



September 24, 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
Washington, DC 20460

Subject: Agency Information Collection Activities; Proposed Renewal of an Existing Collection entitled, "Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances," EPA-HQ-OPPT-2017-0645, EPA ICR No. 0574.18, OMB Control No. 2070-0012

Dear Ms. Bertrand:

The American Chemistry Council (ACC)¹ is pleased to submit these comments on EPA's Information Collection Request (ICR) on Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances. This ICR represents the renewal of an existing ICR that is scheduled to expire on November 30, 2018. The ICR seeks information regarding TSCA Section 5 premanufacture review reporting and exemption requirements for new chemical substances and Significant New Use Reporting Requirements.

The Toxic Substances Control Act (TSCA) was substantially amended in 2016. As of June 22, 2018, changes to Section 5 of the statute, covering new chemicals, became immediately effective. These changes have resulted in significantly increased overall reporting burdens.

Increased Burden During Preconsultation Process and PMN/Exemption Review Process

As EPA notes in the ICR, TSCA Section 5 requires EPA to make determinations regarding the manufacture, processing, distribution in commerce, use and/or disposal of new chemical substances or significant new uses. This process is initiated by the submission of a Pre-Manufacture Notice (PMN) or exemption request (e.g., Low Volume Exemption) for new chemicals. Following the 2016 amendments, EPA has increasingly offered pre-submission consultations to manufacturers in order to provide greater clarity to the types of information that

¹ The American Chemistry Council's member companies manufacture, distribute, process, import, use and dispose of chemical substances regulated under the Toxic Substances Control Act (TSCA). As such, they are obligated to provide information related to the TSCA Inventory and, at times, may need to correct information on that Inventory. ACC's member companies are directly affected by and have a significant interest in this ICR.



would improve and speed EPA's review of the PMN. On June 20, 2018, EPA issued guidance entitled "Points to Consider When Preparing TSCA New Chemical Notifications" to further improve the pre-consultation process.

In addition, as part of its TSCA amendment implementation, EPA may be proposing more Significant New Use Rules (SNURs) than in the past. A SNUR may require a Significant New Use Notification (SNUN).

EPA's ICR reports an increase of 146,312 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. The agency notes that this increase is both an adjustment as well as a program change. We agree that manufacturers have experienced increased burden in the New Chemicals program since the passage of the TSCA amendments; however, we are concerned that the estimates do not fully reflect time and burden in the pre-consultation process. In particular, since EPA's Points to Consider document just became available on June 20, it is not clear that this ICR includes revised estimates to fully reflect the substantial time invested by manufacturers to engage in this process before submitting PMNs or exemption requests. We recommend EPA include an additional upward adjustment, at a minimum, to reflect the time needed by manufacturers to familiarize themselves with this document and process.

Thank you for the opportunity to comment. If you have any questions regarding ACC's comments, please feel free to contact me at Karyn_schmidt@americanchemistry.com, 202-249-6130.

Very truly yours,

Karyn M. Schmidt

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Senior Director
Regulatory & Technical Affairs

