



June 12, 2015

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

Re: Information Quality Act Request for Correction of the TSCA Work Plan for Chemical Assessments: 2014 Update (October 2014) and the TSCA Work Plan Chemicals: Methods Document (February 2012) regarding assessment of phthalic anhydride (CAS number 85-44-9)

Dear Sir or Madam:

The Phthalic Anhydride Producers Panel (PA Panel) of the American Chemistry Council submits this Request for Correction to EPA under its *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (IQ Guidelines).¹ This Request seeks the correction of numerous factual errors in the above referenced documents developed for the Office of Pollution Prevention and Toxics' (OPPT) TSCA Work Plan Chemicals Assessment Process related to potential exposure to phthalic anhydride.

The members of the PA Panel² represent all of the US manufacturing capacity for phthalic anhydride and, according to the most recent data, supply more than 95 percent of the US demand for the chemical.³ Correction of the inaccuracies in the Work Plan assessment of phthalic anhydride therefore is of utmost significance to the members of the PA Panel.

As set forth in the IQ Guidelines, information is objective when it is "presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased."⁴ In its TSCA Work Plan documents, OPPT presents information on phthalic

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 The members of the Phthalic Anhydride Producers Panel are BASF Corporation, ExxonMobil Chemical Company, Koppers, Inc., and Stepan Company.

³ Imports of phthalic anhydride totaled about 12,000 metric tonnes in 2014 (US International Trade Commission 2014 import data base, available at <http://dataweb.usitc.gov>), compared to estimated annual consumption of over 300,000 tonnes (ICIS. US Chemical Profile – Phthalic Anhydride. September 2014. Available at <http://www.icis.com>).

⁴ IQ Guidelines, at 15.



anhydride that is not accurate and fails to meet the requisite standard of objectivity. OPPT has indicated that it uses this Work Plan assessment to focus the activities of its Existing Chemicals Program so that existing chemicals having the highest potential for exposure and hazard are assessed and, if warranted, are subject to risk reduction actions. The accuracy of the information presented in the Work Plan, therefore, will determine the scientific integrity of the Agency's assessment and any actions resulting from that assessment, as well as the message that these actions convey to the market place and the general public.

Correction of the data included for phthalic anhydride under OPPT's Work Plan, as described in this Request, make it clear that the substance should not be included on the list of chemicals for which OPPT plans to initiate a risk assessment under the TSCA Work Plan Chemicals Assessment Process. Since OPPT has indicated its intention to assess each of the Work Plan Chemicals under TSCA, and has provided no other opportunity for comment on the inclusion of phthalic anhydride, the PA Panel is compelled to submit this Request to ensure that the inaccuracies described herein are corrected in a timely manner.

Background

In 2011, OPPT sought comment through an online discussion forum,⁵ stakeholder forum, and webinar on a Discussion Guide⁶ that outlined the two-step process the Agency intended to use as part of its Work Plan program "to identify potential candidate chemicals for near-term review and assignment under the Toxic Substances Control Act."⁷ At the time, ACC submitted comments encouraging OPPT to ensure that its prioritization process was "robust, comprehensive, and science-based." OPPT subsequently released a methods document in February 2012 (Methods Document) that further described the prioritization process and -- for the first time -- identified 83 chemicals, including phthalic anhydride, the Office had selected for assessment. As part of the listing, the Methods Document identified seven of the 83 chemicals for priority review in 2012. Phthalic anhydride and the remaining 75 chemicals were identified as "Additional Work Plan Chemicals," with no timeframe provided for their consideration. While the Methods Document included a Hazard, Exposure, and Persistence and Bioaccumulation scores for each of 83 chemicals, it provided little explanation for the scores beyond the general explanation of the methodology used. Phthalic anhydride was assigned the highest score (3) for both hazard and exposure.⁸

⁵ <http://blog.epa.gov/chemprioritization/>.

⁶ EPA. Discussion Guide: Background and Discussion Questions for Identifying Priority Chemicals for Review and Assessment (August 2011). (Available at <http://www.epa.gov/oppt/existingchemicals/pubs/Chem.Prioritization.August2011.DiscussionGuideOnly.pdf>.)

⁷ EPA. TSCA Work Plan Chemicals: Methods Document. Office of Pollution Prevention and Toxics (February 2012), at 2. (Available at <http://www.epa.gov/oppt/existingchemicals/pubs/wpmethods.pdf>.)

⁸ See table from Methods Document (Enclosure 1).



OPPT subsequently released an update in October 2014⁹ (2014 Update) that removed 13 substances from the list of Work Plan Chemicals because “they no longer present exposure potential from consumer or commercial use.”¹⁰ An additional chemical group, mercury and mercury compounds, was removed because the hazards “are well characterized and EPA has a strong risk reduction effort in place.”¹¹ Quartz also was removed from the Work Plan because the hazards associated with it are limited to the workplace and controlled by regulations issued by the Occupational Safety and Health Administration. A total of 10 chemicals were added to the list based on OPPT’s conclusion that the potential for exposure to these chemicals was greater than originally concluded. The conclusions regarding phthalic anhydride were unchanged, but the Update provided no additional insight into how OPPT arrived at the score for the chemical.

Earlier this year, OPPT staff indicated that phthalic anhydride had been identified as part of the Regulatory Cooperation Council’s (RCC) Chemicals Management Project to be of mutual interest to EPA’s Work Plan program and Environment and Health Canada.¹² The summary for phthalic anhydride recently distributed as part of the RCC discussions¹³ includes information regarding the chemical’s tendency to undergo rapid hydrolysis and its presence as a minor metabolite of phthalate esters that is not reflected in the Work Plan summary for the chemical.

The Methods Document, 2014 Update, and recent RCC summaries for phthalic anhydride and other chemicals were not made available for public review and comment prior to their release. Had the public been given the opportunity to review the documents prior to finalization, commenters would have been able to highlight the significant errors contained in the conclusion about the use and potential for exposure to phthalic anhydride. Correction of the errors identified in this Request reduces the exposure score such that phthalic anhydride would no longer meet the criteria for listing under the TSCA Work Plan Chemicals Assessment Process. Consequently, the chemical likely would no longer be among those identified in the RCC Chemicals Management Plan.

OPPT’s Composite Exposure Score for Phthalic Anhydride

The only information that has been made publicly available about the OPPT’s consideration of phthalic anhydride under the Work Plan program indicates that the chemical received a Hazard Score = 3, an Exposure Score = 3, and a Persistence and Bioaccumulation Score = 1, for a Total Score

⁹ EPA. TSCA Work Plan for Chemical Assessments: 2014 Update. Office of Pollution Prevention and Toxics (October 2014). (Available at [http://www.epa.gov/oppt/existingchemicals/pubs/TSCA Work Plan Chemicals 2014 Update-final.pdf](http://www.epa.gov/oppt/existingchemicals/pubs/TSCA%20Work%20Plan%20Chemicals%202014%20Update-final.pdf).)

¹⁰ The 2014 Update indicates that the changes reflect updated industry data submitted to EPA under the Toxics Release Inventory and Chemical Data Reporting requirements.

¹¹ 2014 Update, at 7.

¹² The PA Panel volunteered to participate in the RCC activity in hopes of informing EPA and Health Canada about the potential for exposure to the chemical. It is not clear whether the joint process will address OPPT’s underlying assumptions about exposure.

¹³ A summary table was distributed to participants for an RCC teleconference held on April 9, 2015. It is included as Enclosure 2.



of 7.¹⁴ According to the process outlined in the Methods Document, chemicals receiving a Total Score of 7 or higher are assigned a “High” ranking and considered Work Plan Chemicals for further analysis through the TSCA Work Plan Chemicals Assessment Process.

The PA Panel does not request changes to the Hazard or Persistence and Bioaccumulation Score assigned to phthalic anhydride by OPPT. The Panel’s Request for Correction applies solely to the Exposure Score for phthalic anhydride which is based on a combination of information for the following three criteria --

- Chemical Use – consideration of consumer product applications as well as industrial and commercial uses that could result in widespread exposures;
- General Population and Environmental Exposure - measured data on the presence of a chemical in biota and environmental media; and
- Release - EPA’s Toxics Release Inventory (TRI) data, or Chemical Data Reporting¹⁵ information for chemicals not subject to TRI reporting, used to “infer potential for environmental and general population exposure.”¹⁶

Regarding the Chemical Use criteria, the Methods Document indicates that phthalic anhydride is “widely used in consumer products” for which it would receive the highest ranking of 3. Under General Population and Environmental Exposure criteria, OPPT’s analysis indicates that the chemical is “present in groundwater and ambient air” for which it would receive a ranking of 2 or 3. For the Release criteria, OPPT indicates that there are “high reported releases to the environment” for which phthalic anhydride would receive the highest ranking of 3.

Based on the rankings for the three exposure criteria, OPPT assigned phthalic anhydride a normalized overall exposure score of 3 corresponding to an overall rank of “high” for potential exposure. The remainder of this Request addresses each of the conclusions regarding the exposure criteria.

Phthalic Anhydride is Not Widely Used in Consumer Products

According to the Cooperative Chemicals Assessment Programme of the Organization of Economic Cooperation and Development (OECD), phthalic anhydride is used as an intermediate (i.e., raw material) in a variety of chemical processes, including in the production of -

- phthalate esters – used as plasticizers in polyvinyl chloride (PVC) resin for a wide variety of applications,

¹⁴ See Enclosure 1.

¹⁵ Formerly referred to as Inventory Update Reporting.

¹⁶ Methods Document, at 13.



- unsaturated polyester resins – used in fiberglass-reinforced plastics for construction, marine, or transportation applications, and in bathroom vanity tops, bathtubs, and shower stalls,
- alkyd resins – used in architectural coatings, product finishes, and special purpose coatings, and
- other products – polyester polyols, isatoic anhydride, intermediates in pigments and dyes, flame retardants for polyester polyols, and intermediates in the agricultural and pharmaceutical sector.¹⁷

This information is consistent with the most recent data available in EPA's Chemical Data Reporting (CDR) data base¹⁸ and in the registration dossier for the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation.¹⁹

Neither the CDR nor REACH data indicate the direct use of phthalic anhydride in consumer products. Among the sources of use and exposure information identified in OPPT's Methods Document, the only references to the presence of the chemical in consumer products are -

- in nail polish as part of a copolymer additive,
- in various paints, dyes, and lacquers in the Nordic countries, and
- as a trace component in wood stains.

The National Institutes of Health (NIH) Household Product Database includes information on three nail products containing a phthalic anhydride/trimellitic anhydride/glycols copolymer.²⁰ The NIH database notes that one of the three nail products was discontinued in 2007. A web search for the other two products reveals that one of the products is no longer available and the other has been reformulated to eliminate the phthalic anhydride-based copolymer.²¹ A search of current nail products in data bases maintained by the Environmental Working Group²² and the Personal Care

¹⁷ OECD. Screening Information Data Sets (SIDS) Initial Assessment Report – Phthalic Anhydride, CAS No. 85-44-9. OECD Cooperative Chemicals Assessment Programme (19-22 April 2005), at 9. Available at <http://www.chem.unep.ch/irptc/sids/OECD/SIDS/85449.pdf>. (OECD SIDS Report)

¹⁸ Available at <http://www.epa.gov/oppt/cdr/>. CDR data for phthalic anhydride is included as Enclosure 3.

¹⁹ Available at <http://echa.europa.eu/>. Information on identified uses from the publicly available REACH dossier for phthalic anhydride is included as Enclosure 4.

²⁰ Since the production of the copolymer involves a reaction of phthalic anhydride with another monomer, it is unlikely that use of the resulting product could have resulted in exposure to either of the monomers.

²¹ <http://www.avon.com>, accessed on May 14, 2015.

²² <http://www.ewg.org/skindeep/>, accessed on May 14, 2015.



Products Council²³ indicates, in fact, that the phthalic anhydride copolymer is no longer used in nail polishes or hardeners.

The Substances in Preparation in Nordic Countries (SPIN) data base, based on Product Registries of Norway, Sweden, Finland, and Denmark and maintained by the Nordic Council of Ministers, lists about 30 products reportedly containing phthalic anhydride in 2013.²⁴ The data base does not distinguish between direct uses of phthalic anhydride, however, and uses of materials that are produced from reactions with the chemical.²⁵ A review of the descriptions of the listed products suggests that most, if not all, include resins and other products made with phthalic anhydride, not the chemical itself. As a consequence, they are unlikely to result in exposure to the chemical.

Phthalic anhydride used as a raw material is consumed in the production of plasticizers, resins, and other products such that detectable amounts of the chemical are unlikely to remain. The PA Panel is unaware of data confirming the presence of measurable amounts of the unreacted chemical in the resulting products. Although the study by Zhu *et al.* (1999)²⁶ reports phthalic anhydride as a trace component in hydrocarbon wood stains, it is not clear whether the chemical was present in the stains or formed as part of the analytical procedure (Gas Chromatography/Mass Spectrometry).²⁷ Available information indicates that phthalic anhydride can result from thermal degradation of other materials in the injection port of a gas chromatograph.²⁸

Since the plasticizers and resins are formed by a chemical reaction it is also unlikely that they will break down to form phthalic anhydride under normal conditions. Degradation of phthalate ester plasticizers was observed by Vainiotalo and Pfaeffli (1990), but only when the plasticizers were exposed to high temperatures.²⁹ The temperatures required for such degradation (180 degrees Celsius or higher) are not routinely encountered and would not be expected to be a source of consumer exposure.

Reports of phthalic anhydride in consumer applications in the US and Europe appear based on the presence of products made with the chemical, such as plasticizers and alkyl resins, rather

²³ <http://www.cosmeticsinfo.org>, accessed on May 14, 2015.

²⁴ The SPIN data base can be accessed at <http://195.215.202.233/DotNetNuke/default.aspx>. A list of products is included as Enclosure 5.

²⁵ OECD SIDS Report, at 23.

²⁶ Zhu J *et al.* Chemical composition analysis and its application in estimation of VOC emission rates from hydrocarbon solvent-based indoor materials. *Chemosphere* 39(14):2535-2547 (1999).

²⁷ OECD SIDS Report, at 17.

²⁸ EPA. OPPT Chemical Fact Sheets – Phthalic Anhydride Fact Sheet: Support Document (CAS No. 85-44-9). EPA 749-F-95-016a (December 1994), at 4. Available at <http://www.epa.gov/chemfact/phtha-sd.pdf>. (OPPT Fact Sheet).

²⁹ Vainiotalo S and Pfaeffli P. Air impurities in the PVC plastics processing industry. *Ann Occup Hyg* 34(6):585-590.



than the chemical itself. Although these plasticizers and resins may be used widely in consumer applications, the available information does not suggest a significant potential for consumer exposure to phthalic anhydride.

Available Data Do Not Indicate that Phthalic Anhydride is Present in Groundwater and Ambient Air

Robust programs exist for monitoring contamination in groundwater and ambient air, including several maintained by EPA and listed as data sources in Appendix B of the Methods Document. Similar monitoring also is conducted in Canada and the European Union. A review of the information available for phthalic anhydride included in the data sources listed by OPPT reveals a dearth of information on the chemical. None of the sources for groundwater contamination include information suggesting the presence of phthalic anhydride. The chemical is not included in EPA's National Contaminant Occurrence Database, the US Geological Survey's National Water Quality Assessment Program, or Washington State's background soil concentration study. There are no reports of phthalic anhydride in EPA's fish tissue studies, Superfund Chemical Data Matrix, or Targeted National Sewage Sludge Survey Report. No water quality criteria exist for phthalic anhydride, nor has the chemical been included on the Agency's Drinking Water Chemical Contaminant Lists (CCLs) 1 through 4.

According to the OPPT Fact Sheet, phthalic anhydride has been identified, but not quantified, in US drinking water. The significance of these findings is clouded by the fact that the chemical was routinely detected in laboratory blanks in at least one study.³⁰ Notwithstanding this concern, OPPT concluded that "the rapid hydrolysis of phthalic anhydride to phthalic acid"³¹ that occurs in aqueous media would preclude any significant transport of the chemical in the aqueous environment."³² As OECD notes, the half-life of phthalic anhydride in aqueous solution is in the range of seconds to minutes.³³

Information on phthalic anhydride concentrations in ambient air is similarly lacking. Despite the fact that phthalic anhydride is listed as a hazardous air pollutant (HAP) under the Clean Air Act, there are very little monitoring data available for the chemical. The significance of these few data is further complicated by evidence that phthalic anhydride is formed during the analytical process.³⁴

A review of the evidence available from EPA and other sources indicates that very little data exist to support OPPT's contention that phthalic anhydride is present in groundwater and ambient air. Phthalic anhydride's tendency to rapidly hydrolyze in water makes it unlikely that the chemical

³⁰ Kolpin DW et al. Pharmaceuticals, hormones, and other organic wastewater contaminants in U.S. streams, 1999-2000: A national reconnaissance. *Environ. Sci. Technol.* 36:1202-1211 (2002).

³¹ A search for information on phthalic acid in the sources listed in the Methods Document also failed to find data regarding its presence in groundwater.

³² OPPT Fact Sheet, at 5.

³³ OECD SIDS Report, at 11.

³⁴ OPPT Fact Sheet, at 4.



will be found to any significant degree in ground and surface water. Information on levels of phthalic anhydride in ambient air is anecdotal and the interpretation of these data is complicated by the potential for the chemical to form during analysis.

Releases of Phthalic Anhydride Do Not Suggest the Potential for Significant Environmental and General Population Exposure

The most recent TRI data indicate that a total of 90 facilities reported releases of phthalic anhydride adding up to about 236,000 pounds in 2013.³⁵ Of that total, 167,000 pounds (71%) were released by only four facilities. The vast majority of the reported releases were as point or fugitive air emissions – 85% of the total reported releases, 96% of the releases reported by the four facilities. While the total TRI releases of phthalic anhydride exceed the nominal threshold of 100,000 pounds specified in the Methods Document, additional data have been developed by EPA that allow OPPT to more robustly assess the potential for environmental and population exposure to these emissions. These data sources include the National Emissions Inventory (NEI)³⁶ which is listed among the primary resources identified in Appendix B of the Methods Document and the closely related National Air Toxics Assessment (NATA).

Under NATA, EPA's Office of Air and Radiation (OAR) has developed a comprehensive tool for assessing exposures to air emissions from phthalic anhydride and the other chemicals designated as HAPs. The assessment is based on emissions information generated for the NEI.

The most recent NATA assessment was conducted with data collected in 2005 and was completed in 2012.³⁷ It provides information on predicted concentrations and estimated exposures for all potential sources of phthalic anhydride on both a county and census-tract basis for 42 states and territories. According to OAR's analysis, the predicted ambient concentration of phthalic anhydride is at or below the limit of detection in all of the 60,900 census tracts analyzed.³⁸ Consequently, the average exposure to the chemical is estimated to be less than 1 microgram per cubic meter ($\mu\text{g}/\text{m}^3$) in all of the census tracts, including those tracts nearest to the facilities reporting TRI emissions. The highest exposures, ranging from 0.16 to 0.28 $\mu\text{g}/\text{m}^3$, were estimated to occur in two census tracts with a combined population of about 8,000.³⁹ These exposures can be expected to be even lower today, given the continued decline in emissions of the chemical since 2005.

³⁵ This total represents a 3-percent reduction from releases reported in 2012 and a 26-percent reduction from 2008 releases. 2008 TRI data were used for the initial chemical ranking in the Methods Document; 2012 TRI data were used for the 2014 Update.

³⁶ The inventory is based primarily upon emission estimates and emission model inputs provided by State, Local, and Tribal air agencies for sources in their jurisdictions, and supplemented by data developed by the EPA.

³⁷ The 2005 NATA results are available at <http://www.epa.gov/ttn/atw/nata2005/tables.html>.

³⁸ Based on a limit of detection of 0.06 ppb (0.366 $\mu\text{g}/\text{m}^3$) reported by Davoli E *et al.* Characterization of odorants emissions from landfills by SPME and GC/MS. *Chemosphere* 51:357-368 (2003).

³⁹ EPA's Office of Research and Development has established a reference dose (RfD) of 2 mg/kg/day for phthalic anhydride, but has not set a reference concentration (RfC).



It is important to note that NATA was developed by OAR to assist in prioritizing sources for national emission standards for HAPs (NESHAPs), under EPA's Clean Air Act authority. Using this authority, EPA promulgated a NESHAP in 1994 to control emissions of HAPs, including phthalic anhydride, from synthetic organic chemical manufacturing facilities. Based on a subsequent risk and technology review, EPA promulgated additional requirements for these facilities in 2006. NESHAPs also have been promulgated for a wide variety of other manufacturing facility types, including those with the potential to release phthalic anhydride.

The NATA estimates for exposure to phthalic anhydride among the general population contrast sharply with OPPT's conclusion that there is a significant potential for environmental or general population exposure to the chemical. Given the existence of national regulations controlling potential emissions of phthalic anhydride from manufacturing facilities, moreover, EPA already has taken appropriate measures to address whatever risk exposure to phthalic anhydride may pose.

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
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