SOCMA
Society of Chemical Manufacturers & Affiliates

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Environmental Protection Agency (EPA)
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
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Via regulations.gov submission

RE: TSCA Chemical Data Reporting Revisions and Small Manufacturer Definition Update for Reporting and Recordkeeping Requirements Under TSCA Section 8(a)

To whom it may concern:

The Society of Chemical Manufacturers & Affiliates (SOCMA) appreciates the opportunity to submit comments on the U.S. Environmental Protection Agency's proposed amendments to the Chemical Data Reporting (CDR) requirements, including the update of the "small manufacturer or processor" standards under Section 8(a).[1]

SOCMA is the national trade association representing the specialty and fine chemical industry. Founded in 1921, SOCMA represents a diverse membership of chemical companies who manufacture unique and innovative chemistries used in a wide range of commercial, industrial and consumer products. SOCMA supports its members through programs and services that maximize commercial opportunities, enhance regulatory and legal compliance and promote industry stewardship.

SOCMA member companies are subject to TSCA and are directly affected by Section 8(a) reporting and recordkeeping requirements. SOCMA supports a number of aspects of the proposed rule, including provisions to ease reporting for co-manufacturers and to incorporate OECD functional use and product and article use codes. SOCMA also strongly supports the update of the current revenue-based size standard but believes that the Agency must make further refinements to provide meaningful small business relief. SOCMA further urges EPA to consider the markedly more adverse impact upon reporting companies of the 2,500 lb reporting threshold for chemicals subject to Section 5(a) rules or Section 5(e) orders, given the dramatic increase in restrictions placed on new chemicals since TSCA was amended.

SOCMA provides the following recommendations to assist the Agency in improving its revisions to the reporting and recordkeeping requirements under TSCA Section 8(a):

I. EPA Should Reevaluate the 2,500 lb Reporting Threshold for Chemicals Subject to Restrictions under Sections 5(a) or (e)

[1] 84 FR 17692 (April 25, 2019).

In response to an Information Collection Request (ICR) entitled "Partial Update of the TSCA Section 8(b) Inventory Data Base, Production and Site Reports (Chemical Data Reporting),"[2] SOCMA filed comments urging the Agency to begin reevaluating its existing CDR threshold for chemical substances subject to Section 5 rules or orders. SOCMA highlighted the dramatic policy changes within the New Chemicals Program since the 2016 TSCA amendments, which have led to the vast majority of new chemical substances being subject to 5(e) consent orders and/or Significant New Use Rules (SNURs) under Section 5(a)(2). The approach by which EPA now conducts its reviews of Pre-Manufacture Notices (PMNs), Microbial Commercial Activity Notices (MCANs), and Significant New Use Notices (SNUNs) will undeniably increase the number of companies subject to the CDR and increase the rule's reporting burdens.

EPA's program statistics clearly demonstrate the enormous impact of this change in policy. Of the 1,018 PMN, MCAN and SNUN cases completed since the passage of the amendments, 467 cases faced restriction in the form of either a Section 5(e) order or an accompanying SNUR.[3] Of the 301 cases that EPA allowed to commercialize "without restrictions," an (unspecified) proportion also have accompanying SNURs. The Agency has affirmed that it will now regularly leverage such "non-order SNURs" on approved cases, stating that the "promulgation of a significant new use rule (SNUR) can be an effective and efficient way to address reasonably foreseen conditions of use about which EPA has concerns, as part of the basis for EPA to conclude that the chemical is not likely to present an unreasonable risk of injury to health and the environment under the conditions of use under section 5(a)(3)(C)."[4] The resulting proliferation of Section 5 restrictions will subject many small and medium-sized companies with new burdensome reporting requirements - regardless of their often minimal production volumes and the low risks inherently attributable to such chemicals (since they are, by definition, restricted such that they do not meet a "may present" unreasonable risk standard).

The Agency's CDR proposal however has not addressed this matter, nor does it contemplate any potential revision to the 2,500 lb reporting threshold. It also unclear whether the economic analysis conducted on the baseline respondent total burden and cost per CDR reporting cycle accounts for the increased number of chemical reports to be submitted as result of the various applicable TSCA Actions.[5] SOCMA believes this matter merits urgent attention, and recommends the Agency evaluate potential remedies in this rulemaking to ease the long-term impact of the 2,500 lb threshold on submitters manufacturing chemicals subject to Section 5(a) or 5(e) restrictions.

It is undeniable that among the TSCA Sections that trigger the 2,500 threshold for CDR reporting, Section 5(a) and 5(e) actions are not like the others, which represent much more definitive and serious risk determinations. Section 5(f) orders and Section 6 rules are the product of an EPA determination that a

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[2] 83 FR 36928 (July 31, 2018).

[3] See Statistics for the New Chemicals Review Program under TSCA, *Statistics from June 22, 2016 - May 21, 2019*, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review#stats. Of the 469 chemicals listed there as subject to restrictions, only two of them (P-17-0024 and P-17-0025) were subject to Section 5(f) orders – *see Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs) Table* (May 30, 2019), available at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/premanufacture-notices-pmns-and-0.

[4] *See* https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/actions-under-tsca-section-5#SNURs

[5] 40 CFR § 711.8(b).

chemical *presents* an unreasonable risk, requiring the Agency to apply any number of restrictions to the chemical "to the extent necessary so that [it] no longer presents such risk."[6] Section 7, meanwhile authorizes the use of civil actions to seize any "imminently hazardous" substance, mixture, or article in instances where such products present an imminent and unreasonable risk of serious or widespread injury to health or to the environment, and are likely to result in such injury before a final Section 6 rule can protect against such risk.[7] These regulatory actions stand in stark contrast to the determinations that now trigger the application of a 5(e) consent order or a SNUR. Indeed, EPA has most frequently issued such restrictions as a result of an insufficient information determination – which requires *no finding at all* regarding risk – or to address reasonably foreseen conditions of use that are outside those intended by the manufacturer – and that by definition *will not occur* unless and until approved by EPA. Even an EPA Section 5(a)(3)(B)(i)(I) determination that a new chemical substance "may present" an unreasonable risk involves a lower hurdle than the more definitive "presents an unreasonable risk" or "imminent hazard" findings under Sections 5(f), 6 and 7.

SOCMA recommends that the Agency limit the applicability of the 2,500 lb threshold to chemicals subject to TSCA Actions under Sections 5(f), 6 or 7. Under this approach, substances subject to Section 5(a) or (e) would be subject to the normal 25,000 pound reporting threshold. At a minimum, EPA should apply the 25,000 lb threshold to chemicals that EPA finds are "not likely to present unreasonable risk" under 5(a)(3)(C), and apply a more appropriate risk-based threshold to other Section 5(a) or (e)-restricted substances; e.g., 10,000 lbs. This approach would be similar to that followed in the Toxic Release Inventory: "For most TRI chemicals, the thresholds are 25,000 pounds manufactured or processed or 10,000 pounds otherwise used. Sixteen TRI chemicals and four TRI chemical categories that meet the criteria for persistence and bioaccumulation have lower thresholds, such as 10 or 100 pounds and 0.1 grams."[8]

SOCMA acknowledges that this tiered risk threshold will require the Agency to more thoroughly monitor and track the restrictions that it applies on chemical substances. SOCMA believes there is value in such an exercise – EPA has ready access to this information and sharing it will assist the regulated community in understanding their recordkeeping and reporting obligations for TSCA-restricted substances. SOCMA recommends that (i) EPA add inventory flags for chemicals subject to rules or orders under Section 5(f), 6, or 7, and (ii) that before the commencement of each CDR cycle, EPA publish a complete list of chemicals subject to the 2,500 threshold.

II. SOCMA Supports Revision of the Size Standard for Small Manufacturers

In its proposed rule, EPA has finally begun to update the two size standards used to define a small manufacturer. The definition has historically utilized a revenue threshold with a volume modifier, and the Agency has proposed maintaining the structural elements of its definition while adjusting the revenue values on the basis of inflation. Under the first updated standard, a manufacturer would be considered small if its total annual sales (combined with any parent company), are less than $110 million. If the annual

[6] TSCA Section 6(a), 15 U.S.C. § 2605(a).
[7] TSCA Section 7(f), 15 U.S.C. § 2606(f).
[8] *See* Consolidated List of Chemicals Subject to the Emergency Planning and Community Right To-Know Act (EPCRA), Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and Section 112(r) of the Clean Air Act, https://www.epa.gov/sites/production/files/2015-03/documents/list_of_lists.pdf, vi.

production or importation volume of a particular substance at any individual site is over 100,000 lbs, however, the manufacturer would not qualify as a small unless it satisfied the second updated standard. Under that standard, a manufacturer would be considered small if its total annual sales (combined with its parent company) are less than $11 million, regardless of the quantity of substances produced or imported.

SOCMA has long advocated for the update of the size standard for small manufacturers under TSCA Section 8(a)(1), which has remained unchanged for decades. Since the initial codification of the standard in 1984, more and more companies, particularly smaller ones, have become subject to CDR as a result of lowered volume triggers for reporting. Meanwhile, the universe of sites deemed to be "small" has contracted merely as a result of inflation. SOCMA believes that any standard the Agency implements must not only support EPA's efforts to collect information adequate for the administration of the TSCA program, but also provide ongoing relief to the small entrepreneurial companies at the forefront of new, specialized and innovative chemistries.

A. EPA Should Establish an Employment-Based Standard for Section 8 Reporting

Last fall, EPA established an employment-based standard for determining which businesses are considered "small business concerns" for purposes of TSCA user fees.[9] SOCMA supported this approach. For purposes of regulatory consistency and simplicity, the Agency should implement an employment-based size standard for CDR reporting as well, supplemented by a 100,00 lb volume modifier. The regulated community would benefit significantly from a single, harmonized classification system to identify small business concerns. The extensive work the Agency conducted in collaboration with the U.S. Small Business Administration (SBA) during the TSCA user fees rulemaking demonstrated that an employment-based methodology better accounts for the unique characteristics of the chemical sector, such as average firm size, start-up costs, entry barriers, and competitiveness within the industry, compared to a receipts-based approach. It is ironic that under this rulemaking, EPA refers to SBA's size standards as "unwieldy" to maintain for TSCA program purposes, even though it only recently affirmed their effectiveness elsewhere.[10] EPA seems to recognize the implicit accuracy of the SBA definition in its economic analysis, noting that "it is intended to reflect the degree of competition within individual industries and is designed for more general use, casts the net more widely," while stressing that this is "without specific attention to valued information losses."[11]

An employment-based threshold would not generate significant information losses, as EPA's analysis demonstrates in its table of CDR impacts under the various size standard options (Table 5-13). That table notes that an SBA size standard with a retained 100,000 lb modifier leads to a nearly equivalent -2% drop in sites reporting and only a -6% drop in chemical reports (compared to -2% for the inflation adjusted option). This is a substantially smaller loss than the 15% report loss that EPA viewed as acceptable when it originally established the current standard.[12] The SBA + 100K method in fact further increases EPA's ability to track total production volume within the CDR, as demonstrated on Table 5-16. While SOCMA is

[9] 83 Fed. Reg. 52694 (Oct. 17, 2018).
[10] Economic Analysis for the Proposed Rule on the TSCA Section 8(a) Small Manufacturer Definition Update (RIN 2070-AK33), 5-19.
[11] Id..
[12] Id. at 1-3.

mindful of EPA's interest in retaining specific chemical reports through use of the revenue-based standard, the Agency should also be mindful of providing effective small business relief, which the SBA standard is more efficiently designed to do.

Finally, EPA's analysis does not provide adequate detail to understand the aggregate costs to industry of a revenues-based approach vs. an employment-based approach. The analysis presents the different per-site costs attributable to the two approaches (compare Tables 5-1 and 5-2), but when it turns to comparing the aggregate costs of the two options, it just uses qualitative, directional indicators (see Table 5-12, p. 5-14). As a result, one can't use aggregate costs to compare the costs of the various options. Based on its experience with the TSCA fees rule, however, SOCMA believes that the employment-based cutoff would impose significantly lower aggregate costs on reporting businesses.

For all these reasons, EPA should use the employment-based approach of the TSCA user fees rule, with a 100,000 lb modifier.

B. Additional Changes Are Needed to the Proposed Revenue-Based Standard

If EPA elects to implement an inflation-adjusted definition, SOCMA urges the Agency to make several changes to its proposed approach.

1. The Agency Should Make Future Inflation Updates Automatic

EPA should commit to updating the size standard threshold every time the inflation index has risen by 20% or more from the last adjustment. The proposed rule does not obligate the Agency to any future action, only stating that "EPA may [do so] *whenever the Agency deems it necessary to do so*, provided that the Producer Price Index for Chemicals and Allied Products has changed more than 20 percent since either the most recent previous change in sales values or the date of promulgation of this rule, whichever is later."[13] This approach has historically been a noncommittal one, as demonstrated by the fact that the current update of the size standard is occurring more than 30 years since promulgation, with the inflation index having risen by more than 129% over that time. It should be a fairly straightforward process for the Agency to rely on its prescribed formula to initiate regular updates to the size standard threshold, just as it does for its annual inflation adjusted penalty policies.

2. EPA Should Use the 2018 PPI

In future updates of the size standard, the Agency proposes to use the Gross Domestic Product (GDP) deflator instead of the PPI to determine adjustments to the total annual sales values.[14] While the Agency states that the GDP deflator represents a broader set of small manufacturers subject to TSCA section 8(a) reporting requirements and is less volatile, it is unclear to SOCMA how this approach more accurately accounts for business activity specifically within the chemical industry. Tracking the performance of parent companies such as large conglomerates and private equity firms is not an effective means of measuring the costs experienced by the industry (NAICS 325) that represents the plurality of businesses to which this

[13] 84 FR 17697 (emphasis added).
[14] 84 FR 17711, 4-3.

rule predominantly applies. The PPI has closely tracked the types of goods and services that chemical companies commonly purchase and has historically represented an accurate measure of the sector's business output. Companies falling into NAICS 325 should not be penalized because some of their competition is owned by more diversified businesses. EPA's economic analysis document on the TSCA Section 8(a) Small Manufacturer Definition Update[15] additionally does not provide any comparative analysis of how the revenue thresholds would change under the proposed update using the GDP deflator, nor does it indicate the potential rate in which the threshold would likely trend over time. Therefore, SOCMA recommends the Agency retain the use of the PPI in future updates of the size standard threshold. Moreover, because EPA intends to conclude this rulemaking at the end of 2019,[16] SOCMA recommends that the Agency update the inflation threshold values for the size standard using the 2018 PPI. The 2018 annual data from the Bureau of Labor Statistics for NAICS 325 is now completed and available for use in this rulemaking. The Agency took a similar action under the TSCA user fees, switching from the 2015 PPI to the 2017 PPI midway through the rulemaking process.[17] It is reasonable for the Agency to do so in this instance as well.

Finally, EPA has chosen to round its inflation adjustment of the threshold by two significant figures – from $112 million to $110 million for the first standard and $11.2 to $11 million for the second standard. The Agency does not, however, provide justification in its economic analysis for claiming that these threshold adjustments are only significant to two places. Considering the length of time it has taken to initiate an update of the size standard, SOCMA believes it is appropriate for EPA to set the thresholds at their actual adjusted values instead of figures that have been rounded down. Otherwise, the resulting numbers will unfairly penalize firms that are excluded due to rounding.

III. SOCMA Supports Provisions to Ease Reporting for Co-Manufactured Chemicals

EPA proposes to revise the reporting process for co-manufacturers (the two parties in a toll or other contract manufacturing situation) through a joint submission mechanism similar to that used for the Inventory Reset. This would essentially enable a multi-reporter process within the e-CDR reporting tool, where the contracting company would initiate the report and identify the chemical substance, its processing, volume, and use-related information as well as the producing company. The producing company would then receive notification and provide the manufacturing-related data and the production volume.

SOCMA strongly endorses EPA's proposal to facilitate co-manufacturing joint submissions, as tolling and other forms of contract manufacturing are extremely common within the specialty chemical sector. This approach will standardize and simplify the CDR reporting process for such arrangements. It will also help facilitate protection of confidential business information (CBI) between the contracting company and the producing company.

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[15] RIN 2070-AK33, 4-3.

[16] Spring 2019 Unified Agenda, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201904&RIN=2070-AK33.

[17] Supplemental Analysis Impact of Small Business Definition on Fee Revenue (RIN 2070-AK27, EPA-HQ-OPPT-2016-0401).

IV. SOCMA Supports the Use of OECD Functional Use and Product and Article Use Codes

EPA proposes to replace the CDR industrial function and commercial/consumer product use codes with codes based on the Organization for Economic Co-operation and Development (OECD)'s functional use and product and article use codes, and to add OECD function categories for commercial/consumer products. SOCMA supports harmonization of the CDR use codes with those used internationally for other country-specific reporting requirements and believes this revision will improve the accuracy of EPA's prioritization and risk evaluation activities. OECD codes more accurately represent exposure pathways for chemicals by better linking the substance with the type of product(s) that they are used in.

V. SOCMA Supports Improvements to the CDR Reporting Application

EPA proposes to implement non-regulatory changes to its electronic reporting application and database to improve user friendliness. Proposed modifications include fill-in-the-blank fields, check boxes, drop-down menus, and the replacement of the pre-formatted Form U with a customized report populated with information that has been provided by the reporter. The Agency also plans to allow up to 25 participants to pilot the revised e-CDRweb to test and assess the changes to the reporting tool. SOCMA commends the Agency for adopting these reforms. We believe they will provide significant value in reducing the reporting burden for submitters and supports EPA's efforts to improve its reporting application. Our only caveat is to request the Agency to expand the pilot beyond 25 users, as we suspect that a significantly larger cohort of users will want to try out the system. A larger pilot population will also give EPA more robust results.

Conclusion

SOCMA appreciates the opportunity to comment on EPA's proposed revisions to the Chemical Data Reporting rule. With the modifications recommended by SOCMA, the proposed rulemaking would meaningfully reduce burdens for CDR reporters without significantly decreasing information collected for the administration of TSCA. SOCMA looks forward to continued involvement and collaboration with EPA on its TSCA implementation efforts in the future.

Respectfully submitted,

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