



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

FEB 25 2016

MEMORANDUM

SUBJECT: Response to comments received on the ICR Renewal entitled "TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals" (EPA-HQ-OPPT-2015-0273)

FROM: Maria J. Doa, Director
Chemical Control Division

A handwritten signature in black ink, appearing to read "M. Doa", is written over the printed name of Maria J. Doa.

TO: Angela Hofmann, Director
Regulatory Coordination Staff

Background

The information collection request addresses Toxic Substances Control Act (TSCA) section 5 reporting and recordkeeping requirements associated with TSCA section 5(a)(2) Significant New Use Rules (SNURs) for existing chemicals.

Section 5 of the Toxic Substances Control Act (TSCA) provides EPA with a regulatory mechanism to monitor and, if necessary, control significant new uses of chemical substances. Section 5 authorizes EPA to determine by rule (i.e., a significant new use rule or SNUR), after considering all relevant factors, that a use of a chemical substance represents a significant new use. If EPA determines that a use of a chemical substance is a significant new use, section 5 requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture (including import) or process the substance for that use.

The relevant factors considered by EPA under TSCA section 5(a)(2) in determining a significant new use are:

- 1) The projected volume of manufacturing and processing of a chemical substance;
- 2) The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance;
- 3) The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance; and
- 4) The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

EPA uses the information obtained through this collection to evaluate the health and environmental effects of the significant new use. As a result of this review, EPA may take regulatory actions, if warranted, under TSCA section 5, 6, or 7 to control the activities for which

it has received a SNUN. These actions include orders to limit or prohibit the manufacture (including import), processing, distribution in commerce, use, or disposal of chemical substances.

The existing chemical SNUN notice must be submitted electronically, via the Central Data Exchange (CDX), using the Agency's electronic-Premanufacture Notification (PMN) software. The SNUN is submitted using the PMN form (see <http://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>).

The ICR is identified by EPA ICR No. 1188.12 and OMB Control No. 2070-0038, and represents the renewal of an existing ICR that is scheduled to expire on July 31, 2016.

The Society of Chemical Manufacturers & Affiliates (SOCMA) and the American Chemistry Council (ACC) responded to the Federal Register notice (80 FR 53151, September 2, 2015) announcing EPA's intent to submit the ICR renewal for TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals to OMB. A summary of their comments and EPA's responses are contained herein.

Public Comments

Society of Chemical Manufacturers & Affiliates (SOCMA)

Comment: In many cases, the greatest burden associated with compliance with a SNUR is the degree of effort required to ascertain whether a particular chemical is subject to a SNUR or proposed SNUR. In this connection, EPA's estimates are seriously inadequate.

In the Supporting Statement for the ICR, EPA notes that it "typically notifies the manufacturer(s) of chemicals subject to a SNUR prior to its issuance." (Id. at 10.) This statement ignores the fact that EPA is likely only to know of companies who reported manufacturing the chemical in their responses to the most recent Chemical Data Reporting Rule. Those responses only capture facilities that manufactured at least 25,000 lbs of the chemical in one of the years covered by that rule. Outside of commodity chemicals and confidential PMN chemicals, it is reasonable to assume that, as a general rule, there are at least as many facilities manufacturing a substance below that volume as there are above it.

EPA Response: EPA uses the best available data to identify manufacturers of a chemical, which in addition to data submitted to EPA via PMNs or CDR, includes information gathered from other databases and trade publications as well as data provided through communication with industry and trade groups during the development of a rule. In addition, EPA issues a press release at the promulgation of both the proposed and final rule stage, which is likely to be distributed or reported on by sources monitored by chemical manufacturers and processors, such as trade associations, trade publications, and online news alerts for the chemical. EPA also publishes a list of all chemicals subject to § 12(b) export notifications that it regularly updates (http://www2.epa.gov/sites/production/files/2015-09/documents/section_12b_public_8_05_15_rev_9_21_15.pdf), and which includes all chemicals subject to a proposed or final SNUR and is searchable by CAS, PMN, or accession

number. EPA's ChemView database, launched in 2013, is publicly searchable and contains non-confidential information on EPA actions on TSCA chemicals, including chemicals subject to final significant new use rules and to TSCA section 12(b) export notification requirements. See <http://www.epa.gov/chemview>. With the October 2015 updates to ChemView, industry can now readily search the ChemView database to determine if a chemical is subject to a SNUR or to export notification requirements. Note that the list of chemicals subject to section 12(b) export notification requirements also includes those chemicals that are covered by a proposed SNUR.

Comment: The even greater shortcoming with EPA's burden analysis, however, is that it explicitly disclaims any attempt to estimate the burden of existing chemical SNURs on companies that start to manufacture or process the chemical after the SNUR is issued: "However, without prior knowledge of chemicals which would be the subject of future SNURs, estimating the number of potentially affected entities subject to 40 CFR 721.5(a)(2) is not possible." (Id. at 9-10.) While it may be true that EPA cannot predict the precise number of such entities, EPA certainly can make reasonable estimates about what those numbers could be, based on the number of entities affected by prior existing chemical SNURs. At a minimum, EPA could choose a range of order-of-magnitude values to develop some illustrative burden estimates.

EPA Response: The impact of a SNUR on companies that manufacture (including import) or process a chemical for a use that is not regulated by the SNUR is discussed in the Economic Analysis for each existing chemical SNUR. The requirements for these firms are fairly minor, depend on the nature of the SNUN, and include things such as customer notification, rule familiarization, and, in some cases, recordkeeping, all of which are burden estimates that are presented in the ICR. EPA does not collect information from firms that do not submit a SNUN but may otherwise be impacted by a SNUR and, therefore, does not have historic estimates of the number of entities that may be impacted. In addition, this number is likely to depend greatly on the types of SNUR promulgated by the Agency. In some cases, EPA may choose to regulate a "dead" chemical where it is reasonable to expect that no firms will be impacted; in other cases, the chemical may have several ongoing uses that are outside the scope of the SNUR. Given these circumstances, EPA cannot provide total cost estimates with any degree of certainty; however, EPA does present unit costs estimates for the activities in which these firms may engage, in both the ICR and the respective Economic Analyses.

Comment: Otherwise, EPA's failure even to attempt to estimate these burdens is a serious shortcoming of the analysis, because this is where the majority of the burden will be experienced. The recent SNUR/SNAC workshops convened by the US/Canadian Regulatory Cooperation Council have highlighted the problems experienced by entities seeking to figure out if a chemical they are interested in manufacturing or processing is covered by a SNUR. While it may only take 10 minutes to verify if a chemical is covered by a SNUR when EPA notifies you (id. at 11), it is vastly more time-consuming otherwise.

As a starting point, most companies refer to Section 15 of the Safety Data Sheet (SDS) for the chemical to determine if it is subject to a SNUR and, if so, what those requirements may be. The absence of any SNUR information in Section 15 is just a trigger for additional due diligence,

however, because many companies preparing an SDS do not include any applicable requirements imposed by other agencies (e.g., EPA) since OSHA does not require them to.

Because of the unreliability of SDSs, companies have been building data systems or subscribing to services that compile the universe of SNUR chemicals and allow users to search chemicals against them. As explained in the workshop, these systems and subscriptions are highly costly to build or to maintain. And, if future SNURs do not list chemicals by CAS number, that task will never be simple. The task is further challenging in the cases of (i) proposed SNURs (which are subject to the § 12(b) export notification) and (ii) SNUR chemicals contained in articles where the SNUR has waived the articles exemption.

In any case, the next source of burden on downstream companies is to determine whether the use they propose to conduct is one of the new uses covered by the SNUR. In the cases where the specific chemical identity specified in the SNUR is CBI, the company has to establish to EPA's satisfaction that it has a bona fide intent to manufacture or process the chemical, per § 721.11 of EPA's TSCA rules.

EPA Response: Currently, EPA requires that upstream firms notify downstream customers of any SNUR on the chemical. While EPA believes this is most efficiently accomplished by annotating the SDS for a product, if the upstream firm chooses not to do this, they must still notify their downstream customers of the regulation. EPA expects this action to minimize the burden on downstream companies. In addition, EPA currently publishes and regularly updates a list of all chemicals subject to § 12(b) export notifications (http://www2.epa.gov/sites/production/files/2015-09/documents/section_12b_public_8_05_15_rev_9_21_15.pdf). This list includes all chemicals subject to a proposed or final SNUR and is searchable by CAS, PMN, or accession number. So while firms may choose to build a database or subscribe to services, this is not a requirement of the rule and EPA currently provides a free list of chemicals subject to SNURs that is publicly available via the link above and via its ChemView database.

In addition to SOCMA's specific comments listed above, SOCMA also communicated more general comments regarding clarifying SNUR requirements, working with OSHA to improve inclusion of SNUR requirements, increasing outreach to stakeholders, and having access to accurate SNUR records. As a continuation of its U.S. SNUR and Canadian Significant New Activity (SNAc) partnership work in 2015, EPA anticipates conducting additional U.S./Canadian work that will improve communications to stakeholders regarding SNUR/SNAc requirements, will try to work with OSHA on including SNUR requirements in SDSs, and will perform other helpful outreach activities.

American Chemistry Council (ACC)

Comment: EPA's burden estimate is based primarily on SNUN filings for final SNURs. In our companies' experience, there is a significant burden from the impact analysis of each proposed SNUR. One ACC member company has spent approximately 100 hours preparing comments on each of two recently proposed SNURs on existing chemicals. On just one of those SNURs, that member company required five supporting personnel, who spent another 50 hours gathering data

and information to help prepare comments on the SNUR. That resource commitment amounted to \$15,000 for that one SNUR alone.

EPA Response: The ICR only needs to account for the burden associated with meeting the regulatory requirements of a final regulation. While EPA appreciates and values industry comments on proposed regulations, there is no regulatory requirement for firms to comment on proposed regulations and, therefore, these costs are voluntarily incurred by firms and do not need to be accounted for in the ICR.

Comment: In EPA's analysis, it acknowledged there will be costs associated with ensuring all provisions of the SNUR are implemented. EPA concluded that because this burden will vary depending on the significant new uses, it could not estimate the burden. Yet the implementation burden is significant for many SNURs, especially in circumstances where some uses are banned and other uses approved or not affected by the SNUR. Some estimated burden, even if only based on recent SNURs, should be included in EPA's analysis.

EPA Response: The impact of a SNUR on companies that manufacture (including import) or process a chemical for a use other than that is regulated by the SNUR is discussed in the Economic Analysis for each existing chemical SNUR, and may include activities such as customer notification, rule familiarization, or recordkeeping. The burdens associated with these activities are currently presented in the ICR.

Comment: While the time required for a customer notification (1 hour per manufacturer per chemical) seems reasonable, the number of companies that would be required to notify customers appears to be too low. Customer notification requirements affect processors in addition to manufacturers and importers, so the estimate of two manufacturers per SNUR does not seem realistic.

EPA Response: EPA's estimate of two firms includes processors as well as manufacturers (including importers) and is on a per-chemical basis, not a per-SNUR basis: "EPA assumes that there are two manufacturers (including importers) or processors per chemical" (page 13 of the ICR document). EPA expects an average of 16 downstream notifications per SNUR. However, the number of downstream notifications is likely to vary greatly depending on the chemical regulated, and, historically, EPA has used the estimate of two firms per chemical. Nonetheless, EPA appreciates the comment and will look into this historical estimate. If recent experience with promulgated SNURs proves to merit a revision to this estimate, then EPA may adjust it through an ICR change request or during the next ICR renewal.

Comment: It also appears that the burden for notification and compliance with the TSCA section 12(b) export notification requirements for proposed and final SNURs has been omitted or overlooked. This should be included in EPA's estimations.

EPA Response: The burden associated with TSCA section 12(b) export notification requirements is currently accounted for under the *Information Collection Request for the Notification of Chemical Exports - TSCA Section 12(b) EPA ICR No. 7095.15, OMC Control No. 2070-0030*, and, therefore, should not be accounted for in this ICR.

Comment: A number of SNURs for existing chemicals have lifted the customary regulatory article exemption. EPA has not included a burden estimate for importers of articles to verify that the articles are in compliance with these SNURs.

EPA Response: The Economic Analysis for each rulemaking presents the potential actions that a company could undertake to identify specific substances in its articles, as well as the associated costs. However, because there are no required paperwork burdens (reporting, recordkeeping, or disclosure requirements) as a result of revoking the article exemption, these costs are not accounted for in this ICR.