September 6, 2016

Mr. David Brooks
Risk Assessment Division (7403T)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Via electronic submittal at www.regulations.gov

Re: Docket Identification (ID) Number EPA-HQ-OPPT-2015-0744: Agency Information Collection Activities; Proposed Renewal of an Existing Collection (EPA ICR No. 0794.16); Comment Request for EPA ICR No. 0794.16 and OMB Control No. 2070-0046, "Notification of Substantial Risk of Injury to Health and the Environment under TSCA Sec. 8(e)

Dear Mr. Brooks:

The American Chemistry Council (ACC)[1] is pleased to submit these comments on EPA's Information Collection Request (ICR) No. 0794.16, noticed in the Federal Register on July 5, 2016 at 81 FR 43601, regarding Notification of Substantial Risk of Injury to Health and the Environment under TSCA Sec. 8(e). ACC's member companies manufacture, distribute, process, import, use, and dispose of chemical substances regulated under the Toxic Substances Control Act (TSCA). As such, our members are required to comply with statutory TSCA 8(e) reporting obligations and associated regulatory mandates. ACC is responding to EPA's specific questions.

1. **Are the data that EPA seeks under this ICR available from any public source, or already collected by another EPA office or by another agency? If so, where can the data be found?**

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $797 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for fourteen percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

Data that EPA seeks under this ICR are often, but not always, available from other public sources, other EPA offices, other federal and state agencies, and private entities. Because penalties for non-compliance with TSCA 8(e) reporting are severe, where it is uncertain whether EPA has been "adequately informed of such information," some companies prefer to report the information to EPA. Companies may face an increased reporting burden by electing either to (1) undertake additional work to determine whether EPA has been informed of the information or (2) accept the ambiguity over whether EPA has been informed and "overreport." EPA can reduce these burdens by offering greater clarity with respect to what documents and information may be considered to be known by the agency.

EPA's existing limited guidance is helpful to identifying types of "substantial risk" information that does not need to be reported under section 8(e). For example, EPA's 1991 guidance[2] set forth categories of information for which the agency considers itself already adequately informed such that it need not be reported, and its June 3, 2003 guidance[3] expanded these categories. The 2003 guidance, however, is not fully reflective of the current state of data availability in the age of information available over the internet and by social media, ease of online searching, open access journals. The guidance, likewise, is not fully reflective of the emergence of modern data sharing agreements between international, federal, and state bodies, such as agency clearinghouses and Memoranda of Agreement EPA enters into with other federal,[4] state[5] or international agencies. ACC strongly recommends EPA update its guidance to reflect greater availability to EPA of data due to these and other developments – such as to clarify whether international journal articles, internet-available media materials, and data generated or published by bodies such as the European Union and Canada are known to EPA. The update would decrease the annual public burden under the Paperwork Reduction Act by reducing confusion and uncertainty as well as by avoiding duplicate reporting of information already known to the agency.

2. Is it clear what is required for data submission? If not, are there any suggestions for clarifying instructions?

Interpreting statutory compliance obligations under Section 8(e) can be complex. It can be difficult to determine whether a submission is mandated by statute. For example, in some cases is difficult to determine whether information from a medical survey or consumer reports reliably ascribes the reported effect to a chemical. The complexity and burden generally does not lie with the technical submission of the document reporting the effect, but is a function of applying the statutory requirements to the facts at hand. This may require multiple levels of technical,

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[2] 1991 Reporting Guide, available at https://www.epa.gov/sites/production/files/2015-09/documents/1991guidance.pdf

[3] 68 Fed. Reg. 33129, 33139 (June 3, 2003) available at https://www.gpo.gov/fdsys/pkg/FR-2003-06-03/pdf/03-13888.pdf

[4] See, e.g., 80 Fed. Reg. 10682 (Feb. 27, 2015), Notice announcing Memorandum of Understanding on Information Shared between U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention and Department of Health and Human Services, Food and Drug Administration, Foods and Veterinary Medicine Program, also available at https://www.epa.gov/pesticides/data-sharing-memorandum-understanding-between-epa-and-fda

[5] See, e.g., Materials Transfer Agreement, May 20, 2013, available at https://www.epa.gov/sites/production/files/2015-07/documents/mta_oehha_shoba_iyer.pdf

scientific, and legal review by trained personnel. Furthermore, the 1991 and 2003 guidance documents fail to explain how a finding of substantial risk can be inferred solely based on hazard or toxicity data, and thus require submission.[6] Clear, updated guidance from EPA which can be quickly and easily located on EPA's website would be helpful. We note that EPA's website, "Reporting a TSCA Chemical Substantial Risk Notice," omits a link to its 2006 Frequent Questions,[7] and the website in general makes it difficult to search for data or relevant studies.

We appreciate that EPA has sunset its old, searchable TSCA 8(e) database. EPA explains in its Supporting Statement that:

> Section 8(e) data on newly discovered chemical hazards/risks is available via EPA's Chemical Data Access Tool (CDAT) (https://java.epa.gov/oppt_chemical_search/). There is also public outreach and information access to section 8(e) data through the TSCA Public Docket, and online databases that include section 8(e) records. OPPT is also currently in the process of migrating these section 8(e) submissions and posting future section 8(e) submissions to EPA's Chemview database (http://java.epa.gov/chemview).

While EPA is in the process of migrating these submissions and moving to Chemview, we suggest that EPA add this information, and clarification, directly to its central webpage, "Reporting a TSCA Chemical Substantial Risk Notice." This would reduce the burden on new Section 8(e) submitters and those in training who are still learning where EPA's information on Section 8(e) requirements is located as well as the function of online tools. It would also be helpful to add a direct link to the TSCA Public Docket.

3. Would you be interested in an electronic/data submission option? What type of alternative would you be most likely to utilize – web form, diskette, CD-ROM?

In 2014, EPA began offering submitters of Substantial Risk Notifications pursuant to TSCA section 8(e), as well as voluntary "For Your Information" (FYI) submitters, the option of filing electronically using EPA's electronic document submission system, the Central Data Exchange (CDX). Use of this system itself imposes an administrative burden, as users must first register to use the CDX portal. Users must also ensure CDX compatibility with their local software, IT specifications and requirements, firewalls and other features. That said, existing chemical manufacturers are already required to use CDX for electronic reporting of information submitted for TSCA Chemical Data Reporting, Pre-Manufacture Notifications, and other reporting under Sections 8 and 4. Within this context, any "new" burden to use CDX for Section 8(e) reporting is negligible, and the initial burdens have generally already been incurred and are attributable elsewhere.

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[6] For example, the 2003 policy statement explains that human health effects could be "so serious that relatively little weight is given to exposure," but does not explain at what point such effects become so serious as to require 8(e) reporting in complete absence of exposure factors. 68 Fed. Reg. 33129, 33138 (June 3, 2003) available at https://www.gpo.gov/fdsys/pkg/FR-2003-06-03/pdf/03-13888.pdf

[7] See, Guidance Documents on Substantial Risk Notifications under TSCA, available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/guidance-documents-substantial-risk-notifications-under

4. **For electronic submission, how should signature requirements be handled – Private Key Infrastructure, PINS and passwords, signed paper cover sheet?**

In light of highly publicized recent data breaches, particularly of the National Security Agency, ACC recommends that EPA solicit expert advice to achieve state of the art security for electronic submissions that include confidential business information.

5. **How does TSCA CBI affect your choice or use of an electronic medium? Would you be more inclined to submit TSCA CBI on diskette than on paper and what benefits would you realize (e.g., burden reduction, greater efficiency in compiling information, etc).**

First, EPA's burden estimates appear accurate based on TSCA language as it existed prior to the LCSA amendments. However, CBI substantiation provisions now apply to TSCA 8(e) submissions where industry makes confidentiality claims, and such submissions comprise a substantial portion of all Section 8(e) submissions. EPA should revise its estimates to account for this change. Even if submitters use the paper option, we expect EPA to convert paper submissions into electronic form and upload them to manage a single, searchable database. If this is the case, the risks of a security breach –regardless of which submittal option is originally chosen – should remain approximately the same. To manage CBI and avoid data breaches, we recommend EPA solicit expert advice to secure its systems as noted above. Notably, system integrity should be maintained in a systematic and consistent manner across federal agencies and with states where EPA has data sharing agreements in place that implicate CBI protected material. EPA should not share CBI protected information with other federal or state agencies unless those agencies can offer and deliver an equivalent level of security as required under Section 14(d) of TSCA.

6. **Do you agree with EPA's estimated burden[8] and costs (the ICR addresses only the costs associated with paperwork)? Are the Bureau of Labor Statistics (BLS) labor rates accurate? If you have any reason to consider the BLS labor rates as used by EPA inaccurate or inappropriate, explain your rationale.**

Our comments here address estimated burden and costs. We believe the ICR underestimates both. EPA's BLS labor rates appear accurate, although we urge EPA to consider that 8(e) reviews often require highly experienced or senior staff with advanced degrees. It is not uncommon for a review committee to be populated by persons with multiple doctorate degrees. EPA's estimate should reflect this.

[8] "Burden" is defined at 5 C.F.R. 1320.3(b) as "the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency, including: (i) Reviewing instructions; (ii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of collecting, validating, and verifying information; (iii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of processing and maintaining information; (iv) Developing, acquiring, installing, and utilizing technology and systems for the purpose of disclosing and providing information; (v) Adjusting the existing ways to comply with any previously applicable instructions and requirements; (vi) Training personnel to be able to respond to a collection of information; (vii) Searching data sources; (viii) Completing and reviewing the collection of information; and (ix) Transmitting, or otherwise disclosing the information."

Burden to Learn Disaggregated Reporting System

EPA states in its Supporting Statement that "it believes the adoption of electronic communications reduces the reporting burden on industry by reducing both the cost and the time required to review, edit and transmit data to the Agency." While we strongly support EPA's move to an electronic reporting system, and believe it creates significant efficiencies for the agency, we disagree with EPA's statement. In practice, an electronic system has not proved to reduce the amount of time needed by a manufacturer to review, edit, or transmit an 8(e) submission compared to doing so by "paper." Greater efficiencies can be gained by consolidating compliance tools and guidance in a central location, which saves users time; however, EPA's current changes to its website and disaggregation of 8(e) guidance, tools, portals, and instructions is likely creating additional burdens and delays, particularly for new submitters who need to be trained on locations and operation.

Burden on Small Businesses

EPA states in its Supporting Statement that, "[s]ince there is no routine reporting or recordkeeping provisions for section 8(e), the true burden on most small entities is practically nonexistent." This is an unsupported assertion. In our view, the current compliance obligation includes training personnel to be able to:

- Respond to a collection of information;
- Search data sources (EPA's online website, portals); and
- Use EPA's electronic systems and follow disparate instructions.

These compliance obligations are quite burdensome for small businesses with little to no prior experience with Section 8(e) obligations. Small businesses developing innovative new chemistries or specialty chemistries in niche areas, which may be dealing with an 8(e) submission for the first time, would likely describe the experience as a significant burden, particularly with respect to training, and navigating EPA's online sites and information.

Submitter Burden Estimate

The Supporting Statement includes EPA's estimate of approximately 49 hours per submission to judge on the section 8(e) applicability of obtained information and to prepare and submit the necessary information. This is broken into an average of 45 hours per submission of managerial staff time to review and evaluate data and an additional 4 hours for staff training on section 8(e) regulatory requirements. We believe this underestimates the time expended.

Complex decisions on 8(e) applicability are often referred to internal 8(e) review committees within companies. These are generally interdisciplinary in nature but supported by several scientists capable of reviewing and analyzing technical and scientific information. A committee may be composed of ten to twenty staff. Different information may require the location and inclusion of specialists, such as a medical doctor, epidemiologist, statistician, or endocrinologist to participate in a specific review. Significant review may be needed to compare a particular

study with an entire body of scientific literature. Legal or regulatory specialists may be needed to evaluate information against EPA's detailed guidance. A more accurate average estimate is an average of 8 managerial (professional/scientific) staff needing 10 hours each to conduct their review, with an average of 2 hours per each of these staff for specialized training, for a total estimate of 96 hours per submission. In practice it is not uncommon for this process, including decisions whether to submit follow up data, to take up to 120 hours of combined staff time. We also note that the agency needs to include consideration of the burden time spent to conduct an 8(e) review and not make a submission, or make an FYI submission.

EPA also is underestimating time needed for training given that 8(e) compliance requires broad company-wide awareness. ACC member companies must train staff in each of the following job functions for Section 8(e) awareness:

- Occupational health professional, including industrial hygienists and physicians;
- Production supervisor;
- Production operator;
- Maintenance supervisor and personnel;
- Purchasing manager;
- Toll manufacturer;
- Research and development professional and technician;
- Sales and marketing professional;
- Engineering design professional;
- Legal professional.

This means that across multiple departments, member companies must engage in training sessions, involving multiple upper-level staff dedicated to diligently preparing accurate and helpful training sessions, and that member companies lose work productivity and burden hours for each staff member engaged during such training sessions.

Burden of Supplemental/Follow-Up Submission(s)

EPA notes that it believes the burden of making follow-up and supplemental decisions to be less than the burden for original submissions. It does not, however, offer any information to support this conclusion. EPA itself is in possession of data that would help inform such a burden estimate; EPA should know how many times it follows up on 8(e) submissions with follow-up requests as well as the nature of the request. This information would help support a well-grounded estimate of average burden. We encourage EPA provide information to support an appropriate estimate. EPA estimates the unit burden for additional submissions to be a mere 0.06 hours, or 3.6 minutes. We believe EPA is likely assuming that follow-up submissions occur in only a small fraction of occasions, but it would be helpful for EPA to explain how it arrives at this fraction.

Estimated Floor for Burden Estimate

The ICR states that "the annual public reporting and recordkeeping burden for this collection of information is estimated to range from 0.5 hours to 50 hours per response, depending upon the

nature of the response." We believe a floor of a mere half hour to make even the simplest 8(e) submission is too low, and that EPA should adjust the time frame accordingly. The importance of 8(e) reporting, the statutory requirement for immediate decision making and reporting on a fast timeline, the frequent need for expert review and research, and the attendant compliance consequences mean that 8(e) reviews and decisions typically follow well-established corporate practices with multiple participants. A floor estimate of 30 minutes to make an 8(e) submission is less than even a single individual would need to review information, make a decision, and undertake an electronic submittal, and this truncated process with only one individual involved would likely be an outlier. It would be more helpful for EPA to indicate its average, rather than reporting an estimated range where the bottom of that range does not reflect typical conditions or practices.

Estimated Burden of FYI Submissions

ACC agrees that the burden of an FYI submission is commensurate with an 8(e) substantial risk submission. The final burden estimates, after correction, should be adjusted accordingly.

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In this ICR renewal, EPA underestimates the burden hours associated with Section 8(e) reporting, and does not offer sufficient factual bases for its stated estimations. EPA should update its estimates with well-substantiated and updated information. EPA should also update its guidance on Section 8(e) reporting for greater clarity on what information is known to the administrator, what is required for data submission, and when toxicity data alone may be sufficient for a finding of substantial risk, as discussed above in Questions 1 & 2.

ACC appreciates the opportunity to comment. If you have any further questions regarding these comments, please feel free to contact me at Richard_Starr@americanchemistry.com or at (202) 249-6443

Sincerely,

Richard Starr
Manager
Regulatory & Technical Affairs