

## PRE-PUBLICATION NOTICE

On April 29, 2024, Michael S. Regan, the EPA Administrator, signed the following document:

Action: **Final Rule**  
Title: **Methylene Chloride; Regulation under the Toxic Substances Control Act (TSCA)**  
FRL #: **8155-01-OCSP**  
Docket ID #: **EPA-HQ-OPPT-2020-0465**

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Once the official version of this document is published in the *Federal Register*, this version will be removed from the Internet and replaced with a link to the official version. At that time, you will also be able to access the on-line docket for this *Federal Register* document at <https://www.regulations.gov>.

For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the Federal Register document.

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 751**

**[EPA-HQ-OPPT-2020-0465; FRL-8155-01-OCSPP]**

**RIN 2070-AK70**

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

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA or the Agency) is finalizing a rule to address the unreasonable risk of injury to health presented by methylene chloride under its conditions of use. TSCA requires that EPA address by rule any unreasonable risk of injury to health or the environment identified in a TSCA risk evaluation and apply requirements to the extent necessary so that the chemical no longer presents unreasonable risk. EPA's final rule will, among other things, prevent serious illness and death associated with uncontrolled exposures to the chemical by preventing consumer access to the chemical, restricting the industrial and commercial use of the chemical while also allowing for a reasonable transition period where an industrial and commercial use of the chemical is being prohibited, provide a time-limited exemption for a critical or essential use of methylene chloride for which no technically and economically feasible safer alternative is available, and protect workers from the unreasonable risk of methylene chloride while on the job.

**DATES:** This final rule is effective on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** EPA has established a docket for this action under Docket ID No. EPA-HQ-OPPT-2020-0465. All documents in the docket are listed on the <https://www.regulations.gov> web

site. Although listed in the index, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through <https://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Ingrid Feustel, Existing Chemicals Risk Management Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-3199; email address:

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## **SUPPLEMENTARY INFORMATION:**

### **I. Executive Summary**

#### *A. Does this action apply to me?*

You may be potentially affected by this rule if you manufacture (defined under TSCA to include import), process, distribute in commerce, use, or dispose of methylene chloride or products containing methylene chloride. TSCA section 3(9) defines the term "manufacture" to mean to import into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedule of the United States), produce, or manufacture. Therefore, unless expressly stated otherwise, importers of methylene chloride are subject to any provisions regulating manufacture of methylene chloride. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a

guide to help readers determine whether this document applies to them. Potentially affected entities include:

- Other Chemical and Allied Products Merchant Wholesalers (NAICS code 424690);
- Crude Petroleum Extraction (NAICS code 211120);
- All Other Basic Organic Chemical Manufacturing (NAICS code 325199);
- Other Chemical and Allied Products Merchant Wholesalers (NAICS code 424690);
- Petroleum Bulk Stations and Terminals (NAICS code 424710);
- Other Basic Inorganic Chemical Manufacturing (NAICS code 325180);
- 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);
- Materials Recovery Facilities (NAICS code 562920);
- Paint and Coating Manufacturing (NAICS code 325510);
- Air and Gas Compressor Manufacturing (NAICS code 333912);
- Gasket, Packing, and Sealing Device Manufacturing (NAICS code 339991);
- Residential Remodelers (NAICS code 236118);
- Commercial and Institutional Building Construction (NAICS code 236220);
- Plumbing, Heating, and Air-Conditioning Contractors (NAICS code 238220);
- Painting and Wall Covering Contractors (NAICS code 238320);
- All Other Miscellaneous Manufacturing (NAICS code 339999);
- Automotive Parts and Accessories Stores (NAICS code 441310);
- All Other Miscellaneous Store Retailers (except Tobacco Stores) (NAICS code

453998);

- Other Support Activities for Air Transportation (NAICS code 488190);
- All Other Automotive Repair and Maintenance (NAICS code 811198);
- Commercial and Industrial Machinery and Equipment (except Automotive and

Electronic) Repair and Maintenance (NAICS code 811310);

- Footwear and Leather Goods Repair (NAICS code 811430);
- Adhesive Manufacturing (NAICS code 325520);
- All Other Miscellaneous Chemical Product and Preparation Manufacturing (NAICS

code 325998);

- Audio and Video Equipment Manufacturing (NAICS code 334310);
- Reupholstery and Furniture Repair (NAICS code 811420);
- All Other Rubber Product Manufacturing (NAICS code 326299);
- All Other Miscellaneous Textile Product Mills (NAICS code 314999);
- All Other Miscellaneous Fabricated Metal Product Manufacturing (NAICS code

332999);

- Oil and Gas Field Machinery and Equipment Manufacturing (NAICS code 333132);
- Bare Printed Circuit Board Manufacturing (NAICS code 334412);
- Other Electronic Component Manufacturing (NAICS code 334419);
- All Other Miscellaneous Electrical Equipment and Component Manufacturing (NAICS

code 335999);

- Printing Machinery and Equipment Manufacturing (NAICS code 333244);
- Petroleum Refineries (NAICS code 324110);
- Petroleum Lubricating Oil and Grease Manufacturing (NAICS code 324191);
- Painting and Wall Covering Contractors (NAICS code 238320);

- Welding and Soldering Equipment Manufacturing (NAICS code 333992);
- New Car Dealers (NAICS code 441110);
- Used Car Dealers (NAICS code 441120);
- Drycleaning and Laundry Services (except Coin-Operated) (NAICS code 812320); and
- Doll, Toy, and Game Manufacturing (NAICS code 339930).

This action may also affect certain entities through pre-existing import, including import certification, and export notification rules under TSCA. Persons who import any chemical substance in bulk form, as part of a mixture, or as part of an article (if required by rule) are also subject to TSCA section 13 import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this final rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), and must comply with the export notification requirements in 40 CFR part 707, subpart D. Any person who exports or intends to export methylene chloride must comply with the export notification requirements in 40 CFR part 707, subpart D.

*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, EPA must by rule apply one or more requirements listed in TSCA section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents such risk.

*C. What action is the Agency taking?*

Pursuant to TSCA section 6(b), EPA determined that methylene chloride presents an unreasonable risk of injury to health, without consideration of costs or other non-risk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the 2020 Risk Evaluation for Methylene Chloride by EPA, under the conditions of use (Refs. 1, 2). A detailed description of the conditions of use that contribute to EPA's determination that methylene chloride presents an unreasonable risk is in Unit II.C.4. Accordingly, to address the unreasonable risk, EPA is issuing this final rule under TSCA section 6(a) to:

(i) Prohibit the manufacture, processing, and distribution of methylene chloride for all consumer use, as outlined in Unit IV.C.;

(ii) Prohibit most industrial and commercial use of methylene chloride and delay prohibition for two conditions of use, as outlined in Unit IV.C.;

(iii) Require a workplace chemical protection program (WCPP), including inhalation exposure concentration limits and related workplace exposure monitoring and exposure controls, for 13 conditions of use of methylene chloride (including manufacture; processing; several industrial and commercial uses such as laboratory use; and disposal), as outlined in Unit IV.B.;

(iv) Identify a de minimis threshold for products containing methylene chloride for the prohibitions and restrictions on methylene chloride, as outlined in Unit IV.A.;

(v) Require recordkeeping and downstream notification requirements for manufacturing, processing, and distribution in commerce of methylene chloride, as outlined in Unit IV.E.; and

(vi) Provide a 10-year time-limited exemption under TSCA section 6(g) for emergency use of methylene chloride in furtherance of the National Aeronautics and Space Administration's mission for specific conditions which are critical or essential and for which no technically and economically feasible safer alternative is available, taking into consideration hazard and



exposure, as outlined in Unit IV.F., with conditions for this exemption to include compliance with the WCPP described in Unit IV.B.

EPA notes that all TSCA conditions of use of methylene chloride (other than the use of methylene chloride in consumer paint and coating removers, which was subject to separate action under TSCA section 6 (84 FR 11420, March 27, 2019) (FRL-9989-29) are subject to this final rule. Condition of use is defined in TSCA section 3(4) to mean the circumstances, as determined by EPA, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

In addition, EPA is amending the general provisions of 40 CFR part 751, subpart A, to define “article,” “authorized person,” “owner or operator,” “potentially exposed person,” “product,” “regulated area,” and “retailer” so that these definitions may be commonly applied to this and other rules under TSCA section 6 that would be codified under 40 CFR part 751.

*D. Why is the Agency taking this action?*

Under TSCA section 6(a), “[i]f the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule... apply one or more of the [section 6(a)] requirements to such substance or mixture to the extent necessary so that the chemical substance no longer presents such risk.” Methylene chloride was the subject of a risk evaluation under TSCA section 6(b)(4)(A) that was issued in June 2020 (Ref. 1). In addition, EPA issued a revised unreasonable risk determination for methylene chloride in November 2022 (Ref. 2) determining that methylene chloride, as a whole chemical substance, presents an unreasonable risk of injury to health under the conditions of use. On May 3, 2023, EPA issued a proposed rule (88 FR 28284) (FRL-8155-02-OCSPP) under TSCA section

6(a) to regulate methylene chloride, so that it no longer presents unreasonable risk. The Agency received public comment on the proposal. With this action, EPA is finalizing with modifications the May 2023 proposed rule so that methylene chloride no longer presents an unreasonable risk. The conditions of use that contribute to the unreasonable risk from methylene chloride are described in Unit III.B.1. of the proposed rule (88 FR 28284) (FRL-8155-02-OCSP).

EPA emphasizes that some of the adverse effects from methylene chloride exposure, including sudden death, can be both immediately experienced and after only a short duration (Ref. 1). Other effects may result in long-term human health impacts which are also considered significant, including liver effects and cancer. Fatalities from acute methylene chloride exposures have been documented and pose a serious public health threat; these fatalities led the agency to prohibit the manufacture, processing, and distribution of methylene chloride for use in consumer paint and coating removers in 2019 (84 FR 11420, March 27, 2019) (FRL-9989-29). This final rule will eliminate the unreasonable risk to human health from the remaining conditions of use of methylene chloride, as identified in the 2020 Risk Evaluation for Methylene Chloride (Ref. 1) and the Revised Unreasonable Risk Determination for Methylene Chloride in November 2022 (Ref. 2).

Although EPA is prohibiting many conditions of use of the chemical where it cannot be used without continuing to present unreasonable risk as described in Unit IV., EPA is not finalizing a complete ban on methylene chloride. While addressing the unreasonable risk, this final rule allows methylene chloride's limited and controlled continued use in tandem with additional worker protections for several purposes, including the production of hydrofluorocarbon-32 (HFC-32), one of the regulated substances that are subject to a phasedown under the American Innovation and Manufacturing (AIM) Act of 2020. For many of the conditions of use for which EPA is finalizing workplace controls under a WCPP, data to support

the industry's position that certain uses could meet the exposure limit and ancillary requirements of an effective WCPP in addressing unreasonable risk were submitted during the risk evaluation, Small Business Advocacy Review (SBAR) Panel process, the comment period following publication of the proposed rule, or during stakeholder outreach, and are available in the corresponding public dockets (EPA-HQ-OPPT-2020-0465; EPA-HQ-OPPT-2019-0437; EPA-HQ-OPPT-2016-0742).

*E. What are the estimated incremental impacts of this action?*

EPA has prepared an Economic Analysis of the potential incremental impacts associated with this rulemaking that can be found in the rulemaking docket (Ref. 3). As described in more detail in the Economic Analysis (Ref. 3), EPA's analysis of the incremental, non-closure-related costs of this rule is estimated to be \$37.0 million annualized over 20 years at a 3% discount rate and \$39.5 million annualized over 20 years at a 7% discount rate. In response to the updated Circular A-4 published in November 2023, the incremental, non-closure related costs of this rule at a 2% discount rate (\$36.4 million annualized over 20 years) is provided in Appendix D of the Economic Analysis (Ref. 3). These costs take compliance with implementation of a WCPP for certain conditions of use into consideration, which would include an Existing Chemical Exposure Limit (ECEL) of 2 ppm (8 mg/m<sup>3</sup>) for inhalation exposures as an 8-hour time-weighted average (TWA), applicable personal protective equipment (PPE) requirements, and reformulation costs of numerous products.

In alignment with the goals of President Biden's Cancer Moonshot, the rule will protect people from cancer and other adverse health effects of methylene chloride by prohibiting most uses of methylene chloride while ensuring essential uses can safely continue (Ref. 4). The actions in this final rule are expected to achieve health benefits for the American public, some of which can be monetized and others that, while tangible and significant, cannot be monetized.

Although some benefits cannot be quantified, they are not necessarily less important than the quantified benefits. The incremental improvements in health outcomes achieved by given reductions in exposure cannot be quantified for non-cancer health effects associated with methylene chloride exposure, and therefore cannot be converted into monetized benefits.

The monetized benefits of this rule are approximately \$24.8 million to \$25.1 million annualized over 20 years at a 3% discount rate and \$19.8 million to \$20.0 million annualized over 20 years at a 7% discount rate. In response to the updated Circular A-4 published in November 2023, the incremental benefits at a 2% discount rate (\$27.1 to \$27.5 million annualized over 20 years) are provided in Appendix D of the Economic Analysis (Ref. 3). The monetized benefits only include potential reductions in risk of liver cancer and lung cancer associated with chronic exposures, and potential deaths avoided from acute methylene chloride exposure. Non-monetized benefits include potential reductions in central nervous system depressant effects; these effects include loss of consciousness and respiratory depression that may result in irreversible coma and hypoxia. Risks from acute exposures to methylene chloride can lead to workplace accidents and are precursors to the more severe central nervous system effects (up to and including death). Other non-monetized benefits include reductions in liver disease (including vacuolization, necrosis, hemosiderosis and hepatocellular degeneration), immune system compromise, and irritation and burns (Ref. 3).

## **II. Background**

### *A. Overview of Methylene Chloride*

As described in more detail in the May 2023 proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSPP), methylene chloride is acutely lethal, a neurotoxicant, and a carcinogen. This final rule is specifically intended to address the unreasonable risk of injury to health that EPA has identified in the 2020 Risk Evaluation for methylene chloride (Ref. 1) and 2022

Revised Unreasonable Risk Determination (Ref. 2), as described in Unit II.C.3. Methylene chloride is a colorless liquid and a volatile chemical with a sweet odor resembling chloroform. It is both produced in and imported into the United States. Methylene chloride is manufactured, processed, distributed in commerce, used, and disposed of as part of many industrial, commercial, and consumer conditions of use. As outlined in Unit II.C.4., methylene chloride is a widely used solvent in a variety of consumer and commercial applications including adhesives and sealants, automotive products, and paint and coating removers. Some evidence suggests that in recent years, use of methylene chloride has been declining in certain sectors (Ref. 3), particularly for consumer products, as the hazards of methylene chloride are well known, and certain uses are highly regulated. As further described in Unit II.B. and in the regulatory appendix (Ref. 5), these regulations include EPA's 2019 final rule addressing unreasonable risk to consumers from methylene chloride use in consumer paint and coating removal by prohibiting manufacturing, processing, and distribution in commerce of methylene chloride for consumer use in paint and coating removal (84 FR 11420, March 27, 2019) (FRL-9989-29).

The total annual aggregate production volume of methylene chloride was between 100 million to 500 million pounds between 2016 and 2019 according to Chemical Data Reporting (CDR) (Ref. 6). One notable high-volume use accounting for approximately one-fifth of all methylene chloride annual production volume is processing as a reactant, which includes the manufacture of HFCs (Ref. 1). This condition of use is described in Unit II.B.1. of the proposed rule, with a description of final requirements to address unreasonable risk in Units II.D.1. and IV. An estimated 35% of the annual production volume of methylene chloride is for pharmaceutical uses, which are not subject to TSCA and will not be regulated by this rule (15 U.S.C. 2602(2)(B)(vi); 21 U.S.C. 321(g)(1)).

#### *B. Regulatory Actions Pertaining to Methylene Chloride*

Because of its adverse health effects, methylene chloride is subject to numerous State, Federal, and international regulations restricting and regulating its use. A summary of EPA regulations pertaining to methylene chloride, as well as other Federal, State, and international regulations, is in the docket (Refs. 1, 5).

As described in more detail in EPA's proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSPP), and the Response to Public Comments document (Ref. 7), EPA considered the adequacy of the current standard for methylene chloride from the Occupational Safety and Health Administration (OSHA) (29 CFR 1910.1052) for protection of workers. EPA notes that the standards for chemical hazards that OSHA promulgates under the Occupational Safety and Health (OSH) Act share a broadly similar purpose with the worker protection-related standards that EPA promulgates under TSCA section 6(a). The control measures OSHA and EPA require to satisfy the objectives of their respective statutes may also, in many circumstances, overlap or coincide. However, there are important differences between EPA's and OSHA's regulatory approaches and jurisdiction, and EPA considers these differences when deciding whether and how to account for OSHA requirements when evaluating and addressing potential unreasonable risk to workers so that compliance requirements are clearly explained to the regulated community. Additional considerations of OSHA standards in the revised unreasonable risk determination are discussed further in the 2022 Revised Unreasonable Risk Determination for Methylene Chloride, published in the *Federal Register* of November 10, 2022 (87 FR 67901) (Ref. 2).

EPA intends for this regulation to be as consistent as possible with the current OSHA standard for methylene chloride, with additional requirements as necessary to address the unreasonable risk. Consistent with TSCA section 9(d), EPA consults and coordinates TSCA activities with OSHA and other relevant Federal agencies for the purpose of achieving the

maximum enforcement of TSCA while imposing the least burdens of duplicative requirements.

*C. Summary of EPA's Risk Evaluation Activities on Methylene Chloride*

In July 2017, EPA published the scope of the methylene chloride risk evaluation (82 FR 31592, July 7, 2017) (FRL-9963-57), and, after receiving public comments, published the problem formulation in June 2018 (83 FR 26998, June 11, 2018) (FRL-9978-40). In October 2019, EPA published a draft risk evaluation (84 FR 57866, October 29, 2019) (FRL-9999-69), and, after public comment and peer review by the Science Advisory Committee on Chemicals (SACC), EPA issued the 2020 Risk Evaluation for Methylene Chloride in June 2020 in accordance with TSCA section 6(b) (85 FR 37942, June 24, 2020) (FRL-10011-16). EPA subsequently issued a draft revised TSCA risk determination for methylene chloride (87 FR 39824, July 5, 2022) (9946-01-OCSP), and, after public notice and receipt of comments, published a Revised Risk Determination for Methylene Chloride in November 2022 (Ref. 2). The 2020 Risk Evaluation for Methylene Chloride and supplemental materials are in docket EPA-HQ-OPPT-2019-0437, and the November 2022 revised unreasonable risk determination and additional materials supporting the risk evaluation process are in docket EPA-HQ-OPPT-2016-0742, on <https://www.regulations.gov>.

*1. 2020 Risk Evaluation.*

In the 2020 Risk Evaluation for Methylene Chloride, EPA evaluated risks associated with 53 conditions of use within the following categories: manufacture (including import), processing, distribution in commerce, industrial and commercial use, consumer use, and disposal (Ref. 1). Descriptions of these conditions of use are in Unit III.B.1. of the proposed rule. The 2020 Risk Evaluation for Methylene Chloride identified significant adverse health effects associated with short- and long-term exposure to methylene chloride. A further discussion of the hazards of methylene chloride is in Unit III.B.1. of the proposed rule (88 FR 28284, May 3, 2023) (FRL-

8155-02-OCSPP).

*2. 2022 Revised Unreasonable Risk Determination.*

As described in more detail in EPA’s proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSPP), EPA revised the original unreasonable risk determination based on the 2020 Risk Evaluation for Methylene Chloride and issued a final revised unreasonable risk determination in November 2022 (Ref. 2). EPA revised the risk determination for the 2020 Risk Evaluation for Methylene Chloride pursuant to TSCA section 6(b) and consistent with Executive Order 13990, (“Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis”) and other Administration priorities (Refs. 8, 9, 10). The revisions consisted of making the risk determination based on the whole-chemical substance instead of making risk determinations for each individual condition of use, which resulted in the revised risk determination superseding the prior “no unreasonable risk” determinations for specific conditions of use (Ref. 2), the withdrawal of the associated TSCA section 6(i)(1) “no unreasonable risk” order, and clarification that the risk determination does not reflect an assumption that all workers are always provided and appropriately wear PPE (Ref. 2).

EPA determined that methylene chloride presents an unreasonable risk of injury to health, and did not identify risks of injury to the environment that contribute to the unreasonable risk determination for methylene chloride. The methylene chloride conditions of use that drive EPA’s determination that the chemical substance poses unreasonable risk to health are listed in the unreasonable risk determination (Ref. 2) and also in Unit III.B.2. of the proposed rule, with descriptions to aid chemical manufacturers, processors, and users in determining how their particular use or activity would be addressed under the final regulatory action.

*3. Description of unreasonable risk.*

EPA has determined that methylene chloride presents an unreasonable risk of injury to



health under the conditions of use, based on acute and chronic non-cancer risks and chronic cancer risks. As described in more detail in EPA's proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP) 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 (Ref. 1). EPA identified neurotoxicity effects (central nervous system) as the most sensitive endpoint of the non-cancer adverse effects from acute inhalation and dermal exposures, and liver effects as the most sensitive endpoint of the non-cancer adverse effects from chronic inhalation and dermal exposures for all conditions of use. EPA identified additional risks associated with other adverse effects (*e.g.*, other nervous system effects, immune system effects, reproductive and developmental effects, and irritation/burns) resulting from acute and chronic exposures. By targeting the sensitive chronic liver effects endpoint for risk management, EPA's final rule will also prevent the unreasonable risks from acute, chronic non-cancer and cancer endpoints associated with methylene chloride. EPA also recognizes the severity of the risks from acute inhalation exposures to methylene chloride, because relatively small increases in acute exposure can lead to extreme adverse effects associated with central nervous system suppression, including coma and death. Occupational fatalities linked to methylene chloride have been recorded as recently as June 2020 (Ref.11) and, most recently by OSHA, in March 2021 and July 2023 (Ref. 12). Eighty-five (85) fatalities between 1980 and 2018 have been documented from methylene chloride in paint and coating removal or adhesive and sealant use, and when methylene chloride is being used as a cleaning or degreasing solvent, 74 of which were in occupational settings; there has been no linear trend indicating a decrease in fatalities during that time period (Ref.11). In some instances, while trained workers were wearing respirators, the respirators were inadequate to protect against

methylene chloride inhalation exposure (Ref.11).

EPA considered potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by the Agency, which are included in the quantitative and qualitative analyses described in the 2020 Risk Evaluation for Methylene Chloride (Ref. 1) and were considered in the determination of unreasonable risk for methylene chloride.

*4. Conditions of use subject to this regulatory action.*

Conditions of use is defined in TSCA section 3(4) to mean the circumstances under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. Conditions of use descriptions are provided in Unit III.B.1. of the proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSPP) and were obtained from EPA sources such as CDR use codes, the 2020 Risk Evaluation for Methylene Chloride and related documents, as well as the Organisation for Economic Co-operation and Development harmonized use codes, and stakeholder engagements. EPA did not receive public comments identifying inaccuracies or necessitating changes to those descriptions; however, EPA received some comments requesting clarification for particular uses, which can be found in the response to comments document (Ref. 7). Additionally, to assist with implementation and compliance with the final rule, in Unit IV.B.1., EPA has provided a description of the conditions of use that are subject to the WCPP.

As in the proposed rule, for the purposes of this final rule, “occupational conditions of use” refers to the TSCA conditions of use described in Units III.B.1.a., b., c., and e. of the proposed rule. Although EPA identified both industrial and commercial uses in the 2020 Risk Evaluation for Methylene Chloride (Ref. 1) for purposes of distinguishing scenarios, the Agency clarified then and clarifies now that EPA interprets the authority Congress gave to the Agency to “regulat[e] any manner or method of commercial use” under TSCA section 6(a)(5) to reach both

industrial and commercial uses.

Additionally, as described in the proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP), in the 2020 Risk Evaluation for Methylene Chloride (Ref. 1), EPA identified and assessed all known, intended, and reasonably foreseen industrial, commercial, and consumer uses of methylene chloride (other than the use of methylene chloride in consumer paint and coating removers, which was subject to separate action under TSCA section 6 (84 FR 11420, March 27, 2019) (FRL-9989-29). EPA determined that all industrial, commercial, and consumer use of methylene chloride evaluated in the 2020 Risk Evaluation for Methylene Chloride contribute to the unreasonable risk of injury to health. As such, for purposes of this risk management rule, “consumer use” refers to all known, intended, or reasonably foreseen methylene chloride consumer uses. Likewise, for the purpose of this risk management rule, “industrial and commercial use” refers to all known, intended, or reasonably foreseen methylene chloride industrial and commercial use.

EPA further notes that this rule does not apply to any substance excluded from the definition of “chemical substance” under TSCA section 3(2)(B)(i) through (vi). Those exclusions include, but are not limited to, any pesticide (as defined by the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; and any food, food additive, drug, cosmetic, or device, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device.

#### *D. EPA’s Proposed Rule under TSCA Section 6(a) for Methylene Chloride*

##### *1. Description of TSCA section 6(a) requirements.*

Under TSCA section 6(a), if the Administrator determines through a TSCA section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the

environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the Agency's risk evaluation, under the conditions of use, EPA must by rule apply one or more of the section 6(a) requirements to the extent necessary so that the chemical substance no longer presents such risk.

The TSCA section 6(a) requirements can include one or more of the following actions alone or in combination:

- Prohibit or otherwise restrict the manufacturing (including import), processing, or distribution in commerce of the substance or mixture, or limit the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce (section 6(a)(1)).
- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of the substance or mixture for a particular use or above a specific concentration for a particular use (section 6(a)(2)).
- Limit the amount of the substance or mixture which may be manufactured, processed, or distributed in commerce for a particular use or above a specific concentration for a particular use specified (section 6(a)(2)).
- Require clear and adequate minimum warning and instructions with respect to the substance or mixture's use, distribution in commerce, or disposal, or any combination of those activities, to be marked on or accompanying the substance or mixture (section 6(a)(3)).
- Require manufacturers and processors of the substance or mixture to make and retain certain records or conduct certain monitoring or testing (section 6(a)(4)).
- Prohibit or otherwise regulate any manner or method of commercial use of the substance or mixture (section 6(a)(5)).
- Prohibit or otherwise regulate any manner or method of disposal of the substance or

mixture, or any article containing such substance or mixture, by its manufacturer or processor or by any person who uses or disposes of it for commercial purposes (section 6(a)(6)).

- Direct manufacturers or processors of the substance or mixture to give notice of the unreasonable risk determination to distributors, certain other persons, and the public, and to replace or repurchase the substance or mixture (section 6(a)(7)).

In the 2023 proposed rule for methylene chloride under TSCA section 6(a) (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP), EPA analyzed how the TSCA section 6(a) requirements could be applied to address the unreasonable risk from methylene chloride so that it no longer presents such risk. Unit II.D.1., summarizes the TSCA section 6 considerations for issuing regulations under TSCA section 6(a). Unit V. outlines how EPA applied these considerations while managing the unreasonable risk from methylene chloride.

As required, EPA developed a proposed regulatory action and one primary alternative regulatory action, which are described in Units IV.A. and IV.B., respectively, of the 2023 proposed rule for methylene chloride (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP). To identify and select a regulatory action, EPA considered the two routes of exposure driving the unreasonable risk, inhalation and dermal, and the exposed populations. For occupational conditions of use, EPA considered how it could directly regulate manufacturing (including import), processing, distribution in commerce, industrial and commercial use, or disposal to address the unreasonable risk. EPA also considered how it could exercise its authority under TSCA to regulate the manufacturing (including import), processing, and/or distribution in commerce of methylene chloride at different levels in the supply chain to eliminate exposures or restrict the availability of methylene chloride and methylene chloride-containing products for consumer use in order to address the unreasonable risk.

As required by TSCA section 6(c)(2), EPA considered several factors, in addition to

identified unreasonable risk, when selecting among possible TSCA section 6(a) regulatory requirements for the proposed rule. EPA's considerations regarding TSCA section 6(c)(2) and section 6(c)(2)(A) for methylene chloride are discussed in full in Unit VI. of the proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP), including the statement of effects with respect to these considerations. After review of the public comments received, EPA has revised its statement of effects considerations in Unit V. of this final rule.

As described in more detail in EPA's proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP), EPA also considered regulatory authorities under statutes administered by other agencies such as the OSH Act, the Consumer Product Safety Act (CPSA), and the Federal Hazardous Substances Act (FHSA), as well as other EPA-administered statutes, to examine 1) Whether there are opportunities to address unreasonable risk under other statutes, such that a referral may be warranted under TSCA section 9(a) or 9(b); or 2) Whether TSCA section 6(a) regulation could include alignment of requirements and definitions in and under existing statutes and regulations to minimize confusion to the regulated entities and the general public.

Additionally, as described in more detail in EPA's proposed rule in Unit V.B. (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP), EPA considered the availability of alternatives when finalizing a prohibition or a substantial restriction (TSCA section 6(c)(2)(C)) (Ref. 13), and in setting final compliance dates in accordance with the requirements in TSCA section 6(d)(1)(B)).

To the extent information was reasonably available, EPA considered pollution prevention strategies and the hierarchy of controls adopted by OSHA and the National Institute for Occupational Safety and Health (NIOSH) when developing its proposed rule, with the goal of identifying risk management control methods that would be permanent, feasible, and effective. EPA also considered how to address the unreasonable risk while providing flexibility to the

regulated community where appropriate, and took into account the information presented in the 2020 Risk Evaluation for Methylene Chloride (Ref. 1), input from stakeholders, insight received during consultations, and anticipated compliance strategies from regulated entities.

Taken together, these considerations led EPA to the proposed regulatory action and primary alternative action described in this unit. Additional details related to how the requirements in this unit were incorporated into development of the proposed rule and primary alternative action are in Unit V. of the proposed rule.

*2. Consultations and other engagement.*

*a. Consultations.*

EPA conducted consultations and outreach as part of development of the May 2023 proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP). The Agency held a federalism consultation from October 22, 2020, until January 23, 2021, as part of the rulemaking process and pursuant to Executive Order 13132. (Ref. 14).

EPA also consulted with tribal officials during the development of the May 2023 proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP) (Ref. 15). The Agency held a tribal consultation from October 7, 2020, to January 8, 2021, with meetings on November 12 and 13, 2020. (Ref. 15). EPA received no written comments as part of this consultation.

EPA's Environmental Justice (EJ) consultation occurred from November 4, 2020, through January 18, 2021. On November 16 through 19, 2020, EPA held public meetings as part of this consultation. These meetings were held pursuant to Executive Orders 12898 and 14008. EPA received three written comments following the EJ meetings, in addition to oral comments provided during the consultations (Refs. 16, 17,18). The proposed rule presents a brief summary of the comments in Unit III.A.1. of that document (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP).

As required by section 609(b) of the Regulatory Flexibility Act (RFA), EPA convened a SBAR Panel to obtain advice and recommendations from Small Entity Representatives (SERs) that potentially would be subject to the rule's requirements. EPA met with SERs before and during Panel proceedings, on November 4, 2020, and January 28, 2021. Panel recommendations were addressed in Unit X.C. of the proposed rule and in the Initial Regulatory Flexibility Analysis (IRFA) (Ref. 19); the Panel report is in the docket (Ref. 20). EPA has also prepared a Final Regulatory Flexibility Analysis (FRFA) (Ref. 21).

The May 2023 proposed rule presents more information regarding the consultations in Units III.A.1., X.C., X.E., X.F. and X.J. of that document (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP).

*b. Other stakeholder consultations.*

For development of the proposed rule, in addition to the formal consultations described in Unit X. of the proposed rule, EPA provided an overview of the TSCA risk management process and the findings in the 2020 Risk Evaluation for Methylene Chloride (Refs. 22, 23) during a Small Business Administration (SBA) Office of Advocacy Environmental Roundtable on September 11, 2020, and in a public webinar on September 16, 2020. Attendees of these meetings were given an opportunity to voice their concerns regarding the risk evaluation and risk management.

Furthermore, during development of the proposed rule, EPA engaged in discussions with representatives from different industries, non-governmental organizations, technical experts, organized labor, and users of methylene chloride. A list of external meetings held during the development of the May 2023 proposed rule is in the docket (Ref. 24); meeting materials and summaries are also in the docket. A summary of the topics discussed during the meetings is in Unit III.A.2. of the proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP).



*c. Children's environmental health.*

The Agency's 2021 Policy on Children's Health (Ref. 25) requires EPA to protect children from environmental exposures by consistently and explicitly considering early life exposures (from conception, infancy, and early childhood and through adolescence until 21 years of age) and lifelong health in all human health decisions through identifying and integrating children's health data and information when conducting risk assessments. TSCA section 6(b)(4)(A) also requires EPA to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." In addition, TSCA section 6(a) requires EPA to apply one or more risk management requirements so that methylene chloride no longer presents an unreasonable risk (which includes unreasonable risk to any relevant potentially exposed or susceptible subpopulations). Information on how the Policy was applied and on the health and risk assessments supporting this action is available under Units II.C., II.D. and V.A., as well as in the 2020 Risk Evaluation for Methylene Chloride, and the Economic Analysis for this rule (Refs. 1, 3).

*3. Proposed regulatory action.*

EPA's proposed rule under TSCA section 6(a) to address the unreasonable risk presented by methylene chloride under its conditions of use (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSPP) included the following:

- (i) Prohibition of the manufacture, processing, and distribution of methylene chloride for all consumer use;
- (ii) Prohibition of most industrial and commercial use of methylene chloride;
- (iii) Requirements for a WCPP, including inhalation exposure concentration limits and

related workplace exposure monitoring and exposure controls, for ten conditions of use of methylene chloride (including manufacture; processing as a reactant; laboratory use; industrial or commercial use in aerospace and military paint and coating removal from safety-critical, corrosion-sensitive components by Federal agencies and their contractors; industrial or commercial use as a bonding agent for acrylic and polycarbonate in mission-critical military and space vehicle applications, including in the production of specialty batteries for such by Federal agencies and their contractors; and disposal);

(iv) Requirements for recordkeeping and downstream notification requirements for manufacturing, processing, and distribution in commerce of methylene chloride;

(v) A 10-year time-limited exemption under TSCA section 6(g) for civilian aviation from the prohibition addressing the use of methylene chloride for paint and coating removal to avoid significant disruptions to critical infrastructure, with conditions for this exemption to include compliance with the WCPP; and

(vi) A 10-year time-limited exemption under TSCA section 6(g) for emergency use of methylene chloride in furtherance of the National Aeronautics and Space Administration's mission for specific conditions which are critical or essential and for which no technically and economically feasible safer alternative is available, with conditions for this exemption to include compliance with the WCPP.

EPA notes that all TSCA conditions of use of methylene chloride (other than the use of methylene chloride in consumer paint and coating removers, which was subject to separate action under TSCA section 6 (84 FR 11420, March 27, 2019) (FRL-9989-29) were subject to the May 2023 proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP) and are subject to this final rule.

The proposed rule included timeframes for implementation. The prohibitions EPA

proposed would take effect in phases, beginning at the top of the supply chain, and coming into full effect after 450 days, as described in Units IV.A.2. and 3. of the proposal. Likewise, for the WCPP, EPA proposed timeframes for phases of compliance, beginning with monitoring at 180 days and full implementation after 360 days, as described in Unit IV.A.1. of the proposed rule.

Under TSCA section 6(c)(2)(A)(iv)(II) through (III), EPA is mandated to consider and propose an alternative regulatory action. This was included in the proposed rule in Unit IV.B. (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP). Similar to the proposed regulatory action, it combined prohibitions and requirements for a WCPP to address the unreasonable risk from methylene chloride under its conditions of use, as well as time-limited exemptions under TSCA section 6(g) for two uses. More specifically, the alternative regulatory action would allow for the WCPP, including requirements to meet an ECEL and EPA Short-Term Exposure Limit (STEL), for several additional conditions of use than would have been allowed under the proposed regulatory action. The alternative regulatory action additionally included longer compliance timeframes for prohibitions and a WCPP.

The alternative regulatory action considered would have allowed a WCPP for the following additional industrial and commercial conditions of use: industrial and commercial use in finishing products for fabric, textiles, and leather; industrial and commercial use as solvent that becomes part of a formulation or mixture; industrial and commercial use as a processing aid; industrial and commercial use for electrical equipment, appliance, and component manufacturing; industrial and commercial use for plastic and rubber products manufacturing; industrial and commercial use in cellulose triacetate film production; industrial and commercial use for oil and gas drilling, extraction, and support activities; and industrial and commercial use in paint or coating removal from safety-critical, corrosion-sensitive components of aircraft owned or operated by air carriers or commercial operators certificated under 14 CFR part 119. At

the time of publication of the proposed rule for methylene chloride, EPA believed a WCPP had the potential to be a viable alternative to the proposed prohibition for these additional industrial and commercial conditions of use because these were generally industrial in nature; owners or operators were likely currently complying with the OSHA methylene chloride standard; and, as far as the Agency was aware, these conditions of use had not resulted in any documented fatalities. However, at the time of proposal, EPA did not have reasonably available information that could confirm that compliance with an ECEL of 2 ppm was possible (e.g., monitoring data or detailed description of activities involving methylene chloride for these conditions of use). Therefore, EPA preliminarily proposed that these conditions of use be prohibited.

The alternative regulatory action also included longer timeframes for implementation of both the prohibitions and WCPP. Those timeframes are described in Unit IV.B. of the proposed rule, respectively (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP).

For a comprehensive overview of the alternative regulatory action, refer to Unit IV.B. of the proposed rule, with the rationale for the primary alternative regulatory action provided in Unit V.B. of the proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP).

#### *4. Public comments received.*

EPA requested comment on all aspects of the proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP) which published on May 3, 2023. The comment period closed on July 3, 2023. EPA received almost 40,000 public comments, with a vast majority received from individuals participating in mass mailer campaigns organized by non-governmental organizations. The public comments also include approximately 200 unique comments from industry stakeholders, trade associations, environmental groups, unions, non-governmental health advocacy organizations, academics, State and local governments, and members of the regulated community. A summary of the comments, as well as EPA's responses, is in the docket

for this rulemaking (Ref. 7). Additionally, Unit III. contains summaries of public comments that informed EPA's regulatory approach in this final rule.

After the close of the public comment period for the proposed rule, EPA held meetings with stakeholders to receive clarifying information on their comments, including affected industry and interested groups, related to the use of methylene chloride. Topics of these meetings included exposure controls, process descriptions, monitoring data, and specific conditions of use. EPA received data as part of and following these stakeholder meetings and has made the information available to the public in the rulemaking docket (EPA-HQ-OPPT-2020-0465) (Ref. 24).

After review of the public comments received from the proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSPP) for methylene chloride, EPA revised certain preliminary considerations that impacted which conditions of use were proposed by EPA to be prohibited or that could continue under the WCPP (Ref. 7). Similarly, based on public comments received, EPA modified for this final rule several proposed compliance timeframes, with details in Unit III.

### **III. Changes from the Proposed Rule**

This unit summarizes the main changes from the proposed rule to the final rule, based on the consideration of the public comments.

#### *A. Changes to conditions of use allowed to continue under WCPP.*

EPA's primary alternative regulatory action described in the proposed rule included several conditions of use under the WCPP, rather than prohibition. As described in Units III.A.1. through 5., EPA's final rule allows three additional conditions of use under the WCPP (Units III.A.1. through III.A.3.) and broadens the scope of two conditions of use allowed to continue under the WCPP, when compared to the proposed rule. The rationale for these changes is

described in this unit and EPA notes that in the event that sensitive information relating to national security or critical infrastructure is submitted to EPA, the Agency will protect such information in accordance with applicable authorities. EPA's final rule also clarifies that this rule permits manufacturing and processing in compliance with the WCPP for export. More information is provided in Unit IV.A. regarding export.

EPA emphasizes that implementation of the WCPP can fully address the unreasonable risk from methylene chloride for the conditions of use allowed to continue, and that these changes do not significantly impact the production volume of methylene chloride expected to remain in commerce when compared to the proposed regulatory action. Taken together, the conditions of use described in Units III.A.1. through 5. account for less than an estimated 2% of the total production volume of methylene chloride.

1. *Industrial and commercial use of methylene chloride as a processing aid.*

EPA is finalizing a WCPP for industrial and commercial use of methylene chloride as a processing aid, as included in the primary alternative regulatory action of EPA's proposal (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP). While EPA proposed to prohibit industrial and commercial use of methylene chloride as a processing aid, this was due to insufficient information at the time of proposal to determine that the sector as a whole could comply with a WCPP. During the Small Business Advocacy Review Panel, EPA received data from a small business using methylene chloride as a processing aid, specifically as a heat transfer fluid, indicating they were able to meet an ECEL of 2 ppm. Initial data indicated that the occupational exposure scenario (cellulose triacetate film manufacturing) used to assess this condition of use in the 2020 Risk Evaluation of methylene chloride (Ref. 1) may not have been representative of the overall types of exposures expected for this condition of use. In the proposed rule, EPA specifically requested comment on the degree to which other entities using methylene chloride as

a processing aid could comply with the proposed WCPP requirements for methylene chloride. Numerous commenters provided EPA with process descriptions, diagrams, and monitoring data, summarized in this unit and in the Response to Comments document, such that EPA is now confident that, in general, entities engaged in this condition of use can meet the requirements of the methylene chloride WCPP (Ref.7).

Numerous commenters submitted information for use of methylene chloride as a processing aid, including as a heat transfer fluid and in the production of separators for lithium-ion batteries, as well as other processing aid uses (Refs. 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36). Many of the same commenters also submitted process descriptions indicating that this use of methylene chloride takes place in a closed system with little or no personnel interaction (Refs. 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37). Some commenters provided EPA with standard operating procedures and describe in detail the use of respiratory protection (including PPE, as well as other exposure controls), including during instances of infrequent maintenance or repair (Refs. 27, 31, 34, 36). Methylene chloride is often cycled continuously through the enclosed process or, in some cases, recovered through a distillation process and reused with high efficiency (Refs. 30, 34). Some companies indicated that they are in compliance with the existing OSHA standard, and though the WCPP requires lower exposure limits, the WCPP processes such as routine monitoring are similar and indicate likely success with regards to WCPP compliance (Refs. 26, 27, 28, 29, 30, 31, 35, 36). Of these companies, some supplied monitoring data that showed compliance levels below the existing OSHA safety standard and demonstrated the ability to measure at or near EPA's proposed methylene chloride WCPP 8-hr TWA of 2 ppm, indicating an ability to comply with the EPA level, and further indicating that the initial exposure data provided by small entity representatives (SERs) during EPA's SBAR process is more appropriately representative for this condition of use than the more general occupational

exposure scenario used by EPA in the 2020 Risk Evaluation for Methylene Chloride (Refs. 26, 27, 34, 36, 37, 38). Additionally, commenters noted that the National Emission Standard for Hazardous Air Pollutants (NESHAP) for Organic Hazardous Pollutants for Equipment Leaks at 40 CFR 63 Subpart H requires a robust leak detection and repair program (Ref. 31).

Use of methylene chloride in the manufacture of separators for lithium-ion batteries for electric vehicles also falls under use as a processing aid. Based on information reasonably available to the Agency at this time, methylene chloride is not currently used in the United States to manufacture lithium-ion battery separators, with some companies choosing to use trichloroethylene (TCE) in the production of battery separators instead (Refs. 39, 40, 41). During the comment period, at least five commenters described their plans to construct manufacturing plants for lithium-ion battery separators, specifically for electric vehicles, that would use methylene chloride as a processing aid (Refs. 42, 43, 44, 45, 46). Commenters described how this would strengthen critical supply chains by revitalizing domestic manufacturing and research and development in accordance with Executive Order on America's Supply Chains (EO 14017) (86 FR 11849, March 1, 2021). Commenters provided details about the process of using methylene chloride in the manufacture of battery separators. Methylene chloride is used in the wet manufacturing method of high-quality battery separators (Refs. 42, 45, 46). In wet manufacturing, polyethylene is treated to form a porous, monolayer film (Refs. 42, 46). This film is then treated with low molecular weight oil, stretched, and exposed to a high-performance solvent to form a uniform microporous structure while recovering and reusing oils in the manufacturing process (Refs. 42, 46). Methylene chloride works quickly at high temperatures, and is also desirable because of its low water solubility, and compatibility with manufacturing equipment (Refs. 42, 46).

Based on the information provided by commenters and other information reasonably



available to the Agency, EPA understands that separators are fundamental components in batteries that provide the necessary separation between the internal anode and cathode components that make batteries work, and that restrictions on the production of battery separators could critically impact the United States battery manufacturing supply chain and impede the expansion of domestic battery production capacity (Refs. 40, 41, 42, 43, 44, 45, 46, 47). EPA understands that battery separator manufacturing processes are highly-engineered, specialty products designed precisely to meet stringent technical specifications that are essential in powering vehicles and systems in the United States' supply chain for multiple critical infrastructure sectors.

A commenter who intends to use methylene chloride in a closed system for battery separator manufacturing submitted monitoring information indicating exposure at or near the ECEL of 2 ppm (Ref. 42). Commenters indicate residual methylene chloride is often treated and recovered as part of this closed process (Refs. 42, 43, 46). EPA agrees that unreasonable risk from methylene chloride when used as a processing aid in the manufacture of lithium-ion battery separators, like other processing aid uses, can be addressed under the WCPP. Importantly, because companies have not yet begun production, they can build their plants with the WCPP requirements in mind (Refs. 42, 46).

On October 24, 2023, as part of a proposed regulation to address the unreasonable risk from TCE under the conditions of use, EPA proposed a 10-year time-limited TSCA section 6(g) exemption for the use of TCE in battery separator manufacturing (88 FR 74712, October 31, 2023). The period of the proposed exemption in the TCE proposed rule would provide sufficient time to transition from TCE to alternatives, such as methylene chloride. As noted by the commenters, methylene chloride is currently used overseas to manufacture high quality lithium-ion battery separators for electric vehicles (Ref. 42). EPA notes that while the use of methylene

chloride in battery separator manufacturing appears to be analogous to use of TCE for the same function, based on reasonably available information, current applications result in different end-use battery products (e.g., lithium-ion battery separators manufactured with methylene chloride and lead acid batteries and lithium battery separators manufactured with TCE). EPA believes in some cases methylene chloride may soon be a technologically feasible safer alternative to the industrial use of TCE as a processing aid in battery separator manufacturing.

Based on information provided by commenters related to processes, current exposure information and exposure mitigation practices, and monitoring data, EPA has determined the unreasonable risk from methylene chloride when used as a processing aid (including as a heat transfer fluid and in battery separator manufacture) could be addressed with a WCPP.

*2. Industrial and commercial use of methylene chloride in plastic and rubber products manufacturing, including polycarbonate manufacturing.*

EPA's primary alternative regulatory action described in the proposed rule included several conditions of use under the WCPP, rather than prohibition. EPA is finalizing a WCPP for industrial and commercial use of methylene chloride in plastic and rubber products manufacturing, including in interfacial polymerization for polycarbonate plastic manufacturing, as included in the primary alternative regulatory action of EPA's proposal (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP). While EPA proposed to prohibit industrial and commercial use of methylene chloride in plastic and rubber products manufacturing, this was due to insufficient information at the time of proposal to determine that compliance with the WCPP would be possible. For example, at the time of proposal, EPA was not aware of any monitoring data or detailed description of methylene chloride activities for this use to confirm that compliance with an ECEL of 2 ppm as an 8-hr TWA would be possible. EPA requested comment on the ability of facilities in this sector to successfully implement the WCPP for this particular use because of the

industrial nature of the use.

Commenters submitted monitoring data for industrial and commercial use of methylene chloride in plastic and rubber products manufacturing, which aided EPA with a determination of whether users could comply with the WCPP. The data provided showed that some companies are close to or already meeting the proposed ECEL without additional measures being necessary (Refs. 26, 35, 36).

A commenter also submitted detailed descriptions of methylene chloride-related activities including for unloading, handling, and recycling; sample collection; PPE procedures and itemized requirements; and safety procedures (Ref. 36). The commenter submitted an OSHA Compliance Plan; training materials for OSHA requirements, PPE, and hazard recognition; and an Exposure Assessment Program guideline as well (Ref. 36). Furthermore, the commenter provided details regarding its interfacial polycarbonate production process using methylene chloride, which is controlled by an automatic distributed control system. As described by the commenter in their comment (and confirmed in a follow-up meeting), workers using the system are in an isolated control room that is in a separate location from the reaction system (Refs. 36, 48). Another commenter stated that their closed reactor system adheres to recognized and generally accepted good engineering practices as referenced in OSHA's Process Safety Management Standard at 29 CFR 1910.119. The commenter also explained that the methylene chloride used within the reactor system is recycled within the processing equipment (Ref. 26).

One commenter explained that PPE, including a full chemical-resistant suit, supplied-air respirators, rubber boots, and chemical gloves are used where manual operations such as unloading, sampling and maintenance activities occur (Ref. 36). During the SBAR process, one SER explained that the methylene chloride is added into the reaction system directly from tank trailers with hard pipes and flange fittings, and the product is also packed under vacuum in a

scrubber system to reduce employee exposures, creating little opportunity for exposures (Ref. 20). Another commenter stated that direct interactions, such as with sampling, are performed inside glove-box containment systems where methylene chloride is used within an enclosure and the user interacts with the sample via a viewing glass and isolation gloves affixed to the enclosure, similar to those used in laboratory settings and in industrial sandblasters (Refs. 26, 35).

The information submitted to EPA as part of the comment period regarding this condition of use, supported by subsequent discussions, demonstrate the users' ability to comply with the WCPP. For this reason, EPA has determined that the unreasonable risk from methylene chloride when used in plastic and rubber products manufacturing (including in polycarbonate manufacture) could be addressed with a WCPP.

*3. Industrial and commercial use of methylene chloride in paint and coating removal from safety critical, corrosion sensitive components of aircraft and spacecraft.*

In the proposed rule, EPA proposed that industrial or commercial use of methylene chloride for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft owned or operated by Federal agencies and their contractors could continue under the WCPP, and that other commercial use of methylene chloride for paint and coating removal would be prohibited. EPA also proposed to provide a 10-year exemption for commercial aviation and commercial aerospace applications from the proposed prohibition on the use of methylene chloride in commercial paint and coating removal. Under the primary alternative regulatory action, EPA included the WCPP for industrial and commercial use in paint or coating removal from safety-critical, corrosion-sensitive components of aircraft owned or operated by air carriers or commercial operators certificated under 14 CFR part 119. After consideration of public comments, EPA has determined to eliminate the distinction between defense-related and

commercial aircraft, and allow under the WCPP the continued commercial use of methylene chloride in paint and coating removal from safety critical, corrosion sensitive components of aircraft and spacecraft.

Several commenters argued for the removal of the distinction between defense-related, or Federal agencies, and commercial aircraft in the proposed rule (Refs. 49, 50, 51). As described by commenters, critical, corrosion-sensitive components are present and necessary for the function of all aircraft and spacecraft irrespective of the customer (Refs. 49, 50), and both defense-related and commercial aviation or aerospace currently continue to use methylene chloride for coating removal on these components. Commenters noted that both Federal and commercial sectors use the same repair and maintenance practices, maintenance facilities, and environmental health and safety practices, and that a typical repair or maintenance scenario is that certain parts are taken off the aircraft and sent to a facility owned and operated by the part/component manufacturer (Refs. 50, 51, 52). These commenters contend that the same standard of hazard and exposure control would therefore be ongoing for both the commercial and the Federal applications, and both would be likely to be equally equipped to comply with a WCPP. Both commercial and defense sectors share the same supply chain, and it is likely that any alternative developed by formulators will be evaluated by both commercial and defense sectors and, if found to be a suitable alternative, would be implemented under a similar timeframe (Ref. 49). For this reason, EPA has determined that the unreasonable risk from methylene chloride when used in paint and coating removal from safety critical, corrosion sensitive components of aircraft and spacecraft could be addressed with a WCPP.

EPA emphasizes that only a narrowly defined subset of commercial use of methylene chloride for paint and coating removal is allowed to continue under the WCPP, due to the heavily industrialized and highly specialized exposure control systems EPA believes to be in

place for both Federal and commercial aviation and aerospace coating removal from corrosion-sensitive safety-critical parts, such as landing gear, gear boxes, turbine engine parts, and other aircraft and spacecraft and components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and magnesium) and composite materials. General paint and coating removal on aircraft and spacecraft with methylene chloride is prohibited. In EPA's view, persons availing themselves of the WCPP would need to have a reasonable basis to conclude that the components on which methylene chloride is used are corrosion-sensitive and safety critical components within the meaning of the definition. EPA believes such persons could rely, in part, on information supplied by the manufacturer of the component. A determination of whether a particular component of an aircraft or spacecraft is a safety-critical corrosion-sensitive component would be a fact-specific determination that takes into account the substrate and character of the component, the effects of methylene chloride paint or coating remover on the component, and other relevant factors.

*4. Industrial and commercial use of methylene chloride as a solvent that becomes part of a formulation or mixture and the solvent will be reclaimed.*

EPA's primary alternative regulatory action described in the proposed rule included several conditions of use under the WCPP, rather than prohibition. EPA is finalizing a WCPP for a sub use of industrial and commercial use of methylene chloride as a solvent that becomes part of a formulation or mixture, as included in the primary alternative regulatory action of EPA's proposal, namely, where that formulation or mixture will be used inside a manufacturing process, and the solvent (methylene chloride) will be reclaimed (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSPP). While EPA proposed to prohibit industrial and commercial use of methylene chloride as a solvent that becomes part of a formulation or mixture, this was due to insufficient information at the time of proposal to determine that the use as a whole could comply with a

WCPP. EPA included this condition of use under the WCPP in the primary alternative regulatory action, and requested comment on additional information that could increase the Agency's certainty that entities engaged in this use could comply with a WCPP.

EPA received numerous comments describing uses of methylene chloride in industrial processes which take place in mostly enclosed systems, such as use of methylene chloride as a processing aid (see Unit III.A.1.) and in plastic product manufacturing (see Unit III.A.2.). Likewise, commenters describe some uses of methylene chloride as a solvent which becomes part of a formulation or mixture where that mixture is used in a manufacturing process and the solvent is reclaimed.

Two commenters describe a process in which methylene chloride is used to dissolve a polycarbonate coating, and then the mixture is run over a surface where the coating is deposited and the solvent is reclaimed (Refs. 53, 54, 55). Another commenter describes the use of methylene chloride in plastic manufacturing processes as a solvent (Ref. 56). As with the other commercial uses, commenters described scenarios where methylene chloride is used in a closed system, and identified that the primary points of exposure in these processes are the periodic and relatively infrequent loading of methylene chloride. As described by commenters, the system is enclosed and the methylene chloride is recovered; the processes are highly industrial and often remotely performed. One company was able to supply monitoring data that indicated exposure levels nearly meeting the proposed ECEL (Ref. 54)

In this way, these commenters' uses of methylene chloride are similar to processing methylene chloride as a reactant, industrial and commercial use of methylene chloride as a processing aid, and industrial and commercial use of methylene chloride in plastic product manufacturing. Namely, when the commercial use of methylene chloride as a solvent that becomes part of a formulation or mixture results in that formulation or mixture used inside a

manufacturing process, the methylene chloride is used functionally in the manufacturing process, frequently in a closed system, and is reclaimed, such that it is not present in the final manufacturing product. Identification of this narrowly described use of methylene chloride within a condition of use, together with information provided by commenters on their specific processes, led EPA to determine that unreasonable risk from methylene chloride when used as a solvent that becomes part of a formulation or mixture, where that formulation will be used in a manufacturing process and the solvent (methylene chloride) will be reclaimed, could be addressed with a WCPP.

*5. Industrial and commercial use of methylene chloride as a bonding agent for solvent welding.*

In the proposed rule, EPA proposed that industrial and commercial use of methylene chloride as a bonding agent for acrylic and polycarbonate in mission-critical military and space vehicle applications be allowed to continue under the WCPP. EPA included within this condition of use the use of methylene chloride in the production of specialty batteries, and identified the WCPP as an appropriate means for addressing the unreasonable risk after a specialty battery manufacturer submitted information on its use of methylene chloride in chemical welding of acrylic and polycarbonate (Ref. 57). This application of methylene chloride, unlike adhesives used to bind two distinct substrates together, dissolves plastic surfaces including, but not limited to, acrylic or polycarbonate and fuses the substrates into one continuous unit with increased strength, durability, and seal integrity (Refs. 58, 59). Mission-critical applications potentially include fabrication of fixtures and enclosures for scientific research; production of optically clear articles such as space vehicle windows, space suit helmet components, or elements of extraterrestrial habitats; or hermetically sealing the plastic cases of specialty batteries. Following publication of the 2023 proposed rule, EPA received additional public comments describing



other applications of methylene chloride used in a similar fashion; however, these applications were not in mission-critical military and space vehicle applications, or in the production of specialty batteries for such applications (Refs. 58, 60, 61).

Bonding agents used to chemically weld acrylics or polycarbonates with methylene chloride do not have a technically or economically feasible safer alternative available. This application is uniquely different from adhesives which do have technically or economically feasible safer alternatives available. Commenters that described their use of methylene chloride indicated that they require low quantities of methylene chloride for its effect and stated that they are currently in compliance with the OSHA methylene chloride standard at 29 CFR 1910.1052 (Refs. 59, 60). Based on the information received, and the similarities across multiple uses of methylene chloride as a bonding agent – but not as an adhesive – EPA believes that the WCPP will address the unreasonable risk for use of methylene chloride as a bonding agent in general, and is therefore expanding its initial scope of this allowed use under the WCPP from mission-critical military and space vehicle applications to general industry.

*B. Delayed compliance dates for prohibitions.*

*1. Commercial use of methylene chloride in refinishing for wooden furniture, decorative pieces, and architectural fixtures of artistic, cultural or historic value.*

EPA proposed to prohibit the commercial use of methylene chloride for paint and coating removal, including for all commercial furniture refinishing. While EPA proposed to exclude commercial furniture refinishing from the regulation of the use of methylene chloride in commercial paint and coating removal in 2017, the 2023 proposed rule did not exclude commercial furniture refinishing from the proposed prohibition on the use of methylene chloride for commercial paint and coating removal, because EPA determined that this use contributes to the unreasonable risk presented by methylene chloride.

EPA's proposed rule included an analysis for an exemption under TSCA section 6(g) for industrial and commercial use of methylene chloride as a paint and coating remover in furniture refinishing, and preliminarily determined that an exemption was not warranted. EPA solicited comment on its analysis, including information on the availability of alternatives, the time needed to implement alternatives, and other information related to this condition of use. After reviewing comments and conducting additional outreach, EPA found, as in the proposed rule, that a broad exemption for commercial use of methylene chloride in paint and coating removal for all types of furniture refinishing uses under TSCA section 6(g)(1)(A) is not warranted because the use of methylene chloride for all types of furniture refinishing is not a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure.

However, EPA acknowledges that for particular circumstances, such as removing coatings from wooden furniture and other items that are of artistic, historic or cultural significance, there is no technically or economically feasible safer alternative to methylene chloride currently available. Therefore, to provide a reasonable and appropriate transition period in the final rule (consistent with TSCA sections 6(c)(2)(C) and 6(d)(1)(E)), EPA is delaying compliance with the prohibition for commercial users engaged in those activities, with certain interim requirements to reduce worker exposures.

As discussed in this unit, while in some cases alternatives are available for commercial use of methylene chloride in refinishing wooden furniture, decorative pieces, and architectural fixtures, this is not the case for wooden pieces that are of artistic, cultural or historic value. These pieces tend to have increased value because of their age; their association to significant cultural figures, buildings, or events; or due to a combination of these factors. Additionally, they may contain complex geometries, such as hand-carved, ornate embellishments and grooves or other

intricate patterns. The aesthetic and structural integrity of these pieces contributes to their value, function, or both, and therefore must be preserved during the refinishing process. In other words, to the extent that alternative methods or formulations may be able to remove a coating, if they affect the underlying substrate's appearance, structural integrity, or functionality, those are not feasible alternatives for wooden pieces that are of artistic, cultural, or historic value. In the absence of such viable alternatives, cultural items such as religious articles of vertu, musical instruments, and ceremonial utensils would be degraded or rendered non-functional. In some cases, these wood pieces may be original, priceless, or irreplaceable and cannot be remade by simply commissioning an artisan to craft a replacement. Examples of these types of artistic, cultural, or historic pieces include but are not limited to: Library furniture and architectural woodwork at Harvard University (Ref. 62); the Reredos at St. Paul's School (Ref. 62); the John F. Kennedy (JFK) Podium at the JFK Library (Ref. 62); and the Arlington Cemetery Old Guard Caisson (Ref. 63).

Based on information provided to EPA, these types of wooden pieces would be aesthetically or structurally compromised by alternative refinishing techniques or chemicals other than methylene chloride (Ref. 64). Alternatives, both chemical and mechanical, can damage the underlying substrate; present flammability hazards; and take much longer to work such that they are prohibitively expensive. This section provides additional details from commenters and other sources on each of these three qualities, which led EPA to determine there are no technically or economically feasible, safer alternatives for use of methylene chloride to refinish wooden pieces of artistic, cultural, or historic value.

At the time of proposal, EPA identified many alternative products to methylene chloride for paint and coating removal, and noted that some may require adjustments to equipment and processes for furniture refinishing or longer periods of time, or may not be appropriate

alternatives for use on wood substrates (88 FR 28313). In public comments, commenters emphasized that these alternatives present their own risks, and that they are more likely to be used in paint and coating removal where the integrity and aesthetics of the substrate may be less critical to the refinished product. Commenters emphasized that for the highly complex geometries which may be common in wooden furniture, decorative pieces, and architectural fixtures of artistic, cultural, or historic value, methylene chloride-containing paint and coating removers are the only products that can remove coatings without damaging the underlying wood (Refs. 62, 65, 66). Similar issues arise when utilizing mechanical or thermal methods, because – while they may be useful for some types of paint and coating removal - they may damage the underlying structure, take so long to work that they are prohibitively expensive, and cannot reach into the grooves of complex geometries (i.e., sanding, media blasting, or heat guns) (Refs. 20, 66, 67, 68, 69).

There are significant challenges to replacing methylene-chloride based paint and coating removers in furniture refinishing; these challenges are exacerbated with wood compositions of artistic, cultural, or historic value, since the integrity or character of the piece would be compromised by alternatives to methylene chloride. Methylene chloride-based formulations are the paint removers of choice for furniture refinishers in part because they are not flammable (Ref. 20). Based on the public comments received, EPA also understands that an abrupt prohibition on use of methylene chloride in this sector could push furniture refinishers to adopt less safe alternatives, notably substances that are flammable. Currently, based on information available to EPA and provided in public comments, some alternative paint and coating removal formulations are flammable (Ref. 3). EPA’s alternatives analysis identified 47 chemicals in paint and coating remover formulations with reasonably available hazard information; of those, 33 are flammable to varying degrees (Ref. 13). EPA notes concern from commenters about the strong

likelihood of regrettable substitutions in instances where combustible materials and flammable liquids may be used in tandem and result in a combined Class-A and Class-B fire, as defined by OSHA in 29 CFR 1910.155 (Refs. 62, 66, 70, 71), in workshops where environmental conditions are likely to contain fine, combustible particulates in larger quantities such as saw dust or wood shavings.

Additionally, based on information provided by commenters, currently available alternative paint and coating removers used in furniture refinishing can take significantly longer for the desired effect and may require multiple applications and scraping to carefully remove the coating, adding additional time and labor to the process (Refs. 66, 70). Multiple applications and manual removal of coatings from artistic, cultural, or historic pieces – particularly those with irregular or intricate shapes – increases the likelihood of damaging the underlying wood substrate and presents increasing labor and cost challenges for this practice. Additionally, an abrupt prohibition of methylene chloride use resulting in additional time and labor would result in a price increase in this sector; as EPA noted in the proposed rule, this may result in significant financial challenges in a sector where profit margins are already narrow at about 3.8% of sales (Ref. 67). Due to the added time, labor, and cost that an alternative would pose, commenters contend that the likelihood of this sector remaining viable would be minimal and, as commenters describe, may result in immediate furniture disposal to landfills that would have otherwise been recycled through refinishing (Refs. 64, 66). As discussed earlier in this unit, commenters have noted that that while alternative chemicals or substitute methods could be used where the integrity and aesthetics of the substrate may be less critical to the refinished product, they also emphasized that methylene chloride is uniquely suitable for removing coatings and refinishing complex pieces made of wood that cannot be replaced if damaged, due to its artistic, cultural, or historic value.

While EPA believes that in many instances, furniture refinishing can be successfully accomplished with alternatives to methylene chloride, in consideration of public comments, EPA has determined that there is no technically or economically feasible alternative that benefits health for commercial use of methylene chloride in paint and coating removal for the refinishing of wooden compositions of artistic, cultural, or historic value, since the integrity or character of the piece would be compromised by alternatives to methylene chloride. Therefore, to provide a reasonable and appropriate transition period, EPA's final rule will delay, until five years after the publication of this final rule, compliance with prohibitions for commercial use of methylene chloride for refinishing wooden pieces which are of artistic, cultural, or historic value, with interim requirements for exposure controls, based on best practices described by furniture refinishers.

Commenters provided information on engineering and exposure controls, allowing EPA to identify how risks could be reduced before prohibitions went into effect, even if the unreasonable risk could not be completely addressed. Based on information received, entities engaged in the use of methylene chloride for commercial furniture refinishing have a number of options for engineering and administrative controls to reduce exposure; some commenters noted that exposures may currently be under the OSHA action level of 12.5 ppm (Ref. 72). Types of controls that facilitate low levels of exposure include engineering controls with linear airflow, such as some spray booths typically used for painting, but which can also be used for paint and coating removal (Ref. 73). Other examples include custom engineering controls where fans bring in fresh exterior air, while an additional ventilation system pulls methylene chloride vapors down and away from the user's personal breathing zone (Refs. 64, 72). Because methylene chloride vapors are heavier than air and naturally flow downward, the intake that removes methylene chloride vapors is intentionally positioned below the working station, and in some instances

incorporated into the refinishing equipment, such as at the base of a flow-over tray, to draw the volatilized methylene chloride vapors down and away from the user quickly (Ref. 72).

Additionally, as commenters noted, it is common practice for refinishing shops to conduct their refinishing activities in batches, so that, for example, methylene chloride is only present in the workplace once a week or month, rather than every day (Refs. 64, 66).

EPA recognizes the challenges of developing and transitioning to technologically and economically feasible alternative paint and coating removers for some applications. However, while some furniture refinishing businesses have successfully implemented custom engineering controls for their operations, EPA remains concerned about the feasibility of long-term WCPP compliance for many businesses in this sector. Custom ventilation systems, as well as equipment and training for the use of supplied-air respiratory protection are burdensome to procure and implement, but would be necessary to ensure protection of human health from this use. Because of the magnitude of exposure for this application, which is primarily conducted in flow over trays and dip tanks, air supplied respirators – and associated monitoring – would likely be a key part of reaching an ECEL of 2 ppm, adding additional expense. While EPA expects a majority of commercial users of methylene chloride to be familiar with the OSHA standard, and therefore familiar with many of the requirements of a successful WCPP, in the furniture refinishing sector many workshops are run by self-employed artisans, who would not be subject to OSHA regulations. EPA has encountered furniture refinishers who were using cartridge respirators, despite the fact that, as specified in the OSHA methylene chloride standard at 29 CFR 1910.1052, only supplied air respirators are effective against methylene chloride, since cartridges are quickly eroded by methylene chloride vapors. Since 1985, at least seven deaths have been attributed to use of methylene chloride for paint stripping in the Reupholstery and Furniture Repair Sector (Ref. 11). While EPA acknowledges the commitment of furniture refinishers that

aim to protect workers while providing a high-quality service, EPA remains concerned that WCPP implementation could present significant and widespread difficulties in this sector, resulting in high non-compliance rates that would undermine the health-protectiveness of the rule and leave unreasonable risks of injury to health unmitigated. In the preamble to the proposed rule, EPA sought public comments regarding the commercial use of methylene chloride in furniture refinishing, as well as detailed information as part of any comments requesting that EPA consider a regulatory alternative that would subject more conditions of use to the WCPP, instead of prohibition. EPA requested that these comments provide “monitoring data and detailed descriptions of methylene chloride involving activities for these conditions of use to determine whether these additional conditions of use could comply with the WCPP such that risks are no longer unreasonable” (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP). For commercial use of methylene chloride in furniture refinishing, EPA did not receive this information and the information provided by commenters did not provide EPA with adequate information to establish that furniture refinishers could successfully comply with the WCPP, or that could serve as a roadmap for how furniture refinishers might adapt their processes to reduce exposures such that the risks were no longer unreasonable (EPA-HQ-OPPT-2020-0465-0228, -0233, -0285). For example, commenters did not provide monitoring data for this condition of use, or detailed estimates of the quantity of methylene chloride used. Information that would have helped EPA to evaluate whether commercial use of methylene chloride in furniture refinishing could continue under the WCPP would have included: monitoring information indicating compliance with the OSHA Permissible Exposure Limit (PEL) or a lower threshold such as the EPA ECEL, potential process changes that could mitigate exposure to methylene chloride, typical administrative and engineering controls, and other occupational, environmental, safety, or health practices that are currently implemented. EPA notes that other industries, such as those engaged in the industrial



and commercial use of methylene chloride as a processing aid and industrial and commercial use of methylene chloride in plastic product manufacturing, were able to provide such data during the comment period. Additionally, while commenters did emphasize the importance of methylene chloride in furniture refinishing, they did not provide specific information regarding EPA's solicitation on comments "on how costs and economic impacts from firm closure may be reduced with longer compliance timeframes."

As described in the proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP), EPA identified the commercial use of methylene chloride in furniture refinishing as contributing to the unreasonable risk and, despite extensive stakeholder engagement (described in Units III.B.1. and V.A.4. of the proposed rule) (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP), could not conclude that work practices could be modified to such an extent that exposures could be reduced sufficiently to address the unreasonable risk. Based on stakeholder interest in continuing this use of methylene chloride, EPA solicited comments in the proposed rule specifically to increase the information available to EPA to inform for this final rule, whether the use could move to the WCPP rather than prohibition. While EPA appreciates the public comments provided, they did not supply the information necessary.

However, in recognition of the challenging and particular circumstances faced by furniture refinishers engaged in restoring and removing coatings from wooden pieces of artistic, cultural, or historic value, and to address the unreasonable risk from methylene chloride contributed by this condition of use, EPA is finalizing a delayed compliance date of five years for the use of methylene chloride in a subset of furniture refinishing for these specialty wood pieces where workshops can meet a minimum standard of exposure control.

In order to participate in the delayed compliance with the prohibition, owners/operators must meet a minimum standard of exposure control. That includes: 1) use of a regulated area; 2)

use of local exhaust ventilation, both bringing air in from outside of the workspace where methylene chloride is being used and pulling methylene chloride vapors away from the potentially exposed persons; and 3) use of any NIOSH Approved® Supplied-Air Respirator (SAR) or airline respirator in a demand mode equipped with a full facepiece (Assigned Protection Factor (APF) 50) or any NIOSH Approved® Self-Contained Breathing Apparatus (SCBA) in demand-mode equipped with a full facepiece or helmet/hood (APF 50) or the appropriate respirator based on initial monitoring as outlined in Unit IV.B.4.b. or 40 CFR 751.109(d) of the regulatory text. EPA expects that within five years, either new alternatives to methylene chloride for paint and coating removal for refinishing wooden pieces of artistic, cultural, or historic value will be identified and put into use, similar to how alternatives to methylene chloride for consumer paint and coating removal were developed and marketed quickly in advance of EPA's 2019 prohibitions, or facilities will be able to refine processes and workshop equipment to incorporate alternative methods for chemical paint and coating removal. EPA emphasizes that the Agency would also continue to be willing to review data on exposures to methylene chloride in furniture refinishing, and in particular any data indicating that furniture refinishers could meet the ECEL of 2 ppm over an 8-hr TWA, the EPA STEL of 16 ppm as a 15-minute TWA, or otherwise consistently comply with the WCPP, and could revise this final rule accordingly if such data were provided.

*2. Industrial and commercial use of methylene chloride in adhesives and sealants.*

EPA proposed to prohibit the industrial and commercial use of methylene chloride in adhesives, sealants, and caulks; paints and coatings; paints and coating removers for non-corrosion sensitive parts; and lubricants. TSCA section 6(d) requires EPA to specify mandatory compliance dates for all requirements of a TSCA section 6(a) rule. The mandatory compliance dates must be “as soon as practicable” and “provide for a reasonable transition period.” Except

for full implementation of a ban or phase-out of a chemical substance, the mandatory compliance date for a requirement in a TSCA section 6(a) rule, including the start of ban or phase-out requirements, must be no later than five years after the date of promulgation of the final rule. EPA proposed that the prohibitions on commercial use of methylene chloride—in adhesives, sealants, and caulks as well as nearly all other commercial uses—take effect 450 days after publication of the final rule in the *Federal Register*. In public comments, regulated entities in the aerospace sector described anticipated challenges with the proposed timeframe for the prohibitions, and requested a 10-year delayed compliance date for their uses of methylene chloride within these conditions of use (Refs. 49, 51, 52). While EPA partially agrees with some aspects of the rationale provided by commenters, EPA maintains that technically and economically feasible alternatives to methylene chloride are currently available for a majority of these applications, and formulations containing methylene chloride are not uniquely specified to industry or military standards for paints and coatings; paints and coating removers for non-corrosion sensitive parts; and lubricants. Therefore, the prohibition timeframes in this final rule, which take full effect after two years as described in Unit III.E., should be sufficient for regulated entities to identify and implement alternatives for paints and coatings; paints and coating removers for non-corrosion sensitive parts; and lubricants.

Two additional commenters requested that EPA consider delayed compliance for use of methylene chloride in adhesives and sealants in the aerospace and defense sectors; one commenter provided rationale in support of a delayed compliance date of five years (Refs. 50, 61). The commenter described how certain methylene chloride adhesives and sealants used in turbine engines and aircraft systems do not currently have methylene chloride-free alternatives identified, including applications such as: use in bonding critical turbine engine hardware, use as a jointing compound in engine parts, adhesive to bond capacitors, transformers, components,

military printed circuit (PC) boards and subassemblies, and gasket sealant in aerospace systems (Ref. 50). The commenter estimated that properly qualifying these products may take as long as five years and requested delayed compliance (Ref. 50). EPA agrees that five years is a reasonable compliance timeframe for the identification and qualification of methylene chloride-free alternatives to both industry and Federal standards for these uses, and is therefore finalizing delayed compliance of five years before prohibition for industrial and commercial use of methylene chloride in adhesives and sealants when that adhesive or sealant is used in aircraft, space vehicle, or turbine applications for structural and safety critical non-structural applications.

In contrast to the delayed compliance with the prohibition for a subset of furniture refinishers as described in Unit III.B.1., EPA is not requiring interim controls during the period of delayed compliance for this subset of adhesive and sealant users. This is because for industrial and commercial use of methylene chloride in adhesives and sealants when that adhesive or sealant is used in aircraft, space vehicles, or turbine applications for structural and safety critical non-structural applications, EPA does not have the same concerns for magnitude of risk that could result in occupational fatalities from acute exposures as EPA has for furniture refinishing. In other words, while unreasonable risk as a result of either acute or chronic exposures exists for industrial and commercial use of methylene chloride in adhesives and sealants when that adhesive or sealant is used in aircraft, space vehicles, or turbine applications for structural and safety critical non-structural applications, the magnitude of those risks in comparison to the benchmark, as well as information about existing controls in this sector, did not lead EPA to determine that prescribing minimum interim controls for the duration of the phaseout was necessary for this use. This is in contrast to commercial use of methylene chloride in furniture refinishing, for which EPA has concerns for fatalities due to acute exposures, as a result of the magnitude of risk for that condition of use. For these adhesive and sealant applications, the

volume of adhesive used, the percent formulation of methylene chloride, as well as the proportion of industrial (as opposed to commercial) workspaces, is much less compared to the furniture refinishing sector, which is reflected by the risk characterization driving the unreasonable risk determination for both furniture refinishing and adhesive and sealant conditions of use (Ref. 1). While interim exposure controls are not required by EPA during the delayed prohibition for this use, EPA expects that owners or operators will continue to comply with OSHA's methylene chloride standard under 29 CFR 1910.1052 until either a successful transition to an alternative has been achieved, or the delayed prohibition timeframe has been exhausted, whichever is sooner.

*C. De minimis threshold.*

In the proposed rule, EPA requested comment on whether the Agency should consider a de minimis threshold of methylene chloride in formulations when finalizing prohibitions, and, if so, what threshold should be considered de minimis. EPA received numerous comments in support of the inclusion of a de minimis threshold (Refs. 30, 37, 49, 51, 52, 55, 56, 65, 74, 75, 76, 77, 787, 79). Of those, a majority of commenters agreed with the EPA suggestion of using 0.1% by weight as the de minimis threshold for the applicability of prohibitions and restrictions on methylene chloride; in some cases, commenters noted that this threshold would be consistent with the requirements under the OSHA Hazard communication standard at 29 CFR 1910.1200 (Refs. 30, 31, 37, 38, 49, 51, 53, 55, 65, 74, 75, 78, 79, 80).

Under 29 CFR 1910.1200, a health hazard is defined as “a chemical which is classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); or aspiration hazard. The criteria for determining whether a

chemical is classified as a health hazard are detailed in Appendix A to 29 CFR 1910.1200 – Health Hazard Criteria.” Appendix A of 29 CFR 1910.1200 indicates that a substance is considered a health hazard if it includes greater than 0.1% of a substance that, like methylene chloride, is classified as a carcinogen (Ref. 81). Other EPA programs, such as the Toxics Release Inventory (TRI) program, have adopted a de minimis threshold of 0.1% for chemicals which are defined as carcinogens or as a potential carcinogen under the National Toxicology Program, International Agency for Research on Cancer, or OSHA (see 40 CFR 372.38(a)).

Some commenters, rather than suggesting a particular de minimis threshold, suggested EPA identify a de minimis that is risk protective (Refs. 82, 83). For methylene chloride, due to the type and quantity of reasonably available information, EPA conducted an analysis using input parameters and exposure scenarios from the 2020 Risk Evaluation for Methylene Chloride to confirm that methylene chloride, when present at a threshold of 0.1% by weight, does not contribute to unreasonable risk under the conditions of use (Ref. 84). EPA’s final rule includes a de minimis threshold of 0.1%. The adoption of a de minimis threshold in this final rule means that products in which methylene chloride is present below 0.1% by weight are not subject to the restrictions outlined in this rulemaking.

#### *D. Changes to timeframes.*

##### *1. Changes to the WCPP timeframe.*

For the conditions of use for which EPA proposed the WCPP, EPA proposed several compliance timeframes, including requirements that initial exposure monitoring be conducted within 180 days of publication of the final rule in the *Federal Register*, that each owner or operator ensure that the airborne concentration of methylene chloride does not exceed the ECEL or EPA STEL for all potentially exposed persons within 270 days of publication of the final rule in the *Federal Register*, and that owners and operators implement an exposure control plan

within 360 days of publication of the final rule in the *Federal Register*. In the primary alternative regulatory action described in the proposed rule, EPA described longer timeframes: initial exposure monitoring under the WCPP within 360 days; that each owner or operator ensure that the airborne concentration of methylene chloride does not exceed the ECEL or EPA STEL for all potentially exposed persons within 450 days of publication of the final rule in the *Federal Register*, and that owners and operators implement an exposure control plan within 540 days of publication of the final rule in the *Federal Register*.

After considering comments regarding timeframes needed for implementing the WCPP, EPA has determined that the timeframes in the alternative regulatory action would ensure that the regulated community has adequate time to assess, formulate, procure, and implement the required chemical safety program for methylene chloride.

EPA's proposed rule included an analysis of the alternative regulatory action and preliminarily determined that the proposed timeframes for compliance with the WCPP were appropriate. For the proposed regulatory action compliance timeframe, EPA adopted timeframes similar to those previously promulgated by OSHA in the 1997 update to the methylene chloride standard at 29 CFR 1910.1052. However, public comments indicated that OSHA's compliance timeframes are not universally appropriate, especially when considering that the proposed ECEL and EPA STEL are an order of magnitude lower than the current OSHA PEL and would require additional time to execute properly, in some instances requiring the adoption of new methods (see section 5.1.2 in the Response to Comments document (Ref. 7) for a full discussion of methylene chloride monitoring methods and the PEL). Commenters also stated an additional concern that the proposed timeframes would be insufficient to document the novel efforts required under the WCPP to document the use of the hierarchy of controls (Ref. 55, 70).

Other commenters highlighted additional challenges with the proposed timeframes. For

example, one commenter anticipated an increasing need for professional services from industrial hygienists, engineers, or others in order to implement and maintain the WCPP as proposed (Ref. 19). To this end, a commenter stated that the proposed regulation could put an unintended strain on the safety industry and laboratories required to analyze monitoring samples due to the sudden increase in demand for such services (Ref. 85). The commenter expressed concern that the increased demand for safety professional services may result in lowered standards and practices (Ref. 85). Other commenters added that facilities would need to determine if a corporate exposure assessment strategy would need to be reassessed for the proposed ECEL and EPA STEL (Refs. 55, 70). Moreover, because the current OSHA standard contains criteria for the discontinuation of air monitoring for methylene chloride, it is likely that some entities have not monitored for inhalation exposures for an extended period of time. For situations such as this, a corporate exposure assessment strategy or similar mechanism would necessitate the procurement of professional services, adding logistical demand for these specialized services.

In consideration of the challenges of initiating the WCPP, even for facilities with industrial hygiene programs in place, and given the difference in the occupational exposure limits between the OSHA PEL and the EPA ECEL that may spur an increase in the need for monitoring or other exposure control assessment infrastructure, EPA determined that a longer compliance deadline of 12 months, as provided in the primary alternative regulatory action described in the proposal, would be an appropriate timeframe to conduct initial monitoring, which likely would require regulated entities to contract new services or realign current industrial hygiene professionals toward WCPP compliance. Adopting this timeframe from the alternative approach (providing 12 months for initial monitoring) is intended to 1) prevent professional safety service sectors from being overwhelmed by new EPA requirements; 2) provide time to procure the necessary services while ensuring the preservation of safety quality,



standards, and practices; and 3) provide additional time for a comprehensive exposure evaluation, increasing the likelihood of successful implementation of the WCPP.

As noted by commenters, the proposed 180-day compliance timeframe would not provide a sufficient amount of time to identify similar exposure groups and facilitate effective initial exposure monitoring, and as a result, this raised concern regarding the successful implementation of the WCPP for regulated entities. When EPA initially proposed compliance timeframes for the WCPP, beginning with initial monitoring at 180 days and requiring full implementation of the WCPP for methylene chloride by 360 days, EPA pursued similar approaches to OSHA's 1997 revision of the methylene chloride standard in an effort to swiftly address unreasonable risk to workers. While EPA expected some processes to be streamlined given the familiarity of its proposed regulatory structure, information submitted to EPA stated that delayed compliance is necessary to identify staffing needs, to properly evaluate facilities for exposures using the ECEL and EPA STEL, and to fully implement the WCPP (Refs. 55, 70). Furthermore, in addition to the possible service professionals identified by EPA in the IRFA (Ref. 19), commenters noted that an expanded scope of individuals would be required to implement a WCPP, including operations managers, process engineers, and process safety management engineers (Refs. 19, 55, 70).

Information was also provided to EPA during the comment period detailing evaluation steps that would be required to assess a facility and fully implement a WCPP, specifically to perform appropriate initial monitoring. The steps noted by commenters included development of an exposure assessment strategy (which requires the identification of stakeholders), the development of methods to gather information, the use of similar exposure groups, the determination of analytical methods, and the training for proper execution of monitoring, including the assessment strategy and exposure characterization (Refs. 55, 70). Another commenter provided information on its process for establishing monitoring to the EPA exposure

level, which substantiated the steps identified by the trade associations. This stakeholder was already in the process of refining its monitoring approach for its unique exposures. The stakeholder claimed that additional time is warranted for targeted exposure evaluations that would be most representative of tasks performed in its facilities (Ref. 48). Given the precedent of existing OSHA methylene chloride standards, EPA recognizes that much of the infrastructure and methods needed for monitoring may already be in place; however, EPA also acknowledges concerns expressed by commenters that adequate time would be needed to monitor to EPA's lower exposure levels (Refs. 55, 70). After consideration of comments and outreach conducted following publication of the 2023 proposed rule, due to the increased scope of exposure evaluation processes and required personnel, EPA determined that a delayed compliance date of 360 days to conduct initial monitoring and 540 days to fully implement the WCPP as described in the proposed primary alternative regulatory action is necessary, and is finalizing such a timeframe in this rule.

Although stakeholders commented that a minimum of 720 days to 1,080 days would be necessary to fully implement the WCPP (Refs. 55, 58, 70), EPA considers that suggested change to the proposed timeframe to be excessively lengthy for methylene chloride and would not be in compliance with the TSCA section 6(d) requirement that implementation dates be as soon as practicable (Refs. 55, 58, 70). EPA recognizes that certain provisions in the Final Rule are new and diverge from existing OSHA regulatory requirements for methylene chloride, and that additional time is warranted to fulfill those requirements. This could include, but is not limited to, the need to formulate an exposure sampling strategy, consult with specialized service providers, contract with specialty service providers or sampling laboratories, purchase PPE and respirators, procure capital for facility retrofitting, train workers on new types of PPE and administrative procedures, calibrate equipment, or design and install new engineering controls

(Refs. 35, 55, 70). Based on comments, outreach, reasonably available information, and long-established OSHA standards for methylene chloride, EPA maintains that the majority of the exposure reduction and worker safety infrastructure needed for compliance is currently in place, but recognizes the fundamental challenge of monitoring to new, lower EPA exposure thresholds. Therefore, EPA determined that, as outlined in the proposed primary alternative regulatory action, providing additional time for the initial monitoring step with staggered requirements following in three-month increments will be sufficient for much of the regulated community and provide significant benefit towards the successful implementation of the WCPP. Specifically, for the private sector, EPA is finalizing the proposed primary alternative regulatory timeframes for WCPP implementation, including 360 days for initial monitoring, 450 days to ensure that no person is exposed to an airborne concentration of methylene chloride that exceeds the ECEL or EPA STEL, and 540 days to implement an exposure control plan.

However, EPA remains concerned about the ability of certain departments and agencies of the Federal government, as well as Federal contractors acting for or on behalf of the Federal government, to comply with these timeframes. The importance of methylene chloride to mission-critical Department of Defense and National Aeronautics and Space Administration (NASA) operations and overall military readiness is discussed in Units III.A.5. and III.B.1., as well as throughout the proposed rule. While, for example, 29 CFR 1960 sets forth procedures and guidelines for ensuring that Federal workers are protected in comparable ways to their private sector counterparts, EPA believes that compliance with this final rule will require increased and different preparations on the part of Federal agencies. For example, Federal agencies must follow procurement requirements which will likely result in increased compliance timelines. In addition, these requirements will require support in the Federal budget, which, for some agencies, is a multi-year process. Therefore, EPA is providing an additional year for agencies of the Federal

government and their contractors, when acting for or on behalf of the Federal government, to comply with the WCPP, including 915 days for initial monitoring, 1,005 days to ensure that no person is exposed to an airborne concentration of methylene chloride that exceeds the ECEL or EPA STEL, and 1,095 days to implement an exposure control plan.

*2. Changes to prohibition timeframes.*

For occupational conditions of use subject to a prohibition, EPA proposed that prohibitions would become effective in a staggered schedule for each stage of the supply chain and would come into effect in 90 days for manufacturers, 180 days for processors, 270 days for distributors to retailers, 360 days for all other distributors and retailers, and 450 days for industrial and commercial uses after the publication date of the final rule in the *Federal Register*. For consumer uses, EPA proposed that the prohibitions of manufacturing, processing, and distribution in commerce of methylene chloride for consumer use would occur in 90 days for manufacturers, 180 days for processors, 270 days for distributing to retailers, and 360 days for all other distributors and retailers after the publication date of the final rule in the *Federal Register*. The EPA proposed primary alternative regulatory action included longer timeframes, which begin at 360 days for manufacturing, 450 days for processors, 630 days for all other distributors and retailers, and 720 days for industrial and commercial users.

Several commenters raised concerns on the timeframe for complying with prohibitions from the proposed regulatory action, stating that it does not allow sufficient time to identify, research, test, qualify, and implement alternative substances or processes (Refs. 75, 83, 86, 87). A commenter also noted that adopting use of alternatives would involve making engineering changes to allow for the manufacturing, processing, and use of alternatives (Ref. 87). Another commenter highlighted the general challenges in implementing shifts to alternative chemicals or formulations for industries with multi-tiered supply chains (Ref. 83). EPA acknowledges and

agrees that there likely will be circumstances in which chemical alternatives may not be an exact, drop-in replacement for conditions of use, or in which new, additional, or modifications to existing engineering equipment could be required, and that coordination with suppliers or customers across the supply chain (including with certifying entities in circumstances where a formulation change may require recertifying a product to meet performance standards, for example) may require a transitioning process. This point was expanded upon by a commenter who stated that the identification, testing, and implementation of alternatives would not only affect the commercial users of methylene chloride, but would also impact their distributors and customers downstream (Ref. 86). Due to these and other concerns, some commenters supported the proposed alternative timeframe for prohibition, which would provide additional time that commenters described as necessary for seeking alternatives, successfully implementing their use, and mitigating supply chain impacts (Refs. 50, 60, 70, 83). After reviewing all of the comments, EPA is modifying the proposed prohibition compliance timeframe for industrial and commercial uses to lengthen it in this final rule, to allow for successful implementation of the prohibitions, as outlined in the proposed alternative regulatory action. This extension will also provide additional time for industry to consult with their upstream suppliers and downstream customers and to make necessary adjustments, thereby mitigating immediate concerns for operational continuity for conditions of use identified in Unit IV.C.

Regarding consumer use of methylene chloride, while many commenters that provided input emphasized the need for a longer prohibition compliance timeframe for manufacturers, formulators, or distributors of these products, other commenters believed EPA should maintain or expedite the timeline for prohibitions related to consumer use (Refs. 88, 89). Commenters emphasized the severity of the hazards posed by methylene chloride (including to consumer users and bystanders to consumer use), particularly the acute hazards which can include death.

Commenters cited the available alternatives for consumer uses, which EPA also noted in the proposed rule (Ref.13). EPA has not found that transitions to alternatives to methylene chloride for consumer use involve the same considerations or the need for extended timeframes as for commercial use. Therefore, EPA is finalizing the prohibition implementation timeframe from the proposed regulatory action for retailer restrictions to expeditiously restrict access by consumers, while allowing additional transition time for the commercial sector. EPA is finalizing this with the proposed alternative action timeframes for manufacture, processing, use, and all other distribution (i.e., non-retailer) for industrial and commercial use, while finalizing the proposed timeframes for distribution to and by retailers for consumers. As described in the proposal, and in Unit IV.C., a retailer is any person or business entity that distributes or makes available products to consumers, including through e-commerce internet sales or distribution.

EPA acknowledges that the final approach potentially allows for manufacturing and processing of methylene chloride and methylene chloride-containing products for three to six months beyond when they could be distributed to or by retailers. EPA took this approach to expeditiously remove methylene chloride-containing products from the consumer market. While EPA acknowledges that, in some cases, upstream manufacturers and processors may lack awareness of the downstream uses of their products, in the case of methylene chloride, manufacturers and processors should be aware of restrictions downstream (distributing to and by retailers) that would make them unable to distribute products that end up on the consumer market, as a result of the 2019 rulemaking prohibiting methylene chloride in paint and coating removers for consumer use because that regulation required manufacturers of methylene chloride, regardless of downstream uses, to revise their SDS effective August 26, 2019 (84 FR 11420, March 27, 2019) (FRL-9989-29). EPA intends to conduct outreach with the regulated community and particularly manufacturers of methylene chloride, who have been actively

engaged throughout the rulemaking and risk evaluation process, to address this issue.

With a combination of proposed timeframes and primary alternative timeframes presented in the proposed rule, the prohibitions under this finalized regulatory action will take effect in 270 days for distributing to retailers, 360 days for retailers distributing more broadly, 360 days for manufacturers, 450 days for processors, 630 days for all other distributors and 720 days for industrial and commercial users following this publication of the final rule in the *Federal Register*. EPA is also finalizing downstream notification requirements in accordance with these changes; details of these changes are outlined in Unit IV.D.2.

*E. Changes to WCPP requirements: Exposure monitoring requirements.*

As part of the WCPP, EPA proposed to require that owners or operators meet certain documentation requirements for each instance of monitoring of methylene chloride, including compliance with the Good Laboratory Practice (GLP) Standards in accordance with 40 CFR part 792.

Numerous commenters expressed concern regarding the requirement that the WCPP include compliance with the GLP Standards at 40 CFR part 792. Commenters stated that it is atypical, for industrial hygiene purposes, to use this standard for air sampling of methylene chloride (Refs. 65, 70, 75, 78). According to the commenters, it is common practice within the industrial hygiene community to have analyses performed by American Industrial Hygiene Association (AIHA) accredited labs (Refs. 65, 78). A commenter further reasoned that because labs in the United States are usually certified by ISO/IEC 17025 Testing and Calibration Laboratories, a standard that differs from the proposed GLP, they recommended that provisions of monitoring results and recordkeeping in the final rule be allowed from any accredited laboratory, without regard to a specific type (Ref. 65).

EPA agrees with the commenter that the WCPP for methylene chloride is incompletely

served by solely relying on the GLP standard initially put forth in the 2023 proposed rule. Given the concern from commenters regarding potential increases in demand for professional safety services and sampling laboratories having a negative impact due to anticipated industry strain and sampling limitations (Refs. 70, 85), EPA is inclined to broaden the scope of laboratory accreditation accordingly. EPA has considered this laboratory capacity issue, in addition to other revisions for finalization in this rule, so that the additional infrastructure is in place for the regulated community to successfully implement the WCPP. Therefore, EPA is finalizing a provision that expands monitoring results and associated recordkeeping requirements to any accredited lab including GLP, AIHA (AIHA Laboratory Accreditation Programs (LAP), LLC Policy Module 2A/B/E of Revision 17.3), or other analogous industry-recognized program.

Another commenter noted that EPA omitted a provision from the OSHA methylene chloride standard that they stated is important for air monitoring and protections to potentially exposed persons. More specifically, the commenter referred to 29 CFR 1910.1052(b) where OSHA defines employee exposure to mean that airborne concentration of methylene chloride that either occurs, or would occur, in the absence of respiratory protection (Ref. 90). EPA agrees with the commenter that exposure monitoring should be conducted without regard to respiratory protection to inform engineering control options and respiratory protection considerations. Therefore, EPA is finalizing this rule to explicitly state that air sampling is required to measure ambient concentrations for methylene chloride without taking respiratory protections into account when being performed. This will ensure the highest degree of protection to potentially exposed persons by logging accurate ambient air concentrations of methylene chloride, thus empowering owners or operators to appropriately consider the hierarchy of controls.

*F. Other changes.*

EPA is also adding a definition of “article” and a definition of “product” to the



definitions that EPA proposed to add to 40 CFR part 751, subpart A. In order to provide additional clarity on the de minimis provision in this final rule, as well as the provisions relating to the refinishing of wooden furniture, decorative pieces, and architectural fixtures of artistic, cultural, or historic value, EPA is incorporating into subpart A the definitions of “article” and “product” that already exist in 40 CFR part 751, subpart E. The article definition is consistent with other article definitions in regulations under TSCA. The product definition makes it clear that when EPA uses the term “product” in this regulation, EPA is not referring to articles. These definitions are consistent with the usage of these terms in previously promulgated TSCA regulations, including the 2021 regulation on 2,4,6-tris(tert-butyl)phenol (86 FR 866, January 6, 2021 (FRL-10018-90), which incorporated the same definitions into 40 CFR part 751, subpart B, and the 2019 regulation prohibiting the manufacture, processing, and distribution of methylene chloride for use in consumer paint and coating removers (84 FR 11420, March 27, 2019) (FRL-9989-29), which does not refer to articles, but uses the term “product” to refer to methylene chloride and mixtures containing methylene chloride. EPA is also promulgating the proposed definitions of “ECEL” and “EPA STEL” in 40 CFR 751.103 rather than in subpart A to allow EPA the flexibility to tailor the definitions to address unique circumstances with future chemicals. Lastly, EPA has revised its proposed description of industrial and commercial use as a laboratory chemical condition of use to provide additional clarity as suggested by a commenter (Ref. 77). The revised description appears in Unit IV.B.1.c.iv.

#### **IV. Provisions of the Final Rule**

EPA intends that each provision of this rulemaking be severable. In the event of litigation staying, remanding, or invalidating EPA’s risk management approach for one or more conditions of use in this rule, EPA intends to preserve the risk management approaches in the rule for all other conditions of use to the fullest extent possible. The Agency evaluated the risk management

options in TSCA section 6(a)(1) through (7) for each condition of use and generally EPA's regulation of one condition of use to address its contribution to the unreasonable risk from methylene chloride functions independently from EPA's regulation of other conditions of use, which may have different characteristics leading to EPA's risk management decisions. Further, the Agency crafted this rule so that different risk management approaches are reflected in different provisions or elements of the rule that are capable of operating independently. Accordingly, the Agency has organized the rule so that if any provision or element of this rule is determined by judicial review or operation of law to be invalid, that partial invalidation will not render the remainder of this rule invalid.

There are many permutations of this. For example, as discussed in Unit IV.C., this final rule prohibits commercial use of paint and coating removal products that contain methylene chloride and are used in furniture refinishing (though a subset of this use has a delayed compliance date, as described in Unit III.B.1.), and also adhesives and sealants that contain methylene chloride (also with a subset of this use having a delayed compliance date as described in Unit III.B.2.). To the extent that a court were to find that EPA lacked substantial evidence to support its prohibition of paint and coating removal products used in furniture refinishing or otherwise found legal issues with EPA's approach to that condition of use, it would have no bearing on other similarly situated conditions of use such as adhesives and sealants unless the specific issue also applies to the particular facts associated with adhesives and sealants. This is reflected in the structure of the rule, which describes the specific prohibitions separately by compliance date.

As another example, for commercial use of methylene chloride in paint and coating removal products used in furniture refinishing and industrial and commercial use of methylene chloride as a laboratory chemical, EPA took different risk management approaches—prohibition

for paint and coating removal products used in furniture refinishing (though a subset of this use has a delayed compliance date, as described in Unit III.B.1.) and application of the WCPP for the industrial and commercial use of methylene chloride as a laboratory chemical. To the extent that a court were to find a legal issue with EPA's approach to the WCPP, impacting industrial and commercial use of methylene chloride as a laboratory chemical, it would have no bearing on EPA's decision to prohibit paint and coating removal products used in furniture refinishing, and vice versa. This is reflected in the structure of the rule, which organizes the prohibitions and the WCPP into different sections of the regulation.

In some circumstances, EPA also intends certain portions of the WCPP to be severable from the rest of the WCPP. For example, EPA intends the methods of compliance with the ECEL and EPA STEL described in paragraph (e)(1) to function somewhat independently. The provisions in paragraph (e)(1)(i) through (iii) are generally applicable to all impacted owners or operators. However, paragraph (e)(1)(iv) is specifically applicable to a scenario where the Department of Defense, based on ongoing or planned military construction that requires Congressional authorization and appropriation prior to start of construction, may need additional time to comply with the requirements of paragraph (e)(1)(i). Since the Department of Defense is also covered by the more general provision in paragraph (e)(1)(i), if a court were to find a legal issue with EPA's decision to provide the independently functioning paragraph (e)(1)(iv) to provide the Department of Defense with additional time in a particular circumstance, it would not have any bearing on EPA's broader regulatory approach reflected in paragraph (e)(1)(i) through (iii) to strike that provision.

EPA also intends all TSCA section 6(a) risk management elements in this rule to be severable from each TSCA section 6(g) exemption. EPA has the authority to promulgate TSCA section 6(g) exemptions "as part of a rule promulgated under [TSCA section 6(a)]." However,

EPA's risk management decisions under TSCA sections 6(a) and 6(c) are independent from EPA's consideration of whether it is appropriate, based on the factors in TSCA section 6(g), to exempt specific conditions of use from the requirements of the TSCA section 6(a) risk management elements in the rule. In other words, EPA first decides whether and how to regulate each condition of use, per TSCA sections 6(a) through (c), and only then determines whether an exemption under TSCA section 6(g) is appropriate. Accordingly, the underlying TSCA section 6(a) risk management elements would not be impacted if a TSCA section 6(g) exemption is determined by judicial review or operation of law to be invalid. Rather, the exempted condition of use would become subject to the underlying TSCA section 6(a) risk management element(s).

To that end, EPA acknowledges that after the issuance of this rule, Federal agencies, their contractors, and other related entities may become aware of important information which indicates a particular use, that would otherwise be prohibited, could meet the criteria of section 6(g) or the requirements of a WCPP. EPA also notes that there are multiple avenues to ask EPA to revisit issues in this TSCA section 6(a) rulemaking, both before and after the mandatory compliance dates are set consistent with TSCA section 6(d). EPA has the authority under TSCA section 6(g) to consider whether a time limited exemption is appropriate and, consistent with TSCA section 6(g)(1), could expeditiously promulgate such exemptions independently from this rulemaking, including consideration of emergency or interim rulemaking. EPA will initiate a notice of proposed rulemaking for public comment on this topic and will add this to the Spring 2024 Regulatory Agenda. Additionally, any person could petition EPA to request that EPA issue or amend a rule under TSCA section 6.

*A. Applicability.*

This final rule sets prohibitions and restrictions on the manufacture (including import), processing, distribution in commerce, commercial use, and disposal of methylene chloride to

prevent unreasonable risk of injury to health in accordance with TSCA section 6(a), 15 U.S.C. 2605(a).

Additionally, pursuant to TSCA section 12(a)(2), this rule applies to methylene chloride even if being manufactured, processed, or distributed in commerce solely for export from the United States because EPA has determined that methylene chloride presents an unreasonable risk to health within the United States. A commenter expressed concern that distribution for export would be prohibited under the proposed rule if the intended use in the destination country is prohibited in the United States, even if it is permissible under other risk mitigation rules in the destination country (Ref. 91). Because distribution in commerce did not contribute to EPA's unreasonable risk determination for methylene chloride, and because this final rule permits manufacturing and processing for various uses under the WCPP, EPA intends this final rule to permit manufacturing and processing in compliance with the WCPP for export, as well as distribution in commerce for export, without regard for the intended use in the destination country. EPA has clarified the regulatory text accordingly.

As discussed in Unit III.C., EPA's final rule is adopting a *de minimis* threshold of 0.1% to account for impurities and the unintended presence of methylene chloride. In other words, the provisions of this rulemaking only apply when methylene chloride is present in a formulation at 0.1% or greater. Additionally, the provisions of this final rule only apply to chemical substances as defined under TSCA section 3. Notably, TSCA Section 3(2) excludes from the definition of chemical substance "any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device" and "any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in

commerce for use as a pesticide.” Additional details regarding TSCA statutory authorities can be found in section 2 of the Response to Comments document (Ref. 7).

*B. Workplace Chemical Protection Program (WCPP).*

*1. Applicability.*

EPA is finalizing the WCPP for the conditions of use for which it was proposed, as well as for additional conditions of use for which either prohibition was proposed, or for which the WCPP was proposed only for a sub-set of uses within the condition of use. EPA has not removed from the WCPP any conditions of use proposed to be included. EPA’s descriptions of changes from the proposed rule are in Unit III. and EPA’s rationale for why the WCPP addresses the unreasonable risk for certain conditions of use is in Unit V. of the proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSPP). EPA is additionally requiring that uses receiving an exemption under TSCA section 6(g), as outlined in Unit IV.E., comply with the WCPP.

EPA is finalizing the WCPP for the following conditions of use: domestic manufacturing; import; processing as a reactant; processing for incorporation into a formulation, mixture, or reaction product; processing in repackaging; processing in recycling; industrial and commercial use as a laboratory chemical; industrial and commercial use as a paint and coating remover from safety critical, corrosion-sensitive components of aircraft and spacecraft; industrial or commercial use as a bonding agent for solvent welding; industrial and commercial use as a processing aid; industrial and commercial use for plastic and rubber products manufacturing; industrial and commercial use as a solvent that becomes part of a formulation or mixture, where that formulation or mixture will be used inside a manufacturing process, and the solvent (methylene chloride) will be reclaimed; and disposal. This unit provides a description of the uses subject to the WCPP in order to assist with compliance.

*a. Manufacturing (includes import).*

i. *Domestic manufacturing.*

This condition of use refers to manufacturing, or producing, a chemical substance within the United States (including manufacturing for export). Manufacture includes the extraction of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances.

ii. *Import.*

This condition of use refers to the act of causing a chemical substance or mixture to arrive within the customs territory of the United States.

b. *Processing.*

i. *Processing as a reactant.*

This condition of use refers to processing methylene chloride in chemical reactions for the manufacturing of another chemical substance or product, *e.g.*, difluoromethane, also known as HFC-32, which is used in fluorocarbon blends for refrigerants, and bis-2,2-dinitropropyl-acetal/formal.

ii. *Processing: incorporation into a formulation, mixture, or reaction product.*

This condition of use refers to when methylene chloride is added to a product (or product mixture) prior to further distribution of the product.

iii. *Processing: repackaging.*

This condition of use refers to the preparation of methylene chloride for distribution in commerce in a different form, state, or quantity. This includes transferring the chemical from a bulk container into smaller containers.

iv. *Processing: recycling.*

This condition of use refers to the process of treating generated waste streams (*i.e.*, which would otherwise be disposed of as waste) that are collected, either on-site or transported to a

third-party site, for commercial purpose. Waste solvents can be restored to a condition that permits reuse via solvent reclamation/recycling. The recovery process may involve an initial vapor recovery or mechanical separation step followed by distillation, purification, and final packaging.

*c. Industrial and commercial uses.*

*i. Industrial and commercial use as a solvent that becomes part of a formulation or mixture, where that formulation or mixture will be used inside a manufacturing process, and the solvent (methylene chloride) will be reclaimed.*

This condition of use refers to industrial or commercial use of methylene chloride added to a product (or product mixture) in an industrial or commercial setting for use inside a closed-loop manufacturing process, where the solvent will be reclaimed and reused.

*ii. Industrial and commercial use as a processing aid.*

This condition of use refers to the industrial or commercial use of methylene chloride to improve the processing characteristics or the operation of process equipment or to alter or buffer the pH of the substance or mixture, when added to a process or to a substance or mixture to be processed. Processing agents do not become a part of the reaction product and are not intended to affect the function of a substance or article created. For methylene chloride, the use as a processing aid condition of use also encompasses use of methylene chloride as a heat transfer fluid, and use in the manufacture of battery separators. Use of methylene chloride as a processing aid also refers to use of methylene chloride in blending powder for flashtube and ignition booster pellets and as a de-sensitizer for nitroglycerine shipment. Additionally, the use of methylene chloride in a closed-loop chiller system that supports performance of FAA-required aviation fuel testing, these are considered under the condition of use industrial and commercial use as a processing aid. The analogous use of methylene chloride in a chiller system in the Department of



Defense McKinley Climatic Laboratory would likewise be considered industrial and commercial use as a processing aid. (EPA notes that these chiller uses were identified under “Industrial and commercial use as a laboratory chemical” under the proposed rule. However, EPA has determined they are more accurately categorized under the condition of use “industrial and commercial use as a processing aid,” as with other heat transfer fluid uses).

*iii. Industrial and commercial use as a laboratory chemical.*

This condition of use refers to 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 rulemaking, EPA emphasizes that industrial and commercial use of methylene chloride as a laboratory chemical applies to research, government, and academic institutions, as well as to industrial and commercial laboratories. Laboratory use of methylene chloride includes Department of Defense sampling, examining, and testing of solid propellants, detail specifications of nitrocellulose, and laboratory analysis for TNT conformity with TNT acidity requirements.

*iv. Industrial and commercial use for plastic and rubber products manufacturing.*

This condition of use refers to the industrial or commercial use of methylene chloride in the manufacture and processing of plastic and rubber products, including in interfacial polymerization for polycarbonate plastic manufacturing.

*v. Industrial and commercial use as a paint and coating remover from safety critical, corrosion-sensitive components of aircraft and spacecraft.*

This condition of use refers to the industrial or commercial use of methylene chloride or

methylene chloride-containing products applied to corrosion-sensitive surfaces to remove paint, coatings, and other finishes and to clean the underlying surface in safety critical components of aircraft and spacecraft.

vi. *Industrial or commercial use as a bonding agent for solvent welding.*

This condition of use refers to the industrial or commercial use of methylene chloride or a solvent blend including methylene chloride to chemically bond polymer substrates including, but not limited to, acrylic or polycarbonate, creating an airtight, waterproof, and in some cases seamless joint.

d. *Disposal.*

This condition of use refers to the process of disposing generated waste streams of methylene chloride that are collected either on-site or transported to a third-party site for disposal.

2. *Overview.*

A WCPP encompasses inhalation exposure thresholds, includes monitoring and recordkeeping requirements to verify that those thresholds are not exceeded, and may include other components, such as dermal protection, to ensure that the chemical substance no longer presents unreasonable risk. Under a WCPP, owners or operators have some flexibility, within the parameters outlined in this unit, regarding how they prevent exceedances of the identified EPA exposure limit thresholds. In the case of methylene chloride, meeting the EPA exposure limit thresholds for certain occupational conditions of use would address the unreasonable risk to potentially exposed persons from inhalation exposure.

EPA is finalizing these requirements to begin taking effect on **[INSERT DATE 360 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for the private sector and on **[INSERT DATE 915 DAYS AFTER DATE OF PUBLICATION IN THE**

**FEDERAL REGISTER]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government, at which point entities would be required to conduct initial monitoring (as described in Unit IV.B.4.b.). Additionally, EPA requires that each owner or operator ensure that the airborne concentration of methylene chloride does not exceed the ECEL or EPA STEL for all potentially exposed persons no later than **[INSERT DATE 450 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** for the private sector, or no later than **[INSERT DATE 1005 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government. Implementation of any needed exposure controls based on initial monitoring and development of an exposure control plan would be required no later than **[INSERT DATE 540 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, for the private sector, or **[INSERT DATE 1095 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government (as described in Unit III.D.1.).

EPA uses the term “potentially exposed person” in this unit and in the regulatory text to include workers, occupational non-users, employees, independent contractors, employers, and all other persons in the work area where methylene chloride is present and who may be exposed to methylene chloride under the conditions of use for which a WCPP would apply. One important reason to define a potentially exposed person for the purposes of a WCPP as any person who may be exposed in the workplace is to emphasize the broad scope of exposures which must be categorized when implementing a WCPP. EPA notes that this definition is intended to apply only in the context of risk management, and specifically in the context of a WCPP (e.g., workers directly using the chemical, workers in the vicinity of the use, students in a laboratory setting). The term is not intended as a replacement for the term Potentially Exposed or Susceptible

Subpopulation as defined by TSCA section 3(12). EPA additionally recognizes that other individuals or communities may be exposed to methylene chloride as consumers, members of fence-line communities, or members of the general population, which is separate and apart from those potentially exposed for the purposes of the regulatory requirements of the WCPP. In those instances, where regulatory requirements address exposures unrelated to a WCPP EPA would use distinct terminology to refer to those other populations. EPA requires a comprehensive WCPP to address the unreasonable risk from methylene chloride to workers directly handling the chemical or in the area where the chemical is being used. Similarly, the 2020 Risk Evaluation for Methylene Chloride (Ref. 1) did not distinguish between employers, contractors, or other legal entities or businesses that manufacture, process, distribute in commerce, use, or dispose of methylene chloride. For this reason, EPA uses the term “owner or operator” to describe the entity responsible for implementing the WCPP in any workplace where an applicable condition of use identified in the following paragraph and subject to the WCPP is occurring. The term includes any person who owns, leases, operates, controls, or supervises such a workplace. While owners or operators remain responsible for ensuring compliance with the WCPP requirements in the workplace, they may contract with others to provide training or implement a respiratory protection program, for example.

EPA emphasizes that this approach is essential for addressing the unreasonable risk presented by methylene chloride, including to individuals who may not be covered by OSHA requirements, such as university students, volunteers, self-employed persons, and state and local government workers who are not covered by a state plan. EPA uses the term “owner or operator” in TSCA programs because the term is used in other EPA programs to describe persons with responsibilities for implementing statutory and regulatory requirements at particular locations. See, for example, section 113 of the Clean Air Act (CAA), 42 U.S.C. 7412, which defines

“owner or operator” as a person who owns, leases, operates, controls, or supervises a stationary source. There is a similar definition in section 306 of the Clean Water Act (CWA), 33 U.S.C. 1316. EPA understands that the use of this term may result in multiple persons bearing responsibility for complying with provisions of this final rule, including the WCPP. However, this is also the case for workplaces regulated by OSHA, including those regulated under OSHA’s general industry standards at 29 CFR part 1910. OSHA’s 1999 Multi-Employer Citation Policy explains which employers should be cited for a hazard that violates an OSHA standard (Ref. 92). The Policy describes four different roles that employers may fill at a workplace and describes who should be cited for a violation based on factors such as whether the employer created the hazard, had the ability to prevent or correct the hazard, and knew or should have known about the hazard. More than one employer may be cited for the same hazard. This final rule will have similar results, in that more than one owner or operator may be responsible for compliance.

The OSHA multi-employer citation policy is an example of a guidance governing situations where more than one regulated entity is present. EPA has received several requests for clarification of the applicability of the term “owner or operator” to sites where more than one entity owns, leases, or controls a workplace where a methylene chloride condition of use is ongoing and where implementation of the WCPP is required. EPA understands that there are a wide variety of situations where these questions could arise, and plans to issue guidance consistent with TSCA authorities that explains how EPA will approach the issue of responsibility for implementation of, and compliance with, the WCPP requirements in practice.

EPA’s implementation of the ECEL as part of a WCPP aligns with, to the extent possible, certain elements of the existing OSHA standard for regulating methylene chloride under 29 CFR 1910.1052. However, EPA is finalizing new, lower exposure thresholds, derived from the TSCA 2020 Risk Evaluation for Methylene Chloride, while aligning with existing requirements

wherever possible (Refs. 1, 93). For methylene chloride, this final rule will eliminate the unreasonable risk from methylene chloride contributed to by the conditions of use subject to the WCPP, enable continued industry use where appropriate, and provide the familiarity of a pre-existing framework for the regulated community.

EPA's requirements include specific exposure limits and ancillary requirements necessary for successful implementation of an ECEL as part of a WCPP. Taken together, these WCPP requirements apply to the extent necessary so that the unreasonable risk from methylene chloride under the conditions of use listed earlier in this unit would no longer be presented.

This unit includes a summary of the WCPP, including a description of the finalized exposure limits including an ECEL, ECEL action level, and EPA STEL; implementation requirements including monitoring requirements; a description of potential exposure controls, including engineering controls, administrative controls, and PPE as it relates to dermal protections and respirator selection; and additional finalized requirements for recordkeeping, workplace participation, and notification in accordance with the hierarchy of controls. This unit also describes compliance timeframes revised from the proposed rule, changes by EPA to certain provisions of the WCPP based on public comments, and addition of new provisions in the WCPP based on public comments used to inform this final rule.

### *3. Existing Chemical Exposure Limit (ECEL), EPA Action Level, Short-Term Exposure Limit (STEL).*

EPA is finalizing as proposed an ECEL under TSCA section 6(a) of 2 ppm (8 mg/m<sup>3</sup>) as an 8-hour TWA based on the chronic non-cancer human equivalent concentration for liver toxicity. EPA has determined that ensuring exposures remain at or below the 8-hour TWA ECEL of 2 ppm will eliminate the unreasonable risk of injury to health resulting from acute and chronic inhalation exposures for certain occupational conditions of use of methylene chloride (Ref. 93).

If ambient exposures are kept at or below the 8-hour TWA ECEL of 2 ppm and at or below the 15-minute TWA EPA STEL of 16 ppm also finalized in this unit, a potentially exposed person will be protected against the effects described in this unit, including effects resulting from acute exposure (central nervous system depression), chronic non-cancer effects (liver toxicity), and cancer. Using the TWA concept, as long as the 8-hr TWA or 15-min EPA STEL are not exceeded, airborne concentrations could temporarily exceed the ECEL.

EPA is finalizing as proposed an ECEL action level at half of the 8-hour ECEL, or 1 ppm ( $4 \text{ mg/m}^3$ ) as an 8-hour TWA. Below the ECEL action level, certain compliance activities, such as periodic monitoring, would be required once every five years as described further in this unit. In this way, EPA's WCPP for methylene chloride aligns with the familiar framework that is in place in 29 CFR 1910.1052 and many other occupational settings where the action level is half the relevant occupational exposure level. OSHA explained that its decision to set the action level at one-half the PEL was based on its successful experience using this fraction as the action level in many standards (e.g., arsenic, ethylene oxide, vinyl chloride and benzene); for most workplaces, the agency found that variability in employee exposures is normally such that an action level set at one-half the TWA PEL is appropriate (Ref. 94).

In addition to the 8-hour TWA ECEL, EPA is finalizing as proposed a STEL of 16 ppm ( $57 \text{ mg/m}^3$ ) as a 15-minute TWA. This STEL is based on the non-cancer endpoint of central nervous system depression resulting from acute exposures. EPA has also determined that ensuring exposures remain at or below the EPA STEL will eliminate the unreasonable risk of injury to health from methylene chloride due to acute inhalation exposures in an occupational setting. EPA is finalizing the EPA STEL as a 15-minute TWA for the protection of potentially exposed persons to methylene chloride for shorter durations and at higher concentrations that fall outside the parameters of the ECEL 8-hour TWA.

In summary, EPA is finalizing as proposed that owners or operators must ensure the airborne concentration of methylene chloride within the personal breathing zone of potentially exposed persons remains at or below 2 ppm as an 8-hour TWA ECEL, with an action level finalized as 1 ppm as an 8-hour TWA. OSHA defines the personal breathing zone as a hemispheric area forward of the shoulders within a six-to-nine-inch radius of a worker's nose and mouth and requires that exposure monitoring air samples be collected from within this space (Ref. 95). EPA is finalizing as proposed that owners or operators must also ensure the airborne concentration of methylene chloride within the personal breathing zone of potentially exposed persons remains at or below a 15-minute TWA, or EPA STEL, of 16 ppm. EPA is finalizing the ECEL and EPA STEL for certain occupational conditions of use to ensure that no person is exposed to inhalation of methylene chloride in excess of these concentrations resulting from those conditions of use. For the identified conditions of use for which the concentration thresholds are being finalized, EPA recognizes that the regulated community has the ability to detect the values for the ECEL, ECEL action level, and EPA STEL because of viable detection limits and analytical methods of methylene chloride for monitoring devices that are widely available in commerce, currently in use, and approved by OSHA and NIOSH, which generally range from 0.2 to 0.4 ppm (Ref. 93). EPA also recognizes that analytical methods for monitoring are available from OSHA and NIOSH that are capable of detecting the exposure limits with a higher degree of accuracy (Refs. 96, 97).

#### *4. Monitoring requirements.*

##### *a. In general.*

Initial monitoring for methylene chloride is critical for establishing a baseline of exposure for potentially exposed persons; similarly, periodic exposure monitoring assures continued compliance over time so that potentially exposed persons are not exposed to levels that would



result in an unreasonable risk of injury to health. Exposure monitoring could be suspended if certain conditions described in this unit are met. Also, in some cases, a change in workplace conditions with the potential to impact exposure levels would warrant additional monitoring, which is also described.

EPA is finalizing as proposed its requirement that owners or operators determine each potentially exposed person's exposure by taking a personal breathing zone air sample, or by taking personal breathing zone air samples that are representative of each potentially exposed person's exposure. Owners or operators will be permitted to consider personal breathing zone air samples to be representative of each potentially exposed person's exposure when one or more samples are taken for at least one potentially exposed person in each job classification in a work area during every work shift, and the person sampled is expected to have the highest methylene chloride exposure; or when one or more samples are taken which indicate the highest likely 15-minute exposures during such operations for at least one potentially exposed person in each job classification in the work area during every work shift, and the person sampled is expected to have the highest methylene chloride exposure. Personal breathing zone air samples taken during one work shift may be used to represent potentially exposed person exposures on other work shifts where the owner or operator can document that the tasks performed and conditions in the workplace are similar across shifts. Additionally, air sampling is required to measure ambient concentrations for methylene chloride without taking respiratory protections into account as sampling is being performed. These final requirements align with the approach taken for characterization of employee exposure in the 1997 OSHA standard for methylene chloride (see 29 CFR 1910.1052(b), (d)(1)(i) and (ii)). EPA is also finalizing requirements that the owner or operator ensure, for initial and periodic monitoring, that their exposure monitoring methods are accurate to a confidence level of 95% and are within (plus or minus) 25% of airborne

concentrations of methylene chloride above the 8-hour TWA ECEL or the 15-minute TWA EPA STEL, or within (plus or minus) 35% for airborne concentrations of methylene chloride at or above the ECEL action level but at or below the 8-hour TWA ECEL. These requirements, including the 35%, would align with the approach taken in the 1997 OSHA standard for methylene chloride (see 29 CFR 1910.1052(d)(1)(iii)). Though EPA is finalizing the accuracy range as proposed, EPA recognizes that more recent monitoring methods and technologies currently exist and allow for greater accuracy, and thus a narrower accuracy range for monitoring results such as the NIOSH 3900 method and the OSHA 1025 method (Refs. 96, 97). To ensure compliance for monitoring activities, EPA is finalizing recordkeeping requirements and will require that owners or operators document their choice of monitoring method outlined in this unit.

*b. Initial exposure monitoring.*

Under the final regulation, each owner or operator of a facility in the private sector that is engaged in one or more of the conditions of use listed earlier in Unit IV.B.1. will be required to perform initial exposure monitoring within 360 days after publication of the final rule to determine the extent of exposure of potentially exposed persons to methylene chloride. In consideration of public comments, EPA has changed the timeframe for completion of initial monitoring from 180 days after publication of the final rule to 360 days after publication of the final rule in the *Federal Register*. As discussed in Unit III.D.1., EPA is providing additional time for Federal agencies and Federal contractors acting for or on behalf of the Federal government to comply with the provisions of the WCPP, so they will be required to conduct initial monitoring within 915 days after publication. Initial monitoring will notify owners and operators of the magnitude of possible exposures to potentially exposed persons with respect to their work conditions and environments. Based on the magnitude of possible exposures in the initial

exposure monitoring, the owner or operator may need to increase or decrease the frequency of future periodic monitoring, adopt new exposure controls (such as engineering controls, administrative controls, and/or a respiratory protection program), or to continue or discontinue certain compliance activities such as periodic monitoring. In addition, the initial monitoring will be required when and where the operating conditions are best representative of each potentially exposed person's work-shift exposures. If the owner or operator chooses to use a sample that is representative of potentially exposed persons' full shift exposures (rather than monitor every individual), such sampling should be representative of the most highly exposed persons in the workplace. Additionally, EPA expects that owners and operators will conduct initial exposure monitoring representative to determine the extent of methylene chloride exposure for potentially exposed persons. EPA understands that certain tasks may occur less frequently or may reflect upset conditions (for example, due to malfunction).

EPA also recognizes that the values for the ECEL action level and EPA STEL may mean that some owners or operators currently in compliance with the OSHA standard would have to establish a new monitoring baseline for EPA's Final Rule for methylene chloride. Aligning with the existing OSHA standard (29 CFR 1910.1052(d)(2)) to the extent possible, EPA is finalizing as proposed that an owner or operator may temporarily forgo initial exposure monitoring if:

(i) An owner or operator could provide EPA with objective data generated during the last five years demonstrating that methylene chloride cannot be released in the workplace in airborne concentrations at or above the ECEL action level (1-ppm 8-hour TWA) and above the EPA STEL (16 ppm 15-minute TWA), and that the data represent the highest methylene chloride exposures likely to occur under reasonably foreseeable conditions of manufacturing, processing, use, or disposal, as applicable, including handling of methylene chloride during those activities. Owners or operators who rely on objective data must maintain records including the use of

methylene chloride evaluated, the source of the objective data, the measurement methods, measurement results, and measurement analysis of the use of methylene chloride, and any other data relevant to the operations, processes, or person's exposure. The oldest objective data used to demonstrate that exposures are below the ECEL action level and EPA STEL will indicate the beginning of the five-year cycles of recurring exposure monitoring as described in Unit IV.B.4.b.;

(ii) Where potentially exposed persons are exposed to methylene chloride for fewer than 30 days per year and the owner or operator has measurements by direct-metering devices that give immediate results and provide sufficient information regarding potentially exposed persons' exposures to determine and implement the control measures that are necessary to reduce exposures to below the ECEL action level and EPA STEL.

As described in more detail later in this unit, the owner or operator must conduct periodic monitoring at least once every five years since its last monitoring. This periodic monitoring must be representative of all the potentially exposed persons in the workplace and the tasks that they are expected to do. Additionally, if a facility were to commence one or more conditions of use listed in Unit IV.B.1. after **[INSERT DATE 360 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, the owner or operator must perform an initial exposure monitoring within 30 days of commencing the condition(s) of use and would be required to conduct periodic monitoring in accordance with Table 1 in Unit IV.B.4.c. For facilities that commence one or more conditions of use listed in Unit IV.B.1. after **[INSERT DATE 360 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, the owner or operator must ensure that the airborne concentration of methylene chloride does not exceed the ECEL or EPA STEL for all potentially exposed persons within 90 days of the initial exposure monitoring.

*c. Periodic exposure monitoring.*

EPA's final rule is aligned with elements of the existing OSHA standard (29 CFR 1910.1052(d)(3)) to the extent possible. Based on the results from the initial exposure monitoring, EPA is finalizing as proposed the following periodic monitoring for owners or operators. These finalized requirements are also outlined in Table 1.

- If the initial exposure monitoring is below the ECEL action level (1 ppm 8-hour TWA) and at or below the EPA STEL (16 ppm 15-minute TWA), the ECEL and EPA STEL periodic monitoring would be required once every five years, except when additional exposure monitoring (Unit IV.B.4.e.) measurements require it.

- If the initial exposure monitoring concentration is below the ECEL action level (1 ppm 8-hour TWA) and above the EPA STEL (16 ppm 15-minute TWA), the ECEL periodic monitoring would be required once every five years or when additional monitoring (Unit IV.B.4.e.) measurements require it, but EPA STEL periodic monitoring would be required every three months.

- If the initial exposure monitoring concentration is at or above the ECEL action level (1 ppm 8-hour TWA) and at or below the ECEL (2 ppm 8-hour TWA), and at or below the EPA STEL (16 ppm 15-minute TWA), the ECEL periodic monitoring would be required every six months.

- If the initial exposure monitoring concentration is at or above the ECEL action level (1 ppm 8-hour TWA) and at or below the ECEL (2 ppm 8-hour TWA), and above the EPA STEL, the ECEL periodic monitoring would be required every six months and EPA STEL periodic monitoring would be required every three months.

- If the initial exposure monitoring concentration is: Above the ECEL (2 ppm 8-hour TWA) and below, at, or above the EPA STEL (16 ppm 15-minute TWA), the ECEL and EPA STEL periodic monitoring would be required every three months.

- The owner or operator would be permitted to transition the ECEL periodic exposure monitoring frequency from every three months to every six months if two consecutive monitoring events taken at least seven days apart indicate that the potential exposure has decreased to or below the ECEL, but at or above the ECEL action level.

- The owner or operator would be permitted to transition from the ECEL periodic exposure monitoring frequency from every six months to once every five years if two consecutive monitoring events taken at least seven days apart indicate that the potential exposure has decreased below the ECEL action level and at or below the EPA STEL. The second consecutive monitoring event would delineate the new date from which the next five-year periodic exposure monitoring must occur.

In addition to the periodic monitoring standards described earlier, EPA is finalizing two additional provisions:

- Based on its monitoring results, if the owner or operator would be required to monitor either the ECEL or EPA STEL in a three-month interval but does not engage in any of the conditions of use listed in Unit IV.B.1. for which the WCPP is finalized over the entirety of those three months, the owner or operator would be permitted to forgo the upcoming periodic monitoring event. However, documentation of cessation of use of methylene chloride would be required, and initial monitoring would be required when the owner or operator resumes or starts any of the conditions of use listed in Unit IV.B.1. for which the WCPP is finalized.

- Based on its monitoring results, if the owner or operator would be required to monitor the ECEL in a six-month interval but does not engage in any of the conditions of use listed in

Unit IV.B.1. for which the WCPP is finalized over the entirety of those six months, the owner or operator would be permitted to forgo the upcoming periodic monitoring event. However, documentation of cessation of use of methylene chloride would be required, and initial monitoring would be required when the owner or operator resumes or starts any of the conditions of use listed in Unit IV.B.1. for which the WCPP is finalized.

- Periodic monitoring would be required to occur at least once every five years if methylene chloride is present.

**Table 1 – Periodic Monitoring Requirements Based on Initial Exposure Monitoring Results**

<b>Air Concentration Condition</b>	<b>Periodic Monitoring Requirement</b>
If the initial exposure monitoring concentration is below the ECEL action level and at or below the EPA STEL	ECEL and EPA STEL periodic monitoring at least once every 5 years.
If the initial exposure monitoring concentration is below the ECEL action level and above the EPA STEL	ECEL periodic monitoring at least once every 5 years, and EPA STEL periodic monitoring required every 3 months.
If the initial exposure monitoring concentration is at or above the ECEL action level and at or below the ECEL; and at or below the EPA STEL	ECEL periodic monitoring every 6 months.
If the initial exposure monitoring concentration is at or above the ECEL action level and at or below the ECEL; and above the EPA STEL	ECEL periodic monitoring every 6 months and EPA STEL periodic monitoring every 3 months.
If the initial exposure monitoring concentration is above the ECEL and below, at, or above the EPA STEL	ECEL periodic monitoring every 3 months and EPA STEL periodic monitoring every 3 months.
If 2 consecutive monitoring events have taken place at least 7 days apart that indicate that potential exposure has decreased from above the ECEL to at or below the ECEL, but at or above the ECEL action level	Transition from ECEL periodic monitoring frequency from every 3 months to every 6 months.
If 2 consecutive monitoring events have taken place at least 7 days apart that indicate that potential exposure has decreased to below the ECEL action level and at or below the EPA STEL	Transition from ECEL periodic monitoring frequency every 6 months to once every 5 years. The second consecutive monitoring event will delineate the new date from which the next 5-year periodic exposure monitoring must occur.

<p>If the owner or operator engages in any of the conditions of use for which WCPP is finalized and is required to monitor either the ECEL or EPA STEL in a 3-month interval, but does not engage in any of those conditions of use for the entirety of the 3-month interval</p>	<p>The owner or operator may forgo the upcoming periodic monitoring event. However, documentation of cessation of manufacture, processing, use, or disposal of methylene chloride must be maintained, and initial monitoring would be required when the owner or operator resumes or starts any of the conditions of use for which the WCPP is finalized.</p>
<p>If the owner or operator engages in any of the conditions of use for which WCPP is finalized and is required to monitor the ECEL in a 6-month interval, but does not engage in any of those conditions of use for the entirety of the 6-month interval</p>	<p>The owner or operator may forgo the upcoming periodic monitoring event. However, documentation of cessation of manufacture, processing, use, or disposal of methylene chloride must be maintained, and initial monitoring would be required when the owner or operator resumes or starts any of the conditions of use for which the WCPP is finalized.</p>

NOTE: Additional scenarios in which monitoring may be required are discussed in Unit IV.B.4.e.

*d. Minimum frequency of exposure monitoring.*

EPA is finalizing the proposed requirement that a monitoring event be conducted at a minimum frequency of every five years by owners or operators using methylene chloride for any condition of use subject to the WCPP. To better reflect the periodic nature of such monitoring, the final rule describes it as a periodic monitoring requirement, rather than a requirement to re-conduct initial exposure monitoring every five years, as it was described in the proposed rule. EPA emphasizes that this monitoring must represent all potentially exposed persons in the workplace. Moreover, EPA is finalizing that monitoring requirements can only be made less frequent based on the results of the initial exposure monitoring or the periodic exposure monitoring outlined under Units IV.B.4.b. and IV.B.4.c., respectively.

*e. Additional exposure monitoring.*

EPA is finalizing the requirement that the owner or operator complying with the WCPP must carry out an additional exposure monitoring after any change that may reasonably be



expected to introduce additional sources of exposure, or result in a change in exposure levels, to methylene chloride. Examples include changes in the production, production volume, use rate, process, control equipment, or work practices that may reasonably be anticipated to cause additional sources of exposure or result in increased exposure levels to methylene chloride; and start-up, shutdown, or malfunction of the facility or facility equipment that may reasonably be anticipated to cause additional sources of exposure or result in increased exposure levels to methylene chloride. This additional exposure monitoring event may result in increased frequency of periodic monitoring. The required additional exposure monitoring should not delay implementation of any necessary cleanup or other remedial action to reduce the exposures to potentially exposed persons.

*5. Exposure control plan.*

EPA is finalizing its requirement that entities implementing the WCPP use elimination and substitution, followed by the use of engineering controls, administrative controls, and work practices prior to requiring the use of PPE (i.e., respirators) as a means of controlling inhalation exposures below EPA's ECEL or STEL, in accordance with the hierarchy of controls (Ref. 98). If an owner or operator chooses to replace methylene chloride with a substitute, EPA recommends careful review of the available hazard and exposure information on the potential substitutes to avoid a substitute chemical that might later be found to present unreasonable risks or be subject to regulation (sometimes referred to as a "regrettable substitution"). EPA expects that, for conditions of use for which EPA is finalizing a WCPP, compliance at most workplaces would be part of an established industrial hygiene program that aligns with the hierarchy of controls.

EPA is finalizing its requirement that the owner or operator demarcate any area where airborne concentrations of methylene chloride are reasonably expected to exceed the ECEL or

the EPA STEL. In response to comments requesting more clarity regarding how regulated areas must be demarcated, EPA has incorporated the language from the analogous OSHA requirement into this final rule. Owners and operators must demarcate regulated areas from the rest of the workplace in any manner that adequately establishes and alerts potentially exposed persons to the boundaries of the area and minimizes the number of authorized persons exposed to methylene chloride within the regulated area. This can be accomplished using administrative controls, e.g., highly visible signifiers, in multiple languages as appropriate (e.g., when potentially exposed persons who are primarily Spanish-speaking are present, owners and operators should post additional highly visible signifiers in Spanish), placed in conspicuous areas. The owner or operator is required to restrict access to the regulated area from any potentially exposed person that lacks proper training or is otherwise unauthorized to enter.

EPA is finalizing the requirement that regulated entities use the hierarchy of controls, instituting one or a combination of controls to the extent feasible, and supplement such protections using PPE, where necessary, including respirators for potentially exposed persons at risk of inhalation exposure above the ECEL or EPA STEL. If efforts of elimination, substitution, engineering controls, and administrative controls are not sufficient to reduce exposures to or below the ECEL or EPA STEL for all potentially exposed persons in the workplace, EPA requires that the owner or operator use feasible controls to reduce methylene chloride concentrations in the workplace to the lowest levels achievable and supplement these controls with respiratory protection and PPE as needed to achieve the ECEL before potentially exposed persons enter a regulated area. In such cases, EPA requires that the owner or operator provide potentially exposed persons reasonably likely to be exposed to methylene chloride by inhalation to concentrations above the ECEL or EPA STEL with respirators affording sufficient protection against inhalation risk and appropriate training on the proper use of such respirators, to ensure

that their exposures do not exceed the ECEL or EPA STEL, as described in this unit. As part of the training requirement, the owner or operator is required to provide information and comprehensive training in an understandable manner (i.e., plain language), considering factors such as the skills required to perform the work activity and the existing skill level of the staff performing the work, and in multiple languages as appropriate (e.g., based on languages spoken by potentially exposed persons) to potentially exposed persons. This training must be provided prior to or at the time of initial assignment to a job involving potential exposure to methylene chloride. Furthermore, EPA also requires that the owner or operator document their efforts in using elimination, substitution, engineering controls, and administrative controls to reduce exposure to or below the ECEL or EPA STEL in an exposure control plan.

EPA is finalizing its requirement that the owner or operator include and document in the exposure control plan or through any existing documentation of the facility's safety and health program developed as part of meeting OSHA requirements or other safety and health standards, the following:

- Identification in the exposure control plan of available exposure controls and rationale for using or not using available exposure controls in the following sequence (i.e., elimination and substitution, then engineering controls and administrative controls) to reduce exposures in the workplace to either at or below the ECEL or to the lowest level achievable, and the exposure controls selected based on feasibility, effectiveness, and other relevant considerations;
- For the exposure controls not selected, document the efforts identifying why these are not feasible, not effective, or otherwise not implemented;
- A description of actions the owner or operator must take to implement exposure controls selected, including proper installation, regular inspections, maintenance, training, or other steps taken;

- A description of regulated areas, how they are demarcated, and persons authorized to enter the regulated areas;
- A description of activities conducted by the owner or operator to review and update the exposure control plan to ensure effectiveness of the exposure controls, identify any necessary updates to the exposure controls, and confirm that all persons are properly implementing the exposure controls; and
- An explanation of the procedures for responding to any change that may reasonably be expected to introduce additional sources of exposure to methylene chloride, or otherwise result in increased exposure to methylene chloride, including procedures for implementing corrective actions to mitigate exposure to methylene chloride.

Under this final rule, owners or operators are prohibited from using rotating work schedules to comply with the ECEL 8-hour TWA. Owners or operators must maintain the effectiveness of any engineering controls, administrative controls, or work practices instituted as part of the exposure control plan. They must also review and update the exposure control plan as necessary, but at least every five years, to reflect any significant changes in the status of the owner or operator's approach to compliance with the exposure control requirements. EPA intends that the exposure control plan identify the *available* exposure controls and, for the exposure controls not selected, document the efforts identifying why these are not feasible, not effective, or otherwise not implemented. For entities for which significant amounts of time are needed to verify suitability of alternatives or procure funds or authorization for additional engineering controls, for example, EPA expects that as those controls become available the exposure control plan would be updated accordingly. EPA requires that the exposure control plan be revisited under certain conditions (and at least every five years) and encourages updates as more sophisticated controls are available.

This final rule requires owners or operators to make the exposure control plan and associated records available to potentially exposed persons, at a reasonable time, place, and manner, within 15 working days of receiving a request. Owners or operators must also provide notice of the availability of the plan and associated records to potentially exposed persons.

*6. Personal protective equipment (PPE).*

Where elimination, substitution, engineering, and administrative controls are not feasible or sufficiently protective to reduce the air concentration to or below the ECEL, or if inhalation exposure above the ECEL is still reasonably likely, EPA is finalizing its minimum respiratory PPE requirements based on an owner or operator's measured air concentration for one or more potentially exposed persons and the level of PPE needed to reduce exposure to or below the ECEL. In those circumstances, EPA is finalizing its requirement that the owner or operator also comply with OSHA's General Requirements for PPE standard at 29 CFR 1910.132 for application of a PPE program. EPA is also requiring that the owner or operator comply with 29 CFR 1910.134 for proper use, maintenance, fit-testing, and training of respirators.

*a. Required dermal protection.*

EPA is finalizing the provision and use of chemically resistant gloves in combination with specific activity training (e.g., glove selection (type, material), expected duration of glove effectiveness, actions to take when glove integrity is compromised, storage requirements, procedure for glove removal and disposal, chemical hazards) for tasks where dermal exposure can be expected to occur. Additionally, EPA is requiring that owners and operators comply with relevant sections of the methylene chloride OSHA standard to minimize and protect potentially exposed persons from dermal exposure, including 29 CFR 1910.1052(h) and (i). Additional information related to choosing appropriate gloves can be found in the NIOSH Hazard Alert (Ref. 99) and in appendix F of the 2020 Risk Evaluation for Methylene Chloride (Ref. 1).

b. *Required respiratory protection.*

EPA is finalizing the following requirements for respiratory protection, based on the exposure monitoring concentrations measured as an 8-hour TWA that exceeds the ECEL (2 ppm) or 15-minute TWA that exceeds the EPA STEL (16 ppm); see also the following table (Table 2). These requirements apply after all other feasible controls are exhausted or proven ineffective to control inhalation exposure (including elimination, substitution, engineering controls, and administrative controls in accordance with the hierarchy of controls). EPA is finalizing its minimum respiratory protection requirements, such that any respirator affording the same or a higher degree of protection than the following proposed requirements may be used. Under this final regulatory action, air-purifying respirators (in contrast to air-supplied respirators) are not permitted as a means of mitigating methylene chloride exposure, as they do not provide adequate respiratory protection against this chemical (Ref. 100). Additionally, EPA acknowledges that there may be respirator limitations dependent upon the nature of the activity in which methylene chloride is used (e.g., a decreased range of motion or access to a small space could hinder PPE use). Nevertheless, owners and operators must provide respirators that are protective of the measured exposure concentration after all other feasible controls are considered.

- If the measured exposure concentration is at or below the ECEL (2 ppm 8-hour TWA) and EPA STEL (16 ppm 15-minute TWA): Respiratory protection is not required.
- If the measured exposure concentration is above 2 ppm and less than or equal to 50 ppm (25 times the ECEL): The required respirator protection is any NIOSH Approved® SAR or airline respirator in a continuous-flow mode equipped with a loose-fitting facepiece or helmet/hood (APF 25).
- If the measured exposure concentration is above 50 ppm and less than or equal to 100 ppm (50 times the ECEL): The required respirator protection is: (i) Any NIOSH Approved®

SAR or airline respirator in a demand mode equipped with a full facepiece (APF 50); or (ii) Any NIOSH Approved® SCBA in demand-mode equipped with a full facepiece or helmet / hood (APF 50).

- If the measured exposure concentration is unknown or at any value above 100 ppm and up to 2,000 ppm (1,000 times the ECEL): The required respirator protection is: (i) Any NIOSH Approved® SAR or Airline Respirator in a continuous-flow mode equipped with a full facepiece or certified helmet/hood (APF 1,000)); or (ii) Any NIOSH Approved® SAR or Airline Respirator in pressure-demand or other positive-pressure mode equipped with a full facepiece and an auxiliary self-contained air supply (APF 1,000)); or (iii) Any NIOSH Approved® SCBA in a pressure-demand or other positive-pressure mode equipped with a full facepiece or certified helmet/hood (APF 1,000+).

**Table 2 – Respiratory Protection Conditions and Requirements**

<b>Concentration Condition</b>	<b>Minimum Required Respirator Protection</b>
At or below the ECEL and EPA STEL	No respirator required.
Above ECEL (2 ppm) and less than or equal to 50 ppm (25 times the ECEL)	Any NIOSH Approved® supplied-air respirator (SAR) or airline respirator in a continuous-flow mode equipped with a loose-fitting facepiece or helmet/hood (APF 25).
Above 50 ppm and less than or equal to 100 ppm (50 times the ECEL)	Either (i) any NIOSH Approved® Supplied-Air Respirator (SAR) or airline respirator in a demand mode equipped with a full facepiece (APF 50); or (ii) any NIOSH Approved® Self-Contained Breathing Apparatus (SCBA) in demand-mode equipped with a full facepiece or helmet/hood (APF 50).
Unknown concentration or at any value above 100 ppm and up to 2,000 ppm (1,000 times the ECEL)	One of (i) any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator in a continuous-flow mode equipped with a full facepiece or certified helmet/hood (APF 1,000); or (ii) any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator in pressure-demand or other positive-pressure mode equipped with a full facepiece and an auxiliary self-contained air supply (APF 1,000); or (iii) any NIOSH Approved® Self-Contained Breathing Apparatus (SCBA) in a pressure-demand or other positive-pressure mode equipped with a full facepiece or certified helmet/hood (APF 10,000).

*7. Additional finalized requirements.*

*a. Workplace participation.*

EPA encourages owners and operators to consult with potentially exposed persons and on the development and implementation of exposure control plans and PPE/respirator programs. EPA is finalizing its requirement that owners and operators provide potentially exposed persons regular access to the exposure control plans, exposure monitoring records, PPE program implementation, and respirator program implementation (such as fit-testing and other requirements) described in 29 CFR 1910.134(l). To ensure compliance with workplace participation, EPA is finalizing its requirement that the owner or operator document the notice to and ability of any potentially exposed person that may reasonably be affected by methylene chloride inhalation exposure to readily access the exposure control plans, facility exposure monitoring records, PPE program implementation, or any other information relevant to methylene chloride inhalation exposure in the workplace.

*b. Notification of monitoring results.*

EPA is finalizing the requirement that when a potentially exposed person's exposure to methylene chloride exceeds the ECEL action level within a regulated area, the owner or operator will be required to inform each potentially exposed person of the quantity, location, manner of use, release, and storage of methylene chloride and the specific operations in the workplace that could result in exposure to methylene chloride, particularly noting where exposures may be above the ECEL or EPA STEL. EPA further requires that the owner or operator must, within 15 working days after receipt of the results of any exposure monitoring, notify each potentially exposed person whose exposure is represented by that monitoring in writing, either individually to each potentially exposed person or by posting the information in an appropriate and accessible location, such as public spaces or common areas, for potentially exposed persons outside of the



regulated area. The notice would be required to identify the ECEL, ECEL action level, and EPA STEL and what they mean in plain language, the exposure monitoring results, and any corresponding respiratory protection required. If the ECEL or STEL is exceeded, the notice would also be required to include a description of the actions taken by the owner or operator to reduce inhalation exposures to or below the ECEL or EPA STEL which states the actions to be taken to reduce exposures. The notice must be posted in multiple languages if necessary (e.g., notice must be in a language that the potentially exposed person understands, including a non-English language version representing the language of the largest group of workers who cannot readily comprehend or read English).

*c. Recordkeeping.*

For each monitoring event of methylene chloride, EPA is requiring that the owner or operator record, similar to OSHA under 29 CFR 1910.1052(m), information including but not limited to, dates; operations involving exposure; sampling and analytical methods; the number of samples; durations, and results of each sample taken; the type of respirator and PPE worn (if any); the potentially exposed persons' names, work shifts, and job classifications; and exposure of all the potentially exposed persons represented by monitoring, indicating which potentially exposed persons were actually monitored. EPA further requires documentation of the following whenever monitoring for the WCPP is required under TSCA section 6(a):

(i) All measurements that may be necessary to determine the conditions (e.g., work site temperatures, humidity, ventilation rates, monitoring equipment type and calibration dates) that may affect the monitoring results;

(ii) All other potentially exposed persons whose exposure was not measured but whose exposure is intended to be represented by the area or representative sampling monitoring;

(iii) Use of established analytical methods such as those outlined in appendix A of the

ECEL memo (Ref. 93) with a limit of detection below the ECEL action level and accuracy of monitoring within 25% for the ECEL and 35% for the EPA STEL, as discussed in Unit IV.B.4.a., so that the owner or operator may identify when the implementation of additional exposure controls is necessary, determine the monitoring frequency according to the requirements described in this unit, and properly identify and provide persons exposed to methylene chloride with the required respiratory equipment and PPE in this unit;

(iv) Compliance with the GLP Standards at 40 CFR part 792 or any accredited lab including AIHA (e.g., AIHA LAP, LLC Policy Module 2A/B/E of Revision 17.3), or other analogous industry-recognized program;

(v) Information regarding air monitoring equipment, including: Type, maintenance, calibrations, performance tests, limits of detection, and any malfunctions.

For owners and operators to demonstrate compliance with the WCPP provisions, EPA is requiring that owners and operators must retain compliance records for five years (although this requirement does not supplant any longer recordkeeping retention time periods such as those required under 29 CFR 1910.1020, or other applicable regulations). EPA is requiring the owner or operator to retain records of:

- Exposure control plan;
- Regulated areas and authorized personnel;
- Facility exposure monitoring records;
- Notifications of exposure monitoring results;
- PPE and respiratory protection used and program implementation; and
- Information and training required under 29 CFR 1910.1052 section (l) and appendix A,

provided by the owner or operator to each potentially exposed person prior to or at the time of initial assignment to a job involving potential exposure to methylene chloride.

EPA emphasizes that all records required to be maintained can be kept in the most administratively convenient form; electronic record form or paper form. The owner or operator is required to document training or re-training of any potentially exposed person as necessary to ensure that, in the event of monitoring results that indicate exposure or possible exposures above the ECEL action level or the EPA STEL, the potentially exposed person has demonstrated understanding of how to safely use and handle methylene chloride and how to appropriately use required PPE. In addition, the owner or operator is required to update the training and requisite documentation when there is reasonable expectation that exposure may exceed the ECEL action level due to change in tasks or procedures.

#### 8. *Compliance timeframes.*

With regard to the compliance timeframe for those occupational conditions of use which are subject to the WCPP, EPA is not finalizing the timeframes proposed. Rather, as discussed in Unit III.D.1., based on consideration of public comments, EPA is finalizing the timeframes considered in the primary alternative action for the private sector and is providing Federal agencies and Federal contractors acting for or on behalf of the Federal government an additional 180 days to comply with each of the provisions of the WCPP. Specifically, EPA is finalizing its requirement that owners and operators in the private sector establish initial exposure monitoring according to the process outlined in this unit within 360 days after date of publication of the final rule in the *Federal Register*, while Federal agencies and Federal contractors acting for or on behalf of the Federal government must conduct initial exposure monitoring within 540 days after the date of publication. EPA is also finalizing its requirement that each owner or operator in the private sector ensure that the airborne concentration of methylene chloride does not exceed the ECEL or EPA STEL for all potentially exposed persons within 450 days after the date of publication of the final rule in the *Federal Register*, while Federal agencies and Federal

contractors acting for or on behalf of the Federal government must comply with the ECEL and the EPA STEL within 630 days after the date of publication. If applicable, each owner or operator must provide respiratory protection sufficient to reduce inhalation exposures to below the ECEL or EPA STEL to all potentially exposed persons in the regulated area within three months after receipt of the results of any exposure monitoring. For the private sector, this will be within 15 months after the date of publication of the final rule in the *Federal Register*. For Federal agencies and Federal contractors acting for or on behalf of the Federal government, this will be within 21 months after the date of publication. For any new facilities, or any facility commencing one or more conditions of use listed in Unit IV.B.1. after **[INSERT DATE 360 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, the timeframe for the requirement for initial exposure monitoring is described earlier in Unit IV.B.4.b.; following that, the requirements and timeframes for periodic monitoring in Unit IV.B.4.c. would apply and owners and operators must ensure that no person is exposed to an airborne concentration of methylene chloride that exceeds the ECEL or EPA STEL within 90 days following the initial exposure monitoring). EPA is also finalizing the requirement that owners and operators demarcate a regulated area within three months after receipt of any exposure monitoring that indicates exposures exceeding the ECEL or EPA STEL. Owners and operators in the private sector shall proceed accordingly to implement an exposure control plan, including institution of feasible exposure controls other than PPE, within 540 days after date of publication of the final rule in the *Federal Register*, while Federal agencies and Federal contractors acting for or on behalf of the Federal government must implement an exposure control plan within 720 days after the date of publication.

*C. Prohibition of manufacture, processing, distribution, and commercial use of methylene chloride.*

In general, EPA is finalizing the prohibitions as proposed, with some modifications, including for compliance timeframes to provide for reasonable transitions, based on consideration of the public comments, as described in Unit III. The rule prohibits manufacture, processing, distribution, and all industrial and commercial use of methylene chloride and methylene chloride containing products, except for those uses which will continue under the WCPP, as identified in Unit IV.B.1. After consideration of public comments, EPA is finalizing timeframes longer than proposed for prohibition of manufacture, processing, distribution, and commercial use of methylene chloride broadly, as well as for particular uses such as commercial use of methylene chloride in adhesives and sealants in aircraft, space vehicles, and turbine applications; and commercial use of methylene chloride in paint and coating removal for the refinishing of wooden pieces of artistic, cultural, or historic value. The rationale for these changes from the proposed rule is in Unit III.B. and Unit III.D.2.

As discussed in Unit IV.A. and in the Response to Comments, the prohibitions do not apply to any substance that is excluded from the definition of “chemical substance” under TSCA section 3(2)(B)(ii) through (vi) (Ref. 7).

The final regulation will impose prohibitions in a staggered timeframe, beginning at the top of the supply chain, as proposed. As discussed in Unit III.D.2., in response to comments received, EPA is finalizing longer timeframes than proposed for prohibition of manufacturing, processing, distributing, or commercial use of methylene chloride, but finalizing as proposed for distribution to and by retailers, in order to expeditiously remove exposures to consumers. EPA is finalizing timeframes for prohibitions according to the following staggered timeframe:

- Within 270 days of publication of the final rule in the *Federal Register* for prohibitions on distributing to retailers;
- Within 360 days of publication of the final rule in the *Federal Register* for prohibitions

on distribution by retailers;

- Within 360 days of publication of the final rule in the *Federal Register* for prohibitions

on manufacturing;

- Within 450 days of publication of the final rule in the *Federal Register* for prohibitions

on processors;

- Within 630 days of publication of the final rule in the *Federal Register* for prohibitions

on all distributors other than retailers; and

- Within 720 days of publication of the final rule in the *Federal Register* for prohibitions

on most industrial and commercial use after the publication date of the final rule in the *Federal Register*.

(Timeframes for prohibitions on distribution of methylene chloride and methylene-chloride containing products to retailers are provided in Unit IV.D., in relation to consumer use).

Additionally, for two conditions of use, EPA is finalizing prohibitions that would take effect in five years. Those two conditions of use are commercial use of methylene chloride in adhesives and sealants in aircraft, space vehicle, and turbine applications for structural and safety critical non-structural applications, and for commercial use of methylene chloride in refinishing wood pieces of artistic, cultural, or historic value (which also includes interim requirements for minimum exposure controls). While EPA had proposed that these prohibitions begin to be implemented within 90 days for manufacturers, 180 days for processors, 270 days for distributors to retailers, 360 days for all other distributors and retailers, and 450 days for industrial and commercial uses after the publication date of the final rule, EPA is modifying the timeframes proposed based on the information received in public comment.

EPA is delaying compliance with the prohibition for a subset of the industrial and commercial use of methylene chloride in adhesives and sealants, namely when that adhesive or

sealant is used in aircraft, space vehicle, or turbine applications for structural and safety critical non-structural applications. As described in Unit III.B.2., this use of methylene chloride includes applications such as use in bonding critical turbine engine hardware, use as a joining compound in engine parts, and adhesive to bond capacitors, transformers, components, military PC boards and subassemblies, and gasket sealants in aerospace systems. Based on information received in public comments, EPA is finalizing delayed compliance of five years before prohibition for industrial or commercial use of methylene chloride for adhesives and sealants in aircraft, space vehicle, and turbine applications for structural and safety critical non-structural applications.

Regarding commercial use of methylene chloride for paint and coating removal for wood furniture, decorative pieces, and architectural fixtures of artistic, cultural, or historic value, as discussed in Unit III.B.1., EPA is modifying the compliance dates proposed for prohibitions and is finalizing a compliance date of five years before prohibitions only for the narrowly described commercial use of methylene chloride in this unit: For refinishing wood pieces of artistic, cultural, or historic value, as discussed in Unit III.B.1.

During the interim period before prohibition, owners or operators must not only restrict refinishing using methylene chloride only to wooden furniture, decorative pieces, and architectural fixtures of artistic, cultural or historic value, but also must meet a minimum standard of exposure control. That includes: 1) Use of a regulated area; 2) use of local exhaust ventilation, both bringing air in from outside of the workspace where methylene chloride is being used and pulling methylene chloride vapors away from the potentially exposed person; and 3) use of any NIOSH Approved® SAR or airline respirator in a demand mode equipped with a full facepiece (APF 50) or any NIOSH Approved® SCBA in demand-mode equipped with a full facepiece or helmet/hood (APF 50) or the appropriate respirator based on initial monitoring as outlined in Unit IV.B.4.b. and in the regulatory text under 40 CFR 751.109(d).

The owner or operator shall document each instance of refinishing wooden furniture, decorative pieces, and architectural fixtures of artistic, cultural or historic value. The documentation shall make record of the date of the refinishing activity, a description of the piece that was refinished and an explanation of its artistic, cultural, or historic value, the owner of the refinished piece, and the methylene chloride product used. EPA generally expects this information to be part of normal business records.

*D. Prohibition of manufacture, processing, and distribution in commerce for consumer use of methylene chloride.*

The final rule prohibits the manufacture, processing, and distribution in commerce of methylene chloride and methylene chloride containing products for all consumer use. EPA is finalizing as proposed the prohibition on retailers from distributing in commerce methylene chloride and all methylene chloride-containing products, in order to prevent products intended for industrial and commercial use under the WCPP from being purchased by consumers. EPA is finalizing that the prohibition on distribution in commerce of methylene chloride within 270 days for distributing to retailers, and 360 days for retailers distributing in commerce after the publication date of the final rule in the *Federal Register*.

A retailer is any person or business entity that distributes or makes available products to consumers, including through e-commerce internet sales or distribution. If a person or business entity distributes or makes available any product to at least one consumer, then it is considered a retailer (40 CFR 751.103). For a distributor not to be considered a retailer, the distributor must distribute or make available products solely to commercial or industrial end-users or businesses. Prohibiting manufacturers (including importers), processors, and distributors from distributing methylene chloride, or any products containing methylene chloride, to retailers prevents retailers from making these products available to consumers, which addresses that part of the



unreasonable risk from methylene chloride contributed by consumer use. EPA first promulgated this definition, with this rationale, in the earlier rule to regulate methylene chloride in consumer paint and coating removers (84 FR 11420, March 27, 2019) (FRL-9989-29) and is finalizing as proposed for this regulation as well.

*E. Other requirements.*

*1. Recordkeeping.*

For conditions of use that are not otherwise prohibited under this final rule, EPA is finalizing as proposed the requirement that manufacturers, processors, and distributors maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with restrictions and other provisions of this final regulation; and that they maintain such records for a period of five years from the date the record is generated. This requirement begins at the effective date of the rule (60 days following publication of the final rule in the *Federal Register*). Recordkeeping requirements ensure that owners or operators can demonstrate compliance with the proposed regulations if necessary. Note that this requirement expands those recordkeeping requirements promulgated in 2019 at 40 CFR 751.109 affecting manufacturers, processors, and distributors of methylene chloride.

*2. Downstream notification.*

For conditions of use that are not otherwise prohibited under this final regulation, EPA is finalizing as proposed the requirements that manufacturers (including importers), processors, and distributors, excluding retailers, of methylene chloride and methylene chloride-containing products provide downstream notification of certain prohibitions through Safety Data Sheets (SDSs) by adding to sections 1(c) and 15 of the SDS the following language:

After **[INSERT DATE 270 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, this chemical substance (as defined in TSCA section 3(2))/product cannot be distributed in commerce to retailers. After **[INSERT DATE 630**

**DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***], this chemical substance (as defined in TSCA section 3(2))/product is and can only be distributed in commerce or processed with a concentration of methylene chloride equal to or greater than 0.1% by weight for the following purposes: (1) Processing as a reactant; (2) Processing for incorporation into a formulation, mixture, or reaction product; (3) Processing for repackaging; (4) Processing for recycling; (5) Industrial or commercial use as a laboratory chemical; (6) Industrial or commercial use as a bonding agent for solvent welding; (7) Industrial and commercial use as a paint and coating remover from safety critical, corrosion-sensitive components of aircraft and spacecraft; (8) Industrial and commercial use as a processing aid; (9) Industrial and commercial use for plastic and rubber products manufacturing; (10) Industrial and commercial use as a solvent that becomes part of a formulation or mixture, where that formulation or mixture will be used inside a manufacturing process, and the solvent (methylene chloride) will be reclaimed; (11) Industrial and commercial use in the refinishing for wooden furniture, decorative pieces, and architectural fixtures of artistic, cultural or historic value **[INSERT DATE 5 YEARS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**; (12) Industrial and commercial use in adhesives and sealants in aircraft, space vehicle, and turbine applications for structural and safety critical non-structural applications until **[INSERT DATE 5 YEARS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**; (13) Disposal; and (14) Export.

To provide adequate time to update the SDS and ensure that all products in the supply chain include the revised SDS, EPA's final rule requires manufacturers revise their SDS within 150 days of publication and processors and distributors revise their SDS within 210 days of publication of the final rule.

The intention of downstream notification is to spread awareness throughout the supply chain of the restrictions on methylene chloride under TSCA and to provide information to commercial end-users about allowable uses of methylene chloride. Note that this requirement would amend and add to the downstream notification requirements promulgated in 2019 at 40 CFR 751.107 for paint and coating removers for consumer use and additionally redesignate that section as 40 CFR 751.111(a). As they become effective, the new amended requirements will supersede those notification requirements promulgated in 2019.

*F. TSCA section 6(g) exemptions.*

EPA is finalizing as proposed a 10-year exemption for emergency use of methylene

chloride in furtherance of the National Aeronautics and Space Administration (NASA)'s mission for the following specific conditions of use: Industrial and commercial use as a solvent for cold cleaning; Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner; Industrial and commercial use in adhesives, sealants and caulks; Industrial and commercial use in adhesive and caulk removers; Industrial and commercial use in metal non-aerosol degreasers; Industrial and commercial use in non-aerosol degreasers and cleaners; and Industrial and commercial use as a solvent that becomes part of a formulation or mixture. The exemption includes additional requirements, pursuant to TSCA section 6(g)(4), including required notification and controls for exposure, to the extent feasible: 1) NASA and its contractors must provide notice to the EPA Assistant Administrators of both the Office of Enforcement and Compliance Assurance and the Office of Chemical Safety and Pollution Prevention of each instance of emergency use within 15 working days and; 2) NASA and its contractors would have to comply with the WCPP described in Unit IV.B. to the extent feasible.

Specifically, this regulation requires NASA and its contractors to notify the EPA Assistant Administrators of both the Office of Enforcement and Compliance Assurance and the Office of Chemical Safety and Pollution Prevention within 15 days of the emergency use. The notification must include a description of the specific use of methylene chloride in the context of one of the conditions of use for which this exemption is being finalized, an explanation of why the use described qualifies as an emergency, and an explanation with regard to the lack of availability of technically and economically feasible alternatives.

EPA expects NASA and its contractors have the ability to implement a WCPP as described in Unit IV.B. for the identified uses in the context of an emergency, to some extent even if not to the full extent of WCPP implementation. Therefore, NASA and its contractors must comply with the WCPP to the extent technically feasible in light of the particular

emergency.

NASA and its contractors would still be subject to the general recordkeeping requirements discussed in Unit IV.B.7.c.

## **V. TSCA Section 6(c)(2) Considerations**

### *A. Health effects of methylene chloride and the magnitude of human exposure to methylene chloride.*

EPA's analysis of the health effects of methylene chloride is in the 2020 Risk Evaluation for Methylene Chloride (Ref. 1). A summary is presented here.

The 2020 Risk Evaluation for Methylene Chloride identified six non-cancer adverse health effects: Effects from acute/short-term exposure, liver effects, immune system effects, nervous system effects, reproductive/developmental effects, and irritation/burns (Ref. 1). The 2020 Risk Evaluation for Methylene Chloride also identified cancer hazards from carcinogenicity as well as genotoxicity, particularly for liver and lung tumors (Ref. 1).

Among the non-cancer adverse health effects, the 2020 Risk Evaluation for Methylene Chloride identified neurotoxicity indicative of central nervous system depression as a primary effect of methylene chloride in humans following acute inhalation exposures (Ref. 1). Identified central nervous system depressive symptoms include drowsiness, confusion, headache, dizziness, and neurobehavioral deficits when performing various tasks. Central nervous system depressant effects can result in loss of consciousness and respiratory depression, possibly resulting in irreversible coma, hypoxia, and eventual death (Ref. 1).

Additionally, the 2020 Risk Evaluation for Methylene Chloride identified the liver as a sensitive target organ for inhalation exposure (Ref. 1). For human health risks to workers and consumers, EPA identified cancer and non-cancer human health risks. Risks from acute exposures include central nervous system risks such as central nervous system depression and a

decrease in peripheral vision, each of which can lead to workplace accidents and are precursors to more severe central nervous system effects such as incapacitation, loss of consciousness, coma, and death. For chronic exposures, EPA identified risks of non-cancer liver effects as well as liver and lung tumors (Ref. 1).

The 2020 Risk Evaluation for Methylene Chloride also identified several irritation hazards from methylene chloride exposure. Following exposures to methylene chloride vapors, irritation has been observed in the respiratory tract and eyes. Direct contact with liquid methylene chloride on the skin has caused chemical burns in workers and gastrointestinal irritation in individuals who accidentally ingested methylene chloride (Ref. 1).

Regarding the magnitude of human exposure, one factor EPA considers for the conditions of use that contribute to the unreasonable risk is the size of the exposed population, which, for methylene chloride, EPA estimates is 785,000 workers, 135,000 occupational non-users, and 15 million consumers (Ref. 1).

In addition to these estimates of numbers of workers, occupational non-users, consumers, and bystanders to consumer use directly exposed to methylene chloride, EPA recognizes there is exposure to the general population from air and water pathways for methylene chloride. (While bystanders are individuals in proximity to a consumer use of methylene chloride, fence-line communities are a subset of the general population who may be living in proximity to a facility where methylene chloride is being used in an occupational setting). EPA separately conducted a screening approach to assess whether there may be risks to the general population from these exposure pathways. This analysis is summarized in full in the proposed rule, which includes information on the SACC peer review (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP). This unit addresses those areas where some risk was indicated at the fence-line, and the use will be continuing under the rule.

EPA's analysis was presented to the SACC peer review panel in March 2022, and EPA is including SACC recommendations, as appropriate, in assessing general population exposures in upcoming risk evaluations.

EPA's fence-line analysis for the water pathway for methylene chloride, based on methods presented to the SACC, did not find risks from incidental oral and dermal exposure to surface water, and while EPA found one facility which indicated acute risk from drinking water, additional assessment of this location identified that there are no source drinking water intakes for public drinking water systems in proximity to the facility estimated to have risk, thereby making risks to the general population through the drinking water pathway unlikely.

Although the initial analysis presented to SACC and the multi-year analysis conducted in response to SACC feedback for methylene chloride indicated exposure and associated risks to select populations within the general population living or working near particular facilities from the ambient air pathway, EPA is unable to formally determine with this screening methodology whether those risks contribute to the unreasonable risk, because the screening methodology was not developed for that purpose. However, EPA believes that the prohibitions being finalized for manufacturing (including importing), processing, and distribution in commerce for all consumer use and most commercial use would address the majority of exposures to the general population, including fence-line communities. Of the 14 facilities which indicated some risk for methylene chloride, under the final regulation, only six will continue to use methylene chloride (three facilities for processing: Incorporation into formulation, mixture, or reaction product, two facilities for plastic and rubber product manufacturing, and one facility for paint and coating remover), and thus exposures at the fence-line at the remainder of those facilities would be addressed.

Of those six facilities, the multi-year analysis indicated potential risk at 100 meters for

only three facilities representing two conditions of use – two for plastic and rubber product manufacturing and one for processing: Incorporation into a formulation, mixture, or reaction process. Anticipated use trends for these three conditions of use are discussed in this unit.

EPA anticipates processing into a formulation, mixture, or reaction product to decline because, while processing into a formulation, mixture, or reaction product will continue under a WCPP, all downstream distribution and use of formulations, mixtures, or reaction products will be prohibited except those handful of uses which will continue under the WCPP, a majority of which require the application of neat methylene chloride, rather than a formulated product. Additionally, the facility with identified risk at the fenceline for processing: Incorporation into formulation, mixture, or reaction product does not appear to have communities currently located at the fenceline based on land use analysis (Ref. 101). For use of methylene chloride in plastic and rubber product manufacturing, EPA does not have reason to believe the use of methylene chloride will increase, nor that there will be significant increase in fenceline exposures in this sector, which is heavily regulated by the CAA (Ref. 102).

For both processing: Incorporation into a formulation, mixture, or reaction product and plastic and rubber product manufacturing, the final rule would require exposure controls via implementation of a WCPP as described in Unit IV.B. While it is plausible that efforts to reduce exposures in the workplace to levels below the ECEL and EPA STEL could lead to adoption of engineering controls that ventilate more methylene chloride outside, EPA determined this outcome is unlikely, particularly for plastic and rubber product manufacturing. This is because, as discussed in Unit III.A.2., monitoring data submitted during the comment period indicates current exposure levels are already very near or below the ECEL so the addition of engineering controls that could, in theory, ventilate more methylene chloride outside is not expected to occur. Additionally, in a scenario where venting methylene chloride out of the work area and into the

outside air, this potential exposure would be required to be limited as a result of the numerous existing NESHAPs for methylene chloride for these conditions of use under the CAA (applicable NESHAPs: 40 CFR part 63 subpart F,G,H, and I, Synthetic Organic Chemical Manufacturing Industry; 40 CFR part 63 subpart DD, Off-Site Waste and Recovery Operations; 40 CFR part 63 subpart YY, Generic MACT I for Polycarbonate production (79 FR 60898, October 8 2014) 40 CFR part 63 subpart VVV, Publicly Owned Treatment Works; and 40 CFR part 63 subpart VVVVVV, the NESHAP for Chemical Manufacturing Area Sources), and any exceedances would be an enforcement issue. Thus, prohibition of manufacture, processing, and distribution in commerce of methylene chloride for all consumer use and most industrial and commercial use, and prohibition of most industrial and commercial use of methylene chloride, is expected to largely address the risks identified in the screening analysis to any general population or fence-line communities close to facilities engaging in methylene chloride use. EPA therefore does not intend to revisit the air pathway for methylene chloride as part of a supplemental risk evaluation.

*B. Environmental effects of methylene chloride and the magnitude of environmental exposure to methylene chloride.*

EPA's analysis of the environmental effects of and the magnitude of exposure of the environment to methylene chloride is in the 2020 Risk Evaluation for Methylene Chloride (Ref. 1). The unreasonable risk determination for methylene chloride is based solely on risks to human health; based on the 2020 Risk Evaluation for Methylene Chloride, EPA determined that exposures to the environment did not contribute to the unreasonable risk.

For all conditions of use, exposures via water for acute and chronic exposures to methylene chloride for amphibians, fish, and aquatic invertebrates do not contribute to the unreasonable risk. To characterize aquatic organisms' exposure to methylene chloride, modeled



data were used to represent surface water concentrations near facilities actively releasing methylene chloride to surface water, and monitored concentrations were used to represent ambient water concentrations of methylene chloride. EPA considered the biological relevance of the species to determine the concentrations of concern for the location of surface water concentration data to produce risk quotients, as well as frequency and duration of the exposure. While some site-specific risk quotients, calculated from modeled release data from facilities conducting recycling, disposal, and wastewater treatment plant activities, exceeded risk benchmarks, uncertainties in the analysis were considered. These uncertainties include limitations in data, since monitoring data were not available near facilities where methylene chloride is released, and data incorporated from the Toxics Release Inventory, which does not include release data for facilities with fewer than ten employees. As an additional uncertainty, the model does not consider chemical fate or hydrologic transport properties and may not consider dilution in static water bodies. Additional analysis indicated that model outputs, rather than monitoring estimates, may best represent concentrations found at the point of discharge from the facilities (Ref. 1).

The toxicity of methylene chloride to sediment-dwelling invertebrates is similar to its toxicity to aquatic invertebrates. Methylene chloride is most likely present in the pore waters and not absorbed to the sediment organic matter because methylene chloride has low partitioning to organic matter. The concentrations in sediment pore water are similar to or less than the concentrations in the overlying water, and concentrations in the deeper part of sediment are lower than the concentrations in the overlying water. Therefore, the risk estimates, based on the highest ambient surface water concentration, do not support an unreasonable risk determination to sediment-dwelling organisms from acute or chronic exposures. There is uncertainty due to the lack of ecotoxicity studies specifically for sediment-dwelling organisms and limited sediment

monitoring data (Ref. 1).

Based on its physical-chemical properties, methylene chloride does not partition to or accumulate in soil. Therefore, the physical chemical properties of methylene chloride do not support an unreasonable risk determination to terrestrial organisms.

*C. Benefits of methylene chloride for various uses.*

As described in the proposed rule, methylene chloride is a solvent used in a variety of industrial, commercial, and consumer use applications, including adhesives, pharmaceuticals, metal cleaning, chemical processing, and feedstock in the production of refrigerant HFC-32 (82 FR 7467). Specifically, methylene chloride use in commercial paint and coating removal provides benefits for some users because it is readily available and works quickly and effectively on nearly all coatings without damaging most substrates. For a variety of additional uses (e.g., adhesives, adhesive removers, cold pipe insulation, welding anti-spatter spray) methylene chloride is relatively inexpensive, highly effective, evaporates quickly, and is not flammable, making it a popular and effective solvent for many years. As of 2016, the leading applications for methylene chloride are as a solvent in the production of pharmaceuticals and polymers and paint removers, although recent regulations and voluntary industry actions are expected to decrease the chemical's use in the paint remover sector (40 CFR part 751, subpart B). The total aggregate production volume ranged from 100 to 500 million pounds between 2016 and 2019 according to CDR (Ref. 6).

*D. Reasonably ascertainable economic consequences of the final rule.*

*1. Likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health.*

The reasonably ascertainable economic consequences of this final rule include several components, all of which are described in the Economic Analysis (Ref. 3). With respect to the

anticipated effects of this final rule on the national economy, EPA considered the number of businesses and workers that would be affected and the costs and benefits to those businesses and workers and did not find that there would be an impact on the national economy (Ref. 3). The economic impact of a regulation on the national economy becomes measurable only if the economic impact of the regulation reaches 0.25% to 0.5% of Gross Domestic Product (GDP) (Ref. 103). Given the current GDP, this is equivalent to a cost of \$40 billion to \$80 billion. Therefore, because EPA has estimated that the non-closure-related cost of the proposed rule would range from \$37.0 million annualized over 20 years at a 3% discount rate and \$39.5 million annualized over 20 years at a 7% discount rate, EPA has concluded that this rule is highly unlikely to have any measurable effect on the national economy (Ref. 3). In response to the updated Circular A-4 published in November 2023, the incremental, non-closure related costs of this rule at a 2% discount rate (\$36.4 million annualized over 20 years) is provided in Appendix D of the Economic Analysis (Ref. 3). In addition, EPA considered the employment impacts of this final rule, and found that the direction of change in employment is uncertain, but EPA expects the short-term and longer-term employment effects to be small.

Of the small businesses potentially impacted by this final rule, 99% (229,635 firms) are expected to have impacts of less than 1% to their firm revenues (rounded metric), 1% (1,668 firms) are expected to have impacts between 1 and 3% to their firm revenues (rounded metric), and 0.5% (1,148 firms) are expected to have impacts greater than 3% to their firm revenues (rounded metric). Excluding end-users, total estimated impacts on small businesses are \$9.3 million (annualized using a 7 percent discount rate). End users with economic and technologically feasible alternatives available do not have economic impacts that are estimated beyond rule familiarization costs (\$1.8 million in total costs, annualized using a 7 percent discount rate).

With respect to this rule's effect on technological innovation, EPA expects this rule to spur more innovation than it will hinder. A prohibition or significant restriction on the manufacture, processing, and distribution in commerce of methylene chloride for uses covered in this final rule may increase demand for existing, as well as development of additional, safer chemical substitutes. In specifying delayed compliance with a restriction, EPA must specify a date as soon as practicable, and that period may be necessary to develop and implement alternatives to a restricted chemical. For example, the 5-year delayed compliance with the prohibition for certain furniture refinishers allows extra time for the continued development and implementation of alternative paint and coating removers to be developed and tested in the marketplace. Outreach with processors indicated some were working on paint and coating removers to fill the void from methylene chloride products in the event of a prohibition in commercial industries (e.g. EPA-HQ-OPPT-2020-0465-0181). This rule is not likely to have significant effects on the environment because, as discussed in Unit II.C.3., methylene chloride does not present an unreasonable risk to the environment, though this rule does present the potential for small reductions in air emissions and soil contamination associated with improper disposal of products containing methylene chloride. The effects of this rule on public health are estimated to be positive, due to the potential prevention of deaths from acute exposure and reduced risk of cancer from chronic exposure to methylene chloride, as well as other reduced risks from other effects which, while tangible and significant, cannot be monetized, as described in Unit V.D.2.

*2. Costs and benefits of the regulatory action and of the one or more primary alternative regulatory actions considered by the Administrator.*

The costs and benefits that can be monetized for this proposed rule are described at length in the Economic Analysis (Ref. 3). The non-closure-related costs for this final rule are

estimated to be \$37.0 million annualized over 20 years at a 3% discount rate and \$39.5 million annualized over 20 years at a 7% discount rate. The monetized benefits are estimated to be \$24.8 to \$25.1 million annualized over 20 years at a 3% discount rate and \$19.8 to \$20.0 million annualized over 20 years at a 7% discount rate. In response to the updated Circular A-4 published in November 2023, the incremental, non-closure related costs of this rule at a 2% discount rate (\$36.4 million annualized over 20 years) and benefits (\$27.1 to \$27.5 million annualized over 20 years) are provided in Appendix D of the Economic Analysis (Ref. 3).

Due to unique circumstances in furniture refinishing, and, in particular, commercial use of methylene chloride in refinishing for wooden furniture, decorative pieces, and architectural fixtures of artistic, cultural or historic value (as discussed in detail in Unit III.B.1.), a prohibition of methylene chloride in this industry may result in firm closures for the sector as a whole. It is possible to estimate that profits for the 4,899 furniture refinishing firms that use methylene chloride are approximately \$63 million using the average estimated revenues per firm for NAICS 811420, Reupholstery and Furniture Repair (\$338,525 is average revenue) and an IRS (2013) estimate for profit in this sector of 3.8% of sales. Profit is related to, but not the same as producer surplus. Producer surplus is generally larger than profit since producer surplus is the difference between total revenue and marginal cost and profit is the difference between total revenue and total cost. Total revenue for the 4,899 furniture refinishing firms that use methylene chloride is estimated to be \$1.7 billion. Total revenue provides a measure of overall economic activity for these firms, but does not directly relate to the potential loss of producer and consumer surplus (i.e., social cost) from potential closures or price increases in the furniture refinishing industry (Ref. 3). In addition, due to the uncertainty of the number and type of closures, EPA is unable to include these potential impacts in the monetized cost estimates for this action.

EPA considered the estimated costs to regulated entities as well as the cost to administer

and enforce alternative regulatory actions. Estimated costs for regulatory alternatives can be found in the Economic Analysis for this final rule (Ref. 3)

This final rule is expected to achieve health benefits for the American public, some of which can be monetized and others that, while tangible and significant, cannot be monetized due to lack of dose-response data, as discussed in Unit I.E. At a discount rate of 2 percent over 20 years the monetized net benefits range from (\$9.3M) to (\$9.0) million (Ref. 3). EPA believes that the balance of costs and benefits of this final rule cannot be fairly described without considering the additional, non-monetized benefits of mitigating the non-cancer adverse effects. The multitude of adverse effects from methylene chloride exposure can profoundly impact an individual's quality of life, as discussed in the proposed rule in Units II.A. (overview), III.B.2. (description of the unreasonable risk), V.A. (discussion of the health effects), and in the Risk Evaluation (85 FR 37942). Some of the adverse effects can be immediately experienced and can result in sudden death; others can have impacts that are experienced for a shorter portion of life but are nevertheless significant in nature. The incremental improvements in health outcomes achieved by given reductions in exposure cannot be quantified for non-cancer health effects associated with methylene chloride exposure, and therefore cannot be converted into monetized benefits. The qualitative discussion throughout this rulemaking and in the Economic Analysis highlights the importance of these non-cancer effects, which are not able to be monetized in the way that EPA is able to for cancer and death. These effects include not only cost of illness but also personal costs such as emotional and mental stress that are hard to measure appropriately. Considering only monetized benefits significantly underestimates the impacts of methylene chloride adverse outcomes and underestimates the benefits of this final rule.

The 2020 Risk Evaluation for Methylene Chloride identified two non-cancer health effects in reviewed scientific literature relevant to children, namely reproductive and

developmental hazards (Ref. 1). The 2020 Risk Evaluation for Methylene Chloride summarizes human health hazards identified in the review of scientific literature, including studies investigating methylene chloride exposure and reproductive and developmental effects as well as developmental neurotoxicity. Some epidemiological studies identified effects that include reduced fertility, spontaneous abortions, oral cleft defects, heart defects, and autism spectrum disorder (ASD). For ASD, due to methodological reasons including confounding by other chemicals and lack of temporal specificity, the 2020 Risk Evaluation for Methylene Chloride did not advance this hazard to a dose response calculation. Additionally, EPA did not carry reproductive/developmental effects forward for dose-response, because epidemiological studies lacked controls for co-exposures and animal studies observed effects mostly at higher methylene chloride concentrations. EPA also did not identify relevant mechanistic information, which informed this decision (Ref. 1). Nonetheless, additional health benefits may be achieved by reducing the incidence of reproductive effects for workers in commercial facilities or companies that use methylene chloride for the commercial uses proposed to be regulated (Ref. 3).

EPA was unable to estimate either the precise reduction in individual risk of these reproductive and developmental effects from reducing exposure to methylene chloride or the total number of cases avoided can be estimated due to a lack of necessary data. Nevertheless, reproductive hazards such as reduced fertility are important considerations. These health effects are serious and can have impacts throughout a lifetime; for example, infertility and fertility treatment can have deleterious social and psychological consequences such as mental distress (Ref. 104).

The potential impacts of these effects include monetary impacts from associated healthcare costs such as fertility treatments, as well as complications from fertility treatments (*e.g.*, higher multiple birth rates), mental stress and emotional suffering, which cannot be

quantified or monetized but should not be ignored.

*3. Cost effectiveness of the regulatory action and of one or more primary alternative regulatory actions considered by the Administrator.*

Cost effectiveness is a method of comparing certain actions in terms of the expense per item of interest or goal. A goal of this regulatory action is to prevent user deaths resulting from exposure to methylene chloride. While preventing potential deaths due to methylene chloride exposure is not the only benefit of this regulatory action, it was the goal selected to use for the cost effectiveness calculations. The final rule regulatory option costs \$27 million per potential prevented death while the alternative option costs \$151 million per potential prevented death (using the 3 percent discount rate), indicating that the final rule option is more cost effective compared to the alternative option (Ref. 3). The primary difference between the final and alternative option is that the alternative includes prohibitions on some uses which fall under WCPP in the final rule, most notably the use of methylene chloride as a processing aid. EPA received multiple public comments providing detailed cost information on the impacts of a prohibition of methylene chloride for this condition of use. This information was incorporated into the cost estimates for the alternative option (Ref. 3).

## **VI. TSCA Section 9 Analysis and Section 14 and 26 Considerations**

### *A. TSCA section 9(a) analysis.*

TSCA section 9(a) provides that, if the Administrator determines, in the Administrator's discretion, that an unreasonable risk may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA, the Administrator must submit a report to the agency administering that other law that describes the risk and the activities that present such risk. TSCA section 9(a) describes additional procedures and requirements to be followed by EPA and the other Federal agency after submission of the report. As discussed in



this Unit, the Administrator does not determine that unreasonable risk from methylene chloride under the conditions of use may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA. EPA's section 9(a) analysis can be found in full in Unit VII.A. of the proposed rule, and responses to comments on that 9(a) analysis can be found in the Response to Comments, section 8.5.1 (Ref. 7).

TSCA section 9(d) instructs the Administrator to consult and coordinate TSCA activities with other Federal agencies for the purpose of achieving the maximum enforcement of TSCA while imposing the least burden of duplicative requirements. For this rulemaking, EPA has coordinated with appropriate Federal executive departments and agencies including but not limited to OSHA, CPSC, and NIOSH to, among other things, identify their respective authorities, jurisdictions, and existing laws with regard to the risk evaluation and risk management of methylene chloride.

As discussed in more detail in the proposed rule, OSHA requires that employers provide safe and healthful working conditions by setting and enforcing standards and by providing training, outreach, education, and assistance. OSHA has established health standards for methylene chloride covering employers in General Industry, Shipyards, and Construction (29 CFR 1910.1052(a)). Gaps exist between OSHA's authority to set workplace standards under the OSH Act and EPA's obligations under TSCA section 6 to eliminate unreasonable risk presented by chemical substances under the conditions of use. OSHA lacks direct jurisdiction over state and local government workers, and does not cover self-employed workers, military personnel, and uniquely military equipment, systems, and operations, and workers whose occupational safety and health hazards are regulated by another Federal agency (for example, the Mine Safety and Health Administration, the Department of Energy, or the Coast Guard) (Ref. 105). The U.S. Consumer Product Safety Commission (CPSC), under authority provided to it by Congress in the

CPSA, protects the public from unreasonable risk of injury or death associated with consumer products. Under the CPSA, CPSC has the authority to regulate methylene chloride in consumer products, but not in other sectors such as automobiles, some industrial and commercial products, or aircraft, for example.

Therefore, EPA maintains that TSCA is the only vehicle to deliver broad protections to consumers who may use formulations that contain methylene chloride and whose use contributes to the unreasonable risk of injury to health from methylene chloride. An action under TSCA is also able to address occupational unreasonable risk and would reach entities that are not subject to OSHA. The timeframe and any exposure reduction as a result of updating OSHA or CPSC regulations for methylene chloride cannot be estimated, while TSCA imposes a much more accelerated two-year statutory timeframe for proposing and finalizing requirements to address unreasonable risk. Regulating methylene chloride's unreasonable risk utilizing TSCA authority will also avoid the situation where a patchwork of regulations amongst several Agencies using multiple laws and differing legal standards would occur and is therefore a more efficient and effective means of addressing the unreasonable risk of methylene chloride. Finally, as discussed in greater detail in the proposed rule, the 2016 amendments to TSCA altered both the manner of identifying unreasonable risk and EPA's authority to address unreasonable risk, such that risk management is increasingly distinct from provisions of the CPSA, FHSA, or OSH Act.

EPA therefore concludes that TSCA is the only regulatory authority able to prevent or reduce unreasonable risk of methylene chloride to a sufficient extent across the range of conditions of use, exposures, and populations of concern. For this reason, in the Administrator's discretion, the Administrator has analyzed this issue and does not determine that unreasonable risk from methylene chloride may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA.

*B. TSCA section 9(b) analysis.*

If EPA determines that actions under other Federal laws administered in whole or in part by EPA could eliminate or sufficiently reduce a risk to health or the environment, TSCA section 9(b) instructs EPA to use these other authorities to protect against that risk “unless the Administrator determines, in the Administrator’s discretion, that it is in the public interest to protect against such risk” under TSCA. In making such a public interest finding, TSCA section 9(b)(2) states “the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk . . . and a comparison of the estimated costs and efficiencies of the action to be taken under this title and an action to be taken under such other law to protect against such risk.”

Although several EPA statutes have been used to limit methylene chloride exposure (Refs. 3,5), regulations under those EPA statutes largely regulate releases to the environment, rather than occupational or consumer exposures. While these limits on releases to the environment are protective in the context of their respective statutory authorities, regulation under TSCA is also appropriate for occupational and consumer exposures and in some cases can provide upstream protections that would prevent the need for release restrictions required by other EPA statutes (e.g., Resource Conservation and Recovery Act (RCRA), CAA, CWA). Updating regulations under other EPA statutes would not be sufficient to address the unreasonable risks from methylene chloride to workers, occupational non-users, consumers, and bystanders who are exposed under its conditions of use. EPA’s section 9(b) analysis can be found in full in Unit VII.B. of the proposed rule, and responses to comments on that 9(b) analysis can be found in the Response to Comments, section 8.5.2 (Ref. 7).

For these reasons, the Administrator does not determine that unreasonable risk from methylene chloride under its conditions of use, as evaluated in the 2020 Risk Evaluation for

Methylene Chloride (Ref. 1), could be eliminated or reduced to a sufficient extent by actions taken under other Federal laws administered in whole or in part by EPA.

*C. TSCA section 14 requirements.*

EPA is also providing notice to manufacturers, processors, and other interested parties about potential impacts to CBI. Under TSCA sections 14(a) and 14(b)(4), if EPA promulgates a rule pursuant to TSCA section 6(a) that establishes a ban or phase-out of a chemical substance, the protection from disclosure of any CBI regarding that chemical substance and submitted pursuant to TSCA will be “presumed to no longer apply,” subject to the limitations identified in TSCA section 14(b)(4)(B)(i) through (iii). Pursuant to TSCA section 14(b)(4)(B)(iii), the presumption against protection from disclosure will apply only to information about the specific conditions of use that this rule prohibits or phases out. Per TSCA section 14(b)(4)(B)(i), the presumption against protection will not apply to information about certain emergency uses that this rule exempts from a ban or phase-out pursuant to TSCA section 6(g). Manufacturers or processors seeking to protect such information may submit a request for nondisclosure as provided by TSCA sections 14(b)(4)(C) and 14(g)(1)(E). Any request for nondisclosure must be submitted within 30 days after receipt of notice from EPA under TSCA section 14(g)(2)(A) stating EPA will not protect the information from disclosure. EPA anticipates providing such notice via the Central Data Exchange (CDX).

*D. TSCA section 26 considerations.*

As explained in the proposed rule, EPA fulfilled TSCA section 26(h) by using scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science. Comments received on the proposed rule about whether EPA adequately assessed reasonably available information under TSCA section 26 on the risk evaluation, and responses to those comments, can be found in Section 8.5.3 of the

Response to Comments document (Ref. 7).

## VII. 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 itself physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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### **VIII. 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 14094: Modernizing Regulatory Review*

This action is a “significant regulatory action” as defined under section 3(f)(1) of Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023). Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for Executive Order 12866 review. Documentation of any changes made in response to Executive Order 12866 review is available in the docket. EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis (Ref. 3), is available in the docket and summarized in Unit I.E.

#### *B. Paperwork Reduction Act (PRA)*

The information collection activities in this final rule have been submitted to OMB for approval under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR No. 2735.02 and OMB Control No. 2070-0229 (Ref. 106). You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

There are three primary provisions of the final rule that are expected to increase burden under the PRA.

The first is downstream notification, which will be carried out by updates to the relevant SDS and which is required for manufacturers, processors, and distributors in commerce of methylene chloride, who will provide notice to companies downstream upon shipment of methylene chloride about the prohibitions. The information submitted to downstream companies through the SDS will provide knowledge and awareness of the restrictions to these companies.

The second primary provision of the rule that is expected to increase burden under the PRA is WCPP-related information generation, recordkeeping, and notification requirements (including development of exposure control plans; exposure level monitoring and related recordkeeping; development of documentation for a PPE program and related recordkeeping; development of documentation for a respiratory protection program and related recordkeeping; development and notification to potentially exposed persons (employees and others in the workplace) about how they can access the exposure control plans, exposure monitoring records, PPE program implementation documentation, and respirator program documentation; and related recordkeeping).

The third primary provision of the rule that is expected to increase burden under the PRA is recordkeeping for interim requirements for commercial use of methylene chloride for refinishing wood pieces of artistic, historic or cultural significance (including documentation of details related to the refinishing activity and records demonstrating compliance with the exposure reduction controls).

*Respondents/affected entities:* Persons that manufacture, process, use, distribute in commerce, or dispose of methylene chloride or products containing methylene chloride. See also Unit I.A.

*Respondent's obligation to respond:* Mandatory (TSCA section 6(a) and 40 CFR part 751).

*Estimated number of respondents:* 237,969.

*Frequency of response:* On occasion.



*Total estimated burden:* 149,090 hours (per year). Burden is defined at 5 CFR 1320.3(b).

*Total estimated cost:* \$16,563,299 (per year), includes \$4,451,405 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the *Federal Register* and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

### *C. Regulatory Flexibility Act (RFA)*

Pursuant to sections 603 and 609(b) of the RFA, 5 U.S.C. 601 *et seq.*, EPA prepared an IRFA for the proposed rule and convened a SBAR Panel to obtain advice and recommendations from SER that potentially would be subject to the rule's requirements. Summaries of the IRFA and Panel recommendations are presented in the proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSP).

As required by section 604 of the RFA, EPA prepared a FRFA for this action (Ref.21). The FRFA addresses the issues raised by public comments on the IRFA for the proposed rule. The complete FRFA is available for review in the docket and is summarized here.

#### *1. Statement of need and rule objectives.*

Under section 6(a) of TSCA (15 U.S.C. 2605(a)), if EPA determines after a TSCA section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more

requirements listed in TSCA section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents such risk. Methylene chloride was the subject of a risk evaluation under TSCA section 6(b)(4)(A) that was issued in June 2020. In addition, in November 2022, EPA issued a revised unreasonable risk determination that methylene chloride as a whole chemical substance presents an unreasonable risk of injury to health under the conditions of use. As a result, EPA is taking action to the extent necessary so that methylene chloride no longer presents such risk.

EPA developed this final rule after considering EPA's unreasonable risk determination for methylene chloride, information provided in public comments on the proposed rule, findings from and comments on the SBAR panel, other required consultations, and additional public outreach. For more information on the proposed rule, SBAR panel, and outreach efforts for this action, see the docket for this rulemaking (Docket ID Number EPA-HQ-OPPT-2020-0465).

To address the identified unreasonable risk, this rule: (1) Prohibits the manufacture, processing, and distribution in commerce of methylene chloride for consumer use; (2) prohibits most industrial and commercial uses of methylene chloride using the alternative timeframes from the proposed rule; (3) delays prohibition timeframes for two conditions of use of methylene chloride (including as a paint remover in furniture refinishing) to allow for reasonable transitions to alternatives; (4) requires a WCPP to be implemented within the alternative timeframes from the proposed rule for several occupational conditions of use, including three conditions of use for which the WCPP was not proposed; (5) removes the proposed distinction between Federal and commercial use of methylene chloride for two conditions of use under the WCPP; (6) allows for a de minimis threshold of methylene chloride in for products to account for impurities and non-intentional presence; (7) requires recordkeeping and downstream notification requirements for several conditions of use of methylene chloride; and (8) provides certain time-limited

exemptions from requirements for uses of methylene chloride which are critical that have no technically feasible, safer alternative available.

*2. Significant issues raised by the public comments in response to the IRFA and EPA response.*

An industry trade organization commented that the proposed rule “discriminates” against small businesses by providing them no opportunity to use methylene chloride under the proposed WCPP. The commenter also stated that the proposed rule contravenes the RFA by failing to discuss comments provided by small businesses. The commenter also faulted EPA for not discussing feedback received from small businesses regarding substitution costs prior to the proposed rule.

**EPA Response:** EPA’s primary responsibility under TSCA is to address unreasonable risks presented by the chemical substance under the conditions of use, irrespective of the size of the business. Entities of any size under the conditions of use for which EPA is finalizing the WCPP, phaseouts, or time-limited exemptions may continue to process or use methylene chloride under the restrictions and requirements of the rule; EPA is not prohibiting or limiting participation due to firm size. Regarding the RFA, as required by the RFA, EPA convened a SBAR Panel, solicited input from SERs, used that feedback to generate Panel recommendations, incorporated those recommendations into the proposed rule, and published an IRFA and FRFA. EPA also identified the impacts of this rulemaking on small businesses (Ref. 19) and sought to identify flexibilities that could be provided. For the Economic Analysis, to the extent possible, EPA included specific and detailed substitution costs; however, most information the Agency received was not detailed enough to be incorporated.

*3. SBA Office of Advocacy comments and EPA response.*

SBA Office of Advocacy provided comments on the proposed rule (EPA-HQ-OPPT-2020-0465). The comments below reflect a portion of the comments received by the SBA Office of Advocacy during the comment period. For the full list of comments and responses, see Section 3 of the FRFA (Ref.21).

**Comment:** SBA Office of Advocacy requested that EPA accept additional data after the close of the public comment period.

**EPA Response:** The Agency is working to finalize rules consistent with statutory timeframes under TSCA section 6(c)(1), which are to propose a risk management rulemaking within one year of a final risk evaluation for the chemical substance, and to finalize the rulemaking within two years of the final risk evaluation. Should a late submission contain data that could be used to inform a future rulemaking, EPA may consider such information at that time.

**Comment:** SBA Office of Advocacy stated that, while EPA refers to uncertainty as to capacity for ECEL compliance as justification for proposed bans of methylene chloride, TSCA does not specify any level of certainty or compliance capability. TSCA simply requires that the unreasonable risk be addressed only to the extent necessary. SBA Office of Advocacy further stated that, by issuing the ECEL, EPA has identified the threshold at which the unreasonable risk is considered addressed, so if a user can comply with the ECEL, as proposed by EPA, there should be no unreasonable risk present. In the commenter's view, speculating about compliance capability goes beyond the scope of the statute.

**EPA Response:** EPA disagrees with the interpretation that TSCA requires EPA to ignore available information related to the ability of workplaces to successfully implement the WCPP for methylene chloride. The fact that there continue to be occupational deaths and nonfatal incidents related to methylene chloride exposure, as well as ongoing non-trivial levels of

noncompliance with the OSHA Methylene Chloride Standard (Ref. 11), indicate that compliance with regulatory controls on workplace exposures to methylene chloride, including the WCPP, cannot be assumed. Moreover, if EPA were to regulate all workplaces via implementation of the WCPP, EPA believes that it would present significant and widespread implementation difficulties across multiple industry sectors, leading to high non-compliance rates that would undermine the health-protectiveness of the rule. EPA is aware that there remain ongoing non-trivial levels of noncompliance with the existing OSHA Methylene Chloride Standard. For example, between October 2022 through September 2023, OSHA issued 44 citations and conducted 14 inspections on their methylene chloride standard, spanning 11 industries including furniture manufacturing and automotive repair. In addition, OSHA has documented a fatality from methylene chloride as recently as July 2023 (Ref. 11, 12, 107, 108). Given this background, EPA does not believe it is reasonable to assume that entities with ongoing difficulty implementing the WCPP will cease use of methylene chloride because they are unable to comply with the WCPP. Rather, EPA expects that those entities would instead continue attempting (albeit unsuccessfully) to implement such protections, leaving the unreasonable risk unmitigated. Accordingly, EPA's rule would fail to ensure that methylene chloride no longer presents an unreasonable risk to health, as required by TSCA section 6(a). Conversely, where EPA has information demonstrating that companies can meet the WCPP reliably, there is a record basis upon which EPA can determine that the condition of use can continue under the WCPP without contributing to the unreasonable risk posed by methylene chloride. EPA notes that all industry sectors had numerous opportunities to provide the agency with monitoring or other data to indicate the ability for effective exposure reduction for their uses, but, in some cases, none were provided.

**Comment:** SBA Office of Advocacy asserted that EPA's proposal exceeds the statutory directive because it would prohibit the use of methylene chloride as a processing aid even for a business that provided data indicating that worker inhalation exposures were frequently below the ECEL or even the level of detection. SBA Office of Advocacy also argued that EPA's consideration in the alternative regulatory action of allowing the WCPP-controlled use of methylene chloride as a processing aid and for other uses indicates that such an option would address unreasonable risks.

**EPA Response:** In the proposed rule, EPA signaled its willingness to reconsider the proposed prohibition on the commercial use of methylene chloride as a processing aid should EPA receive adequate supporting information during the public comment period. As a result of the information provided by the business referenced by SBA Office of Advocacy, and additional information received during the comment period, the final rule permits the commercial use of methylene chloride as a processing aid to continue under the WCPP.

**Comment:** SBA Office of Advocacy stated that the proposed ECEL Action Level is too low and cannot be measured in real time on-site. SBA Office of Advocacy stated that the ECEL Action Level should be adjusted to account for the practical limitations faced by small businesses and ensure the ECEL Action Level is both feasible and accurately measurable in real-time.

**EPA Response:** EPA notes that while real-time monitoring is not required for rule compliance, EPA understands the practical benefits of real-time occupational exposure monitoring. EPA notes that in the response to comments, multiple stakeholders acknowledged the viability of real-time detection for methylene chloride at 1 ppm. EPA acknowledges that some portable monitoring devices may not be able to reliably detect the action level in real-time. In conditions that may ideally benefit real-time monitoring measurements or expedited results, stationary monitoring devices such as mass spectrometers, as noted by another commenter, may

be helpful. EPA may not always set the action level for a given chemical at one half the assigned ECEL value. In some situations, EPA may adjust the action level in a risk management rule as part of the WCPP.

*4. Estimate of the number of small entities to which the final rule applies.*

This final rule potentially affects small manufacturers (including importers), processors, distributors, retailers, users of methylene chloride or of products containing methylene chloride, and entities engaging in disposal. EPA estimates that the final rule would affect approximately 237,969 firms using methylene chloride, of which 232,451 small entities (based on SBA definitions published in March 2023) have estimated impacts. End users with economic and technologically feasible alternatives available do not have estimated cost impacts beyond rule familiarization costs except for vapor degreasing and furniture refinishing. For a full description of the estimated number of small entities affected by this rule, see the FRFA (Ref.21).

*5. Projected reporting, recordkeeping and other compliance requirements of the final rule.*

*a. Compliance requirements.*

EPA is prohibiting most conditions of use of methylene chloride. As described in the final rule, EPA is prohibiting all manufacturing (including import), processing, and distribution in commerce of methylene chloride for consumer use. After the publication date of the final rule in the *Federal Register*, prohibitions on manufacturing, processing, and distribution in commerce of methylene chloride for consumer use will occur in 360 days for manufacturers, 450 days for processors, 270 days for distributing to retailers, and 360 days for all other distributors and retailers.

EPA is also prohibiting manufacturing (including import), processing, distribution in commerce of methylene chloride for commercial use, and all commercial use of methylene

chloride other than those conditions of use for which EPA is finalizing a WCPP or providing a time-limited exemption under TSCA section 6(g). The prohibitions for these commercial uses would become effective following prohibitions relevant to these uses in stages of the supply chain before the industrial and commercial use (e.g., manufacturing and processing). The restrictions follow a staggered schedule for each stage of the supply chain. Prohibitions come into effect in 360 days for manufacturers, 450 days for processors, 270 days for distributing to retailers, 630 days for all other distributors and retailers, and 720 days for industrial and commercial uses after the publication date of the final rule.

EPA is finalizing a prohibition compliance date delayed by five years after the publication date of the final rule for commercial use of methylene chloride in furniture refinishing for wood pieces of artistic, cultural, or historic value where workshops can meet a minimum standard of exposure control. Additionally, EPA is finalizing a delayed prohibition compliance date of five years for industrial and commercial use in adhesives and sealants in aircraft, space vehicle, and turbine applications for structural and safety critical non-structural applications after the publication date of the final rule.

For other conditions of use that contribute to the unreasonable risk from methylene chloride, EPA is finalizing a WCPP to address the unreasonable risk as outlined in Unit IV.

A WCPP encompasses inhalation exposure thresholds, includes monitoring and recordkeeping requirements to verify that those thresholds are not exceeded, and other components, such as dermal protection, to ensure that the chemical substance no longer presents unreasonable risk. In the case of methylene chloride, meeting the exposure thresholds finalized by EPA for certain occupational conditions of use would address unreasonable risk driven by inhalation exposure from those conditions of use for potentially exposed persons.

*b. Classes of small entities subject to the compliance requirements.*



The small entities that would be potentially directly regulated by this rule are small businesses that manufacture (including import), process, distribute in commerce, use, or dispose of methylene chloride, including retailers of methylene chloride for end-consumer uses.

*c. Professional skills needed to comply.*

Entities subject to this rule that manufacture (including import), process, or distribute methylene chloride in commerce for consumer use would be required to cease such activity. The entity would be required to modify their Safety Data Sheet to inform their customers of the prohibition on manufacture, processing, and distribution of methylene chloride for consumer use. They would also be required to keep records of how much methylene chloride they sold, and to whom, and maintain a copy of the method they use for notifying their customers. None of these activities require any special skills.

Entities that use methylene chloride in any of the industrial and commercial conditions of use that are prohibited would be required to cease those activities. Restriction or prohibition of these uses will likely require the implementation of an alternative chemical or the cessation of use of methylene chloride in a process or equipment that may require persons with specialized skills, such as engineers or other technical experts. Instead of developing an alternative method themselves, commercial users of methylene chloride may choose to contract with another entity to do so.

Entities that are permitted to continue to manufacture, process, distribute in commerce, use, or dispose of methylene chloride are required to implement a WCPP and would have to meet the provisions of the program for continued use of methylene chloride. Adaption to a WCPP may require persons with specialized skills such as an engineer, chemist, health and safety professional, or laboratory technicians to process monitoring samples. Instead of implementing the WCPP themselves, entities that use methylene chloride may choose to contract

with another entity to do so. Records would have to be maintained for compliance with a WCPP. While this recording activity itself may not require a special skill, the airborne concentrations to be measured and recorded may require persons with specialized skills such as an industrial hygienist or laboratory technician. Additionally, potentially exposed persons reasonably likely to be exposed to methylene chloride by inhalation to concentrations above the ECEL or EPA STEL are required to be trained for the proper use of respirators. While this does not necessarily entail a specialized skill, it does require specialized training for those handling methylene chloride within regulated areas and includes activity-specific training for proper PPE use such as gloves. EPA's respirator provision, in alignment with OSHA under 29 CFR 1910.134(c)(1)(ii), also requires medical qualification to employ the use of respirators. While this is also not a specialized skill, it is a specialized pre-qualifier for use of respirators.

Refinishers of wood pieces of artistic, cultural, or historic value using methylene chloride may need to exercise use of additional exposure controls such as engineering, administrative, and PPE/respirators. Establishing adequate controls for this use may require knowledgeable persons with specialized skills or equipment such as an engineer or a health and safety professional. Instead of developing the required exposure mitigation methods themselves to demonstrate compliance, commercial users of methylene chloride for this use may choose to contract with another entity to do so.

*6. Steps taken to minimize economic impact to small entities.*

*a. SBAR Panel.*

As required by section 609(b) of the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), EPA conducted outreach to small entities and convened a SBAR Panel on November 4, 2020, to obtain advice and recommendations of representatives of the small entities that potentially would be subject to the rule's requirements. The Panel solicited

input on all aspects of these proposed regulations. Thirteen potentially impacted small entities served as small-entity representatives (SERs) to the Panel, representing a broad range of small entities from diverse geographic locations. The Panel Report was signed on October 28, 2021.

Consistent with the RFA/SBREFEA requirements, the Panel evaluated the assembled materials and small-entity comments on issues related to elements of the regulatory flexibility analysis. It is important to note that the Panel's findings and discussion were based on the information available at the time the final report was prepared. For the full list of Panel recommendations, see Section 8.A. of the FRFA (Ref.21).

EPA detailed the SBAR Panel's request for comment on these specific topics in the IRFA and proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSPP) and solicited comment from the public. During the comment period, the public provided comment on some of these areas. Those comments and others received on the proposed rule and EPA's responses are in the Response to Comments document in the docket (Ref. 7).

*b. Alternatives considered.*

To identify the regulatory approach that would address the unreasonable risk from methylene chloride, EPA analyzed alternative regulatory approaches to identify which would be feasible, reduce burden to small businesses, and achieve the objective of the statute (i.e., applying one or more requirements list in TSCA section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents an unreasonable risk). As described in more detail in Unit V. of the proposed rule (88 FR 28284, May 3, 2023) (FRL-8155-02-OCSPP), and Unit II.D. of the final rule, EPA considered several factors, in addition to identified unreasonable risk, when selecting among possible TSCA section 6(a) requirements. To the extent practicable, EPA factored into its decisions: the effects of methylene chloride on health and the environment, the magnitude of exposure to methylene chloride of human beings and the environment, the

benefits of methylene chloride for various uses, and the reasonably ascertainable economic consequences of the rule. As part of this analysis, EPA considered a wide variety of control measures to address the unreasonable risk from methylene chloride such as weight fractions, prescriptive controls, and a certification and limited access program. EPA's consideration of these alternative control measures is described in detail in the IRFA for the proposed rule, and throughout Unit V.A.4. of the proposed rule.

Based on consideration of public comments received on the proposed rule, EPA has made some changes from the proposed rule to the final rule. These changes include the finalization of additional conditions of use under the WCPP, rather than prohibition, and changes to timeframes for compliance for the WCPP and for prohibitions. Additional changes to the rule based on consideration of public comments are detailed in Unit III of the final rule and include identification of a de minimis threshold of methylene chloride in formulations, and modifications to provisions of the WCPP (including to exposure monitoring requirements). For additional information and rationale towards alternative actions, see Unit III.D. of this final rule and Section 8.B. of the FRFA (Ref.21).

In addition, EPA is preparing a Small Entity Compliance Guide to help small entities comply with this rule. EPA expects that this guide will be made available on the EPA website prior to the effective date of this final rule.

*D. Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action will affect entities that use methylene chloride. It is not expected to affect State, local, or Tribal governments because the use of use of methylene chloride by government entities is minimal. This action is not expected to result in expenditures by State, local, and Tribal

governments, in the aggregate, or by the private sector, of \$100 million or more (when adjusted annually for inflation) in any 1 year. Accordingly, this action is not subject to the requirements of sections 202, 203, or 205 of UMRA.

*E. Executive Order 13132: Federalism*

EPA has concluded that this action has federalism implications, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because regulation under TSCA section 6(a) may preempt state law. EPA provides the following federalism summary impact statement. The Agency consulted with state and local officials early in the process of developing the proposed action to permit them to have meaningful and timely input into its development. This included a consultation meeting on October 22, 2020, and a background presentation on September 9, 2020. EPA invited the following national organizations representing State and local elected officials to these meetings: Association of State Drinking Water Administrators, National Association of Clean Water Agencies, Western States Water Council, National Water Resources Association, American Water Works Association, Association of Metropolitan Water Agencies, Association of Clean Water Administrators, Environmental Council of the States, National Association of Counties, National League of Cities, County Executives of America, U.S. Conference of Mayors, and National Association of Attorneys General. A summary of the meeting with these organizations, including the views that they expressed, is available in the docket (Ref. 14). As discussed in Unit VIII.E. and in the proposed rule, during Federalism consultation meetings EPA provided information on TSCA section 6 regulations and participants discussed preemption as well as the relationship between TSCA and existing statutes such as the CWA and Safe Drinking Water Act (SDWA) (Ref. 14). EPA provided an opportunity for these organizations to provide follow-up comments in writing but did not receive any such comments.

*F. 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 will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Methylene chloride is not manufactured, processed, or distributed in commerce by Tribes and, therefore, this rulemaking would not impose substantial direct compliance costs on Tribal governments. Thus, Executive Order 13175 does not apply to this action.

Notwithstanding the lack of Tribal implications as specified by Executive Order 13175, EPA consulted with Tribal officials during the development of this action, consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, which EPA applies more broadly than Executive Order 13175.

The Agency held a Tribal consultation from October 7, 2020, to January 8, 2021, with meetings on November 12 and 13, 2020. Tribal officials were given the opportunity to meaningfully interact with EPA concerning the current status of risk management. During the consultation, EPA discussed risk management under TSCA section 6(a), findings from the 2020 Risk Evaluation for Methylene Chloride, types of information to inform risk management, principles for transparency during risk management, and types of information EPA sought from Tribal officials (Ref. 15). EPA briefed Tribal officials on the Agency's risk management considerations and Tribal officials raised no related issues or concerns to EPA during or in follow-up to those meetings (Ref. 15). EPA received no written comments as part of this consultation.

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

Executive Order 13045 (62 FR 19885, April 23, 1997) directs Federal agencies to include

an evaluation of the health and safety effects of the planned regulation on children in Federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is not subject to Executive Order 13045 because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children as reflected by the conclusions of the methylene chloride risk evaluation (Ref. 1). EPA did not find that the adverse health impacts for children and for men and women of reproductive age was disproportionate in comparison to other populations. While there is some evidence of an association between methylene chloride and developmental neurological effects, the literature contains methodological limitations in human studies and concentration limitations in animal studies, and thus reproductive/development effects were not carried forward to dose-response. However, EPA's Policy on Children's health applies to this action. Information on how the Policy was applied is available under "Children's Environmental Health" in Unit II.D.2.c.

*H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not a "significant energy action" under Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution or use of energy and has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.

*I. 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 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 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 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. 93). EPA recognizes that there may be voluntary consensus standards that meet the criteria (Ref. 109).

*J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All*

EPA believes that the human health and environmental conditions that exist prior to this action do not result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with environmental justice concerns in accordance with Executive Order 12898 (59 FR 7629, February 16, 1994) and Executive Order 14096 (88 FR 25251, April 26, 2023). As described more fully in the Economic Analysis for this rulemaking (Ref. 3), EPA conducted an analysis to characterize the baseline conditions faced by communities and workers affected by the regulation to identify the potential for disproportionate impacts on communities with EJ concerns using information about the facilities, workforce, and communities potentially affected by the regulatory options under current conditions, before the regulation would go into effect. The analysis drew on publicly available data provided by EPA,



U.S. Census Bureau, and Centers for Disease Control and Prevention (CDC), including data from TRI, EPA Enforcement and Compliance History Online (ECHO), National Air Toxics Assessment (NATA), the American Community Survey, and the Behavioral Risk Factor Surveillance System. The baseline characterization suggests that workers in affected industries and regions, as well as residents of nearby communities, are not more likely to be people of color than the general population in affected states, although this varied by use assessed.

Based on reasonably available information, EPA believes that there are not potential EJ concerns in communities surrounding facilities subject to this regulation (Ref. 3). Therefore, EPA believes that this action is likely to not result in new disproportionate and adverse effects on communities with EJ concerns. This regulatory action would apply requirements to the extent necessary so that methylene chloride no longer presents an unreasonable risk. While this regulatory action will address unreasonable risks from methylene chloride under the conditions of use as required by TSCA section 6(a), EPA is not able to quantify the distribution of the change in risk for affected populations due to data limitations that prevented EPA from conducting a more comprehensive analysis of such a change.

EPA additionally identified and addressed potential EJ concerns by conducting outreach to advocates of communities that might be subject to disproportionate exposure to methylene chloride.

On November 16 and 19, 2020, EPA held public meetings as part of this consultation. (Ref. 110). See also Unit II.D. These meetings were held pursuant to Executive Order 12898 and Executive Order 14008, Tackling the Climate Crisis at Home and Abroad (86 FR 7619, February 1, 2021). EPA received three written comments following the EJ meetings, in addition to oral comments provided during the consultations (Refs. 16, 17,18). In general, commenters supported strong regulation of methylene chloride to protect lower-income communities and workers.

Commenters supported strong outreach to affected communities, encouraged EPA to follow the hierarchy of controls, favored prohibitions, and noted the uncertainty of use—and in some cases inadequacy—of PPE.

The information supporting this Executive Order review is contained in Unit II.D., as well as in the Economic Analysis (Refs. 3, 110). EPA’s presentations, a summary of EPA’s presentation and public comments made, and fact sheets for the EJ consultations related to this rulemaking are available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/environmental-justice-consultations-methylene-chloride>. These materials are also available in the public docket for this rulemaking.

*K. Congressional Review Act (CRA)*

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action meets the criteria set forth in 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 751**

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

**Michael S. Regan,**

*Administrator.*

Therefore, for the reasons stated in the preamble, 40 CFR chapter I is amended to read 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.

2. Amend § 751.5 by adding in alphabetical order definitions for “article”, “authorized person”, “owner or operator”, “potentially exposed person”, “product”, “regulated area”, and “retailer”. The additions read as follows:

**§ 751.5 Definitions.**

\* \* \* \* \*

*Article* means a manufactured item:

- (1) Which is formed to a specific shape or design during manufacture;
- (2) Which has end use function(s) dependent in whole or in part upon its shape or design during end use; and
- (3) Which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.

*Authorized person* means any person specifically authorized by the owner or operator to enter, and whose duties require the person to enter, a regulated area.

\* \* \* \* \*

*Owner or operator* means any person who owns, leases, operates, controls, or supervises

a workplace covered by this part.

\* \* \* \* \*

*Potentially exposed person* means any person who may be exposed to a chemical substance or mixture in a workplace as a result of a condition of use of that chemical substance or mixture.

*Product* means the chemical substance, a mixture containing the chemical substance, or any object that contains the chemical substance or mixture containing the chemical substance that is not an article.

*Regulated area* means an area established by the regulated entity to demarcate areas where airborne concentrations of a specific chemical substance exceed, or there is a reasonable possibility they may exceed, the applicable Existing Chemical Exposure Limit (ECEL) or the EPA Short Term Exposure Limit (EPA STEL).

*Retailer* means a person who distributes in commerce or makes available a chemical substance or mixture to consumer end users, including e-commerce internet sales or distribution. Any distributor with at least one consumer end user customer is considered a retailer. A person who distributes in commerce or makes available a chemical substance or mixture solely to commercial or industrial end users or solely to commercial or industrial businesses is not considered a retailer.

\* \* \* \* \*

3. Amend subpart B by revising § 751.101 to read as follows:

**§ 751.101 General.**

(a) *Applicability.* This subpart sets certain restrictions on the manufacture (including import), processing, distribution in commerce, use, and disposal of methylene chloride (CASRN 75-09-2) to prevent unreasonable risks of injury to health.

(b) *De minimis threshold*. Unless otherwise specified in this subpart, the prohibitions and restrictions of this subpart do not apply to products containing methylene chloride at thresholds less than 0.1 percent by weight. This provision does not apply to § 751.105.

4. Amend § 751.103 by:

a. Revising the definition of “distribution in commerce”;

b. Adding in alphabetical order definitions for “ECEL”, “ECEL action level”, and “EPA STEL”.

The revisions and additions read as follows:

**§ 751.103 Definitions.**

\* \* \* \* \*

*Distribution in commerce* has the same meaning as in section 3 of the Act, except that the term does not include retailers for purposes of §§ 751.111 and 751.113.

*ECEL* is an Existing Chemical Exposure Limit, and means an airborne concentration calculated as an eight (8)-hour time-weighted average (TWA).

*ECEL action level* means a concentration of airborne methylene chloride of 1 part per million (1 ppm) calculated as an 8-hour time weighted average (TWA).

*EPA STEL* is a Short Term Exposure Limit, which is an EPA regulatory limit on workplace exposure to an airborne concentration of a chemical substance, based on an exposure of less than eight hours.

\* \* \* \* \*

5. Amend § 751.105 by revising the section heading to read as follows:

**§ 751.105 Prohibition of manufacturing (including import), processing, and distribution in commerce related to consumer paint and coating removal.**

6. Redesignate § 751.107 as new § 751.111(a) in subpart B and add new § 751.107 in

subpart B to read as follows:

**§ 751.107 Other prohibitions of manufacturing (including import), processing, distribution in commerce, and use.**

(a) *Applicability.* (1) This section applies to all manufacturing (including import), processing, and distribution in commerce of methylene chloride for consumer use other than for the paint and coating removal use addressed under § 751.105.

(2) This section applies to: (i) All manufacturing (including import), processing, and distribution in commerce of methylene chloride for industrial or commercial use, other than for the conditions of use addressed under § 751.109(a); and

(ii) All commercial or industrial use of methylene chloride, other than the conditions of use addressed under § 751.109(a).

(3) This section does not apply to manufacturing, processing, or distribution in commerce of methylene chloride solely for export that meets the conditions described in TSCA section 12(a)(1)(A) and (B).

(b) *Prohibitions.* (1) After **[INSERT DATE 270 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, all persons are prohibited from distributing in commerce (including making available) methylene chloride, including any methylene chloride-containing products, to retailers for any use.

(2) After **[INSERT DATE 360 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, all retailers are prohibited from distributing in commerce (including making available) methylene chloride, including any methylene chloride-containing products, for any use.

(3) After **[INSERT DATE 360 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, all persons are prohibited from manufacturing (including import)

methylene chloride, for the uses listed in paragraphs (a)(1) and (2) of this section except for those uses specified in paragraphs (b)(7) through (9) of this section.

(4) After **[INSERT DATE 450 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, all persons are prohibited from processing methylene chloride, including any methylene chloride-containing products, for the uses listed in paragraphs (a)(1) and (2) of this section except for those uses specified in paragraphs (b)(7) through (9) of this section.

(5) After **[INSERT DATE 630 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, all persons are prohibited from distributing in commerce (including making available) methylene chloride, including any methylene chloride-containing products, for any use described in paragraphs (a)(1) and (2) of this section except for those uses specified in paragraphs (b)(7) through (9) of this section.

(6) After **[INSERT DATE 720 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, all persons are prohibited from industrial or commercial use of methylene chloride, including any methylene chloride containing products, for the uses listed in paragraph (a)(2) of this section except for those uses specified in paragraphs (b)(7) through (9) of this section.

(7) After **[INSERT DATE 10 YEARS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, all persons are prohibited from manufacturing (including import), processing, distribution in commerce, or use of methylene chloride, including any methylene chloride containing products, for industrial or commercial use in an emergency by the National Aeronautics and Space Administration or its contractors as described in § 751.115(b).

(8) After **[INSERT DATE 5 YEARS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** all persons are prohibited from manufacturing (including import),

processing, distribution in commerce, or use of methylene chloride, including any methylene chloride containing products, for industrial or commercial use for paint and coating removal for refinishing of wooden furniture, decorative pieces and architectural fixtures of artistic, cultural, or historic significance, with interim requirements as described in § 751.117.

(9) After **[INSERT DATE 5 YEARS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** all persons are prohibited from manufacturing (including import), processing, distribution in commerce, or use of methylene chloride, including any methylene chloride-containing products, for industrial or commercial use for adhesives and sealants in aircraft, space vehicle, and turbine applications for structural and safety critical non-structural applications.

7. Redesignate § 751.109 as new § 751.113 and add new § 751.109 to read as follows:

**§ 751.109 Workplace Chemical Protection Program.**

(a) *Applicability.* The provisions of this section apply to the following conditions of use of methylene chloride, including manufacturing and processing for export, except to the extent the conditions of use are prohibited by §§ 751.105 and 751.107:

- (1) Manufacturing (domestic manufacture);
- (2) Manufacturing (import);
- (3) Processing: as a reactant;
- (4) Processing: incorporation into a formulation, mixture, or reaction product;
- (5) Processing: repackaging;
- (6) Processing: recycling;
- (7) Industrial and commercial use as a laboratory chemical;
- (8) Industrial or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and spacecraft;



(9) Industrial or commercial use as a bonding agent for solvent welding;

(10) Industrial and commercial use as a processing aid;

(11) Industrial and commercial use for plastic and rubber products manufacturing;

(12) Industrial and commercial use as a solvent that becomes part of a formulation or mixture, where that formulation or mixture will be used inside a manufacturing process, and the solvent (methylene chloride) will be reclaimed;

(13) Disposal;

(b) *Relationship to 29 CFR part 1910.* For purposes of § 751.109:

(1) Any provisions applying to “employee” in 29 CFR 1910.132, 29 CFR 1910.134, and 29 CFR 1910.1052 also apply equally to potentially exposed persons; and

(2) Any provisions applying to “employer” in 29 CFR 1910.132, 29 CFR 1910.134, and 29 CFR 1910.1052 also apply equally to any owner or operator for the regulated area.

(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 after **[INSERT DATE 1005 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government, **[INSERT DATE 450 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for other owners and operators, or beginning 4 months after introduction of methylene chloride into the workplace if methylene chloride use commences after **[INSERT DATE 360 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, consistent with paragraphs (d), (e), and (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 after **[INSERT DATE 1005 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government, **[INSERT DATE 450 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for other owners and operators, or beginning 4 months after introduction of methylene chloride into the workplace if methylene chloride use commences after **[INSERT DATE 360 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, consistent with paragraphs (d), (e), and (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), (4), (5), (6), and (7) by **[INSERT DATE 1005 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government, **[INSERT DATE 450 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for other owners and operators, or within 3 months after receipt of the results of any monitoring data consistent with paragraphs (d) of this section.

(ii) Establish a regulated area wherever a potentially exposed person's exposure to airborne concentrations of methylene chloride exceeds or can reasonably be expected to exceed either the ECEL or EPA STEL.

(iii) Demarcate regulated areas from the rest of the workplace in any manner that adequately establishes and alerts potentially exposed persons to the boundaries of the area and minimizes the number of authorized persons exposed to methylene chloride within the regulated area.

(iv) Restrict access to the regulated area by any potentially exposed person who lacks

proper training, personal protective equipment, or is otherwise unauthorized to enter.

(d) *Exposure monitoring.* (1) *In general.* (i) *Characterization of exposures.* Owners or operators must determine each potentially exposed person's exposure, without regard to respiratory protection, by either:

(A) Taking a personal breathing zone air sample of each potentially exposed person's exposure; or

(B) Taking personal breathing zone air samples that are representative of each potentially exposed person's exposure.

(ii) *Representative samples.* Owners or operators are permitted to consider personal breathing zone air samples to be representative of each potentially exposed person's exposure, without regard to respiratory protection, when they are taken as follows:

(A) *ECEL.* The owner or operator has taken one or more personal breathing zone air samples for at least one potentially exposed person in each job classification in a work area during every work shift, and the person sampled is expected to have the highest methylene chloride exposure.

(B) *EPA STEL.* The owner or operator has taken one or more personal breathing zone air samples which indicate the highest likely 15-minute exposures during such operations for at least one potentially exposed person in each job classification in the work area during every work shift, and the person sampled is expected to have the highest methylene chloride exposure.

(C) *Exception.* Personal breathing zone air samples taken during one work shift may be used to represent potentially exposed person exposures on other work shifts where the owner or operator can document that the tasks performed and conditions in the workplace are similar across shifts.

(iii) *Accuracy of monitoring.* Owners or operators must ensure that the methods used to

perform exposure monitoring produce results that are accurate to a confidence level of 95%, and are:

(A) Within plus or minus 25% for airborne concentrations of methylene chloride above the ECEL or the EPA STEL; or

(B) Within plus or minus 35% for airborne concentrations of methylene chloride at or above the ECEL action level but at or below the ECEL.

(iv) *Currency of monitoring data.* Owners or operators are not permitted to rely on monitoring data that is more than 5 years old to demonstrate compliance with initial or periodic monitoring requirements for either the ECEL or the EPA STEL.

(2) *Initial monitoring.* By **[INSERT DATE 915 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government, by **[INSERT DATE 360 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for other owners and operators, or within 30 days of introduction of methylene chloride into the workplace, whichever is later, each owner or operator covered by this section must perform an initial exposure monitoring to determine each potentially exposed person's exposure, unless:

(i) An owner or operator has objective data generated within the last 5 years prior to **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** that demonstrates to EPA that methylene chloride cannot be released in the workplace in airborne concentrations at or above the ECEL action level (1-ppm 8-hour TWA) or above the EPA STEL (16 ppm 15-minute TWA) and that the data represents the highest methylene chloride exposures likely to occur under conditions of use described in paragraph (a) of this section; or

(ii) Where potentially exposed persons are exposed to methylene chloride for fewer than 30 days per year, and the owner or operator has measurements by direct-metering devices which

give immediate results and which provide sufficient information regarding exposures to determine and implement the control measures that are necessary to reduce exposures to below the ECEL action level and EPA STEL.

(3) *Periodic monitoring.* The owner or operator must establish an exposure monitoring program for periodic monitoring of exposure to methylene chloride in accordance with Table 1.

**Table 1 to Paragraph (d)(3) – Periodic Monitoring Requirements Based on Initial Exposure Monitoring Results**

<b>Air Concentration Condition Observed during Initial Exposure Monitoring</b>	<b>Periodic Monitoring Requirement</b>
If the initial exposure monitoring concentration is below the ECEL action level and at or below the EPA STEL	ECEL and EPA STEL periodic monitoring at least once in every 5 years.
If the initial exposure monitoring concentration is below the ECEL action level and above the EPA STEL	ECEL periodic required at least once every 5 years, and EPA STEL periodic monitoring required every 3 months.
If the initial exposure monitoring concentration is at or above the ECEL action level and at or below the ECEL; and at or below the EPA STEL	ECEL periodic monitoring every 6 months.
If the initial exposure monitoring concentration is at or above the ECEL action level and at or below the ECEL; and above the EPA STEL	ECEL periodic monitoring every 6 months and EPA STEL periodic monitoring every 3 months.
If the initial exposure monitoring concentration is above the ECEL and below, at, or above the EPA STEL	ECEL periodic monitoring every 3 months and EPA STEL periodic monitoring every 3 months.
If 2 consecutive monitoring events have taken place at least 7 days apart that indicate that potential exposure has decreased from above the ECEL to at or below the ECEL, but at or above the ECEL action level	Transition from ECEL periodic monitoring frequency from every 3 months to every 6 months.
If 2 consecutive monitoring events have taken place at least 7 days apart that indicate that potential exposure has decreased to below the ECEL action level and at or below the EPA STEL	Transition from ECEL periodic monitoring frequency from every 6 months to once every 5 years. The second consecutive monitoring event will delineate the new date from which the next 5-year periodic exposure monitoring must occur.
If the owner or operator engages in any conditions of use described in paragraph (a) of this section and is required to	The owner or operator may forgo the upcoming periodic monitoring event. However, documentation of cessation of use of methylene

monitor either the ECEL or EPA STEL in a 3-month interval, but does not engage in any of those uses for the entirety of the 3-month interval	chloride must be maintained, and initial monitoring is required when the owner or operator resumes or starts any of the conditions of use described in paragraph (a) of this section.
Owner or operator engages in any conditions of use described in paragraph (a) of this section and is required to monitor the ECEL in a 6-month interval, but does not engage in any of those uses for the entirety of the 6-month interval.	The owner or operator may forgo the upcoming periodic monitoring event. However, documentation of cessation of the condition(s) of use must be maintained until periodic monitoring resumes, and initial monitoring is required when the owner or operator resumes or starts any of the conditions of use described in paragraph (a) of this section.

(4) *Additional monitoring.* The owner or operator must conduct the exposure monitoring required by paragraph (d)(2) of this section within 30 days after any change that may reasonably be expected to introduce additional sources of exposure to methylene chloride, or otherwise result in increased exposure to methylene chloride compared to the most recent monitoring event. Examples of situations that may require additional monitoring include changes in production, process, control equipment, or work practices, or a leak, rupture, or other breakdown.

(5) *Notification of monitoring results.* (i) The owner or operator must inform potentially exposed persons of monitoring results within 15 working days.

(ii) This notification must include the following:

(A) Exposure monitoring results;

(B) Identification and explanation of the ECEL, ECEL Action Level, and EPA STEL;

(C) Whether the airborne concentration of methylene chloride exceeds the ECEL action level, ECEL or the EPA STEL.

(D) If the ECEL or EPA STEL is exceeded, descriptions of actions taken by the owner or operator to reduce exposure in accordance with paragraph (e)(1)(i).

(E) Explanation of any required respiratory protection provided in accordance with as paragraphs (e)(1)(ii) and (f) of this section;

(F) Quantity of methylene chloride in use at the time of monitoring;

(G) Location of methylene chloride use at the time of monitoring;

(H) Manner of methylene chloride use at the time of monitoring; and

(I) Identified releases of methylene chloride.

(iii) Notice must be provided in plain language writing, in a language that the person understands, to each potentially exposed person or posted in an appropriate and accessible location outside the regulated area with an English-language version and a non-English language version representing the language of the largest group of workers who do not read English.

(6) *Observation of monitoring.*

(i) The owner or operator must provide affected potentially exposed persons an opportunity to observe exposure monitoring conducted in accordance with this paragraph (d) that is representative of the potentially exposed person's exposure.

(ii) The owner or operator must ensure that potentially exposed persons are provided with personal protective equipment appropriate for the observation of monitoring.

(e) *ECEL control procedures and plan.* (1) *Methods of compliance.* (i) By **[INSERT DATE 1095 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government, or by **[INSERT DATE 540 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** for other owners and operators, 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.

(ii) If the feasible controls, required by paragraph (e)(1)(i) of this section that can be instituted do not reduce exposures for potentially exposed persons to or below the ECEL or EPA

STEL, then the owner or operator must use such controls to reduce exposure to the lowest levels achievable by these controls and must supplement those controls with the use of respiratory protection that complies with the requirements of paragraph (f) of this section to reduce exposures to or below the ECEL or EPA STEL.

(iii) Where an owner or operator cannot demonstrate exposure below the ECEL, including through the use of all feasible engineering controls, work practices, or administrative controls as described in paragraph (e)(1)(i) of this section, and, has not demonstrated that it has appropriately supplemented with respiratory protection that complies with the requirements of paragraphs (e)(1)(ii) and (f) of this section, this will constitute a failure to comply with the ECEL.

(iv) For the Department of Defense and Federal contractors acting for or on behalf of the Department of Defense, in the event that ongoing or planned construction is necessary to implement the feasible controls required by paragraph (e)(1)(i) such that no one is exposed above the ECEL or EPA STEL, the deadlines in that paragraph are extended to **[INSERT DATE 1,825 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**. Ongoing or planned construction efforts to address exposures above the ECEL and EPA STEL must be documented in the exposure control plan required by paragraph (e)(2).

(2) *Exposure control plan.* By **[INSERT DATE 1095 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government, or by **[INSERT DATE 540 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for other owners and operators, the owner or operator must develop and implement an exposure control plan.

(i) *Exposure control plan contents.* The exposure control plan must include



documentation of the following:

(A) Identification of exposure controls that were considered, including those that were used or not used to meet the requirements of paragraph (e)(1)(i) of this section, in the following sequence - elimination, substitution, engineering controls, and work practices and administrative controls;

(B) For each exposure control considered, a rationale for why the exposure control was selected or not selected based on feasibility, effectiveness, and other relevant considerations;

(C) A description of actions the owner or operator must take to implement the exposure controls selected, including proper installation, regular inspections, maintenance, training, or other actions;

(D) A description of regulated areas, how they are demarcated, and persons authorized to enter the regulated areas;

(E) A description of activities conducted by the owner or operator to review and update the exposure control plan to ensure effectiveness of the exposure controls, identify any necessary updates to the exposure controls, and confirm that all persons are properly implementing the exposure controls; and

(F) An explanation of the procedures for responding to any change that may reasonably be expected to introduce additional sources of exposure to methylene chloride, or otherwise result in increased exposure to methylene chloride, including procedures for implementing corrective actions to mitigate exposure to methylene chloride.

(ii) *Exposure control plan requirements.* (A) The owner or operator must not implement a schedule of personnel rotation as a means of compliance with the ECEL.

(B) The owner or operator must maintain the effectiveness of any controls, instituted under paragraph (e) of this section.

(C) The exposure control plan must be reviewed and updated as necessary, but at least every 5 years, to reflect any significant changes in the status of the owner or operator's approach to compliance with paragraphs (c), (d), and (e) of this section.

(iii) *Availability of exposure control plan.* (A) Owners or operators must make the exposure control plan and associated records, including exposure monitoring, respiratory protection program implementation, and dermal protection program implementation records, available to potentially exposed persons.

(B) Owners or operators must notify potentially exposed persons of the availability of the plan and associated records within 30 days of the date that the exposure control plan is completed and at least annually thereafter. The notification must be provided in accordance with the requirements of paragraph (d)(5)(iii) of this section.

(C) Upon request by the potentially exposed person, the owner or operator must provide the specified records at a reasonable time, place, and manner. If the owner or operator is unable to provide the requested records within 15 days, the owner or operator must, within those 15 days, inform the potentially exposed person requesting the record(s) of the reason for the delay and the earliest date when the record can be made available.

(3) *Respirator requirements.* The owner or operator must supply a respirator, selected in accordance with paragraph (f) of this section, to each potentially exposed person who enters a regulated area and must ensure each potentially exposed person uses that respirator whenever methylene chloride exposures may exceed the ECEL or EPA STEL.

(f) *Respiratory protection.* (1) *Respirator conditions.* After **[INSERT DATE 1005 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government, after **[INSERT DATE 450 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL***

**REGISTER]** for other owners and operators, or within 3 months after receipt of the results of any exposure monitoring as described in paragraph (d) of this section, owners or operators 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 paragraph (d)(1)(iii)) and as specified in this paragraph 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.

(2) *Respirator selection criteria.* The type of respiratory protection that regulated entities must select and provide to potentially exposed persons in accordance with 29 CFR 1910.1052(g)(3)(i), is directly related to the monitoring results, as follows:

(i) If the measured exposure concentration is at or below the ECEL or EPA STEL: no respiratory protection is required.

(ii) If the measured exposure concentration is above 2 ppm and less than or equal to 50 ppm: the respirator protection required is any NIOSH Approved® supplied-air respirator (SAR) or airline respirator in a continuous-flow mode equipped with a loose-fitting facepiece or helmet/hood (APF 25).

(iii) If the measured exposure concentration is above 50 ppm and less than or equal to 100 ppm the respirator protection required is:

(A) Any NIOSH Approved® Supplied-Air Respirator (SAR) or airline respirator in a demand mode equipped with a full facepiece (APF 50); or

(B) Any NIOSH Approved® Self-Contained Breathing Apparatus (SCBA) in demand-mode equipped with a full facepiece or helmet/hood (APF 50).

(iv) If the measured exposure concentration is unknown or at any value above 100 ppm and up to 2,000 ppm the respirator protection required is:

(A) Any NIOSH Approved® Supplied-Air Respirator (SAR) or airline respirator in a continuous-flow mode equipped with a full facepiece or certified helmet/hood that has been tested to demonstrate performance at a level of a protection of APF 1,000 or greater. (APF 1,000); or

(B) Any NIOSH Approved® Supplied-Air Respirator (SAR) or airline respirator in pressure-demand or other positive-pressure mode equipped with a full facepiece and an auxiliary self-contained air supply (APF 1,000); or

(C) Any NIOSH Approved® Self-Contained Breathing Apparatus (SCBA) in a pressure-demand or other positive-pressure mode equipped with a full facepiece or certified helmet/hood (APF 10,000).

(3) *Minimal respiratory protection.* Requirements outlined in paragraph (e)(2) of this section represent the minimum respiratory protection requirements, such that any respirator affording a higher degree of protection than the required respirator may be used.

(g) *Dermal protection.* (1) After **[INSERT DATE 1005 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government, or after **[INSERT DATE 450 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for other owners and operators, owners or operators 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.

(2) Owners or operators must minimize and protect potentially exposed persons from

dermal exposure in accordance with 29 CFR 1910.1052(h) and (i).

(h) *Training.* Owners or operators must provide training in accordance with 29 CFR 1910.1052(l)(1) through (6) to potentially exposed persons prior to or at the time of initial assignment to a job involving potential exposure to methylene chloride. In addition, if respiratory protection or PPE must be worn within a regulated area, owners or operators must provide training in accordance with 29 CFR 1910.132(f) to potentially exposed persons within that regulated area.

8. Amend redesignated § 751.111 by revising the text to read as follows:

**§ 751.111 Downstream notification.**

(a) After August 26, 2019, and before **[INSERT DATE 150 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, each person who manufactures (including imports), and before **[INSERT DATE 210 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** processes or distributes in commerce methylene chloride for any use must, prior to or concurrent with the shipment, notify companies to whom methylene chloride is shipped, in writing, of the restrictions described in § 751.105. Notification must occur by inserting the following text in Section 1(c) and Section 15 of the SDS provided with the methylene chloride or with any methylene chloride-containing product:

This chemical/product is not and cannot be distributed in commerce (as defined in TSCA section 3(5)) or processed (as defined in TSCA section 3(13)) for consumer paint or coating removal.

(b) Beginning on **[INSERT DATE 150 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, each person who manufactures (including import) methylene chloride for any use 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 in accordance with paragraph (d) of this section.

(c) Beginning on **[INSERT DATE 210 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, 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 described in this subpart in accordance with paragraph (d) of this section.

(d) The notification required under paragraphs (b) and (c) of this section must occur by inserting the following text in Section 1(c) and Section 15 of the SDS provided with the methylene chloride or with any methylene chloride-containing product:

After **[INSERT DATE 270 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, this chemical substance (as defined in TSCA section 3(2))/product cannot be distributed in commerce to retailers. After **[INSERT DATE 630 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, this chemical substance (as defined in TSCA section 3(2))/product is and can only be distributed in commerce or processed with a concentration of methylene chloride equal to or greater than 0.1% by weight for the following purposes: (1) Processing as a reactant; (2) Processing for incorporation into a formulation, mixture, or reaction product; (3) Processing for repackaging; (4) Processing for recycling; (5) Industrial or commercial use as a laboratory chemical; (6) Industrial or commercial use as a bonding agent for solvent welding; (7) Industrial and commercial use as a paint and coating remover from safety critical, corrosion-sensitive components of aircraft and spacecraft; (8) Industrial and commercial use as a processing aid; (9) Industrial and commercial use for plastic and rubber products manufacturing; (10) Industrial and commercial use as a solvent that becomes part of a formulation or mixture, where that formulation or mixture will be used inside a manufacturing process, and the solvent (methylene chloride) will be reclaimed; (11) Industrial and commercial use in the refinishing for wooden furniture, decorative pieces, and architectural fixtures of artistic, cultural or historic value **[INSERT DATE 5 YEARS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**; (12) Industrial and commercial use in adhesives and sealants in aircraft, space vehicle, and turbine applications for structural and safety critical non-structural applications until **[INSERT DATE 5 YEARS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**; (13) Disposal; and (14) Export.

9. Amend redesignated § 751.113 by revising the text to read as follows:

#### **§ 751.113 Recordkeeping Requirements.**

(a) *General records.* Each person who manufactures (including imports), processes, or

distributes in commerce any methylene chloride after August 26, 2019, must retain in one location at the headquarters of the company, or at the facility for which the records were generated beginning **[INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, documentation showing:

(1) The name, address, contact, and telephone number of companies to whom methylene chloride was shipped;

(2) A copy of the notification provided under § 751.111; and

(3) The amount of methylene chloride shipped.

(b) *Exposure control records.* Owners or operators must retain records of:

(1) The exposure control plan as described in § 751.109(e)(2)

(2) Implementation of the exposure control plan described in § 751.109(e)(2), including:

(i) Any regular inspections, evaluations, and updating of the exposure controls to maintain effectiveness; and

(ii) Confirmation that all persons are properly implementing the exposure controls.

(3) Personal protective equipment (PPE) and respiratory protection used by potentially exposed persons and program implementation, including fit-testing, pursuant to § 751.109(f) and (g); and

(4) Information and training provided pursuant to § 751.109(h); and

(5) Occurrence and duration of any start-up, shutdown, or malfunction of exposure controls or of facility equipment that causes air concentrations to be above the ECEL or EPA STEL and subsequent corrective actions taken during start-up, shutdown, or malfunctions to mitigate exposures to methylene chloride.

(c) *Objective data.* Objective data generated during the previous 5 years, when used to forgo the initial exposure monitoring, must include:

(1) The use of methylene chloride being evaluated;

(2) The source of objective data,

(3) The measurement methods, measurement results, and measurement analysis of the use of methylene chloride; and

(4) Any other relevant data to the operations, processes, or person's exposure.

(d) *Exposure monitoring records.* (1) Owners or operators are required to retain monitoring records that include, at minimum, the information described at 29 CFR 1910.1052(m)(2)(ii)(A) through (F). For the purposes of this paragraph (d)(1), cross-referenced provisions in 29 CFR 1910.1052(m)(2)(ii) applying to an "employee" apply equally to potentially exposed persons and cross-referenced provisions applying to an "employer" also apply equally to owners or operators.

(2) For each monitoring event of methylene chloride required under this subpart, owners or operators must also document the following:

(i) All measurements that may be necessary to determine the conditions that may affect the monitoring results;

(ii) The identity of all other potentially exposed persons whose exposure was not measured and whose exposure is intended to be represented by the area or representative sampling monitoring;

(iii) Use of established analytical methods;

(iv) Compliance with the Good Laboratory Practice Standards in accordance with 40 CFR part 792 or use of a laboratory accredited by the AIHA or another industry-recognized program; and

(v) Information regarding air monitoring equipment including: Type, maintenance, calibrations, performance tests, limits of detection, and any malfunctions.



(3) Owners or operators must maintain copies of exposure monitoring notifications provided pursuant to § 751.109(d)(5).

(e) *Availability of exposure control plans.* Owners or operators must document the notice to and ability of any potentially exposed persons to access the exposure control plan and other associated records in accordance with § 751.109(e)(2)(iii).

(f) *Records related to § 751.115 exemptions.* To maintain eligibility for an exemption described in § 751.115, the records maintained by the owners or operators must demonstrate compliance with the specific conditions of the exemption.

(g) *Records related to the refinishing of wooden furniture, decorative pieces, and architectural fixtures.* (1) Owners and operators of workplaces engaged in the industrial or commercial use of methylene chloride for the refinishing of wooden furniture, decorative pieces, and architectural fixtures of artistic, cultural, or historic value must document each instance of refinishing such pieces.

(2) The documentation required by paragraph (g)(1) of this section must include:

- (i) The date of the refinishing activity;
- (ii) A description of the wooden piece that was refinished and an explanation of its artistic, cultural, or historic value;
- (iii) The name of the owner of the refinished wooden piece;
- (iv) The name of the individual(s) that refinished the wooden piece;
- (v) A description of the methylene chloride product used and the quantity of the product used to perform the refinishing; and
- (vi) Records demonstrating compliance with the requirements of § 751.117.

(h) *Minimum record retention period.* The records required under this section must be retained for at least 5 years from the date that such records were generated.

10. Add § 751.115 to read as follows:

**§ 751.115 Exemptions.**

(a) *In general.* (1) Time-limited exemptions described in this section are established in accordance with 15 U.S.C. 2605(g)(1).

(2) To be eligible for the exemptions established in this section, regulated parties must comply with all conditions promulgated in this section for such exemptions in accordance with 15 U.S.C. 2605(g)(4).

(b) *Exemption for Emergency Use by the National Aeronautics and Space Administration under 15 U.S.C. 2605(g)(1)(A).* The use of methylene chloride or methylene chloride-containing products in an emergency by the National Aeronautics and Space Administration and its contractors operating within the scope of their contracted work for the conditions of use identified in paragraph (b)(1) is exempt from the requirements of § 751.107(b)(3) through (6) until **[INSERT DATE 10 YEARS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

(1) *Applicability.* This exemption shall apply to the following specific conditions of use:

- (i) Industrial and commercial use as solvent for cold cleaning;
- (ii) Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner;
- (iii) Industrial and commercial use in adhesives, sealants, and caulks;
- (iv) Industrial and commercial use in adhesive and caulk removers;
- (v) Industrial and commercial use in metal non-aerosol degreasers;
- (vi) Industrial and commercial use in non-aerosol degreasers and cleaners; and
- (vii) Industrial and commercial use as solvent that becomes part of a formulation or mixture.

(2) *Emergency use.* (i) *In general.* An emergency is a serious and sudden situation

requiring immediate action, within 15 days or less, necessary to protect:

(A) Safety of the National Aeronautics and Space Administration's or their contractors' personnel;

(B) The National Aeronautics and Space Administration's missions;

(C) Human health, safety, or property, including that of adjacent communities; or

(D) The environment.

(ii) *Duration.* Each emergency is a separate situation; if use of methylene chloride exceeds 15 days, then justification must be documented.

(3) *Eligibility.* To be eligible for the exemption, the National Aeronautics and Space Administration and its contractors must:

(i) Select methylene chloride because there are no technically and economically feasible safer alternatives available during the emergency.

(ii) Perform the emergency use of methylene chloride at locations controlled by the National Aeronautics and Space Administration or its contractors.

(iii) Comply with the following conditions:

(A) *Notification.* Within 15 working days of the emergency use by the National Aeronautics and Space Administration or its contractors, the National Aeronautics and Space Administration and its contractors must provide notice to the EPA Assistant Administrators of both the Office of Enforcement and Compliance Assurance and the Office of Chemical Safety and Pollution Prevention that includes the following:

(1) Identification of the condition of use detailed in paragraph (b)(1) of this section to which the emergency use applies;

(2) An explanation for why the emergency use met the definition of emergency in paragraph (b)(2)(i) of this section; and

(3) An explanation of why methylene chloride was selected, including why there were no technically and economically feasible safer alternatives available in the particular emergency.

(B) *Exposure*. The owner or operator must comply with and document such compliance efforts under the Workplace Chemical Protection Program provisions in § 751.109, to the extent technically feasible in light of the particular emergency.

(C) *Recordkeeping*. The owner or operator of the location where the use takes place must comply with the recordkeeping requirements in § 751.113.

11. Add § 751.117 to read as follows:

**§ 751.117 Interim Requirements for Paint and Coating Removal for the Refinishing of Wooden Furniture, Decorative Pieces, and Architectural Fixtures of Artistic, Cultural, or Historic Value.**

Beginning [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and notwithstanding the timeframes identified in § 751.109, all persons using methylene chloride, including any methylene chloride containing products, for industrial and commercial use for the refinishing of wooden furniture, decorative pieces and architectural fixtures of artistic, cultural, or historic value must:

- (a) Establish a regulated area in accordance with § 751.109(c)(3);
- (b) Use local exhaust ventilation, both bringing air in from outside and pulling methylene chloride vapors away from the potentially exposed person; and
- (c) Provide minimum respiratory protection:
  - (1) Use any NIOSH Approved® Supplied-Air Respirator (SAR) or airline respirator in a demand mode equipped with a full facepiece (APF 50) or any NIOSH Approved® Self-Contained Breathing Apparatus (SCBA) in demand-mode equipped with a full facepiece or helmet/hood (APF 50); or

(2) Use the appropriate respirator based on initial monitoring as identified in § 751.109(f)(2).

(d) Comply with the recordkeeping requirements in § 751.113(g).

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