Response to Comments Received on the ICR Renewal entitled "Notification of Substantial Risk of Injury to Health and the Environment under TSCA Section 8(e))" (EPA-HQ-OPPT-2015-0744-0003)

Background

Under section 8(e) of the Toxic Substances Control Act (TSCA), "any person who manufactures [including imports], processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA] Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information." (15 U.S.C. 2607(e)).

TSCA section 8(e) continues to be an important and useful tool for early warning and identification of potential substantial risk situations allowing EPA and others to focus their limited resources on chemicals or mixtures of highest concern. The submission of section 8(e) information makes it possible for the Agency and others to learn quickly about potential new chemical hazards/risks posed by exposure to chemical substances, to conduct more complete assessments and, if needed, take effective action to eliminate or reduce such risks in a timely manner.

The ICR is identified by EPA ICR No. 0794.16 and OMB Control No. 2070-0046, and represents the renewal of an existing ICR that is scheduled to expire on February 28, 2017.

The American Chemistry Council (ACC) and the Environmental Working Group (EWG) responded to the Federal Register notice (81 FR 43601, July 5, 2016) announcing EPA's intent to submit the ICR renewal for TSCA section 8(e) to OMB. A summary of their comments and EPA's responses are contained herein.

Public Comments

American Chemistry Council (ACC)

TSCA Section 8(e) Guidance

ACC states that EPA can reduce reporting burdens by updating its guidance to clarify what information EPA considers to be known by the Agency.

TSCA Section 8(e) Website

ACC asks that EPA's website include the previously publicly available TSCA section 8(e) Frequent Questions and add text explaining the availability of TSCA section 8(e) submissions via EPA's Chemical Data Access Tool (CDAT) and ChemView.

Central Data Exchange (CDX)

ACC discusses the burden associated with TSCA section 8(e) submitters' use of EPA's Central Data Exchange (CDX).

Security of Electronic Submissions Containing CBI

ACC recommends that EPA solicit expert advice to achieve state of the art security for electronic submissions that contain confidential business information (CBI).

CBI Security Requirements for Other Federal or State Agencies

ACC recommends that EPA not share CBI with other federal or state agencies unless those agencies can offer and deliver security as required by TSCA section 14(d).

Burden and Cost Estimates

Overall, ACC questions the estimated costs to industry associated with section 8(e) and similar reporting covered in the scope of this ICR renewal. A number of estimates and analytical decisions were challenged, leading to the conclusion that burden and cost estimates are underestimated. ACC states that EPA should update estimates with well-substantiated and updated information.

Environmental Working Group (EWG)

EWG states that it "resoundingly support[s]" EPA's intention to renew OMB approval of its TSCA section 8(e) information collection authority.

Response to Comments

EPA would like to thank ACC and EWG for submitting comments for this ICR. EPA has carefully reviewed the comments submitted and believes that changes to the ICR narrative are not warranted for the following reasons.

Pursuant to section 8(e) of TSCA, manufacturers (including importers), processors, or distributors of a chemical substance or mixture who obtain substantial risk information have an obligation to immediately inform the EPA Administrator of substantial risk information unless they have actual knowledge that the Administrator has been adequately informed of such information. As further specified in Part VII(a) of the June 3, 2003, TSCA section 8(e) Reporting Guidance, any information that can be obtained in its entirety in well-established and well-recognized scientific publications and scientific databases that are available to the public is exempt from reporting under section 8(e) of TSCA. Summaries of studies do not constitute studies in their entirety and do not satisfy the reporting obligation under section 8(e) of TSCA. Therefore, if all pertinent substantial risk information that a company would be required to report to EPA under TSCA section 8(e) is publically available in its entirety in one of these publications or reports, that information would not have to be reported to EPA under section 8(e) of TSCA. If all pertinent substantial risk information is not available in such a publically available publication or report, or if additional substantial risk information related to these publications or reports is later obtained by a company, that further information should be considered for TSCA

section 8(e) reporting to ensure that all section 8(e) reporting obligations are met. Regardless of the U.S. company's involvement in data generated or published, in U.S. or internationally, once a U.S. manufacturer, processor, or distributor of a chemical substance or mixture in commerce in the U.S. obtains TSCA section 8(e) substantial risk information, including data originating from a foreign source, the TSCA section 8(e) reporting requirements apply. Since circumstances under which certain information need not be reported to EPA have not changed, EPA does not have plans to make additional updates to the TSCA section 8(e) guidance at this time.

EPA will republish the frequent questions on EPA's TSCA section 8(e) website. EPA will also update the TSCA section 8(e) website to include links to EPA's Chemical Data Access Tool (CDAT) and ChemView.

ACC acknowledges that for the most part the burden associated with users making TSCA section 8(e) submissions via CDX has been addressed elsewhere [i.e., in other ICRs]. ACC further acknowledges that the burden for new users not already registered with CDX is negligible. ACC made no recommendation with respect to this comment.

A recommendation to enhance the security of Agency computer systems that contain CBI, including but not limited to TSCA section 8(e) submissions, is beyond the scope of the renewal of this information collection. Nonetheless, EPA is fully aware of concerns about computer system security in general and data breaches in particular, and the importance of maintaining and strengthening security of those systems.

The EPA TSCA CBI Protection Manual requires that other federal agencies, in order for their employees to obtain access to TSCA CBI, must have in place security standards that equal or surpass those that apply to EPA employees and contractors. EPA has never received a request for CBI from a state agency. If the Agency were to receive such a request, EPA would provide CBI material to a state agency only if said agency has security standards in place at least equivalent to those required of EPA employees and contractors.

A number of analytical decisions and estimates were challenged without the provision of data to inform an updated revision. EPA asserts that practices have been in place over time and have withstood repeated OMB reviews via ICR renewals. Therefore, the bases for the burden and cost estimates are robust, and the current estimates for this ICR renewal are reasonable.

The item-by-item responses are provided below.

A	**Introductory Section** – ACC states that EPA's BLS labor rates are not reflective of actual labor costs due to senior staff with advanced degrees and multiple PhD degrees.
Response	EPA uses an hourly basis for respondents involved in activities requiring technical, managerial, and clerical labor 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.
B	**Burden to Learn Disaggregated System** – ACC discusses implementation-specific issues that have created inefficiencies.
Response	The methodology for providing e-reporting estimates has been in place in previous ICR

	renewals was unchanged in this renewal. The only change in this renewal is the incidence rate for e-reporting submissions to the basis of 100% e-reporting.
C	**Burden on Small Business** – ACC critiques the statement in impacts of the information collection on small businesses, in particular, "[s]ince there is no routine reporting or recordkeeping provisions for section 8(e), the true burden on most small entities is practically nonexistent."
	The ICR Supporting Statement posted on docket ID number EPA-HQ-OPPT-2015-0744 for the section 8(e) ICR renewal does not include this statement. Note that the small entity flexibility assessment in the ICR Supporting Statement is supported by longstanding practice with repeated OMB approvals via ICR renewals.
D &E	**Submitter Burden Estimate** - ACC states that unit burdens are understated for Section 8(e) – Initial Submission at 49 hours and for the Section 8(e) follow up/Supplemental Submission.
Response	The unit burden estimates for these activities are supported by longstanding practice with repeated OMB approvals via ICR renewals.
F	**Estimated Floor for Burden Estimate** – ACC objects to the low end per- response estimate of 0.5 hours, based on the quote: "the annual public reporting and recordkeeping burden for this collection of information is estimated to range from 0.5 hours to 50 hours per response, depending upon the nature of the response."
Response	The ICR Supporting Statement posted on docket ID number EPA-HQ-OPPT-2015-0744 for the section 8(e) ICR renewal does not estimate a range with a floor. The burden statement is: "The annual public burden for this collection of information, which is approved under OMB Control No. 2070-0046, is estimated to be 50.06 hours per initial section 8(e) submission and 4.06 hours per follow-up/supplemental section 8(e) submission. The same estimates apply to FYI initial and follow-up submissions. For CDX registrations, burden per registration is estimated at 0.53 hours. Burden is defined in 5 CFR 1320.3(b)."
G	**Estimated Burden of FYI Submissions** – ACC agrees that the methodology for estimating FYI submissions as commensurate with 8(e) substantial risk submission, but does not agree with the unit burden estimates for the 8(e) substantial risk submission.
Response	As stated above, the unit burden estimates for activities associated with section 8(e) initial and follow up submissions supported by longstanding practice with repeated OMB approvals via ICR renewals.

EWG did not offer any recommendations with respect to the renewal of this information collection.