October 24, 2025

Submitted to: **Regulations.gov, Docket ID EPA-HQ-OPPT-2021-0303**

Katherine Sleasman
Office of Program Support (7602M)
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
1200 Pennsylvania Ave., N.W
Washington, DC 20460-0001

Re: Re: Agency Information Collection Activities; Proposals, Submissions, and Approvals: Consolidation of Methylene Chloride; Regulation under TSCA § 6(a). 90 Fed. Reg. 41391-92 (August 25, 2025). EPA ICR No. 2556.04 OMB Control No. 2070-0204.

Dear Ms. Sleasman:

The American Chemistry Council (ACC) appreciates the opportunity to submit the following comments to the U.S. Environmental Protection Agency (EPA) regarding renewal and consolidation of several existing approved Information Collection Requests (ICRs) under the Paperwork Reduction Act concerning the regulation of methylene chloride under Section 6(a) of the Toxic Substances Control Act.

As part of our comments, ACC requests that EPA change its burden estimate for the ICR and reconsider certain aspects of the rule to eliminate duplicative and overlapping requirements between the long-standing OSHA standards and the EPA rule.

If you have any questions or need further clarification on our comments, please feel free to contact me at Paul_DeLeo@americanchemistry.com or 202-249-6415.

Sincerely,

Paul C. DeLeo

Paul C. DeLeo, PhD
Senior Director

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Comments of the American Chemistry Council to the U.S. Environmental Protection Agency Regarding Potential Renewal and Consolidation of Several Existing Approved Information Collection Requests Regarding the Regulation of Methylene Chloride Under the Toxic Substances Control Act.

October 2025

EPA-HQ-OPPT-2021-0303

submitted to https://www.regulations.gov.

I. Introduction

In a notice in the Federal Register, the U.S. Environmental Protection Agency (EPA or Agency) solicited comments on potential renewal and consolidation of several existing approved Information Collection Requests (ICRs) under the Paperwork Reduction Act being proposed to the Office of Management and Budget regarding the regulation of methylene chloride under Section 6(a) of the Toxic Substances Control Act (TSCA).

The American Chemistry Council (ACC) provided comments in November 2021 on an existing ICR regarding regulation of methylene chloride in 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).[1]

Here we provide responses to the EPA request for comments and information regarding the ICR consolidation and renewal below.[2] A summary comparison of the annual burden estimated by EPA to that reported by ACC members illustrates significant shortcomings in EPA's analysis (see Table 2 below).

ACC requests that EPA change its burden estimate for the ICR after considering the information from our members that we are providing. In addition, ACC requests that EPA reconsider certain aspects of the rule to eliminate duplicative and overlapping requirements between the long-standing OSHA standards and the EPA rule.

[1] https://www.regulations.gov/comment/EPA-HQ-OPPT-2021-0303-0005
[2] 90 Fed. Reg. 41391, August 25, 2025.

II. EPA Questions

A. EPA requested comments and information to enable it to evaluate whether the proposed collection of information is necessary for the proper performance of Agency functions, including whether the information will have practical utility.

ACC does not believe the information requested is necessary for the proper performance of EPA functions.

In June 2020, EPA released the final risk evaluation for methylene chloride determining that most of the conditions of use (COUs) associated with occupational settings presented an unreasonable risk of injury to human health. The final methylene chloride rule[3] was intended to address those unreasonable risks, however, the final rule duplicates existing regulations, is misaligned with existing regulations and is based on a risk evaluation that is seriously flawed.

1. *The proposed collection of information is duplicative and therefore unnecessary.*

Methylene chloride is the subject of a detailed occupational health standard in regulations from the Occupational Safety and Health Administration (OSHA) that require numerous systems and controls to limit exposure to methylene chloride below the permissible exposure limit (PEL) identified in the standard (29 CFR § 1910.1052).

2. *The proposed collection of information is misaligned with other existing collections of information and therefore counterproductive.*

The EPA methylene chloride regulation (40 CFR 751 Subpart B) duplicates portions of the OSHA regulations, but it is not aligned with others. As such, it imposes additional unnecessary costs to navigate the misalignment with no additional benefit to the regulated entity or the American public. For example, the responsible party in the OSHA regulations is the employer while the responsible party in the EPA regulations is the owner or operator. Consequently, each potentially regulated employer, owner or operator of a site must clarify responsibilities for the duplicative regulations.

[3] 89 Fed. Reg. 39254, May 8, 2024.

3. *The findings of the underlying risk evaluation of methylene chloride are inaccurate, therefore the regulation of methylene chloride for many conditions of use is unnecessary and the information collection unnecessary.*

ACC commented repeatedly to EPA regarding the flaws associated with the risk evaluation for methylene chloride and the findings of unreasonable risk. For example, TSCA Section 6(b)(4)(F)(iv) requires EPA to "take into account, where relevant, the **likely** duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance" (emphasis added). However, many of the exposure estimates associated with the risk evaluation and the findings of unreasonable risk are based on assumptions of *highly unlikely* duration, intensity, and frequency of exposures. Moreover, those findings of unreasonable risk are often based on assumptions of a workplace with no exposure controls and out of compliance with OSHA regulations. In determining whether unreasonable risk is presented, EPA's consideration of occupational exposure scenarios should consider reasonably available information on the implementation and use of occupational exposure control measures such as engineering and administrative controls and personal protective equipment.

B. EPA requested comments and information to enable it to evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

ACC conducted a survey of its members to understand the burdens associated with complying with the requirement of the Workplace Chemical Protection Program (WCPP) for COUs that are not prohibited. We received responses to our survey from 12 ACC member companies related to eight COUs for which they were planning to develop a WCPP (Table 1).

Table 1. Number of ACC survey respondents compared to EPA economic analysis. [4]

Use Category	Condition of Use	Number of Facilities*	Number of Workers*	ACC Member Respondents
Manufacturing	**Manufacturing**	6	533	3
Processing as a reactant	**Processing** as a reactant	35	703	3
Incorporation Into Formulation, Mixture or Reaction Product	**Processing**: Incorporation into a formulation, mixture, or reaction product	54	310	1
	Industrial and commercial use as solvent that becomes part of a formulation or mixture			
Waste Handling, Disposal, Treatment and Recycling	**Processing:** Recycling	1,091	7,493	1
	Disposal			
Laboratory Use	**Industrial & commercial use** as a lab. chemical	56	183	8
Processing Aid, Plastics Manufacturing, and Solvent Welding	**Industrial & commercial use** as processing aid	44	352	3
	Industrial and commercial use as a solvent that becomes part of a formulation or mixture…			1
	Industrial and commercial use for plastic and rubber products manufacturing			1
	Industrial or commercial use as a bonding agent for solvent welding			

We compare burdens that our members reported to those found in the economic analysis.

Table 2. Comparison of EPA average annual burden estimate with burden reported by ACC members.

	Average Annual Burden per Respondent	
Compliance Activity	**Agency Estimate[5]**	**ACC Member Reported**
Rule Familiarization (WCPP)	1 hr	hundreds of hours
Downstream Notification (SDS)	0.66 hr	<8 hr up to 50 hr
Respiratory Monitoring	7 hours + $708[6] ($258/worker)[4]	($230 to $290 per sample)
Respiratory Recordkeeping	2.9 hr	<8 hr to 480 hr
Respiratory Notification	0.28 hr	1 - 60 hr per monitoring event
Exposure Control Plan	N/A	<8 hr to 480 hr
Training	N/A	<8 hr to 400 hr
Engineering Controls	N/A	$100,000's to $1,000,000's

[4] USEPA. 2024. Economic Analysis of the Final Regulation of Methylene Chloride Under TSCA Section 6(a), Table ES-2. https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0465-0420.

[5] Supporting Statement for an Information Collection Request for Methylene Chloride Regulation Under TSCA Section 6(a), available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0303-0010.

[6] Non-labor costs

We received responses to our survey from 12 ACC members. One company reported employing 500 to 1,000 workers in the United States, four reported employing 1,000 to 5,000 workers, four reported employing 5,000 to 10,000 and three reported employing over 10,000 workers. Members reported that they expect to implement a WCPP under the Methylene Chloride Rule for eight specific COUs noted in Table 1 above. Those eight COUs involve specific manufacturing, processing and industrial or commercial uses. However, EPA reported a relatively limited number of facilities involved in those Use Categories (compared to other Use Categories, e.g., Furniture Refinishing, Aerosol Spray Cleaning/Degreasing). While we cannot say whether our members are definitively representative of any Use Category or COU, we note, for example, that the economic analysis estimates six facilities involved in manufacturing of methylene chloride and we received responses from three members, some of whom have multiple facilities.

1. *EPA's estimates of costs associated with a WCPP are inaccurate across use categories.*

In its Cost Analysis chapter of the economic analysis (Chapter 7), EPA focuses on five Key Quantified Elements:

- Costs of rule familiarization and downstream notification (Section 7.5)
- Costs of the prohibition of products containing methylene chloride (Section 7.6)
- Costs of the prohibition of methylene chloride for vapor degreasing (Section 7.7)
- Costs for switching to alternatives to methylene chloride as a processing aid (Section 7.8)
- Costs of a Workplace Chemical Protection Program (Sections 7.9, 7.10 and 7.11)

Since our survey was focused on the burdens associated with permitted COUs subject to a WCPP, we will only discuss the first and last bulleted items, costs of rule familiarization and downstream notification (Section 7.5), and the cost of developing and implementing a WCPP (Sections 7.9, 7.10 and 7.11).

a. Rule Familiarization and Downstream Notification

The greatest discrepancy estimates of level of effort (staff time) between EPA's economic analysis and member responses is rule familiarization. The economic analysis states:

> *The 6,483 facilities with PRA burdens and costs associated with a WCPP or other respiratory protection requirements are assumed to incur an initial cost of $214* [per facility] *for a 3-hour burden associated with rule familiarization*. (Page 10-14).

Our members told us their organizations were spending hundreds to thousands of hours of staff effort to understand and implement systems to comply with the regulations. Respondents to our survey said:

- *100's of hours of talking about the new rule and deadlines to different levels of the organization funding exposure assessment, providing feedback, etc…*
- *Approximately 400 hours*
- *Compliance with TSCA risk management regulations is a shared responsibility across various functional groups of the company, including but not limited to industrial hygiene, product stewardship, technical services, transportation, facility/plant staff, government affairs, legal, etc. Estimated level of staff effort exceeds 2080 hours, across company functional groups.*
- *Other workload impacts not included in the survey included the following: Review of new rule to understand content and applicability; Development of internal Standard outlining requirements and actions needed for compliance; Development of tools and templates to support implementation; Identification of impacted work groups and existing exposure data; Multiple communications with impacted workgroups to ensure understanding of implementation actions and track progress; and Development new training content. The estimated hours for this work is about 700 hours.*

As noted above, the duplication and lack of alignment with the OSHA standard for methylene chloride makes compliance with the regulations (and associated collection of information) particularly challenging. Our members are spending tens of thousands of dollars more on staff hours than the costs estimated by EPA simply to understand the path to compliance within their organizations.

With respect to downstream notification, the economic analysis states:

> *Each person who processes or distributes in commerce methylene chloride or methylene chloride-containing products for any use must, prior to or concurrent with the shipment, notify companies to whom methylene chloride is shipped, in writing, of the restrictions on its use. It is assumed that 32 respondents (manufacturers, import, and repackage facilities) accomplish this by modifying the SDS to note the restrictions and the burden associated with the downstream notification requirements, including the related recordkeeping, is 2 hours, with an associated labor cost of $189.* (Page 10-14)

Respondents to our survey said:

- *Estimated 20 hours per quarter.*
- *Company estimates staff hours to update affected SDSs are 50 hours.*
- *Production estimates 8 hours; Labs none/not applicable*

Several respondents noted that downstream notification was not applicable for the laboratory use condition of use. However, two respondents suggested that there may be monitoring and training burdens associated with downstream notification though it was not clear who might bear such a burden.

b. Exposure Monitoring

The economic analysis estimated that the costs associated with an exposure monitoring of ten workers sampled were $3,005 (Table 7-49) based on a fixed cost of approximately $423 and a variable cost per worker of $258 (Table 7-50).

Ten of twelve respondents indicated for initial monitoring that they expected to collect and analyze <50 samples (5 respondents), 50 – 100 samples (2 respondents) or 200 – 300 samples (3 respondents). The following internal staff effort was reported among respondents: 8-12 hours (for each of two lab sites), 9-18 hours per task (each task was monitored 3-6 times and each instance required about 3 hours of IH time), less than 20 hours, 30 hours, 50 hours, 60-80 hours (15-20 hours/quarter), 100 hours, 135 hours, 360 hours, and 600 hours. Presumably, increased level of effort is associated with increased sample collection, and it suggests that 1-2 hours of internal staff time is required for each sample collected. Collection of samples associated with laboratory use appeared to be the least burdensome.

In addition, members reported the following external costs associated with initial monitoring for things like hiring consultants and the cost of the analytical lab: less than $2,000, $4,000, $10,000 – $15,000, $11,000, $15,000, $20,000, $28,000, and $34,000 ($14,000 for a consultant and $20,000 for method development). Again, presumably, increased external costs are associated with increased sample collection.

The estimate of cost per worker in the economic analysis ($258 per worker) appears comparable to what our members are experiencing on a <u>cost per sample</u> basis (approximately $230 to $290 per sample) if sample collection is strictly one per worker.

The biggest discrepancies between the Cost Analysis from the economic analysis and actual costs appear to be regarding the number of affected facilities and workers. For example, the economic analysis estimates that there are only 56 facilities and 183 workers for the Laboratory Use category who would be affected by the new regulations when we

know there are hundreds of laboratories (maybe thousands) and thousands of workers and other individuals (e.g., students) that are likely among those potentially exposed to methylene chloride in a laboratory setting. For the conditions of use with the highest number of potentially exposed workers (manufacturing and processing as a reactant), the average number of workers per facility reported in the economic analysis are 89 and 20, respectively,[2] and yet at least four of our members tell us they are collecting 50 – 100 samples or 200 – 300 samples. Likewise, for the four other conditions of use that our members indicated were relevant to their facilities, the average number of workers per facility ranges from 3 – 8 which appears to be much lower than the number of samples our members are collecting for those COUs if they are collecting only one sample per worker on average.

c. *Notifications and Recordkeeping*

The economic analysis used an OSHA estimate to approximate the **notification** burden for employers:

> *OSHA estimated that it will take a human resources manager 15 minutes per sample (i.e., per employee being monitored) to provide the required recordkeeping for exposure monitoring, which includes recording the sampling results and notifying the employee of the sampling results.* (P. 7-85)

ACC members noted variable levels of effort associated with notifying employees: less than 1 hour, 8 hours per monitoring event, 18 hours, 20 hours, 25 hours, about 60 hours, and 96 hours (24 hours per quarter). One member noted the many tasks associated with notifying employees:

- prepare individual letter(s),
- document notification,
- prepare anonymized posting for others in same similar exposure group (SEG), and
- maintain record of all in SEG.

The economic analysis used an OSHA estimate to approximate the **recordkeeping** burden for employers:

> *OSHA estimated that it will take 4 hours for small employers (those with fewer than 20 employees) and medium employers (those with between 20 and 499 employees) and 8 hours for large employers (those with 500 or more employees) to develop the program and provide the appropriate recordkeeping.* (P. 7-85)

ACC members indicated levels of effort associated with the new recordkeeping requirements that are generally higher than those estimated in the economic analysis:

- <8hours per year
- 24-30 hours of staff work
- 5-10 hours per site; approximately 30 hours for the company
- 40 hours per year
- 48 hours total: 16 hours per year for each of three sites
- 60 hours
- 40 hours per month (480 hours per year)

d. Exposure Control Plan

The methylene chloride regulations require that the WCPP include the development and implementation of an exposure control plan (ECP). The economic analysis does not contemplate this activity. ACC members provided the following estimates for preparation of an exposure control plan:

- less than 8 hours (one time)
- 10 hours each for internal lab ECP
- 48 hours total: 16 hours for each of three sites
- 50 hours
- 60+ hours (one production site)
- Approximately 80 hours (two responses)
- Estimated 135 staff hours.
  - Drafting and reviewing the plan
  - Necessary reviews, revisions, and approvals and
  - Employee acknowledgement and associated training.

e. Exposure Controls

Respondents indicated that the might implement a variety of engineering controls, administrative controls (especially training), and application of new personal protective equipment (PPE) to comply with the WCPP. EPA's economic analysis and ICR supporting statement only considers (PPE).

i. Engineering Controls

The EPA's economic analysis did not consider potential engineering controls installed to meet the requirements of the WCPP. Five respondents described plans and associated costs for engineering controls to be included or already installed in their facilities:

- *$ 15,000 monitors installed + estimated 50 -100 hours/quarter.*
- *Some facilities could alter some equipment which may cost $150,000.*
- *Design and installation of engineering controls: Estimated $605,000 and 160 staff hours. These estimates are not inclusive of tariffs that could be as high as 39 percent of total equipment costs.*
- *Already invested and completed over $0.8 million USD since the WCPP into effect.*
    - *1) Scrubber drains with enclosures (est.3000 ft) - completed*
    - *2) Re-located the QA labs to upgraded ventilation and fume hood labs - completed*
    - *3) Installation of improved design Sampling Pots (Minimum to zero emission) – completed*
    - *4) Installed more than 100 Air monitors with alarms*
- *New engineering controls for sampling points and equipment draining: $6,700,000 for equipment installation. Annual costs associated with the new equipment has not been estimated.*

ii. Training

The economic analysis and supporting statement only consider minimal training (one hour per employee per year) associated with dermal PPE. Only three respondents indicated that they would implement new dermal protection and associated training with their WCPP. However, eight respondents noted new training burdens associated with their WCPP beyond training on dermal protection:

- Approximately 1-8 hours of additional training
- <8 hours (one time) for training development
- 16 hours for WCPP-related training
- 24 hours (8 hours per year, 3 times per year), not included needed documentation
- 25 hours in training development plus 55 hours of training deployment initially
- About 130 hours
- 400 hours (200 hours per site annually X two sites)

One respondent stated more generally “Existing training programs on methylene chloride, respiratory protection, PPE, need to be revised to incorporate EPA references. Additional people will require training.”

iii. Personal Protective Equipment

The methylene chloride regulations require that the WCPP include respiratory protection for all persons potentially exposed to methylene chloride above the ECEL or ECEL STEL. One of the challenges with respiratory protection to methylene chloride is that conventional cartridge respirators are not sufficiently effective, so supplied air is necessary which is much more expensive to provide. The economic analysis estimates initial costs of supplied air of approximately $1,350 to $1,500 and recurring costs of $800 – $900 per year.

The costs for respiratory protection to methylene chloride estimated in the EPA economic analysis seem realistic. Only two respondents to the ACC survey indicated that they expected to implement new respiratory PPE in order to comply with the regulations. Those respondents provided the following estimates of costs:

- For regulated areas and supplied air requirements estimated staff resources are 110 hours with an estimated cost of $10,000.
- Estimating $25,000.

One additional respondent noted that they would need to provide gloves that are chemically resistant to methylene chloride with activity-specific training where dermal contact with methylene chloride is possible. As such, the respondent noted the following level of effort: *Glove trials with users to ensure selection of appropriate gloves for various tasks, stocking of new gloves, updating PPE Grids and procedures. Estimate about 120 hours*.

2. *Summary of EPA estimates of costs associated with a WCPP compared to ACC member survey.*

The costs estimated by EPA to implement a WCPP for methylene chloride are inaccurate because, while some key elements are accurately characterized, others underestimate the needed level of effort or the number of entities that will implement them. In addition, there are key elements that are completely missing.

- EPA's estimate of per worker costs associated with initial and recurring monitoring appear to be consistent with costs ACC members have incurred or expect to incur provided only one sample per worker is necessary. Likewise, the costs associated with application of supplied air respirators as personal protective equipment which are an expensive option appear to be accurate.

- EPA's Cost Analysis for rule familiarization, worker notification, downstream notification, and recordkeeping are significantly underestimated particularly with respect to the cost of firms trying to understand how to comply with the EPA regulations which are duplicative and misaligned with the OSHA methylene chloride standard, other OSHA standards and current industrial hygiene practices.
- EPA's Cost Analysis does not consider costs associated with development of the exposure control plan, training, engineering controls, and process changes that companies might implement to reduce potential exposures to workers. Planning and implementing engineering controls can require hundreds of thousands of dollars of capital and take years to complete.

C. EPA requested comments and information that will enable it to enhance the quality, utility, and clarity of the information to be collected.

As noted above, ACC believes the easiest way to enhance the quality, utility and clarity of the information collected under EPA regulations is to align EPA regulations with OSHA regulations, in this case, the OSHA standard for methylene chloride.

D. EPA requested comments and information that will enable it to minimize the burden of the collection of information on those who are to respond.

Again, ACC believes the easiest way to minimize the burden of the collection of information on those who are to respond is to align EPA regulations with the existing OSHA standard for methylene chloride. Any firm that can document it is following the OSHA standard for methylene chloride should not have to implement additional controls, recordkeeping, or notification. With respect to the difference between the OSHA PEL for methylene chloride (25 ppm as an 8-hr time weighted average (TWA)) and ECEL (2 ppm, 8-hr TWA), firms should not be required to collect new monitoring information at a lower detection limit if they can show through statistical analysis of their existing data that the **likely** air exposure concentration is at or below the ECEL. In addition, since the ECEL was derived based on an assumption of daily exposure **frequency** of 260 days per year for 40 years, and exposure **duration** of 8 hours per day, EPA should make clear that for firms meeting the OSHA standard but having air concentrations exceeding the ECEL, the WCPP is met provided that the frequency and duration of worker exposure are significantly below that used to calculate the ECEL (i.e., 8 hours per day, 260 days per year for 40 years).

III. Conclusion

EPA needs to amend its ICR for Regulation of Methylene Chloride under TSCA Section 6(a) to include all relevant elements associated with compliance with the rule, accurate estimates of the number of responses, the time spent, and additional costs incurred by each respondent *before* it is resubmitted to OMB. In addition, EPA should reconsider the methylene chloride regulations under 40 CFR 751 Subpart B and eliminate unnecessary duplication or misalignment with other existing regulations including the long-standing OSHA standards.