

MEMORANDUM

SUBJECT: Response to Comment Received on a Renewal Request Submitted to OMB for Review and Approval; Comment Request; 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 Coordination Staff
Office of Chemical Safety and Pollution Prevention

Background

On November 27, 2018, EPA published a notice in the Federal Register 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. 60845, November 27, 2018. The public comment period closed on December 27, 2018. EPA received one comment.

Public Comment

EPA received one comment during the comment period from the TSCA New Chemicals Coalition (NCC). The TSCA NCC is a group of representatives from over 20 companies that assembled to identify new chemical notification issues under amended TSCA. In their comment, the TSCA NCC provided revised estimates of burdens for certain activities that had not been identified by EPA or that the TSCA NCC stated had been underestimated by EPA. The TSCA NCC encouraged EPA to consider utilizing these revised burden estimates. EPA has considered these revised estimates and has adopted them in this updated supporting statement.

Response to Comment

Regarding the NCC comment letter, EPA appreciates the thoughts on several topics contained in the comment offering helpful industry perspective. The topics discussed in the comment letter were: 1) the likelihood of a decrease in submissions; 2) EPA's explanation of industry burden in the ICR's Support Statement; and 3) EPA's estimation of time for notice preparation. As to NCC's belief that the volume of submissions to EPA will stabilize and not drop the 20 percent that EPA estimates, EPA disagrees. Consistent with statements in its Supporting Statement to this ICR, submissions have dropped significantly since fees were increased in October 2018. Whereas in Fiscal Year 2018, 753 valid submissions were sent to the EPA, now, more than eight months into Fiscal Year 2019, fewer than 350 total valid submissions have been submitted. While EPA could receive a large number of submissions within the last three months of this fiscal year, it appears that EPA's estimate is more accurate than NCC's belief that total submissions will remain consistent.

Next, NCC points out that factors listed in the Supporting Statement for industry stakeholder burden need to be expanded for PMNs. While NCC does not distinguish which type of notice should be subject to increased burden, EPA increased the burden estimate primarily for TSCA section 5(a)(1) submissions or just the PMN and not SNUNs, MCANs or exemptions. If EPA increased the burden for more than just the PMN this response will explain.

First, NCC believes EPA does not properly account for new Confidential Business Information (CBI) burden on industry stakeholders to ensure CBI is adequately protected. EPA believes CBI under amended TSCA is described fully in the Supporting Statement and is furthermore accounted for in section 6(a)(i) with a burden estimate of 16.245 hours per PMN submission.

NCC added that pre-notification consultations and EPA's "Points to Consider When Preparing TSCA New Chemicals Notifications" are important, although unrequired, parts of pre-submission activities not accounted for properly by EPA in its Supporting Statement. EPA had included 1.4 hours of managerial and technical burden per notice (i.e., PMNs, SNUNs, MCANs and exemption applications) to read through and become familiar with the document. In response to NCC's comments concerning PMNs, EPA has increased the burden hours by 10 hours for managerial/technical hours per PMN. Regarding post-submission activities for PMN submissions, NCC is concerned that submission evaluation continually requires more effort from industry to respond to information requests. NCC further stated that post notification activities should not be limited to burden associated with implementation of 5(e) and 5(f) orders. EPA agrees that these factors should be taken into account in the Supporting Statement in both pre- and post-submission activities and reflected in the burden hours needed from industry stakeholders to file and complete a PMN or SNUN.

Lastly, NCC suggests that EPA underestimated time needed to prepare a PMN in the ICR. In gathering average review times from its 20 members, NCC believes technical review of PMNs increased by 120 hours and managerial time increased 30 hours since TSCA was amended. NCC believes this increase is due mostly to the need for a determination for every submission whereas before nearly 80% of all submissions were dropped by day 21 of any review period. In tandem with the need to consider prenotice consultations, the review of CBI and creating a more robust submission, NCC believes burden times should be increased. EPA agrees and has increased the burden per PMN by an additional 10 hours for review of the "Points to Consider" document; added 30.67 hours for PMN preparation; and added an additional 15 hours of burden to 20% of PMNs submitted for "Pre-Notification Consultation".

EPA further agrees with NCC that post-submission matters do not simply include assisting EPA in preparing of section 5(e) and 5(f) orders. In its letter, NCC estimates that post-notification time should include factors such as: responding to EPA requests for additional information, time spent on requesting suspensions, as well as review of orders. In light of these added tasks, EPA adds an additional 97.5 hours of burden to Post-Notification Communication applying to all PMNs.

With the helpful comments from NCC, EPA reviewed and increased burden hours and, as a result, increased the labor hours for PMNs from 109.325 to 250.498. With these changes to the unit burden estimates, the new total estimated respondent burden increased to 192,156 hours.