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SOLUTIONS FOR SPECIALTIES

August 7, 2020

Mr. Mark Hartman
Deputy Director for Management
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, N.W.
Washington, DC 20460

Dear Mr. Hartman:

I am writing you on behalf of the Society of Chemical Manufacturers & Affiliates (SOCMA) regarding EPA's upcoming revisions to the fees rule under the Toxic Substances Control Act (TSCA). We appreciate the Agency's general invitation to interested persons to offer suggestions for inclusion in its notice of proposed rulemaking, consistent with its obligation to "consult and meet with parties potentially subject to the fees or their representatives."[1]

SOCMA is the national trade association dedicated to the specialty and fine chemical industry. We represent companies that manufacture innovative chemistries that enable and enhance the performance of countless commercial, industrial, and consumer products. SOCMA members are subject to TSCA and have had direct experience with the first iteration of the user fees rule since it was issued in October 2018.

Section 26(b)(1) of TSCA limits fees to those "that [are] sufficient and not more than reasonably necessary to defray the cost" related to the administration of the Act. When the Agency calculated what fees to propose in its 2018 rulemaking, EPA based its figures on current costs. The statute's use of the phrase "reasonably necessary to defray the cost," however, requires EPA to also account for what its costs reasonably should be. By not adequately doing so in the first fees rule, the Agency (and industry) encountered significant practical difficulties during implementation of the rule, many of which continue to impact the effectiveness of the TSCA program.

SOCMA therefore would like to provide advance feedback to the Agency regarding revisions that would materially improve the TSCA fees rule and ensure costs better account for various economic and competitive externalities.

SOCMA offers three principal recommendations for EPA's fees rule proposal:

[1] 15 U.S.C. § 2625(b)(4)(E).

- EPA should implement *de minimis* exemptions from Section 6 risk evaluation fees;
- EPA should reduce the fees for Section 5 pre-manufacture notices; and
- EPA should eliminate fees on Section 5 exemption requests.

I. EPA Should Implement *De Minimis* Exemptions for Risk Evaluation Fees

SOCMA commends and strongly endorses EPA's decision to exempt chemicals manufactured or imported as a byproduct or impurity or imported in an article from the TSCA risk evaluation fees. Including this exemption will significantly improve the self-identification process for future High Priority chemicals and enhance the fairness of the fees rule. EPA should also include non-isolated intermediates in its Section 6 fee exemption, given the likelihood of overlap of that concept with impurities. It would be very helpful if EPA provided a list of examples in the rule to help companies distinguish between byproducts, impurities and non-isolated intermediates.

In addition to codifying the exemptions for byproducts and impurities, SOCMA recommends that EPA establish two numerical *de minimis* exemptions, one based on the percent concentration of the chemical substance and one based on production or importation volume. The ongoing process to identify subject parties for the next 20 High Priority chemicals has shown that scenarios will arise where there are a limited number of companies who will share the $1.35 million fee for an individual chemical. This scenario can become highly unfair if one of those companies only manufactured or imported a small volume of a substance, making them liable for a fee that could be extremely disproportionate to the value of their past commercial activity. This is particularly worrisome when a company has manufactured or imported a High Priority chemical for purposes of research and development, since such activities tend to be non-commercial in nature and frequently involve very small quantities.

SOCMA's proposed numerical exemptions would greatly simplify the compliance process for companies by (i) making it much easier for a company to determine whether it is required to pay a fee and (ii) avoiding the need to make difficult interpretive decisions about what constitutes a byproduct, impurity or article. SOCMA's proposed exemptions would also not materially affect the fees paid by companies who manufactured or imported greater volumes, as they would only exempt producers of small quantities.

Percentage-based exemption. SOCMA is aware of a company that "manufactured" a High Priority chemical substance at a concentration of 4 ppm. To avert this situation, the Agency should adopt a 1.0% noncarcinogens/0.1% carcinogens *de minimis* standard (by weight or volume). This benchmark is well understood by industry since it also triggers coverage for TSCA 12(b) export notifications and the OSHA Hazard Communication Standard.

Volume-based exemption. SOCMA is also aware of a company that had to pay a risk evaluation fee for having imported 4 grams of a chemical substance. SOCMA thus recommends that the agency establish a *de minimis* production/importation volume exemption from the self-identification requirements for manufacture and import. SOCMA recommends that the Agency implement a 2,500 lb per year threshold for the risk evaluation self-identification requirements. Because EPA will continue to rely predominantly upon Chemical Data Reporting (CDR) information to identify companies responsible

for such fees, it would be reasonable to align the most stringent bar for reporting[2] under the CDR with the threshold for which a company must self-identify, and exempt any companies that fall under that volume.[3]

EPA ultimately has a statutory obligation to "take into account the ability to pay of the person required to pay such fee."[4] SOCMA's proposed *de minimis* exemption for Section 6 risk evaluation fees would be a straightforward and reasonable means of accounting for scenarios where a company's financial circumstances could be seriously affected by having to pay a very significant fee for having manufactured or imported a substance in limited volumes.

II. EPA Should Reduce Fees on Section 5 Pre-Manufacture Notices

The first iteration of the TSCA fees rule increased the cost to submit a PMN/SNUN by 540%, to $16,000 for one submission. During the rulemaking, EPA estimated that the increased fee would cause a 20% drop in PMN submissions. SOCMA argued at the time that this was likely an underestimate due to the expensive and time-consuming animal tests that PMNs are now regularly subject to, in addition to the protracted review periods for such notices.

The concerns regarding the cost prohibitiveness for such submissions have unfortunately been borne out since the fees rule was implemented, with the number of PMN submissions dropping significantly. Based on EPA public data[5], there only around 180 PMN and SNUN submissions in 2019, the first full year since the rule went into effect. This is an enormous drop-off compared to the approximately 1,000 cases per year the Agency was managing pre-LCSA, and still a very significant reduction – one-half – compared to the period between LCSA and the fees rule, when EPA was averaging approximately 400 cases per year. There can be no dispute that increasing PMN and SNUN fees six-fold has had a chilling effect on the number of annual submissions.

In the preamble to the final fees rule, EPA noted that "TSCA calls for EPA to implement TSCA in a manner that does not 'impede' or create 'unnecessary' barriers to technological innovation.''[6] It also said that it "appreciates commenters' concerns regarding increased TSCA section 5 fees and potential impacts to chemical innovation."[7] Finally, EPA noted that, while it "currently lacks the experience and information to more narrowly tailor fees while still meeting the collection requirements in TSCA,"[8]

> EPA expects to gain valuable experience implementing this initial fee structure. Ultimately, EPA believes this initial experience and information gained from tracking actual costs will help EPA to

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[2] 2,500 lb is the lowest volume threshold for which a chemical substance must be reported through CDR. It applies if the chemical is subject to a TSCA action, such as a rule proposed or promulgated under TSCA section 4, 5(b)(4), or 6, or an order in effect under TSCA section 5(e), or relief that has been granted under a civil action under TSCA section 5 or 7.

[3] Other international chemical regulatory frameworks also provide similar *de minimis* exemptions to users, which further justifies such a provision in the TSCA fees rule. For example, ECHA requires a REACH registration of substances manufactured or imported at one tonne or more per year and exempts volumes below that threshold.

[4] 15 U.S.C. § 2625(b)(1).

[55] *See* https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/premanufacture-notices-pmns-and

[6] 83 Fed. Reg. 52694, 52705 (Oct. 17, 2018).

[7] *Id.*

[8] *Id.*

> continue refining methodologies for calculating fees, and will inform potential revisions to the fee structure in the future.[9]

EPA now has empirical information demonstrating that the level of PMN fees has discouraged innovation. SOCMA strongly urges EPA to reduce these fees in the upcoming rule so they do not continue to act as a market barrier for new chemistries.[10] SOCMA believes that a 50% reduction in PMN/SNUN fees would help encourage submissions, while still accounting for the work required on the part of Agency staff in reviewing cases. Further, the Agency plans to issue a procedural rule this fall for the new chemicals program to promote greater efficiencies, minimize rework, and reduce the length of time that new chemicals are under review.[11] The savings in costs to the Agency attributable to this upcoming rulemaking would further justify the Agency bringing down its fees for new chemical notices.

III. EPA Should Not Impose Fees on Section 5 Exemption Requests

EPA should return to its previous practice of not imposing a fee for the submission of an exemption request under Section 5 of TSCA. (Or at minimum, it should reduce such fees.) Activities that qualify for an exemption tend to be extremely restrictive in volume, manufacturing methods, and end use applications, and thus have not yet established whether they are commercially viable to permit submission of a PMN.

In SOCMA members' experience, when a company submits an exemption request, it has little certainty whether a product will be commercially successful. In fact, the company ordinarily is simultaneously conducting research and development when it initiates the submission. (Companies frequently must move forward with a submission rapidly, and at risk, if they do not want to miss the opportunity of working with a potential customer.) As a result, the specification on the substance might not yet be set – customers may, midway through development, request that the specification be changed from liquid to solid form, or may request a different purity grade. These details are worked out by the time a company submits a PMN and has reasonably verified commercial viability, but at the exemption stage there are no guarantees. This makes the associated fees for an exemption an added deterrent, limiting a company's ability to engage in experimentation and product development, since the potential losses on their upfront investment are much greater.

The cost of an exemption request therefore disincentivizes efforts by innovative companies to develop and bring new chemicals to market. It is not surprising then that, based on EPA public data[12], exemption requests have fallen by approximately 25% compared to their historical averages. For the reasons just articulated with respect to PMNs, SOCMA also strongly urges EPA to reconsider imposing fees for exemption requests, and instead include the costs of reviewing those applications in the aggregate of the overhead costs that the user fees are designed to recover. The Agency did so for the review of Confidential Business Information (CBI) claims, which benefited innovation since trade secrecy is key to maintaining a

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[9] *Id.* at 52698.

[10] SOCMA recognizes that the current PMN fee is "only moderately higher" than the previous statutory fee, adjusted for inflation. *Id*. at 52705. While that might have been a compelling consideration all else being equal, it is clear that EPA's implementation of the LCSA has greatly complicated the process, and increased the overall cost, of obtaining a PMN. Thus, EPA should be seeking to reduce its PMN fee to a level below the previous fee, adjusted for inflation, to at least partially offset those other disincentives to filing a PMN.

[11] RIN: 2070-AK65.

[12] *See* https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/exemptions-table

competitive advantage in the early life of a new commercial chemical. Fees collected from Section 5 exemptions should be evaluated with the same considerations. Exemption fees also represent a small portion of the overall fees the Agency is collecting under the TSCA program, further demonstrating that cost shifting this activity would not have a major detrimental effect on the other fee-able activities under the program.

IV. Other Technical Clarifications and Improvements

SOCMA offers additional recommendations for EPA to propose, or at least seek comment, on during the upcoming TSCA fees rulemaking. Addressing these additional items would improve and add clarity to the rule's requirements:

Section 4

- Table six in the final TSCA fees rule indicates that the fee for a test order is $9,800 and the fee for a test rule is $29,500.[13] EPA's website confirms this as well.[14] However, the Code of Federal Regulations has these figures reversed:

  > (vi) *Test rule.* Persons shall remit a fee totaling $9,800 for each test rule.
  > (vii) *Test order.* Persons shall remit a fee totaling $29,500 for each test order.[15]

  It is evident from EPA's explanation of how it set the fees that the CFR language is a mistake.[16] EPA should correct it.

- EPA should modify its fees for Test Orders and Enforceable Consent Agreements (ECAs) to make the latter less than the former. Companies entering into ECAs are cooperating with EPA, while the latter may not be, and so the former should be given the benefit of paying lower fees, even if the agency's costs are greater.

Section 5

- EPA should commit to its statutory obligation of providing full refunds to submitters when it fails to make a determination on a notice by the end of the applicable review period and the notice has not been withdrawn by the submitter. The final fees rule stated that "EPA does not believe it should be required to issue a refund if the TSCA review period expires," and that "most submitters have appreciated the flexibility to suspend the review period, as doing so is often in their best interest."[17] However, this language elides the reality that submitters are powerless to resist such "voluntary" suspensions, since they otherwise risk having their submission denied. EPA is obligated to give effect to the words of the statute and should commit to issuing refunds in such scenarios.

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[13] 83 FR 52706.
[14] *See* https://www.epa.gov/tsca-fees/tsca-fees-table.
[15] 40 C.F.R. § 700.45(c)(2)(vi) & (vii).
[16] *See* 83 FR 52704 (Section 4 fees set at 3.5% of EPA's estimated activity cost for each activity; estimated activity cost for a test order = $279,000; $279,000 x 0.035 = $9,765).
[17] 83 FR 52709.

- EPA should add a refund category "if no substantial work was performed on the notice."[18] EPA only provides a 75% refund when the submitter withdraws within the first 10 days of a submission, but does not provide a comparable refund any time that EPA has not conducted any of its review procedures within the first 10 days. A "no substantial work" refund mechanism would help ensure that EPA complies with the statute and new chemical notices do not languish. This is an equitable result as EPA adds new requirements to submitters via its upcoming new chemicals rulemaking.

Section 6

- The rule should state unambiguously that manufacture and import for non-TSCA uses is exempted from the self-identification requirements.

- The rule should clarify that import for export-only commercial activity is exempted from the self-identification requirements.

- EPA should establish a "Reasonably Ascertainable" due diligence standard for the self-identification requirement, in manner that is similar to the standard for information reporting under TSCA section 8(a).[19] Doing so would ensure that internal company efforts to determine reporting obligations do not become overly burdensome or expensive to conduct in the limited time available during the notification period.

Conclusion

SOCMA values its relationship with EPA and appreciates the opportunity to provide advance feedback on the Agency's TSCA fees rulemaking. We would welcome further discussion with EPA on its fees proposal to ensure the proposed revisions are practical, minimally burdensome, and encourage innovation in the chemical sector.

If you have any questions, please contact me at jrothstein@socma.org or 571-348-5122.

Respectfully submitted,

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[18] 42 U.S.C. § 2625(b)(4)(G).
[19] TSCA § 8(a)(2); 42 U.S.C. § 2603(a)(2).