



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

SEP 25 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Response to Comments Received on the ICR Renewal entitled "Partial Update of the TSCA Section 8(b) Inventory Data Base, Production and Site Reports (Chemical Data Reporting)" (EPA-HQ-OPPT-2013-0721-0001)

FROM: Maria J. Doa, Director
Chemical Control Division

A handwritten signature in black ink, appearing to read "Maria J. Doa", is written over the printed name and title of the sender.

TO: Angela Hofmann, Director
Regulatory Coordination Staff

Background

Under TSCA section 8(b) (15 USC 2607), the Environmental Protection Agency (EPA) is required to compile and keep current, via periodic inquiry, the TSCA Chemical Substance Inventory (TSCA Inventory). Under TSCA section 8(a), EPA is authorized to collect certain information on chemical substances manufactured (including imported) or processed in the United States. The TSCA Chemical Data Reporting (CDR) rule, codified at 40 CFR 711, collects basic chemical substance manufacturing information for selected chemical substances on the TSCA Inventory. EPA has used the CDR to collect this information seven times beginning in 1986, and to collect additional information relating to the manufacture, processing, and use of those chemical substances, beginning in 2006. The last collection was in 2012 and the next will be in 2016.

The ICR is identified by EPA ICR No. 1884.08 and OMB Control No. 2070-0162, and represents the renewal of an existing ICR that is scheduled to expire on January 31, 2015.

The American Chemistry Council (ACC) and the Society of Chemical Manufacturers & Affiliates (SOCMA) responded to the Federal Register notice (79 FR 29442, May 22, 2014) announcing EPA's intent to submit the ICR renewal for TSCA section 8(b) to OMB. A summary of their comments and EPA's responses are contained herein.

Public Comments

American Chemistry Council (ACC)

Information Collection

ACC stated that to the best of its knowledge, the information collected under the CDR is not available elsewhere to the Agency.

ACC posed questions about the requirements for data submission in the 2016 CDR, specifically concerning the chemical volumes tracked in non-principal reporting years, the tracking/reporting of chemicals which trigger the under-2,500 pounds threshold (e.g., questions on the chemicals and the rule), process and use reporting, and clarifications concerning contract manufacturers/toll manufacturers.

Electronic Reporting and Recordkeeping

ACC stated that it supports the electronic reporting of information under the CDR, but noted that a number of system issues have adversely impacted the functionality of the electronic system. ACC believes these system issues should be corrected ahead of the 2016 reporting period.

Burden Cost Analysis

ACC asserts that the use of average burden estimates tends to dilute the magnitude of the burden for companies with large numbers of chemicals to report. ACC believes the average value used by EPA for number of chemicals per report is significantly below the typical average for ACC companies.

ACC asserts that the reduced volume trigger of 2,500 lbs., applicable to certain chemical substances, requires many companies to develop systems to track all chemicals and develop data on more chemicals than will ultimately be reported, adding to the ongoing burden of developing systems to generate the required information.

ACC questions whether EPA has accurately estimated the burden associated with obtaining information on production volume, especially with respect to imports of mixtures.

ACC asserts that EPA's estimate of the average burden per site is lower than the time spent by most of the ACC companies.

ACC also questions EPA's conversion of the burden estimates for a reporting cycle into an annual burden value, by dividing the burden estimate over the four-year cycle of the CDR. ACC suggests that it would be more accurate to treat the burden estimate as corresponding to just the burden in the principal reporting year itself, and then add to that burden value to account for additional burden in the interim years.

ACC asserts that the time needed to become familiar with the eCDR software does not appear to be adequately reflected in the burden estimates, even for experienced submitters, because modifications to the 2012 CDR software will be required.

Reporting Production Volume for Each Year of Four Years

ACC states that in general, most companies will track the production volume on an annual basis.

Society of Chemical Manufacturers & Affiliates (SOCMA)

Necessity of Information Collection

SOCMA states that since most of the information EPA seeks is specific to a submitter's business, it is not likely available from other offices at EPA, other agencies, or from a public source. SOCMA believes the information can be used to maintain the TSCA Inventory, and that the Agency should be able to use some of the information to help with prioritization.

Enhancing Information Collection

SOCMA asserts that it is often difficult or impossible for manufacturers to know how their chemicals are later being processed or used. Therefore, SOCMA suggested that the information collected under CDR could be enhanced by EPA efforts to poll industrial or commercial downstream entities.

SOCMA asserts that it is important to make clear what information is required, why it is being collected, how it will be used, and to provide plenty of guidance and allow enough time for the company to gather the information and complete the submission.

SOCMA noted that webinars, guidance documents, and training modules associated with 2012 reporting are useful and substantive resources.

Minimizing Burden

SOCMA expressed its support for electronic reporting. SOCMA believes that, overall, electronic reporting has helped to streamline reporting, but raised some technical concerns about the xml submission process, and noted the importance of having a robust technical support staff at EPA available to assist companies.

SOCMA asserts that the time requirements for reporting on imported blends are quite different from the time requirements of commodity manufacturers/importers.

SOCMA asserts that the phase-in of lowered production volumes will substantially increase the number of chemicals to be reported as compared to previous years. SOCMA believes the ICR should take these lower production volumes into consideration.

SOCMA asserted that EPA should demonstrate how it is using the information it collects and ensure electronic reporting is reliable and user friendly.

Response to Comments

EPA would like to thank ACC and SOCMA 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.

The burden estimates presented in the ICR supporting statement are reasonable estimates for the average CDR submitter and EPA recognizes that some sites may have a higher or lower burden. As such, particular circumstances may not be average and, therefore, the estimate may not accurately reflect a submitter's individual circumstances. ACC's comments did not provide an analytical basis or alternate estimate to substantiate claims that the burden for reporting will be, on average, greater than that estimated in the Agency's analysis. If ACC would like to provide additional specific data, EPA would be willing to evaluate and consider these in future burden estimates.

EPA does not believe that it has underestimated the effort to collect, organize, verify, and report CDR data. EPA expects that it is standard business practice to track and appropriately maintain (including organization and verification) records of production volumes and other information for all chemicals manufactured at a given site. Reporting individual chemical volumes within a mixture is not a new requirement. The underlying burden estimates in the ICR are based on an industry survey conducted for the 2002 IUR Amendments and should include the burden associated with determining the volumes of individual chemicals within a mixture, because this was a requirement at the time the survey was conducted.

EPA has accounted for the increase in chemicals and reports that will be submitted as a result of the reduction in the production volume threshold for specific regulated chemical substances from 25,000 lbs to 2,500 lbs. For those chemicals not subject to TSCA regulations, the reporting threshold remains the same as for the 2012 reporting period at 25,000 lbs. EPA has also included estimates for compliance determination that incorporates the estimated burden associated with comparing production volumes of all chemicals to the reporting threshold for chemicals at an average site. Once a submitter has made a compliance determination that it has reporting obligations under the CDR, it can rely on production volume information already reasonably available, in the ordinary course of business, to determine that particular chemical substances do not need to be reported under the CDR.

EPA has also analyzed the potential impacts of the reduction in the production volume threshold for reporting processing and use information from 100,000 lbs to 25,000 lbs to all submitters, including potential burden to small businesses. EPA recognizes that reducing the reporting threshold for processing and use information increases the reporting burden, however it does not increase the number of chemicals and reports submitted.

ACC's comments did not provide an analytical basis or alternate estimate to substantiate claims that it would be more accurate to develop annual burden values by a different methodology. If ACC would like to provide additional specific data, EPA would be willing to evaluate and consider these in future burden estimates.

EPA expects to modify the CDR reporting tool for 2016 reporters to make it more user friendly and would therefore, expect some reductions in burden for those reporters. EPA also acknowledges that with any new or revised system, industry could incur some burden associated with testing and ensuring data compatibility with the reporting tool. However, EPA has no way to estimate the burden for these activities nor for the tradeoffs between anticipated burden

reductions and potential burden increases. ACC did not provide any analytical basis from which EPA could develop such an estimate.

EPA appreciates the comments received regarding clarification of the data submission requirements and improvements to the electronic reporting process. EPA is currently working to update and improve the guidance documents and electronic reporting system for the 2016 CDR reporting cycle.