

Responses to Comments Received on Proposed Revisions to the Information Collection Request (ICR) for Section 4 of the Toxic Substances Control Act (TSCA)

Background

On June 1, 2020 (85 FR 33151), the U.S. Environmental Protection Agency (EPA) published a notice in the Federal Register and on June 3, 2020 sent consultation emails to nine recipients announcing that it was planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for revisions to an existing collection of information under TSCA section 4. The public comment period closed on July 31, 2020. The Agency received comments in response to this notice from the Center for Specialty Chemical Science, LLC (CSCS), a subsidiary of the Society of Chemical Manufacturers & Affiliates (SOCMA), the Environmental Defense Fund (EDF), and the American Chemistry Council (ACC). No comments were received in response to the consultation requests.

Public Comments and EPA Responses

CSCS Comments:

Comment 1: CSCS commented that EPA’s practices for administering the granting and oversight of the exemption process for test rules do not effectuate TSCA and violate the Paperwork Reduction Act (PRA) and EPA’s regulations, and treat compliant companies unfairly. The CSCS commented that testing costs under TSCA section 4 should be shared among manufacturers benefiting from the testing. The commenter cited TSCA section 4 and EPA’s TSCA section 4 implementing regulations that require other manufacturers who obtain an “exemption” under TSCA section 4(c) to certify and pay fair and equitable reimbursement to the person or persons who incurred the costs of complying with the testing requirements. The commenter remarked that EPA, historically, has done nothing to assure that companies receiving exemptions reimburse the test sponsor(s), including notifying paying companies when EPA has issued a conditional exemption to another company or taking action against persons in violation of the test rule. The commenter remarked that these practices contravene the PRA by imposing upon the test sponsors of a test rule, the full cost of: identifying other entities conditionally exempt under a test rule, trying to persuade those conditionally exempted parties to pay their fair and equitable share, paying the appropriate administrative fee to initiate an arbitration if the exempted parties do not meet their obligations, and advancement of the full cost of the arbitration. The commenter also remarked that paying parties will bear an equal share of arbitration costs to pursue such arbitration. The commenter remarked that this regime does not minimize the burden of the information collection on respondents and entities most adversely affected pursuant to 44 U.S.C. 3504(c)(3), or maximize the public benefit from information collected for the Federal Government pursuant to 44 U.S.C. 3504(c)(4) by causing difficulty in assembling consortia of companies to bear the cost of a test rule.

CSCS commented that as EPA considers amendments to the 40 CFR 791 regulations, as referenced in the ICR Supporting Statement, that this would be a good opportunity to ensure that such revisions contain new steps that would comply with the law, provide fairness to test rule recipients, and minimize burdens on companies paying the costs of testing. The commenter remarked that this ICR revision provides an opportunity to implement new practices under its

existing regulations including suggesting EPA require an exemption applicant to provide, either with an exemption application or when they submit a test rule fee, documentation showing the applicant company has contractually agreed to pay, within the reimbursement period, fair and reasonable compensation to the [test sponsor]. CPSC also suggested notifying an exemption applicant by letter when a conditional exemption is granted and for a conditional exemption be conditioned on a requirement that the applicant file notice with EPA prior to the end of the reimbursement period with either a receipt indicating payment of compensation or a certification and documentation that the applicant has made a good faith offer to pay compensation. The commenter also suggested EPA notify test sponsors when an exemption application is submitted and send a letter, at the request of a paying entity claiming a failure at good-faith attempts to negotiate, to an exemption holder reminding such exemption holder of the obligations under TSCA, EPA's rules, and its sworn statement.

Response: The Agency has utilized approaches over the years to reduce burden on the regulated community. It has followed statutory requirements when pursuing testing actions such as first making particular “findings” in accordance with the statute prior to promulgating test rules to ensure that only necessary data would be developed. It has also allowed for the formation of consortia so that entities subject to a test rule may collaborate and make many decisions regarding how regulated entities would carry out and share costs of testing and to prevent duplicative testing. EPA has also sought out the submission of relevant existing data to be submitted voluntarily.

The Agency is considering amendments to the TSCA section 4 implementing regulations and will take the commenter's suggestions into account. There are, however, several noteworthy aspects of the TSCA Lautenberg Act amendments of 2016 that may mitigate some of the commenter's concerns.

It is anticipated, as described in the ICR Supporting Statement, that the Agency may use its order authority explicitly provided by the Lautenberg Act amendments to require the development of information under TSCA section 4, as needed, during this ICR cycle. It is anticipated that the issuance of orders would mitigate the issues presented by the commenter for test rules because unlike rules, all entities subject to the order would be known and included in the order; therefore the test sponsor(s) would know the identity of the entities potentially subject to reimbursement requirements when the order is issued.

Furthermore, when rulemaking under TSCA section 4 is utilized, the new reporting requirements associated with the *Fees for Administration of Toxic Substances Control Act* rule (“Fees Rule”), covered by the ICR with OMB Control No. 2070-0208, will add to the Agency's ability to identify entities subject to such testing action since those parties subject to a section 4 test rule (or order) would be required to identify themselves for purposes of submitting the applicable fees.

Comment 2: CSCS also commented that the ICR Supporting Statement does not cover several categories of costs and understates others and that the Supporting Statement should have been completely revised instead of conducting a “markup” of the currently approved ICR. The commenter suggested that the Supporting Statement should have considered actions required of

the companies paying for the costs of testing to identify and collect reimbursement for non-participants including researching the identity of non-paying respondents, engaging with non-payers to ascertain their willingness to participate, negotiating a cost sharing formula and other reimbursement terms, preparing data sharing agreements, and if necessary, pursuing reimbursement through the arbitration process, including paying an administrative fee and advancing the costs of the arbitration. The commenter estimated costs, on average, to be \$55,000. The commenter also claimed that, based on experience, consortium administration costs should be at least 25% of the laboratory costs instead of 15%, not including fees paid to experts, and that additional fees as a percentage of laboratory costs are warranted for sponsoring and managing lower cost studies to compensate sponsoring consortia for fixed costs that do not vary according to the value of the underlying study. The commenter also claimed that the estimated burden does not include the activities of the recipient reviewing the test rule or order, comprehending its scope, and reviewing chemical formulations to determine compliance requirements. Additionally, the commenter claimed 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). Lastly, the commenter remarked that small entities and consortia using outside experts and legal review would be unlikely to obtain such review for \$53.40 per hour and estimated the rate of \$159.40 per hour instead to reflect current market rates.

Response: The Agency believes the revisions made to the currently approved ICR Supporting Statement are appropriate based on amendments to TSCA under the Lautenberg Act and believes it appropriately presents such revisions in a format that both describes changes to the TSCA section 4 program and estimated changes in burden projected to be associated with the three-year cycle. In order to present changes to the relevant substantive portions of TSCA and burden estimate changes since the currently approved ICR, it is important to include both legacy program activities as well as projected program activities.

The Agency did not include costs for reimbursement arbitration for multiple reasons. The primary reason being this activity has not been undertaken in past ICR cycles. Based on this prior history, the Agency is assuming zero reimbursement arbitration actions will occur during the 3-year ICR cycle covered by this ICR. While the Agency does acknowledge test orders are new component to TSCA program under the 2016 Lautenberg Act amendments, and TSCA section 6 risk evaluation activities are expected to increase section 4 activities, companies are identified in the test orders and through actions under separate Fees Rule reporting requirements. If a company decided to start the reimbursement arbitration process, the finding or identifying of non-participant companies would already be available through the details of the test order. In general, EPA will update its preliminary estimates to reflect more recent projections of the potential number of orders that may be issued.

The estimate of consortium administration being 15 percent of the total laboratory costs is used to maintain consistency between the assumptions of this ICR and those used in the final Fees Rule. As the Fees Rule went through the EO 12886 rule review process and was finalized in September 2018, the Agency does not agree that deviating from those assumptions is appropriate at this time without significant documentation and data.

Costs for some pre-reporting activities are included in the activity under “Letter of Intent.” The activity of “compliance determination” is not included in the burden calculations because it involves a task of negligible burden by which the respondent recognizes whether each chemical subject to the test rule or order is a chemical that the company manufactures. Also, with the issuance of test orders, the Agency will have conducted much of the pre-reporting activities as part of its determination of which manufacturers (including importers) and /or processor are to be issued the order.

EDF Comments:

Comment 1: EDF provided several comments related to the battery of tests included in the ICR Supporting Statement. EDF commented that the Agency should include other types of tests to pursue information on chemicals subject to current or upcoming risk evaluations under TSCA section 6. EDF commented that there have been data gaps that need to be addressed with a wide range of tests, including health effects and exposure studies. EDF also commented that the test battery considerations under the revisions included in this ICR Supporting Statement present a reduction in tests and test types from the currently approved ICR, and should not be reduced, but rather expanded upon.

Response: The purpose of providing a test battery in the ICR Supporting Statement is to estimate projected burden over the course of the following three-year ICR cycle for information collection activities associated with TSCA section 4 information development actions. It is not to indicate that EPA is limited to those specific tests in carrying out its programmatic information collection activities under TSCA section 4 in all cases. The number of section 4 actions to be issued, which companies will be subject to those actions, and what specific testing requirements under those actions will be based on information needs identified by EPA to support EPA’s review of chemicals on a case-by-case basis. The testing battery used in this ICR is included as a proxy for the burden and cost associated with TSCA section 4 actions the Agency may require industry to perform. It is not intended to be comprehensive or exhaustive, but as an estimate of the potential burden and costs a company may experience as a result of a TSCA section 4 action. As the implementation of this section of TSCA evolves, so will the methodology the Agency uses to provide projected estimates of these burdens.

Comment 2: EDF commented that it is not clear whether the ICR’s estimates for the number of testing actions to be issued consider testing through TSCA section 4 to pursue the development of information for new chemicals under TSCA section 5. The commenter remarked that the TSCA reforms of 2016 provided the Agency with explicit authority to do so and suggested that section 4 should be utilized for purposes of developing information related to new chemical notices and applications received by the Agency under TSCA section 5.

Response: While section 4(a)(2) provides some testing authority pertaining to TSCA section 5, EPA notes that section 5(e) provides its own testing authority, such that specific tests required in a section 5(e) order might not rely at all upon section 4(a)(2). That being said, this ICR specifically mentions that the Agency has the explicit authority to pursue the development of information pursuant to several approaches, including for certain TSCA section 5 purposes. The number of estimated testing actions in this ICR are projections based on recent information and

past experience. The ICR Supporting Statement is not intended to state or imply that the Agency is limited to pursuing testing actions under any one particular testing authority under TSCA section 4(a). The Agency will continue to update such estimates as the TSCA section 4 program continues to develop pursuant to the Lautenberg Act amendments and as experience and data continue to become available, estimates and projections will be refined accordingly. Note that current information collection activities, including related to testing and developing information, pursuant to TSCA section 5 are covered under the existing ICR with OMB Control No. 2070-0012.

Comment 3: EDF also commented that the ICR’s discussion related to confidentiality/confidential business information (CBI) does not accurately reflect TSCA section 14. The commenter highlighted certain descriptions in the ICR Supporting Statement including “[c]onfidentiality of responses: [r]espondents may claim all or part of a document confidential,” (page 4 of ICR Supporting Statement); “to the extent that reported information is not considered to be CBI, environmental groups, environmental justice advocates, industry, state and local government entities and other members of the public may have access to this information for their own use,” (page 8 of the ICR Supporting Statement); and “CBI substantiation to support confidentiality claims for relevant data elements for the overall submission throughout the testing period (see list of transactions in Table 4) must be provided in conjunction with the study plan transmittal. The CBI substantiations address chemical identity (chemID) and other data elements.” (pages 23, 26, and 28 of Supporting Statement). The commenter remarked that these statements are not accurate in light of details related to what information may be claimed as CBI under TSCA section 14 and what may not and what entities may have access to such information.

Response: The commenter takes statements in the ICR regarding information that may be confidential and assumes that EPA is making assertions about what information is entitled to confidential treatment under TSCA.

Rather, EPA is acknowledging the requirements in Agency confidentiality regulations at 40 CFR part 2, subpart B that information claimed as confidential must be protected in accordance with these regulations until and unless a determination is made that the information is not entitled to confidential treatment, and (in accordance with TSCA §14(g)(2), the submitter is given advance notice of EPA’s determination.¹ Consistent with this, the description within the “confidentiality” section of part 3(f) on page 11 of the ICR Supporting Statement includes, in part, the following:

Information submitted to EPA in response to test rules, test orders, and consent agreements, is, in most cases, non-confidential. Respondents may claim all or part of a document submitted to be confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14, 40 CFR part 2, 40 CFR 790, and any specific confidentiality requirements under a particular testing action.

In this context, the use of the word “document” is not intended to imply that an entire study or

¹ Under statute and regulations, certain limited disclosures of additional information claimed as confidential may be made.

particular document submitted under a TSCA section 4 action would, or under TSCA section 14 is permitted to be claimed CBI. It is merely meant to describe that claiming and substantiating CBI are generally part of the burden associated with the information collection activities. The use of the phrase “other data elements” is also not intended to convey that certain health and safety studies, if not otherwise protected from disclosure under TSCA section 14, would be. The reference to chemical identity and other data elements in the ICR is merely to recognize that TSCA section 14 specifies certain aspects related to chemical identity compared to various other types of information claimed CBI, and therefore this is noted in the ICR.

The descriptions are also not intended to convey that if a particular entity has the statutory or other relevant authority to access CBI information, that such information would be improperly withheld from such entities. As stated in the excerpt above from page 11 of the ICR Supporting Statement, the Agency will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14, 40 CFR part 2, 40 CFR 790, and any specific confidentiality requirements under a particular testing action.

ACC Comments:

Comment 1: ACC commented that the EPA must take the steps necessary to facilitate the efficient collection of information through its TSCA section 4 testing authority should the use of that authority be warranted. ACC acknowledged certain statutory provisions noted in the ICR Supporting Statement including requirements related to vertebrate testing under TSCA section 4(h) and tiered testing [under section 4(a)(4)]. The commenter recommended ways the Agency could minimize the overall burden to respondents of EPA’s future TSCA section 4 testing requirements by providing more specifics about how these statutory provisions would be implemented by the Agency when using its section 4 testing authority, as well as utilizing the Agency’s authority under TSCA section 8 before proceeding with exercising its authority under TSCA section 4, and consulting and collaborating with potential respondents of TSCA section 4 testing requirements.

Response: Tiered testing provisions of TSCA section 4 will be considered depending on whether particular information needs are fulfilled by lower tiered testing compared with more advanced testing. The Agency has been pursuing relevant alternatives to vertebrate testing, and will continue to review and develop viable alternatives to vertebrate testing and the use of lower tiered testing as it implements its TSCA section 4 testing authority, in line with the statutory requirements and the information available. More information about the Agency’s Strategic Plan and alternatives to vertebrate testing under TSCA can be found at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce>. The Agency appreciates these suggestions and the suggestions to consult and collaborate with potential test action respondents and to utilize section 8 authority before exercising section 4 authority.

Comment 2: ACC also commented that the Agency appeared to have undertaken a thorough analysis and the average hourly wages used by the agency in the ICR appeared to be appropriate and reasonable, but noted that it could not evaluate the accuracy of the number of chemicals per action, the number of respondents, or the estimates of the number of activities discussed in the

ICR without more context to how these estimates were determined without more detail regarding the assumptions and methodologies used.

Response: As presented in the ICR Supporting Statement, including Appendix C, certain estimated inputs such as number of chemicals per action and number of sponsors are derived from estimates presented in the Economic Analysis associated with the Fees Rule (2018), with appropriate updates for the ICR, accounting for prospective generic assumptions for the next three-year ICR cycle. Also, details about the methodologies used for this ICR are provided throughout the ICR with additional information on the methodology presented in appendices such as Appendix E. The assumptions considered in this ICR will be further refined and updated in future ICR renewals, as appropriate, as more data and experience related to the implementation of the new aspects of the TSCA section 4 testing program become available and evident.