February 25, 2022

Katherine Sleasman, Mission Support Division (7101M)
Office of Program Support
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460–0001
Submitted via: www.regulations.gov

Subject: **Agency Information Collection Activities; Proposed Renewal and Consolidation of Two Currently Approved Collections Under Section 5 of the Toxics Substances Control Act; Comment Request; Docket Identification (ID) Number EPA-HQ-OPPT-2021-0660-0001**

Dear Ms. Sleasman:

The American Chemistry Council (ACC) appreciates the opportunity to provide comments on the EPA's December 27, 2021 information collection request (ICR), proposed renewal and consolidation of two currently approved collections under Section 5 of the Toxics Substances Control Act. ACC and its members have consistently supported transparency and consistency in the data collection process. We recognize that the information gathered during the premanufacture review of new chemical substances and the reviews of significant new use rules for new and existing chemical substances help to support EPA's activities to meet its mission of protecting human health and the environment.

As the EPA is considering consolidating and renewing the current ICRs it must ensure that: (1) it accurately captures the cost to U.S. businesses; (2) provides more clarity in what information is being sought, the process for considering the information provided, and how that information will be used to support the agency's decision-making during the review process; and (3) improve the electronic submission processes to minimize the burden on submitters. ACC offers the following comments that the agency should address prior to finalizing any renewals to the current ICRs.

- **Update the Estimated Delay Cost –** The agency should update its "Supporting Statement for an Information Collection Request (ICR) Under the Paperwork Reduction Act (PRA)" to better reflect the actual estimated delay cost for premanufacture notices (PMNs) and significant new use notices (SNUNs) resulting from delays in the submission review process. EPA has estimated delay cost of $34,290 for a PMN or a SNUN based on calculating the average cost per submission, using the midpoint of the low and high delay cost estimates (1993 dollars) and inflating to 2016 dollars using the Bureau of Labor Statistics' Producer Price Index data for the Chemical Manufacturing industry. This

estimate does not appear to fully capture the resulting loss of profits by manufactures due to the sometimes year long delays in the review process. For example, one company indicated an anticipated loss of approximately $150,000 due to a PMN that went well beyond the 90-day review period. Delays with respect to PMNs and SNUNs may not only impact the cost to manufactures in lost sales and potentially result in supply chain disruptions, but also could result in the offshoring of manufacturing. EPA should provide additional detail in how delay costs are calculated, including if there is a set delay timeframe that is being used to calculate the delay costs (e.g., X dollars in loss of profit per day times the number of days of the delay in excess of the original review timeline).

- **Provide More Clarity in the Process for Review and Approval –** The agency must ensure that its reviews are focused on evaluating potential for human health and environmental risk and not only on hazard. This includes using the most up-to-date exposure modeling and data provided by the submitter. The Agency is specifically encouraged to update its "Points to Consider When Preparing TSCA New Chemical Notifications" to reflect additional information regarding the established processes for submitters to provide additional information and amendments to their original submissions. This will not only help aid EPA with refining its assumptions but also minimize delays in the review process. It would be helpful if the agency provided additional clarification regarding: the process for when and how amendments to submissions are requested; if there is a time limit or limit to the number of amendments allowed during the PMN or SNUN process; and if there is an opportunity to establish a clearer schedule between the "Initial Chemistry Review," the "Chemical Review and Search Strategy," the Structure Activity Team ("SAT") and the regulatory decision making to ensure regular discussions between the EPA and the submitters are occurring throughout the review process. Providing more guidance regarding this process and the opportunity for submission of additional information will allow the submitter to provide relevant information in a timely manner to inform EPA decision-making and potentially minimize the number of amendments to submissions. While these comments are focused on the PMN and SNUN process, they are also applicable to the Low Volume Exemption (LVE) process, and EPA should work to incorporate best practices and process improvements to ensure the application of the most relevant data.

- **Provide Clarity in How Collected Data Informs Decision-Making** – It continues to remain unclear how the information that EPA collects during this process is ultimately utilized, in lieu of default assumptions or modeling, to reach decisions about human health or environmental risk. EPA should better articulate how the collection of information related to manufacturing, formulation, and application for PMN and SNUN submissions along with exposure and environmental release data is used in the development of exposure scenarios and characterizing risk.

- **Improve the Electronic Submission Processes –** Submission for new chemical reviews occur primarily through the EPA's Central Data Exchange (CDX). ACC has previously noted ongoing technical issues with EPA's CDX and continues to encourage the agency to perform a complete overhaul of the system.

ACC appreciates the opportunity to provide these comments and encourages the Agency to incorporate this feedback prior to finalizing the ICRs. Please feel free to contact me by phone: 202-249-6129 or email: kat_gale@americanchemistry.com with any questions.

Sincerely,

Kat Gale
Director, Regulatory & Scientific Affairs

700 Second St., NE | Washington, DC 20002 | (202) 249.7000