



December 23, 2015

Information Quality Guidelines Staff
Mail Code 2811A
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: Request for reconsideration of Agency denial of request for correction of the TSCA Work Plan Chemicals: Methods Document (February 2012) and the TSCA Work Plan for Chemical Assessments: 2014 Update (October 2014) regarding assessment of phthalic anhydride; RFC #15003

Dear Sir or Madam:

The Phthalic Anhydride Producers Panel (PA Panel) of the American Chemistry Council submits this Request for Reconsideration to EPA under its *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (EPA IQ Guidelines).¹ The PA Panel's Request for Correction (RFC #15003) of numerous factual errors in documents developed for the Office of Pollution Prevention and Toxics' (OPPT) TSCA Work Plan Chemicals Assessment Process related to potential exposure to phthalic anhydride (PA) was submitted on June 12, 2015. The Request was denied in a letter from Assistant Administrator James J. Jones dated November 23, 2015. Both the original Request and the Agency's response are enclosed.

The information on PA and the other chemicals presented in the 2012 Work Plan Chemicals Methods Document and the 2014 Update has the potential to result in major cross-Agency or cross-media policies and must be considered "influential scientific, financial, or statistical information."² As such, federal guidance requires that OPPT, not only ensure the quality, objectivity, and utility of the information, but also that it provide "sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public."³

¹ EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*, EPA/260R-02-008 (Oct. 2002).

² EPA IQ Guidelines, at 20. The 2012 Methods Document notes that OPPT considered presence in biota, drinking water, ambient and indoor air, and house dust as part of the Work Plan assessment.

³ OMB. *Guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by federal agencies* (OMB Guidelines). 67 *Federal Register* 8456 (February 22, 2002).



Assistant Administrator Jones' denial does not respond to the significant factual issues raised by our Request. The letter asserts, rather, that the underlying information and conclusions for PA presented in the TSCA Work Plan are "consistent" with the EPA's IQ Guidelines. It fails, however, to explain how OPPT met the essential requirements of the OMB guidelines to "make [the] methods transparent by providing documentation, ensure quality by reviewing the underlying methods used in developing the data and consulting (as appropriate) with experts and users, and keep users informed about corrections and revisions."⁴

OPPT provides no explanation in its response to RFC #15003, or in the 2012 Methods document or 2014 Update, as to what specific information it used to determine that PA was "widely used in consumer products" or that it was "present in groundwater and ambient air." Rather, OPPT's response points to a stakeholder process during which the Agency sought input on the general criteria to be used in identifying Work Plan chemicals. In fact, PA meets none of the six factors that Assistant Administrator Jones identifies as the basis for these Work Plan criteria. As described in our Request for Correction, moreover, a review of the data identified by OPPT as sources of use and exposure information⁵ failed to produce evidence to support EPA's conclusions relative to PA.

Contrary to the suggestion in the response, OPPT provided no opportunity for stakeholder input on the inclusion of PA and the other substances identified in the Work Plan documents prior to publication of the 2012 Methods Document or the 2014 Update. In light of the Assistant Administrator's own description of the Work Plan substances as those "having the highest potential for exposure and hazard," the failure to provide appropriate opportunity for public comment on the identified substances contradicts the assertion that the Work Plan process is consistent with the requirement to ensure transparency and quality.

The Agency's response to the PA Panel's Request also contradicts the information provided in the 2014 Update about corrections and revisions to the Work Plan list. Although it may be true that OPPT considered updated Toxic Release Inventory (TRI) and Chemical Data Reporting (CDR) information as described in the response, it is clear that other information also was considered. As we noted in our Request for Correction, the 2014 Update announced the removal of several substances from the Work Plan because they no longer present an exposure potential from consumer use, are already well characterized and controlled, or present only a workplace hazard. Since each of these conclusions apply equally to PA, it is not clear why PA was not also removed. This seemingly arbitrary consideration of the Work Plan substances in the 2014 Update is not consistent with the requirement for transparency in the IQ Guidelines.

While the addition of a problem formulation step represents an improvement to the Work Plan assessment program, it does not absolve OPPT of the obligation to ensure the

⁴ OMB Guidelines, at 8453.

⁵ EPA Methods Document, at 20.



quality of the process used to identify Work Plan substances that the Agency believes have “the highest potential for exposure and hazard.” In its 2002 guidelines OMB explains that “[a]gencies shall treat information quality as integral to every step of an agency’s development of information, including creation, collection, maintenance, and dissemination.”⁶ [Emphasis added] Contrary to the statement in the Agency’s response, all of the information provided in our Request for Correction was readily available at the time OPPT developed the Work Plan substance list. In fact, much of the information was developed by the Agency itself. The suggestion that OPPT did not have this information when it considered PA for inclusion in the Work Plan further highlights its failure to ensure the quality of the disseminated information.

The PA Panel requests that OPPT revise its conclusions about the potential exposure to phthalic anhydride to accurately reflect the available information on uses, emissions, and environmental presence of the substance. Such revision will clearly indicate that the potential for exposure to the chemical is quite low and that review under the Work Plan Chemicals Assessment Process is not supported by the available information.

Please feel free to contact me at 202-249-6727 or srisotto@americanchemistry.com if you have questions on the above information.

Sincerely,

Steve Risotto

Stephen P. Risotto
Senior Director
Chemical Products and Technology Division

Enclosures

cc: W. Cleland-Hamnett, OPPT Director
T. Henry, OPPT Risk Assessment Division

⁶ OMB Guidelines, at 8459.

