

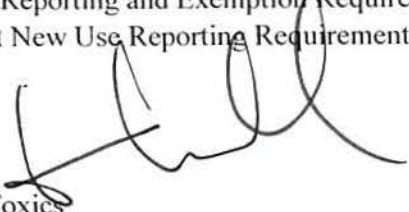


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

NOV 14 2018

**MEMORANDUM**

**SUBJECT:** Response to Comments Received on Proposed Renewal of Information Collection Request for Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances

**FROM:** Lance Wormell, Acting Director  
Chemical Control Division  
Office of Pollution Prevention and Toxics 

**TO:** Angela Hofmann, Director  
Regulatory and Information Coordination Staff  
Office of Chemical Safety and Pollution Prevention

**Background**

On July 25, 2018, EPA published a notice in the Federal Register proposing to renew an Information Collection Request (ICR) for Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances to the Office of Management and Budget (OMB), and requesting public comment. 83 Fed. Reg. 35269, July 25, 2018. The public comment period closed on September 24, 2018. EPA received two comments.

**Public Comment**

EPA received two comments: one substantive comment related to the ICR and one comment unrelated to the ICR and in support of EPA's mission. The substantive comment comes from the American Chemistry Council (ACC) and asks the EPA to increase the estimates of burden related to the pre-submission consultation process as well as the burden required for industry to review EPA's "Points to Consider When Preparing TSCA New Chemical Notifications" document released in June 2018.

**Response to Comments**

In response to the comment expressing a general support of the Agency, EPA appreciates the commenter taking time to offer her support.

With regard to the ACC comments, EPA appreciates the thoughtful comments submitted by ACC concerning the burden associated with the voluntary activities of reading the "Points to Consider" document and engaging with EPA in a pre-notice consultation on the PMN review process. Though a voluntary activity, EPA did estimate the burden to respondents with regard to the "Points to Consider" document. As noted in its Supporting Statement attached to the ICR, EPA estimated that it could take submitters 1.4 managerial and technical hours per notice to familiarize themselves with the document. This burden estimate is based upon the average time it took several volunteers who were generally knowledgeable about TSCA activities to review the actual document. Similarly, EPA did describe the availability of a voluntary pre-submission consultation process in its Support Statement to the ICR. Since

pre-submission consultation is voluntary, can vary between submitters, and is not an option that all submitters take advantage of, EPA is hesitant to further adjust the burden on submitters in this ICR since the subject ICR is for the purpose of assessing required reporting burden associated with PMN submission.

EPA believes that to adjust the current estimate of the burden hours in this ICR to account for time associated with an activity not required by statute and not routinely used by submitters would create an inaccurate estimate of the burden on submitters for this process. Therefore, EPA finds no compelling reason to change its current ICR burden estimates for the pre-submission activities associated with the TSCA New Chemicals review program in this ICR.