



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

OCT 18 2018

MEMORANDUM

SUBJECT: Response to Comment Received on Proposed Renewal of the Information Collection Request for Toxic Substances Control Act Section 8(d) Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies

FROM: Lance Wormell, Acting Director
Chemical Control Division
Office of Pollution Prevention and Toxics

A handwritten signature in black ink, appearing to read "Lance Wormell", written over the "FROM:" field.

TO: Angela Hofmann, Director
Regulatory Coordination Staff
Office of Chemical Safety and Pollution Prevention

Background

On July 25, 2018 (83 FR 35271), the U.S. Environmental Protection Agency published a notice in the Federal Register announcing that it was planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for renewal of the collection of unpublished health and safety studies under the TSCA section 8(d) Health and Safety Data Reporting Rule. The public comment period closed on September 24, 2018. The Agency received one comment.

Public Comment

The EPA received one public comment in response to its proposed renewal of the TSCA section 8(d) ICR. The comment, from the American Chemistry Council (ACC), reiterates support of a tiered information gathering process for prioritization and risk evaluation under TSCA as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. ACC comments that as part of the tiered approach the Agency should use its authority under TSCA section 8(a) and 8(d) to seek additional existing information when necessary. Based on their use of the Agency's authorities the comment concludes that the burden estimate presented by the Agency is too low, "[t]o the extent that EPA begins using its section 8(d) authority more frequently pursuant to the TSCA prioritization process (or for the collection of additional, more refined health and safety information for the risk evaluations of chemicals designated high priority), this

will necessarily add to burden and cost estimates. As a result, the current estimates in this ICR are too low and do not adequately account for the new TSCA prioritization and risk evaluation processes.”

Response

The Agency appreciates the comment regarding the burden estimate of the proposed renewal of the TSCA 8(d) Health and Safety Data Reporting Rule ICR, however, the Agency does not believe a change to the burden estimate is warranted at this time because there is no burden data to support such a change. The Agency bases its estimates for ICR renewals on available burden data and educated forecasts, where applicable. In this ICR renewal, given that EPA has not yet used its TSCA section 8(d) authority to support prioritization and risk evaluation under amended TSCA, the Agency is relying on using existing actual data from past activity to calculate burden.

In the final rulemaking, *Procedures for Prioritization of Chemicals for Risk Evaluation under the Toxic Substances Control Act* (82 FR 33753; July 20, 2017), the Agency indicated that it intends to use a tiered approach to gather information. As a general matter, EPA will first review existing literature and reasonably available information. Then, as necessary for identified information needs, EPA may issue a voluntary call to the public for relevant information or otherwise engage directly with stakeholders, followed, as necessary, by exercise of EPA’s authorities under TSCA to require submission or generation of new information. Depending on the outcome of the early tiers in EPA’s information gathering process, the use of section 8(d) authority will vary. Therefore, the revision of burden estimates is more appropriately addressed in subsequent renewals of this information collection when the Agency will have a better understanding of its actual use of section 8(d) and data to refer to in calculating such estimates.

The following sentence in the Supporting Statement (<https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0646-0002>) has been revised, to better support the current burden estimate: “In addition, EPA will require that copies of unpublished health and safety studies be submitted on chemicals that are being considered for prioritization under section 6 of TSCA or in the early stages of risk assessment or when action to control exposure is being considered by EPA or another federal agency.” It is possible that under amended TSCA the Agency could use its authority under TSCA section 8(d) more frequently, however, the decision to use TSCA section 8(d) will more likely be made on a chemical-by-chemical basis. As such the Agency is revising the sentence to read, “In addition, EPA may require that copies of unpublished health and safety studies be submitted on chemicals that are being considered for prioritization under section 6 of TSCA or in the early stages of risk assessment or when action to control exposure is being considered by EPA or another federal agency.”