PRE-PUBLICATION NOTICE

On Wednesday, April 19, 2023, Michael S. Regan, the EPA Administrator, signed the following document:

Action:	Proposed Rule
Title:	Methylene Chloride; Regulation under Section 6(a) of the Toxic Substances Control Act (TSCA)
FRL #:	8155-02-OCSPP
Docket ID #:	EPA-HQ-OPPT-2020-0465

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA-HQ-OPPT-2020-0465; FRL-8155-02-OCSPP]

RIN 2070-AK70

Methylene Chloride; Regulation under Section 6(a) of the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to address the unreasonable risk of injury to human health presented by methylene chloride under its conditions of use as documented in EPA's June 2020 Risk Evaluation for Methylene Chloride and November 2022 revised risk determination for methylene chloride prepared under the Toxic Substances Control Act (TSCA). 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. Methylene chloride, also known as dichloromethane, is acutely lethal, a neurotoxicant, a likely human carcinogen, and presents cancer and non-cancer risks following chronic exposures as well as acute risks. Central nervous system depressant effects can result in loss of consciousness and respiratory depression, resulting in irreversible coma, hypoxia, and eventual death, including 85 documented fatalities from 1980 to 2018, a majority of which were occupational fatalities (see Unit II.A.). Nevertheless, methylene chloride is still a widely used solvent in a variety of consumer and commercial applications including adhesives and sealants, automotive products, and paint and coating removers. To address the identified unreasonable risk, EPA is proposing

to: prohibit the manufacture, processing, and distribution in commerce of methylene chloride for consumer use; prohibit most industrial and commercial uses of methylene chloride; require a workplace chemical protection program (WCPP), which would include a requirement to meet inhalation exposure concentration limits and exposure monitoring for certain continued conditions of use of methylene chloride; require recordkeeping and downstream notification requirements for several conditions of use of methylene chloride; and provide certain time-limited exemptions from requirements for uses of methylene chloride that would otherwise significantly disrupt national security and critical infrastructure.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Under the Paperwork Reduction Act, comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0465, through the Federal eRulemaking Portal at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

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

MethyleneChlorideTSCA@epa.gov;

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

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by the proposed action if you manufacture (defined under TSCA to include import), process, distribute in commerce, use, or dispose of methylene chloride or products containing 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);
- 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 certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final TSCA section 6(a) rule are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 Code of Federal Regulations (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 proposed 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.

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

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

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if the U.S. Environmental Protection Agency, hereinafter EPA or "the Agency," 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 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 drive EPA's determination that methylene chloride presents an unreasonable risk is included in Unit III.B.2. Accordingly, to address the unreasonable risk, EPA is proposing, 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.A.3.;

(ii) Prohibit most industrial and commercial use of methylene chloride, as outlined in Unit IV.A.2.;

(iii) Require 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), as outlined in Unit IV.A.1.;

(iv) Require recordkeeping and downstream notification requirements for manufacturing, processing, and distribution in commerce of methylene chloride, as outlined in Unit IV.A.4.;

(v) Provide 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, as outlined in Unit IV.A.5., with conditions for this exemption to include compliance with the WCPP described in Unit IV.A.1.; and

(vi) Provide a 10-year time-limited exemption under TSCA section 6(g) for emergency use of methylene chloride in furtherance of 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, as outlined in Unit IV.A.5., with conditions for this exemption to include compliance with the WCPP described in Unit IV.A.1.

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)) are subject to this proposal. Condition of use is defined in TSCA 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. EPA is requesting public comment on all aspects of this

proposal.

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 (2020 Risk Evaluation for Methylene Chloride) (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. As a result, EPA is proposing to take action to the extent necessary so that methylene chloride no longer presents such risk. The unreasonable risk is described in Unit III.B.1. and the conditions of use that drive the unreasonable risk for methylene chloride are described in Unit III.B.2.

EPA emphasizes that some of the adverse effects from methylene chloride exposure can be immediately experienced and only for a short duration; others, however, can result in sudden death. Other effects may result in long-term impacts and should likewise be considered significant. Methylene chloride's hazards are well established. 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 proposed rule would 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 and the revised unreasonable risk determination for methylene chloride in November 2022.

EPA is not proposing a complete ban on methylene chloride. The agency recognizes that continued use of methylene chloride in one of the TSCA conditions of use may complement the agency's efforts to address climate-damaging hydrofluorocarbons (HFCs) under the American Innovation and Manufacturing Act of 2020 (AIM Act), thereby supporting human health and environmental protection under these programs, and that, for these HFC-related, reactant processing uses, workplace controls to address unreasonable risk can be implemented. Therefore, while addressing the unreasonable risk, this rule proposes to allow methylene chloride's continued use in tandem with additional worker protections for the production of HFC-32, one of the regulated substances that are subject to a phasedown under the AIM Act. While HFC-32 is one of the regulated substances subject to the phasedown in production and consumption by 85% over the next 15 years, HFC-32 is likely to be used to facilitate the transition from certain other HFCs and HFC blends with higher global warming potentials in certain applications. EPA expects that, by allowing for the continued use of methylene chloride in the production of HFC-32, this approach would complement EPA's work under the AIM Act. For many of the conditions of use for which EPA is proposing workplace controls under a WCPP, data was submitted during the risk evaluation and Small Business Advocacy Review (SBAR process that indicates some facilities may already be in compliance with the proposed methylene chloride Existing Chemical Exposure Limit (ECEL). Additionally, the requirements in this proposal would prohibit uses that account for approximately one third of the total annual production volume of methylene chloride generated (TSCA and non-TSCA uses), leaving a sufficient supply in circulation to provide a source for these critical or essential uses for which EPA is

proposing to allow continued use (Unit IV.A.), either under a WCPP or through a TSCA section 6(g) exemption (Ref. 3).

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) and in Units VI.D. and X.D., EPA's analysis of the incremental, non-closure-related costs of this proposed rule is estimated to be $13.2 million annualized over 20 years at a 3% discount rate and $14.5 million annualized over 20 years at a 7% discount rate. These costs take compliance with implementation of a WCPP for certain conditions of use into consideration, which would include an ECEL of 2 ppm (8 mg/m^3) for inhalation exposures as an 8-hour time-weighted average (TWA), applicable personal protective equipment (PPE) requirements, and reformulation costs of numerous products. In addition to the monetized costs discussed previously there are unknown economic impacts of potential firm closures in the furniture refinishing industry as discussed in the Economic Analysis. Potential average lost profits range from $14,000 (one firm closing) to $67 million under the extreme and unlikely assumption of a complete sector shutdown (Ref. 3). EPA had also received comments following SBAR meetings where submitted exposure measurements indicated an ability to achieve ECEL levels, suggesting that a WCPP for certain uses is achievable; this is further discussed in Unit V.A.1. Unquantified costs exist, including determining the best substitute for the firm's specific needs and how a different product may impact a firm's existing workflow (*e.g.*, does a different adhesive take longer to dry) and how a firm may work through the hierarchy of controls to comply with a WCPP. Although some costs cannot be quantified, they are not necessarily less important than the quantified costs. The most notable unquantified cost is change in labor and wait times within applications for which methylene chloride use is more

efficient than substitute methods or alternative chemicals for achieving desired results. Additionally, in the unique case of furniture refinishing (within the commercial paint and coating removal condition of use), alternatives to products containing methylene chloride may not be economically viable and may cause damage to the substrate, and thus the prohibition of this use could impact the sector significantly. After publication of the proposed rule for methylene chloride in paint and coating removal (82 FR 7464, January 19, 2017) (FRL-9958-57), EPA, in collaboration with the Small Business Administration's Office of Advocacy, conducted a workshop on furniture refinishing in Boston, Massachusetts, on September 12, 2017 (82 FR 41256, August 30, 2017) (FRL-9966-83) to address information gaps for the furniture refinishing sector identified in that proposed rule. The workshop was well attended by over 100 furniture refinishing experts, industry professionals, nongovernmental organizations, academic experts, and State and Federal government partners (Ref. 4). The informative discussion among the participants and invited speakers touched on the commercial and consumer use of methylene chloride in furniture refinishing, the potential effects that regulation may have on businesses, alternatives to methylene chloride, health risks associated with methylene chloride, and labeling of consumer and commercial products (speaker presentations, transcript notes, and public comments are available in the docket EPA-HQ-OPPT-2017-0139).

EPA estimates that as many as 5,000 furniture refinishers still use methylene chloride, a majority of which are small businesses. While the amount of methylene chloride paint removers used per firm for furniture refinishing can vary greatly, industry stakeholder information indicates one 55-gallon drum every two months (Ref. 4). This would result in an estimated 2.3 million gallons of formulated paint remover used annually. The amount of methylene chloride included in this estimate would depend on the percent in formulation used by the furniture refinishing firms. The impact of a prohibition of methylene chloride for furniture refinishing

could result in the closure of an unknown number of the 5,000 potentially affected furniture refinishing firms using methylene chloride in the baseline.

Based on the estimated revenues per firm presented in Table 3-1 of the Economic Analysis and the 5,000 estimated number of furniture refinishing firms using methylene chloride (see Table 6-12 in the Economic Analysis), the total revenue for furniture refinishing firms using methylene chloride is approximately $1.8 billion. According to IRS (2013) data, profit in this sector is about 3.8% of sales. Therefore, closure of affected furniture refinishing firms using methylene chloride following this rulemaking has an upper bound for economic impacts of $1.8 billion in total revenue, and $67 million in terms of the total profit, under the assumption that all affected firms fully close. A detailed discussion of potential economic impacts as a result of varying percentages of furniture refinishing firms closing is provided in the Economic Analysis in section 7.11 (Ref. 3).

EPA identified many alternative products for paint and coating removers, though many may require longer periods of time, replacement of equipment, or rework of processes in order to work for furniture refinishing uses. These may not be appropriate alternatives as they could damage the wood substrate. Mechanical or thermal methods (*i.e.*, sanding, media blasting, and heat guns) are also potential alternatives for this sector, though they likewise they require different processes, and often require more time (Refs. 3, 4, 5, 6). For furniture refinishing, as with other commercial uses, the health benefits that would result from prohibiting this use of methylene chloride, including deaths avoided, are further discussed in the Economic Analysis (Ref. 3).

The actions proposed in this 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 monetized benefits of this rule are approximately $17.7 million to $18.5 million annualized over 20 years at a 3% discount rate and $13.4 million to $13.9 million annualized over 20 years at a 7% discount rate. The monetized benefits only include potential reductions in risk of liver cancer, lung cancer, 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

Methylene chloride is acutely lethal, a neurotoxicant, and a likely human carcinogen. This proposed 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 and unreasonable risk determination, as described in Unit III.B.2. Methylene chloride is a colorless liquid and a volatile chemical with a sweet odor resembling chloroform. It is 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 III.B.1., 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. 7), these regulations include EPA's 2019 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 aggregate production volume of methylene chloride ranged from 100 million to 500 million pounds between 2016 and 2019 according to Chemical Data Reporting (CDR) (Ref. 8). 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 hydrofluorocarbons (HFCs) (Ref. 1). This condition of use is described in Unit III.B.2., with a description of proposed requirements to address unreasonable risk in Unit III.B.3, and V.1. An estimated 35% of the annual production volume of methylene chloride is for pharmaceutical uses, which are not subject to TSCA and would 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 other Federal, State, and international regulations, is in the docket (Refs. 1, 7).

C. Consideration of Occupational Safety and Health Administration (OSHA) occupational health standards in TSCA risk evaluations and TSCA risk management actions

TSCA requires EPA to evaluate whether 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 by the Administrator, under the conditions of use. Conditions of use are the circumstances, as determined by the Administrator, under which a chemical is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. If EPA determines through risk evaluation that a chemical substance presents an unreasonable risk, TSCA section 6 requires EPA to issue regulations applying one or more control requirements to the extent necessary so that the chemical substance no longer presents such risk. Although EPA must consider, and in some cases factor-in, to the extent practicable, non-risk factors as part of TSCA section 6(a) rulemaking (see TSCA section 6(c)(2)), EPA must nonetheless still ensure that the selected regulatory requirements apply "to the extent necessary so that the chemical substance or mixture no longer presents [unreasonable] risk." 15 U.S.C. 2605(a). This risk-based requirement is distinguishable from approaches mandated by other laws, including the Occupational Safety and Health Act (OSH Act), which includes both significant risk and feasibility (technical and economic) assessments in its rulemaking.

Congress intended for EPA to consider occupational risks from chemicals it evaluates under TSCA, among other potential exposures, as relevant and appropriate. As noted previously, section 6(b) of TSCA requires EPA to evaluate risks to potentially exposed or susceptible subpopulations identified as relevant by the Administrator. TSCA section 3(12) defines the term "potentially exposed or susceptible subpopulation" as "a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly."

The OSH Act similarly requires OSHA to evaluate risk specific to workers prior to

promulgating new or revised standards and requires OSHA standards to substantially reduce significant risk to the extent feasible, even if workers are exposed over a full working lifetime. *See* 29 U.S.C. 655(b)(5); *Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 642 (1980) (plurality opinion).

Thus, the standards for chemical hazards that OSHA promulgates under the OSH Act share a broadly similar purpose with the 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, as this section outlines, 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 (such as those described in Unit II.B.2.) when evaluating and addressing potential unreasonable risk to workers so that compliance requirements are clearly explained to the regulated community.

1. OSHA requirements.

OSHA's mission is to ensure that employees work in safe and healthful conditions. The OSH Act establishes requirements that each employer comply with the General Duty Clause of the Act (29 U.S.C. 654(a)), as well as with occupational safety and health standards issued under the Act.

a. General Duty Clause of the OSH Act.

The General Duty Clause of the OSH Act requires employers to keep their workplaces free from recognized hazards that are causing or are likely to cause death or serious physical harm to employees. The General Duty Clause is cast in general terms, and does not establish specific requirements like exposure limits, personal protective equipment (PPE)), or other specific protective measures that EPA could potentially consider when developing its risk

evaluations or risk management requirements. OSHA, under limited circumstances, has cited the General Duty Clause for regulating exposure to chemicals. To prove a violation of the General Duty Clause, OSHA must prove employer or industry recognition of the hazard, that the hazard was causing or likely to cause death or serious physical harm, and a feasible method to eliminate or materially reduce the hazard was available. In rare situations, OSHA has cited employers for violation of the General Duty Clause where exposures were below a chemical-specific permissible exposure limit (PEL). In such situations, OSHA must demonstrate that the employer had actual knowledge that the PEL was inadequate to protect its employees from death or serious physical harm. Because of the heavy evidentiary burden on OSHA to establish violations of the General Duty Clause, it is not frequently used to cite employers for employee exposure to chemical hazards.

b. OSHA standards.

OSHA standards are issued pursuant to the OSH Act and are found in title 29 of the CFR. There are separate standards for general industry, construction, maritime and agriculture sectors, general standards applicable to a number of sectors (*e.g.*, OSHA's Respiratory Protection standard), and a methylene chloride standard. OSHA has numerous standards that apply to employers who operate chemical manufacturing and processing facilities, as well as to downstream employers whose employees may be occupationally exposed to hazardous chemicals.

OSHA sets legally enforceable limits on the airborne concentrations of hazardous chemicals, referred to as PELs, established for employers to protect their workers against the health effects of exposure to hazardous substances (29 CFR parts 1910, Subpart Z; 1915, Subpart Z; 1926, Subparts D and Z). Under section 6(a) of the OSH Act, OSHA was permitted an initial 2-year window after the passage of the Act to adopt "any national consensus standard and any

established Federal standard." 29 U.S.C. 655(a). OSHA used this authority in 1971 to establish PELs that were adopted from Federal health standards originally set by the Department of Labor through the Walsh-Healy Act, in which approximately 400 occupational exposure limits were selected based on the American Conference of Governmental Industrial Hygienists (ACGIH) 1968 list of Threshold Limit Values (TLVs). In addition, about 25 exposure limits recommended by the American Standards Association (now called the American National Standards Institute) (ANSI) were adopted as PELs.

Following the 2-year window provided under section 6(a) of the OSH Act for adoption of national consensus and existing Federal standards, OSHA has issued health standards following the requirements in section 6(b) of the Act. OSHA has established approximately 30 PELs under section 6(b)(5) as part of comprehensive substance-specific standards that include additional requirements for protective measures such as use of PPE, establishment of regulated areas, exposure assessment, hygiene facilities, medical surveillance, and training. These ancillary provisions in substance-specific OSHA standards further mitigate residual risk that could be present due to exposure at the PEL.

Though many OSHA PELs have not been updated since they were established in 1971, the methylene chloride PEL was last updated as part of the OSHA methylene chloride standard in 1997. In many instances, scientific evidence has accumulated suggesting that the current limits of many PELs are not sufficiently protective. On October 10, 2014, OSHA published a *Federal Register* document in which it recognized that many of its PELs are outdated and inadequate for ensuring protection of worker health (79 FR 61384). In addition, health standards issued under section 6(b)(5) of the OSH Act must reduce significant risk only to the extent that it is technologically and economically feasible to do so. OSHA's legal requirement to demonstrate that its section 6(b)(5) standards are technologically and economically feasible at the time they

are promulgated often precludes OSHA from imposing exposure control requirements sufficient to ensure that the chemical substance no longer presents a significant risk to workers.

In sum, the great majority of OSHA's chemical standards are outdated or do not sufficiently reduce significant risk to workers. They would, in either case, be unlikely to address unreasonable risk to workers within the meaning of TSCA, since TSCA section 6(b) unreasonable risk determinations may account for unreasonable risk to more sensitive endpoints and working populations than OSHA's risk evaluations typically contemplate, and EPA is obligated to apply TSCA section 6(a) risk management requirements to the extent necessary so that the unreasonable risk is no longer presented.

Because the requirements and application of TSCA and OSHA regulatory analyses differ, and because OSHA's chemical-specific standards are decades old and may include outdated assumptions regarding the most sensitive end-point and/or the technological and economic feasibility of the standards, it is necessary for EPA to conduct risk evaluations and, where it finds unreasonable risk to workers, develop risk management requirements for chemical substances that OSHA also regulates, and it is expected that EPA's findings and requirements may sometimes diverge from OSHA's. However, it is also appropriate that EPA consider the chemical standards that OSHA has already developed to limit the compliance burden to employers by aligning management approaches required by the agencies, where alignment will adequately address unreasonable risk to workers. The following section discusses EPA's consideration of OSHA standards in its risk evaluation and management strategies under TSCA.

2. Consideration of OSHA standards in TSCA risk evaluations.

When characterizing the risk during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in scenarios where no mitigation measures are assumed to be in place for the purpose of determining unreasonable risk (see Unit II.C.2.a.). (It

should be noted that there are some cases where scenarios may reflect certain mitigation measures, such as in instances where exposure estimates are based on monitoring data at facilities that have existing engineering controls in place.) In addition, EPA believes it is appropriate to also evaluate the levels of risk present in scenarios considering applicable OSHA requirements (*e.g.*, chemical-specific PELs and/or chemical-specific standards with PELs and additional ancillary provisions), as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. By characterizing risks using scenarios that reflect different levels of mitigation, EPA risk evaluations can help inform potential risk management actions by providing information that could be used during risk management to tailor risk mitigation appropriately to address any unreasonable risk identified (see Unit II.C.2.b. and Unit II.C.3.).

a. Risk characterization for unreasonable risk determination.

When making unreasonable risk determinations as part of TSCA risk evaluations, EPA cannot assume as a general matter that all workers are always equipped with and appropriately using sufficient PPE, although it does not question the public comments received on the 2020 Risk Evaluation for Methylene Chloride regarding the occupational safety practices often followed by industry respondents. When characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. This approach of not assuming PPE use by workers considers the risk to potentially exposed or susceptible subpopulations (workers and occupational non-users) who may not be covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan. Mitigation scenarios included in the EPA risk evaluation (*e.g.*, scenarios considering use of PPE) likely represent current practice in many facilities where

companies effectively address worker and bystander safety requirements. However, the Agency cannot assume that all facilities will have adopted these practices for the purposes of making the TSCA risk determination.

Therefore, EPA makes its determinations of unreasonable risk based on scenarios that do not assume compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE. Making unreasonable risk determinations based on such scenarios should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread noncompliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by an OSHA State Plan, or because their employer is out of compliance with OSHA standards, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

b. Risk evaluation to inform risk management requirements.

In addition to the scenarios described previously, EPA risk evaluations may characterize the levels of risk present in scenarios considering applicable OSHA requirements (*e.g.*, chemical-specific PELs and/or chemical-specific health standards with PELs and additional ancillary provisions) as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. EPA's evaluation of risk under scenarios that, for example, incorporate use of engineering or administrative controls, or PPE, serves to inform its risk management efforts. Characterizing risks using scenarios that reflect different levels of mitigation can help inform potential risk management actions by providing information that could be used during risk management to tailor risk mitigation to address worker exposures

where the Agency has found unreasonable risk. In particular, as discussed later in this unit, EPA can use the information developed during its risk evaluation to determine whether alignment of EPA's risk management requirements with existing OSHA requirements or industry best practices will adequately address unreasonable risk as required by TSCA.

3. Consideration of OSHA standards in TSCA risk management actions.

When undertaking risk management actions, EPA: 1) Develops occupational risk mitigation measures to address any unreasonable risk identified by EPA, striving for consistency with applicable OSHA requirements and industry best practices, including appropriate application of the National Institute for Occupational Safety and Health (NIOSH) hierarchy of controls (Ref. 9) (hereafter referred to as "hierarchy of controls"), when those measures would address an unreasonable risk; and 2) Ensures that EPA requirements apply to all potentially exposed workers in accordance with TSCA requirements. 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 applicability of TSCA while avoiding the imposition of duplicative requirements.

Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules that require risk management practices that may be already common practice in many or most facilities. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers, especially in cases where current OSHA standards may not apply to them or not be sufficient to address the unreasonable risk.

4. Methylene Chloride and OSHA requirements

EPA incorporated the considerations described earlier in this Unit into the 2020 Risk Evaluation for Methylene Chloride, the November 2022 revised unreasonable risk determination

for methylene chloride, and this rulemaking. Specifically, in the TSCA 2020 Risk Evaluation for Methylene Chloride, EPA presented risk estimates based on workers' exposures with and without respiratory protection. EPA determined that even when respirators are used by workers, most of the conditions of use evaluated presented an unreasonable risk. Additional considerations of OSHA standards in the revised unreasonable risk determination are discussed further in the *Federal Register* notice announcing that document (Ref. 19) (87 FR 67901, November 10, 2022). In Units III.B.3. and V., EPA outlines the importance of considering the hierarchy of controls when developing risk management actions in general, and specifically when determining if and how regulated entities may meet a risk-based exposure limit for methylene chloride. The hierarchy of controls is a prioritization of exposure control strategies from most protective and preferred to least protective and preferred techniques. In order of precedence, they are: elimination of the hazard, substitution with a less hazardous substance, engineering controls, administrative controls such as training or exclusion zones with warning signs, and, finally, use of PPE (Ref. 9). Under the hierarchy of controls, the use of respirators (and all PPE) should only be considered after all other measures have been taken to reduce exposures, and then under the context of the OSHA Respiratory Protection Standard at 29 CFR 1910.134. As discussed in Units III.A.1. and V.A.1., EPA's risk management approach would not rely solely or primarily on the use of respirators to reduce exposures to workers so that methylene chloride does not present unreasonable risk; instead, EPA is proposing prohibitions for or affecting most conditions of use and a WCPP for certain industrial and commercial uses. The WCPP would require consideration of the hierarchy of controls before use of respirators and other PPE. The WCPP is discussed in full in Units IV.A.1. and V.A. As discussed further in Unit V.A.1., for many of the conditions of use for which EPA is proposing a WCPP, data was submitted during the risk evaluation and SBAR process that indicates some facilities may

already be in compliance with the proposed methylene chloride ECEL.

In accordance with the approach described earlier in Unit II.C.3., 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. Notable differences between the WCPP and the OSHA standard are the exposure limits and the action levels. The WCPP would include an Existing Chemical Exposure Limit (ECEL) of 2 ppm as an 8-hour TWA to address unreasonable risk for chronic cancer and non-cancer inhalation endpoints, and acute non-cancer endpoints, as well as an EPA Short Term Exposure Limit (EPA STEL) of 16 ppm as a 15-minute TWA to address any peak exposures which may result in additional unreasonable risk from acute inhalation. A regulated entity must comply with both the 8-hour TWA ECEL and the 15-minute TWA EPA STEL to completely address the unreasonable risk. EPA recognizes that for methylene chloride, the ECEL and EPA STEL would be significantly lower than the OSHA PEL (25 ppm as an 8-hour TWA) and STEL (125 ppm). In addition to the distinctions in statutory requirements described in this Unit, EPA has identified factors contributing to the differences in these levels, outlined here (Ref. 14).

EPA considers the methylene chloride ECEL to represent the best available science under TSCA section 26(h), since it was derived from information in the 2020 Risk Evaluation for Methylene Chloride, which is the result of a rigorous systematic review process that investigated the entirety of the reasonably available current literature in order to identify all relevant adverse health effects. Additionally, by using the information from the 2020 Risk Evaluation for Methylene Chloride, the ECEL incorporates advanced modeling and peer-reviewed methodologies, including accounting for exposures to potentially exposed or susceptible subpopulations, as required by TSCA.

The ECEL is an 8-hour occupational inhalation exposure limit based on the point of

departure of the endpoint that drives the unreasonable risk determination (chronic non-cancer liver effects, in the case of methylene chloride), and takes into consideration the uncertainties identified in the 2020 Risk Evaluation for Methylene Chloride (Ref. 11). The ECEL represents the concentration at or below which an adult human, including a member of a potentially exposed or susceptible subpopulation, would be unlikely to suffer adverse effects if exposed for a working lifetime. EPA has determined as a matter of risk management policy that ensuring exposures remain at or below the ECEL will eliminate- any unreasonable risk of injury to health. In addition to the ECEL, as part of this rulemaking, EPA is setting an ECEL-action level, a value half of the ECEL, that would trigger additional monitoring action to ensure that workers are not exposed to concentrations above the ECEL.

The OSHA PEL is an 8-hour time -weighted average (TWA) based on an employee's average airborne exposure in any 8-hour work shift of a 40-hour work week that shall not be exceeded (Ref. 12). OSHA is required to promulgate a standard that reduces significant risk to the extent that it is technologically and economically feasible to do so (81 FR 16285).

For methylene chloride, the ECEL is based on the most sensitive point of departure (POD) across acute, chronic non-cancer, and cancer endpoints. As demonstrated in the ECEL memo, chronic liver toxicity is the basis of the methylene chloride ECEL (Ref. 11). Both inhalation and oral studies identified liver effects as sensitive non-cancer effects linked with exposure to methylene chloride in animals. Overall, based on limited human evidence and strong evidence in multiple animal species from highly rated studies based on systematic review, the weight of the scientific evidence supported EPA’s finding that non-cancer liver effects follow methylene chloride exposure.

EPA used liver lesions in rats as indicated by cellular vacuolization in Nitschke *et al*, 1988 as the basis of the chronic non-cancer POD. Study data was run through a physiological-

based pharmacokinetic (PBPK) model to more accurately account for both inter-species differences and human variability. Internal PBPK-modeled doses were also benchmark-dose modeled in order to better refine the POD estimate, resulting in a human equivalent concentration (HEC) of 4.8 ppm based on continuous exposure with a benchmark margin of exposure (MOE) (equal to the product of all uncertainty factors) of 10. The resulting ECEL is 2 ppm.

The EPA STEL is based on decreased visual performance identified in an acute inhalation study on human subjects. Putz *et al*. (1979) is a well-conducted study of 12 volunteers that identified decreased visual peripheral performance after 1.5 hour of exposure to 195 ppm (200 ppm nominal) (Ref. 13). Because this study used a single concentration, it is not amenable to dose-response modeling, so EPA used the lowest observed adverse effects concentration (LOAEC) of 195 ppm. Adjusting to a more appropriate exposure duration of 8-hour for occupational scenarios resulted in a HEC of 80 ppm with benchmark MOE of 30. The resulting acute exposure limit is 16 ppm, eight times higher than the overall ECEL.

The OSHA PEL for methylene chloride was adopted in 1971 and updated in 1997 (62 FR 1494, January 10, 1997). The OSHA PEL is set at 25 ppm, based on cancer from the same National Toxicology Program (1986) study cited for cancer effects in the 2020 Methylene Chloride Risk Evaluation (Ref. 14) (though EPA found this was not the most sensitive POD, and thus set an ECEL of 2 ppm, based on non-cancer liver effects from Nitschke *et al*., 1988 (Refs. 15, 16)).

The OSHA PEL utilized a PBPK model to derive lifetime excess risk estimates for cancer. The PEL was set at 25 ppm based on estimated lifetime risk of 2.4 to 3.6 cases per 1000 or 2.4-3.66x10^{-3} (E^{-3}) at that exposure level. EPA used a benchmark of 1 in 10,000 (10^{-4}) for individuals in industrial and commercial work environments for purposes of the unreasonable

risk determination for methylene chloride (Ref. 2), and at that cancer risk level EPA calculates the exposure limit based on cancer to be approximately 42 ppm – almost double the OSHA PEL.

OSHA acknowledges that the 10^{-3} threshold is "100 to 1000 times higher than the risk levels generally regarded by other Federal Agencies as on the boundary between significant and insignificant risk" and notes that "even at the final PELs, the risks to workers clearly remain significant." (62 FR 1494, January 10, 1997).The 1997 decision to not derive a PEL lower than 25 ppm was based on economic and technical analysis, with OSHA stating, "because of the lack of documented feasibility data for potential PELs of less than 25 ppm, OSHA has concluded that there is not enough information available to support lowering the 8-hour TWA PEL or STEL further at this time" (62 FR 1494, January 10, 1997).

As for non-cancer liver effects that are the basis of the ECEL, OSHA determined that "chronic exposure to [methylene chloride] caused toxic effects in rat and mouse liver and cancer in mouse liver. These studies appear to have been well conducted and the differences in toxicity observed across studies were likely due to differences in dose or route of exposure… [L]imited evidence supports the hypothesis that [methylene chloride] causes human hepatotoxicity, based on the data in the Ott study. The remaining studies and case reports do not provide clear evidence of a causative role of [methylene chloride] in hepatotoxicity. The Agency [OSHA] has set the exposure limits based on cancer and [central nervous system] effects and has not reached final conclusions on this issue" (62 FR 1514-1515, January 10, 1997). As discussed in Units II.D., III.B.A., and VII.D., the ECEL represents the best available science at time of publication of the 2020 Risk Evaluation for Methylene Chloride.

D. 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-OCSPP), 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.2. The 2020 Risk Evaluation for Methylene Chloride identified significant adverse health effects associated with short- and long-term exposure to methylene chloride, including central nervous system effects up to and including death from acute inhalation exposures, non-cancer liver effects from chronic inhalation, and cancer from chronic inhalation exposures to methylene chloride, as well as acute central nervous system effects and chronic non-cancer liver effects from dermal exposure. A further discussion of the hazards of methylene chloride is in Unit III.B.1.

2. 2022 Revised Unreasonable Risk Determination.

EPA has been revisiting specific aspects of its first ten TSCA existing chemical risk evaluations, including the methylene chloride risk evaluation, to ensure that the risk evaluations upon which risk management decisions are made better align with TSCA's objective of protecting health and the environment. For methylene chloride, 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. 17, 18, 19). The revisions consisted of making the risk determination based on the whole-chemical substance instead of by individual conditions of use (which resulted in the revised risk determination superseding the prior "no unreasonable risk" determinations (Ref. 2) the withdrawal of the associated TSCA section 6(i)(1) "no unreasonable risk" order; and clarifying that the risk determination does not reflect an assumption that all workers are always provided and appropriately wear PPE (Ref. 2).

In determining whether methylene chloride presents unreasonable risk under the conditions of use, EPA considered relevant risk-related factors, including, but not limited to: the effects of the chemical substance on health (including cancer and non-cancer risks) and human exposure to the substance under the conditions of use (including duration, magnitude and frequency of exposure); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any potentially exposed or susceptible subpopulations); the severity of hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties.

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

health. The unreasonable risk determination is driven by risks to workers and occupational non-users (workers who do not directly handle methylene chloride but perform work in an area where methylene chloride is present) from occupational exposures (*i.e.*, during manufacture, processing, industrial and commercial uses, or disposal), and to consumers and bystanders from consumer use of methylene chloride. EPA did not identify risks of injury to the environment that drive 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., with descriptions to aid chemical manufacturers, processors, and users in determining how their particular use or activity would be addressed under the proposed regulatory provisions.

While the 2020 Risk Evaluation for Methylene Chloride estimated different risks for occupational non-users and workers, the benchmark (and thus the ECEL and EPA STEL value) is the same for both populations. That is, while workers and occupational non-users may have different exposure patterns, the level of exposure such that risks are no longer unreasonable is the same for both workers and occupational non-users. Thus, for the purposes of risk management, the distinction between worker and occupational non-user is no longer relevant, and both are encompassed by the definition of a potentially exposed person, as outlined in Unit IV.A.1.a. EPA additionally emphasizes that the inclusion of occupational non-users itself does not exceed the scope of those individuals that are already covered by the OSHA PEL, as the methylene chloride OSHA standard applies to all employees within a regulated area, regardless of whether they directly handle methylene chloride.

3. Fenceline Screening Analysis.

The 2020 TSCA Risk Evaluation for Methylene Chloride excluded the assessment of certain exposure pathways that were or could be regulated under another EPA-administered

statute (see section 1.4.2 of the 2020 Risk Evaluation for Methylene Chloride (Refs. 1, 2)). This resulted in the surface water, drinking water, and ambient air pathways for methylene chloride exposure not being assessed for human health risk to the general population. In June 2021, EPA made a policy announcement on the path forward for TSCA chemical risk evaluations, indicating that EPA would, among other things, examine whether the exclusion of certain exposure pathways from the risk evaluations would lead to a failure to identify and protect fenceline communities (Refs. 10, 20).

In order to assess the potential for risk to the general population in proximity to a facility releasing methylene chloride, EPA developed the TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0, which was presented to the SACC in March 2022, with a report issued by the SACC on May 18, 2022 (Ref. 21). This analysis is discussed in Unit VI.A.

III. Regulatory Approach

A. Background

Under TSCA section 6(a), if the Administrator determines, in accordance with TSCA section 6(b)(4)(A), that the manufacture (including import), processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or any combination of such activities, presents an unreasonable risk of injury to health or the environment, EPA must by rule apply one or more of the following requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk.

• 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)).

As described in Unit III.B., EPA assessed how the TSCA section 6(a) requirements could be applied to address the unreasonable risk found to be present in the 2020 Risk Evaluation for Methylene Chloride and the final revised unreasonable risk determination, so that methylene chloride no longer presents such unreasonable risk. EPA's proposed regulatory action and a primary alternative regulatory action are fully discussed in Unit IV. EPA is requesting public comment on the proposed regulatory action and primary alternative regulatory action.

Under the authority of TSCA section 6(g), EPA may consider granting a time-limited exemption for a specific condition of use for which EPA finds that: 1) The specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; 2) Compliance with the requirement would significantly disrupt the national economy, national security, or critical infrastructure; or 3) The specific condition of use, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety. Further, the Administrator may by rule, extend, modify, or eliminate an exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or modification or is no longer necessary. Based on reasonably available information, EPA has considered the issue and is proposing that a TSCA section 6(g) exemption is warranted for certain conditions of use, as detailed in Unit IV.A.5. EPA is requesting comment on the proposed rule's section 6(g) exemption provisions and rationale.

TSCA section 6(c)(2)(A) requires EPA, in proposing and promulgating section 6(a) rules, to consider and include a statement of effects addressing certain factors, including the costs and benefits and the cost effectiveness of the proposed regulatory action and of the one or more primary alternative regulatory actions considered by the Administrator. Also, under TSCA section 6(c)(2), EPA must consider the effects of the chemical substance or mixture on health or the environment and the magnitude of the exposure, which can include impacts to health or the environment in fenceline communities. TSCA section 6(c)(2) considerations are discussed in Unit VI.

TSCA section 6(c)(2)(C) requires that, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use and in setting an appropriate

transition period for such action, EPA consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute when the proposed prohibition or restriction takes effect. Unit III.B.4. includes more information regarding EPA's consideration of alternatives, and Unit V. provides more information on EPA's considerations more broadly under TSCA section 6(c)(2).

As described in this Unit, EPA carried out required consultations as described later in this unit and also considered impacts on children's environmental health as part of its approach to developing this TSCA section 6 regulatory action.

1. Consultations.

EPA conducted consultations and outreach as part of development of this proposed regulatory action. The Agency held a federalism consultation from October 22, 2020, until January 23, 2021, as part of this rulemaking process and pursuant to Executive Order 13132. This included a background presentation on September 9, 2020, and a consultation meeting on October 22, 2020. During the consultation, EPA met with State and local officials early in the process of developing the proposed action in order to receive meaningful and timely input into its development (Ref. 22). During the consultation, participants and EPA discussed preemption, EPA's authority under TSCA section 6 to regulate identified unreasonable risk, what activities would be potentially regulated in the proposed rule, and the relationship between TSCA and existing statutes – particularly the Clean Water Act (CWA) and Safe Drinking Water Act (SDWA) (Ref. 22).

Methylene chloride is not manufactured (including imported), processed, distributed in commerce, or regulated by tribal governments. However, EPA consulted with tribal officials during the development of this proposed action (Ref. 23). 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 risk managers 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 that would be helpful to inform risk management, principles for transparency during the risk management process, and types of information EPA is seeking from tribes (Ref. 23). EPA received no written comments as part of this consultation.

In addition to the formal consultations, EPA also conducted outreach to advocates for communities that might be subject to disproportionate exposure to methylene chloride, including underrepresented communities such as minority populations, low-income populations, and Indigenous peoples. EPA's Environmental Justice (EJ) consultation occurred from November 4, 2020, through January 18, 2021. On November 16 and 19, 2020, EPA held public meetings as part of this consultation. These meetings were held pursuant to and in compliance with Executive Orders 12898 and 14008. EPA received three written comments following the EJ meetings, in addition to oral comments provided during the consultations (Refs. 24, 25, 26). 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 in regulating methylene chloride, favored prohibitions, and noted the uncertainties associated with use of PPE (*e.g.*, in some cases, use of PPE did not provide adequate protection given the exposure scenario).

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 are in Unit X.C. and in the Initial Regulatory Flexibility Analysis (Ref. 27); the Panel report is in

the docket (Ref. 6).

Units X.C., X.E., X.F., and X.J. provide more information regarding the consultations.

2. Other stakeholder consultations.

In addition to the formal consultations described in Unit X., EPA attended a Small Business Administration (SBA) Office of Advocacy Environmental Roundtable on September 11, 2020 and held a public webinar on September 16, 2020. At both events EPA staff provided an overview of the TSCA risk management process and the findings in the 2020 Risk Evaluation for Methylene Chloride (Ref. 28). Attendees of these meetings were given an opportunity to voice their concerns regarding the risk evaluation and risk management.

Furthermore, EPA has engaged in discussions with representatives from different industries, non-governmental organizations, technical experts, and users of methylene chloride. A list of external meetings held during the development of this proposed rule is in the docket (Ref. 29); meeting materials and summaries are also in the docket. The purpose of these discussions was to hear from users, academics, manufacturers, and members of the public health community about practices related to commercial and consumer uses of methylene chloride; public health impacts of methylene chloride; the importance of methylene chloride in the various uses subject to this proposed rule; frequently used substitute chemicals or alternative methods; engineering control measures and PPE currently in use or feasibly adoptable; and other risk-reduction approaches that may have already been adopted or considered for industrial, commercial or consumer uses.

3. Children's Environmental Health.

The Agency's 2021 Policy on Children's Health (Ref. 30) 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).

The 2020 Risk Evaluation for Methylene Chloride evaluated exposures of infants, toddlers, older children (11 to 15 years and 16 to 20 years), and males and females of reproductive age; while EPA identified exposures to these populations (as bystanders, consumers, or workers) as driving the unreasonable risk for methylene chloride, EPA did not find that the adverse health impacts for these groups 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 (Ref. 1).

More specifically, the 2020 Risk Evaluation for Methylene Chloride released in June 2020 considered impacts on both children and adults from occupational and consumer use from inhalation and dermal exposures, as applicable. For occupational use, the risk evaluation considered males (>16 years of age) and females of reproductive age (>16 years of age to less than 50 years of age) for both dermal and inhalation exposures. For consumer use, EPA evaluated dermal exposures for children ages 11 to 15 and 16 to 20 years of age, and the

evaluation of bystander exposure from inhalation exposures included infants, toddlers and older children. While risks to children are not disproportionate, effects observed in studies include central nervous system impairment from acute inhalation exposure and liver toxicity from chronic inhalation exposure. The risks described in this section would be addressed by the proposed regulatory action described in Unit IV.

B. Regulatory Assessment of Methylene Chloride

1. Description of conditions of use.

This Unit describes the TSCA conditions of use that drive the unreasonable risk for methylene chloride. Condition of use descriptions 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 acknowledges that some of the terms here may be defined under other statutes; however, the descriptions in this unit are intended to provide clarity to the regulated entities who will implement the provisions of this rulemaking under TSCA section 6(a).

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 solvent for batch vapor degreasing.

This condition of use refers to the process of heating methylene chloride to its volatilization point and using its vapor to remove dirt, oils, greases, and other surface

contaminants (such as drawing compounds, cutting fluids, coolants, solder flux, and lubricants) from metal parts, electronics, or other articles in batch open-top vapor degreasers or closed-loop vapor degreasing in industrial or commercial settings.

ii. Industrial and commercial use as solvent for in-line vapor degreasing.

This condition of use refers to the process of heating methylene chloride to its volatilization point and using its vapors to remove dirt, oils, greases, and other surface contaminants from textiles, glassware, metal surfaces, and other articles using conveyorized or continuous-web vapor degreasing machines in industrial or commercial settings.

iii. Industrial and commercial use as solvent for cold cleaning.

This condition of use refers to the industrial or commercial use of methylene chloride as a non-boiling solvent in cold-cleaning to dissolve oils, greases, and other surface contaminants from textiles, glassware, metal surfaces, and other articles.

iv. Industrial and commercial use as solvent for aerosol spray degreaser/cleaner.

This condition of use refers to industrial or commercial use of methylene chloride in aerosol degreasing as an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from fabricated parts or machinery (including circuit boards and electronics).

v. Industrial and commercial use in adhesives, sealants, and caulks.

This condition of use refers to industrial or commercial use of methylene chloride in adhesives, sealants, and caulks to promote bonding between other substances, promote adhesion of surfaces, or prevent seepage of moisture or air.

vi. Industrial and commercial use in paints and coatings.

This condition of use refers to industrial or commercial use of methylene chloride in paints or coatings applied to surfaces, usually to enhance properties such as water repellency,

gloss, fade resistance, ease of application, or foam prevention, etc.

vii. Industrial and commercial use in paint and coating removers.

This condition of use refers to industrial or commercial use of methylene chloride or methylene chloride-containing products applied to surfaces to remove paint, coatings, and other finishes and to clean the underlying surface, including but not limited to furniture refinishing.

viii. Industrial and commercial use in adhesive and caulk removers.

This condition of use refers to industrial or commercial use of methylene chloride in products in industrial or commercial settings applied to surfaces to unbind substances or remove sealants and to clean the underlying surface by softening adhesives, caulks, and other glues so they can be removed.

ix. Industrial and commercial use in metal aerosol degreasers.

This condition of use refers to the industrial or commercial use of methylene chloride in aerosol degreasing as an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from fabricated parts, machinery, or other metal substrate.

x. Industrial and commercial use in metal non-aerosol degreasers.

This condition of use refers to the industrial or commercial use of methylene chloride in liquid degreasing to remove residual contaminants from fabricated parts, machinery, or other metal substrate.

xi. Industrial and commercial use in finishing products for fabric, textiles, and leather.

This condition of use refers to industrial or commercial use of methylene chloride in the finishing of fabrics at fabric or textile mills, including in products that impart color or other desirable properties to fabrics or textiles. The methylene chloride may be added during the manufacturing of the textile or during the finishing, such as pressing of the fabric.

xii. Industrial and commercial use in automotive care products (functional fluids for air

conditioners).

This condition of use refers to the industrial or commercial use of methylene chloride for one or more operational properties in a closed system in products intended for automotive care and includes automotive air conditioner refrigerant and as a refrigerant with stop leak sealant.

xiii. Industrial and commercial use in automotive care products (interior car care).

This condition of use refers to the industrial or commercial use of methylene chloride in cleaning agents used to remove stains from interior carpets and textiles in automotive vehicles.

xiv. Industrial and commercial use in automotive care products (degreasers).

This condition of use refers to the industrial or commercial use of methylene chloride in liquid or aerosol degreasing to remove residual contaminants from automotive substrates and articles.

xv. Industrial and commercial use in apparel and footwear care products.

This condition of use refers to the industrial or commercial use of methylene chloride in apparel and footwear care products as post-market waxes, polishes, or other media and applied to footwear, textiles, or fabrics to impart color or other desirable properties.

xvi. Industrial and commercial use in spot removers for apparel and textiles.

This condition of use refers to the industrial or commercial use of methylene chloride or methylene chloride-containing products applied from squeeze bottles, hand-held spray bottles, or spray guns, either before or after a cleaning cycle on apparel and textiles. After application, the methylene chloride or product is removed by manually scraping or flushing away the stain by using a brush, spatula, pressurized air, or steam.

xvii. Industrial and commercial use in liquid lubricants and greases.

This condition of use refers to the industrial or commercial use of methylene chloride in liquids that reduce friction, heat generation, and wear between surfaces.

xviii. Industrial and commercial use in spray lubricants and greases.

This condition of use refers to the industrial or commercial use of methylene chloride in sprays that reduce friction, heat generation, and wear between surfaces.

xix. Industrial and commercial use in aerosol degreasers and cleaners.

This condition of use refers to the industrial or commercial use of methylene chloride in aerosol degreasing as an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from a fabricated part or other substrate.

xx. Industrial and commercial use in non-aerosol degreasers and cleaners.

This condition of use refers to the industrial or commercial use of methylene chloride in liquid degreasing to remove residual contaminants (such as oils, greases, and similar materials) from a fabricated part or other substrate (such as textiles, glassware, products, and other articles).

xxi. Industrial and commercial use in cold pipe insulations.

This condition of use refers to the industrial or commercial use of methylene chloride when typically applied in aerosolized form in products used in building and construction materials to provide insulation.

xxii. Industrial and commercial use as a solvent that becomes part of a formulation or mixture.

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.

xxiii. 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.

xxiv. Industrial and commercial use as propellant and blowing agent.

This condition of use refers to the industrial or commercial use of methylene chloride in the production of polyurethane foam including as a blowing agent and as a solvent for cleaning equipment.

xxv. 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. In response to a request for clarification, EPA agrees that use of methylene chloride in a closed-loop chiller system used to perform FAA-required aviation fuel testing is considered industrial and commercial use as a laboratory chemical (Ref. 31). The analogous use of methylene chloride in a chiller system in the Department of Defense McKinley Climactic Laboratory would likewise be considered industrial and commercial use as a laboratory chemical.

xxvi. Industrial and commercial use for electrical equipment, appliance, and component manufacturing.

This condition of use refers to the industrial or commercial use of methylene chloride in electrical and electronic products; their maintenance; their manufacture, such as in the production of printed circuit boards; and at wholesalers and retail stores.

xxviii. 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.

xxix. Industrial and commercial use in cellulose triacetate film production.

This condition of use refers to the industrial or commercial use of methylene chloride as a chemical processor for polycarbonate resins and cellulose triacetate (photographic film).

xxx. Industrial and commercial use as anti-spatter welding aerosol.

This condition of use refers to the industrial or commercial use of methylene chloride in formulations to prevent spatter from adhering to metal surfaces during welding.

xxxi. Industrial and commercial use for oil and gas drilling, extraction, and support activities.

This condition of use refers to the industrial or commercial use of methylene chloride in the extraction, development, and preparation of oil, liquid crude petroleum, and gas. Activities may include exploration for crude petroleum and natural gas, core sampling, drilling wells, operating separator, emulsion breakers, and distilling equipment.

xxxii. Industrial and commercial use for toys, playgrounds, and sporting equipment.

This condition of use refers to the industrial or commercial use of methylene chloride in the manufacture of toys intended for children's use (and child-dedicated articles), including fabrics, textiles, and apparel (which may include stuffed toys, blankets, or comfort objects) as well as plastic articles (hard) (which may include dolls, toy cars, toy animals, or teething rings).

xxxiii. Industrial and commercial use in lithographic printing plate cleaner.

This condition of use refers to the industrial or commercial use of methylene chloride in lithographic printing for the cleaning of plates and rollers.

xxxiv. Industrial and commercial use in carbon remover, wood floor cleaner, and brush cleaner.

This condition of use refers to the industrial or commercial use of methylene chloride in formulated products to remove carbon and other dirt and residues from a variety of surfaces

including floors and brushes.

d. Consumer uses.

i. Consumer use as a solvent in aerosol degreasers/cleaners.

This condition of use refers to consumer use of products containing methylene chloride as a solvent for cleaning or degreasing in the form of an aerosol spray degreaser or cleaner. The products are used to dissolve oils, greases, and similar materials from textiles, glassware, metal surfaces, and other articles.

ii. Consumer use in adhesives and sealants.

This condition of use refers to consumer use of methylene chloride in single or two-component products used to fasten other materials together or prevent the passage of liquid or gas.

iii. Consumer use in brush cleaners for paints and coatings.

This condition of use refers to consumer use of products containing methylene chloride to clean brushes after using them to apply paints or coatings.

iv. Consumer use in adhesive and caulk removers.

This condition of use refers to consumer use of products containing methylene chloride to remove, loosen, or deteriorate any adhesive or caulk from a substrate, such as floor adhesive removal.

v. Consumer use in metal degreasers.

This condition of use refers to consumer use of products containing methylene chloride for the degreasing of metals, such as coil cleaners and electronics cleaners.

vi. Consumer use in automotive care products (functional fluids for air conditioners).

This condition of use refers to consumer use of products containing methylene chloride for automotive care and includes automotive air conditioner refrigerant and leak sealant.

vii. Consumer use in automotive care products (degreasers).

This condition of use refers to consumer use of products containing methylene chloride for automotive care and includes products for degreasing automotive parts, such as brakes, carburetors, engines, and gaskets.

viii. Consumer use in lubricants and greases.

This condition of use refers to consumer use of products containing methylene chloride to reduce friction, heat generation, and wear between solid surfaces, such as engines and brakes.

ix. Consumer use in cold pipe insulation.

This condition of use refers to consumer use of products containing methylene chloride used in building and construction materials to provide insulation.

x. Consumer use in arts, crafts, and hobby materials glue.

This condition of use refers to consumer use of arts, crafts, and hobby materials, such as glues, containing methylene chloride.

xi. Consumer use in an anti-spatter welding aerosol.

This condition of use refers to consumer use of products containing methylene chloride to prevent the spatter of the welding from sticking to welding material or a nearby surface (for example, workbenches).

xii. Consumer use in carbon removers and other brush cleaners.

This condition of use refers to consumer use of products containing methylene chloride for cleaning applications to remove carbon, inks and paints, grease, or other foreign matter. The cleaning operations include carbon removers (for example, to clean appliances, pots, and pans) and other applications that usually involve the use of a brush (for example, in lithographic printing cleaners, in taxidermy, and in wood and floor cleaners).

e. 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.

f. Terminology in this proposed rule.

For the purposes of this proposed rulemaking, "occupational conditions of use" refers to the TSCA conditions of use described in Units III.B.1.a, b, c, and e. Although EPA identified both industrial and commercial uses in the 2020 Risk Evaluation for Methylene Chloride 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, in the 2020 Risk Evaluation for Methylene Chloride, 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)). EPA determined that all industrial, commercial, and consumer use of methylene chloride evaluated in the 2020 Risk Evaluation for Methylene Chloride drives the unreasonable risk of injury to health. As such, for purposes of this risk management rulemaking, "consumer use" refers to all known, intended, or reasonably foreseen methylene chloride consumer uses. Likewise, for the purpose of this risk management rulemaking, "industrial and commercial use" refers to all known, intended, or reasonably foreseen methylene chloride industrial and commercial use.

EPA further notes that this proposed rule does not apply to any substance excluded from the definition of "chemical substance" under TSCA section 3(2)(B)(ii) 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.

EPA is not proposing to incorporate the descriptions in Units III.B.1.a through III.B.1.e. into the regulatory text as definitions. EPA requests comment on whether a definition should be promulgated for each condition of use of methylene chloride and, if so, whether the descriptions in this Unit are consistent with the conditions of use evaluated in the 2020 Risk Evaluation for Methylene Chloride and whether they provide a sufficient level of detail such that they would improve the clarity and readability of the regulation if promulgated.

2. Description of unreasonable risk under the conditions of use.

EPA has determined that methylene chloride presents an unreasonable risk of injury to human health under the conditions of use based on acute and chronic non-cancer risks and chronic cancer risks. 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. However, EPA also 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 endpoint for risk management, EPA's action will also eliminate the unreasonable risks from acute, chronic

non-cancer and cancer endpoints from 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. 32). Eighty-five occupational 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; there has been no linear trend indicating a decrease in fatalities during that time period (Ref. 32). In some instances, while workers were wearing respirators, the respirators were inadequate to protect against methylene chloride inhalation exposure (Ref. 32). Unit VI.A. summarizes the health effects and the magnitude of the exposures in more detail.

To make the unreasonable risk determination for methylene chloride, EPA evaluated exposures to workers, occupational non-users, consumer users, and bystanders using reasonably available monitoring and modeling data for inhalation and dermal exposures. In addition, EPA conducted a screening level analysis to assess risks from the air and water pathways to fenceline communities. A discussion of EPA's analysis and the expected effects of this rulemaking on fenceline communities is in Unit VI.A.

For the 2020 Risk Evaluation for Methylene Chloride, EPA considered potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by the Agency. There are several groups of individuals with greater exposure to methylene chloride relative to the general population, including: 1) Workers and occupational non-users, and 2) Consumer users and bystanders to consumer use of products containing methylene chloride (Ref. 1). EPA also identified several human subpopulations which may have greater susceptibility than the general population to the hazards of methylene chloride, including individuals with certain

genetic polymorphisms (variant forms of a specific DNA sequence) that may make them more susceptible to getting cancer from methylene chloride, and individuals with cardiac disease and other comorbidities, who may be at increased risk for angina from acute exposures (Ref. 1). All potentially exposed or susceptible subpopulations are included in the quantitative and qualitative analyses described in the 2020 Risk Evaluation for Methylene Chloride and were considered in the determination of unreasonable risk for methylene chloride. As discussed in Units II.D. and VI.A., the 2020 Risk Evaluation for Methylene Chloride excluded the air and water exposure pathways from the published risk evaluations and may have caused some risks to be unaccounted for in the risk evaluation. EPA considers receptors exposed to methylene chloride through those pathways to constitute a subset of the general population and categorizes them as fenceline communities; they may also be considered potentially exposed or susceptible subpopulations. See Unit VI.A. for further discussion on assessing and protecting risk to fenceline communities.

3. Description of TSCA section 6 requirements for risk management.

EPA examined the TSCA section 6(a) requirements (listed in Unit III.A.) to identify which ones have the potential to eliminate the unreasonable risk from methylene chloride. This Unit summarizes the TSCA section 6 considerations for issuing regulations under TSCA section 6(a). Unit V. outlines how EPA applied these considerations specifically to 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. 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 (see Unit III.B.1.f.), 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 does not have direct authority to regulate consumer use. Therefore, EPA 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) requirements. To the extent practicable, EPA factored into its decisions: (i) the effects of methylene chloride on health and the environment, (ii) the magnitude of exposure to methylene chloride of human beings and the environment, (iii) the benefits of methylene chloride for various uses, and (iv) the reasonably ascertainable economic consequences of the rule. In evaluating the reasonably ascertainable economic consequences of the rule, EPA considered 1) The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; 2) The costs and benefits of the proposed regulatory action and one or more primary alternative regulatory actions considered; and 3) The cost effectiveness of the proposed regulatory action and of the one or more primary alternative regulatory actions considered. TSCA section 6(c)(2)(A) considerations for methylene chloride are discussed in full in Unit VI., including the statement of effects of the proposed rule with respect to these considerations.

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 for all or part of this risk management action to be addressed 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.

In addition, EPA followed other TSCA requirements such as considering the availability of alternatives when contemplating prohibition or a substantial restriction (TSCA section 6(c)(2)(C), as outlined in Unit III.B.4.), and setting proposed compliance dates in accordance with the requirements in TSCA section 6(d)(1)(B) (described in the proposed and alternative regulatory action in Unit IV.).

To the extent information was reasonably available, EPA considered pollution prevention strategies and the hierarchy of controls adopted by OSHA and NIOSH, as discussed in Unit II.C.4., when selecting regulatory actions, with the goal of identifying risk management control methods that are 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, as well as input from stakeholders (as described in Unit III.A.) and anticipated compliance strategies from regulated entities.

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

As demonstrated by the number of distinct programs addressed in this rulemaking and the structure of this proposed rule in addressing them independently, EPA generally intends the rule's provisions to be severable from each other. EPA expects to provide additional detail on severability in the final rule once the Agency has considered public comments and finalized the regulatory language.

IV. Proposed Regulatory and Alternative Regulatory Actions

This Unit describes the proposed regulatory action by EPA so that methylene chloride will no longer present an unreasonable risk of injury to health. In addition, as indicated by TSCA section 6(c)(2)(A), EPA must consider the costs and benefits and the cost-effectiveness of the proposed regulatory action and one or more primary alternative regulatory actions. In the case of methylene chloride, the proposed regulatory action is described in Unit IV.A. and the alternative regulatory action considered is described in Unit IV.B. An overview of the proposed regulatory action and primary alternative regulatory action for each condition of use is in Unit IV.C.

A. Proposed Regulatory Action

EPA is proposing under TSCA section 6(a) to: Require a WCPP, including inhalation exposure concentration limits and related monitoring, for ten conditions of use, outlined in Unit IV.A.1.; Prohibit most industrial and commercial use of methylene chloride, outlined in Unit IV.A.2.; Prohibit the manufacture, processing, and distribution in commerce of methylene chloride for all consumer use (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), outlined in Unit IV.A.3.; Establish recordkeeping and downstream notification requirements, outlined in Unit IV.A.4.; and Provide a 10-year, time-limited exemption under TSCA section 6(g) for paint and coating removal by civilian aviation from a prohibition that would significantly disrupt critical infrastructure, as outlined in Unit IV.A.5., with conditions for this exemption to include compliance with the WCPP described in Unit IV.A.1.

1. Workplace Chemical Protection Program (WCPP).

a. Overview.

As described in Unit I., under TSCA section 6(a), 15 U.S.C. 2605(a), EPA is required to issue a regulation applying one or more of the TSCA section 6(a) requirements to the extent

necessary so that the unreasonable risk of injury to human health or the environment from a chemical substance is no longer presented. The TSCA section 6(a) requirements provide EPA the authority to limit or prohibit a number of activities, including, but not limited to, restricting or regulating the manufacture, processing, distribution in commerce, commercial use, or disposal of the chemical substance. Given this statutory authority, EPA may find it appropriate in certain circumstances to propose a WCPP for certain occupational (*i.e.*, industrial and commercial) conditions of use. 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 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. EPA's intention is to require a comprehensive WCPP that would 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 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 described in Units III.B.1.a. through III.B.1.e. and subject to the WCPP is occurring. The term includes any person who owns, leases, operates, controls, or supervises such a workplace.

EPA is proposing a 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 or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and spacecraft 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 applications by Federal agencies and their contractors; and disposal (EPA's rationale is provided in Unit V.). EPA is additionally proposing to require that uses receiving an exemption under TSCA section 6(g), as outlined in Unit IV.A.5., comply with the WCPP. EPA is proposing that these requirements take effect 180 days after publication of the final rule, at which point entities would be required to conduct initial monitoring (as described in Unit IV.A.1.c.). Additionally, EPA would require the implementation of any needed exposure controls based on initial monitoring and development of an exposure control plan within 1 year of publication of the final rule (Unit IV.A.1.d.). EPA believes these timeframes are achievable because they are consistent with the timeframes in OSHA's 1997 standard for methylene chloride (62 FR 1494, January 10, 1997). EPA is requesting comment on these proposed implementation timeframes for the WCPP requirements.

When considering and developing a WCPP that includes an ECEL, EPA coordinates and consults with other Federal agencies to achieve the maximum enforcement of TSCA while avoiding imposing duplicative requirements, consistent with TSCA section 9(d). For methylene

chloride, EPA's streamlined approach for implementing the ECEL would seek to align with, to the extent possible, certain elements of the existing OSHA standard for regulating methylene chloride under 29 CFR 1910.1052. The OSHA PEL, action level, STEL, and ancillary requirements have established a strong precedent for exposure limit threshold requirements within the regulated community. However, the existing PEL and STEL do not eliminate the unreasonable risk identified by EPA under TSCA, and EPA is therefore proposing to apply new, lower, exposure thresholds, derived from the TSCA 2020 Risk Evaluation for Methylene Chloride, while aligning with existing requirements wherever possible (Refs. 1, 11). For methylene chloride, this approach would eliminate the unreasonable risk driven 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 proposed requirements include specific exposure limits and ancillary requirements necessary for the ECEL's successful implementation as part of a WCPP. Taken together, these WCPP requirements would apply to the extent necessary so that the unreasonable risk driven by the conditions of use listed earlier in this Unit would no longer be presented. EPA's proposal would align with existing requirements from the OSHA methylene chloride standard at 29 CFR 1910.1052 to the extent possible (also summarized in Unit V.A.). As discussed in Unit II.B.3., because the unreasonable risk driven by these occupational conditions of use cannot be addressed entirely through the continued application of the OSHA standard and associated requirements, EPA is proposing additional requirements for lower exposure limits, user notification, recordkeeping, periodic monitoring, and respirator selection criteria as part of the WCPP. EPA acknowledges that the values of the ECEL, the ECEL action level, and the EPA STEL, outlined in Unit IV.A.1.b., may mean that some entities that are currently in compliance with the OSHA standard will have to increase the frequency and scope of their compliance

activities in order to achieve compliance with the requirements being proposed in this action, such as through the implementation of engineering controls to reduce exposures to the extent feasible, periodic exposure monitoring frequency (Unit IV.A.1.c.iii.), establishment of regulated areas (Unit IV.A.1.d.), use of respiratory protection (Unit IV.A.1.e.ii.), and notification of monitoring results (Unit IV.A.1.f.ii.).

This Unit includes a summary of the WCPP, including a description of proposed exposure limits including an ECEL, ECEL action level, and EPA STEL; proposed 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 requirements proposed for recordkeeping, workplace participation, and notification in accordance with the hierarchy of controls. This Unit also describes compliance timeframes for these proposed requirements.

b. Existing Chemical Exposure Limit (ECEL), EPA Action Level (AL), and Short-Term Exposure Limit (STEL)

To reduce exposures in the workplace and address the inhalation exposures to methylene chloride for occupational conditions of use that drive to the unreasonable risk of injury to human health, EPA is proposing an ECEL under TSCA section 6(a) of 2 ppm (8 mg/m^3) as an 8-hour TWA based on the chronic non-cancer human equivalent concentration for liver toxicity. EPA has determined, as a matter of risk management policy, that ensuring exposures remain at or below the ECEL will eliminate the unreasonable risk of injury to health resulting from acute and chronic inhalation exposures for certain occupational conditions of use. EPA's description for how the requirements related to an ECEL would address the unreasonable risk driven by those occupational conditions of use and the rationale for the regulatory approach of a WCPP are in Unit V.A.

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, a potentially exposed person would be protected against the effects described in Unit III.B.3., including effects resulting from acute exposure (central nervous system depression), chronic non-cancer effects (liver toxicity), and cancer. As an example, the incremental individual cancer risk at the 8-hour ECEL is 5.1×10^{-6}, which is lower than the occupational benchmark for cancer risk of 1×10^{-4} cited in the 2020 Risk Evaluation for Methylene Chloride and the NIOSH Chemical Carcinogen Policy (Ref. 33).

EPA is also proposing to establish an ECEL action level at half of the 8-hour ECEL, or 1 ppm (4 mg/m^3) as an 8-hour time-weighted average. The ECEL action level would be a definitive cut-off point below which certain compliance activities, such as periodic monitoring, would not be required as described further in this Unit. As explained by OSHA, an action level provides employers and employees with confidence that exposure reduction actions could be taken before inhalation exposure to methylene chloride exceeds the inhalation exposure limit (Ref. 34). EPA agrees with this reasoning and, like OSHA, expects the inclusion of an ECEL action level will stimulate innovation within industry to reduce exposures to methylene chloride to levels below the action level (Ref. 34). Therefore, EPA has identified a need for an action level for methylene chloride and is proposing a level that would be half the 8-hour ECEL, which is in alignment with the precedented approach established by OSHA (Ref. 34).

In addition to the 8-hour TWA ECEL, EPA is proposing a STEL of 16 ppm (57 mg/m3) as a 15-minute TWA. This short-term exposure limit is based on the non-cancer endpoint of central nervous system depression resulting from acute exposures. EPA has also determined, as a matter of risk management policy, that ensuring exposures remain at or below the EPA STEL will eliminate the unreasonable risk of injury to health driven by acute inhalation exposures in an occupational setting. EPA is proposing the EPA STEL 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 time-weighted average. EPA is also proposing the EPA STEL in consideration of the severe and potentially irreversible hazards of such short-term exposures, which, as described in Unit II.B.2., can range from blurred vision to death.

In summary, EPA is proposing 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 identified as 1 ppm as an 8-hour TWA. EPA is also proposing 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 a 15-minute TWA, or EPA STEL, of 16 ppm. EPA is proposing 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, thus eliminating the unreasonable risk of injury to human health driven by those conditions of use. For the identified conditions of use for which the concentration thresholds are being proposed, EPA expects that the regulated community has the ability to detect the values for the ECEL, ECEL action level, and EPA STEL because these limits are above the detection limits of methylene chloride 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. 11). EPA's methodology and inputs for the ECEL and EPA STEL values is directly derived from the peer reviewed analysis in the 2020 Risk Evaluation for Methylene Chloride, which was also subject to public comment (Ref 13). As with all aspects of this rulemaking, the public is welcome to comment on the methodology for the ECEL and EPA STEL values.

As discussed further in Unit V.A.1., for many of the conditions of use for which EPA is

proposing a WCPP, data was submitted during the risk evaluation and SBAR process that indicates some facilities may already be in compliance with the proposed methylene chloride ECEL. As noted previously in this Unit, EPA expects that, if inhalation exposures for affected occupational conditions of use are kept at or below the ECEL and EPA STEL, potentially exposed persons reasonably likely to be exposed in the workplace would be protected from the unreasonable risk associated with covered occupational conditions of use. EPA is also proposing to require owners or operators to comply with additional requirements that would be needed to ensure successful implementation of the ECEL and EPA STEL.

c. Monitoring requirements.

i. In general.

Monitoring requirements are a key component of implementing EPA's proposed requirements for a WCPP. 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 proposes to require that owners or operators determine each potentially exposed person's exposure by taking a personal breathing zone air sample of each potentially exposed person's exposure, or by taking personal breathing zone air samples that are representative of each potentially exposed person's exposure. Owners or operators would 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. These requirements align with the approach taken for characterization of employee exposure in the 1997 OSHA standard for methylene chloride (see 29 CFR 1910.1052(d)(1)(i) and (ii)). EPA also proposes to require that the owner or operator ensure, for initial and periodic monitoring, that their methods and metering results used in performance of the exposure monitoring 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)). EPA acknowledges that new monitoring methods or technologies may have been developed since 1997 that would allow for greater accuracy, and thus a smaller range for monitoring results, and EPA requests comment on the exposure monitoring accuracy requirements outlined in this Unit. Therefore, while the EPA requirements utilize the values of the ECEL, ECEL action level, and EPA STEL, the approach should be familiar to the regulated community. To ensure compliance for monitoring activities, EPA proposes recordkeeping requirements outlined in this Unit. EPA acknowledges that the 25% buffer for the 8-hour and 15-

minute TWA potentially could allow some exposures above the exposure limits proposed here. EPA requests comment on these buffers' effects and any alternatives to account for measurement variance or uncertainty.

ii. Initial exposure monitoring.

Under the proposed regulation, each owner or operator of a facility engaged in one or more of the conditions of use listed earlier in Unit IV.A.1.a. would be required to perform initial exposure monitoring 180 days after publication of the final rule to determine the extent of exposure of potentially exposed persons to methylene chloride. Initial monitoring would 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 monitoring sample would be required to be taken when and where the operating conditions are best representative of each potentially exposed person's full-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 include persons closest to the source of methylene chloride, so that the monitoring results would be representative of the most highly exposed persons in the workplace. Additionally, analogous to the OSHA standard, EPA expects that owners and operators would conduct initial exposure monitoring representative of all tasks a potentially exposed person would be expected to do. EPA understands that certain tasks may occur less frequently or may reflect upset conditions (for example, due to malfunction). EPA is soliciting comments regarding how owners and operators could conduct

initial exposure monitoring to ensure that it is representative of all tasks likely to be conducted by potentially exposed persons.

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 re-establish a monitoring baseline. Aligning with the existing OSHA standard (29 CFR 1910.1052(d)(2)) to the extent possible, EPA is proposing 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 5 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. The oldest objective data used to demonstrate that exposures are below the ECEL action level and EPA STEL will indicate the beginning of the 5-year cycles of recurring initial exposure monitoring as described in this Unit;

(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, unlike the OSHA standards in 29 CFR 1910.1052(d)(2) to (d)(3), the owner or operator must conduct an initial monitoring at least once every 5 years since its last monitoring. This new initial monitoring would have to 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.A.1.a. after the effective date of the rule, the owner or operator would be required to perform initial exposure monitoring within 180 days and would be required to, at a minimum, conduct initial exposure monitoring every 5 years thereafter if methylene chloride is present in the facility. EPA is soliciting comments regarding the proposed requirement for recurring 5-year initial exposure monitoring.

iii. Periodic exposure monitoring.

EPA's proposal 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 proposing the following periodic monitoring for owners or operators. These proposed requirements are also outlined in Table 1.

• If all samples taken during the initial exposure monitoring reveal: a concentration 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 not be required, except when additional exposure monitoring (Unit IV.A.1.c.v.) 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 not be required except when additional monitoring (Unit IV.A.1.c.v.) measurements require it, but EPA STEL periodic monitoring would be required every 3 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 would be required to be monitored every 6 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 would be required to be monitored every 6 months and EPA STEL would be required to be monitored every 3 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 would be required to be monitored every 3 months.

• The owner or operator would be permitted to alter the periodic exposure monitoring frequency from every 3 months to every 6 months if two consecutive monitoring events taken at least 7 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 periodic exposure monitoring frequency of every 6 months to an initial exposure monitoring frequency of once every 5 years if two consecutive monitoring events taken at least 7 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 5-year initial exposure monitoring must occur.

In addition to the periodic monitoring standards described earlier, EPA is proposing 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 3-month interval but does not engage in any of the conditions of use listed in Unit IV.A.1.a. for which the WCPP is proposed over the entirety of those 3 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.A.1.a. for which the WCPP is proposed.

• Based on its monitoring results, if the owner or operator would be required to monitor the ECEL in a 6-month interval but does not engage in any of the conditions of use listed in Unit IV.A.1.a. for which the WCPP is proposed over the entirety of those 6 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.A.1.a. for which the WCPP is proposed.

• Initial monitoring would be required to occur at least once every 5 years if methylene chloride is present. EPA requests comment on the timeframes for periodic monitoring outlined in this Unit, particularly whether more frequent monitoring may be possible or recommended.

Table 1 — Periodic Monitoring Requirements Based on Initial Exposure Monitoring Results

Air Concentration Condition	Periodic Monitoring Requirement
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 not required.
If the initial exposure monitoring concentration is below the ECEL action level and above the EPA STEL	ECEL monitoring not required and EPA STEL 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 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 monitoring every 6 months and EPA STEL monitoring every 3 months.
If the initial exposure monitoring concentration is above the ECEL and below, at, or above the EPA STEL	ECEL monitoring every 3 months and EPA STEL monitoring every 3 months.
Two consecutive monitoring events have taken place 7 days apart that indicate that potential exposure has decreased from above	Reduce periodic monitoring frequency from every 3 months to every 6 months.

the ECEL to at or below the ECEL, but at or above the ECEL action level	
Two consecutive monitoring events have taken place 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 periodic monitoring frequency of every 6 months to initial monitoring once every 5 years. The second consecutive monitoring event will delineate the new date from which the next 5-year initial exposure monitoring must occur.
If the owner or operator engages in any of the conditions of use for which WCPP is proposed 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	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 proposed.
Owner or operator engages in any of the conditions of use for which WCPP is proposed 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	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 proposed.

NOTE: Additional scenarios in which monitoring may be required are discussed in Unit IV.A.1.c.v.

iv. Minimum frequency of exposure monitoring.

EPA is proposing to require that an initial monitoring event be conducted at a minimum frequency of every 5 years by owners or operators using methylene chloride for any condition of use subject to the WCPP. This in contrast to OSHA's standards in 1910.1052(d)(2) to (d)(3) whereby employers would otherwise be permitted to discontinue monitoring indefinitely based on monitoring results. Moreover, EPA is proposing that monitoring requirements could only be made less frequent based on the results of the initial exposure monitoring or the periodic exposure monitoring outlined under Unit IV.A.1.c.iii.

OSHA's standards in 1910.1052(d)(2)(i) through (iii) allow for a discontinuation of initial monitoring which subsequently precludes the need for periodic monitoring unless

additional monitoring is required under certain conditions. Given the steep dose response for methylene chloride that may lead up to and include fatalities as a result of inhalation exposure, EPA is instead proposing to require that a minimum initial monitoring frequency be established at 5-year intervals. EPA is requesting public comments on the proposed conditions for periodic monitoring for methylene chloride as part of implementation of the WCPP that differ from OSHA's existing monitoring requirements under 29 CFR 1910.1052.

v. Additional exposure monitoring.

In addition to initial and periodic monitoring, there are some additional circumstances that would require a new initial exposure monitoring. EPA is proposing that the owner or operator complying with the WCPP would carry out this additional exposure monitoring (analogous to those requirements outlined in 29 CFR 1910.1052(d)(4)) 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.

d. Exposure Control Plan (ECP).

EPA recommends and encourages the use of pollution prevention as a means of controlling exposures whenever practicable. Pollution prevention, also known as source

reduction, is any practice that reduces, eliminates, or prevents pollution at its source (*e.g.*, elimination and substitution, as described in the hierarchy of controls). While the WCPP is intended to be non-prescriptive to allow more flexibility to regulated entities than requiring specific prescriptive controls, EPA is proposing to require the use of elimination and substitution, followed by the use of engineering controls, administrative controls, and work practices prior to requiring the use of respirators as a means of controlling inhalation exposures below EPA's ECEL or STEL, in accordance with the hierarchy of controls. If an owner or operator chooses to replace methylene chloride with a substitute, EPA recommends that they carefully review 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 proposing a WCPP, compliance at most workplaces would be part of an established industrial hygiene program that aligns with the hierarchy of controls. Workplaces that cannot, in accordance with that hierarchy, eliminate the source of methylene chloride emissions or replace methylene chloride with a substitute would be required to use feasible engineering controls, and subsequently feasible administrative controls, to implement process changes to reduce exposures following the hierarchy of controls (Ref. 9). EPA also expects those owners or operators already implementing the OSHA PEL of 25 ppm as an 8-hour TWA would revise their monitoring program to follow EPA's ECEL requirements with EPA's lower ECEL of 2 ppm as an 8-hour TWA and EPA's STEL of 16 ppm as a 15-minute TWA.

Analogous to the OSHA Standard (29 CFR 1910.1052(e)), EPA is proposing to require 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. This regulated area would be demarcated using administrative controls, *e.g.*, highly visible signifiers, in multiple

languages as appropriate, placed in conspicuous areas, and documented through training and recordkeeping. The owner or operator would be required to restrict access to the regulated area from any potentially exposed person that lacks proper training or is otherwise unauthorized to enter.

EPA proposes to require regulated entities use the hierarchy of controls to the extent feasible and supplement further protections using PPE, 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 proposes to require the owner or operator to use feasible controls (including elimination, substitution, engineering controls, or administrative controls and work practices) to reduce methylene chloride concentrations in the workplace to the lowest levels achievable and, analogous to the requirements under 29 CFR 1910.1052(e)(3), 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 would require 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. EPA also proposes to require that the owner or operator document their efforts to use elimination, substitution, engineering controls, and administrative controls to reduce exposure to or below the ECEL or EPA STEL in an exposure control plan. In addition, analogous to the requirements under 29 CFR 1910.1052(f)(2), an owner or operator would be prohibited from rotating work schedules to comply with the ECEL 8-hour TWA.

EPA proposes to require 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:

(i) Identification 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;

(ii) If exposure controls were not selected, document the efforts identifying why these are not feasible, not effective, or otherwise not implemented;

(iii) Actions taken to implement exposure controls selected, including proper installation, maintenance, training, or other steps taken;

(iv) Regular inspections, evaluations, and updating of the exposure controls to ensure effectiveness and confirmation that all persons are using them accordingly;

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

(vi) Objective data generated during the previous 5 years, when used to forgo the initial exposure monitoring, must include: the use of methylene chloride being evaluated, the source of objective data, measurement methods, measurement results, and measurement analysis of the use of methylene chloride, and any other relevant data to the operations, processes, or person's exposure.

e. 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 proposes to set 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 proposing to require 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 proposing that the owner or operator comply with 29 CFR 1910.134 for proper use, maintenance, fit-testing, and training of respirators. EPA recognizes that there may be limitations in using certain types of PPE or respirator protection for various work scenarios such as cost, time burdens, ergonomic and dexterity considerations, climate, size, and capability.

i. Required dermal protection.

EPA is proposing to require 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 proposing to require owners and operators to continue to 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. 35) and in appendix F of the 2020 Risk Evaluation for Methylene Chloride (Ref. 1). EPA requests comment on the degree to which additional guidance

related to use of gloves might be necessary. Additionally, EPA requests comment on whether EPA should specifically incorporate dermal protection into the exposure control plan and require consideration of the hierarchy of controls for dermal exposures.

ii. Required respiratory protection.

EPA is proposing 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 (16ppm); see also the following table (Table 2). These requirements would 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 proposing to establish 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. While this Unit includes respirator selection requirements for respirators of Assigned Protection Factor (APF) of 1,000 or greater, EPA does not anticipate that respirators beyond APF 25 will be widely or regularly used to address unreasonable risk, particularly when other controls are put in place. EPA anticipates that owners or operators would attempt to minimize respirator costs by reducing inhalation exposures levels so that, if a respirator is needed, a supplied-air respirator could be used in lieu of a self-contained breathing apparatus. Under this proposed regulatory option, as with existing OSHA regulations, air-purifying respirators (in contrast to air-supplied respirators) would not be permitted as a means of mitigating methylene chloride exposure, as they do not provide adequate respiratory protection against this chemical (Ref. 36). Additionally, EPA acknowledges in Unit V.A.1. 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).

• If the measured exposure concentration is at or below the ECEL (2 ppm 8-hour TWA) and EPA STEL (16 ppm 15-minute TWA): no respiratory protection would be required.

• If the measured exposure concentration is above 2 ppm and less than or equal to 50 ppm (25 times the ECEL): the respirator protection required would be any NIOSH-certified supplied-air respirator (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 respirator protection required would be: (i) Any NIOSH-certified Supplied-Air Respirator (SAR) or airline respirator in a demand mode equipped with a full facepiece (APF 50); or (ii) Any NIOSH-certified Self-Contained Breathing Apparatus (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 respirator protection required would be: (i) Any NIOSH-certified 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-certified Supplied-Air Respirator (SAR) or Airline Respirator in pressure-demand or other positive-pressure mode equipped with a full facepiece (APF 1,000)); or (iii) Any NIOSH-certified Self-Contained Breathing Apparatus (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

Concentration Condition	**Minimum Required Respirator Protection**
At or below the ECEL and EPA STEL	No respirator required
Above ECEL (2 ppm) and less than or equal to 50 ppm	Any NIOSH-certified supplied-air respirator (SAR) or airline respirator in a continuous-flow mode equipped with a loose-

(25 times the ECEL)	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-certified Supplied-Air Respirator (SAR) or airline respirator in a demand mode equipped with a full facepiece (APF 50)); or (ii) any NIOSH-certified 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-certified 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-certified Supplied-Air Respirator (SAR) or Airline Respirator in pressure-demand or other positive-pressure mode equipped with a full facepiece (APF 1,000); or (iii) any NIOSH-certified 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)

f. Additional proposed requirements.

i. Workplace participation.

EPA encourages owners and operators to consult with potentially exposed persons on the development and implementation of exposure control plans and PPE/respirator programs. EPA is proposing to require owners and operators to 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 in workplace participation, EPA is proposing 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.

ii. Notification of monitoring results.

EPA proposes that when a potentially exposed person's exposure to methylene chloride exceeds the ECEL action level within a regulated area, the owner or operator would 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, analogous to those requirements outlined in 29 CFR 1910.1052(l). EPA proposes 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 (as described in Unit IV.A.1.d.). 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. 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 refer to a document available to the potentially exposed persons which states the actions to be taken to reduce exposures, and to 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). While 15 working days is consistent with requirements under the OSHA methylene chloride standard, EPA notes that it may be preferable to require more expedient notification of monitoring results, and that precedent exists in some circumstances for faster notification timeframes (*e.g.*, OSHA requirements for the construction sector require a 5-day timeframe). EPA therefore requests comment on the 15-day timeframe for notification of potentially exposed persons of monitoring results and the possibility for a shorter timeframe, such as 5 days.

iii. Recordkeeping.

For each monitoring event of methylene chloride, OSHA requires under 29 CFR 1910.1052(m) that the employer record 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 exposed employees' names, work shifts, and job classifications; and exposure of all the employees represented by monitoring, indicating which potentially exposed persons were actually monitored. EPA is requiring that this information is kept by the owner or operator of record for potentially exposed persons. In addition to the requirements outlined in 29 CFR 1910.1052(m)(2), EPA is proposing to require 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 monitoring 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. 11) 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.A.1.c.ii., 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 proposed in this Unit;

(iv) Compliance with the Good Laboratory Practice Standards at 40 CFR part 792;

(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 proposing that owners and operators must retain compliance records for 5 years, unless a longer retention time is 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.

All records required to be maintained by this Unit could be kept in the most administratively convenient form (electronic or paper). The owner or operator would be required to document training or re-training (analogous to 29 CFR 1910.1052(l)(5)) 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. EPA expects that the content of such training will not exceed what is already required by 29 CFR 1910.1052 section (l) and appendix A. In addition, the owner or operator would be 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.

g. Compliance timeframes.

With regard to the compliance timeframe for those occupational conditions of use which are subject to the WCPP, EPA is proposing to require that owners and operators establish initial exposure monitoring according to the process outlined in this Unit by [180 days after date of publication of the final rule in the *Federal Register*]. EPA is proposing to require 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 by [270 days after the date of publication of the final rule in the *Federal Register*], and 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 3 months after receipt of the results of any exposure monitoring or within 9 months after the date of publication of the final rule in the *Federal Register* (for any new facilities, or a facility commencing one or more conditions of use listed in Unit IV.A.1.a. after the effective date of the final rule, the timeframe for the requirement for initial exposure monitoring is described earlier in Unit IV.A.1.c.ii.; following that, the requirements and timeframes in this Unit would apply). EPA is also proposing to require owners and operators demarcate a regulated area within 3 months after receipt of any exposure monitoring that indicates exposures exceeding the ECEL or EPA STEL. Owners and operators should proceed accordingly to implement an exposure control plan by [360 days after date of publication of the final rule in the *Federal Register*]. EPA requests comment relative to the ability of owners or operators to conduct initial monitoring by [180 days after date of publication of the final rule in the *Federal Register*], and anticipated timelines for any procedural adjustments needed to comply with the requirements outlined in this Unit. EPA may finalize

shorter or longer compliance timeframes based on public comment.

2. Prohibition of certain industrial and commercial uses

Except for those uses which will continue under the WCPP, EPA is proposing to prohibit industrial and commercial use of methylene chloride, including use of methylene chloride in: solvent for batch vapor degreasing; solvent for in-line vapor degreasing; solvent for cold cleaning; solvent for aerosol spray degreaser/cleaner; adhesives, sealants, and caulks; paints and coatings; paint and coating removers (including furniture refinishers); adhesive and caulk removers; metal aerosol degreasers; metal non-aerosol degreasers; finishing products for fabric, textiles and leather; automotive care products (functional fluids for air conditioners); automotive care products (interior car care); automotive care products (degreasers); apparel and footwear care products; spot removers for apparel and textiles; liquid lubricants and greases; spray lubricants and greases; aerosol degreasers and cleaners; non-aerosol degreasers and cleaners; cold pipe insulations; solvent that becomes part of a formulation or mixture; processing aid; propellant and blowing agent; electrical equipment, appliance, and component manufacturing; plastic and rubber products manufacturing; cellulose triacetate film production; anti-spatter welding aerosol; oil and gas drilling, extraction, and support activities; toys, playground and sporting equipment; carbon remover, wood floor cleaner, and brush cleaner; and lithographic printing plate cleaner. This does not include manufacturing and processing of methylene chloride for commercial use or industrial and commercial use of methylene chloride as a laboratory chemical, for which EPA is proposing to require compliance with a WCPP for the reasons described in Unit III.B.3. This rationale is discussed further in Unit V.A.1.

As Discussed in Unit III.B.1.f., the restrictions in this proposed rule do not apply to any substance that is excluded from the definition of "chemical substance" under TSCA section 3(2)(B)(ii) through (vi). However, EPA requests comment on the impacts, if any, the proposed

prohibition described in this Unit, or other aspects of this proposal, may have on the production and availability of any food, food additive, drug, cosmetic, device, or other substance excluded from the definition of "chemical substance" under TSCA section 3(2)(B)(ii) through (vi).

As discussed in Unit III.B.3., based on consideration of alternatives, the broad range of work environments and activities, and the severity of the hazards of methylene chloride, EPA determined that prohibition is the best way to address the unreasonable risk from methylene chloride driven by the conditions of use identified in this Unit. EPA requests comment regarding the number of entities that could potentially close as well as associated costs with a prohibition of methylene chloride for certain industrial and commercial conditions of use identified in this Unit. EPA would also like comment on whether it should consider a *de minimis* level of methylene chloride in formulations for certain continuing industrial and commercial uses to account for impurities (*e.g.*, 0.1% or 0.5%) when finalizing the prohibitions described in this Unit, and, if so, what level should be considered *de minimis*.

EPA is proposing that the prohibition for uses described in this section 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). This proposal includes restrictions 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. When proposing these compliance dates, EPA considered sustained awareness of risks, including acute fatalities, resulting from methylene chloride exposure as well as precedent established by the OSHA standards (62 FR 1494, January 10, 1997). EPA has no information indicating that the proposed compliance dates are not practicable for the activities that would be prohibited, or that additional time is needed for products affected

by the proposed restrictions to clear the channels of trade. However, EPA requests comment on whether additional time is needed, for example, for products affected by proposed restrictions to clear the channels of trade. EPA may finalize shorter or longer compliance timeframes based on public comment.

Additionally, EPA recognizes that there may be instances where an ongoing use of methylene chloride that has implications for national security or critical infrastructure as it relates to other Federal agencies (*e.g.*, DOD, NASA) is identified after the methylene chloride rule is finalized, but the final rule prohibits that use. For instances like that, EPA requests comments on an appropriate, predictable process that could expedite reconsideration for uses that Federal agencies or their contractors become aware of after the final rule is issued using the tools available under TSCA, aligning with the requirements of TSCA section 6(g). One example of an approach could be the establishment by rulemaking of a Federal agency category of use that would require implementation of the WCPP and periodic reporting to EPA on details of the use as well as progress in discontinuing the use or finding a suitable alternative. To utilize the category of use a Federal agency would petition EPA, supported by documentation describing the specific use (including documentation of the specific need, service life of any relevant equipment, and specific identification of any applicable regulatory requirements or certifications, as well as the location and quantity of the chemical being used); the implications of cessation of this use for national security or critical infrastructure (including how the specific use would prevent injuries/fatalities or otherwise provide life-supporting functions); exposure control plan; and, for Federal agency uses where similar adoption by the commercial sector may be likely, concrete steps taken to identify, test, and qualify substitutes for the uses (including details on the substitutes tested and the specific certifications that would require updating; and estimates of the time required to identify, test, and qualify substitutes with supporting documentation). EPA

requests comment on whether these are the appropriate types of information for use in evaluating this type of category of use, and whether there are other considerations that should apply. EPA would make a decision on the petition within 30 days and publish the decision in the *Federal Register* shortly after. Additionally, during the year following the petition, EPA would take public comment on the approved petition and no later than 180 days after submitting the petition to EPA, the requesting agency would submit monitoring data indicating compliance with the WCPP at each relevant location as well as documentation of efforts to identify or qualify substitutes. In the absence of that confirmatory data, the utilization of the generic Federal agency category of use would expire within one year of the date of receipt by EPA of the petition. EPA could undertake a TSCA section 6(g) rulemaking for those instances where the federal agency could not demonstrate compliance with the WCPP. This is just one example of a potential process. EPA requests comments on a process that could expedite reconsideration for uses that Federal agencies or their contractors become aware of after the final rule is issued.

3. Prohibition of manufacturing, processing, and distribution of methylene chloride for consumer use.

In the 2020 Risk Evaluation for Methylene Chloride, EPA evaluated consumer use of methylene chloride: as a solvent in aerosol spray degreasers/cleaners; in adhesives and sealants in single component glues and adhesives and sealants in caulks; in paints and coatings in brush cleaners and in adhesive/caulk removers; in metal products in aerosol and non-aerosol degreasers and cleaners; in automotive care products in functional fluids for air conditioners and in degreasers; in lubricants and greases in liquid and spray lubricants and greasers and in aerosol and non-aerosol degreasers and cleaners; in building and construction materials in cold pipe insulation; in arts, crafts, and hobby materials in crafting glue and cement/concrete; and in other uses such as anti-spatter welding aerosol and in carbon remover and brush cleaner. All consumer

uses evaluated in the 2020 Risk Evaluation for Methylene Chloride drive unreasonable risk of injury to health. As such, for purposes of this risk management rulemaking, "consumer use" refers to all known, intended, or reasonably foreseen methylene chloride consumer uses. EPA is proposing to prohibit the manufacturing, processing, and distribution in commerce of methylene chloride for all consumer use. (The proposed prohibitions would not extend to the use of methylene chloride in consumer paint and coating removers since that use was not evaluated in the 2020 Risk Evaluation for Methylene Chloride and manufacturing, processing, and distribution for that use are already prohibited. 84 FR 11420 (March 27, 2019)).

As discussed in Unit III.B.3., based on consideration of the severity of the hazards of methylene chloride in conjunction with the limited options available to adequately address the identified unreasonable risk to consumers and bystanders under TSCA section 6(a), EPA is proposing to address the unreasonable risk from consumer use by prohibiting the manufacturing (including import), processing, and distribution in commerce of methylene chloride for consumer use in order to remove methylene chloride and products containing methylene chloride from the market, thereby effectively eliminating instances of consumer use.

Additionally, EPA is proposing to prohibit 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 outlined in Unit IV.A.1. from being purchased by consumers. 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 would prevent retailers from making these products available to consumers, which would help address that part of the unreasonable risk driven by consumer use of methylene chloride (Ref. 37). EPA promulgated a similar prohibition for retailers in the 2019 final rule addressing unreasonable risk from consumer use of methylene chloride in Paint and Coating Removal (84 FR 11420, March 27, 2019), and has not received negative feedback from retailers regarding sales losses. EPA has continued to receive feedback from stakeholders, including small businesses, on particular strategies they suggest could be used to ensure that distribution only occurs to commercial entities, such as requiring a business number (Ref. 6). To that end, EPA would like comment on whether distributors that are not retailers should be required to use tax IDs or other verification methods prior to selling methylene chloride or products containing methylene chloride to ensure consumers are not purchasing methylene chloride or industrial or commercial products containing methylene chloride.

Additionally, during litigation on the 2019 final rule petitioners argued that EPA's definition of "retailer" was so broad as to cover all commercial entities, creating supply chain issues for commercial users seeking to attain and use the chemical for commercial activities (*Lab. Council for Latin Am. Advancement v. United States Env't Prot. Agency*, 12 F.4th 234 (2d Cir. 2021)). EPA has not found this to be the case; small businesses that are non-retail distributors exist and even participated as small entity representatives consulted as part of the SBAR process for this rulemaking. Nonetheless, EPA is soliciting comment on whether similar supply chain issues for uses that are permitted under the WCPP are anticipated.

EPA is proposing that the prohibitions of manufacturing, processing, and distribution in commerce of methylene chloride for consumer use described in this section would occur in 90 days for manufacturers, 180 days for processers, 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*. EPA considered irreversible health effects and risks, such as acute fatalities, associated with methylene chloride when proposing compliance dates. EPA has no information indicating these compliance dates are not practicable for the activities that would be prohibited, or that additional time is needed for products affected by proposed restrictions to clear the channels of trade. However, EPA requests comment on whether additional time is needed, for example, for products affected by proposed restrictions to clear the channels of trade. EPA may finalize shorter or longer compliance timeframes based on public comment. EPA would also like comment on whether it should consider a *de minimis* level of methylene chloride in formulations for certain continuing industrial and commercial uses to account for impurities (*e.g.*, 0.1% or 0.5%) when finalizing these prohibitions, and, if so, what level should be considered *de minimis*.

4. Other requirements.

a. Recordkeeping.

For conditions of use that are not otherwise prohibited under this proposed regulation, EPA is also proposing 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 proposed regulation; and that they maintain such records for a period of 5 years from the date the record is generated. EPA notes that this 5-year record retention period is an increase from the 3-year requirements for records related to consumer paint and coating removal finalized in the 2019 final rule. However, the 3-year requirement still applies to records generated under that rule. EPA is proposing that this requirement begin at the effective date of the rule (60 days following publication of the final rule in the *Federal Register*). Recordkeeping requirements would ensure that owners or operators can demonstrate compliance with the proposed regulations if necessary. Note that this requirement would expand those

recordkeeping requirements promulgated in 2019 at 40 CFR 751.109 affecting manufacturers, processors, and distributors of methylene chloride.

b. Downstream notification.

For conditions of use that are not otherwise prohibited under this proposed regulation, EPA is proposing 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 [270 days after date of publication of the final rule in the *Federal Register*], this chemical/product cannot be distributed in commerce to retailers. After [360 days after date of publication of the final rule in the *Federal Register*], this chemical/product is and can only be distributed in commerce or processed 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 acrylic and polycarbonate in mission-critical military and space applications, including in the production of specialty batteries for such applications that is performed by the Department of Defense, the Department of Homeland Security, or the National Aeronautics and Space Administration or their contractors at locations controlled by the agency or the agency's contractor; (7) Industrial or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and spacecraft that are owned or operated by the U.S. Department of Defense, the National Aeronautics and Space Administration, the U.S. Department of Homeland Security, and the Federal Aviation Administration that is performed by the agency or agency contractors at locations controlled by the agency or the agency's contractor; (8) Industrial or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of other aircraft and spacecraft until [10 years after date of publication of the final rule in the *Federal Register*], and (9) Disposal.

The intention of downstream notification is to spread awareness throughout the supply chain of the restrictions on methylene chloride under TSCA as well as 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 751.111(a). As they become effective, the new amended requirements would supersede those notification requirements promulgated in 2019.

To provide adequate time to update the SDS and ensure that all products in the supply chain include the revised SDS, EPA is proposing a 150-day period for manufacturers and a 210-day period for processors and distributors to implement the proposed SDS changes (following publication of the final rule).

EPA requests comments on the appropriateness of identified compliance timeframes for recordkeeping and downstream notification requirements described in this Unit.

5. TSCA section 6(g) exemptions.

Under TSCA section 6(g)(1), EPA may grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture. TSCA section 6(g)(1)(B) permits such an exemption if EPA finds that compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure.

TSCA section 6(g)(2) requires EPA to analyze the need for the exemption, and to make public the analysis and a statement describing how the analysis was taken into account when proposing an exemption under TSCA section 6(g). To that end, based on discussions and information provided by industry stakeholders, EPA has analyzed the need for different exemptions and is proposing to grant two of them, with conditions as required under TSCA section 6(g)(4) and described in Units IV.A.5.a.ii. and IV.A.5.b.ii. This Unit presents the results of that analysis.

a. Uses of methylene chloride for paint and coating removal essential for critical infrastructure.

i. Analysis of the need for TSCA section 6(g)(1)(B) exemption for commercial aviation and aerospace.

EPA has preliminarily determined that a prohibition on the commercial use of methylene chloride for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and aerospace vehicles for commercial aviation and aerospace would significantly disrupt the national economy and critical infrastructure. Aviation has been designated by co-sector agencies DHS and DOT as a key subsector in the Transportation Systems Sector, one of 16 designated critical infrastructure sectors. There are no technically feasible alternatives currently available for methylene chloride used in paint and coating removal for safety-critical, corrosion-sensitive components of aircraft and aerospace vehicles. Thus, commercial aviation and aerospace compliance with the proposed ban on methylene chloride use in commercial paint and coating removal would significantly disrupt critical infrastructure.

As explained by a commenter on the 2017 Notice of Proposed Rulemaking (NPRM), all aircraft have similar safety-critical, corrosion-sensitive components of the type described by DOD (Ref. 38). For example, commercial aircraft often contain components, such as landing gear, that are made from high-strength alloy steels. According to this commenter, the aerospace industry, like DOD, has made significant investments in the evaluation of alternative methods and materials for removing coatings. The commenter states that the industry has had some success, depending upon the substrate, surface treatment, and coating system, but investigation continues into both chemical and non-chemical means. Non-chemical methods, such as plastic beads, were not suitable in all instances due to concerns about damaging the substrate. Many alternative chemical strippers were not effective on all coatings, which caused corrosion concerns in some cases. According to this commenter, benzyl alcohol is a qualified alternative paint remover for some paint formulations but cannot be considered a “drop-in” replacement for

all applications due to performance concerns.

The concerns expressed by this commenter about corrosion-sensitive components on aircraft and aerospace equipment echo the concerns over methylene chloride alternatives expressed by DOD and discussed at length in the preamble to EPA's 2017 proposal. For example, both the commenter and DOD stated that currently available substitute chemicals cannot completely remove certain coatings (Ref. 38). This results in improperly applied, incompletely adhering replacement coatings, which may result in corrosion of underlying critical parts. For another example, according to the commenter and DOD, substitute chemicals are also incompatible with some underlying metallic, nonmetallic, and composite materials, resulting in material damage to critical components, and the potential for an increased risk of catastrophic failure of safety critical parts. The commenter on the 2017 NPRM also stated that the process for evaluating and then adopting alternatives in aviation applications is a multi-year process. According to the commenter, the materials required to remove coatings on aircraft parts must be developed by a material formulator to meet technical performance requirements and must be "qualified by the Original Equipment Manufacturer (OEM), and then shown to not cause harm to the aircraft or negatively affect performance to the FAA prior to implementation" (Ref. 38). The commenter stated that this can take years, with no guarantee of success, so a longer timeframe for aviation and aerospace to make the transition is appropriate. The commenter suggested that 10 years would be a realistic estimate of the time needed.

More recently, Boeing provided information to EPA indicating that the company has invested considerable resources over many years to qualify and implement alternatives to methylene chloride, including a combination of acid, alkaline, and hydrogen peroxide-activated benzyl alcohol removers and plastic media blast (Ref. 31). Boeing continues to evaluate potential alternatives, such as laser ablation, which the company believes will, if implemented, eliminate

hazardous waste, address ergonomic challenges and save significant time over traditional paint and coating removal operations. According to Boeing, the company has identified several paint and coating removal applications with no feasible alternatives to methylene chloride (Ref. 31). These include:

• Large parts or parts with complex geometries that cannot undergo media blasting or strip tank immersion either due to size constraints or entrapment concerns, and where hand abrasion is impractical;

• Situations in which selective coating removal is needed, *e.g.*, the preservation of a conversion coating;

• Effective removal of oven-cured paints and coatings;

• Localized removal of coatings on overhaul or rework parts to reveal part markings and serial numbers;

• Stripping of parts preceding non-destructive testing, where other coating removal methods such as media blasting could hide defects; and

• Removal of polyvinyl formal or polyurethane insulating enamel from copper magnet wire.

While there are alternatives available for many applications, the public comments on the 2017 NPRM, and the information provided by Boeing in 2022 demonstrate there are several aviation and aerospace applications for which there are limited alternatives to methylene chloride for paint and coating removal, due to concerns about damage to the substrate, and these limited alternatives take longer to work. EPA has preliminarily determined that lengthening the time that commercial aircraft and spacecraft are out of service due to necessary safety inspections and repairs will have a considerable adverse impact on air travel and other infrastructure elements such as satellite placement. Therefore, EPA has preliminarily determined that requiring

commercial aviation and aerospace sectors to comply at this time with the ban on methylene chloride use in paint and coating removal would cause significant disruption to critical infrastructure. In addition, EPA has preliminarily determined that compliance at this time with the proposed ban on the manufacture, processing, and distribution in commerce of methylene chloride for commercial paint and coating removal for these specific commercial aviation and aerospace uses would also result in a significant disruption to critical infrastructure. EPA's proposed conditions for this exemption are described in this Unit, including proposed requirements to comply with the WCPP.

EPA acknowledges that in many cases commercial aviation facilities may be more sophisticated and industrialized than other commercial paint and coating removal operations. However, at the time of proposal, data available to EPA demonstrate that the risks from paint and coating removal in the aviation sector do not differ significantly from other commercial paint and coating removal (Ref. 1). As shown in the 2020 Risk Evaluation for Methylene Chloride, high-end and central tendency estimates for aircraft paint stripping are three orders of magnitude below the benchmark for acute inhalation risks and four orders of magnitude below the benchmark for chronic non-cancer inhalation risks (Ref. 1). Even if use of APF 50 air supplied respirators were assumed, the risks that remain for both high-end and central tendency would be an order of magnitude below the benchmark for both endpoints (Ref. 1). Therefore, while EPA expects that some of these facilities could successfully follow the requirements of the WCPP, based on qualitative information provided by stakeholders, this expectation is not sufficiently supported by monitoring data in the 2020 Risk Evaluation for Methylene Chloride. As a result, there is significant uncertainty whether the requirements of the WCPP could be implemented successfully in this sector for this particular use on a consistent and reliable basis, in part due to the diversity of facilities in this sector. EPA understands that generally large commercial aviation

facilities could have industrial hygiene expertise, sophisticated engineering and administrative controls, and experience with rigorous safety requirements and methods for ensuring continuous strong safety records (Ref. 31). However, EPA is concerned about the ability of smaller aircraft repair shops to implement the WCPP over the long term, particularly for this condition of use. While EPA recognizes that the proposed TSCA section 6(g) exemption for commercial aircraft paint and coating removal could also cover these smaller aircraft repair shops, the exemption is time-limited and ultimately would result in these small shops using alternatives to methylene chloride. While Federal agencies and contractors should be regulated under the WCPP, the Agency is proposing that commercial use of methylene chloride for a similar type of paint and coating removal be regulated with a time-limited, conditional exemption under TSCA section 6(g), due to notable differences in the two sectors. Specifically, exposure information assessed by EPA resulted in key differences in risk estimates for paint and coating removal by civilian aviation and DOD (see discussion in this Unit and Unit V.A.1.). Additionally, as described in Unit V.A.1., Federal and Federal contractor facilities are subject to multiple levels of oversight as a result of the governmental and public nature of their activities, while many civilian aviation facilities are not likely to experience the same level of scrutiny. EPA emphasizes that in the absence of information, it must still ensure that unreasonable risks are addressed. Because EPA has found inadequate information to otherwise determine whether the unreasonable risk would be addressed when using methylene chloride under a WCPP for commercial use of methylene chloride for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and aerospace vehicles for commercial aviation and aerospace, EPA has determined that the proposed exemption under TSCA section 6(g) allowing for time-limited, conditional use of methylene chloride for this critical use is the appropriate approach.

EPA recognizes that in some situations, certain facilities may do both Federal contractor

and commercial aviation work and may use methylene chloride for paint and coating removal from safety-critical, corrosion-sensitive components on military, Federal, or commercial aviation. EPA requests comment on whether such co-located activities in a facility should be subject to the WCPP, rather than the exemption under TSCA section 6(g). Additionally, EPA seeks additional information and requests comment on whether it is possible to distinguish between commercial aviation facilities that would be able to meet the WCPP and those that would not, including what criteria should be used for such distinctions (*e.g.*, size of facility, volume or type of work performed, record of exposure reduction practices). EPA also requests comment on the extent to which specific commercial aviation and aerospace uses or types of facilities could fully comply with the WCPP to address identified unreasonable risk.

ii. Proposed exemptions for uses of methylene chloride for paint and coating removal that are essential for critical infrastructure.

For the reasons discussed in this Unit, EPA is proposing 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. In defining the scope of the exemption to limit the exemption to commercial aviation and aerospace, EPA looked to the definitions and provisions of the Federal Aviation Regulations in title 14 of the CFR. Air carriers and commercial operators are certificated under 14 CFR part 119. Repair stations are certificated under 14 CFR part 145. To effectively prevent significant disruptions to critical infrastructure including commercial aviation and aerospace, EPA would make this exemption available to three different groups of commercial entities. In each case, the exemption would be available only for the use of methylene chloride to remove paint and coatings from safety-critical, corrosion-sensitive components of aircraft or aerospace vehicles. The first group would consist of those facilities that primarily maintain and repair aircraft used by air carriers and

commercial operators. More specifically, maintenance and repair facilities operated by air carriers and commercial operators certificated under 14 CFR part 119 would be eligible for the exemption, as would be repair stations certificated under 14 CFR part 145, if their primary business is performing maintenance, preventive maintenance, rebuilding, or alteration of aircraft operated by air carriers and commercial operators certificated under 14 CFR part 119. The second group would consist of manufacturers of aircraft intended for, or capable of being used by, air carriers and commercial operators certificated under 14 CFR part 119. The third group would consist of any person manufacturing or repairing spacecraft, space vehicles, or payloads or similar hardware that is intended for, or used in, commercial space transportation operations subject to 14 CFR chapter III.

The conditions for the proposed exemption would be: 1) The use of methylene chloride for commercial paint or coating removal by certificated air carriers, commercial operators, or repair stations, or by manufacturers of aircraft or aerospace vehicles or hardware, would be limited to the -safety-critical, corrosion-sensitive components on aircraft and aerospace vehicles; 2) The use of methylene chloride for paint or coating removal would be required to be performed on the premises of the certificated air carrier or commercial operator or repair station, or of the manufacturer of aircraft or aerospace vehicles or hardware; and 3) The certificated air carrier, commercial operator, repair station, or manufacturer of aircraft or aerospace vehicles and hardware manufacturer would have to comply with the WCPP discussed in Unit IV.A.1.

EPA wishes to make clear that the exemption for the commercial aerospace and aviation industry would only be available for the purpose of paint and coating removal from components of aircraft and spacecraft that are corrosion-sensitive and safety critical components, 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. In addition, these components would have to be of the type that not only require their paint or coatings to be removed for inspection and maintenance but also would be so negatively affected by the use of paint and coating removal chemicals or methods other than methylene chloride that the safety of the system could be compromised. General paint and coating removal on aircraft and spacecraft would not be authorized under this exemption. One commenter on the 2017 proposal suggested that EPA clarify that only the manufacturer of the component may make this determination. In EPA's view, persons availing themselves of the exemption 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.

The entities subject to the proposed exemption would nonetheless still be subject to the proposed general recordkeeping requirements discussed in Unit IV.A., the WCPP recordkeeping requirements discussed in Unit IV.A.1.f.iii., and requirements to maintain records that demonstrate compliance with the exemption conditions, including the condition that methylene chloride only be used for paint and coating removal from corrosion-sensitive and safety critical components of an aircraft or spacecraft. Pursuant to TSCA section 6(g)(3), if this proposed exemption is finalized, EPA may by rule later extend, modify, or eliminate the exemption, on the basis of reasonably available information and after adequate public justification, if EPA determines the exemption warrants a change. EPA would initiate this rulemaking process (*e.g.*,

proposed rule, final rule) at the request of any regulated entity benefiting from such an exemption, as appropriate. The Agency is open to engagement throughout the duration of any TSCA section 6(g) exemption, and emphasizes that to ensure continuity in the event of an extension or modification request, such a request should come at least 2 years prior to the expiration of an exemption.

EPA requests comments on all aspects of the proposed TSCA section 6(g) exemption from the proposed prohibition on use of methylene chloride in commercial paint and coating removal for paint and coating removal essential for critical infrastructure by certificated commercial air carriers, commercial operators, or repair stations, or by manufacturers of aircraft or aerospace vehicles and hardware, noting that the proposed exemptions would be limited to the safety-critical, corrosion-sensitive components on aircraft and aerospace vehicles, including safety-critical components.

b. Certain emergency uses of methylene chloride for which no technically and economically feasible safer alternative is available.

i. Analysis of the need for TSCA section 6(g)(2)(A) exemption for NASA certain uses in an emergency.

EPA also considered a TSCA section 6(g) exemption for emergency use of methylene chloride in the furtherance of NASA's mission. Under TSCA section 6(g)(1)(A), EPA may "grant an exemption from a requirement of a . . . rule for a specific condition of use of a chemical substance or mixture, if the Administrator finds that the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure." For certain specific conditions of use, EPA proposes that use of methylene chloride by NASA and its contractors in an emergency be exempt from the requirements of this rule because it is a critical or essential use provided that (1)

there is an emergency; and (2) NASA selected methylene chloride because there are no technically or economically feasible safer alternatives available during the emergency.

NASA operates on the leading edge of science seeking innovative solutions to future problems where even small volumes of an otherwise prohibited chemical substance could be vital to crew safety and mission success. During interagency review, NASA expressed concerns that there will likely be circumstances where a specific, EPA-prohibited condition of use may be identified by NASA during an emergency as being needed in order to avoid or reduce situations of harm or immediate danger to human health, or the environment, or avoid imperiling NASA space missions. In such cases, it is possible that no technically and economically feasible safer alternative would be available that meets the stringent technical performance requirements necessary to remedy harm or avert danger to human health, the environment, or avoid imperiling NASA space missions.

An emergency is a serious and sudden situation requiring immediate action to remedy harm or avert danger to human health, the environment, or to avoid imperiling NASA space missions. In NASA's case, there may be instances where the emergency use of methylene chloride for specific conditions of use is critical or essential to remedying harm or averting danger to human health, the environment, or avoiding imperiling NASA space missions. Because of the immediate and unpredictable nature of emergencies described in this Unit and of the less forgiving environments NASA operates in that offer little to no margin for error, it is likely that, at the time of finalization of this proposal, alternatives to emergency methylene chloride use may not be available in a timely manner to avoid or reduce harm or immediate danger (Ref. 39). In this way, these emergencies for particular conditions of use meet the criteria for an exemption under TSCA section 6(g)(1)(A), because the emergency use of methylene chloride for listed conditions of use is critical or essential and no technically and economically feasible safer

alternative will be available in a timely manner, taking into consideration hazard and exposure.

In support of the TSCA section 6(g)(1)(A) emergency use exemption, NASA submitted detailed criteria which they must use to screen, qualify, and implement materials to be used in spacecraft equipment, as well as historical case studies that outline the loss of life and loss of assets in the discharge of previous missions. In one of several examples detailed, the Apollo I command module fire that claimed the lives of three American astronauts demonstrated the need for careful testing and continuity of materials (Ref. 39). Moreover, due to NASA's rigorous safety testing requirements under various environmental conditions, technically and economically feasible safer alternatives may not be readily available during emergencies and may require certain conditions of use of methylene chloride to alleviate the emergency.

In another example, NASA identified a scenario concerning a mission to the International Space Station (ISS) whereby, during a launch evolution, the countdown was paused immediately prior to launch (T-2 minutes). NASA engineers identified a clogged filter and supply line as the primary issue, which required immediate attention (*i.e.*, line flushing and filter cleaning). In this type of emergency scenario, an already approved chemical substance rated for space system applications is necessary to immediately remedy the situation. Although methylene chloride was not used in this particular incident, if it were needed, in the future to address such an emergency, then the proposed exemption would allow for its lawful use—the countdown would resume and the launch would occur. Conversely, without an exemption under the specific condition of use (*e.g.*, industrial and commercial use in non-aerosol degreasers and cleaners), NASA's use of methylene chloride would be otherwise prohibited, which would put NASA in an untenable position of having to choose to either violate the law or place the mission (and potentially the health and safety of its employees involved in the mission) at risk.

As described in Unit IV.A.5.a., the identification and qualification of compatible

materials in the context of aviation is iterative and involves expansive collaboration between original equipment manufacturers, federal agencies, and qualifying institutions. This is equally, if not more so, the case in the context of human space flight operations undertaken by NASA (Ref. 39). NASA's mission architecture requirements often are developed many years in advance of an actual launch occurring. As part of mission planning, space systems are designed, full scale mock-ups are built, and mission critical hardware is constructed using materials qualified for spaceflight. Once NASA's mission architecture requirements are developed, NASA may need to retain emergency access to methylene chloride because its alternatives may not have yet gone through NASA's rigorous certification process before their use. Allowing NASA to retain emergency use of methylene chloride would reduce the chances that this rule will hinder future space missions for which mission architecture infrastructure is being developed or is already built. While NASA considers alternatives to the chemical substances it currently uses in its space system designs, NASA has not yet identified technically and economically feasible alternatives to proven chemistries in many current applications. While EPA acknowledges that the use of methylene chloride in emergency situations may be necessary in the near term, it is also EPA's understanding that NASA will continue its work to identify and qualify alternatives to methylene chloride. Thus, as with the exemption described in Unit IV.A.5.a., EPA is proposing an exemption duration of 10 years.

ii. Proposed exemption for use of methylene chloride for emergency uses in the context of human space flight for certain uses.

For the reasons discussed in this Unit, EPA is proposing a 10-year exemption for emergency use of methylene chloride in furtherance of NASA's mission for the following specific conditions of use: Industrial and commercial use as 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 solvent that becomes part of a formulation or mixture. EPA is also proposing to include additional requirements as part of the exemption, 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 Administrator of each instance of emergency use within 15 days and; 2) NASA and its contractors would have to comply with the WCPP described in Unit IV.A.1. to the extent feasible.

EPA is proposing to require that NASA notify EPA within 15 days of the emergency use. The notification would 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 proposed, 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.

As with the exemption described in Unit IV.A.5.a., EPA expects NASA and its contractors have the ability to implement a WCPP as described in Unit IV.A.1. for the identified uses in the context of an emergency, to some extent even if not to the full extent of WCPP implementation. Therefore, EPA is proposing to require that during emergency use, NASA must comply with the WCPP to the extent technically feasible in light of the particular emergency.

Under the proposed exemption, NASA and its contractors would still be subject to the proposed general recordkeeping requirements discussed in Unit IV.A.

EPA requests comment on this TSCA section 6(g) exemption for continued emergency use of methylene chloride in the furtherance of NASA's mission as described in this Unit, and whether any additional conditions of use should be included, in particular for any uses qualified

for space flight for which no technically or economically feasible safer alternative is available. Additionally, EPA requests comment on what would constitute sufficient justification of an emergency.

c. Analysis of the need for a TSCA section 6(g) exemption for commercial furniture refinishing.

While EPA in the past has proposed to exclude commercial furniture refinishing from regulation of the use of methylene chloride in commercial paint and coating removal, this proposed rule does not exclude commercial furniture refinishing from the proposed prohibition on the use of methylene chloride for commercial paint and coating removal, because EPA has determined that this use drives the unreasonable risk for methylene chloride, reasonably available information demonstrates that alternative methods or substitute chemicals are available to some extent, and, based on reasonably available information, EPA has not found that a TSCA section 6(g) exemption is warranted for the use of methylene chloride in commercial furniture refinishing. The 2020 Risk Evaluation for Methylene Chloride identified risks for commercial use of methylene chloride in paint and coating removal, including furniture refinishing, as a result of acute and chronic non-cancer exposures that would not be mitigated by an APF 50 respirator. The 2020 Risk Evaluation for Methylene Chloride identified risks for commercial use of methylene chloride in paint and coating removal, including furniture refinishing, as a result of acute and chronic non-cancer exposures that would not be mitigated by an APF 50 respirator. EPA identified many alternative products for paint and coating removers. However, some may require longer periods of time or rework of equipment and processes in order to work for furniture refinishing uses, or, though they may be used as paint and coating removers in other contexts, may not be appropriate alternatives for use on wood substrates. EPA's consideration of alternatives, including for safety and flammability, is discussed further in Unit V.B., the

Economic Analysis, and Alternatives Assessment (Ref. 3, Ref. 40). Mechanical or thermal methods (*i.e.*, sanding, media blasting, or heat guns) are also potential alternatives for this sector, though likewise they may damage the substrate, require different processes, and often requires more time (Refs. 33, 55, 66). While the economic impacts of prohibiting the commercial use of methylene chloride for furniture refinishing may be significant for this sector, it is unclear whether this will result in firm closures, and, if so, how many. Given the magnitude of the risks resulting from this use, including the documented fatalities (Ref. 32), the likely inability of this sector to comply with a WCPP (as described in Unit V.A.), and the availability of some alternatives, EPA determined that a prohibition would be necessary the identified risks that drive the unreasonable risk to health, as discussed in Unit V.A.1. EPA requests comment on all aspects of this preliminary determination that a TSCA section 6(g) exemption is not warranted for the use of methylene chloride in furniture refinishing, including information on the availability of alternatives and the time needed to implement alternatives. EPA emphasizes that the Agency is seeking input regarding whether an exemption is needed and welcomes information related to this condition of use during the public comment period.

B. Primary Alternative Regulatory Action

As indicated by TSCA section 6(c)(2)(A)(iv)(II) through (III), EPA must consider the costs and benefits and the cost effectiveness of the proposed regulatory action and one or more primary alternative regulatory actions considered by the Agency. An overview of the proposed regulatory action and alternative regulatory action for each condition of use is in Unit IV.C.

The primary alternative regulatory action described in this notice combines prohibitions and requirements for a WCPP to address the unreasonable risk from methylene chloride driven by the various conditions of use, as well as time-limited exemptions under TSCA section 6(g) for two uses. While in some ways it is similar to the proposed regulatory action, the primary

alternative regulatory action described in this notice would allow a WCPP, including requirements to meet an ECEL and EPA STEL, for several additional conditions of use than would be allowed under the proposed regulatory action. The alternative regulatory action additionally would include longer compliance timeframes for prohibitions and a WCPP, as described in this Unit.

As in the proposed regulatory action described in Unit IV.A.1., EPA's primary alternative regulatory action described in this notice would include WCPP, including requirements to meet an ECEL and EPA STEL for: manufacturing: domestic manufacture; manufacturing: import; processing: as a reactant; processing: incorporation into a formulation, mixture, or reaction product; processing: repackaging; processing: recycling; industrial and commercial use as a laboratory chemical; and disposal.

In addition, the primary alternative regulatory action described in this notice would require a WCPP for 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. EPA believes a WCPP may be a viable alternative to the proposed prohibition for these additional industrial and commercial conditions of use because, as discussed in Unit V.A., these conditions of use are generally industrial in nature; owners or operators are likely currently

complying with the OSHA methylene chloride standard, so they should be familiar with what is being required to meet the ECEL; and, as far as the Agency is aware, these conditions of use have not resulted in any documented fatalities. Because of the industrial nature of the sectors relevant to these conditions of use, the owner or operator may have the capability to successfully implement a WCPP to ensure that the unreasonable risk, as a result of exposure to methylene chloride, are prevented. However, at the time of proposal, EPA has not yet received any monitoring data or detailed description of methylene chloride involving activities for these conditions of use to confirm that compliance with an ECEL of 2 ppm is possible. Therefore, concerns about the feasibility of implementing an ECEL for these additional industrial and commercial conditions of use, as discussed in Unit V.3., led EPA to propose that they be prohibited (see Unit IV.A.2.). EPA does not have sufficient information to confidently conclude that facilities engaged in these conditions of use could meet the ECEL for methylene chloride. Therefore, EPA requests comment on the ways in which methylene chloride may be used in the conditions of use that would be prohibited (under the proposed regulatory action) due to concerns about feasibility of implementing an ECEL, and the degree to which users of methylene chloride in these sectors could successfully implement the WCPP, including requirements to meet an ECEL and EPA STEL, described in Unit IV.A.1. EPA is also requesting comment on whether to consider a regulatory alternative that would subject more conditions of use to a WCPP, instead of prohibition, than those currently contemplated in the primary alternative regulatory action. EPA also requests 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.

Specifically with regards to the condition of use “Industrial and commercial use as a processing aid,” EPA notes that the description of this condition of use (in Unit III.B.1.c.xxiii.)

covers a broad range of chemical use activities. During the SBAR Panel, one SER provided process descriptions, diagrams, and monitoring data which indicated that particular entity may already be able to meet an ECEL of 2 ppm. This particular entity uses methylene chloride as a heat transfer fluid in a closed system. Information provided to EPA indicated that inhalation exposures were frequently below the ECEL and in some cases below the level of detection, and while dermal exposure were possible, they could be mitigated through use of PPE (Ref. 6). EPA's 2020 Risk Evaluation for Methylene Chloride incorporated exposure estimates from a different type of processing aid application that did not resemble the SER's use, which is highly specialized and may be considered a sub-use of the condition of use as a whole. EPA requests comment on the degree to which other entities using methylene chloride as a processing aid may otherwise comply with the proposed WCPP requirements for methylene chloride. In the case that several entities are able to demonstrate the continued use of methylene chloride without subjecting workers to unreasonable risk is possible, through a combination of monitoring data and process description, EPA acknowledges its willingness to finalize a regulation under which this particular sub-use of the condition of use, or the condition of use as a whole could continue under the WCPP.

Additionally, EPA notes that the alternatives analysis did not specifically identify any alternatives for this condition of use (Ref. 40). This is a limitation of the type of analysis done, which was specifically based on the use of alternative formulations currently on the market, and therefore not applicable to most processing uses. EPA emphasizes that this is not a positive finding that alternatives do not exist for this condition of use. To that end, EPA requests comment on the degree to which alternatives may or may not be available for use of methylene chloride as a heat transfer fluid and in other processing aid applications.

In the event that EPA is not able to identify any alternatives for this condition of use, and

additional information is not provided that would allow EPA to determine that the WCPP could address unreasonable risk driven by this condition of use, EPA will consider finalizing a prohibition that allows for an appropriate phaseout in accordance with TSCA section 6(d). Alternatively, in the event that EPA is unable to identify alternatives for this condition of use, and EPA determines through new information provided that prohibition of the use would significantly impact national security or critical infrastructure, EPA will consider an exemption under TSCA section 6(g).

Under the primary alternative regulatory action, EPA would prohibit the manufacture, processing, and distribution in commerce of methylene chloride for all consumer use. Additionally, under the primary alternative regulatory action described in this notice and considered by EPA, other than those conditions of use listed earlier for inclusion under the WCPP, EPA would prohibit the remaining industrial and commercial uses, including two uses for which EPA is proposing the WCPP as the regulatory action: industrial or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and spacecraft by Federal agencies and their contractors; and industrial or commercial use as a bonding agent in the production of specialty batteries for military or space applications by Federal agencies and their contractors. Recordkeeping and downstream notification would be required as described in Unit IV.A.4.

For industrial or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and spacecraft by Federal agencies and their contractors, and industrial or commercial use as a bonding agent in the production of specialty batteries for military or space applications by Federal agencies and their contractors, the alternative regulatory action would include an exemption from the prohibition for 10 years under TSCA section 6(g). For the duration of this exemption, regulated entities would be required to

comply with the WCPP to the extent practicable.

For these two uses, EPA has conducted an analysis of the application of this rulemaking and found that a TSCA section 6(g) exemption may be warranted if the primary alternative regulatory action considered by EPA is adopted, in its entirety or in relevant part, in the final rule. Based on discussions with and information provided by industry stakeholders, EPA understands that these two uses of methylene chloride by DoD, NASA, and other Federal agencies are essential for national security and critical infrastructure.

As discussed in greater detail in Unit V.B., EPA is aware that there are specific military uses for which methylene chloride is essential for paint and coating removal and for which there are no suitable alternatives currently available. The military readiness of DOD's warfighting capability is paramount to ensuring national security, which includes ensuring the maintenance and preservation of DOD's warfighting assets. DOD has identified safety-critical uses of methylene chloride for ensuring military aviation readiness. These consist of the use of methylene chloride for the removal of coatings from safety-critical, corrosion-sensitive military aviation components, such as landing gear, gear boxes, and turbine engine parts, that not only require their coatings be removed for inspection and maintenance but also would be so negatively affected by the use of technically incompatible, substitute paint removal chemicals or methods that the safe performance of the aircraft could be compromised.

EPA has evaluated the effect that a prohibition on methylene chloride for industrial or commercial paint and coating removal could have on military readiness and preliminarily determines that an exemption would be warranted under TSCA section 6(g)(1)(B) to avoid the significant deleterious impacts on national security that compliance with the proposed prohibition could entail, should the primary alternative regulatory action be adopted in the final rule in whole or in part. More specifically, because the available alternatives either cannot be

used on certain substrates, such as high-strength steel or magnesium, or take an unacceptably long time to work in certain situations, compliance with the proposed prohibition would result in important military assets being off-line for significantly longer inspection and repair periods, which would significantly disrupt national security.

In addition, as noted by commenters on EPA's 2017 NPRM, there are other Federal agencies that use safety-critical, corrosion-sensitive components on aviation and space applications and stated that the proposed exemption should also apply to those Federal agencies and their contractors. These commenters asserted that, without an exemption for NASA, the Department of Homeland Security (DHS), and the Federal Aviation Administration (FAA), the proposed prohibition on the use of methylene chloride for industrial or commercial paint and coating removal could negatively affect national security and critical infrastructure.

EPA's analysis of the potential impacts on DOD's military readiness and national security is equally applicable to NASA, DHS, and FAA. As stated by commenters on EPA's 2017 NPRM (Ref. 46), aircraft and other assets operated by DHS, NASA, and the FAA also contain safety-critical, corrosion-sensitive components of the type described by DOD, and suitable alternatives to methylene chloride are similarly not available for all applications. Those agencies are also responsible for assets that are essential to national security or constitute critical infrastructure and contain safety-critical, corrosion-sensitive components on which methylene chloride is used for paint and coating removal. The Coast Guard, one of the five Armed Services of the United States, is a military branch within DHS. Like the four Armed Services within DOD, the Coast Guard is also responsible for warfighting assets that may require the use of methylene chloride for the removal of coatings from safety-critical, corrosion-sensitive components. The Coast Guard's military readiness is as important as the military readiness of the four Armed Services within DOD. Similarly, the readiness of U.S. Customs and Border

Protection aviation for monitoring and protecting the borders of the United States is an integral part of national security. As for NASA, the United States Space Priorities Framework notes that space systems (*e.g.*, flight components of satellites and space craft) are part of the nation's critical infrastructure and that the United States has significant national security interests in space (Ref. 41). The integrity and performance of our national airspace system, overseen by the FAA, is a matter of both national security and critical infrastructure. FAA-operated aircraft ensure the integrity of instrument approaches to airports and airway procedures that constitute our National Airspace System infrastructure (Ref. 42). The FAA's Flight Program Operations accomplishes this through the airborne inspection of space- and ground-based instrument flight procedures and the validation of electronic signals in space transmitted from ground navigation systems, evaluating accuracy, aeronautical data, human factors fly-ability, and obstacle clearance.

As discussed in Unit V.B., substitute chemicals for paint and coating removal for safety-critical, corrosion-sensitive components are not technically feasible as they have one or more technical limitations; are incompatible with underlying materials; and/or do not support the coating removal requirements of safety inspections, non-destructive inspection, material assessment, or field repair processes. Therefore, EPA has preliminarily determined that DHS, NASA, and FAA compliance with a prohibition on the use of methylene chloride for industrial or commercial paint and coating removal, which would preclude use of methylene chloride for removal of paint and coatings from safety-critical, corrosion-sensitive components of these agencies' aircraft and other assets, would significantly disrupt national security and critical infrastructure in the same way that DOD's compliance with a prohibition would. In addition, due to concerns about impacts to the availability of methylene chloride for use in removing paint and coatings from safety-critical, corrosion-sensitive components, EPA has preliminarily determined that a ban on the manufacture, processing, and distribution in commerce of methylene chloride

for industrial or commercial paint and coating removal for these safety-critical, corrosion-sensitive components would also significantly disrupt national security and critical infrastructure. For this reason, if the primary alternative regulatory action considered by EPA is adopted, in its entirety or in relevant part, in the final rule, an exemption under TSCA section 6(g) would be warranted to prevent significant disruption of national security and critical infrastructure.

EPA has also analyzed the need for a TSCA section 6(g) exemption for use of methylene chloride as a bonding agent in the production of specialty batteries for use in critical energy storage applications in military and space exploration settings, including defense applications such as precision guided weapons, military airframes, satellites, space launch vehicles, and spacecraft. According to a maker of these batteries, all major military and space applications, such as aircraft (F-35, B2), radios, and Mars mission equipment, require these batteries to function in very harsh conditions, including operation to -40 °C and storage at -54 °C (Ref. 47). As discussed further in Unit V.B., EPA understands that methylene chloride is a superior bonding agent for this process because of its unique evaporative qualities, and that availability of technologically and economically feasible alternatives to methylene chloride is lacking.

As discussed in this Unit, EPA recognizes that military readiness is paramount to ensuring national security, and that space systems are part of our critical infrastructure and have impacts on national security. Therefore, EPA has preliminarily determined that DOD and NASA compliance with a prohibition on the use of methylene chloride as a bonding agent in the production of specialty batteries for use in critical energy storage applications in military and space exploration settings would significantly disrupt national security and critical infrastructure, should the primary alternative regulatory action be adopted in the final rule in whole or in part. In addition, due to concerns about impacts to the availability of methylene chloride for use as a bonding agent in the production of these specialty batteries, EPA has preliminarily determined

that a prohibition on the manufacture, processing, and distribution in commerce of methylene chloride for use as a bonding agent in the production of specialty batteries for use in critical energy storage applications in military and space exploration settings would also significantly disrupt national security and critical infrastructure. For this reason, if the primary alternative regulatory action considered by EPA is adopted, in its entirety or in relevant part, in the final rule, an exemption under TSCA section 6(g) would be warranted to prevent significant disruption of national security and critical infrastructure.

Given the potential severity of impacts from acute exposures, EPA's proposed regulatory action would include relatively rapid compliance timeframes. However, it is possible that longer timeframes would be needed for entities to come into compliance; therefore, the primary alternative regulatory action described in this notice would include longer timeframes for implementation than the proposed regulatory action. The prohibitions under the primary alternative regulatory action would take effect in 360 days for manufacturers, 450 days for processers, 540 days for distributing to retailers, 630 days for all other distributors and retailers, and 720 days for industrial and commercial users after publication of the final rule in the *Federal Register* (in contrast to 90 days for manufacturers, 180 days for processers, 270 days for distributing to retailers, 360 days for all other distributors and retailers, and 450 days for industrial and commercial users after publication of the final rule in the *Federal Register* in the proposed action described in Unit IV.A.). Similarly, the compliance timeframes for the WCPP under the primary alternative regulatory action would be extended by 6 months in comparison to the proposed action described in Unit IV.A: EPA would require that regulated entities establish initial exposure monitoring according to the process outlined in Unit IV.A. within 12 months, ensure that the airborne concentration of methylene chloride does not exceed the ECEL or EPA STEL within 15 months (and provide respiratory protection if necessary), and implement an

exposure control plan within 18 months. EPA requests comment on the ability of regulated entities engaged in the additional conditions of use that would be subject to a WCPP under the primary alternative regulatory action to conduct initial monitoring within 12 months, anticipated timelines for any procedural adjustments needed to comply with the requirements, and the extent to which this option could result in additional exposure, compared the proposed regulatory option as described in Unit IV.A. Overall, EPA requests comment on any advantages or drawbacks for the timelines outlined in this Unit, compared to the timelines identified for the proposed regulatory action in Unit IV.A.

As noted earlier in this Unit, for some conditions of use, both the proposed regulatory action and primary alternative regulatory action would result in a prohibition. EPA emphasizes that for those conditions of use, the primary alternative regulatory action includes a different timeline for implementation of the prohibition, in comparison to the proposed regulatory action. As discussed in more detail in Unit V.A., for those conditions of use, EPA also considered other regulatory approaches available under TSCA section 6(a). However, EPA found that none of these other regulatory approaches would address the unreasonable risk.

Where EPA has determined that a chemical substance presents unreasonable risk under TSCA section 6(b)(4), EPA must undertake rulemaking to "apply one or more of the [TSCA § 6(a)(1) through (7)] requirements to such substance . . . to the extent necessary so that the chemical substance . . . no longer presents such risk." TSCA § 6(a). "In proposing and promulgating [such] a rule," EPA must "consider and publish a statement based on reasonably available information with respect to . . . the reasonably ascertainable economic consequences of the rule, including consideration of . . . (II) the costs and benefits of the proposed . . . regulatory action and of the [one] or more primary alternative regulatory actions considered by [EPA]; and (III) the cost effectiveness of the proposed regulatory action and of the [one] or more primary

alternative regulatory actions considered by [EPA].” EPA interprets this to mean that Congress intended this “primary alternative regulatory action” to be another regulatory option under TSCA § 6(a)(1) through (7) that would meet the requirements of TSCA § 6(a), namely address the unreasonable risk identified under TSCA section 6(b)(4) “to the extent necessary so that the chemical substance . . . no longer presents such risk.” Here, the proposed regulatory action is comprised of a mix of proposed options under TSCA section 6(a), each directed at specific conditions of use and with specified timeframes for compliance. The primary alternative regulatory options considered by the Agency would adjust the overall mix of TSCA section 6(a) requirements, including compliance timeframes, resulting in a proposed regulatory action that is more restrictive in some ways and less restrictive in others. For conditions of use where the only options that would address the unreasonable risk are prohibition options under TSCA § 6(a)(2), the proposed option and the primary alternative regulatory option are distinct because implementing prohibitions on differing timetables under TSCA section 6(d) would result in a different mix of regulatory options with different costs, benefits, and cost effectiveness than the proposed regulatory action.

C. Overview of Conditions of Use and Proposed Regulatory Action and Primary Alternative Regulatory Action

The following Table 3 is a side-by-side depiction of the proposed regulatory action with the primary alternative regulatory action for each condition of use. Additionally, timeframes between the proposed and primary alternative regulatory action differ as outlined in Units IV.A. and B; those Units also contain additional details such as exemptions proposed under TSCA section 6(g) and delayed compliance dates under TSCA section 6(d) for specific applications.

Table 3 – EPA Proposed or Alternative Action by Condition of Use

	Action

Condition of Use	Proposed Regulatory Action	Primary Alternative Action
Industrial and commercial use as solvent for batch vapor degreasing	Prohibit	Prohibit
Industrial and commercial use as solvent for in-line vapor degreasing	Prohibit	Prohibit
Industrial and commercial use as solvent for cold cleaning	Prohibit	Prohibit
Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner	Prohibit	Prohibit
Industrial and commercial use in adhesives, sealants and caulks	Prohibit	Prohibit
Industrial and commercial use in paints and coatings	Prohibit	Prohibit
Industrial and commercial use in paint and coating removers	Prohibit	Prohibit
Industrial and commercial use in paint and coating removers from safety critical, corrosion-sensitive components of aircraft and spacecraft owned or operated by DOD, NASA, DHS, FAA	WCPP	Prohibit, with a 10-year time-limited exemption and interim WCPP
Industrial and commercial use in paint and coating removers from safety-critical, corrosion-sensitive components of aircraft owned or operated by air carriers or commercial operators	Prohibit, with a 10-year time-limited exemption and interim WCPP	WCPP
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 applications	WCPP	Prohibit, with a 10-year time-limited exemption and interim WCPP
Industrial and commercial use in adhesive and caulk removers	Prohibit	Prohibit
Industrial and commercial use in metal aerosol degreasers	Prohibit	Prohibit
Industrial and commercial use in metal non-aerosol degreasers	Prohibit	Prohibit
Industrial and commercial use in finishing products for fabric, textiles and leather	Prohibit	WCPP
Industrial and commercial use in automotive care products (functional fluids for air conditioners)	Prohibit	Prohibit
Industrial and commercial use in automotive care products (interior car care)	Prohibit	Prohibit
Industrial and commercial use in automotive care products (degreasers)	Prohibit	Prohibit

Industrial and commercial use in apparel and footwear care products	Prohibit	Prohibit
Industrial and commercial use in spot removers for apparel and textiles	Prohibit	Prohibit
Industrial and commercial use in liquid lubricants and greases	Prohibit	Prohibit
Industrial and commercial use in spray lubricants and greases	Prohibit	Prohibit
Industrial and commercial use in aerosol degreasers and cleaners	Prohibit	Prohibit
Industrial and commercial use in non-aerosol degreasers and cleaners	Prohibit	Prohibit
Industrial and commercial use in cold pipe insulations	Prohibit	Prohibit
Industrial and commercial use as solvent that becomes part of a formulation or mixture	Prohibit	WCPP
Industrial and commercial use as a processing aid	Prohibit	WCPP
Industrial and commercial use as a propellant and blowing agent	Prohibit	Prohibit
Industrial and commercial use for electrical equipment, appliance, and component manufacturing	Prohibit	WCPP
Industrial and commercial use for plastic and rubber products manufacturing	Prohibit	WCPP
Industrial and commercial use in cellulose triacetate film production	Prohibit	WCPP
Industrial and commercial use as anti-spatter welding aerosol	Prohibit	Prohibit
Industrial and commercial use for oil and gas drilling, extraction, and support activities	Prohibit	WCPP
Industrial and commercial use in toys, playground and sporting equipment	Prohibit	Prohibit
Industrial and commercial use in carbon remover, wood floor cleaner, and brush cleaner	Prohibit	Prohibit
Industrial and commercial use in lithographic printing plate cleaner	Prohibit	Prohibit
Consumer use as solvent in aerosol degreasers/cleaners	Prohibit[1]	Prohibit[1]
Consumer use in adhesives and sealants	Prohibit[1]	Prohibit[1]
Consumer use in brush cleaners for paints and coatings	Prohibit[1]	Prohibit[1]
Consumer use in adhesive and caulk removers1	Prohibit[1]	Prohibit[1]
Consumer use in metal degreasers	Prohibit[1]	Prohibit[1]

Consumer use in automotive care products (functional fluids for air conditioners)	Prohibit[1]	Prohibit[1]
Consumer use in automotive care products (degreasers)	Prohibit[1]	Prohibit[1]
Consumer use in lubricants and greases	Prohibit[1]	Prohibit[1]
Consumer use in cold pipe insulation	Prohibit[1]	Prohibit[1]
Consumer use in arts, crafts, and hobby materials glue	Prohibit[1]	Prohibit[1]
Consumer use in an anti-spatter welding aerosol	Prohibit[1]	Prohibit[1]
Consumer use in carbon removers and other brush cleaners	Prohibit[1]	Prohibit[1]
Manufacturing (Domestic manufacturing)	WCPP	WCPP
Manufacturing (Import)	WCPP	WCPP
Processing: processing as a reactant	WCPP	WCPP
Processing: incorporation into a formulation, mixture, or reaction product	WCPP	WCPP
Processing: repackaging	WCPP	WCPP
Processing: recycling	WCPP	WCPP
Industrial and commercial use as a laboratory chemical	WCPP	WCPP
Disposal	WCPP	WCPP

[1]Prohibit manufacture, processing, and distribution in commerce for the consumer use

V. Rationale for the Proposed Regulatory and Primary Alternative Regulatory Actions

This Unit describes how the considerations described in Unit III.B.3. were applied when selecting among the TSCA section 6(a) requirements to arrive at the proposed and primary alternative regulatory actions described in Unit IV.A. and B.

A. Consideration of Risk Management Requirements Available under TSCA Section 6(a)

1. Workplace Chemical Protection Program (WCPP).

One option EPA considered for occupational conditions of use was establishing a WCPP, which would include an ECEL and related required implementation measures, such as monitoring. As described in Unit IV.A.1., the WCPP for methylene chloride would be non-prescriptive, in the sense that owners and operators would not be required to use specific equipment or engineering controls prescribed by EPA to achieve the exposure concentration

limit. Rather, a performance-based exposure limit would enable owners and operators to determine how to most effectively meet the exposure limits based on conditions at their workplace, aligned with the hierarchy of controls. However, due to the low exposure levels and stringent requirements in the WCPP necessary to address the unreasonable risk from methylene chloride, EPA identified only a relatively small number of conditions of use where the Agency expects the WCPP can be successfully implemented.

The central components of the WCPP are the ECEL and EPA STEL. EPA has determined as a matter of risk management policy that ensuring exposures remain at or below the ECEL and EPA STEL would eliminate any unreasonable risk of injury to health driven by inhalation exposures for occupational conditions of use subject to the WCPP.

In the case of methylene chloride, EPA has calculated the ECEL for methylene chloride to be 2 ppm (8 mg/m^3) for inhalation exposures as an 8-hour TWA in workplace settings, based on the chronic non-cancer human equivalent concentration for liver toxicity from inhalation exposures. This is the concentration at which an adult human, including a member of a susceptible subpopulation, would be unlikely to suffer adverse effects if exposed for a working lifetime (Ref. 11). EPA chose the chronic non-cancer liver toxicity endpoint as the basis for this exposure limit as it is the most sensitive of the endpoints identified, and therefore will be protective of both acute and chronic cancer inhalation endpoints over the course of a working day and lifetime.

However, the well-established and severe acute hazard identified for methylene chloride, from blurred vision to death, can be experienced in much shorter timeframes. Therefore, EPA determined a short-term exposure limit, or EPA STEL, of 16 ppm (57 mg/m^3) as a 15-minute TWA, based on the non-cancer endpoint of central nervous system depression resulting from acute exposures, was necessary in order to ensure the unreasonable risk was fully addressed in

occupational settings (Ref. 11).

Once EPA identified the appropriate risk-based inhalation limits to address identified unreasonable risk, EPA carefully considered the appropriateness of such a program for each occupational condition of use of methylene chloride, in the context of the unreasonable risk.

Particular factors related to work activities that may make it difficult for certain conditions of use to comply with an ECEL are worth further discussion. One example includes work activities that may take place in the field, such as on-site paint removal or the use of adhesives in construction or renovation, making it challenging to establish a regulated area and conduct monitoring. In other contexts, the donning of air-supplied respirators would create challenges for movement and feasibility of work activities that may take place in small, enclosed spaces. Similarly, work activities that require a high range of motion or for some other reason could create challenges for the implementation of respiratory PPE are not good candidates for a WCPP, such as use as an anti-spatter welding aerosol, where use of a welding mask would impede the donning of an air-supplied respirator.

EPA also considered the feasibility of exposure reduction sufficient to address the unreasonable risk, even in facilities currently complying with the OSHA methylene chloride standard. While EPA acknowledges the regulated community's expected familiarity with OSHA PELs generally, as well as facilities' past and ongoing actions to implement the methylene chloride PEL and corresponding methods of compliance in OSHA's methylene chloride standard, EPA's exposure limits would be a full order of magnitude lower than the OSHA PEL. (The differences between the ECEL and EPA STEL and the OSHA PEL are discussed in more detail in Unit II.C.4.) This creates a significant amount of uncertainty as to the ability of facilities engaging in most industrial and commercial conditions of use to meet the ECEL and EPA STEL (and associated action levels) without relying on the use of PPE (or as discussed previously, if

the nature of the activity precludes use of PPE required to meet such a level), and, therefore, whether exposures could be reduced in a manner aligned with the hierarchy of controls, because under that hierarchy PPE is considered a measure of last resort.

EPA understands that this uncertainty extends to the applicability of respirators as well. Although respirators, specifically SCBAs, could reduce exposures to levels that are protective of non-cancer and cancer risks, not all workers may be able to wear respirators. Individuals with impaired lung function due to asthma, emphysema, or chronic obstructive pulmonary disease, for example, may be physically unable to wear a respirator. OSHA requires that a determination regarding the ability to use a respirator be made by a physician or other licensed health-care professional, and annual fit testing is required for tight-fitting, full-face piece respirators to provide the required protection. Individuals with facial hair, such as beards or sideburns that interfere with a proper face-to-respirator seal, cannot wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue, and reduced work efficiency (63 FR 1152, January 8, 1998). According to OSHA, "improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health" (63 FR 1189 through 1190).

In contrast to considerations that would weigh against the likelihood of a facility within a condition of use to successfully implement WCPP, there are certain considerations that indicate a condition of use is a good fit for effective risk management via WCPP. Based on reasonably available information, including monitoring data, and information related to considerations described previously in this Unit, EPA's confidence that requirements to meet an ECEL and EPA STEL can be implemented is highest for highly standardized and industrialized settings,

such as where methylene chloride is used in a closed system.

For example, one of the conditions of use for which EPA is proposing to require compliance with the WCPP is processing of methylene chloride as a reactant. A large volume of methylene chloride is processed for this condition of use, which almost entirely goes towards the manufacture of the hydrofluorocarbon HFC-32 (Refs. 3, 44). Monitoring data and exposure information submitted by industry, including by small entity representatives as part of the SBAR process, suggests that methylene chloride exposures in some facilities may already be below levels that would be consistent with the proposed ECEL (Refs. 6, 45, 46). Additionally, HFC-32 is one of the regulated substances identified in the AIM Act. Among other things, the AIM Act authorizes EPA to address listed HFCs in three main ways: phasing down HFC production and consumption through an allowance allocation program; facilitating sector-based transitions to next-generation technologies; and issuing certain regulations for purposes of maximizing reclamation and minimizing releases of HFCs and their substitutes from equipment and ensuring the safety of technicians and consumers. EPA anticipates that many entities currently using HFCs with higher global warming potential will transition to alternatives with lower global warming potential as requirements under the AIM Act take effect. HFC-32, while being one regulated substance subject to the overall phasedown in production and consumption of regulated substances under the AIM Act, is likely to be used to facilitate the transition from other HFCs and HFC blends with higher global warming potential in certain applications. By allowing for the continued, controlled use of methylene chloride in the manufacture of HFC-32, efforts to shift to chemicals with lower global warming potential would not be impeded by this rulemaking. Allowing this use to continue, subject to compliance with the WCPP, would complement industry's ongoing effort to abate the use of hydrofluorocarbons with higher global warming potential.

An additional strong candidate for WCPP is industrial and commercial use of methylene chloride as a laboratory chemical. Laboratory settings are expected to be more conducive to the implementation of engineering controls such as fume hoods to ventilate vapors and adequately reduce overall exposure to methylene chloride consistent with the hierarchy of controls.

For both these conditions of use (processing of methylene chloride as a reactant and industrial and commercial use as a laboratory chemical), the 2020 Risk Evaluation for Methylene Chloride indicates that only small reductions in exposure are needed for WCPP compliance. Based on analysis in the 2020 Risk Evaluation for Methylene Chloride describing expected exposures with and without use of PPE, EPA identified an air-supplied respirator of APF 25 as the minimum respiratory PPE that is sufficient to mitigate the unreasonable risk driven by both of these conditions of use (note for OSHA APF 25 is the minimum allowable respiratory PPE for methylene chloride, as filter and cartridge respirators are not protective against methylene chloride vapors). This suggested that, for these conditions of use, the reductions in exposure required to achieve a level that would not present unreasonable risk may be less than in other instances, which, together with other considerations previously described, including monitoring data indicating exposures near or below the ECEL, adds to EPA's confidence that facilities engaging in these two conditions of use could meet the WCPP requirements. Additionally, industrial and commercial use of methylene chloride as a laboratory chemical is necessary to provide for the analysis of monitoring samples required to demonstrate compliance with the WCPP under this proposed regulation.

An additional candidate for the WCPP is paint and coating removal from safety-critical, corrosion-sensitive components on military and Federal aviation. Regarding military aviation, as part of interagency collaboration with the DOD on the NPRM issued in January 2017 (Ref. 47), EPA was made aware that there are specific military uses for which methylene chloride is

essential for paint and coating removal for which there are no suitable alternatives currently available (see further discussion in Unit V.B.). These consist of the use of methylene chloride for the removal of coatings from corrosion-sensitive components on military aviation, including safety-critical components made of specialty metallic, nonmetallic, and composite materials. More specifically, this includes components such as landing gear, gear boxes, turbine engine parts, and other military aircraft components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and magnesium) and composite materials that require their coatings be removed for inspection and maintenance. Similarly, as stated by commenters on EPA's 2017 NPRM (Ref. 38), aircraft and other assets operated by DHS, NASA, and the FAA also contain safety-critical, corrosion-sensitive components of the type described by DOD, and suitable alternatives to methylene chloride are similarly not available for all applications.

As described further in Unit V.B., EPA concluded that under TSCA section 6(c)(2)(C) that technologically and economically feasible alternatives that benefit health or the environment would not be readily available as a substitute for these specific safety-critical uses on corrosion-sensitive components. However, under TSCA section 6(a), EPA must still address identified risks such that they are no longer unreasonable. EPA considered the appropriateness of the WCPP for this subset of activities under industrial or commercial use of methylene chloride for commercial paint and coating removal, and emphasizes that this consideration was made very narrowly for the use of methylene chloride for paint and coating removal for safety-critical, corrosion-sensitive components, and not for more general use of methylene chloride in paint and coating removal by Federal agencies or their contractors, or for aircraft or spacecraft paint and coating removal more broadly. Rather, EPA's consideration of the appropriateness of the WCPP takes into account the specifics of the components from which the coatings are being removed (and thus the lack of suitable alternatives for this particular subset of uses), and the relevant paint

and coating removal processes. EPA notes that these activities are expected to take place in highly industrialized facilities in which regulated areas may already be established, for compliance with current regulations for methylene chloride or other chemicals, and that the paint and coating removal work in these facilities would not take place in small or enclosed spaces (rather, parts would frequently be removed for coating removal) (Ref. 48). Additionally, EPA considered whether exposures could feasibly be reduced sufficiently so that the risks were no longer unreasonable. To that end, during the risk evaluation for methylene chloride, DOD submitted additional monitoring data for their particular activities involving use of methylene chloride for paint and coating removal. EPA's risk evaluation shows that, in comparison with other uses of methylene chloride for paint and coating removal, the magnitude of exposure, and thus the risks, are much lower for DOD's specified use. More specifically, EPA's risk evaluation found that central tendency risks for DOD uses of methylene chloride for commercial paint and coating removal do not exceed the acute or chronic non-cancer inhalation benchmarks, and high-end risks for those same endpoints could be addressed using the minimum allowable PPE for methylene chloride (Ref. 1). In addition to exposure reductions, EPA also considered whether other components of the WCPP could be effectively implemented, including development of exposure reduction plans, exposure monitoring, administrative controls, and workplace participation. During the development of this proposed rulemaking, discussions with DOD confirmed what was suggested by EPA's risk evaluation – that is, the remaining uses by DOD and other Federal agencies (*e.g.*, DHS, NASA, and FAA) of methylene chloride for paint and coating removal for safety-critical, corrosion-sensitive components are highly industrialized and take place in controlled settings with numerous protections for workers already in place. In this way, use of methylene chloride for the removal of coatings from corrosion-sensitive components on military aviation, including safety-critical components made of specialty metallic,

nonmetallic, and composite materials resembles other uses of methylene chloride for which the WCPP is being proposed, such as laboratory use. EPA further expects that Federal and Federal contractor facilities are subject to multiple levels of oversight as a result of the governmental and public nature of their activities, while civilian aviation facilities are not likely to experience the same level of scrutiny. Federal government procurement is also subject to the Federal Acquisition Regulations System in Title 49 of the CFR, which prescribes, among other things, health and environmental management and oversight requirements for Federal contracts. For this reason, EPA is proposing a WCPP for this particular subset of the methylene chloride commercial paint and coating remover condition of use. EPA requests comment and further information regarding the Agency's expectations that Federal and Federal contractor facilities would be subject to a higher level of oversight than non-Federal or contractor facilities, and that existing or expected controls would be successful in achieving the requirements of the WCPP.

Similarly, EPA has examined the use of methylene chloride as a bonding agent for acrylic and polycarbonate in mission-critical military and space vehicle applications by Federal agencies and their contractors (Ref. 43) and is proposing WCPP for this subset of the commercial use of methylene chloride in adhesives condition of use. 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 sealing the plastic cases of specialty batteries.

A stakeholder that produces lithium and silver oxide zinc batteries described how they are used in critical energy storage applications in military and space exploration settings, including defense applications such as precision guided weapons, military airframes, satellites, space launch vehicles, and spacecraft. (The stakeholder also described use of these batteries in medical devices; EPA notes that the TSCA definition of "chemical substance" excludes, under

TSCA section 3(2)(B)(vi), "any food, food additive, drug, cosmetic, or device . . . when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device." 15 U.S.C. 2602(2)(B)(vi). To the extent that bonding agents in the production of specialty batteries for medical applications qualify as a "device" as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, those particular uses that qualify as a "device" would be excluded from the "chemical substance" definition if "manufactured, processed, or distributed in commerce for use as a . . . device," and would therefore not be subject to the rule if finalized). This stakeholder requested an exemption under TSCA section 6(g) for this use of methylene chloride. According to the requester, all major military and space applications, such as aircraft (F-35, B2), radios, and Mars mission equipment, require these batteries to function in very harsh conditions, including operation to -40 °C and storage at -54 °C.

Methylene chloride is used as a bonding agent for assembly of the plastic casings for these specialty batteries. The requester views the casing as a critical component of the battery because it houses and protects the cell anodes and cathodes. The requester explains that, during the solvent bonding process, methylene chloride dissolves the plastic slightly, allowing the polymers to form a physical bond comprised of the parent material. This results in a fully bonded battery casing which acts as a single Unit, rather than individual pieces integrated with layers of a different material. According to the requester, methylene chloride is a superior bonding agent for this process because of its unique evaporative qualities. In the requester's view, methylene chloride's low evaporation rate results in a higher degree of polymer bonding and a stronger casing, with less residue to inhibit the bonding process. The requester is not aware of any substance other than methylene chloride that would enable the production of battery casings of sufficient strength and durability for these specialty batteries. The requester further contends that

the governmental and other entities for whom the requester produces these batteries prevent the substitution for methylene chloride in their contract specifications.

EPA's consideration of the lack of availability of technologically and economically feasible alternatives, pursuant to TSCA section 6(c)(2)(C), was one factor in the proposed determination not to prohibit manufacture, processing, distribution in commerce, and use of methylene chloride as a bonding agent for acrylic and polycarbonate in mission critical military and space vehicle applications, such as in the production of specialty batteries for use in such applications (Ref. 48) (discussed further in Unit V.B.). However, under TSCA section 6(a), EPA must still address identified risks such that they are no longer unreasonable. Based on information provided by NASA and the vendor, EPA determined that the production of these specialty batteries necessarily occurs in a highly industrialized and well-controlled environment, which EPA does not expect to be replicated for most uses of methylene chloride in general use adhesives. Such a highly industrialized and well-controlled environment would allow for establishment of a regulated area and effective monitoring. Additionally, EPA expects that, for this specific use, facilities would be able to successfully implement the WCPP, including exposure reduction to levels below which the unreasonable risk would not be present due primarily to the small quantities of methylene chloride used, as well as to the engineering and other controls in place. For example, in the vendor's process, "methylene chloride is a component of the bonding cement that is moved through an entirely closed tubing system into a vented reservoir and vented enclosure for bonding and curing" (Ref. 48). In this way, use of methylene chloride as a bonding agent in specialty batteries resembles other uses of methylene chloride for which the WCPP is being proposed such as laboratory use and paint and coating removal by Federal agencies on safety-critical, corrosion-sensitive aircraft components. For this reason, EPA is proposing a WCPP for this particular subset of the methylene chloride

commercial use in adhesives condition of use. EPA requests comment and further information regarding the Agency's expectations that the facilities in which this use is carried out are industrialized and highly controlled, and that existing or expected exposure reduction and workplace controls would be successful in achieving the requirements of the WCPP. EPA also notes that while the Agency is not aware of any similar use of methylene chloride as a bonding element for batteries for commercial spaceflight or other use, it requests comment and information on any such use.

For methylene chloride to be available for processing as a reactant and industrial and commercial use as a laboratory chemical, it must be manufactured (including imported), processed, and distributed in commerce. Likewise, as long as methylene chloride remains in use, it must also be disposed of. The manufacturing, processing, and disposal conditions of use for methylene chloride include, to some extent, the factors described earlier in this Unit favor the successful implementation of the WCPP (*e.g.*, they do not take place in the field (*i.e.*, they do not take place outside of a highly controlled environment) and are highly industrialized). Regulating upstream manufacturing and processing of methylene chloride is a key component of the supply-chain approach for risk management of commercial and consumer use of methylene chloride. Therefore, as discussed in Unit IV.A.1., EPA is proposing the WCPP for manufacture (including importing) and processing for certain uses, and disposal to ensure that workers are not subject to the unreasonable risk from methylene chloride as it moves throughout the supply chain.

Additionally, for methylene chloride, the strong precedent for dermal protection set by 29 CFR 1910.1052, in combination with the risk characterization in the 2020 Risk Evaluation for Methylene Chloride which indicated chemically resistant gloves, together with activity specific training are sufficient to address the unreasonable risk, led EPA to propose a dermal PPE requirement as part of the WCPP (Ref. 1).

As discussed in the Economic Analysis, there is some uncertainty relative to the burden of recycling and disposal facilities that would be required to implement a WCPP under this proposed regulation, particularly in implementing an air monitoring program. For example, disposal facilities may be receiving methylene chloride intermittently; however, facilities that currently receive methylene chloride-containing products or formulations for disposal may not receive methylene chloride in the future, as restrictions are finalized. As many of these facilities are small entities, EPA is requesting comment on what regulatory flexibilities (*e.g.*, extended compliance) may be afforded to entities that would continue to recycle and dispose of methylene chloride under the proposed regulation.

2. Prohibition.

Because both EPA's 8-hour ECEL and 15-minute EPA STEL are significantly lower than the OSHA PEL and STEL, there is a high degree of uncertainty as to whether most industrial and commercial users will be able to comply with such a level and thus whether the unreasonable risk would be addressed. As discussed earlier in this Unit, this uncertainty, combined with the severity of the risks of methylene chloride and the prevalence of cost-effective alternative processes and products (Ref. 3), has led EPA to propose prohibitions, rather than compliance with the WCPP, for most industrial and commercial uses of methylene chloride, as outlined in Unit IV.A.2.

EPA also considered the potential for methylene chloride use to increase in particular sectors, such as vapor degreasing applications, where it has largely been phased out because of the well-established hazard (Refs. 3, 49). In order to prevent the potential for use of methylene chloride to increase in a sector that has already moved away from it, use of methylene chloride in vapor degreasing would be prohibited under the proposed regulatory and primary alternative regulatory action. The decline in use of methylene chloride was one of several considerations

that led EPA to propose to prohibit use of methylene chloride in vapor degreasing.

Regarding industrial, commercial, and consumer uses of methylene chloride, TSCA section 6(a)(2) provides EPA with the authority to prohibit or otherwise restrict the manufacture (including import), processing, or distribution in commerce of a substance or mixture "for a particular use" to ensure that a chemical substance no longer presents unreasonable risk. For this rule, EPA proposes that "for a particular use" includes consumer use more broadly, as well as industrial and commercial use, which encompasses the individual industrial, commercial, and consumer uses evaluated in the 2020 Risk Evaluation for Methylene Chloride. Given the severity and ubiquitous nature of the risks identified in the 2020 Risk Evaluation for Methylene Chloride for all industrial, commercial, and consumer use, and noting that those conditions of use encompass all known, intended, and reasonably foreseen use of methylene chloride (other than 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)), EPA proposes that prohibiting manufacture (including importing), processing, and distribution in commerce of methylene chloride for most industrial and commercial use and all consumer use is reasonable and necessary to eliminate the unreasonable risk of methylene chloride from industrial, commercial, and consumer use, including by precluding retailers from selling methylene chloride and methylene chloride-containing products to consumers for unspecified end-uses. (The proposed prohibitions would not extend to the use of methylene chloride in consumer paint and coating removers since manufacturing, processing, and distribution for that use are already prohibited.) EPA believes that any retailer selling methylene chloride-containing products to consumers for unspecified end-uses would be selling products for use by consumers for one of the consumer uses EPA evaluated in the 2020 Risk Evaluation for Methylene Chloride and found to drive the unreasonable risk for methylene chloride in the 2022 revised risk determination.

EPA's proposed requirements to address unreasonable risk to consumers and bystanders to consumer use are described in Unit IV.A.

A key consideration regarding consumer uses is the role of retailers and other distributors. A retailer is defined in 40 CFR 751.103 as any entity that makes available a chemical substance or mixture to consumer end users, including through e-commerce internet sales or distribution, and is not specific to retailers of methylene chloride. Previously, in the 2019 methylene chloride TSCA section 6(a) risk management rulemaking addressing consumer use of methylene chloride in paint and coating removal (Ref. 37), EPA prohibited (*see* 40 CFR 751.105(c)) retailers from distributing in commerce paint and coating removers containing methylene chloride, as well as distribution to retailers under 40 CFR 751.105(b) (Ref. 37). To meet the same goal of protecting consumers from accessing methylene chloride-containing products that could pose unreasonable risk, for a broader range of consumer use, EPA considered using a similar provision to ensure that retailers will not be able to purchase methylene chloride for sale or distribution to consumers, or to make available to consumers products containing methylene chloride. This provision aims to help prevent the use of methylene chloride in non-industrial settings or for off-label uses by consumers. For these reasons, as described in Unit IV.A.3., EPA's proposal to address unreasonable risk from methylene chloride includes prohibition on the distribution in commerce of methylene chloride to and by retailers.

3. Primary alternative regulatory option.

EPA acknowledges that for some of the occupational uses that it is proposing to prohibit, there may be some activities or facilities that could implement workplace protection requirements necessary to ensure that exposure remain below the ECEL and EPA STEL. In some cases, they may be able to undertake more extensive risk reduction measures than EPA currently anticipates. Therefore, for EPA's primary alternative regulatory action described in Unit IV.B.,

EPA is considering and requesting comment on a WCPP, including requirements to ensure exposures remain below an ECEL and EPA STEL, for some conditions of use of methylene chloride in addition to those conditions of use which are proposed to be subject to a WCPP under the proposed regulatory action (*i.e.*, those additional uses listed in Unit IV.B.). This includes conditions of use that have not resulted in documented acute fatalities, where reasonably available information suggests minimal ongoing use, where reasonably available information suggests use of methylene chloride may increase if other solvents are significantly restricted for that use such as for other solvents undergoing risk evaluation under TSCA section 6(b), and where the regulated entities may have fewer challenges implementing requirements to meet an ECEL and EPA STEL because work activities may occur in sophisticated facilities or take place in a closed system. The additional conditions of use which would be subject to WCPP under the primary alternative regulatory action described in this notice meet all of these criteria. However, EPA was not able to identify reasonably available information such as monitoring data or detailed activity descriptions to indicate with certainty that relevant regulated entities for these conditions of use could sufficiently mitigate identified unreasonable risk through a WCPP. Due to this uncertainty, EPA is requesting comment on the ways in which methylene chloride may be used in the additional conditions of use that would be subject to a WCPP under the primary alternative regulatory action, and the degree to which users of methylene chloride in these sectors could successfully implement the WCPP, including requirements to meet an ECEL and EPA STEL, as described in Unit IV.A.1., for the conditions of use listed for the primary alternative regulatory action in Unit IV.B.

Additionally, As discussed in Unit V.A.1. and 2., EPA acknowledges that for the occupational uses for which it is proposing the WCPP, there are varying degrees of uncertainty as to whether industrial and commercial owners and operators are able implement workplace

protection requirements necessary to ensure that exposures remain below the ECEL and EPA STEL. For this reason, EPA's alternative regulatory action would prohibit two uses for which EPA is proposing the WCPP (industrial or commercial use for paint and coating removal from safety-critical, corrosion-sensitive components of aircraft and spacecraft by Federal agencies and their contractors; and industrial or commercial use as a bonding agent in the production of specialty batteries for military or space applications by Federal agencies and their contractors). Because of the importance of these uses for national security and critical infrastructure, EPA's alternative regulatory action would include a time-limited exemption under TSCA section 6(g) from the prohibition for these two uses, for a period of 10 years, during which time the regulated entity would comply with a WCPP to the extent practicable. The analyses for these exemptions are in Unit IV.B.

4. Risk management requirements considered but not proposed.

Since it is unlikely that all facilities with occupational exposures to methylene chloride would be able to implement a WCPP, including requirements to meet an ECEL and EPA STEL, EPA also examined the extent to which a certification and limited access program restricting methylene chloride use to trained and licensed users could ensure that only certain workers employed by a facility would be able to purchase and subsequently use methylene chloride. Under a limited access program, entities would submit a self-certification to the distributor at the point of purchasing the products. The self-certification could consist of a statement indicating that the facility is implementing a WCPP to control exposures to methylene chloride, as well as a connection between the purchaser and the facility (*e.g.*, a current employee). As discussed earlier in this Unit, because of the severity of acute risks from methylene chloride which could potentially lead to fatalities, and the high potential for diversion of commercial products of methylene chloride for non-commercial use, EPA has significant concerns regarding the

appropriateness of a certification and limited access program for methylene chloride. These concerns are supported by previous comments received as part of public comments on the Advance Notice of Proposed Rulemaking for Methylene Chloride Commercial Paint and Coating Removal: Training, Certification and Limited Access Program expressing unease in implementing a training, certification and limited access program for methylene chloride (Ref. 50).

Several commenters on the Advance Notice of Proposed Rulemaking for Methylene Chloride Commercial Paint and Coating Removal: Training, Certification and Limited Access Program identified what they believe would be insufficiencies in training, certification, and limited access to methylene chloride (Ref. 50). Commenters expressed concerns that this type of program would not provide enough safeguards and would not eliminate unreasonable risk to workers. Commenters were skeptical of a training program's efficacy noting that deaths related to methylene chloride exposure still occurred with workers who were trained and wearing PPE (Ref. 50).

Several commenters believed that a training, certification, and limited access program would not be feasible. A commenter suggested that an effective training model to examine is the Alaska Hazardous Paint Certification program, which includes hands-on training and practice in local exhaust ventilation techniques and equipment and PPE gloves, clothing, and respirators. In the Alaskan program, a minimum of 16 hours for initial training, with at least 6 hours of hands-on training as well as 8-hour refresher class every 3 years, are necessary requirements. Moreover, commenters expressed that a robust training, certification, and limited access program would include multiple layers of training and certification and supporting documentation. A commenter also highlighted that "small businesses do not have the same resources for implementing safety programs as larger ones, yet they account for a very large percentage of

[methylene chloride] users." In light of these comments, EPA decided to account for uncertainty related to ECEL implementation and compliance for certain uses by proposing prohibitions on those uses, rather than proposing a self-certification and limited access program. Nonetheless, EPA is requesting comment on the inclusion of a certification, training, and limited access program for any uses that would be subject to a WCPP, in addition to the requirements outlined in Unit IV.A.1.

Another option that EPA considered for occupational conditions of use was requiring specific, prescribed engineering controls, administrative controls, or PPE to reduce exposures to methylene chloride in occupational settings. These prescriptive requirements would be supported by information in the 2020 Risk Evaluation for Methylene Chloride. As described in Units III.A.1. and 2., EPA received input during required consultations and additional engagement that options that align with the hierarchy of controls (*i.e.*, elimination and substitution of hazards in the workplace), which could be accomplished through the implementation of a WCPP with a risk-based exposure limit, should be preferred over prescriptive controls (*Refs. 9, 51*). Inadequacy of engineering, administrative, and PPE control measures to lower exposure below the exposure limit would mean that elimination or substitution would be the only viable methods of addressing unreasonable risk, creating in effect a de-facto prohibition. Additionally, prescriptive controls present significant uncertainties related to their feasibility and consistency of proper use.

EPA determined that such prescriptive controls (*i.e.*, engineering or administrative controls, or PPE) may not be able to eliminate unreasonable risk for some conditions of use when used in isolation. In the 2020 Risk Evaluation for Methylene Chloride, many conditions of use still drive the unreasonable risk even with the application of air-supplied APF 50 respirators (Ref. 1). Additionally, where data were reasonably available, EPA modeled the change in air

rates that would be needed to eliminate unreasonable risk and found that in some cases it was not possible to eliminate unreasonable risk with changes in airflow alone, while in other cases the change in airflow needed would not be feasible to achieve (Ref. 1). Because of the uncertainty regarding the feasibility of exposure reductions through prescriptive controls alone, EPA determined that a WCPP, including requirements to meet an ECEL and EPA STEL (which would be accompanied by monitoring requirements) in tandem with the implementation of engineering controls, administrative controls, and/or PPE as elements of the program, as appropriate, would more successfully reduce exposure so that the unreasonable risk is addressed. For occupational conditions of use where compliance with the WCPP is unlikely to eliminate the unreasonable risk driven by those conditions of use, prohibitions (rather than prescribed controls) would be more appropriate to ensure that methylene chloride does not present unreasonable risk under the conditions of use.

EPA also considered limiting the weight fraction of methylene chloride in consumer products and conducted an analysis using the Consumer Exposure Models for the 2020 Risk Evaluation for Methylene Chloride to estimate whether this would reduce risks from consumer conditions of use that drive the unreasonable risk for methylene chloride, such that they no longer drive the unreasonable risk (Ref. 52). For all consumer conditions of use, the weight fraction or concentration identified through this modeling that would address the unreasonable risk through inhalation or dermal pathways was so low that it was highly unlikely that methylene chloride would still serve its functional purpose in the formulation. EPA thus concluded that a weight fraction limit would essentially function as a prohibition yet with a greater amount of uncertainty regarding compliance and no increased benefit to consumer users; it was therefore not a preferred option for consumer uses. (Refs. 1, 52).

5. Additional considerations.

After considering the different regulatory options under TSCA section 6(a), alternatives (described in Unit III.B.4.), compliance dates, and other requirements under TSCA section 6(c), EPA developed the proposed regulatory action described in Unit IV.A. to address the unreasonable risk from methylene chloride. To ensure successful implementation of this proposed regulatory action, EPA considered other requirements to support compliance with the proposed regulations, such as requiring monitoring and recordkeeping to demonstrate compliance with the WCPP, or downstream notification regarding the prohibition on manufacturing, processing, and distribution in commerce of methylene chloride, and products containing methylene chloride, for consumer use. These proposed requirements are described in Unit IV.A.

Under TSCA section 6(g)(1)(B), EPA may grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture if compliance with the requirement would significantly disrupt the national economy, national security, or critical infrastructure. Based on reasonably available information, EPA has found that a TSCA section 6(g) exemption is warranted for certain uses. Therefore, EPA is proposing to grant exemptions from the rule requirements under TSCA section 6(g), as detailed in Unit IV.A.5. Unit IV.A.5. also provides a description of the request for exemption from the rule requirements that EPA is not proposing to grant. TSCA section 6(g) assumes a particular use cannot continue such that the risks are no longer unreasonable. However, EPA notes that information may be provided during the public comment period indicating this may not be case. For example, new information may demonstrate compliance with a WCPP is possible.

As required under TSCA section 6(d), any rule under TSCA section 6(a) must specify mandatory compliance dates, which shall be as soon as practicable with a reasonable transition period, but no later than 5 years after the date of promulgation of the final rule (except in the case

of a use exempted under TSCA section 6(g)). For ban or phase-out requirements, EPA must specify mandatory compliance dates for the start of ban or phase-out requirements, which must be as soon as practicable but no later than 5 years after the date of promulgation of the final rule (except in the case of a use exempted under TSCA section 6(g)), and for full implementation of ban or phase-out requirements, which must be as soon as practicable. These compliance dates are detailed in Unit IV.A. and IV.B.

B. Consideration of Alternatives in Deciding Whether to Prohibit or Substantially Restrict Methylene Chloride

Under TSCA section 6(c)(2)(C), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, EPA must consider, to the extent practicable, whether technically and economically feasible alternatives that benefit human health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect. To that end, in addition to an Economic Analysis (Ref. 3), EPA conducted an Alternatives Assessment, using reasonably available information (Ref. 40).

For this assessment, EPA identified and analyzed alternatives to methylene chloride in products relevant to industrial, commercial, and consumer conditions of use proposed to be prohibited or restricted, even if such restrictions are not anticipated to substantially prevent the condition of use. EPA is aware of the lack of viable alternatives to methylene chloride for several conditions of use and considered that information to the extent practicable in the development of the regulatory options as described in Unit III.B.3.

As an example, EPA's consideration of the lack of viable alternatives to processing methylene chloride in the manufacture of HFC-32 taken in context with the risk estimates,

monitoring data, and expected work practices informed EPA's proposed approach of WCPP for this condition of use. Similarly, when proposing WCPP for industrial or commercial use of methylene chloride for paint and coating removal from mission- and safety-critical, corrosion sensitive components of aircraft and spacecraft by Federal agencies or their contractors, EPA considered how the safety-critical, corrosion-sensitive components would be so negatively affected by the use of technically incompatible, substitute paint removal chemicals or methods that the safe performance of the aircraft could be compromised. There are no known substitutes for methylene chloride for this particular use. As discussed in the preamble to the 2017 NPRM, DOD has actively sought to reduce its use of methylene chloride in paint and coating removal since 1990. DOD has replaced most of its usage of methylene chloride for paint and coating removal with mechanical methods, benzyl alcohol products, other solvents, and laser ablation. In an effort to reduce the use of all hazardous air pollutants (HAPs) such as methylene chloride, the Army has conducted tests to identify and test the effectiveness of HAP-free paint and coating removers on military high-performance coatings (Ref. 53). In another example, the Air Force in December 2015 significantly reduced the use of methylene chloride for removing coatings on flight control parts and is now using substitute chemical products, primarily those with benzyl alcohol formulations (Ref. 48). Similarly, the Navy has transitioned substitutes to paint methylene chloride use when alternatives with equal performance are identified. For DOD, this evaluation of and transition to safer alternatives is ongoing and substitutions are approved where technically feasible and commensurate with performance and mission-readiness requirements.

DOD continues to pursue potential substitutes for methylene chloride. However, for safety-critical, corrosion-sensitive components on military aviation, including safety-critical components, DOD has found that currently available substitute chemicals for paint and coating removal have one or more technical limitations. These include the inability to effectively remove

specific military high performance or chemical resistant coatings and incompatibility with underlying metallic, nonmetallic, and composite materials, resulting in material damage to critical components. In addition, substitute chemicals or methods currently available do not support DOD's need for coating removers that enable critical safety inspection, non-destructive inspection, material assessment, or field repair processes. For example, benzyl alcohol has replaced methylene chloride in many DOD paint and coating removal applications. However, acid benzyl alcohol formulations, which work more quickly than alkaline formulations, cannot be used on high-strength steel or magnesium metals because there is the potential for resulting hydrogen embrittlement (Ref. 54). In DOD's experience, the alkaline benzyl alcohol formulations require 25 to 50% more time than methylene chloride and are more labor-intensive, particularly on very thick coatings or polyurethane coatings with water-based primers (Ref. 54). In addition, the reaction rate for alkaline benzyl alcohol formulations is very slow when the temperature is below 65 degrees, so paint and coating removal in cold locations with this alternative must be performed in a heated area (Ref. 54). As described earlier in Unit V.A.1., aircraft and other assets operated by DHS, NASA, and the FAA also contain safety-critical, corrosion-sensitive components of the type described by DOD, and suitable alternatives to methylene chloride are similarly not available for all applications. Substitute chemicals for paint and coating removal for safety-critical, corrosion-sensitive components are not technically feasible as they have one or more technical limitations; are incompatible with underlying materials; and/or do not support the coating removal requirements of safety inspections, non-destructive inspection, material assessment, or field repair processes. Therefore, EPA has evaluated the effect that a significant restriction on the use of methylene chloride would have for industrial and commercial paint and coating removal by DOD, DHS, NASA, and FAA and concluded that under TSCA section 6(c)(2)(C) that technologically and economically feasible

alternatives that benefit health or the environment would not be readily available as a substitute. Due to the essential nature of this subset of activities under industrial or commercial use of methylene chloride as a paint and coating remover, EPA's consideration of the availability of technologically and economically feasible alternative was one factor in the proposed determination not to prohibit manufacture, processing, distribution in commerce, and use of methylene chloride for paint and coating removal for safety-critical, corrosion sensitive components.

As an additional example, EPA considered the information provided regarding a lack of viable alternatives for the use of methylene chloride in chemical bonding of acrylic and polycarbonate, specifically for specialty batteries for use in military and space applications. As described earlier in Unit V.A., EPA received information from a stakeholder, as part of a request for an exemption under TSCA section 6(g), describing how methylene chloride is uniquely suited as a bonding agent for these specialty batteries. Upon receipt of the TSCA section 6(g) exemption request summarized in this unit, EPA consulted with NASA, and NASA provided information on its effort to screen alternative adhesives for the chemical bonding of acrylic and polycarbonate. Specifically, NASA identified ten materials and completed screening-level testing for six of those ten materials as of the publication of this proposed rule. Results submitted to EPA indicate that none of the materials tested met the technical requirements for chemical bonding applications (Ref. 47). While vendors submitting the TSCA section 6(g) exemption request predicted a timeline of at least one year to find a replacement for the bonding agent for specialty batteries, NASA noted that the projected substitution timeline applies only to the vendor's own battery production process. The total timeline, including qualification testing for human spaceflight, is a complex, multi-year process that could only begin after the vendor's substitution was completed.

NASA additionally emphasized that losing access to qualified high-performance substances such as specialty batteries would have immediate effects for currently ongoing space-flight programs, including the Artemis Program, with the potential to introduce an unacceptable level of risk to crew, vehicle, and viability of the program. Qualification of materials for human spaceflight can take years and significant resources to accomplish, while potentially impacting program production schedule and launch manifest.

NASA has emphasized that specific Artemis components have been designed to work with the identified specialty batteries with polycarbonate casing bonded using methylene chloride. The safety and reliability of these batteries has been established in uncrewed Artemis I test missions, and the next flights will take humans back to the Moon. A change of battery material would require recertification of multiple hardware pieces, retesting of crew and vehicle safety, and disrupt parts production and launch schedules that are already underway. NASA notes that stockpiling of batteries would not be an option, as batteries have a 2-year shelf life.

For this use, EPA has concluded under TSCA section 6(c)(2)(C) that technologically and economically feasible alternatives that benefit health or the environment would not be readily available as a substitute. Due to the essential nature of this subset of activities under industrial or commercial use of methylene chloride as an adhesive, a paint and coating remover, EPA's consideration of the availability of technologically and economically feasible alternative was one factor in the proposed determination not to prohibit manufacture, processing, distribution in commerce, and use of methylene chloride as a bonding agent in the production of specialty batteries for use in military and space applications.

EPA also notes that, for some conditions of use, EPA was unable to identify products currently available for sale that contain methylene chloride. EPA is soliciting comments on whether there are actually products in use or available for sale relevant to these conditions of use

that contain methylene chloride at this time, so that EPA can ascertain whether there are alternatives that benefit human health or the environment. These conditions of use are detailed in the Alternatives Assessment (Ref. 40).

For conditions of use for which products currently containing methylene chloride were identified, EPA identified several hundred commercially available alternative products that do not contain methylene chloride, and listed in the Alternatives Assessment, to the extent practicable, their unique chemical components, or ingredients. For each of these chemical components or ingredients, EPA identified whether it functionally replaced methylene chloride for the product use and screened product ingredients for human health and environmental hazard, as well as identified flammability and global warming potential where information was reasonably available (Ref. 40). EPA then assigned a rating to the human health and environmental hazards, using a methodology described in the Alternatives Assessment document. EPA identified 65 total alternative products in the paint and coating remover category, of which furniture refinishing is a subcategory (Ref. 48). As described in the Economic Analysis, while not all of these alternative products may meet the specific use for some furniture refinishing uses, mechanical or thermal methods may be non-chemical alternatives to using products containing methylene chloride for paint and coating removal. EPA did not find barriers to pricing, customer satisfaction, coating removal performance, or content (specifically volatile organic compounds, or VOC) that may be caused by restricting the use of methylene chloride in this product category in general. For fire safety, the restriction of methylene chloride in this product category is met by products with very high flash points, or products with evaporation barriers that restrict vapor generation (Ref. 3). Therefore, EPA finds that there are technological and economically feasible alternatives in the marketplace.

In general, EPA identified products containing ingredients with a lower hazard screening

rating than methylene chloride for certain endpoints, while some ingredients presented higher hazard screening ratings than methylene chloride (Ref. 40). These alternative hazard screening ratings are described in detail in the Alternatives Assessment grouped under common product use categories (Ref. 40). EPA has therefore, pursuant to TSCA section 6(c)(2)(C), considered, to the extent practicable, whether technically and economically feasible alternatives that benefit human health or the environment, compared to the use proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction becomes effective. EPA is additionally requesting comment on the alternatives analysis as a whole.

VI. 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 drive 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, fenceline 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). As mentioned in Unit II.D., EPA has separately conducted a screening approach to assess whether there may be risks to the general population from these exposure pathways. While the use of this screening approach indicates some level of risk to fenceline communities, EPA cannot determine, without further data and quantitative analysis, whether the risk to these communities would be an unreasonable risk. This Unit summarizes the results of that fenceline analysis. Although EPA is not making a determination of unreasonable risk based on the fenceline screening analysis, the proposed regulatory action described in Unit IV. is expected to reduce the risks identified in the screening approach.

As described in Unit II.D., EPA's analysis was presented to the SACC peer review panel in March 2022, and EPA plans to consider SACC feedback (including the SACC recommendation to EPA to consider multiple years of release data to estimate exposures and associated risks) and make decisions regarding how to assess general population exposures in upcoming risk evaluations, such as for 1,4-dioxane and for the forthcoming 20 High Priority Substances. For methylene chloride, EPA recognizes that a key input into the fenceline assessment was data on releases from the most recent Toxics Release Inventory (TRI) reporting year and that the use of more than one year of data could result in different conclusions. Accordingly, in this Unit EPA presents the results of its analysis of the extent to which including more than one year of TRI data impacts EPA's conclusions regarding fenceline risks (Ref. 55).

EPA's fenceline 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.

Additionally, EPA's analysis, as presented to the SACC, identified 14 facilities, representing nine conditions of use, with some indication of expected exposure and associated cancer risk to receptors within select distances evaluated from 5 to 100 meters from the inhalation pathway. Those nine conditions of use are: industrial and commercial use in non-aerosol degreasers and cleaners; industrial and commercial use as a solvent for in-line vapor degreasing; industrial and commercial use as a solvent for cold cleaning; industrial and commercial use in aerosol spray degreasers and cleaners; industrial and commercial use in cellulose triacetate film production; industrial and commercial use in plastic and rubber product manufacturing; processing: incorporation into a formulation, mixture, or reaction product; industrial and commercial use as a propellant and blowing agent; and industrial and commercial use in paint and coating removers. Under the proposed regulatory action described in Unit IV.A., all of the conditions of use with an indication of risk from 5 to 100 meters would be prohibited, with the exception of processing: incorporation into a formulation, mixture, or reaction product.

Of those 14 facilities with indicated risk, only three had an indication of risk out to 100 meters from a releasing facility. Those three facilities represent three total conditions of use: industrial and commercial use in non-aerosol degreasers and cleaners; industrial and commercial use for plastic product manufacturing; and industrial and commercial use as a propellant and blowing agent. Under the proposed regulatory action described in Unit IV.A., these three conditions of use, as well as all of the conditions of use with an indication of risk at 5 to 100 meters would be prohibited, with the exception of processing: incorporation into a formulation, mixture, or reaction product.

Following SACC feedback, EPA applied a slightly modified pre-screening methodology to evaluate 6 years of methylene chloride release data (2015 through 2020 Toxic Release

Inventory data as well as the 6-year average of that data) for those 14 facilities where there was an indication of exposure and associated risk via the ambient air pathway. The multi-year analysis further supported EPA's findings (indications of exposure and associated risks) from the original analysis for five of the 14 facilities, representing four conditions of use, which indicated exposure and associated risk at 100 meters from a releasing facility. Those four conditions of use are: processing: incorporation into a formulation, mixture, or reaction product; industrial and commercial use in non-aerosol degreasers and cleaners; industrial and commercial use for plastic product manufacturing; and industrial and commercial use as a propellant and blowing agent. For the additional nine facilities, the multi-year analysis did not indicate risks at 100 meters. The multi-year analysis incorporated 6 years of TRI data and found that while the annual releases may vary by as much as a factor of 10, the overall estimated exposure concentrations and associated risk calculations varied by no more than three times. Additionally, typical cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk above benchmarks ranging from 1 in 1,000,000 to 1 in 10,000 (*i.e.*, $1x10^{-6}$ to $1x10^{-4}$), in some cases depending on the subpopulation exposed. (see, *e.g.*, EPA's interpretation set forth in 54 FR 38044, September 14, 1989) which discusses the use of benchmarks for purposes of section 112 of the Clean Air Act (CAA); see also EPA's interpretation of the upper bound of acceptable risk and the preferred benchmark described in the Letter of Concern regarding EPA Complaint Nos. 01R-22-R6, 02R-22-R6, and 04R-22-R6 see page 3 footnotes 5 and 6 and page 6 (Ref. 56)). In this fenceline analysis for the ambient air pathway for methylene chloride, estimates of risk to fenceline communities were calculated using $1x10^{-6}$ as the benchmark for cancer risk in fenceline communities. While EPA is unable to determine, based on the screening level fenceline analysis, whether risks to the general population drive the unreasonable risk, as a matter of risk management policy EPA considers the range of $1x10^{-6}$ to $1x10^{-4}$ as the appropriate benchmark

for increased cancer risk for the general population, including fenceline communities. It is preferable to have the air concentration of methylene chloride result in an increased cancer risk closer to the $1x10^{-6}$ benchmark, with the $1x10^{-4}$ benchmark generally representing the upper bound of acceptability for estimated excess cancer risk. The benchmark value is not a bright line, and the Agency considers a number of factors when determining unreasonable risk, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (*e.g.*, duration, magnitude, or frequency of exposure, or population exposed). Under the proposed regulatory action described in Unit IV.A., all of the conditions of use with an indication of risk at 100 meters would be prohibited, with the exception of processing: incorporation into a formulation, mixture, or reaction product.

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 receptors within the general population at particular facilities, EPA is unable to formally determine with this analysis whether those risks drive the unreasonable risk. However, EPA believes that the prohibitions being proposed for manufacturing (including importing), processing, and distribution in commerce for 45 of 53 uses, including all consumer use and most commercial use, would address the majority of exposures to the general population. Of the 14 facilities which indicated some risk for methylene chloride, under the proposed regulatory option, only 3 could continue to use methylene chloride (all for processing: incorporation into formulation, mixture, or reaction product), and thus exposures to the fenceline at the remainder of those facilities would be addressed.

Under the proposed rule, only ten conditions of use would continue, namely domestic manufacturing (for downstream uses that would continue under the WCPP); import; processing as a reactant; processing: incorporation into a formulation, mixture, or reaction product;

processing as repackaging; processing as recycling; industrial and commercial use as a laboratory chemical; 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. Of those conditions of use, only processing: incorporation into formulation, mixture, or reaction product has risk indicated at the fenceline, and based on land use analysis, there do not appear to be communities currently located at the fencelines (Ref. 57). Additionally, over time this condition of use can reasonably be expected to decline because, while processing into a formulation, mixture, or reaction product would continue under a WCPP, all downstream distribution and use of formulations, mixtures, or reaction products (except for laboratory use and any time limited exemptions that could be established under TSCA section 6(g)) would be prohibited.

For all ten conditions of use that would remain ongoing, the proposed rule would require exposure controls via implementation of a WCPP as described in Unit IV.A.1. In the instances where 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 believes this potential exposure would be limited as a result of the existing National Emission Standards for Hazardous Air Pollutants (NESHAPs) for methylene chloride for these conditions of use under the CAA (applicable NESHAPs: 40 CFR part 63 subpart F, Synthetic Organic Chemical Manufacturing Industry; 40 CFR part 63 subpart DD, Off-Site Waste and Recovery Operations; 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 that any exceedances are an enforcement issue. Thus, EPA's proposal to prohibit manufacture,

processing, and distribution in commerce of methylene chloride for all consumer use and most industrial and commercial use, and to prohibit 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 fenceline 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 drive the unreasonable risk.

For all conditions of use, the unreasonable risk determination is not driven by exposures via water for acute and chronic exposures to methylene chloride for amphibians, fish, and aquatic invertebrates. 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, indicated risk, 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

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 hydrofluorocarbon-32 (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. 8).

D. Reasonably Ascertainable Economic Consequences of the Proposed 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 proposed rule include several components, all of which are described in the Economic Analysis for this proposed rule (Ref. 3). With respect to the anticipated effects of this proposed 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. 58). 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 $13.2 million annualized over 20 years at a 3% discount rate and $14.5 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 addition, EPA considered the employment impacts of this proposed 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. To that end, EPA is requesting public comment on short term and longer-term employment effects from this proposal.

Of the small businesses potentially impacted by this proposed rule, 98% (225,248 firms) are expected to have impacts of less than 1% to their firm revenues (rounded metric), 0.1% (118 firms) are expected to have impacts between 1 and 3% to their firm revenues (rounded metric), and 0.03212.1% (4,905 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). Thus, the estimated total impact of the rule on small businesses ranges from $11.1 to $73.6 million (see section 7.11 of the Economic Analysis). Commercial paint and coating removers are one product type where for which methylene chloride is likely the most effective product for many applications. In particular, alternatives to methylene chloride paint and coating removers in commercial furniture refinishing may not be as cost-effective for this use because they may take more time to achieve the desired outcome or require alternate processes affecting operations that present challenges for certain businesses. The impact of a prohibition of methylene chloride for furniture refinishing could result in the closure of an unknown number of affected entities or business lines. As discussed in Unit I.E., closure of affected furniture refinishing firms using methylene chloride following this rulemaking has an upper bound for economic impacts of $1.8 billion in total revenue, and $67 million in terms of the total profit,

under the assumption that all affected firms fully close due to the restrictions on methylene chloride. A detailed discussion of potential economic impacts as a result of varying percentages of furniture refinishing firms closing is provided in the Economic Analysis in section 7.11 (Ref. 3).

With respect to this proposed 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 proposed rule may increase demand for existing, as well as development of additional, safer chemical substitutes. This proposed rule is not likely to have significant effects on the environment because, as discussed in Unit VI.B., methylene chloride does not present an unreasonable risk to the environment, though this proposed 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 proposed 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.

2. Costs and benefits of the proposed 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 in the Economic Analysis (Ref. 3). The non-closure-related costs for this proposed rule are estimated to be $13.2 million annualized over 20 years at a 3% discount rate and $14.5 million annualized over 20 years at a 7% discount rate. The monetized benefits are estimated to be $17.7 to $18.5 million annualized over 20 years at a 3% discount rate and $13.4 to $13.9 million annualized over 20 years at a 7% discount rate.

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

and enforce alternative regulatory actions. The primary alternative regulatory action is described in detail in Unit IV.B. The estimated annualized, non-closure-related costs of the primary alternative regulatory action are $12.4 million at a 3% discount rate and $13.3 million at a 7% discount rate over 20 years (Ref. 3). The estimated annualized benefits of this primary alternative regulatory action are $17.7 to $18.5 million at a 3% discount rate and $13.4 to $13.9 million at a 7% discount rate over 20 years (Ref. 3).

This proposal 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. EPA believes that the balance of costs and benefits of this proposal 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 Units II.A. (overview), III.B.2. (description of the unreasonable risk), V.A. (discussion of the health effects), and the Risk Evaluation. 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 proposed rule. As the proposed option is more restrictive and

therefore more protective than the primary alternative option, the value of unquantified benefits may be higher for the proposed option. This implies that the difference between the proposed and primary alternative options is larger than it appears, in favor of the proposed option, based on monetized benefits alone.

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. 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, animal studies observed effects mostly at higher methylene chloride concentrations, and EPA identified no relevant mechanistic information (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. 59).

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 proposed 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 proposed regulatory action is to prevent user deaths resulting from exposure to methylene chloride. The proposed regulatory action would cost, excluding closure-related costs, $9.9 million per potential prevented death while the primary alternative regulatory action would cost, excluding closure-related costs, $9.3 million per potential prevented death (using the 3% discount rate). While the primary alternative regulatory action would be lower in cost compared to the proposed action, the difference is small and both options are considered to have similar levels of cost effectiveness in decreasing the potential for death from exposure to methylene chloride (Ref. 3). See Chapter 9 of the Economic Analysis for greater detail on the cost effectiveness of the proposed and primary regulatory actions.

4. Requests for comment on economic analysis.

As described in the Economic Analysis, two conditions of use, Processing: Recycling and Disposal, are responsible for the majority (~60%) of the estimated total $13 million non-closure-related costs of the rule. Given the prevalence of small entities in this sector, EPA requests comment on what regulatory flexibilities, within the scope of TSCA and mitigating unreasonable

risk, may be afforded to these conditions of use to reduce burden of complying with the WCPP.

As described in the Economic Analysis and the Alternatives Assessment, alternatives for methylene chloride as a processing aid were not identified. EPA requests information on potential alternative processing aids to methylene chloride as it relates to the proposed regulatory option for this COU. The Economic Analysis includes a qualitative discussion of uncertainty in cost estimates, including uncertainties related to the cost of reformulating products that currently contain methylene chloride, which could be underestimated, or overestimated. EPA requests comment on additional aspects of reformulation, including any costs that may be associated with mitigating countervailing risks of alternative formulations. Additionally, EPA requests comment on the degree to which qualities or properties of methylene chloride, beyond those discussed in the Economic Analysis and summarized in Unit VI.C. may make methylene chloride a preferable choice when compared to alternatives with similar costs and effectiveness. EPA also requests comment regarding information to estimate transition costs to suitable alternatives, including how often these costs might be incurred or what the specific costs would be per-user or per-firm when they are incurred. Similarly, EPA requests comment on how costs and economic impacts from firm closures may be reduced with longer compliance timeframes. Finally, EPA requests comment on how better to monetize the benefits of each alternative in the Economic Analysis and whether EPA should consider any other categories of benefits.

VII. 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, for this proposed rule, 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.

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 proposed rule, EPA has coordinated with appropriate Federal executive departments and agencies including OSHA and the Consumer Product Safety Commission (CPSC) to identify their respective authorities, jurisdictions, and existing laws with regard to risk evaluation and risk management of methylene chloride, which are summarized in this Unit.

As discussed in more detail in Unit II.C., 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. As noted previously, to set PELs for chemical exposure, OSHA must first establish that the new standards are economically and technologically feasible (79 FR 61384, 61387, Oct. 10, 2014). When setting the 8-hour TWA PEL for methylene chloride in 1997, OSHA concluded that "at the 25 ppm PEL the residual risk still greatly exceeds any significant risk threshold," but set the PEL at that level because it was the lowest level for which OSHA could document technological and economic feasibility across

the affected industries at that time (62 FR 1494, 1575 January 10, 1997; 63 FR 50172, 50713, September 22, 1998). Thus, if OSHA were to initiate a new action to lower its PEL, the difference in requirements between the OSH Act and TSCA could result in the OSHA PEL still being set at a higher level than the risk-based exposure limit for methylene chloride determined by EPA to be necessary to address the unreasonable risk identified under TSCA. However, EPA believes that the feasibility of technology has advanced over the last 25 years such that for certain conditions of use, based on monitoring data received during the risk evaluation and feedback during SBAR, EPA's risk-based level of 2 ppm is achievable, and indeed, is already being achieved. For most industrial and commercial conditions of use, EPA has determined it is not feasible to meet the ECEL and is thus proposing to prohibit those uses. In addition, OSHA may set exposure limits for workers, but its authority is limited to the workplace and does not extend to consumer uses of hazardous chemicals, and thus OSHA cannot address the unreasonable risk from methylene chloride under all of its conditions of use, which include consumer uses. OSHA also does not have direct authority over State and local employees, and it has no authority over the working conditions of State and local employees in States that have no OSHA-approved State Plan under 29 U.S.C. 667.

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. CPSC issued its methylene chloride guidance under the FHSA, which does not include the same jurisdictional exceptions as the CPSA. Recently, CPSC revised its labeling guidance for methylene chloride under the FHSA to provide more immediate guidance and clarity to consumers and industry regarding the acute hazards associated with using methylene chloride-

based paint removers while they remain on the market (83 FR 12254, March 21, 2018). However, while EPA believes that the updated CPSC labeling guidance, if properly implemented by industry, would prevent some users from using methylene chloride paint and coating removal products in an unsafe manner, for the reasons described in the proposal, it is unlikely to address the unreasonable risks to consumers under a 9(a) determination by the Administrator. Furthermore, in a letter to EPA regarding paint and coating removers, CPSC stated "because TSCA gives EPA the ability to reach both occupational and consumer uses, we recognize that EPA may address risks associated with these chemicals in a more cohesive and coordinated manner given that CPSC lacks authority to address occupational hazards." (EPA-HQ-OPPT-2016-0231-0154).

Therefore, EPA maintains that TSCA is the appropriate vehicle to deliver broad protections to consumers who may use formulations that contain methylene chloride and whose use drives the unreasonable risk of injury to health from methylene chloride. An action under TSCA also would be 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 2-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.

Moreover, 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., In a TSCA section 6

risk management rule, following an unreasonable risk determination, EPA must apply risk management requirements to the extent necessary so that the chemical no longer presents unreasonable risk and only consider costs and benefits of the regulatory action to the extent practicable, 15 U.S.C. 2605(a) and (c)(2). By contrast, a consumer product safety rule under the CPSA must include a finding that "the benefits expected from the rule bear a reasonable relationship to its costs." 15 U.S.C. 2058(f)(3)(E). Additionally, the 2016 amendments to TSCA reflect Congressional intent to "delete the paralyzing 'least burdensome' requirement," 162 Cong. Rec. S3517 (June 7, 2016), a reference to TSCA section 6(a) as originally enacted in 1976, which required EPA to use "the least burdensome requirements" that protect "adequately" against unreasonable risk, 15 U.S.C. 2605(a) (1976). However, a consumer product safety rule under the CPSA must impose "the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated." 15 U.S.C. 2058(f)(3)(F) Analogous requirements, also at variance with recent revisions to TSCA, affect the availability of action CPSC may take under the FHSA relative to action EPA may take under TSCA. 15 U.S.C. 1262. But EPA's substantive burden under TSCA section 6(a) is to apply requirements to the extent necessary so that the chemical substance no longer presents the unreasonable risk that was determined in accordance with TSCA section 6(b)(4)(A) without consideration of cost or other non-risk factors.

EPA therefore concludes that TSCA is the most appropriate 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. This unreasonable risk can be addressed in a more coordinated, efficient, and effective manner under TSCA than under different laws implemented by different agencies. Further, there are key differences between the finding requirements of TSCA and those of the OSH Act, CPSA, and FHSA. For these reasons,

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, 7), 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.*, RCRA, CAA, CWA).

The primary exposures and unreasonable risk to consumers, bystanders, workers, and occupational non-users would be addressed by EPA's proposed prohibitions and restrictions under TSCA section 6(a). In contrast, the timeframe and any exposure reduction as a result of updating regulations for methylene chloride under RCRA, CAA, or CWA cannot be estimated,

nor would they address the direct human exposure to consumers, bystanders, workers, and occupational non-users from the conditions of use evaluated in the 2020 Risk Evaluation for Methylene Chloride. More specifically, none of EPA's other statutes (*e.g.*, RCRA, CAA, and CWA) can address exposures to workers and occupational non-users related to the specific activities that result in occupational exposures associated with disposal activities. EPA therefore concludes that TSCA is the most appropriate regulatory authority able to prevent or reduce risks of methylene chloride to a sufficient extent across the range of conditions of use, exposures, and populations of concern.

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, 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 confidential business information that may occur if this rule is finalized as proposed. 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 confidential business information 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). If this rule is finalized as proposed, then pursuant to TSCA section 14(b)(4)(B)(iii), the presumption against protection from disclosure would apply only to information about the specific conditions of use that this rule would prohibit or phase out. Similarly, if this rule is finalized as proposed, the presumption against protection from disclosure would not apply to certain uses that this rule proposes to

exempt from the ban or phase-out pursuant to TSCA section 6(g). Per TSCA section 14(b)(4)(B)(i), the presumption against protection would not apply to information about these conditions of use. However, the presumption against protection would apply to information about conditions of use that are not exempt from the ban or phase-out, pursuant to TSCA section 6(g). Manufacturers or processors seeking to protect such information would be able to submit a request for nondisclosure as provided by TSCA sections 14(b)(4)(C) and 14(g)(1)(E). Any request for nondisclosure would need to be submitted within 30 days after receipt of notice from EPA under TSCA section 14(g)(2)(A). EPA anticipates providing such notice via the Central Data Exchange (CDX).

D. TSCA Section 26 Considerations

In accordance with TSCA section 26(h), EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science. As in the case of the unreasonable risk determination, risk management decisions for this proposed rule, as discussed in Unit III.B.3. and Unit V., were based on a risk evaluation that was subject to public comment and independent, expert peer review, and developed in a manner consistent with the best available science and based on the weight of the scientific evidence as required by TSCA sections 26(h) and (i) and 40 CFR 702.43 and 702.45. In particular, the ECEL and EPA STEL values incorporated into the WCPP are derived from the analysis in the 2020 Risk Evaluation for Methylene Chloride; they likewise represent decisions based on the best available science and the weight of the scientific evidence (Ref. 11). The ECEL value of 2 ppm as an 8-hour TWA is based on the chronic non-cancer human equivalent concentration (HEC) for liver toxicity identified in the 2020 Risk Evaluation for Methylene Chloride, which is the concentration at which an adult human would be unlikely to suffer adverse effects if exposed for a working lifetime, including susceptible subpopulations. The EPA STEL

of 16 ppm as a 15-minute TWA is derived from the non-cancer endpoint of central nervous system depression resulting from acute exposures that was identified in the 2020 Risk Evaluation for Methylene Chloride.

The extent to which the various information, procedures, measures, methods, protocols, methodologies, or models, as applicable, used in EPA's decisions have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for this rule. Additional information on the peer review and public comment process, such as the peer review plan, the peer review report, and the Agency's response to public comments, can be found at EPA's risk evaluation docket at EPA-HQ-OPPT-2020-0465.

VIII. Requests for Comment

EPA is requesting public comment on all aspects of this proposal, including the proposed and primary alternative regulatory actions and all supporting analysis. Additionally, within this proposal, the Agency is soliciting feedback from the public on specific issues throughout this proposed rule. For ease of review, this section summarizes those specific requests for comment.

1. EPA is requesting public comment on the proposed regulatory action and primary alternative regulatory action. (Unit III.A.).

2. EPA is requesting comment on the proposed rule's TSCA section 6(g) exemptions' provisions and rationales. (Unit III.A.).

3. Following Panel recommendations in the Panel report (Ref. 6) and in response to SERs recommendations, EPA is requesting comment on the following topics as outlined in the SBAR Panel Report:

a. EPA requests comment on the extent to which a regulation under TSCA section 6(a) could minimize requirements, such as testing and monitoring protocols, recordkeeping, and reporting requirements, which may exceed those already required under OSHA's regulations for

methylene chloride.

b. EPA requests comment on the feasibility of complying with and monitoring for an Existing Chemical Exposure Limit (ECEL) of 2 ppm. In particular, EPA requests comment on changes that may be needed to meet such a standard, for example changes related to elimination of methylene chloride or substitution, engineering controls, process changes, and monitoring frequency.

c. EPA requests comment on workplace monitoring for implementation of an ECEL. EPA is soliciting information related to the frequency of monitoring, initial monitoring, and periodic monitoring for workplace exposure levels and how a lower exposure level from the OSHA PEL may impact the frequency of periodic monitoring. Specifically, EPA requests comment about when this may impact the frequency of periodic monitoring where initial monitoring shows that employee exposures are above the level that would initiate requirements for compliance with the ECEL or an OSHA STEL.

d. EPA requests comment on reasonable compliance timeframes for small businesses, including timeframes for reformulation of products or processes containing methylene chloride; implementation of new engineering or administrative controls; changes to labels, SDSs, and packaging; implementation of new PPE, including training and monitoring practices; and supply chain management challenges. EPA also requests comment on establishing differing compliance or reporting requirements or timetables that take into account the limited resources available to small entities.

e. EPA requests comment on the feasibility and availability of various prescriptive engineering controls to reduce exposure levels, and information on any technologies or prescriptive control options used in combination for addressing the unreasonable risk.

f. EPA requests comment on providing an option of either complying with the ECEL or

implementing various administrative and engineering controls, such as those employed in a closed-loop system, including information on how a small business can demonstrate that such controls eliminate the unreasonable risk for that use.

g. EPA requests comment on establishing a certification program for the use of methylene chloride by the furniture refinishing industry as well as measures to address the unreasonable risk for commercial use of methylene chloride in paint and coating removal for furniture refinishing.

h. EPA requests comment on means by which small businesses can maintain access to methylene chloride for industrial and commercial uses including establishing training, certification, and limited access programs.

i. EPA requests comment on TSCA section 6(g)(1) exemptions for any MIL-SPEC programs where methylene chloride is specified or required for a specific end-use application.

j. EPA requests comment on temporary work practices to allow for limited circumstances, including but not limited to equipment failure or maintenance activity, where monitoring may not be feasible to comply with an ECEL.

k. EPA requests comment on the extent to which methylene chloride may be used in the same facility for TSCA and non-TSCA uses.

4. EPA requests comment on whether a definition should be promulgated for each condition of use of methylene chloride and, if so, whether the descriptions in Unit III.B.1.f. are consistent with the conditions of use evaluated in the 2020 Risk Evaluation for Methylene Chloride and whether they provide a sufficient level of detail such that they would improve the clarity and readability of the regulation if promulgated. (Unit III.B.1.f.).

5. EPA is requesting comment on the proposed implementation timeframe for the WCPP requirements; EPA proposes that they would take effect 180 days after publication of the final

rule, at which point entities would be required to conduct initial monitoring (as described in Unit IV.A.1.c.) and develop an exposure control plan within 1 year of publication of the final rule (Unit IV.A.1.a. and d.). (Unit IV.A.1.a.).

6. EPA acknowledges that new monitoring methods or technologies may have been developed since 1997 that would allow for greater accuracy, and thus a smaller range for monitoring results, and EPA requests comment on the exposure monitoring accuracy requirements. (Unit IV.A.1.c.i.).

7. EPA acknowledges that the 25% buffer for the 8-hour and 15-minute TWA potentially could allow some exposures above the exposure limits proposed here. EPA requests comment on these buffers' effects and any alternatives to account for measurement variance or uncertainty. (Unit IV.A.1.c.i.).

8. EPA is soliciting comments regarding how owners and operators could conduct initial exposure monitoring to ensure that it is representative of all tasks likely to be conducted by potentially exposed persons. (Unit IV.A.1.c.ii.).

9. EPA is soliciting comments regarding the proposed requirement for recurring 5-year initial exposure monitoring. (Unit IV.A.1.c.ii.).

10. EPA requests comment on the timeframes for periodic monitoring outlined in Unit IV.A.1.c.iii, particularly whether more frequent monitoring may be possible or recommended. (Unit IV.A.1.c.iii.).

11. EPA is requesting public comments on the proposed conditions for periodic monitoring for methylene chloride as part of implementation of the WCPP that differ from OSHA's existing monitoring requirements under 29 CFR 1910.1052. (Unit IV.A.1.c.iv.).

12. EPA requests comment on the degree to which additional guidance related to use of gloves might be necessary. Additionally, EPA requests comment on whether EPA should

specifically incorporate dermal protection into the exposure control plan and require consideration of the hierarchy of controls for dermal exposures. (Unit IV.A.1.e.i.).

13. EPA requests comment on the 15-day timeframe for notification of potentially exposed persons of monitoring results and the possibility for a shorter timeframe, such as 5 days. (Unit IV.A.1.f.ii.).

14. EPA requests comment relative to the ability of owners or operators to conduct initial monitoring by 180 days after publication of the final rule, and anticipated timelines for any procedural adjustments needed to comply with the requirements outlined in Unit IV.A.1. (Unit IV.A.1.g.).

15. EPA requests comment on the impacts, if any, the proposed prohibition described in Unit IV.A.2., or other aspects of this proposal, may have on the production and availability of any food, food additive, drug, cosmetic, device, or other substance excluded from the definition of "chemical substance" under TSCA section 3(2)(B)(ii) through (vi). (Unit IV.A.2.).

16. EPA requests comment regarding the number of entities that could potentially close as well as associated costs with a prohibition of methylene chloride for certain industrial and commercial conditions of use identified in Unit IV.A.2. (Unit IV.A.2.).

17. EPA would like comment on whether it should consider a *de minimis* level of methylene chloride in formulations for certain continuing industrial and commercial uses to account for impurities (*e.g.*, 0.1% or 0.5%) when finalizing the prohibitions described in Unit IV.A., and, if so, what level should be considered *de minimis* (Units IV.A.2., and IV.A.3.).

18. EPA is proposing that the prohibition of certain industrial and commercial conditions of use described in Unit IV.A.2 would occur 90 days after the publication date of the final rule for manufacturers, 180 days for processors, 270 days for distributing to retailers, 360 days for all other distributors and retailers, and 450 days for industrial and commercial uses. EPA requests

comment on whether additional time is needed, for example, for products affected by proposed restrictions to clear the channels of trade. (Unit IV.A.2.).

19. EPA requests comments on an appropriate, predictable process that could expedite reconsideration for uses that Federal agencies or their contractors become aware of after the final rule is issued using the tools available under TSCA, aligning with the requirements of TSCA section 6(g). EPA requests comment on the appropriate types of information for use in evaluating this type of category of use, and other considerations that should apply. (Unit IV.A.2).

20. EPA would like comment on whether distributors that are not retailers should be required to use tax IDs or other verification methods prior to selling methylene chloride or products containing methylene chloride to ensure consumers are not purchasing methylene chloride or commercial or industrial products containing methylene chloride. (Unit IV.A.3.).

21. During litigation (see *Lab. Council for Latin Am. Advancement v. United States Env't Prot. Agency*, 12 F.4th 234 (2d Cir. 2021)) on a previous rulemaking (84 FR 11420, March 27, 2019) petitioners argued that EPA's definition of "retailer" was so broad as to cover all commercial entities, creating supply chain issues for commercial users seeking to attain and use the chemical for commercial activities. EPA has not found this to be the case; small businesses that are non-retail distributors exist and even participated as small entity representatives consulted as part of the SBAR process for this rulemaking. Nonetheless, EPA is soliciting comment on whether similar supply chain issues for uses that are permitted under the WCPP are anticipated. (Unit IV.A.3.).

22. EPA is proposing that the prohibition of manufacturing, processing, and distribution for consumer use described in Unit IV.A.3. would occur 90 days after the publication date of the final rule for manufacturers, 180 days for processers, 270 days for distributing to retailers, and 360 days for all other distributors and retailers after the publication date of the final rule. EPA

requests comment on whether additional time is needed, for example, for products affected by proposed restrictions to clear the channels of trade. (Unit IV.A.3.).

23. EPA requests comments on the appropriateness of identified compliance timeframes for recordkeeping and downstream notification requirements described in Unit IV.A.4. (Unit IV.A.4.b.).

24. EPA recognizes that in some situations, certain facilities may do both Federal contractor and commercial aviation work and may use methylene chloride for paint and coating removal from safety-critical, corrosion-sensitive components on military, Federal, or commercial aviation. EPA requests comment on whether such co-located activities in a facility should be subject to the WCPP, rather than the exemption under TSCA section 6(g). Additionally, EPA seeks additional information and requests comment on whether it is possible to distinguish between commercial aviation facilities that would be able to meet the WCPP and those that would not, including what criteria should be used for such distinctions (*e.g.*, size of facility, volume or type of work performed, record of exposure reduction practices). EPA also requests comment on the extent to which specific commercial aviation and aerospace uses or types of facilities could fully comply with the WCPP to address identified unreasonable risk. (Unit IV.A.5.a.i.).

25. EPA requests comments on all aspects of the proposed TSCA section 6(g) exemption from the proposed prohibition on use of methylene chloride in commercial paint and coating removal for paint and coating removal essential for critical infrastructure by certificated commercial air carriers, commercial operators, or repair stations, or by manufacturers of aircraft or aerospace vehicles and hardware, noting that the proposed exemptions would be limited to the safety-critical, corrosion-sensitive components on aircraft and aerospace vehicles, including safety-critical components. (Unit IV.A.5.a.ii.).

26. EPA requests comment on this TSCA section 6(g) exemption for continued emergency use of methylene chloride in the furtherance of NASA's mission as described in this unit, and whether any additional conditions of use should be included, in particular for any uses qualified for space flight for which no technically or economically feasible safer alternative is available. Additionally, EPA requests comment on what would constitute sufficient justification of an emergency. (Unit IV.A.5.b.ii.).

27. EPA requests comments on all aspects of the preliminary determination that a TSCA section 6(g) exemption is not warranted for the use of methylene chloride in furniture refinishing, including information on the availability of alternatives and the time needed to implement alternatives. EPA emphasizes that the Agency is seeking input regarding whether an exemption is needed and welcomes information related to this condition of use during the public comment period. (Unit IV.A.5.c.).

28. Primary alternative regulatory action: EPA requests comment on the ways in which methylene chloride may be used in the additional conditions of use that would be subject to a WCPP under the primary alternative regulatory action, and the degree to which users of methylene chloride in these sectors could successfully implement the WCPP, including requirements to meet an ECEL and EPA STEL, as described in Unit IV.A.1., for the conditions of use listed for the primary alternative regulatory action in Unit IV.B. EPA is also requesting comment on whether to consider a regulatory alternative that would subject more conditions of use to a WCPP, instead of prohibition, than those currently contemplated in the primary alternative regulatory action. EPA also requests 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. (Unit IV.B.).

29. Primary alternative regulatory action: EPA requests comment on the degree to which entities using methylene chloride as a processing aid may comply with the proposed WCPP requirements for methylene chloride. EPA requests comment on the degree to which alternatives may or may not be available for use of methylene chloride as a heat transfer fluid and in other processing aid applications. (Unit IV.B.).

30. Primary alternative regulatory action: EPA requests comment on the ability of regulated entities engaged in the additional conditions of use that would be subject to a WCPP under the primary alternative regulatory action to conduct initial monitoring within 12 months, anticipated timelines for any procedural adjustments needed to comply with the requirements, and the extent to which this option could result in additional exposure, compared the proposed regulatory option as described in Unit IV.A. Overall, EPA requests comment on any advantages or drawbacks for the timelines outlined in Unit IV.B., compared to the timelines identified for the proposed regulatory action in Unit IV.A. (Unit IV.B.)

31. EPA requests comment and further information regarding the Agency's expectations that Federal and Federal contractor facilities would be subject to a higher level of oversight than non-Federal or contractor facilities, and that existing or expected controls would be successful in achieving the requirements of the WCPP. (Unit V.A.1.).

32. EPA requests comment and further information regarding the Agency's expectations that the facilities in which use of methylene chloride as a bonding agent in specialty batteries is carried out are industrialized and highly controlled, and that existing or expected exposure reduction and workplace controls would be successful in achieving the requirements of the WCPP. EPA also notes that while the Agency is not aware of any similar use of methylene chloride as a bonding element for batteries for commercial spaceflight or other use, it requests comment and information on any such use. (Unit V.A.1.).

33. EPA is requesting comment on what regulatory flexibilities may be afforded to entities that will continue to recycle and dispose of methylene chloride under the proposed regulation. (Unit V.A.1.).

34. EPA is requesting comment on the inclusion of a certification, training, and limited access program for any uses that would be subject to a WCPP, in addition to the requirements outlined in Unit IV.A.1. (Unit V.A.4.).

35. For some conditions of use, EPA was unable to identify products currently available for sale that contain methylene chloride. EPA is soliciting comments on whether there are actually products in use or available for sale relevant to these conditions of use that contain methylene chloride at this time, so that EPA can ascertain whether there are alternatives that benefit human health or the environment. (Unit V.B.).

36. EPA is requesting comment on the alternatives analysis as a whole. (Unit V.B.).

37. EPA considered the employment impacts of this proposed 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. To that end, EPA is requesting public comment on short term and longer-term employment effects from this proposal. (Unit VI.D.1.).

38. As described in the Economic Analysis, two conditions of use, Processing: Recycling and Disposal, are responsible for the majority (~60%) of the estimated total $12 million in non-closure-related costs of the rule. Given the prevalence of small entities in this sector, EPA requests comment on what regulatory flexibilities, within the scope of TSCA and mitigating unreasonable risk, may be afforded to these conditions of use to reduce burden of complying with the WCPP. (Unit VI.D.4.).

39. As described in the Economic Analysis and the Alternatives Analysis, alternatives for methylene chloride as a processing aid were not identified. EPA requests information on

potential alternative processing aids to methylene chloride as it relates to the proposed regulatory option for this COU. (Unit VI.D.4.).

40. The Economic Analysis includes a qualitative discussion of uncertainty in cost estimates, including uncertainties related to the cost of reformulating products that currently contain methylene chloride, which could be underestimated, or overestimated. EPA requests comment on additional aspects of reformulation, including any costs that may be associated with mitigating countervailing risks of alternative formulations. (Unit VI.D.4.)

41. EPA requests comment on the degree to which qualities or properties of methylene chloride, beyond those discussed in the Economic Analysis and summarized in Unit VI.C., may make methylene chloride a preferable choice when compared to alternatives with similar costs and effectiveness. (Unit VI.D.4.)

42. EPA requests comment regarding information to estimate transition costs to suitable alternatives, including how often these costs might be incurred or what the specific costs would be per-user or per-firm when they are incurred. (Unit VI.D.4.)

43. EPA requests comment on how costs and economic impacts from firm closures may be reduced with longer compliance timeframe. (Unit VI.D.4.)

44. EPA requests comment on how better to monetize the benefits of each alternative in the Economic Analysis and whether EPA should consider any other categories of benefits. (Unit VI.D.4.)

IX. 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**.

1. EPA. Risk Evaluation for Methylene Chloride (MC). EPA Document #740-R1-8010

2. EPA. Final Revised Unreasonable Risk Determination for Methylene Chloride. November 2022.

3. EPA. Economic Analysis of the Proposed Regulation of Methylene Chloride. RIN 2070-AK70. August 2022.

4. Public Workshop on Use of Methylene Chloride in Furniture Refinishing in collaboration with the Small Business Administration Office of Advocacy. September 12, 2017.

5. EPA Workshop on Furniture Refinishing and Methylene Chloride. September 12, 2017.

6. EPA. Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule Toxic Substances Control Act (TSCA) Section 6(a) Methylene Chloride. October 28, 2021.

7. EPA. Regulatory Actions Pertaining to Methylene Chloride. January 24, 2023.

8. EPA. Access CDR Data: 2020 CDR Data. Last Updated on May 16, 2022.

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10. EPA. Methylene Chloride; Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability. *Federal Register* (87 FR 67901, November 10, 2022

11. EPA. Existing Chemical Exposure Limit (ECEL) for Occupational Use of Methylene Chloride. December 10, 2020.

12. OSHA. Standard Interpretations: 8-hr total weight average (TWA) permissible exposure limit (PEL). Accessed October 6, 2022.

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chloride on human performance. J Environ Pathol Toxicol 2: 97-112. 1979.

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17. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. *Federal Register* (86 FR 7037, January 25, 2021).

18. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *Federal Register* (86 FR 7009, January 25, 2021).

19. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. *Federal Register* (86 FR 7619, February 1, 2021).

20. EPA Press Release. EPA Announces Path Forward for TSCA Chemical Risk Evaluations. June 2021.

21. SACC. Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022-01. March 15-17, 2022.

22. EPA. Notes from Federalism Consultation on Forthcoming Proposed Rulemakings for Methylene Chloride and 1-Bromopropane under TSCA Section 6(a). Office of Pollution Prevention and Toxics. October 22, 2023.

23. EPA. Notes from Tribal Consultations on Forthcoming Proposed Rulemakings for Methylene Chloride and 1-Bromopropane under TSCA Section 6(a). Office of Pollution

Prevention and Toxics. November 12-17, 2020.

24. Liz Hitchcock; Safer Chemicals Healthy Families. 11/20 Environmental Justice Consultations for 1-Bromopropane and Methylene Chloride. November 20, 2020.

25. California Communities Against Toxics *et al*. Comment letter re TSCA environmental justice consultations. November 13, 2020.

26. Swati Rayasam; Program on Reproductive Health and the Environment (PRHE). PRHE follow up documents from EJ consultation meeting. November 30, 2020.

27. EPA. Initial Regulatory Flexibility Analysis for Methylene Chloride; Regulation of Methylene Chloride under TSCA §6(a) Proposed Rule; RIN 2070-AK70. November 22, 2022.

28. EPA. Methylene Chloride: Risk Evaluation and Risk Management under TSCA Section 6. SBA Small Business Roundtable. September 11, 2020.

29. EPA. Stakeholder Meeting List for Proposed Rulemaking for Methylene Chloride under TSCA Section 6(a). October 27, 2022.

30. EPA. 2021 Policy on Children's Health. October 5, 2021.

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32. Anh Hoang; Kathleen Fagan; Dawn L. Cannon; *et al*. Assessment of Methylene Chloride–Related Fatalities in the United States, 1980-2018. JAMA Intern Med. 2021.

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January 2013.

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43. Aaron Rice; EaglePicher Technologies. Re: TSCA Section 6(g) Exemption Request for Use of N-methylpyrrolidone and Methylene Chloride in Production of Specialized Batteries. June 3, 2022.

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45. Halogenated Solvents Industry Alliance Inc. (HSIA). Docket No. EPA-HQ-OPPT-2016-0742. August 16, 2018.

46. EPA. Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule Toxic Substances Control Act (TSCA) Section 6(a) Methylene Chloride. Appendix B: Written Comments Submitted by Small Entity Representatives. October 28, 2021.

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Certain Uses Under TSCA Section 6(a). *Federal Register* (82 FR 7464, January 19, 2017

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49. EPA. Meeting with Baron-Blakeslee on Risk Management under TSCA Section 6 for Trichloroethylene, Perchloroethylene, 1-Bromopropane, and Methylene Chloride. April 1, 2021

50. EPA. ANPRM. Methylene Chloride; Commercial Paint and Coating Removal Training, Certification and Limited Access Program. *Federal Register* (84 FR 11466, March 27, 2019

51. EPA. Notes from Environmental Justice Consultations on Forthcoming Proposed Rulemakings for Methylene Chloride and 1-Bromopropane under TSCA Section 6(a). Office of Pollution Prevention and Toxics. November 16 - 19, 2020.

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X. 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 Orders 12866: Regulatory Planning and Review and 13563: Improving Regulation and Regulatory Review

This action is an economically significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations during that review have been documented in the docket. EPA prepared an Economic Analysis of the potential costs and benefits associated with this action, which is available in the docket and is summarized in Units I.E. and VI.D. (Ref. 3).

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted to OMB for review and comment 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. 2735.01 (Ref. 60). You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

There are two primary provisions of the proposed rule that may increase burden under the PRA. The first is downstream notification, which would be carried out by updates to the relevant SDS and which would be required for manufacturers, processors, and distributors in commerce of methylene chloride, who would provide notice to companies downstream upon shipment of methylene chloride about the prohibitions. The information submitted to downstream companies through the SDS would provide knowledge and awareness of the restrictions to these companies. The second primary provision of the proposed rule that may 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 development of documentation demonstrating eligibility for an exemption from the proposed prohibitions, and related recordkeeping).

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).

Frequency of response: On occasion.

Estimated number of respondents: 237,929.

Total estimated burden: 129,772 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $10,385,871 (per year), includes $2,809,809 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. After display in the *Federal Register* when approved, the OMB control numbers for EPA regulations in 40 CFR are listed in 40 CFR part 9 and displayed on the form and instructions or collection portal, as applicable.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs using the interface at *https://www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. OMB must receive comments no later than [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 603 of the RFA, 5 U.S.C. 601 *et seq*., EPA prepared an initial regulatory flexibility analysis (IRFA) that examines the impact of the proposed rule on small entities along with regulatory alternatives that could minimize that impact (Ref. 27). The complete IRFA is available for review in the docket and is summarized here.

1. Need for the rule.

Under TSCA section 6(a) (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 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 proposing to take action to the extent necessary so that methylene chloride no longer presents such risk.

2. Objectives and legal basis for the rule.

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. EPA has determined through a TSCA section 6(b) risk evaluation that methylene chloride presents an unreasonable risk under the conditions of use.

3. Description and number of small entities to which the rule will apply.

The proposed 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 proposed rule would affect approximately 237,930 firms using methylene chloride, of which 230,266 are estimated to be small entities. End users with economic and technologically feasible alternatives available do not have estimated cost impacts beyond rule familiarization costs. Alternative

products that are drop-in substitutes (*i.e.*, requiring no changes by the user in how the product is used) are available for most uses including adhesives, various degreasers, or lubricants and greases. However, in some cases some effort might be required by firms using methylene chloride products to identify suitable alternatives, test them for their desired applications, learn how to use them safely and effectively, and implement new processes for using the alternative products. The information to estimate how often these costs might be incurred or what the specific costs would be per-user or per-firm when they are incurred is not available. Therefore, EPA is unable to consider these costs quantitatively in the IRFA or Economic Analysis.

4. Projected compliance requirements.

To address the unreasonable risk EPA has identified, EPA is proposing to: (i) Prohibit the manufacture (including import), processing, and distribution in commerce of methylene chloride for all consumer use (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); (ii) prohibit most industrial and commercial uses of methylene chloride; (iii) require a WCPP for certain industrial and commercial conditions of use, including inhalation exposure concentration limits; (iv) require recordkeeping and downstream notification requirements for several conditions of use; and (v) provide time-limited exemptions under TSCA section 6(g) for military and civilian aviation from the prohibition addressing the use of methylene chloride for paint and coating removal to avoid significant disruptions to national security and critical infrastructure.

EPA is proposing to prohibit most conditions of use. For other conditions of use that drive the unreasonable risk determination for methylene chloride, EPA proposes a WCPP to address the unreasonable risk. A WCPP would encompass 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. Under a WCPP, owners or operators would have some flexibility, within the parameters outlined in Unit IV.A.1., regarding the manner in which they prevent exceedances of the identified exposure thresholds. Therefore, EPA generally refers to the WCPP approach as a non-prescriptive approach. In the case of methylene chloride, meeting the exposure thresholds proposed 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.

EPA's proposed requirements include the specific exposure limits that would be required to meet the TSCA section 6(a) standard to apply one or more requirements to the substance so that it no longer presents unreasonable risk, and also include ancillary requirements necessary for the ECEL's successful implementation as part of a WCPP.

EPA is not proposing reporting requirements beyond downstream notification (third-party notifications). Regarding recordkeeping requirements, three primary provisions of the proposed rule relate to recordkeeping. The first is recordkeeping for PPE: under the proposed regulatory action, facilities complying with the rule through WCPP would be required to develop and maintain records associated with a dermal and inhalation protection and in accordance with an exposure control plan. Additionally, under the proposed regulatory action, facilities complying with the rule through a WCPP would be required to monitor exposure levels and maintain records of this monitoring. Last, under the proposed regulatory action, facilities complying with the rule through a WCPP would be required to notify potentially exposed persons of monitoring results.

a. 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.

b. Professional skills needed to comply.

Entities that would be subject to this proposal that manufacture (including import), process, or distribute methylene chloride in commerce for consumer use would be required to cease under the proposed rule. The entity would be required to modify their Safety Data Sheet or develop another way 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 under the proposed rule. 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 would be permitted to continue to manufacture, process, distribute, use, or dispose of methylene chloride would be 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 or health and safety professional. 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 information

to be measured and recorded may require persons with specialized skills such as an industrial hygienist.

5. Relevant Federal rules.

Because of its health effects, methylene chloride is subject to numerous State, Federal, and international regulations restricting and regulating its use. The following is a summary of the regulatory actions pertaining to methylene chloride; for a full description see appendix A of the 2020 Risk Evaluation for Methylene Chloride.

EPA has issued numerous rules and notices pertaining to methylene chloride under its various authorities. Methylene chloride is a hazardous air pollutant (HAP) under the CAA (42 U.S.C. 7412(b)(1)). EPA promulgated National Emission Standards for Hazardous Air Pollutants (NESHAPs) for methylene chloride for several industrial source categories.

With this proposed rule under TSCA section 6, certain uses identified under these NESHAPs would be prohibited while other uses would be subject to a WCPP. Moreover, the proposed rule would allow methylene chloride's continued use in processing as a reactant for the manufacture of HFC-32 and subject to compliance as part of a WCPP.

Programs within EPA implementing other environmental statutes, including, but not limited to, the RCRA, the Comprehensive Environmental Response, the Compensation, and Liability Act (CERCLA), the SDWA, and the CWA, classify methylene chloride as a hazardous waste, a hazardous substance, a volatile organic contaminant, and a toxic pollutant, respectively. Releases into the environment of methylene chloride in excess of 1,000 pounds must be reported under CERCLA (40 CFR 302.4). While TSCA shares equity in the regulation of methylene chloride, EPA does not anticipate this rule to duplicate nor conflict with the aforementioned programs' classifications and associated rules.

In addition to regulations administered by the EPA, methylene chloride is also subject to

regulations by other Federal agencies.

In 2005, the Secretary of Transportation listed methylene chloride as a hazardous material with regard to transportation that is subject to regulations prescribing requirements applicable to the shipment and transportation of listed hazardous materials under the Hazardous Materials Transportation Act (70 FR 34381, June 14, 2005).

OSHA has a standard for regulating methylene chloride under 29 CFR 1910.1052. The OSHA PEL, action level, STEL, and ancillary requirements have established a strong precedent for exposure threshold requirements within the regulated community. However, EPA recognizes that the existing PEL and STEL do not eliminate the unreasonable risk identified by EPA under TSCA, and EPA is therefore proposing to apply new, lower exposure thresholds, derived from the 2020 Risk Evaluation for Methylene Chloride, while aligning with existing requirements wherever possible. For methylene chloride, this approach would eliminate the unreasonable risk driven by certain conditions of use, reduce burden for complying with the regulations, and provide the familiarity of a pre-existing framework for the regulated community.

Under the FHSA enforced by CPSC, household products are required to have hazardous substance labels for products that contain methylene chloride. In 1987, CPSC issued a decision to require labeling of household products that contain methylene chloride under the FHSA (52 FR 34698, September 14, 1987). Labels indicated that inhalation of methylene chloride vapor has caused cancer in certain laboratory animals, and the labels specified precautions to be taken during use by consumers. In 2018, in response to a petition, CPSC updated the labeling policy for paint strippers containing methylene chloride to include a warning of the acute hazards from inhalation of methylene chloride vapors in addition to the chronic hazards (83 FR 12254, March 21, 2018, and 83 FR 18219, April 26, 2018). With the proposed prohibition on the manufacture, processing, and distribution in commerce of methylene chloride for paint and coating removal

under TSCA, EPA anticipates that CPSC may require labeling for any products that fall outside of the scope of TSCA and would not present conflict.

In pesticides, methylene chloride was registered as an antimicrobial pesticide in 1974 pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C 136 *et seq*.). Methylene chloride was also a pesticide product inert ingredient used as a solvent and co-solvent, and as a dispersing and wetting agent. In June 1998, EPA published a *Federal Register* document that designated methylene chloride as a List 1 inert ingredient due to its toxicological and other concerning effects (63 FR 34384, June 24, 1998) (FRL-5792-3). In 2002, EPA revoked pesticide tolerance exemptions for methylene chloride as an extraction solvent and as a post-harvest fumigant for crops established under the Federal Food, Drug, and Cosmetic Act (FFDCA) (67 FR 16027, April 4, 2002) (FRL-6833-3).

In 1989, the Food and Drug Administration (FDA) banned methylene chloride as an ingredient in all cosmetic products because of its animal carcinogenicity and likely hazard to human health under the FFDCA (54 FR 27328, June 29, 1989). Before 1989, methylene chloride had been used in aerosol cosmetic products, such as hairspray (Ref. 61).

6. Significant alternatives to the proposed rule.

As discussed further in Unit V.A.4. and the IRFA, EPA considered – in addition to the prohibition and WCPP that are proposed - 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. The Agency determined that some methods either did not effectively address the unreasonable risk presented by methylene chloride or there was uncertainty in conditions of use that would be less able to comply with a comprehensive WCPP to adequately protect potentially exposed persons. The primary alternative regulatory action was considered and found to provide greater uncertainty in addressing the unreasonable risk from

methylene chloride under the conditions of use.

As required by the RFA section 609(b), EPA also convened a SBAR Panel to obtain advice and recommendations from small entity representatives that potentially would be subject to the rule's requirements. The SBAR Panel evaluated the assembled materials and small-entity comments on issues related to elements of an IRFA. The panel recommended EPA include certain requests for comment, which can be found in Unit VIII. (number 3.a through 3.k) and summarized in the Initial Regulatory Flexibility Assessment (Ref. 27). The full SBAR Panel Report is in the rulemaking docket (Ref. 6).

D. Unfunded Mandates Reform Act (UMRA)

This action contains a federal mandate under UMRA, 2 U.S.C. 1531–1538, that may result in expenditures of $100 million or more for state, local and tribal governments, in the aggregate, or the private sector in any one year. Accordingly, the EPA has prepared a written statement required under UMRA section 202. The statement is included in the docket for this action and briefly summarized here.

EPA estimates the compliance costs of the proposed rule to the private sector to be approximately to be $13.2 million annualized over 20 years at a 3% discount rate and $14.5 million annualized over 20 years at a 7% discount rate. However, the costs of the rule to the private sector are difficult to completely quantify. EPA’s upper-bound estimate for the potential economic impact of the proposed rule on firms subject to the proposed prohibition on the use of methylene chloride in commercial furniture refinishing involves a worst-case assumption that all of as many as 5,000 furniture refinishing firms will fully close due to the proposed prohibition. As described in more detail in Units I.E. VI.D.2. and Tables 3-1 and 6-12 of the Economic Analysis (Ref. 3), EPA estimates the upper-bound economic impact of potential closures of affected furniture refinishing firms using methylene chloride following this rulemaking to be

$1.8 billion in total lost revenue, and $67 million in terms of the total lost profit, under the assumption that all affected firms fully close due to the proposed restrictions on methylene chloride. Thus, the Agency concludes that cost of the rule to the private sector may exceed the inflation-adjusted UMRA threshold of $100 million in any one year.

Nevertheless, the economic impact of a regulation on the national economy is generally considered to be measurable only if the economic impact of the regulation reaches 0.25 percent to 0.5 percent of GDP (Ref. 58). Given the current GDP of $23.17 trillion, this is equivalent to a cost of $58 billion to $116 billion. Therefore, EPA has concluded that this rule is highly unlikely to have any measurable effect on the national economy. Additional information on EPA's estimates of the benefits and costs of this action are provided in Units I.E. and VI.D.2., and in the Economic Analysis for this action (Ref. 3). Information on the authorizing legislation is provided in Unit I.B. Information on prior consultations with affected State, local, and tribal governments is provided in Unit III.A.1.

This action is not subject to the requirements of UMRA section 203 because it contains no regulatory requirements that might significantly or uniquely affect small governments.

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. As set forth in TSCA section 18(a)(1)(B), the issuance of rules under TSCA section 6(a) to address the unreasonable risks presented by a chemical substance has the potential to trigger preemption of laws, criminal penalties, or administrative actions by a State or political subdivision of a State that are: 1) Applicable to the same chemical substance as the rule under TSCA section 6(a); and 2) Designed to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of that same chemical. TSCA section 18(c)(3)

applies that preemption only to the "hazards, exposures, risks, and uses or conditions of use" of such chemical included in the final TSCA section 6(a) rule.

EPA provides the following preliminary 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. 22). As discussed in Unit III.A.1., during Federal 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 SDWA. (Ref. 22). 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.

Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, EPA consulted with tribal officials during the development of this action. 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. 23). 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. 23). EPA received no written comments as part of this consultation.

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

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) 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. Accordingly, this action's health and risk assessments are contained in Units III.A.3., III.B.2., and V.A., as well as in the 2020 Risk Evaluation for Methylene Chloride, and the Economic Analysis for this proposed rulemaking (Refs. 1, 3).

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.

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 proposes not to require the use of specific, prescribed analytic methods. Rather, the Agency plans to 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. 11). EPA recognizes that there may be voluntary consensus standards that meet the proposed criteria (Ref. 62). EPA requests comments on whether it should incorporate such voluntary consensus standards in the rule and seeks information in support of such comments regarding the availability and applicability of voluntary consensus standards that may achieve the sampling and analytical requirements of the rule in lieu of the PBMS approach.

J. Executive Orders 12898: Federal Actions to Address Environmental Justice in Minority

Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or Indigenous peoples) and low-income populations.

EPA believes that the human health and environmental conditions that exist prior to this action do not result in disproportionate and adverse effects on people of color, low-income populations, and/or Indigenous peoples. The documentation for this decision is contained in the Economic Analysis (Ref. 3), which is in the public docket for this action. As part of the Economic Analysis for this rulemaking, EPA conducted an environmental justice analysis using information about the facilities, workforce, and communities potentially affected by the regulatory options under current conditions, before the proposed regulation would goes 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 intent of the analysis was to characterize the baseline conditions faced by communities and workers to identify the potential for disproportionate impacts on minority and low-income populations.

EPA believes that this action is not likely to result in new disproportionate and adverse effects on people of color, low-income populations and/or Indigenous peoples. However, while this regulatory action would apply requirements to the extent necessary so that methylene chloride no longer presents an unreasonable risk, EPA is not able to quantify the distribution of the change in risk across affected workers, communities, or demographic groups due to data

limitations that prevented EPA from conducting a more comprehensive analysis of such a change.

EPA additionally identified and addressed environmental justice concerns by conducting outreach to advocates of communities that might be subject to disproportionate exposure to methylene chloride, such as minority populations, low-income populations, and Indigenous peoples.

On November 16 and 19, 2020, EPA held public meetings as part of this consultation. (Ref. 51). See also Unit III.A.1. These meetings were held pursuant to and in compliance with 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. 24, 25, 26). 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 Units II.D., III.A.1., and VI.A., and well as in the Economic Analysis (Ref. 3, 51). EPA's presentations, a summary of EPA's presentation and public comments made, and fact sheets for the environmental justice 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.

List of Subjects in 40 CFR Part 751

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

Dated: Click or tap to enter eSignature date.

Michael S. Regan,

Administrator.

Therefore, for the reasons stated in the preamble, EPA proposes to amend 40 CFR chapter I 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 section 751.5 by adding in alphabetical order definitions for "authorized person," "ECEL," "EPA STEL," "owner or operator," "potentially exposed person," "regulated area," and "retailer." The additions read as follows:

§ 751.5 Definitions

* * * * *

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.

* * * * *

ECEL is an Existing Chemical Exposure Limit, which is an EPA regulatory limit on workplace exposure to an airborne concentration of a chemical substance, generally based on an eight (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.

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 occupationally exposed to a chemical substance or mixture in a workplace as a result of a condition of use of that chemical substance or mixture.

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 ECEL or the 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.

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.

4. Amend § 751.103 by adding 1 definition in alphabetical order to read as follows:

§ 751.103 Definitions.

* * * * *

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).

* * * * *

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) The provisions of this section apply 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) The provisions of this section apply to all manufacturing (including import), processing, and distribution in commerce of methylene chloride for industrial or commercial use, and to all commercial or industrial use of methylene chloride, other than the conditions of use addressed under § 751.109(a).

(b) Prohibitions.

(1) After [90 days after the date of publication of the final rule 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 paragraph (b)(7) of this section.

(2) After [180 days after the date of publication of the final rule 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 paragraph (b)(7) of this section.

(3) After [270 days after the date of publication of the final rule in the *Federal Register*], all persons are prohibited from distributing in commerce methylene chloride, including any methylene chloride-containing products, to retailers for any use.

(4) After [360 days after the date of publication of the final rule 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.

(5) After [360 days after the date of publication of the final rule 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 paragraph (b)(7) of this section.

(6) After [450 days after the date of publication of the final rule 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 paragraph (b)(7) of this section.

(7) After [10 years after the date of publication of the final rule 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 or coating removal from safety critical, corrosion-sensitive components of aircraft or spacecraft as described in § 751.115(b)(1) through (3).

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, 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 that are owned or operated by the U.S. Department of Defense, the National Aeronautics and Space Administration, the U.S. Department of Homeland Security, and the Federal Aviation Administration that is performed by the agency or the agency's contractor at locations controlled by the agency or the agency's contractor.

(9) 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 applications that are performed by the U.S. Department of Defense, the National Aeronautics and Space Administration, or the U.S. Department of Homeland Security or their contractors at locations controlled by the agency or the agency's contractor; and

(10) Disposal;

(b) Relationship to 29 CFR part 1910.

For purposes of § 751.109:

(1) Any provisions applying to "employee" in 29 CFR 1910.1020, 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 1910.1020, 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.

The owner or operator must ensure the following:

(1) *Existing Chemical Exposure Limit (ECEL)*. 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.

(2) *EPA short-term exposure limit (EPA STEL)*. 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.

(3) *Regulated areas*. Owners or operators must establish and maintain regulated areas in accordance with 29 CFR 1910.1052(e)(2), (4), (5), (6), and (7), within 3 months after receipt of the results of any monitoring data as outlined in paragraph (d) of this section. Owners or operators must 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.

(d) Exposure monitoring.

(1) *In general*.

(i) *Characterization of exposures*. Owners or operators must determine each potentially exposed person's exposure 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 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*.

(i) After [180 days after the date of publication of the final rule in the *Federal Register*] each owner or operator of a workplace where methylene chloride is present must perform an initial exposure monitoring to determine each potentially exposed person's exposure, except under the following temporary conditions:

(A) An owner or operator can provide EPA with objective data generated during the last 5 years 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

(B) 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.

(ii) An owner or operator must re-conduct an initial exposure monitoring at least once every 5 years if methylene chloride is present in the workplace.

(3) *Periodic monitoring*. Where the initial exposure monitoring shows exposure at or above the ECEL action level at or above the EPA STEL, 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 § 751.109 – Periodic Monitoring Requirements Based on Initial Exposure Monitoring Results

Air Concentration Condition Observed during Initial Exposure Monitoring	Periodic Monitoring Requirement
If the initial exposure monitoring concentration is below the ECEL action level and at or below the EPA STEL	ECEL and EPA STEL monitoring not required.
If the initial exposure monitoring concentration is below the ECEL action level and above the EPA STEL	ECEL monitoring not required, and EPA STEL 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 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 monitoring every 6 months and EPA STEL monitoring every 3 months.
If the initial exposure monitoring concentration is above the ECEL and below, at, or above the EPA STEL	ECEL monitoring every 3 months and EPA STEL monitoring every 3 months.
Two consecutive monitoring events have taken place 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	Reduce ECEL periodic monitoring frequency from every 3 months to every 6 months.
Two consecutive monitoring events have taken place 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 of every 6 months to initial monitoring once every 5 years. The second consecutive monitoring event will delineate the new date from which the next 5-year initial 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 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	The owner or operator may forgo the upcoming periodic monitoring event. However, documentation of cessation of use of methylene 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.

NOTE: Additional scenarios in which monitoring may be required are discussed paragraph (d)(4).

(4) *Additional monitoring*. The owner or operator must conduct an additional initial exposure monitoring immediately 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.

(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 in plain language;

(C) Explanation of any corresponding required respiratory protection as described in paragraph (f);

(D) Descriptions of actions taken by the owner or operator to reduce exposure;

(E) Quantity of methylene chloride in use;

(F) Location of methylene chloride use;

(G) Manner of methylene chloride use;

(H) Identified releases of methylene chloride; and

(I) Whether the airborne concentration of methylene chloride exceeds the ECEL or the EPA STEL.

(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.

(e) ECEL Control Procedures and Plan.

(1) *Method of Compliance*. After [360 days after the date of publication of the final rule in the *Federal Register*], the owner or operator must institute and maintain the effectiveness of engineering controls and work practices 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. Wherever the feasible engineering controls and work practices which can be instituted are not sufficient to reduce exposures for potentially exposed person to or below the ECEL or EPA STEL, the owner or operator must use them to reduce exposure to the lowest levels achievable by these controls and must supplement them by 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. Wherever engineering controls and work practices are not feasible, the owner or operator must use respiratory protection that complies with the requirements of paragraph (f) of this section to reduce exposures for potentially exposed persons to or below the ECEL or EPA STEL. Where an owner or operator cannot demonstrate the use of engineering controls or work practices that result in exposure below the ECEL or EPA STEL, and has not demonstrated that it has supplemented the risk of exposure with respiratory protection, this will constitute a failure to comply with the ECEL. Additionally, the owner or operator must not implement a schedule of personnel rotation as a means of compliance with the ECEL.

(2) *Exposure Control Plan Requirements*. After [360 days after the date of publication of the final rule in the *Federal Register*], the owner or operator must include and document in an exposure control plan the following:

(i) identification of exposure controls and rationale for using or not using exposure

controls in the following sequence - elimination, substitution, engineering controls, and administrative controls - to reduce exposures in the workplace to either at or below the ECEL or EPA STEL or to the lowest level achievable, and the exposure controls selected based on feasibility, effectiveness, and other relevant considerations;

(ii) if exposure controls were not selected, document the efforts identifying why these are not feasible, not effective, or otherwise not implemented;

(iii) actions taken to implement exposure controls selected, including proper installation, maintenance, training or other steps taken;

(iv) regular inspections, evaluations, and updating of the exposure controls to ensure effectiveness and confirmation that all persons are using them accordingly;

(v) 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; and

(vi) objective data generated during the previous 5 years, when used to forgo the initial exposure monitoring, must include: the use of methylene chloride being evaluated, the source of objective data, measurement methods, measurement results, and measurement analysis of the use of methylene chloride, and any other relevant data to the operations, processes, or person's exposure.

(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 [270 days after the date of publication of the final rule in the *Federal Register*] 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-certified 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-certified Supplied-Air Respirator (SAR) or airline respirator in a demand mode equipped with a full facepiece (APF 50); or

(B) Any NIOSH-certified 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-certified 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

(B) Any NIOSH-certified Supplied-Air Respirator (SAR) or airline respirator in pressure-demand or other positive-pressure mode equipped with a full facepiece (APF 1,000); or

(C) Any NIOSH-certified 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) represent the minimum respiratory protection requirements, such that any respirator affording a higher degree of protection than the required respirator may be used.

(4) *Workplace participation*. Owners or operators must document the notice to and ability of any potentially exposed person to access the exposure control plan and other associated records.

(g) Dermal protection.

(1) 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), 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 [150 days after the date of publication of the final rule in the *Federal Register*] for each person who manufactures (including imports), and before [210 days after the date of publication of the final rule in the *Federal Register*] for each person who 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 [150 days after the date of publication of the final rule 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 [210 days after the date of publication of the final rule 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 August 26, 2019, this chemical/product is not and cannot be distributed in commerce or processed for consumer paint or coating removal. After [270 days after the date of publication of the final rule in the *Federal Register*] this chemical/product cannot be distributed in commerce to retailers for any use. After [360 days after the date of publication of the final rule in the *Federal Register*], this chemical/product is and can only be processed or distributed in commerce 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 acrylic and polycarbonate in mission-critical military and space vehicle applications, including in the production of specialty batteries for such applications that are performed by the U.S. Department of Defense, the National Aeronautics and Space Administration, or the Department of Homeland Security or their contractors at locations controlled by the agency or the agency's contractor; (7) Industrial or commercial use for paint and coating removal from safety- critical, corrosion-sensitive components of aircraft and spacecraft that are owned or operated by the U.S. Department of Defense, the National Aeronautics and Space Administration, the U.S. Department of Homeland Security, and the Federal Aviation Administration that is performed by the agency or the agency's contractor at locations controlled by the agency or the agency's contractor; (8) Industrial or commercial use for paint and coating removal from safety critical, corrosion-sensitive components of other aircraft or spacecraft until [10 years after the date of publication of the final rule in the *Federal Register*]; and (9) Disposal.

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, 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 monitoring records.

Owners or operators are required to retain monitoring records in accordance with 29 CFR 1910.1052(m)(2) Additionally, for each monitoring event of methylene chloride required under this subpart, owners or operators must document the following:

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

(2) The identity of 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;

(3) Use of established analytical methods;

(4) Compliance with the Good Laboratory Practice Standards in accordance with 40 CFR part 792; and

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

(c) Exposure control records.

Owners or operators must retain records of:

(i) Exposure control plan as described in paragraph 751.109(e)(2);

(ii) Regulated areas and authorized personnel;

(iii) Facility exposure monitoring records;

(iv)Notifications of exposure monitoring results;

(v) Personal protective equipment (PPE) and respiratory protection used by potentially exposed persons and program implementation, including fit-testing; and

(vi) Information and training provided pursuant to subsection (i) of this section.

(d) 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.

(e) Minimum record retention period.

The records required under paragraphs (a) through (c) of 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 as described in paragraphs (b)(1) through (b)(3) provided for through § 751.107(b)(7) are established in this section in accordance with 15 U.S.C. 2605(g)(1)(B).

(2) Time-limited exemptions as described in paragraph (b)(4) are established in this section in accordance with 15 U.S.C. 2605(g)(1)(A).

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

(b) Time-Limited Exemptions.

(1) 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 until [10 years after the date of publication of the final rule in the *Federal Register*]. The following are specific conditions of this exemption:

(i) The paint or coating removal must be performed on the premises of maintenance or repair facilities operated by air carriers or commercial operators certificated under 14 CFR part 119 or at repair stations certificated under 14 CFR part 145, if their primary business is performing maintenance, preventive maintenance, rebuilding, or alteration of aircraft operated by air carriers and commercial operators certificated under 14 CFR part 119.

(ii) The owner or operator of the location where the paint or coating removal is being performed must comply with the Workplace Chemical Protection Program provisions in § 751.109.

(iii) The owner or operator of the location where the paint or coating removal is being performed must comply with the recordkeeping requirements in § 751.113.

(2) Paint and coating removal from safety-critical, corrosion-sensitive components of aircraft intended for, or suitable for operation by, air carriers and commercial operators certificated under 14 CFR part 119 until [10 years after the date of publication of the final rule in the *Federal Register*]. The following are specific conditions of this exemption:

(i) The paint or coating removal must be performed at locations owned or operated by the manufacturer of the aircraft.

(ii) The owner or operator of the location where the paint or coating removal is being performed must comply with the Workplace Chemical Protection Program provisions in § 751.109.

(iii) The owner or operator of the location where the paint or coating removal is being

performed must comply with the recordkeeping requirements in § 751.113.

(3) Paint and coating removal from safety-critical, corrosion-sensitive components of spacecraft used in, or intended for use in, commercial space transportation operations subject to 14 CFR chapter III, including payloads such as satellites and similar hardware, until [10 years after the date of publication of the final rule in the *Federal Register*]. The following are specific conditions of this exemption:

(i) The paint or coating removal must be performed at locations owned or operated by the manufacturer of the spacecraft or payload or similar hardware.

(ii) The owner or operator of the location where the paint or coating removal is being performed must comply with the Workplace Chemical Protection Program provisions in § 751.109.

(iii) The owner or operator of the location where the paint or coating removal is being performed must comply with the recordkeeping requirements in § 751.113.

(4) Use of methylene chloride or methylene chloride-containing products identified in paragraph (b)(4)(i) in an emergency by the National Aeronautics and Space Administration and its contractors operating within the scope of their contracted work until [10 years after the date of publication of the final rule in the *Federal Register*].

(i) *Applicability*. The emergency use exemption described in this paragraph (b)(4) shall apply to the following specific conditions of use as described in paragraph (b)(4)(i)(A)(1) through (7).

(A) Conditions of use subject to this exemption:

(*1*) Industrial and commercial use as solvent for cold cleaning

(*2*) Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner

(*3*) Industrial and commercial use in adhesives, sealants and caulks

(*4*) Industrial and commercial use in adhesive and caulk removers

(*5*) Industrial and commercial use in metal non-aerosol degreasers

(*6*) Industrial and commercial use in non-aerosol degreasers and cleaners

(*7*) Industrial and commercial use as solvent that becomes part of a formulation or mixture

(B) Emergency use.

(*1*) *In general*. An emergency is a serious and sudden situation requiring immediate action, within 15 days or less, necessary to protect:

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

(*ii*) National Aeronautics and Space Administration's missions;

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

(*iv*) The environment.

(*2*) *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 National Aeronautics and Space Administration or its contractors.

(ii) *Requirements*. To be eligible for the emergency use exemption described in this paragraph (b)(4), National Aeronautics and Space Administration and its contractors must comply with the following conditions:

(A) *Notification*. Within 15 days of the emergency use by National Aeronautics and Space Administration and its contractors, National Aeronautics and Space Administration must provide notice to EPA that includes the following:

(*1*) Identification of the conditions of use detailed in paragraph (b)(4)(i)(A) that the emergency use fell under;

(*2*) An explanation for why the emergency use met the definition of emergency in paragraph (b)(4)(i)(B); 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 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.

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