



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA-HQ-OPPT-2020-0465; FRL-8155.1-01-OCSPP]

RIN 2070-AL28

Methylene Chloride; Regulation under the Toxic Substances Control Act (TSCA); Compliance

Date Extensions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is proposing to extend the compliance date applicable to certain entities subject to the regulation of methylene chloride recently promulgated under the Toxic Substances Control Act (TSCA). Specifically, EPA is proposing to extend by 18 months the Workplace Chemical Protection Program (WCPP) and the associated recordkeeping compliance dates for laboratories that are not owned or operated by agencies or Federal contractors acting on behalf of the Federal government. Under this proposal, all laboratories, whether federal or not, would have the same compliance dates, which would be aligned with current compliance dates for Federal agencies and Federal contractors. EPA is proposing to extend the compliance dates for associated laboratory activities detailed in this proposal to avoid disruption of important functions such as the use of environmental monitoring methods needed for cleanup sites and wastewater treatment, as well as activities associated with university laboratories. The use of environmental monitoring methods, a common function of non-federal laboratories, is important to EPA's mission to ensure that the air is safe to breathe, water is safe for drinking or recreating, and disposal activities protect the environment.

DATES: Comments must be received on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0465, using the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets/>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Daniel Whitby, Existing Chemicals Risk Management Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-0598; email address: MethyleneChlorideTSCA@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this rule if you use methylene chloride in a laboratory setting for the following activities; the industrial or commercial use of methylene chloride in a laboratory process or in specialized laboratory equipment for instrument calibration/maintenance; chemical analysis, chemical synthesis, extracting and purifying other chemicals; dissolving other substances; executing research, development, test and evaluation methods; and similar activities, such as use as a solvent, reagent, analytical standard, or other experimental use. For the purposes of this proposed rulemaking, EPA emphasizes that industrial and commercial use of methylene chloride as a laboratory chemical applies to all laboratories, including industrial, commercial, academic and research laboratories, except for those laboratories owned or operated by a Federal agency or a Federal contractor acting on behalf of the Federal government for research, government, and academic institutions. Under the following list of North American Industrial Classification System (NAICS) codes, potentially affected entities may include:

- Testing Laboratories (NAICS code 541380);
- Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology (NAICS code 541715);
- Hazardous Waste Treatment and Disposal (NAICS code 562211);
- Solid Waste Combustors and Incinerators (NAICS code 562213);

B. What is the agency's authority for taking this action?

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines through a TSCA section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment for one or more condition(s) of use.

With the obligation to promulgate these rules, the Agency also has the inherent authority to amend them if circumstances change, including based on the receipt of new information and in relation to compliance deadlines established under TSCA section 6(d). It is well settled that EPA has inherent authority to reconsider, revise, or repeal past decisions to the extent permitted by law so long as the Agency provides a reasoned explanation. See *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); see also *FDA v. Wages & White Lion Invs., L.L.C.*, 145 S. Ct. 898, slip op. at 20 (2025). Here, as explained further in Unit I.D., based on information submitted by regulated entities, the Agency proposes that revised compliance dates are necessary to address recently-received information that the original compliance dates for laboratories not owned or operated by Federal agencies, or Federal contractors acting on behalf of the Federal government, are not practicable and do not provide adequate transition time because they disrupt environmental monitoring and associated laboratory-based activities discussed further in Unit II.C.3.

C. What action is the agency taking?

EPA is proposing to amend the regulations at 40 CFR 751.109 to extend the WCPP compliance dates for the industrial or commercial use of methylene chloride as a laboratory chemical, established in the May 2024 final rule (Ref. 1), for an additional 18 months to match the compliance dates for Federal agencies and their contractors. Specifically, for laboratories not owned or operated by Federal agencies, or Federal contractors acting on behalf of the Federal government, this proposal would extend the compliance date for initial monitoring from May 5, 2025 to November 9, 2026, the compliance date for establishing regulated areas and ensuring compliance with the Existing Chemical Exposure Limit (ECEL) from August 1, 2025 to February 8, 2027, and the compliance date for ensuring the methods of compliance as well as developing and implementing an exposure control plan from October 30, 2025, to May 10, 2027.

The May 2024 final rule for methylene chloride (Ref. 1) prohibits the manufacture (including import), processing, use, and distribution of methylene chloride and methylene chloride-containing products for all consumer use and most industrial and commercial uses, with specified exclusions; requires owners and operators of workplaces engaged in the manufacture, processing, and use of methylene chloride for permitted uses to comply with a Workplace Chemical Protection Program (WCPP) to reduce exposures; and requires persons manufacturing, processing, or distributing in commerce methylene chloride and products containing methylene chloride to notify their customers of these prohibitions and restrictions. The compliance dates for the prohibitions began as early as February 3, 2025, while the first compliance date for the WCPP provisions is May 5, 2025, for initial exposure monitoring (Ref. 1).

EPA is interested in receiving new specific information that was not accessible during the proposed or final rulemaking on the barriers to WCPP compliance for different kinds of laboratories, and in any information that shows the exposure reductions that fume hoods or other enclosures currently in use in laboratories provide to address risks such that they are no longer unreasonable. EPA seeks comment on these compliance difficulties and on legitimate reliance interests, if any, on the original deadlines, that the Agency should consider in the course of this limited rulemaking. EPA notes that it has not, and is not, reopening the entirety of the methylene chloride final rule by issuing this proposal. Accordingly, EPA requests that commenters limit their submissions to the laboratory compliance deadline issues raised in this proposed rule.

D. Why is the agency taking this action?

EPA is issuing this proposal to address the unanticipated hardships that were inadvertently created for laboratories by the May 2024 final rule on methylene chloride (Ref. 1) due to the widespread, often mandatory, use of methylene chloride as a laboratory chemical that was not fully understood by EPA before the rule was published. Although EPA responded to comments and revised provisions of the final rule in consideration of commenter's concerns on laboratory use of methylene chloride, shortly after the final rule was published in May 2024, many representatives of various laboratories using methylene chloride began contacting EPA with questions about the applicability of the rule, difficulties in complying with the requirements of the WCPP, and other concerns (Ref. 1). Many of these laboratories, especially

those associated with local governments or universities, use methylene chloride in small quantities and somewhat infrequently (Refs. 2, 3). For example, one police department submitted a post-rulemaking inquiry to EPA to discuss their use of methylene chloride in the detection of controlled substances. Several universities contacted EPA to ask about how the rule applies to their activities, such as solvent extractions performed by students in an organic chemistry laboratory (Refs. 4, 5, 6, 7, 8). Several of the university laboratories that contacted EPA indicated that their use of methylene chloride occurred exclusively under a fume hood. They questioned whether initial monitoring would still be required, and whether initial monitoring would have to be done for each fume hood in use on the campus (Refs. 3, 5, 6, 7, 8).

Environmental monitoring laboratories also contacted EPA shortly after the final rule was published. They provided additional information on the various EPA test methods and voluntary consensus standards used in compliance testing that require the use of methylene chloride, including methods that are part of EPA's SW-846 Hazardous Waste Test Methods Compendium (available online at <https://www.epa.gov/hw-sw846>), such as Method 0010, used in the determination of destruction and removal efficiency of semivolatile principal organic hazardous compounds (POHCs) from incineration systems or the determination of particulate emission rates from stationary sources (Refs. 9, 10, 11). In the view of these laboratories, EPA should not be imposing the burden of the TSCA WCPP on laboratories that are using methylene chloride pursuant to EPA methods mandated for use by other regulatory programs. Rather, these laboratories believe that EPA should first revise its mandatory analytical methods that require the use of methylene chloride to allow for the use of other solvents, or other techniques that would reduce methylene chloride use by environmental monitoring laboratories. These laboratories also have concerns about their ability to meet the TSCA rule's requirements to perform initial monitoring of potentially exposed person's exposures by the compliance deadline.

While EPA received several comments along these lines during the public comment period on the proposed rule, EPA was not aware of the breadth of laboratories needing to comply with the WCPP as a result of mandatory EPA methods that require the use of methylene chloride to perform the analysis, posing unique compliance challenges when combined with other requirements of the WCPP such as

conducting exposure monitoring, developing exposure control plans, and assess and acquire necessary PPE based on the exposure monitoring.

E. What are the incremental economic impacts?

EPA evaluated the potential incremental economic impacts and determined that these changes would have minimal impacts on the estimated costs and benefits of the existing action and would primarily result in a delay in when those costs and benefits begin accruing. Quantified costs are expected to be the same as estimated in the final rule but will not be incurred until the proposed compliance date extension expires. The extension would also postpone when decreases in potential exposures to methylene chloride in laboratory settings and delay when potential benefits begin to accrue. On balance, this proposed further extension of the compliance dates is appropriate to prevent the disruptive consequences of requiring laboratories to begin implementing the WCPP by May 5, 2025, without a further compliance extension.

II. Background

A. The May 2023 Notice of Proposed Rulemaking

1. *Summary of the notice of proposed rulemaking.* In May 2023, EPA proposed a rule under TSCA section 6(a) to address unreasonable risk of injury to human health presented by methylene chloride under 52 of its 53 total conditions of use (Ref. 10). In the 2023 notice of proposed rulemaking (Ref. 10), EPA noted that methylene chloride was a widely used solvent in a variety of commercial and consumer applications and has a number of known health effects that may result from exposure. As described in more detail in EPA's proposed rule and as described in the TSCA section 6(b) 2020 Risk Evaluation for Methylene Chloride, EPA identified non-cancer adverse effects from both acute and chronic inhalation and dermal exposures to methylene chloride, and cancer from chronic inhalation and dermal exposures to methylene chloride (Refs. 10, 13). To address the unreasonable risks, the 2023 proposed rule (Ref. 10) sought to prohibit the manufacture, processing, and distribution in commerce of methylene chloride for consumer use; require a workplace chemical protection program (WCPP) for those industrial and commercial uses not proposed to be prohibited, which included a requirement to meet inhalation exposure concentration limits for both an 8-hour time-weighted average and 15-minute time-weighted average exposures, and to conduct exposure monitoring for certain continued conditions of use

of methylene chloride; prohibit most industrial and commercial uses of methylene chloride; require recordkeeping and downstream notification requirements for several conditions of use of methylene chloride; and provide certain time-limited exemptions from requirements for uses of methylene chloride that would otherwise significantly disrupt national security or critical infrastructure.

2. *Summary of the comments received on the notice of proposed rulemaking.* After publication of the 2023 proposed rule for methylene chloride (Ref. 10), EPA opened a public comment from May 3, 2023, to July 3, 2023. During this time, EPA received almost 40,000 public comments, the vast majority of which were submitted by individuals participating in mass mailer campaigns requesting that EPA protect workers and consumers expeditiously and to strengthen the proposed requirements (Refs. 14, 15, 16, 17). Other commenters requested expansion of the WCPP to include additional conditions of use or to allow all industrial and commercial conditions of use under the WCPP, additional time for compliance with the WCPP (ranging from 6 months to 5 years), additional exemptions under TSCA section 6(g), and a de minimis regulatory threshold (Refs. 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46). EPA also received specific information from various industry sectors requesting changes to the proposed rule, including information from laboratories that use methylene chloride. For a full discussion of comments related to WCPP compliance timeframes, refer to Final Rule Unit III.D.1., and Response to Comments section 5.1.7 (Refs. 1, 47)

Comments were received by laboratory-affiliated organizations such as the American Council of Independent Laboratories (ACIL), Pace Analytical, and the Environmental Monitoring Coalition (EMC) (Refs. 48, 49, 50). While ACIL's comment expressed broad support of the 2023 proposed rule, their comment conveyed the concerns of its members regarding use of methylene chloride in environmental testing and compliance required by EPA's analytical methods (Ref. 48). Similarly, EMC stated that the proposed rule could affect environmental compliance monitoring, remediation of hazardous waste sites, and emergency responses thereby impacting public health and the environment (Ref. 50). ACIL suggested that for laboratories conducting environmental and food safety testing using methylene chloride, potentially exposed persons should be protected through prescriptive controls such as ventilation and dermal PPE instead of the WCPP (Ref. 48). Both ACIL's and EMC's comments, which were supported by Pace Analytical, requested that EPA revise its analytical methods under other statutes prior to

finalizing the TSCA regulation and to grant the private sector and Voluntary Consensus Standard Bodies the opportunity to develop new approaches that reduce the amount of the solvent within a shorter timeframe than EPA's process to develop new analytical methods (Refs. 48, 49, 50). ACIL highlighted challenges and costs associated with meeting the exposure monitoring compliance date, training requirements, validation of new methods, modification of equipment, and reaccreditation of the laboratories by third parties (Ref. 48). This issue is discussed further in Unit II.C.2.

Other commenters provided remarks on various aspects of the laboratory condition of use and its coverage under the 2023 proposed rule's WCPP. An independent commenter expressed concern that the approach of laboratories under the WCPP was unreasonable because the scale of use is not analogous to industry (Ref. 51). The commenter also highlighted that colleges and universities may contain numerous amounts of laboratories which would place an unacceptable burden on them to comply with the proposed rule's WCPP. The American Chemical Society (ACS) iterated a similar concern for small scale use of methylene chloride in laboratories and exposure monitoring under the proposed WCPP (Ref. 52). Their comment cited concerns for the WCPP compliance costs and costs of retaining safety professional services (Ref. 52). Additionally, ACS stated that tracking personnel for the WCPP's recordkeeping in an academic environment is impractical because the turnover rate among universities for students/faculty is high and requested that EPA adopt a different approach (Ref. 52).

B. The May 2024 Final Rule

On May 8, 2024, EPA published the final regulation for methylene chloride under TSCA section 6(a) (Ref. 1). Many of the provisions in the 2023 proposed rule were finalized as proposed. EPA considered information received through public comments, making a number of revisions to: include additional uses under the WCPP, broaden the scope of some WCPP uses to include those in the private sector in addition to the Federal agencies, provide a delayed prohibition for two conditions of use, include a *de minimis* regulatory threshold, extend the compliance dates for the WCPP and prohibition, and revise specific provisions of the WCPP. For a complete description of these changes, see Unit III. of the 2024 final regulation (Ref. 1). This Unit additionally provides a summary of comments which compelled EPA to extend the compliance timeframes for the WCPP.

EPA originally proposed that the WCPP compliance activities begin with initial monitoring to be completed at six months. However, after considering information received from commenters, EPA finalized the WCPP compliance activities to begin at 12 months for general industry users and at 30 months for Federal agencies and their contractors from the date of publication of the final rule, by which time regulated entities would be required to complete their initial monitoring. This revision to the compliance timeframe resulted from public commenters, such as those described in the previous paragraphs, who stated that the proposed compliance timeframes for the WCPP were inadequate to implement for several reasons including: challenges associated with the implementation of recordkeeping for the hierarchy of controls; that the proposed rule did not account for the increased demand of professional safety services; and because development of an exposure assessment strategy would require additional time (Refs. 33, 34, 36, 53, 54). During the public comment period, commenters submitted concerns that the Good Laboratory Practice standards were atypical within the industrial hygiene community to use for air monitoring samples (Refs. 25, 34, 36, 44). Based on these comments, in addition to revising the compliance timeframes after consideration of public comments, the Agency revised its approach to expand the analysis of monitoring results and associated recordkeeping requirements to any accredited lab including GLP, AIHA (Laboratory Accreditation Program), and analogous industry-recognized programs.

The 2024 methylene chloride final rule's WCPP, with revisions prompted by public commenters, includes and finalizes exposure limits; initial, periodic, and additional exposure monitoring requirements; regulated areas; PPE and respirator requirements; an exposure control plan; recordkeeping; and notification requirements (Ref. 1).

C. Impacts of the 2024 Final Rule on Laboratories

As discussed in Unit II.A. and B., EPA's final regulation of methylene chloride addresses unreasonable risk of injury to human health presented by all known, intended and reasonably foreseen uses of methylene chloride. Since the publication of the final rule, EPA has received many inquiries requesting clarification with respect to that final rule, but a majority of those inquiries came from laboratories, and some inquirers provided new information or additional context to the challenges specific

to laboratories with implementation of the WCPP. That information is summarized in more detail in this Unit.

1. *The utility of methylene chloride as a laboratory solvent.* EPA recognizes that methylene chloride has numerous uses in pharmaceuticals, research and development, academia, and environmental monitoring and compliance laboratories. It is a common laboratory solvent due to its polarity, low boiling point, and inability to act as a proton donor in a reaction, making it suitable for various applications like liquid chromatography, extractions, synthesis, and purification. Its volume of use is often low and may vary from laboratory to laboratory. In environmental testing and compliance laboratories, methylene chloride is an analyte that is required to be monitored. For these types of laboratories, environmental testing is conducted in situations where contaminant level requirements exist under certain environmental statutes. Methylene chloride is also used in sample preparation before an analysis of persistent organic pollutants (Ref. 55).

2. *Use of methylene chloride in analyses of environmental monitoring samples.* Although a few commenters on the 2023 proposal (Ref. 10) noted that laboratories performing sample analysis for environmental monitoring and environmental compliance purposes would be affected by the rule (Refs. 48, 49, 50), after the final rule was issued in May 2024 (Ref. 1), EPA began receiving more information on the number of laboratories involved in environmental monitoring and environmental compliance testing, the variety of EPA-approved and mandatory methods that require the use of methylene chloride as a solvent, and the equipment and procedures used by these laboratories that ensure that worker exposures are low. According to the ACIL, their members perform more than 3 million tests annually using methylene chloride, many of which are performed pursuant to regulatory requirements of other statutes and use more than 50 EPA-approved methods or voluntary consensus standards that mandate the use of methylene chloride as a solvent (Refs. 48, 56). In addition to the previously-mentioned Method 0010 (Ref. 9), used to test the efficiency of incineration systems or determine particulate emission rates, other hazardous waste test methods (known as SW-846 methods) that require the use of methylene chloride include Method 3511, Organic Compounds in Water by Microextraction, and Method 3535A, Solid-Phase Extraction, which is used to isolate target organic analytes from aqueous samples (Ref. 9). EPA's National Primary Drinking Water Regulations at 40 CFR part 141 require methods that use methylene

chloride, including Method 506, used to detect phthalate and adipate esters in drinking water, and Method 525.2, used to detect organic compounds in drinking water (Ref. 57). EPA's National Pollutant Discharge Elimination System regulations under the Clean Water Act also require, at 40 CFR part 136, methods that use methylene chloride, including Method 608 for organochlorine pesticides and polychlorinated biphenyls, Method 612 for chlorinated hydrocarbons, and Method 613 for 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (Refs. 9, 58, 59, 60). The Clean Air Act also requires under its regulations methods that use methylene chloride, including, under 40 CFR part 60, Method 23A, the Determination of Polychlorinated Dibenzo-*p*-Dioxins, Polychlorinated Dibenzofurans, Polychlorinated Biphenyls, and Polycyclic Aromatic Hydrocarbons from Stationary Sources (Ref. 61).

Many analytical methods that must be used for environmental testing involve the use of methylene chloride. Unlike other affected entities, environmental testing laboratories are currently unable to select an alternative analytical method that does not require the use of methylene chloride due to requirements to use certain analytical methods. As such, these laboratories are not afforded the same ability or flexibility to eliminate the use of methylene chloride or substitute alternative solvent chemicals as other industries are able to do under the same rule. Many of these analytical methods do not list alternative chemicals that may be used in place of methylene chloride in the analytical method, and the process to revise or develop new analytical methods using different chemicals is a multi-year process that would exceed the WCPP compliance dates (Ref. 48). EPA now recognizes that the specification for the use of methylene chloride in analytical methods limits the ability of laboratories to exercise certain exposure control methods under the WCPP's Exposure Control Plan, including elimination and substitution, prior to implementing PPE and/or respirators.

According to a commenter, laboratories analyzing environmental samples for monitoring and compliance purposes explained that their use of methylene chloride typically occurs in areas with high-level ventilation and in a fume hood (Ref. 48). This practice is intended to protect workers from exposure to methylene chloride and prevents contamination of laboratory surfaces and the air by methylene chloride that could compromise the analysis of the samples (Ref. 48). The American Council of Independent Laboratories noted that, in order to ensure that such contamination is not occurring, their laboratories routinely test blank samples for contamination (Ref. 48). They further noted that laboratory

accreditation organizations ensure that accredited laboratories are monitoring processes for potential contamination on a regular basis (Ref. 48). Thus, ACIL concludes that, if exposure to high levels of methylene chloride was occurring, their routine testing for sample contamination would likely flag such problems (Ref. 48). After EPA promulgated the May 2024 final rule, ACIL referred to statements presented in the Response to Comments document and in a public webinar that the Agency's data and rationale supported the use of fume hoods as an exposure control to protect laboratory personnel (Refs. 47, 56, 62). As EPA stated in the Response to Public Comments and the public webinar, the Agency maintains high confidence in laboratories' ability to achieve the protective measures needed to address the unreasonable risk and to meet the requirements of the WCPP and ECEL (Refs. 47, 62).

During the proposed rule's public comment period, one of the main concerns voiced by environmental monitoring laboratories was the cost and difficulty of performing initial monitoring, and, potentially, periodic monitoring (Refs. 48, 49, 50). Due to compliance costs as a result of the final regulation, ACIL stated that smaller laboratories serving rural communities may cease environmental analyses that require the use of methylene chloride-based methods (Ref. 56). According to other laboratories, most have not had to perform exposure monitoring under the OSHA Methylene Chloride Standard, 29 CFR 1910.1052, because they are complying with the OSHA Laboratory Standard at 29 CFR 1910.1450, and monitoring is not required unless there is reason to believe that exposure levels routinely exceed the applicable OSHA action level, which for methylene chloride is 12.5 ppm (Refs. 52, 63, 64, 65). In their view, compliance with the containment requirements of the Laboratory Standard at 29 CFR 1910.1450, such as proper use of fume hoods or glove boxes, precludes ambient methylene chloride levels that exceed the TSCA action level, as well as the OSHA action level (Refs. 52, 63, 64, 65). These commenters did not provide monitoring data in support of their views, and while EPA agrees that proper use of fume hoods or glove boxes would likely be sufficient to address unreasonable risks from methylene chloride, without monitoring information to demonstrate as such, any laboratory could not be considered to be in compliance with the WCPP.

Some organizations indicated a desire to undertake an arduous and potentially costly process to revise existing analytical method requirements rather than monitoring to demonstrate compliance with the ECEL, which, as noted above, could likely be met with use of laboratory hoods. Two organizations

expressed that the better approach would be for EPA to work with the FDA, States, and standards-setting organizations to revise mandatory analytical methods to not require the use of methylene chloride, although they recognized that this would take a significant amount of time, and is outside the scope of a 6(a) TSCA rulemaking. One mentioned the phase-out of chlorofluorocarbons (CFCs) as an example, and stated that EPA took 20 years to conduct the needed research and to make the needed regulatory changes to remove the requirement to employ CFCs as solvents in its required oil and grease methods. They further noted that the use of methylene chloride is specified in many more methods than CFCs were. EPA understands the appeal of this approach, which would result in the elimination of methylene chloride hazards in many laboratories. However, EPA has determined that methylene chloride can be safely used in laboratories operating under the WCPP, so there is no need to terminate use of an effective solvent.

3. *Use of methylene chloride in other laboratories.* After EPA promulgated the final rule in 2024, representatives of academic laboratories also began contacting the Agency about the rule's impacts. EPA heard from individual universities, such as the University of California and Purdue University, as well as from the College Safety Health Environmental Management Association (CSHEMA) and the American Chemical Society, speaking on behalf of academic teaching and research laboratories. These stakeholders explained additional challenges that academic laboratories face in complying with the final rule.

Universities often have multiple campuses, with a variety of laboratories on each, and methylene chloride is typically used only infrequently in most of these laboratories. In their view, it would be cost prohibitive to perform initial monitoring, and periodic monitoring if necessary, in each laboratory that they control, particularly where it is unlikely that anyone may be routinely exposed to methylene chloride (Ref. 48). In addition, because EPA's final rule extends protections beyond workers to all potentially exposed persons in the area, students will be covered by the rule and will potentially have to be provided with training, medically qualified to don a respirator, fit-tested for respirator use, and issued PPE and respirators, and records would have to be kept accordingly.

Law enforcement agencies and laboratories also shared information with EPA after promulgation of the final rule. The Texas Department of Public Safety, New York City Police Department, the Johnson County (KS) Sheriff's Office, and the Wyoming State Crime Laboratory described the use of methylene chloride in small quantities for testing purposes, such as testing for controlled substances, like cocaine

and heroin (Refs. 66, 67, 68, 69). These labs requested clarity on how the rulemaking would apply to their use, including if EPA was aware of alternatives to methylene chloride for testing of controlled substances and asking if methylene chloride use could continue with an exposure control plan in place.

III. Provisions of this Proposed Rule

A. Establishing Compliance Dates

TSCA section 6(d) includes a number of provisions relating to establishment of effective or compliance dates applicable to TSCA section 6 rules. TSCA section 6(d)(1)(A) directs EPA to specify a date on which the TSCA section 6(a) rule is to take effect that is “as soon as practicable,” while TSCA section 6(d)(1)(B) requires EPA to specify mandatory compliance dates for each requirement of a rule promulgated under TSCA section 6(a), which must be as soon as practicable but no later than five years after promulgation, with few exceptions.

EPA’s 2023 NPRM would have required entities subject to the WCPP to conduct initial exposure monitoring no later than six months after the final rule was published, establish regulated areas and provide personal protective equipment (PPE) within the next three months, and develop and implement an exposure control plan three months after that, or within one year of the publication of the final rule. Many industry commenters thought that the compliance dates for WCPP implementation were too ambitious, while environmental advocacy organizations thought that industry should be required to comply sooner with worker protection measures once monitoring data showing exceedances of the ECEL or STEL was obtained. Industry commenters cited concerns about the availability of industrial hygiene personnel and monitoring methods, as well as the time it would take to implement engineering and administrative controls in the workplace.

In balancing questions over the practicability of WCPP compliance dates with the interest in protecting workers from unreasonable risks, EPA determined that the proposed timeframe was not practicable for all who would need to comply with it. Therefore, the final rule provided an additional six months of time for all owners and operators to implement the WCPP. Federal agencies and their contractors have approximately 18 additional months to comply with the WCPP, based on EPA’s concern about the ability of certain departments and agencies of the Federal Government to achieve compliance with the private-sector timeframes and given the importance of methylene chloride to mission-critical

Department of Defense and National Aeronautics and Space Administration operations and overall military readiness. For more information on this issue, see Unit III.D.1 of the 2024 final rule.

B. Proposed Compliance Date Extension for the Industrial and Commercial Use of Methylene Chloride as a Laboratory Chemical

As a result of the information from laboratories and organizations representing laboratories subsequent to the publication of the 2024 final rule, EPA is proposing to extend the compliance dates applicable to non-federal owners and operators that use methylene chloride as a laboratory chemical, aligning with timeframes for Federal laboratories and Federal contractors. Under this proposal, such laboratories would have until November 9, 2026 to conduct initial monitoring, until February 8, 2027 to establish regulated areas and ensure compliance with the ECEL and EPA STEL, and until May 10, 2027 to develop and implement an exposure control plan. EPA has based this proposal on number of challenges to WCPP compliance identified by laboratories, including their inability to choose a different, less toxic solvent when performing analyses, especially environmental monitoring sample analyses that must be performed in accordance with specified methods, and the availability and cost of industrial hygiene personnel to conduct initial monitoring. In EPA's view, the newly proposed compliance dates are practicable and represent a reasonable transition period under TSCA section 6(d). Moreover, using compliance dates already established for Federal agencies and their contractors avoids the confusion that EPA may have created by having multiple compliance dates for various WCPP provisions.

EPA requests comments and specific information addressing:

- The ability of the various laboratories to comply with the requirements of the WCPP by the newly proposed compliance dates.
- Alternative compliance timeframes for laboratories that represent dates that are as soon as practicable and provide for a reasonable transition period.
- Information related to laboratory use of methylene chloride, addressing risks associated with that use, that may not have been previously available to EPA during risk management and should now be considered.
- The costs of compliance with the WCPP for laboratories, such as the cost of: obtaining the services of an industrial hygienist, identifying relevant tasks associated with methylene chloride exposure,

collecting and analyzing exposure samples, including the cost of equipment necessary to collect exposure samples, training, recordkeeping, implementing engineering and administrative controls and PPE, and modifying existing chemical hygiene plans developed under 29 CFR 1910.1450 to meet the requirements of 40 CFR 751.109(e)(2).

- The cost differential of compliance between EPA requirements (40 CFR 751.109) and the current OSHA laboratory standard (29 CFR 1910.1450)
- The number of potentially exposed persons who operate in various laboratories under the workplace chemical protection program requirements and the costs and benefits.

EPA also welcomes comments, including data supporting alternative approaches to ensuring that potentially exposed persons are protected when they are working in, or otherwise present in, laboratories where methylene chloride is being used. For example, several commenters on the 2023 proposal took note of the approach taken in EPA's proposed TSCA section 6 rule on perchloroethylene (Ref. 48), which addressed laboratory exposures to perchloroethylene by requiring fume hoods or other enclosures and dermal protection. EPA understands that much of the methylene chloride use in laboratories is done under a fume hood or in glove boxes or other enclosures that limit air concentrations in the vicinity of the use. However, data in the methylene chloride risk evaluation indicates the potential for air concentrations in laboratories to exceed the ECEL. EPA is interested in any information that describes exposure reductions that fume hoods or other enclosures currently in use in laboratories provide that may reduce risks such that they are no longer unreasonable.

IV. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Methylene Chloride; Regulation under the Toxic Substances Control Act; Final Rule. RIN 2070-AK70. *Federal Register* (89 FR 39254) (FRL-8155-01-OCSP). May 8, 2024.
<https://www.govinfo.gov/content/pkg/FR-2024-05-08/pdf/2024-09606.pdf>
2. EPA. American Chemical Society Meeting Memo. January 7, 2025.
3. EPA. American Council of Independent Laboratories Meeting Memo. January 8, 2025.
4. EPA. Temple University Correspondence Memo. July 16, 2024.
5. EPA. University of Minnesota Meeting Memo. December 3, 2024.
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V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action under Executive Order 12866 (58 FR 51735, October 4, 1993) and was therefore not submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is expected to be an Executive Order 14192 deregulatory action. This proposed rule is expected to provide burden reduction by providing relief against existing compliance deadlines.

C. Paperwork Reduction Act (PRA)

This action does not impose any new information collection activities or burden subject to OMB review and approval under the PRA, 44 U.S.C. 3501 *et seq.* However, this action defers the costs associated with paperwork and recordkeeping burden for an existing information collection because the

delayed compliance date alters the time horizon of the collection's analysis. Burden is defined in 5 CFR 1320.3(b). OMB has previously approved the information collection activities contained in the existing regulations and associated burden under OMB Control No. 2070-0229 (EPA ICR No. 2735.02). An agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the *Federal Register*, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* In making this determination, EPA concludes that the impact of concern for this action is any significant adverse economic impact on small entities, and the Agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities because the rule relieves regulatory burden. This action would extend the compliance dates for several provisions of the WCPP for approximately 18 months for the industrial and commercial use of methylene chloride as a laboratory chemical. We have therefore concluded that this action would relieve regulatory burden for those entities engaged in the industrial and commercial use of methylene chloride as a laboratory chemical.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999) because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000) because it does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

This action is not a “covered regulatory action” under Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not an economically significant regulatory action as defined by Executive Order 12866.

I. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA)

Pursuant to the NTTAA section 12(d), 15 U.S.C. 272, the Agency has determined that this proposed rulemaking involves environmental monitoring or measurement, specifically for occupational inhalation exposures to methylene chloride. Consistent with the Agency’s Performance Based Measurement System (PBMS), EPA has decided not to require the use of specific, prescribed analytic methods. Rather, the Agency will allow the use of any method that meets the prescribed performance criteria. The PBMS approach is intended to be more flexible and cost-effective for the regulated community; it is also intended to encourage innovation in analytical technology and improved data quality. EPA is not precluding the use of any method, whether it constitutes a voluntary consensus standard or not, as long as it meets the performance criteria specified.

For this proposed rulemaking, the key consideration for the PBMS approach is the ability to accurately detect and measure airborne concentrations of methylene chloride at the ECEL, the ECEL action level, and the EPA STEL. Some examples of methods which meet the criteria are included in appendix A of the ECEL memo (Ref. 71). EPA recognizes that there may be voluntary consensus standards (Ref. 72).

List of Subjects in 40 CFR Part 751

Environmental protection, Chemicals, Export notification, Hazardous substances, Import certification, Reporting and recordkeeping.

Lee Zeldin,

Administrator.

For the reasons set forth in the preamble, the EPA proposes to amend 40 CFR part 751 as follows:

**PART 751—REGULATION OF CERTAIN CHEMICAL SUBSTANCES AND MIXTURES
UNDER SECTION 6 OF THE TOXIC SUBSTANCES CONTROL ACT**

1. The authority citation for part 751 continues to read as follows:

Authority: 15 U.S.C. 2605, 15 U.S.C. 2625(l)(4).

2. Amend § 751.109 by revising paragraphs (c), (d)(2), (e), (f), and (g) to read as follows:

§ 751.109 Workplace Chemical Protection Program.

* * * * *

(c) *Exposure limits*—(1) *ECEL*. The owner or operator must ensure that no person is exposed to an airborne concentration of methylene chloride in excess of 2 parts of methylene chloride per million parts of air (2 ppm) as an 8-hour TWA:

(i) After February 8, 2027, for Federal agencies, Federal contractors acting for or on behalf of the Federal Government, and owners or operators when using methylene chloride as a laboratory chemical;

(ii) After August 1, 2025, for other owners and operators; or

(iii) Beginning 4 months after the owner or operator introduces methylene chloride into the workplace, if methylene chloride use commences after May 5, 2025, consistent with paragraphs (d) through (f) of this section.

(2) *EPA STEL*. The owner or operator must ensure that no person is exposed to an airborne concentration of methylene chloride in excess of 16 parts of methylene chloride per million parts of air (16 ppm) as determined over a sampling period of 15 minutes:

(i) After February 8, 2027, for Federal agencies, Federal contractors acting for or on behalf of the Federal Government, and owners or operators when using methylene chloride as a laboratory chemical;

(ii) After August 1, 2025, for other owners and operators; or

(iii) Beginning 4 months after the owner or operator introduces methylene chloride into the workplace, if methylene chloride use commences after May 5, 2025, consistent with paragraphs (d) through (f) of this section.

(3) *Regulated areas.* The owner or operator must: (i) Establish and maintain regulated areas in accordance with 29 CFR 1910.1052(e)(2) and (4) through (7):

(ii) After February 8, 2027, for Federal agencies, Federal contractors acting for or on behalf of the Federal Government, and owners or operators when using methylene chloride as a laboratory chemical;

(iii) After August 1, 2025, for other owners and operators; or

(iv) Within 3 months after the owner or operator's receipt of the results of any monitoring data consistent with paragraph (d) of this section.

* * * * *

(d) * * *

(2) *Initial monitoring.* Each owner or operator covered by this section must perform an initial exposure monitoring to determine each potentially exposed person's exposure:

(i) By November 9, 2026, for Federal agencies, Federal contractors acting for or on behalf of the Federal Government, and owners or operators when using methylene chloride as a laboratory chemical;

(ii) By May 5, 2025, for other owners and operators; or

(iii) Within 30 days of the owner or operator introducing methylene chloride into the workplace, whichever is later, unless:

* * * * *

(e) *ECEL control procedures and plan.* (1) *Methods of compliance.* The owner or operator must institute one or a combination of elimination, substitution, engineering controls, work practices, or administrative controls to reduce exposure to or below the ECEL and EPA STEL except to the extent that the owner or operator can demonstrate that such controls are not feasible:

(i) By May 10, 2027, for Federal agencies, Federal contractors acting for or on behalf of the Federal Government, and owners or operators using methylene chloride as a laboratory chemical;

(ii) By October 30, 2025, for other owners and operators; or

(iii) Within 7 months of the owner or operator introducing methylene chloride into the workplace.

(2) *Exposure control plan.* The owner or operator must develop and implement an exposure control plan:

(i) By May 10, 2027, for Federal agencies, Federal contractors acting for or on behalf of the Federal Government, and owners or operators using methylene chloride as a laboratory chemical;

(ii) By October 30, 2025, for other owners and operators, the owner or operator must develop and implement an exposure control plan; or

(iii) Within 7 months of the owner or operator introducing methylene chloride into the workplace.

* * * * *

(f) *Respiratory protection—(1) Respirator conditions.* The owner or operator must provide respiratory protection to all potentially exposed persons in the regulated area as outlined in paragraph (c)(3) of this section, and according to the provisions outlined in 29 CFR 1910.134(a) through (l) (except 29 CFR 1910.134(d)(1)(iii)) and as specified in this paragraph (f) for potentially exposed persons exposed to methylene chloride in concentrations above the ECEL or the EPA STEL. For the purpose of this paragraph (f), the maximum use concentration (MUC) as used in 29 CFR 1910.134 must be calculated by multiplying the assigned protection factor (APF) specified for a respirator by the ECEL or EPA STEL:

(i) After February 8, 2027, for Federal agencies, Federal contractors acting for or on behalf of the Federal Government, and owners or operators using methylene chloride as a laboratory chemical;

(ii) After August 1, 2025, for other owners and operators; or

(iii) Within 3 months after the owner or operator's receipt of the results of any exposure monitoring as described in paragraph (d) of this section.

* * * * *

(g) *Dermal protection.* The owner or operator must require the donning of gloves that are chemically resistant to methylene chloride with activity-specific training where dermal contact with methylene chloride is possible, after application of the requirements in paragraph (e) of this section, in accordance with the NIOSH hierarchy of controls:

(1) After February 8, 2027, for Federal agencies, Federal contractors acting for or on behalf of the Federal Government, and owners or operators using methylene chloride as a laboratory chemical;

(2) After August 1, 2025, for other owners and operators.

* * * * *

