments that was issued in 2012. In 2014, the EPA updated the TSCA Work Plan to reflect updated industry data on chemical releases and potential exposures that was submitted to the EPA through the Toxics Release Inventory in 2011 and the TSCA Chemical Data Reporting requirements in 2012. This was the first update to the TSCA Work Plan for Chemical Assessments, and, as newer data from TRI and CDR become available, the EPA has indicated it intends to update the TSCA Work Plan for Chemical Assessments. The agency uses this Work Plan to focus the activities of the Existing Chemicals Program in the Office of Pollution Prevention and Toxics so that existing chemicals having the highest potential for exposure and hazard are assessed, and, if warranted, are subject to risk reduction actions.

In preparing the TSCA Work Plan, the EPA provided several opportunities for stakeholder participation, including review and comment on the methodology the agency intended to use for the TSCA Work Plan. The agency also followed the EPA IQGs to ensure the utility, objectivity, and integrity of the information disseminated. The information provides specific references to the best available science and supporting studies, and is presented with applicable uncertainties and limitations discussed. The TSCA Work Plan is also formatted and designed with the intended audience in mind, and was distributed in a secure manner to protect the document from deliberate or accidental alteration.

Like other planning tools used by the EPA, the TSCA Work Plan for Chemical Assessments and the TSCA Work Plan Chemicals Methods Document, are not risk assessments or major work products that require peer review. Rather, the dissemination of these planning documents is intended to make the EPA planning process more accessible and transparent to the public at an early stage. The methodology was used to identify chemicals for further assessment. In fact, the EPA specifically notes in the TSCA Work Plan for Chemical Assessments that identification of a chemical on the TSCA Work Plan does not itself constitute a finding by the agency that the chemical presents a risk to human health or the environment. Rather, identification of a chemical on the TSCA Work Plan indicates only that the agency intends to consider it for assessment. The agency believes that identifying these chemicals early in the review process affords all interested parties the opportunity to bring additional relevant information on those chemicals to the agency's attention.

Also note that the EPA has added a problem formulation step prior to reaching a decision on whether to fully assess a chemical. Problem formulation is an opportunity for the public to submit information that the EPA did not have when it put the chemical on the Work Plan. The information provided in your letter on phthalic anhydride may be considered during an assessment, but the EPA has not yet reached that point in its assessment process.

If you are dissatisfied with this response, you may submit a Request for Reconsideration. The EPA requests that any such RFR be submitted within 90 days of the date of the EPA's response. If you choose to submit a RFR, please send a written request to the EPA Information Quality Guidelines Processing Staff via mail (Information Quality Guidelines Processing Staff, Mail Code 2811R, U.S. EPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460); electronic mail (quality@epa.gov); or fax ([202]

565-2441). If you submit a RFR, please reference the request number assigned to the original Request for Correction (RFC #15003). Additional information about how to submit an RFR is listed on the EPA Information Quality Guidelines website at <http://epa.gov/quality/informationguidelines/index.html>.

Sincerely,

A handwritten signature in black ink, appearing to read 'James J. Jones', written over a horizontal line.

James J. Jones
Assistant Administrator

Enclosures

cc: Ann Dunkin, EPA Chief Information Officer
Monica Jones, Director of Quality Staff
Renee Wynn, Acting Assistant Administrator, Office of Environmental Information