Center for Specialty Chemical Science
A subsidiary of SOCMA

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U.S. Environmental Protection Agency
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Via regulations.gov submission

RE: Proposed Revisions to ICR No. 1139.12, "TSCA Section 4 Test Rules, Test Orders, Enforceable Consent Agreements (ECAs), Voluntary Data Submissions, and Exemptions from Testing Requirement," 85 FR 33151 (June 1, 2020)

To whom it may concern:

The Center for Specialty Chemical Science, LLC (CSCS), a subsidiary of the Society of Chemical Manufacturers & Affiliates (SOCMA), is pleased to submit these comments on EPA's update of its existing Information Collection Request (ICR) regarding its activities under Section 4 of the Toxic Substances Control Act (TSCA). These comments are focused on improving EPA's practices in connection with granting and overseeing exemptions from Section 4 test rules and orders. As explained below, those practices have historically imposed undue and unfair burdens on the entities who complied with test rules. In doing so, EPA has violated both the Paperwork Reduction Act (PRA) and its own TSCA rules and has failed to effectuate the intent of the statute.

The 2016 amendments to TSCA substantially revised Section 4 -- among other things, they authorized EPA to issue test orders, not just rules. The Supporting Statement for this ICR[1] indicates that EPA intends to apply the exemption and data reimbursement provisions of its Section 4 implementing regulations to test orders as well as rules. The document also states that EPA is in the process of updating those regulatory provisions to reflect the changes of 2016.[2] EPA will clearly need to do so. That update presents EPA with the perfect opportunity also to revise its exemption practices, so that they comply with the law and treat test rule recipients fairly. This ICR revision in turn presents EPA with the opportunity, in the meantime, to implement new and better practices as interpretations of its existing rules. Clearly, Congress anticipated that EPA would take more actions under Section 4 after the 2016 amendments than it did before. EPA should act now to ensure that this greater level of activity does not result in a greater level of injustice.

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 maintains a strong

[1] Docket Number EPA-HQ-OPPT-2015-0436-0018 (April 25, 2020).
[2] Page 7 of the Supporting Statement states: "Certain regulations are currently undergoing revisions to more closely conform with the language and authorities under the Lautenberg Act, including TSCA section 4(c) reimbursement process regulations at 40 CFR part 791 . . . ." EPA has not identified this rulemaking on its Semiannual Regulatory Agenda, however. It should do so.

record of member service through programs that maximize commercial opportunities, enhance regulatory and legal compliance, and promote industry stewardship.

CSCS represents chemical-specific consortia focused on addressing scientific, regulatory, and technical issues of common interest to the specialty chemical industry. CSCS manages the use and oversight of all consortia studies completed by and commissioned through SOCMA over the last four decades. Staffed by a team of experts and supported by industry leaders, CSCS has significant expertise in establishing and managing consortia, developing test protocols and navigating government risk evaluations of chemical substances.

CSCS advances and defends the position of chemical substances critical to the commercial success of manufacturers, importers, and downstream users. It currently administers consortia formed to comply with previous Section 4 test rules and expects to administer consortia formed to comply with future test rules and orders. Several historical consortiums managed by SOCMA have been faced with entities that obtained an exemption from a test rule but have made no effort to pay their share of the costs of compliance. Thus, we have a vital interest in seeing that EPA complies with the PRA and its TSCA rules – and treats our members fairly – in granting exemptions from such rules.

Our comments below make three principal points:

1. EPA's historic practices in granting and overseeing exemptions from test rules do not effectuate TSCA, violate the PRA and EPA's TSCA rules, and treat compliant companies unfairly.

2. EPA should amend its Section 4 implementing regulations to make its exemption practices legally compliant and fair. In the meantime, however, it can implement additional practices under its existing regulations to promote those goals. In particular, EPA could require that any application for exemption from a test rule or order be accompanied by documentation showing that the applicant has agreed contractually to pay, before expiration of the reimbursement period, fair and reasonable compensation to the company/ies paying for the testing required by the rule.

3. The Supporting Statement should be revised to account for the costs of pursuing exemption holders who do not pay fair and equitable reimbursement of testing costs. It should also increase its estimated costs for administering consortia and paying for technical assistance. Finally, it should include a company's costs of determining whether it is covered by a test rule or order.

I. EPA's Historic Practices in Granting and Overseeing Exemptions from Test Rules Do Not Effectuate TSCA, Violate the PRA and EPA's TSCA Rules, and Treat Compliant Companies Unfairly

As EPA is aware, compliance with Section 4 typically involves the conduct of tests costing hundreds of thousands, if not millions, of dollars. And the benefits of that testing will be shared by all manufacturers and importers of the subject chemical. Thus, the companies who undertake such testing have a strong interest in ensuring that all who share in those benefits also share in the costs. The TSCA statute recognizes this data compensation interest. So do EPA's regulations, albeit less clearly. Unfortunately, the way EPA has implemented these regulations has effectively allowed companies who obtain exemptions from test rules to free ride, with impunity, on the expenditures of others.

In clear language that has been unchanged since 1970, the statute declares that, where an exemption has been

granted, unless the parties can agree on compensation,

> the Administrator *shall order the person granted the exemption to provide fair and equitable reimbursement* (in an amount determined under rules of the Administrator)—
>
> (i) to the person who previously submitted such information, for a portion of the costs incurred by such person in complying with the requirement to submit such information, and
>
> (ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.[3]

EPA's Section 4 regulations implement this language in more roundabout fashion. First, they state that "[m]anufacturers subject to a test rule . . . who do not submit to EPA either a letter of their intent to conduct tests or a request for an exemption from testing . . . will be considered in violation of that rule . . . ."[4] Second, and more to the point, they provide that "[e]ach applicant for an exemption shall submit the following sworn statement [referred to as a "Statement of financial responsibility"] with his or her application:

> I understand that if this application is granted before the reimbursement period described in section 4(c)(3)(B) of TSCA expires, I must pay fair and equitable reimbursement to the person or persons who incurred or shared in the costs of complying with the requirement to submit data and upon whose data the granting of my application was based.[5]

Historically, however, *EPA has done nothing to assure that companies receiving an exemption actually do pay the compensation that they swear they will pay when they file their exemption requests*. Rather, EPA's data reimbursement rules (40 C.F.R. Part 791) rely on a test sponsor to initiate a costly arbitration proceeding against a recalcitrant exemption holder. Indeed, EPA has historically not even notified paying companies when it has issued a conditional exemption to another company. Thus, paying companies are forced to do substantial detective work even to find out the existence and identity of such companies.

EPA's practices have been a source of deep frustration for Section 4 payors for decades. As noted earlier, several consortia we have administered in recent years have been faced with entities that obtained an exemption but have made no effort to pay their share of the costs of a test rule. In effect, these entities just "ghost" the paying companies, not responding to phone calls or even threatening letters. Clearly, these companies are aware that EPA will take no action against them for violating their sworn statements of financial responsibility. Needless to say, this conduct only encourages such behavior by other companies.

In effect, EPA's practices have treated persons who faithfully comply with a test rule no better than the "potentially responsible parties" or PRPs who are jointly and severally liable for having contaminated a Superfund site, and who must pay EPA and then try to identify and seek contribution from other polluters.

We submit that EPA's practices violate its own regulations, as the Agency takes no action against persons who are "in violation of th[e test] rule," or to see that exemption holders actually live up to their sworn statements of

[3] 15 U.S.C. § 2605(c)(3)(A) (emphasis added).
[4] *See* 40 C.F.R. § 790.45(e).
[5] *Id.* § 790.99.

financial responsibility. These practices certainly contravene the Paperwork Reduction Act, as they impose upon payors under a test rule the full cost of:

- identifying other entities who have been conditionally exempted from the rule;
- trying to persuade them to pay their fair and equitable share;
- paying "the appropriate administrative fee"[6] to initiate an arbitration if the exempted parties do not meet their obligations; and
- advancing the full cost of the arbitration.[7]

Paying parties also bear an "equal" share of the ultimate cost of the arbitration unless the hearing officer determines differently.[8] In other words, despite having stepped up to pay the cost of a test rule, and after initiating an arbitration and winning an order to compel the free-riders to pay their fair share, the complying parties still have to bear half the cost of the process to produce that outcome.

This regime can hardly be described as "minimize[ing] the burden of the collection of information on those who are to respond,"[9] "with particular emphasis on those . . . entities most adversely affected."[10] And by making it more difficult to assemble consortia of companies to shoulder the costs of a test rule, EPA's practices do not "maximize the . . . public benefit from information collected . . . for the Federal Government."[11] The prospect that EPA will now be issuing test orders, as well as rules, means that these injustices will only proliferate. EPA should modify its practices to be fairer, to more fairly effectuate the intent of Congress, and to truly minimize burdens on paying companies. It can easily do so, as explained below.

II. It Would Be Easy for EPA to Make Its Exemption Practices Legally Compliant and Fair

As noted earlier, the 2016 amendments to TSCA authorized EPA to issue test orders, as well as rules. The Supporting Statement indicates that EPA intends to apply the exemption and data reimbursement provisions of its Section 4 implementing regulations to test orders. It also states that EPA will update its Section 4 regulations to implement these and other aspects of the 2016 amendments. That undertaking presents EPA with the perfect opportunity to ensure that the new rules contain new steps that would comply with the law and treat test rule recipients fairly. In the meantime, this ICR revision presents EPA with the opportunity to implement some new and better practices as interpretive glosses on its existing rules, especially 40 C.F.R. §§ 790.45(e) & 790.99.

Implementation of these new practices would be facilitated by the fact that, under the 2016 amendments, persons liable under TSCA test orders and rules will now also be identified and required to pay fees under Section 26(b) of TSCA. EPA will begin re-evaluating its TSCA fees rule this year, and this issue would be a timely and appropriate topic to include in that reevaluation as well.

The single most important practice that EPA should implement is that, when a company seeks exemption from a test rule, it should be required to provide EPA, as part of its application, with documentation showing that the company has agreed contractually to pay, before expiration of the reimbursement period, fair and reasonable

[6] *Id.* § 791.20(c).
[7] *Id*. § 791.39(a)(2).
[8] *Id*. § 791.39(b).
[9] 85 Fed. Reg. 33151.
[10] 44 U.S.C. § 3504(c)(3).
[11] *Id*. § 3504(c)(4).

compensation to the company/ies paying for the testing required by the rule. If EPA determines that 30 days[12] is not enough time for companies to execute such agreements, they could be required to provide the same documentation when they submit a test rule fee.[13]

EPA's Section 4 rules provide that a certified letter is one of three ways that EPA can notify an applicant that EPA has granted it a conditional exemption.[14] CSCS understands that EPA's practice, at least in recent years, has not been to mail such letters. Another new practice that EPA could adopt to facilitate the payment of fair and equitable compensation to persons incurring the costs of testing under Section 4 would be for EPA to routinely send such letters, and for the conditional grant of the exemption to require the applicant to file notice with EPA, before expiration of the reimbursement period, attaching either:

1. A receipt from the test sponsors indicating payment of fair & reasonable compensation; or
2. A certification, and documentation, that the applicant has made a good faith offer to do so.

At the request of a paying entity who attests that an exempted entity has failed to respond to communications or to engage in good-faith negotiations, EPA could send a letter to the latter entity, reminding it of its obligation under TSCA, EPA's rules and its own sworn statement, and noting that recalcitrance in this regard is an appropriate factor to consider when a hearing officer determines what constitutes fair and equitable contribution.

Finally, EPA could notify test sponsors whenever an exemption application is submitted.

All or some combination of these options would more fairly effectuate the intent of Congress and EPA's regulations, and minimize burdens on paying companies, while EPA rewrites its Section 4 rules.

III. EPA's Supporting Statement Fails to Account for Several Categories of Costs and Understates Others. It Should Be Revised to Correct These Shortcomings

The Supporting Statement for this ICR appears to be a markup of the document that was submitted to OMB in 2016 in support of the previous ICR. Given the extensive changes in TSCA procedures and costs generated by the amendments of later that year, the Supporting Statement should have been completely revised from the prior version. As EPA revises the current Statement for submission to OMB, it should correct the following shortcomings:

Most apposite to the point of these comments, the Supporting Statement does not contain any consideration of actions required of the companies that step up to pay the cost of testing to identify and collect reimbursement of compliance costs from non-participants. This includes:

- Researching the identity of non-paying respondents;
- Engaging with non-payors to ascertain their willingness to participate;
- Negotiating a cost sharing formula and other reimbursement terms;
- Preparing data sharing agreements; and
- If necessary, contesting requested reimbursement through arbitration (including, as noted earlier, paying an administrative fee and advancing the costs of the arbitration).

[12] Test rule commitments are due 30 days after the effective date of a test rule. *See* 40 C.F.R. §§ 790.45(a) & 790.80(b)(1).
[13] Test rule fees are due 120 days after the effective date of the rule. *See id.* § 700.45(g)(3)(i).
[14] *See id*. § 790.87(c)(1)(iii).

These costs can be very substantial. We estimate $55,000.00, on average.

As for the companies that voluntarily step up, the Supporting Statement says simply:

> In addition to laboratory costs, there are also costs for consortium management . . . . Consortium management costs, which includes activities such as identifying manufacturers, meetings, organizing payment for testing, developing contracts for testing, and employing toxicologists who may be hired to provide technical expertise, are estimated at 15 percent of total laboratory costs.[15]

Based on SOCMA's experience in managing numerous consortia over the last 50 years and negotiating reimbursement in the United States and Europe, consortium administration should be at least 25% of laboratory costs, without regard for additional fees paid to experts. Furthermore, additional fees as a percentage of laboratory costs are warranted for sponsoring and managing lower cost studies, in order to compensate sponsoring consortia for fixed costs which do not vary according to value of the underlying study.

Also,

- The Statement does not include the estimated burden associated with a company's need to review the test rule or order, comprehend its scope, and review chemical formulations to determine whether the rule or order applies to the company. The American Chemistry Council noted this shortcoming in the Supporting Statement for the 2016 ICR, and it has been perpetuated in this document.

- The costs reflected in the Supporting Statement are far lower than current costs. This is particularly true for professional time for management and review. For example, Table 9 indicates that a corporate review labor rate of $53.40 was applied to calculate total cost of corporate review (14 hours yielding a total cost of $1,121.10).[16] Small entities and consortia using outside experts and legal review are unlikely to obtain such review for $53.40 per hour. We submit that a rate of $159.40 per hour would be more reflective of current market rates.

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SOCMA CSCC appreciates the opportunity to comment on this ICR revision. We will be following up with the TSCA program office to continue to press the concerns described above but would welcome any questions you have about these comments. I can be reached at 571-348-5106 or dwawer@socma.org.

Sincerely,

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[15] Supporting Statement at 30.
[16] *Id* at 24.

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