

Document Control Officer (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

November 2, 2015

RE: TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals; EPA-HQ-OPPT-2015-0273; 80 FR 53151 (September 2, 2015)

Dear Document Control Officer:

The Society of Chemical Manufacturers & Affiliates (SOCMA) submits the following response to several specific questions on the renewal Information Collection Request (ICR) for TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals (OMB Control No. 2070-0038) contained in a consultation email to SOCMA from Jeffrey Taylor of OPPT's Existing Chemicals Branch dated September 30, 2015. As we explain below, the ICR is inadequate in its current form because it makes no attempt to estimate the principal burden associated with existing chemical SNURs: the challenge of determining if a chemical that one wishes to manufacture or process for the first time is subject to a previously-issued SNUR.

We also offer some additional comments on the ICR referenced above. Specifically, we identify some of the challenges our members face in understanding SNUR requirements and communicating them downstream. We also offer some suggestions for how EPA could clarify SNUR requirements and otherwise help reduce the burdens associated with SNURs.

SOCMA is the only US-based trade association dedicated solely to the specialty chemical industry. Over 70% of SOCMA's active members are small businesses.

I. Responses to Questions from Jeffrey Taylor

1. Information Collection

Is the information that the Agency seeks under this ICR available from any public source, or already collected by another office at EPA or by another agency?

We are not aware that the information requested in responses to SNURs is readily available anywhere else, so the request is not duplicative. Almost by definition, a person proposing to manufacture or process a chemical for a new use is doing something that has not been done before, and so there would be no other way for EPA to obtain that information. The only exception might be where a use occurred in the past but had been discontinued.

If yes, where can the Agency find the data?

If a use occurred in the past but was discontinued prior to issuance of the SNUR, the administrative record for that SNUR may contain information on that historic use.

Do you understand that you are required to submit or maintain records of certain data elements?

Yes.

Is the format of the reporting forms clear, logical, and easy to complete?

Yes.

2. Electronic SNUN Reporting

What, if any, benefits are you experiencing from using the e-PMN software and submitting your SNUN notices via CDX (e.g., burden reduction, greater efficiency in compiling the information, etc.)?

There are clear benefits to using CDX for submissions, such as having to prepare only one document electronically in lieu of 3 paper copies. The preparation is also generally easier. For example, pulldown menus help streamline filling out the PMN/SNUN form. Prompts alert the submitter in case certain fields were not completed, helping to reduce the margin of error and facilitating accurate data entry. The preparation of the sanitized version of the form is a particular improvement, since it is automatically generated. Being able to attach documents electronically is great, particularly if they are large.

Despite the obvious benefits being realized there are also instances, particularly with small businesses, where trying to deal with the idiosyncrasies of software issues has been a terrible burden. It is not uncommon for a small business to not have a dedicated IT department - thus some issues have caused tremendous delays in submissions. In some instances, allowing a paper or CD submission could significantly reduce burden, and should be considered.

Are the online instruction manuals and guidance documents for using the software and submitting SNUN notices electronically accurate and understandable?

The present eTSCA systems are having issues such as incompatibilities with the IT environments of many companies, making it so submissions in some cases cannot be made. One SOCMA member company noted that it had spent hundreds of hours trying to overcome IT barriers, delaying submissions and thus commercialization. At the same time, SOCMA understands the burden on EPA is large in dealing with so many IT environments. We appreciate that the CDX help desk continues to be very responsive and helpful. SOCMA also appreciates EPA's outreach on the topic of CDX via recent webinars and at conferences like GlobalChem.

Do you agree with EPA's estimated burden and costs?

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.

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.

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.

SOCMA believes the foregoing burdens are attributable to the legal requirement to submit a SNUN, and should be taken into account by EPA in this ICR. To the extent it does not, SOCMA believes the current ICR is inadequate and should be rejected by OMB.

II. More General Comments in Response to the ICR

As just noted, the ICR does not ask about the broader burdens of SNURs and how the supply chain can be impacted. SOCMA feels that it is important to highlight some of the major challenges that our members face in communicating and understanding SNURs, and would like to share some thoughts on improvements. SNURs can have a broad reach, beyond just manufacturers and importers. EPA could substantially relieve the burdens experienced by those impacted by these regulations by clarifying how it presents SNUR requirements, by working with OSHA to improve inclusion of SNUR requirements in SDS, and by greater outreach on SNURs and their most common requirements.

A. Clarifying SNUR Requirements

It can be really difficult to understand the regulatory, hazard communication, and recordkeeping requirements associated with SNURs. The regulatory requirements for SNURs are presented in a very confusing way since there is, in essence, a menu of fairly broad requirements at the beginning of 40 CFR Part 721, followed by a very large list of SNUR chemicals that have only CFR code references to which one must refer back to fully understand what is required. This is very time consuming, and has a high potential for error.

Since the CFR is electronic, there is no longer any reason to save space by cross-referencing. The Agency could dramatically simplify the presentation of SNUR requirements by simply putting them all in one place, spelled out. For example, it could express a requirement as: "This is what one must do (or not do) – don't discharge to water above N ppb, wear gloves, respirator, etc. If you desire to manufacture or use the substance in a manner that, for any reason, does not allow you to abide by these provisions, then you must file a SNUN to obtain prior approval by EPA."

As noted earlier, companies typically communicate the existence of a SNUR via Section 15 of a Safety Data Sheet (SDS), usually by providing the CFR citation. Sometimes the specific recordkeeping requirements are outlined as well. In other cases, however, manufacturers do not note the existence of the SNUR. In some cases, they may express the SNUR requirements in other sections of the SDS – but again, they may not. Indeed, they may specify worker protections at variance with those specified in the SNUR. For all these reasons, SOCMA would support some sort of harmonization between OSHA and EPA’s requirements in this connection. We urge EPA to consult more actively with OSHA about how OSHA can encourage employers to include SNUR information in Section 15. Such an approach could help reduce burden and streamline compliance.

It would also be helpful if EPA provided more outreach on SNURs that could include background on them, insight on their many different types, the various recordkeeping requirements they may entail, and resources the regulated community can access. EPA could conduct webinars to do just that.

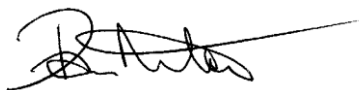
One resource the agency offers that is very helpful in regards to new chemical SNURs is the list of over 50 chemical categories in the New Chemicals Program. SOCMA commends EPA for developing this list and making it public. It helps stakeholders identify potential triggers for SNURs and is an example of guidance that has proven to be somewhat of a guarantee in certain instances that a SNUR is possible on a new chemical submission.

B. Timing and Accuracy of Records

It is particularly important for EPA to update its records on SNURs as frequently as possible so that they accurately reflect all final SNURs and do not refer to revoked ones. It is critical that these formal records be accurate, so that manufacturers and their customers are aware of what requirements may be associated with certain chemical substances. Many companies refer to the TSCA inventory to check the status of a chemical. Therefore, it is important for EPA to update it regularly. SOCMA recommends EPA update this database every month, or at least every quarter.

SOCMA appreciates the opportunity to provide comments and would be happy to answer any questions or provide more detail. You can reach me at 202-721-4158 or newtond@socma.com.

Sincerely,



Dan Newton
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