UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 9 2016

MEMORANDUM

SUBJECT: American Chemistry Council comments on TSCA section 4 ICR (EPA ICR No. 1139.11;
OMB Control No. 2070-0033) Supporting Statement

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Overview

EPA published a proposed information collection request (ICR) renewal for section 4 of the Toxic Substances Control Act (TSCA) in the Federal Register in March 2016 (81 FR 13790, March 15, 2016) for public notice and comment. One public comment was received from the American Chemistry Council (ACC). This memorandum addresses the ACC comment and the planned response.

In general, the ACC comment questions the estimated costs to industry of the chemical testing required by EPA under section 4 of TSCA in the ICR. In particular, the ACC states that EPA has underestimated and miscalculated the industry burden associated with the ICR, and that bipartisan legislation that will significantly affect the scope of EPA's section 4 authority and, consequently, estimated annual burdens associated with the ICR is likely to gain Congressional approval this year. The ACC asks, therefore, that EPA either (1) withdraw the ICR renewal, after addressing public comments and modifying the ICR appropriately, once the modifications to TSCA are made final, or (2) if the ICR renewal is approved, "resubmit the ICR request following enactment of TSCA reform legislation."

EPA will, of course, take appropriate steps to revise its regulations and other pertinent documents in accordance with any legislative amendments that are enacted. At this time, however, there is no reason to delay or disrupt the renewal of this ongoing information collection effort pending such developments. Moreover, should TSCA amendments be enacted, EPA will need time to understand and interpret whatever new provisions are enacted.

The ACC's specific comments are addressed in turn as follows.

1. EPA "continues" to overstate its authority to require testing under section 4, because it has maintained since 1993 that TSCA authorizes EPA, once it has found that testing is necessary, to require any type of health or environmental effects testing necessary to address unanswered questions about the effects of the substance and need not limit the scope of testing required to the factual basis for the unreasonable risk finding." According to the ACC, this overstatement of authority enlarges the scope of EPA's authority under section 4 "beyond the plain language of the statute" because section 4 requires that test data required by EPA relate to effects for which there is an insufficiency of data and relevant to the determination of unreasonable risk of injury to health or the environment. The ACC suggests that EPA anticipate "the significant shift in Section 4 authority in TSCA reform legislation" and adopt a new, more restricted interpretation that EPA must ensure testing requirements are relevant to the data gaps that supported the unreasonable risk finding that made testing necessary.

As stated above, EPA will take appropriate steps, after due consideration and in an appropriate timeframe to revise its regulations and other pertinent documents in accordance with any legislative amendments that are enacted. Moreover, the present interpretation has been in effect for over twenty years and, for the reasons provided in 1993 when it was adopted, EPA continues to find the interpretation reasonable and justified.

2. EPA revised its methodology for estimating the annual burden and costs to industry in this ICR renewal, but failed to accurately consider the cost of collection and total annual industry burden as a whole. Specifically, EPA's methodology for estimating annual burden changed in two ways: the definition of "response" changed so that all studies and activities conducted on one chemical are viewed as a single response and the Agency altered some of its assumptions about the frequency and length of testing activity. Changing the definition of "response" from a "per-activity" to a "per-chemical" definition has "important ramifications should EPA regularly exercise Section 4 order authority instead of Section 4 rulemaking authority."

The phrase "Section 4 order authority" used by the ACC refers to the TSCA amendments anticipated by the ACC, and the phrase "Section 4 rulemaking authority" used by the ACC refers to the current TSCA statute. As stated above, EPA will take appropriate steps, after due consideration and in an appropriate timeframe to revise its regulations and other pertinent documents in accordance with any legislative amendments that are enacted.

Moreover, the change from a "per activity" to a "per-chemical" basis in the response unit is made in order to increase the transparency of the estimate. The number of chemicals is a more intuitive basis with which to scale this unit and has no impact on total burden results. It is merely a different algebraic formulation of the same thing. Formerly, each activity was individually multiplied by the number of chemicals to get the number of burden hours. Under the new response unit definition, the sum of the hours from the related activities is multiplied by the number of chemicals.

3. The new definition makes it difficult to anticipate or understand what costs or activities may be properly considered as part of EPA's estimated 'non-reporting' burden," because EPA "does not estimate the burden of activities taken by companies prior to a Section 4 test rule in determining whether they are obligated to respond. EPA fails to include the burden of activities shouldered by companies that are not respondents even though "burden" under the Paperwork Reduction Act includes companies that do not necessarily submit information to

EPA as part of their obligations to respond to a test rule, but may provide information for EPA to ensure compliance with the test rule.

This ACC comment describes respondent activities that are typically included in ICRs as "compliance determination." EPA assesses the activities as theoretically relevant but so minimal in burden that the estimate is essentially zero (i.e., determining if the chemical(s) of the test rule are manufactured by the one's own firm is part of the respondent firm's resident knowledge). This analytical decision is supported by longstanding practice with repeated OMB approvals via ICR renewals.

Note: as part of this response to comments, and as an additional enhancement for accuracy, EPA is renaming the category "non-reporting costs" to "testing costs" in order to avoid confusion, as all tasks described in the ICR Supporting Statement are required under PRA.

4. EPA's description of "non-reporting administrative costs" does not include "the estimated burden associated with a company's need to review the Section 4 test rule, comprehend its scope, and review chemical formulations to determine the test rule's applicability."

EPA refers ACC to the ICR Supporting Statement, Section 4(b)(ii) under "Document Preparation Activities," item "(a) Review rulemaking and/or participate in ECA or VTA discussions." This categorization as reporting burden and inclusion as a document preparation activity is supported by longstanding practice with repeated OMB approvals via ICR renewals.

Note: EPA is renaming the category "non-reporting costs" to "testing costs" in order to avoid confusion, as all tasks described in the ICR Supporting Statement are required under PRA.

5. EPA does not adequately explain the basis for its assumptions regarding the burden associated with other "non-reporting administrative costs." For example, EPA "flatly assumes that these costs total approximately 25% of only the laboratory costs, without further explaining why the management of a consortium would constitute just 15% of that total, and only 10% would be used to cover the costs of technical experts," when, "[i]n reality, non-reporting administrative costs associated with test rule responses can significantly exceed the estimates provided by EPA" and the costs of managing a consortium vary significantly.

The "non-reporting administrative costs" (now termed "testing administrative costs") are based on a percentage of testing costs. The percentages of 15% and 10% are not meant to reflect the experience of specific respondents, but, rather, are chosen as bases by which a total cost for each category is computed. Individual respondent experiences, therefore, may vary and differ from the bases. This approach is supported by longstanding practice and by repeated OMB approvals via ICR renewals.

6. EPA also revised its methodology and assumptions about the frequency and length of testing activity by assuming that long term studies are three years in duration, but does not explain how or whether that assumption accurately reflects the realities of long-term laboratory testing, and that it will issue significantly fewer test rules per year.

   Also, EPA should explain why long-term studies, which involve a more intensive and frequent analysis of data points as well as continuous recordkeeping and study oversight, do not involve annual burdens greater than short-term studies beyond current estimations.

As presented in Table 3 of the ICR Supporting Statement, the frequency of activities are assessed more accurately via a pro-rated calculation. The change in this ICR renewal involves mapping out activities according to the stated timelines in a coordinated and comprehensive manner. The average annual frequency of the activity is obtained from the overall map of activities over three years. Use of an average annual frequency puts the activity-level unit burdens in the correct units for ICR estimates (hours per year). More specifically, when spread out over three years, the annual burden for three long term studies is lower than that for seven short term studies simply due to the lower number of long term studies relative to short term studies (total of ten tests, as presented in Table 1 of the same document). Note that the assumptions of a three-year period for long term tests and a one-year period for short term test are supported by longstanding practice with repeated OMB approvals via ICR renewals.

After applying updates for e-reporting, this ICR renewal retains, for the most part, the same "per-activity" estimates that are supported by longstanding practice with repeated OMB approvals via ICR renewals. The extended labor associated with long-term testing is incorporated into the unit burden estimates per activity (see Table A in Attachment 3 of the ICR Supporting Statement).

7. EPA's estimate of the overall burden of both short- and long-term studies is drastically lower than in prior ICRs because it has sharply reduced the estimated number of test rules, and chemicals covered by such rules, but the assumption of far fewer test rules has not been explained or justified by the Agency in this renewal and, based on past history, will likely underestimate the burden on companies required to respond.

EPA's estimate is based on recent history. EPA has issued only three test rules, and entered into only one enforceable consent agreement, in the last ten years, and has no immediate reason to predict that this trend will not continue.

8. EPA's assumptions magnify other errors in the Agency' estimates: The Agency's estimated hourly "rate per activity labor" severely underestimates standard industry costs.

EPA uses an hourly basis for respondents conducting corporate and/or laboratory reviews and applies the wage rates published by the Bureau of Labor Statistics (BLS) for manufacturing industries with adjustments for fringe benefits and overhead. The BLS is a reliable government source for providing average wage rates to use in computing overall costs. Therefore, individual respondent wage rates may vary and differ from this basis. EPA's procedure using BLS wage rates is supported by longstanding practice with repeated OMB approvals via ICR renewals.

9. EPA's estimated hours for laboratory and corporate review for short-term studies fails to reflect the real-world hours needed for consultants and consortium members to interact with laboratories, conduct site visits, report on laboratory conditions, review testing protocol, and draft results and reports. With regard to long-term studies, EPA without explanation removes laboratory review from the estimated burden hours, but there is no basis for EPA's implication that long-term studies do not require laboratory review.

As already explained, the activity-level unit burdens for corporate reviews and laboratory reviews are supported by longstanding practice with repeated OMB approvals via ICR renewals. Regarding the inconsistency between short-term and long-term studies with respect to the inclusion of laboratory reviews, EPA acknowledges that both types of studies should include this activity, and is revising estimates accordingly.

10. EPA errs in calculating the burden of the Agency' e-reporting program. The Agency claims that e-reporting through CDX completely removes typing and printing costs for studies of all types. E-reporting may reduce postage costs, but does not obviate the need for member company staff or lab reviewers to type and print materials associated with a testing requirement during interim stages of response activities. Lab work and quality assurance demand the significant use of paperwork, reporting, and tracking. … EPA does not offer a justification or breakdown for the number of hours spent typing or printing interim reports, results, and studies. EPA also maintains that CDX registration only imposes .180 burden hours and the electronic signature .350 hours. … however, the CDX process can be confusing, and requires considerable technical staff time to understand CDX requirements and verify receipt of reports.

For the e-reporting adjustments in this ICR renewal, EPA implemented changes consistent with the e-PMN rule, as described in a footnote in Section 6(a) of the ICR Supporting Statement:

> "The primary effects of the e-reporting rule on burden estimates involve cutting recordkeeping burden to half its paper-based value, eliminating clerical burden in other activities, and adding an activity to account for electronic registration (see EPA 2013b). Additionally non-labor costs are eliminated due to reductions in paper and postage costs. See Table D in Attachment 3 for a comparison of activity level burdens before and after e-reporting."

As shown in the table, given that the activity for "Type and Print Results" is 100% clerical, it is eliminated under e-reporting conditions. Moreover, for the specific unit burdens associated with CDX registration, this ICR renewal uses the most recent OMB-approved estimates of the EPA Section 5 ICR Renewal (OMB Control Number 2070-0012).