September 20, 2018

Charlotte Bertrand
Acting Principal Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
US Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Avenue, NW (Mail Code 1701M)
Washington, DC 20460

Subject: Agency Information Collection Activities; Proposed Renewal of an Existing Collection Entitled "Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies;" EPA-HQ-OPPT-2017-0646; EPA ICR No. 0575.16; and OMB Control No. 2070-0004.

Dear Ms. Bertrand:

The American Chemistry Council (ACC)[1] is pleased to submit these comments on Environmental Protection Agency's (EPA's) Information Collection Request (ICR) on "*Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies*" pursuant to EPA's request (83 Fed. Reg. 35271 on July 25, 2018).

The chemical industry is committed to helping EPA meet its goals to enhance the quality of information available on chemicals in commerce. As part of the Agency's efforts to improve manufacturing data recording and reporting, it is important that the Agency consider industry's burden under current program requirements. For this ICR, EPA has requested feedback on the burden of compliance with TSCA Section 8(d). ACC appreciates the opportunity to provide comments on the burden associated with new requirements as well as existing burdens not accounted for in EPA's calculations.

1. **EPA Should Utilize Section 8(d) for Information and Data Collection during Prioritization of Chemicals for TSCA Risk Evaluations**

ACC has advocated for a tiered information/data collection process for prioritization and risk evaluations under the Lautenberg amendments to TSCA. A tiered, iterative approach to

[1] The American Chemistry Council's member companies manufacture, chemical substances regulated under the Toxic Substances Control Act (TSCA). As such, they are obligated to provide information related to the TSCA Inventory under section 8(d). ACC's member companies are directly affected by and have a significant interest in this ICR.

information collection is efficient at ensuring a focus on information and data "needs" for prioritization and risk evaluation purposes. In our comments on the proposed prioritization rule, for example, we urged that the Agency first gather reasonably available information about a chemical's hazards, uses and potential exposures. Then where needed, make requests for voluntary data submission. If more information is still needed for prioritization, EPA should then use its Section 8 authorities as a next step; and only after determining that new information is necessary should EPA consider using its Section 4 authority. Specifically, our comments[2] stated:

> ACC is well aware that information about potential hazards and potential uses and exposures of a chemical is critical to sound decision-making by EPA – for both prioritization and risk evaluation decisions. ACC is also well aware of the aggressive timeframes within which both prioritization and risk evaluations must be conducted. ACC strongly believes that both prioritization and risk evaluation processes are more efficient if they use iterative and tiered processes and that these processes help ensure science-based decision-making. ACC recommends therefore that EPA clearly distinguish in the prioritization process rule those elements that are specific to gathering of reasonably available information and those elements relating to the development of existing or new information through TSCA Sections 8 and 4.
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> For example, information gathering about candidate chemicals for high and low priority designations should be clearly sequential and iterative. EPA should first gather reasonably available information about potential hazards, uses and potential exposures of a candidate chemical and integrate that information. Sources of such information could include: QSAR and read-across information; information from the Chemical Data Reporting (CDR) and from EPA's Dashboard; information from the TSCA Work Plan Chemicals program as well as from other EPA efforts to develop and assess chemicals such as EPA's High Production Volume (HPV) Challenge Program, its Voluntary Children's Chemical Evaluation Program (VCCEP) and its Chemical Assessment and Management Program (ChAMP); exposure scenario information –both actual or estimated from exposure models; information from Canada's Chemical Management Program (CMP) and from the European Chemical Agency's (ECHA) robust study summaries developed for REACH; and REACH use scenarios (though EPA must be cognizant of potential differences in EU and U.S. use scenarios and address these through U.S.-centric use mapping).
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> As EPA is gathering reasonably available information, it could also request voluntary submission of information about a candidate chemical's potential hazards, uses and exposure from manufacturers, processors, distributors and users of candidate chemicals. It

[2] ACC Comments on EPA's Procedures for Prioritization of Chemicals for Risk Under the Toxic Substances Control Act as amended by the Lautenberg Chemical Safety Act, 82 FR 33753, p. 13, March 20, 2017.

should invite discussions with manufacturers, processors, distributors and downstream users of a candidate chemical.

If EPA concludes after it has implemented those initial information gathering steps that it still needs more information to prioritize, it should then turn to its Section 8(a) and 8(d) rule authority to seek additional existing information. Only if after using its Section 8 authority EPA determines that new information is necessary to prioritize should EPA then consider using its Section 4 test rule/order or consent agreement authorities to develop that information. Section 4 imposes limitations on when EPA can develop new information for prioritization. Congress generally expected EPA to base prioritization decisions on reasonably available information. EPA should acknowledge these limitations in the final rule – both in the preamble and the rule itself.

The Agency has already published its final prioritization rule[3] and will soon be releasing its "pre-prioritization" approach regarding how it will identify potential candidate chemicals for high priority and low priority designations. The Agency has not yet implemented its prioritization rule to identify high and low priority chemicals, however. To the extent that EPA begins using its Section 8(d) authority more frequently pursuant to the TSCA prioritization process (or for the collection of additional, more refined health and safety information for the risk evaluations of chemicals designated high priority), this will necessarily add to burden and cost estimates. As a result, the current estimates in this ICR are too low and do not adequately account for the new TSCA prioritization and risk evaluation processes.

If you have any questions on ACC's comments, please feel free to contact me at 202-249-6198.

Sincerely,

Brett Howard, J.D., Ph.D.
Director – Chemicals Management
Regulatory & Technical Affairs

[3] 82 Fed. Reg. 33,753 (2017), codified at 40 C.F.R. 702 Subpart A.