VIA ELECTRONIC SUBMISSION

May 16, 2016

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Environmental Protection Agency
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Office of Information and Regulatory Affairs
Office of Management and Budget (OMB)
Attention: Desk Officer for EPA
725 17th Street, NW
Washington, DC 20503

RE: Docket Identification (ID) number EPA-HQ-OPPT-2015-0436: Agency Information Collection Activities; Proposed Renewal of an Existing Collection (EPA ICR No. 1139.11, OMB Control No. 2070-0033)

Dear Sir or Madam:

The American Chemistry Council (ACC) is pleased to submit these comments on EPA's Information Collection Request (ICR) No. 1139.11, noticed in the Federal Register on March 15, 2016 at 81 Fed. Reg. 13790, regarding Toxic Substances Control Act (TSCA) Section 4 Test Rules, Consent Orders, Enforceable Consent Agreements, Voluntary Testing Agreements, Voluntary Data Submission, and Exemptions from Testing Requirements.

ACC represents the U.S. business of chemistry, an $801 billion enterprise and key element of America's economy.[1] ACC's member companies manufacture, distribute, process, import, use, and dispose of chemical substances regulated under the Toxic Substances Control Act (TSCA). As such, our members are obligated to monitor and respond accordingly to any test rule issued by EPA under Section 4 of TSCA, and thus have a significant interest in EPA's action.

[1] ACC's members apply the science of chemistry to make innovative products and provide advanced services that improve health, safety, and quality of life for consumers. The Council is committed to improved environmental, health, and safety performance through Responsible Care®, common sense public policy advocacy, and health and environmental research and testing.

ACC has responded to several past EPA requests for comment on its intended renewal of TSCA Section 4 information collection activities. The current ICR collection request, however, comes at a time when bipartisan legislation to modify TSCA has passed in both the House and Senate, is now in conference, and is likely to gain Congressional approval this year. Once enacted, the legislation will significantly affect the scope of EPA's Section 4 authority and the consequent estimated annual burdens associated with the ICR. For example, EPA is likely to have broader order authority to require the generation of new information – a significant expansion of authority would not require EPA to make the findings now mandated in TSCA Section 4(a). In addition, EPA has underestimated and miscalculated the industry burden associated with the ICR. For these reasons, ACC believes that EPA should withdraw the ICR renewal after ensuring that EPA addresses public comments, modify it appropriately once the modifications to TSCA are made final, and only then submit the ICR to OMB for approval. Alternatively, if OMB approves this ICR renewal, OMB should require EPA to resubmit the ICR request following enactment of TSCA reform legislation.

A. EPA's Should not Overstate Authority for the Collection under TSCA Section 4(a).

The current renewal continues to overstate EPA's scope of authority to require testing under TSCA Section 4.[2] The current ICR Supporting Statement reads:

> Once the Agency has made a finding under TSCA section 4(a)(1), EPA may require any type of health or environmental effects testing necessary to address unanswered questions about the effects of the chemical substance. EPA need not limit the scope of testing required to the factual basis for the TSCA section 4(a)(1)(A)(i) or (B)(i) findings, as long as EPA finds that there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and that testing is necessary to develop the data.[3]

As ACC has commented in the past, this statement enlarges the scope of EPA's authority under Section 4 beyond the plain language of the statute.

EPA should recognize the significant shift in Section 4 authority in TSCA reform legislation and clarify in this ICR that the Agency must ensure testing requirements are *relevant* to the data gaps recognized as part of the Agency's finding under 4(a)(1)(A) or 4(a)(1)(B). Section 4(a) requires that data sought by the Agency in connection with a test rule relate to effects for which there is an insufficiency of data, and must be "*relevant* . . . to the determination . . . [of] unreasonable risk of injury to health or the environment."[4] EPA has maintained since its

[2] ACC made this same point in its October 2000, August 2004, and March 2005 comments on the ICR for TSCA Section 4 information collection activities.
[3] EPA ICR No. 1139.11 Supporting Statement at 4-5.
[4] 15 U.S.C. Section 2603(a) (emphasis added).

1993 Statement of Policy[5] that TSCA authorizes the Administrator to "require any type of health or environmental effects testing necessary to address unanswered questions about the effects of the substance,"[6] but merely repeating this position does not make it so.

ACC agrees that EPA is free to require testing to develop data for a chemical or mixture with respect to its effects, but that data must nevertheless be *relevant to* the Agency's initial, specified findings under 4(a)(1)(A) or 4(a)(1)(B). EPA has only required testing under Section 4 for approximately 200 chemicals in TSCA's 40 years of existence,[7] and Congress has pointed out that EPA's failure to "[identify] specific information needs" in its chemical testing requirements is part of the reason for modifications to Section 4.[8] EPA must establish that there is a reasonable correlation between the type of testing required and the knowledge gaps identified,[9] whether EPA proceeds under its current Section 4(a) rulemaking authority (for both Section 4 "A" and "B" findings), or under the broader order authority contemplated by TSCA reform.

B. EPA's Estimation of the Burden Miscalculates the Cost of Collection and Ignores Relevant Information

With this ICR renewal, EPA revised the methodology it used to estimate the annual burden and costs to industry, but has failed to accurately consider the cost of collection and total annual industry burden as a whole. The Agency's methodology in estimating annual burden has changed in two ways: the definition of "response" has changed, and the Agency has altered some of its assumptions about the frequency and length of testing activity.[10]

EPA proposes to change the definition of "response" under all future testing requirements under Section 4 to mean the collection of related activities involving a battery of an estimated ten tests,[11] all pertaining to one specified chemical.[12] With these changes, all studies and activities performed for the testing of one chemical are now viewed as a single response. This changes the previous definition from a "per-activity" definition to a "per-chemical" one. Notably, this change will have important ramifications should EPA regularly exercise Section 4 order authority instead of Section 4 rulemaking authority.

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. 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. With the new definition, a per-chemical response will include evaluation of all 10 potential tests. In its Supporting Statement for this ICR, EPA states

[5] 58 Fed. Reg. 28736
[6] *Id*. at 28738 col. 3.
[7] S. 697, Rpt. 114-167 (June 18, 2015) at 3.
[8] *Id*.
[9] See, e.g., ACC Comments to EPA ICR No. 1139.07, OMB No. 2070-0033, March 7, 2005.
[10] EPA's decision to do so also magnifies the effect of the Agency's other methodological errors commented on by the Council in prior years.
[11] EPA specifies that it assumes seven short term and three long term tests will be conducted.
[12] EPA ICR No. 1139.11 Supporting Statement at 14-15.

that "non-reporting administrative costs" may include "identifying manufacturers, meetings, organizing payment for testing, developing contracts for testing…"[13] However, EPA's description 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.

In addition to ignoring pre-reporting costs, the Agency does not adequately explain the basis for its assumptions regarding the burden associated with other "non-reporting administrative costs."[14] For instance, EPA flatly assumes that these costs total approximately 25 percent of only the laboratory costs, without further explaining why the management of a consortium would constitute just 15 percent of that total, and only 10 percent would be used to cover the costs of technical experts.[15] In reality, non-reporting administrative costs associated with test rule responses can significantly exceed the estimates provided by EPA. Depending upon the chemicals or mixtures involved, as well as other factors, the costs of managing a consortium vary significantly. For instance, EDSP Tier 1 testing for acetone cost over $155,000 for trade association management, quality assurance, and consortium funding, on top of nearly $670,000 in laboratory costs.[16] EPA's cursory explanations regarding administrative costs do not accurately reflect the true nature of the burden associated with a test rule.

Furthermore, and as ACC noted in our March 2005 comments, EPA fails to include the burden of activities shouldered by companies that are not respondents. Under the Paperwork Reduction Act, "burden" includes the "time, effort, or financial resources expended by *persons* to generate . . . information . . . *to* or *for* a Federal Agency, including . . . reviewing instructions; . . . [and] searching data sources" (emphasis added).[17] This definition therefore 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. It is manifest that many companies will need to determine if they manufacture or import the substances covered, and to determine if they are obligated to respond to the test rule or order. ACC urges EPA to include these costs in future burden estimations.

In this ICR, EPA also revised its methodology and assumptions about the frequency and length of testing activity. The Agency now assumes that long-term studies are three years in duration, and that it will issue significantly fewer test rules per year.[18] EPA explains that it is making this change because in prior ICRs, "long-term study activities were being counted every year, generating an 'over-count' (relative to short-term studies) by a factor of three for the

[13] *Id*. at 17.
[14] EPA states that "non-reporting administrative costs" include 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 for the testing.
[15] *Id*.
[16] EPA ICR Renewal Survey: *Response of the ACC Acetone EDSP Testing Consortium*, October 12, 2012. Scientific consulting fees added another $85,000 to the total consortium costs, and archival costs brought an additional $27,000 future burden (archival costs are incurred over a multi-year period), making the total administrative costs approximately $280,000; about %40 of laboratory costs.
[17] 44 U.S.C. 3503(2).
[18] In prior ICRs, EPA assumed that six test rules, involving 15 chemicals each, would be issued annually.

activity-level burdens of long-term studies."[19] However, EPA does not explain how or whether that assumption accurately reflects the realities of long-term laboratory testing.

The Agency should explain why long-term studies do not involve annual burdens greater than short-term studies beyond current estimations. In our view, long-term studies involve a more intensive and frequent analysis of data points as well as continuous recordkeeping and study oversight. For example, in long-term aquatic studies, labs pull samples multiple times per week to send updates to the lab consultant, and if those samples reveal a problem with the testing environment or protocol,[20] the consultant and the lab must work together to resolve the issue, requiring multiple hours of expert labor. EPA's decision not to further extend the burden estimation of long-term studies, without providing a basis for doing so, is inconsistent with real-world practice and experience.

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. In prior ICR renewals, EPA assumed a total of six test rules annually, involving 15 chemicals each.[21] With this renewal however, EPA assumes that only two test rules will be issued annually, each with an average of 5 chemicals.[22] It may well be that EPA expects to propose far fewer test rules under Section 4, especially if broader order authority is conferred on EPA as a result of legislative modifications to TSCA. But EPA does not note this as its rationale. 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.

Finally, EPA's assumptions magnify other errors in the Agency's estimates. The Agency's estimated hourly "rate per activity labor"[23] severely underestimates standard industry costs. For chemical testing generally, technical and managerial labor used for Laboratory and Corporate Review can cost between $150 and $250 per hour, according to ACC member companies. For instance, lab testing performed by ACC member companies has required, at minimum, lab consulting costs at the rate of $185 per hour. EPA's estimated hours for laboratory and corporate review for short-term studies[24] 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

[19] EPA ICR 1139.11 Supporting Statement at 15 n.7. It is also worth noting that the Agency magnifies its error in failing to include pre-reporting costs in activity-level burden estimations, as the calculations for long- and short-term study costs are based on those burden estimates.
[20] For instance, acceptance criteria require that lab temperatures remain within a certain range, and that a certain number of control organisms have to be alive at the end of a study. If acceptance criteria are not met, the reliability of the study comes under question, and the laboratory may be forced to repeat steps in the process or repeat the study entirely, multiplying the cost to industry.
[21] EPA ICR 1139.11 Supporting Statement at 35, Table 21 n. b.
[22] *Id.*
[23] EPA ICR No. 1139.11 Supporting Statement Attachment 3, Table A. EPA uses this specific terminology in the estimate tables, and the Council understands this to mean the hourly rate of labor charged by staff and professionals working on a response.
[24] *Id.* As well as EPA's assumed 9 hours of corporate review for long-term studies.

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.

EPA also errs in calculating the burden of the Agency's e-reporting program. The Agency claims in this ICR renewal that e-reporting through the CDX program results in a complete removal of typing and printing costs for studies of all types.[25] 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. If the Agency insists that such costs are included in the estimated burden for other collection activities, it does not say so, and does not offer a justification or breakdown for the number of hours spent typing or printing interim reports, results, and studies.[26] EPA also maintains that CDX registration only imposes .180 burden hours and the electronic signature .350 hours. ACC believes, however, that the CDX process can be confusing, and requires considerable technical staff time to understand CDX requirements and verify receipt of reports. EPA therefore does not accurately estimate costs associated with CDX registration and e-reporting.

This ICR renewal anticipates a significant, if not drastic reduction in the estimated annual burden of testing requirements under TSCA Section 4 without adequate factual basis. EPA should revise the ICR renewal to more clearly reflect the authority of existing Section 4 and the likely expansion of that authority to include test orders. The Agency should also revise its estimated burden to account for the definitional changes to its methodology, assumptions about the frequency and length of testing activity, and e-reporting and paperwork burden estimations, particularly with respect to both test rule and test order authority.

ACC appreciates the opportunity to comment. If you have any questions regarding these comments, please feel free to contact me at Richard_Starr@americanchemistry.com, or at (202) 249-6443.

Sincerely,

Richard Starr
Manager
Regulatory & Technical Affairs

[25] *Id.* Attachment 3, Table D.
[26] For instance, ACC member sources indicate that even just 2-year rodent studies can involve 400-500 page reports that review lab protocol and progress, and must be passed back and forth for multiple stages of review between laboratories and reviewers.