



November 1, 2021

Ms. Niva Kramek
Existing Chemicals Risk Management Division (7404T)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, D.C. 20460-000
Kramek.niva@epa.gov

RE: Comments of the American Chemistry Council on the Agency's Information Collection Activities; Proposed Renewal of an Existing Collection and Request for Comment; Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a), 86 Fed. Reg. 48700 (Aug. 31, 2021); Docket No. EPA-HQ-OPPT-2021-0303; FRL-8753-01-OCSPP

Dear Ms. Kramek:

The American Chemistry Council (ACC)¹ is pleased to submit these comments on the Environmental Protection Agency's (EPA) Information Collection Activities; Proposed Renewal of an Existing Collection and Request for Comment; Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a).

The chemical industry is committed to helping EPA meet its goals to enhance the quality of information available on chemicals in commerce. As part of the EPA's efforts to improve manufacturing data recording and reporting, it is important that the EPA consider industry's burden under current program requirements. For this Information Collection Request (ICR), EPA has requested comments on four topics: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (2) the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumption

¹ The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier, and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a \$486 billion enterprise and a key element of the nation's economy. It is among the largest exporters in the nation, accounting for ten percent of all U.S. goods exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.



used; (3) the quality, utility, and clarity of the information to be collected; and (4) the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other forms of informational technologies, e.g., permitting electronic submission response.

A. Necessity and Practical Utility of the Proposed Collection of Information

Although ACC and its members generally support the necessity of the downstream notification, we question the practical utility of the regulation.² As written, the downstream notification section of the Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a) rule (Rule) requires that “[E]ach person who manufactures, processes, or distributes in commerce methylene chloride for any use after August 26, 2019 must, prior to or concurrent with the shipment, notify companies to whom methylene chloride is shipped, in writing, of the restrictions described in this subpart...”³ EPA’s failure to set a de minimis threshold extends the impact of the regulation to products that may contain trace amounts of methylene chloride as an impurity or byproduct. EPA should consider the added monitoring and tracking burden incurred by stakeholders for trace amounts of methylene chloride in its estimates. EPA should reconsider the practical utility of the downstream notification requirement for cases where accounting for methylene chloride presence at such a low concentration would only provide minimal, if any, benefit.

B. EPA’s Methodology and Assumptions are Flawed; The Burden Estimate is Inaccurate

Methodology and Assumptions are Flawed

The methodology used and assumptions made by EPA for estimating the burden associated with compliance of these regulations is flawed and, therefore, the burden is underestimated. As mentioned above, without a de minimis reporting threshold, the requirement for downstream notification requirement applies to **all** manufacturers and processors of methylene chloride, including cases where methylene chloride may be present in trace amounts as an impurity or byproduct. As noted in EPA’s Supporting Statement, the data source used by EPA for creating its burden estimates for this ICR is based on data submitted to EPA through its Chemical Data Reporting (CDR).⁴ This methodology is flawed because, unlike this regulation, CDR does not require reporting of chemical data that: is manufactured at less than 25,000 lbs. per site per year; or is manufactured at less than 2,500 lbs. per site per year if subject to a certain TSCA actions; or if the chemical is an impurity or byproduct.⁵ By relying only on CDR data for its methodology to calculate the burden, EPA’s method does not capture the stakeholders that may be burdened by this reporting requirement that fall outside these requirements.

To accurately account for the manufacturers and producers that are required to comply with these regulatory requirements, EPA must adjust its estimate upward to account for reporting by companies manufacturing methylene chloride as an impurity or byproduct. ACC estimates annual burden hours would be between 14 and 36, costing between \$1,115 and \$2,927 – a significant

² 40 CFR § 751.107

³ 84 Fed. Reg. 11420 (Mar. 27, 2019)

⁴ EPA Supporting Statement, Renewal of Existing Information Collection Request for Confidentiality Rules, p. 10.

⁵ 40 CFR §711.8 and §711.9



increase from EPA's annual estimate of 6.96 hours and \$298. This estimate differs from EPA's in that it includes firms that produce other chlorinated methanes (chloroform, methyl chloride, and trichloroethylene), and the range reflects uncertainty regarding the number of manufacturers, importers, and processors based on 2016 CDR information. Although these calculations might not account for the manufacturers, importers, and processors that intentionally add methylene chloride in small amounts, it is a more accurate burden estimate than the one currently proposed by EPA.

Regulatory compliance considerations

EPA should consider another issue complicated by the lack of a de minimis reporting threshold for risk management regulations and the corresponding obligation created by monitoring and tracking trace amounts. EPA notes in its Supporting Statement that this reporting is a "one and done" reporting requirement or that there is "no recurring reporting obligation," believing most manufacturers completed the obligation during the first ICR.⁶ Taking that assumption into account, EPA reduced the amount of methylene chloride manufacturing sites from 19 to 14. While this addresses manufacturers and processors of products intentionally containing methylene chloride, it may not accurately reflect those manufacturers and processors where methylene chloride is present as an unintentionally added impurity or byproduct in trace amounts. For many of these stakeholders, the process remains straightforward: they either receive the information from their raw material supplier, or the stakeholder is the manufacturer of the product and have the information firsthand. The stakeholders must continue to monitor these products to confirm the information remains accurate, that the raw material suppliers do not change, and update the Safety Data Sheets (SDS) accordingly, should changes occur. However, for stakeholders reporting de minimis values, this is not a "one-time burden." There are additional burdens imposed on stakeholders to remain in compliance with these regulations that are not accounted for in either EPA's methodology or its burden estimates.

EPA should amend its methodology and its underlying assumptions so that the burden estimates are accurately assessed or reconsider incorporating a de minimis threshold to align with the Occupational Safety and Health Administration (OSHA) carcinogenic reporting threshold of 0.1%, prior to submitting this ICR to the Office of Budget and Management (OMB) for final review.

C. Enhancing the Quality, Utility, and Clarity of Information Collected

To better enhance the quality, utility, and clarity of the information collected for this risk management rule and those in the future, EPA should consider reopening the Rule to incorporate a de minimis threshold to align with the OSHA carcinogenic reporting threshold of 0.1%. Should EPA not incorporate a de minimis reporting threshold aligned with OSHA, EPA should revise its methodology for calculating burden estimates to accurately capture the full spectrum of stakeholders affected by the regulation.

EPA is embarking on the risk management phase of TSCA on many, or all, of the first ten High-Priority Substances, including methylene chloride. EPA should consider the implications of not including de minimis thresholds in its risk management rules (and other lessons learned) when moving forward in all future risk management actions.

⁶ EPA Supporting Statement, pages 3-4, 5, 10



D. Minimizing Burden Collection

While reopening the Rule to incorporate a de minimis threshold may require some effort on EPA's part, it would be the most efficient and effective approach in the long-term to rectify the apparent oversight in the original rulemaking. Alternatively, but less effectual, EPA should revise the burden estimates, the methodologies for calculating the burden estimates, and the assumptions to include the compliance burden met by manufacturers, importers, and processors of methylene chloride that are present at trace amounts, either intentionally or unintentionally as impurities and byproducts.

E. Conclusion

In its proposed ICR renewal, EPA has relied on outdated, inaccurate, and incomplete data and information to develop its burden and cost estimates to renew its ICR on methylene chloride. As a result, the data and information should not be relied upon to support the ICR on methylene chloride regulation of paint and coating removal for consumer use under TSCA Section 6(a). Prior to renewing this ICR, EPA should work with stakeholders to discuss the noted issues and concerns. This ICR will not expire until May 31, 2022, and thus provides stakeholders and the Agency adequate time to work together to resolve these issues.

ACC appreciates the opportunity to comment. If you have any further questions regarding these comments, please feel free to contact me at Kat_Gale@americanchemistry.com.

Sincerely,

Kat Gale

Kat Gale
Manager, Regulatory & Technical Affairs

