



December 26, 2018

Via Docket Submission

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460-0001

Re: Comments on Information Collection Request for Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances under the Toxic Substances Control Act; Docket ID Number EPA-HQ-OPPT-2017-0645

Dear Sir or Madam:

This letter is submitted on behalf of the Toxic Substances Control Act (TSCA) New Chemicals Coalition (TSCA NCC)¹ in response to the U.S. Environmental Protection Agency's (EPA) request for comment on the information collection request (ICR) submitted to the Office of Management and Budget (OMB) on Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances (EPA ICR No. 0574.18, OMB Control No. 2070-0012).² While the TSCA NCC appreciates that EPA has acknowledged an increase in industry burden within this ICR, the increase of 18,054 hours (compared with the burden value currently approved by OMB) is not sufficient. EPA's estimate for the industry respondent burden outlined in the ICR and the associated Supporting Statement³ does not reflect reality or the experience of

¹ The TSCA NCC is a group of representatives from over 20 companies that have come together to identify new chemicals notification issues under amended TSCA and to work collaboratively with EPA to address them.

² 83 Fed. Reg. 60845 (Nov. 27, 2018).

³ Support Statement for an Information Collection Request (ICR) under the Paperwork Reduction Act, "Pre-Manufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for



our member companies, and the TSCA NCC urges EPA to revisit the time and resources expended by industry to make these notifications.

EPA Assumption that PMN Submissions Will Drop Is Likely Incorrect

In its calculations, EPA assumed that the number of premanufacture notices (PMN), Significant New Use Notices (SNUN), and Microbial Commercial Activity Notices (MCAN) would drop by 20 percent due to increased notice fees that became effective in October 2018. While TSCA NCC believes there will be some impact on the level of submissions due to the fees, it likely will be temporary and not as high as 20 percent. The reality is that industry will continue to innovate and commercialize new chemical products at a rate similar to that experienced in the past, which means regulatory notification activities will also continue.

Industry Burden Factors Need to Be Expanded

According to the Support Statement, the identified activities associated with industry stakeholder responses under this ICR are the submission of the notices, implementation of TSCA Section 5(e) and 5(f) consent order restrictions, marking information as confidential, preparing substantiation of confidential claims, recordkeeping burdens, and burdens associated with Central Data Exchange (CDX) registration.

EPA notes that the increase in reporting burden reflects changes under the amended TSCA for substantiation of certain information claimed as confidential and expectations related to the EPA “Points to Consider When Preparing TSCA New Chemicals Notifications.” The TSCA NCC believes that EPA has underestimated the time needed for adherence to these two new policies, particularly for the confidential business information (CBI) substantiation requirements. The CBI changes under amended TSCA are substantial and, given the criticality of ensuring CBI is adequately protected, industry stakeholders will be expected to expend the time and resources necessary for compliance.

In addition, EPA does not include pre-notification consultations with EPA as part of the anticipated activities associated with this ICR. EPA staff has consistently encouraged stakeholders to participate in such consultations. Therefore, although not a requirement *per se*, time and resources expended as part of pre-notification consultations should be viewed and counted as a part of industry notifiers’ response burden.

Chemical Substances,” EPA ICR No. 0574.18 (Nov. 15, 2018).



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Likewise, the need for prolonged post-notification communications with EPA staff has become the norm.⁴ While the TSCA NCC recognizes that EPA is making progress with Section 5 reviews, the reality is that evaluations almost invariably extend past the statutory 90-day timeline, and not infrequently go on for a year or more. This necessitates industry stakeholders initiating and responding to EPA information requests to answer questions and provide additional details on hazards, exposure, risks, manufacturing, processing, conditions of use, and other aspects of the case. There is also the need for ongoing communications with and information requests from EPA, for example, to determine status, to meet in person and/or teleconference with EPA staff to discuss issues or explain points directly, negotiate or respond to proposed requirements in Section 5(e) orders (generally involving a continuing series of discussions and/or exchanges of written responses), to further extend voluntary suspensions (including securing approval by industry management), to estimate completion time and keep management informed, and to secure necessary industry management review and signature on consent orders. TSCA NCC members have reported spending between 50 to 175 hours annually per PMN on these post submission activities. Again, the significant time and resources expended in preparing a compelling and legally sufficient chemical notification are extensive and should be reflected accurately in the industry burden estimate.

In this regard, we note that in unit 6(d) of EPA's Supporting Statement for this ICR, the cost estimates include EPA's costs in reviewing cases and making determinations, and in taking regulatory action. Industry notifiers are intimately involved in providing EPA with the information needed post-notification for its review and determinations, and in negotiating and agreeing on the terms of consent orders. It is not sufficient, in the post-notification context, to account only for industry's "burden associated with implementation of TSCA section 5(e) and 5(f) consent order restrictions" (opening paragraph of unit 6 of the Supporting Statement), as the present ICR appears to do.

EPA Underestimates Industry Time for Notice Preparation

TSCA NCC members have reviewed their internal processes for preparation and submission of PMNs. In their evaluations, members have determined that company technical review and input is about 120 hours, followed by about 30 hours of management review. This

⁴ Historically, approximately 80 percent of PMN cases were "dropped" from EPA review by about day 21 whereas under the new law, virtually all PMN cases receive additional EPA review with the overwhelming majority being the subject of requests from EPA for voluntary suspensions beyond day 90. While we do not have access to these figures, they are available to EPA and will provide valuable information in undertaking additional analyses to account for these burdens.



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average of 150 hours of company staff and management time for preparation of the PMN is significantly higher than the 109.33 average calculated by EPA for these activities.

We note that these figures do not include burdens that are incurred during pre-notification consultations, the initial 90 days of review, or costs that are required to obtain completion of EPA's often-extended review, including finalization of consent orders when required. Here, TSCA NCC members' experience varies depending on the issues/complexities presented, but it is estimated to range between 50 and 175 hours per PMN.

Using EPA's assumption that 409 PMNs will be submitted per year (likely an underestimate given EPA's assumption that submissions will be reduced by 20 percent), EPA's calculations for a PMN burden is off by 16,360 hours. This calculation does not account for industry burdens associated with pre-submission consultations and the post-notification period when PMNs are reviewed, determinations made, and regulatory actions taken. The burden figures we have provided above for these latter components of the review process, when applied to the 409 PMNs, yields an estimated additional burden of 20,450 to 71,575 hours. Taking the midpoint of this range equals an estimated 46,013 hours of additional PMN burden for the post-notification period.

Thank you for the opportunity to submit these comments. If there are any questions regarding this letter, please do not hesitate to contact me at 202-833-6581 or kroberts@lawbc.com.

Respectfully submitted,

Kathleen M. Roberts