IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

LABOR COUNCIL FOR LATIN AMERICAN ADVANCEMENT and NATURAL RESOURCES DEFENSE COUNCIL, INC.,	)	
Petitioners,	)	
v.	)	No. _____
U.S. ENVIRONMENTAL PROTECTION AGENCY and, ANDREW R. WHEELER, Administrator, United States Environmental Protection Agency,	)	
Respondents.	)	

PETITION FOR REVIEW
of a final rule of the U.S. Environmental Protection Agency

Pursuant to Rule 15 of the Federal Rules of Appellate Procedure, the Administrative Procedure Act, 5 U.S.C. §§ 701-706, and the Toxic Substances Control Act § 19(a), 15 U.S.C. § 2618(a), the Labor Council for Latin American Advancement and Natural Resources Defense Council hereby petition this Court for review of a final rule of the U.S. Environmental Protection Agency (EPA) entitled "Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a)," which is published at 84 Fed. Reg. 11,420 (March 27, 2019), and was issued for purposes of judicial review on April

10, 2019. *See* 40 C.F.R. § 23.5(a); 15 U.S.C. § 2618(a)(2) (citing 28 U.S.C. § 2112). A copy of the challenged rule is attached as **Exhibit A**.

Dated: April 18, 2019

Respectfully submitted,

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Exhibit A

or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 18, 2019.

Donna Davis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 180.704 to subpart C to read as follows:

§ 180.704 Sulfometuron-methyl; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide sulfometuron-methyl, including its metabolites and degradates, in or on the commodity in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only sulfometuron-methyl, (methyl 2-[[[[(4,6-dimethyl-2-pyrimidinyl)amino]carbonyl]amino] sulfonyl]benzoate), in or on the following raw agricultural commodities:

Commodity	Parts per million
Sugarcane, cane [1]	0.1

[1] There are no U.S. Registrations on Sugarcane as of September 24, 2018.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2019–05877 Filed 3–26–19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA–HQ–OPPT–2016–0231; FRL–9989–29]

RIN 2070–AK07

Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Methylene chloride, also called dichloromethane, is a volatile chemical used in paint and coating removal products. In this final rule, EPA has determined that the use of methylene chloride in consumer paint and coating removal presents an unreasonable risk of injury to health due to acute human lethality. In order to address the unreasonable risk, EPA is prohibiting the manufacture (including import), processing, and distribution in commerce of methylene chloride for consumer paint and coating removal, including distribution to and by retailers; requiring manufacturers (including importers), processors, and distributors, except for retailers, of methylene chloride for any use to provide downstream notification of these prohibitions; and requiring recordkeeping. While EPA proposed a determination of unreasonable risk from the use of methylene chloride in commercial paint and coating removal, EPA is not finalizing that determination in this rule. EPA is soliciting comment, through an advance notice of proposed rulemaking (ANPRM) published elsewhere in this issue of the **Federal Register**, on questions related to a potential training, certification, and limited access program as an option for risk management for all of the commercial uses of methylene chloride in paint and coating removal.

DATES: This final rule is effective May 28, 2019.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0231, is available at *http://www.regulations.gov.* A public version of the docket is available for inspection and copying between 8:30 a.m. and 4:30 p.m., Monday through Friday, excluding Federal holidays, at the U.S. Environmental Protection Agency, EPA Docket Center Reading Room, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Joel Wolf, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–0432; email address: *MCConsumerPR@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 potentially be affected by this final action if you manufacture (including import), process, or distribute in commerce methylene chloride (CASRN 75–09–2). 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 may include:

- Chemical and Allied Products Manufacturers (NAICS code 32411)
- Chemical and Allied Products and Merchants Wholesalers (NAICS code 4246)
- Building Materials and Supplies Dealers (NAICS code 4441)

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 rule are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that a shipment of the chemical substance (in this case, methylene chloride) 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 subject to regulation under section 6 (in this case, methylene chloride) 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 final 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 EPA determines 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, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk.

With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which a completed risk assessment was published prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, TSCA section 26(l)(4) (15 U.S.C. 2625(l)(4)) provides that EPA "may publish proposed and final rules under [TSCA section 6(a)] that are consistent with the scope of the completed risk assessment and consistent with other applicable requirements of [TSCA section 6]." Methylene chloride is such a chemical substance. It is listed in the 2014 update to the TSCA Work Plan and the 2014 final risk assessment includes consumer uses of paint and coating removal, among other uses (Refs. 1 and 2). EPA is publishing this final rule under TSCA section 6(a) in accordance with that discretionary statutory authority.

C. What action is the Agency taking?

EPA is making a final determination that the use of methylene chloride in consumer paint and coating removal presents an unreasonable risk of injury to health due to acute human lethality. Accordingly, EPA is issuing a final rule under section 6(a) of TSCA to prohibit the manufacture (including import), processing, and distribution in commerce of methylene chloride for consumer paint and coating removal (including distribution to and by retailers). This final rule also requires manufacturers (including importers), processors, and distributors, except for retailers, of methylene chloride for any use to provide downstream notification of the prohibitions throughout the supply chain; and requires limited recordkeeping. More details on these requirements are in Unit III.B.

In the proposed rule for methylene chloride in paint and coating removal (Ref. 3), EPA proposed an unreasonable risk determination for methylene chloride in commercial paint removal uses. In addition, EPA proposed to regulate under TSCA section 6(a) manufacture (including import), processing, distribution in commerce and use of methylene chloride in paint and coating removal for certain commercial uses. As noted previously, exercising its discretion under section 26(l)(4), EPA is not finalizing the proposed unreasonable risk determination and the proposed regulation for commercial uses of methylene chloride in paint and coating removal in this final action. Rather, EPA is soliciting comment, through an ANPRM published elsewhere in this issue of the **Federal Register**, on questions related to a potential training, certification, and limited access program as an option for risk management for all of the commercial uses of methylene chloride in paint and coating removal. More details on the proposed rule are in Unit II.B.2.

In the proposed rule for methylene chloride in paint and coating removal, EPA also proposed to regulate under TSCA section 6(a) N-methylpyrrolidone (NMP) in paint and coating removal. EPA is not finalizing the proposed regulation for NMP as part of this action. NMP use in paint and coating removal will be incorporated into the risk evaluation currently being conducted under TSCA section 6(b). More information about the proposed rule and NMP is in Unit II.B.2.

D. Why is the Agency taking this action?

Based on EPA's analysis of consumer exposures to methylene chloride in paint and coating removal, EPA is making a final determination that the use of methylene chloride in consumer paint and coating removal presents an unreasonable risk of injury to health due to acute human lethality. This final rule addresses the unreasonable risk, which may include death due to asphyxiation, in a manner that results in the chemical no longer presenting that unreasonable risk. Effects from acute exposure during use of methylene chloride in paint and coating removal may include neurological impacts such as dizziness, incapacitation, loss of consciousness, coma, and death (Ref. 2).

As noted in Unit III.A., EPA is regulating certain conditions of use of methylene chloride related to consumer paint and coating removal, which is estimated to comprise less than 10% of the total use of the chemical (Ref. 4).

E. What are the estimated impacts of this action?

As described in more detail in the Economic Analysis (Ref. 4), EPA's analysis of the cost of this rule is estimated to be $3.8 to $13.6 million annualized over 20 years at a 3% discount rate and $3.8 to $13.7 million annualized over 20 years at a 7% discount rate. Because the costs estimated in this rule are variable, the values at the different discount rates are similar. Unquantified costs include potential loss of producer and consumer surplus associated with possible reductions in paint and coating removal activity. There may also be unquantified costs associated with performance of alternatives including longer time for products to work and countervailing hazards from alternative chemicals including potentially higher flammability and exposure to other toxic chemicals.

Preventing exposure to methylene chloride in consumer paint and coating removal results in monetized benefits, as well as non-monetized benefits. Monetized benefits include the prevention of deaths resulting from acute adverse effects that occur at a known rate among consumer users. Non-monetized benefits result from the prevention of some non-cancer adverse effects to the nervous system. Thus, there is not a quantification or monetary valuation estimate for the overall total benefits. Based on the benefits that EPA can monetize, the benefits for this rule are approximately $3.5 million per year over 20 years at 3% and 7% discount rate (Ref. 4).

F. Children's Environmental Health

This action is consistent with the 1995 EPA Policy on Evaluating Health

Risks to Children (*http://www.epa.gov/children/epas-policy-evaluating-risk-children*). In its TSCA Work Plan Risk Assessment for methylene chloride, EPA identified risks from inhalation exposure to children who may be present as bystanders in homes where consumer paint and coating removal occurs. These risks may include neurological effects such as cognitive impairment, sensory impairment, dizziness, incapacitation, and loss of consciousness (leading to risks of falls, concussion, and other injuries). Supporting information on the health effects of methylene chloride exposure to children is available in the Toxicological Review of Methylene Chloride (Ref. 5) and the Final Risk Assessment on Methylene Chloride (Ref. 2), as well as Unit II.A.

II. Background

A. Methylene Chloride, Health Effects, Risks, and Other Regulatory Actions

Methylene chloride (CASRN 75–09–2) 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 (Ref. 2). According to the 2016 Chemical Data Reporting (CDR) information, approximately 264 million pounds of methylene chloride were domestically manufactured or imported into the United States in 2015, with the bulk of the volume domestically manufactured (Ref. 6). Most methylene chloride is produced and used for purposes other than paint and coating removal, which represents less than 10% of total use of methylene chloride (Ref. 4). In terms of environmental releases, 271 facilities reported a total of 3.4 million pounds of releases of methylene chloride to the 2015 Toxics Release Inventory (Ref. 7). Individuals are exposed to methylene chloride from industrial/commercial and consumer sources in different settings, such as homes and workplaces, and through multiple routes (inhalation, dermal, and ingestion).

Methylene chloride is acutely lethal, a neurotoxicant, and a likely human carcinogen. This final rule is specifically intended to prevent the unreasonable risks of injury to health due to acute human lethality from use of methylene chloride for consumer paint and coating removal. The risk assessment presents a detailed description of the range of adverse acute and chronic health effects associated with methylene chloride (Ref. 2).

The primary target organ of methylene chloride acute toxicity is the brain, and neurological effects result from either direct narcosis or the formation of carbon monoxide. The accumulation of carboxyhemoglobin in the blood can lead to sensory impairment, dizziness, incapacitation, loss of consciousness, heart failure, and death. The neurotoxic and cardiovascular effects may be exacerbated in fetuses and in infants with higher residual levels of fetal hemoglobin when exposed to high concentrations of methylene chloride (Ref. 2).

Based on data from the Occupational Safety and Health Administration (OSHA), the Consumer Product Safety Commission (CPSC), state records, and publicly reported information, EPA identified 49 fatalities from 1976 to 2016 (Ref. 3 at p. 7482) resulting from consumer or commercial worker exposure to methylene chloride during paint and coating removal. However, this may be an underestimate of the deaths that have occurred (Refs. 7 and 8). More details are provided in the proposed rule (Ref. 3 at p. 7468).

Since the publication of the January 19, 2017, proposed rule, EPA has learned of four additional fatalities due to methylene chloride in paint and coating removal (Ref. 10). Two of the victims were independent contractors working for small or family-owned businesses, the third was a small business owner, and the fourth was a consumer who died while using a methylene chloride paint and coating removal product to remove paint (Ref. 10). Many of the victims used paint and coating removers easily available to consumers through retailers. This may not constitute an exhaustive list of fatalities, rather, those that were brought to the attention of the Agency since publication of the proposed rule.

The use of methylene chloride in paint and coating removal presents an increased risk of death and nervous system effects for many of the estimated 1.3 million consumers and residential bystanders who use or are exposed to methylene chloride through consumer paint and coating removal each year (Ref. 4). Of particular concern is the potential for acute neurological impairment (central nervous system depressant effects) for consumers using methylene chloride for paint and coating removal. In the risk assessment, the upper-end scenarios for consumer users had 4-hour exposures of 233 parts per million (ppm). As described in the risk assessment, the Acute Exposure Guideline (AEGL–2), which is the threshold for disability for an 8-hour exposure, is 60 ppm. In humans, acute exposure to methylene chloride above 200 ppm results in acute neurobehavioral deficits measured in psychomotor tasks including: Tests of hand-eye coordination, visual evoked response changes, and auditory vigilance. In a few cases, cardiotoxic effects (*i.e.*, evidenced by electrocardiogram changes) were reported in humans (Ref. 2).

Some populations are currently at disproportionate risk for the health effects associated with use of methylene chloride in paint and coating removal, including children present in homes where consumer paint and coating removal is conducted. EPA's full analysis, conducted as part of compliance with Executive Order 13166 (65 FR 50121, August 11, 2000) and Executive Order 12898 (59 FR 7629, February 16, 1994) is described in the proposed rule (Ref. 3 at pp. 7476, 7525).

While the primary concern has been human health, there is potential for methylene chloride exposures to adversely impact ecological receptors. Methylene chloride is mainly released to the environment in air, and to a lesser extent in water and soil, due to industrial/commercial and consumer uses as a solvent, in aerosol products, and in paint and coating removal. Methylene chloride is moderately persistent and its bioaccumulation potential is low. Though volatile, methylene chloride has negligible atmospheric photochemical reactions, and is therefore exempt from being classified as a volatile organic compound (VOC) as defined at 40 CFR 51.100(c).

The proposed rule presented a comprehensive overview of regulatory actions by EPA, other Federal agencies, and state and international agencies pertaining to methylene chloride use in paint and coating removal and actions addressing methylene chloride waste disposal, releases to air and contamination of groundwater, drinking water, and soils (Ref. 3 at p. 7469). EPA presents here a summary of those actions, with a focus on those that have changed since the proposed rule.

EPA has issued several final rules and notices pertaining to methylene chloride under EPA's various authorities. Under the Clean Air Act, which designates methylene chloride as a hazardous air pollutant (HAP), EPA has promulgated several National Emissions Standards for Hazardous Air Pollutants (NESHAPs) addressing specific sources for methylene chloride emissions, including area sources engaged in paint stripping, surface coating of motor vehicles and mobile equipment, and miscellaneous surface coating

operations, and a 2015 update to a 1995 NESHAP for Aerospace Manufacturing and Rework Facilities (42 U.S.C. 7412(b)(1)) CAA). Methylene chloride is listed as a hazardous waste under the Resource Conservation and Recovery Act (RCRA) (Hazardous Waste No. U080, for discarded commercial products, and Waste Nos. F001, F002, for spent halogenated solvents including those halogenated solvents used in degreasing) and as a hazardous constituent in appendix VIII to 40 CFR part 261 (Ref. 2). The Emergency Planning and Community Right-to-Know Act, section 313, lists methylene chloride on the Toxics Release Inventory (TRI) (Ref. 2). The Safe Drinking Water Act requires EPA to determine the level of contaminants in drinking water at which no adverse health effects are likely to occur, with EPA setting a maximum contaminant level goal of zero and an enforceable maximum contaminant level for methylene chloride (dichloromethane) at 0.005 milligrams/Liter (mg/L) or 5 parts per billion (ppb) (57 FR 31776, July 17, 1992).

Other Federal agencies with regulations on methylene chloride include the Food and Drug Administration (FDA), which has banned methylene chloride as an ingredient in all cosmetic products (21 CFR 700.19); OSHA, which has a permissible exposure limit (PEL) of 25 ppm as an eight-hour time-weighted average (TWA) and a 15-minute short-term exposure limit (STEL) of 125 ppm; and CPSC, which has updated its labeling policy for household products containing methylene chloride.

In 2016, CPSC was petitioned by the Halogenated Solvents Industry Alliance to amend its guidance contained in the Statement of Interpretation and Enforcement Policy on the Labeling of Certain Household Products Containing Methylene Chloride; CPSC published that petition and requested public comments (81 FR 60298, September 1, 2016). In response to that petition, CPSC updated the cautionary labeling policy for paint strippers containing methylene chloride to recommend the inclusion of language on the principal display panel of the label and on the back or other panel to specifically describe the risk of fatality from acute exposure in enclosed spaces (83 FR 12254, March 21, 2018; 83 FR 18219, April 26, 2018). CPSC's recommendations also included providing specific examples of spaces in which the product should not be used, incorporating precautionary information for indoor use, and warning against foreseeable inappropriate actions that are not sufficiently protective, such as use of a dust mask to provide protection against vapors. More information on CPSC's updates are in Unit III.A.4.

Several states have taken actions to reduce or make the public aware of risks from methylene chloride. In November 2017, California EPA's Department of Toxic Substances Control (DTSC) proposed to list paint strippers with methylene chloride as a priority product under its Safer Consumer Products regulations (Ref. 11). Methylene chloride is on DTSC's list of candidate chemicals (Ref. 12). If finalized, California's regulation on methylene chloride in paint and coating removers would trigger notification requirements for responsible entities, such as manufacturers and importers to DTSC, and require those companies making paint strippers with methylene chloride to analyze alternatives to determine if methylene chloride is essential and whether there are available alternatives.

B. History of This Rulemaking

This rule finalizes certain parts of the regulation proposed on January 19, 2017 (Ref. 3) with respect to methylene chloride use for consumer paint and coating removal. The proposed rule followed EPA's 2014 final risk assessment of methylene chloride for paint and coating removal. The changes in this final rule from the proposal are discussed in Unit III.

1. TSCA Work Plan and Methylene Chloride Risk Assessment. In 2012, EPA released the initial list of TSCA Work Plan chemicals identified for further assessment under TSCA as part of its chemical safety program (Ref. 1). The process for identifying these chemicals was based on a combination of hazard, exposure, and persistence and bioaccumulation characteristics, and is described in the "TSCA Work Plan Chemicals: Methods Document" (Ref. 13). Under the TSCA Work Plan chemical criteria, methylene chloride ranked high for health hazards and exposure potential. Methylene chloride also appeared in the 2014 update of the TSCA Work Plan for Chemical Assessments.

EPA finalized a TSCA Work Plan Chemical Risk Assessment for methylene chloride in paint and coating removal (methylene chloride risk assessment) in August 2014, following the 2013 peer review of the 2012 draft methylene chloride risk assessment. The completed 2014 risk assessment and all documents from the peer review process are available in Docket Number EPA–HQ–OPPT–2012–0725.

The 2014 methylene chloride risk assessment evaluated health risks to consumers, among others, from inhalation exposures from methylene chloride use in paint and coating removal. A more detailed discussion of the risk assessment is included in the proposed rule (Ref. 3 at p. 7470). The risk assessment identified risks of concern following acute (short-term) exposures for consumers and others conducting paint removal with methylene chloride, as well as for exposed bystanders, including residents of homes in which paint removal is conducted. The acute risks identified include death; neurological impacts such as dizziness, incapacitation, loss of consciousness, and coma (Ref. 2).

The assessment identified risks from acute exposures to methylene chloride when used for consumer paint and coating removal, including (Ref. 2):

- Acute risks of neurological effects for consumer users of methylene chloride as a paint remover.
- Acute risks of neurological effects for bystanders (including children) in the location in which paint removers containing methylene chloride are used by residents (*i.e.* consumer paint and coating removal). These risks are also present for exposures to methylene chloride in a location after the paint removal work is complete, because methylene chloride can remain in the air in spaces that are enclosed, confined, or lacking ventilation.

Among the comments on the proposed rule, an overview of which is given in Unit II.B.3., EPA received 28 comments related to the 2014 risk assessment. Twelve mass-mailing campaigns, resulting in over 100,000 public comments, and four individual comments reiterated or supported the conclusions of the risk assessment. A separate individual comment provided a list of additional references documenting the health effects and deaths from methylene chloride use. Other commenters identified what they believe were shortcomings in the risk assessment, such as an underestimation of risk; lack of proper consideration of available data; deficiencies in risk estimation; an overestimation of risk; and lack of verification of data and fatality incident reports. Other comments included additional information from local governments regarding fatalities and adverse effects from use of methylene chloride in paint removers. There were also comments related to carcinogenicity.

The Small Business Advocacy Review (SBAR) Panel convened in support of this action heard from several Small Entity Representatives (SERs) who expressed concerns about the underlying methylene chloride risk assessment (Ref. 14). Many of the

concerns expressed by these SERs were already expressed in the public comments and the peer review comments on the methylene chloride risk assessment. The Summary of External Peer Review and Public Comments and Disposition document in the risk assessment docket (EPA–HQ–OPPT–2012–0725) explains how EPA responded to the comments received.

EPA appreciates the comments supporting the conclusions of the risk assessment and those providing additional information. Some commenters expressed concern about analytical shortcomings in the risk assessment. However, the risk assessment relied on previous assessments that used current hazard and risk assessment methodology documented in EPA guidance. In particular, the hazard and dose response information in the risk assessment were developed by reputable organizations and subject to peer review processes and the cancer descriptor ''likely carcinogenic in humans'' is based on EPA's Toxicological Review using a weight of evidence approach (Ref. 5). The methylene chloride risk assessment was also peer reviewed. The comments on the risk assessment that were received during the comment periods on the proposed rule, and EPA's responses, are in the Response to Comments document (Ref. 15).

2. EPA's proposed rule under TSCA Section 6(a) for methylene chloride. EPA proposed to prohibit the manufacture (including import), processing, and distribution in commerce of methylene chloride for all consumer and most types of commercial paint removal, and to prohibit most commercial use of methylene chloride for paint and coating removal. Exercising its discretion under section 26(l)(4), EPA is not finalizing the portion of the proposal relating to commercial paint and coating removal today. EPA will address commercial paint and coating removal in the future after soliciting comment, through an ANPRM published elsewhere in this issue of the **Federal Register**, on questions related to a potential training, certification, and limited access program.

EPA proposed a determination of unreasonable risk from the use of NMP in paint and coating removal. However, exercising its discretion under section 26(l)(4), EPA is not finalizing the proposed unreasonable risk determination for NMP in paint and coating removal at this time. EPA intends to incorporate NMP use in paint and coating removal in the risk evaluation for NMP. EPA has concluded that the Agency's assessment of the potential risks from this widely used chemical will be more robust if the potential risks from these conditions of use are evaluated by applying standards and guidance under amended TSCA. In particular, this includes ensuring the evaluation is consistent with the scientific standards in Section 26 of TSCA, including using best available science and systematic review approaches. Additional information on the NMP risk evaluation process, including public meetings, supporting documents, and public comments, is available in Docket Number EPA–HQ–OPPT–2016–0743.

In the proposed rule, EPA described supplemental analyses used to inform certain aspects of risk management for methylene chloride in paint and coating removal (Ref. 3 at p. 7472). These analyses were consistent with the scope of the methylene chloride risk assessment and were based on the peer-reviewed methodology used in the risk assessment (Ref. 3 at p. 7521). While EPA stated in the proposed rule that these analyses would be peer reviewed prior to promulgation of a final rule and received one comment on the proposed rule to that effect, they will not be peer reviewed at this time because EPA is not finalizing regulatory approaches informed by the results of those analyses.

In the proposed rule for methylene chloride in paint and coating removal (Ref. 3), EPA proposed an unreasonable risk determination for commercial uses of methylene chloride in paint and coating removal, including commercial furniture refinishing. EPA, in collaboration with the Small Business Administration's Office of Advocacy, conducted a workshop on furniture refinishing in Boston, MA on September 12, 2017 (82 FR 41256, August 30, 2017) (FRL–9966–83). A transcript of the meeting and speaker presentations are available in Docket Number EPA–HQ–OPPT–2017–0139.

In the proposed rule, EPA requested comment on a process for receiving and evaluating petitions requesting EPA to promulgate statutory exemptions. While EPA is not finalizing an exemption process in this rule, EPA will take the commenters' suggestions into account as EPA considers how to proceed in the future with respect to exemptions under TSCA section 6(g).

3. Public comments and other public input. The proposed rule provided for a 90-day comment period, ending on April 19, 2017; this comment period was extended until May 19, 2017, in response to public requests (82 FR 20310, May 1, 2017) (FRL–9961–66). Even though EPA received requests for a lengthier extension of the comment periods, the Agency concluded that a 30-day extension of the initial comment period was sufficient.

EPA received more than 147,000 comments on the proposed rule. Commenters included private citizens, potentially affected businesses, trade associations, environmental and public health advocacy groups, state and local governments, and other Federal agencies. Most of the comments received through mass mail campaigns and individual public comments supported the rule and urged EPA to prohibit the use of methylene chloride in paint and coating removal to stop putting families, workers and communities at risk, citing the lethality of methylene chloride and fatalities due to paint and coating removal with methylene chloride. Other commenters opposed the rule, and questioned EPA's authority for issuing it. In this preamble, EPA has responded to many of the comments relevant to methylene chloride in consumer paint and coating removal; however, the more comprehensive version of EPA's response to comments related to this final action can be found in the Response to Comments document (Ref. 15). Public interest in the proposed rule extended beyond the comments received on the proposal and at a furniture refinishing workshop described earlier. EPA continued discussions with the public to receive clarification on comments received on the proposed rule. This included meetings requested by W. M. Barr, Breast Cancer Prevention Partners, Natural Resources Defense Council, and Safer Chemicals Healthy Families, to discuss their comments and by families who have lost relatives using methylene chloride in paint removal (Refs. 16, 17, 18 and 19). EPA staff also attended a demonstration hosted by W. M. Barr of various paint and coating removal products (Ref. 20). EPA also consulted with state officials to discuss methylene chloride deaths reported since the proposal. (Ref. 21 and. Ref. 15).

4. Risk evaluation of methylene chloride. EPA announced in December 2016 its designation of methylene chloride as one of the ten chemical substances that will undergo risk evaluation pursuant to section 6(b)(2)(A) of TSCA (81 FR 91927, December 19, 2016) (FRL–9956–47). The purpose of the risk evaluation under section 6(b)(4)(A) is to determine whether methylene chloride presents an unreasonable risk of injury to health or the environment under the conditions of use. The scope of the methylene

chloride risk evaluation identifies, among other issues, the conditions of use, including manufacturing, processing, and other uses beyond paint removal, such as adhesives and degreasing. If EPA makes a determination of unreasonable risk in the final risk evaluation for any of the other methylene chloride conditions of use included in that risk evaluation, EPA will subsequently issue a section 6(a) rule applying risk management requirements to the extent necessary so that such unreasonable risk is no longer present.

With respect to this final rule for methylene chloride in consumer paint and coating removal, although some commenters questioned EPA's authority to issue a final rule on methylene chloride in paint and coating removal without finalizing the peer review of the supplemental analysis and other commenters urged EPA to use its discretion not to finalize the rule and instead re-evaluate the paint and coating removal use under the risk evaluation under section 6(b)(4)(A), the Agency is exercising its discretion to proceed with this final rule addressing unreasonable risk from methylene chloride in consumer paint and coating removal in accordance with TSCA section 26(l)(4). TSCA section 26(l)(4) (15 U.S.C. 2625(l)(4)) provides that, for a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which a completed risk assessment was published prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA "may publish proposed and final rules" under TSCA section 6(a) that are consistent with the scope of the completed risk assessment and with other applicable requirements of TSCA section 6. Methylene chloride was listed in the 2014 update to the TSCA Work Plan and the completed risk assessment was published in 2014. EPA is publishing this final rule under TSCA section 6(a) in accordance with that discretionary authority.

EPA is conducting a risk evaluation of the other conditions of use of methylene chloride under TSCA section 6(b). Additional information regarding the risk evaluation for the other conditions of use of methylene chloride, including public meetings, supporting documents, and public comments, is available in Docket Number EPA–HQ–OPPT–2016–0742.

III. Provisions of This Final Rule

EPA carefully considered all the public comments related to consumer paint and coating removal, as well as other information reasonably available in order to develop this final rule. As indicated previously, in this final action EPA is only addressing methylene chloride in consumer paint and coating removal and will address methylene chloride in commercial paint and coating removal in the future after soliciting comment, through an ANPRM published elsewhere in this issue of the **Federal Register**, on questions related to a potential training, certification, and limited access program. The changes from the proposed action to this final action related to methylene chloride in consumer paint and coating removal are:

- Further clarification in the final rule that paint and coating removers containing methylene chloride cannot be distributed to or by retailers and clarification that a retailer includes a person that distributes in commerce or makes available a chemical substance, mixture or article to consumers, including via internet sales or distribution. Any distributor with at least one consumer client is considered a retailer;
- A decision not to finalize the proposal's requirement for the distribution in commerce of methylene chloride for paint and coating removal in containers with a volume of less than 55 gallons. This requirement would have imposed an additional mitigation measure to address the risks to consumers from methylene chloride in consumer paint and coating removal. However, in this final rule, by eliminating access to methylene chloride for consumer paint and coating removal, via the retailer distribution restrictions, the unreasonable risk from consumer paint and coating removal use is addressed:
- A change in the date that the requirements begin for recordkeeping and for downstream notification of the prohibitions in this rule, from 45 days to 90 days after the effective date of the rule;
- Clarification that the downstream notification requirement should be done through the safety data sheets (SDSs) and provision of language required in the SDSs; and
- A provision allowing required records to be kept either at a company's headquarters or at the facility for which the records were generated.

In addition, this action finalizes the general provisions related to definitions, exports and imports requirements, and enforcement and inspections. These provisions were originally presented in another proposed rule, entitled "Trichloroethylene; Regulation of Certain Uses Under TSCA section 6(a)" (Ref. 23). As EPA is newly establishing 40 CFR part 751 to address the regulation of certain chemical substances and mixtures under TSCA section 6, the Agency intended that the general provisions presented in Subpart A of the proposed rule on trichloroethylene apply to all TSCA section 6 chemical substance regulations presented in part 751 (Ref. 23 at p. 91623). EPA's proposed rule on methylene chloride and NMP use in paint and coating removal specifically proposed to build upon the proposed part 751 presented therein, stating that the "proposal relies on general provisions in the proposed part 751, subpart A, which can be found at 81 FR 91592 (December 16, 2016)" (Ref. 3 at p. 7519), and that "40 CFR part 751, as proposed to be added at 81 FR 91592 (December 16, 2016), is proposed to be further amended" by adding proposed regulatory provisions addressing paint and coating removal uses of methylene chloride and NMP in subparts B and C, respectively (Ref. 3 at p. 7529). Since the trichloroethylene rule has not been finalized, the proposed general provisions are included in this final action with two modifications:

1. Further elaboration of TSCA section 6(a) requirements; and
2. A minor modification to clarify that inspections will be conducted at EPA discretion in accordance with TSCA section 11 and are not required under that authority.

A. Scope and Applicability

In this final action, EPA is regulating the manufacture (including import), processing and distribution in commerce of methylene chloride for consumer paint and coating removal, including distribution of methylene chloride for consumer paint and coating removal to and by retailers. The details of the prohibitions and requirements of this final rule are in Unit III.B.

1. Paint and coating removal products. Methylene chloride has been used for decades in paint and coating removal in products intended for both consumer and commercial uses. Paint and coating removal, also referred to as paint stripping, is the process of removing paint or other coatings from a surface. Coatings can include paint, varnish, lacquer, graffiti, polyurethane, or other high-performance or specialty coatings. Surfaces or substrates may be the interior or exterior of buildings, structures, vehicles, aircraft, marine craft, furniture, or other objects and include a variety of materials, such as wood, metals, plastics, concrete, and fiberglass. Paint and coating removal can be conducted in consumer or occupational settings (Ref. 2).

Paint and coatings can be removed by chemical, mechanical, or thermal means. Chemical paint removers can include solvents, such as methylene chloride, or caustic chemicals. Solvents permeate the top of the coating and dissolve the bond between the coating and the substrate (Ref. 22). Following the application of the chemical paint remover, the coating can be more easily peeled, scraped, or mechanically removed from the substrate. Techniques for applying the paint remover chemical include manual coating or brushing, tank dipping, flow-over systems, spray applications (manually or through automation), pouring, and wiping and rolling (manual or automated) (Ref. 2). Methylene chloride has been used to remove paint and coatings from walls, trim, furniture, architectural features, patios or decks, ceilings, bathtubs, floors, civilian aircraft, marine craft, cars, trucks, railcars, tankers, storage vessels, and other vehicles or their component parts to prepare for new coatings. Methylene chloride is typically applied to the surface using a hand-held brush, then left on to soften the old coating, and once curing has occurred, the old coating is scraped or brushed off to clean the surface. For bathtub refinishing, methylene chloride is poured and brushed onto a bathtub using a paintbrush and then scraped from the bathtub after leaving the remover to cure for 20 to 30 minutes (Ref. 4). Consumer use of methylene chloride in paint and coating removal occurs in consumer settings, such as homes, workshops, basements, garages, attics, and outdoors. More information on specific paint removal techniques is in the methylene chloride risk assessment (Ref. 2).

Though some users are switching to substitutes and alternative methods, methylene chloride use continues because it is readily available and works quickly and effectively on nearly all coatings without damaging most substrates. In addition, some users prefer methylene chloride because it is less flammable than some other solvents; however, paint and coating removal products formulated with methylene chloride tend to contain high concentrations of co-solvents that are flammable (Ref. 24). Also, methylene chloride is extremely volatile, has strong fumes, and evaporates quickly so that it must be reapplied for each layer of paint or coating to be removed.

Products intended for one specific type of paint removal project can be easily used in a different setting, including by consumers or hobbyists (Refs. 8, 9, 10, and 25). Additionally, consumers can easily use paint removal products intended for or marketed to professional users since paint removal products are readily available at many big box, local hardware, and paint specialty stores. It should be noted that, while voluntary, several retailers have committed to phase out methylene chloride paint and coating removal products. EPA identified 59 different products for paint and coating removal that contain methylene chloride, formulated by 10 different firms. This is approximately 54% of the total number of paint and coating removal products EPA identified (109 products) (Ref. 24). Paint and coating removers containing methylene chloride are frequently sold at stores that sell products to consumers as well as professional users. Additionally, due to the wide availability of products available on the internet and through various additional suppliers that serve commercial and consumer customers, consumers may foreseeably purchase a variety of paint and coating removal products containing methylene chloride. EPA estimated that approximately 1.3 million consumers and residential bystanders who use or are exposed to methylene chloride through consumer paint and coating removal each year (Ref. 4).

2. Regulatory considerations. To identify the regulatory approach that would address the unreasonable risk presented by methylene chloride in paint and coating removal, EPA analyzed a wide range of regulatory options under section 6(a) in the proposed rule (Ref. 3 at pp. 7472, 7479).

Section 6(c)(2)(A) of TSCA requires EPA, in proposing and promulgating section 6(a) rules, to include a statement addressing certain factors, including the costs and benefits and the cost effectiveness of the regulatory action and of the one or more primary alternative regulatory actions considered by the Administrator. In the proposed rule, EPA described its consideration of several alternative regulatory actions. One of the proposal's primary alternative regulatory actions consisted of: (i) An occupational respiratory protection program for the commercial uses proposed for regulation; (ii) a prohibition on distribution in commerce of methylene chloride for paint and coating removal in containers with a volume of less than 55 gallons and 5 gallons for certain formulations as a means of limiting consumer access to methylene chloride paint and coating removal products (though it did not include restrictions on manufacturing, processing, or distribution of methylene chloride for consumer paint and coating removal); and (iii) required downstream notification.

Since this final rule is not addressing commercial paint and coating removal, the primary alternative regulatory action considered in this final rule is slightly modified from the proposed rule, in that it does not include the occupational respiratory protection program for the commercial uses. Therefore, the primary alternative regulatory action for this final rule consists of: (*a*) Prohibition on distribution in commerce of methylene chloride for paint and coating removal in containers with a volume of less than 55 gallons and 5 gallons for certain formulations; and (*b*) downstream notification.

This final regulatory action is consistent with the regulatory action proposed, which includes a prohibition on the manufacture, processing and distribution in commerce of methylene chloride for consumer paint and coating removal. The primary alternative regulatory action considered would have imposed additional mitigation measures to address the risk to consumers (*i.e.* 55-gallon containers) with additional burdens to processors and distributors; however, by eliminating access to methylene chloride for consumer paint and coating removal, via the retailer distribution restrictions, the unreasonable risk for consumer paint and coating removal use is addressed.

The cost of the final rule is less than the cost of the primary alternative regulatory action considered. EPA's assessment of the costs and benefits of the primary alternative regulatory action are described in the Economic Analysis (Ref. 4) and in Unit III.A.3.

3. TSCA section 6(c)(2) considerations. TSCA section 6(c)(2)(A) requires EPA to consider and publish a statement based on reasonably available information with respect to the chemical's effects on health and the magnitude of human exposure to the chemical. The following is EPA's statement with respect to this final rule.

i. Health effects, exposure, and environmental effects. Methylene chloride is a neurotoxicant that can be acutely lethal. Exposure to methylene chloride can result in a range of adverse health effects, including effects on the nervous system, liver, respiratory system, kidneys, and reproductive systems. Methylene chloride is also a likely human carcinogen. The magnitude of exposure of human beings to methylene chloride use in consumer paint and coating removal is characterized by the number of users, in the case of this final action is estimated to be 1.3 million consumers and

residential bystanders who may not be engaged in paint and coating removal but who are exposed via inhalation to the chemical as a result of consumer paint and coating removal each year (Ref. 4). While methylene chloride is moderately persistent, given its low bioaccumulation and low hazard for aquatic toxicity (Ref. 2), the magnitude of potential environmental impacts on ecological receptors is judged to be low for the environmental releases associated with methylene chloride in consumer paint and coating removal (Ref. 3 at pp. 7468, 7489).

ii. The benefits of the chemical substance or mixture for various uses. Methylene chloride use in 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. In addition to paint and coating removal, 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 (Ref. 3 at p. 7467).

iii. The reasonably ascertainable economic consequences of the rule. The reasonably ascertainable economic consequences of this rule include several components, all of which are described in the Economic Analysis for this final rule (Ref. 4). With respect to the anticipated effects of this 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 a significant impact on the national economy. In addition, EPA considered the employment impacts of this final rule, and found that the direction of change in employment is uncertain, but EPA expects the short-term and longer-term employment effects to be small. EPA estimates that impacts on small businesses are insignificant; EPA estimates that this final rule would affect approximately 7 small entities, with all small businesses having a cost impact of less than 1% of the annual revenue.

With respect to this rule's effect on technological innovation, EPA expects this rule to spur innovation, not hinder it. A prohibition on the manufacture, processing, and distribution of this use of methylene chloride is likely to increase demand for chemical substitutes. This rule is not likely to have significant effects on the environment, though it does present the potential for small reductions in air emissions and soil contamination associated with improper disposal of paint and coating removers containing methylene chloride. The effects of this rule on public health are estimated to be positive, due to the prevention of deaths from consumer exposure to methylene chloride when engaging in paint and coating removal with these products.

The costs and benefits that can be monetized for this rule are described at length in Unit III.F and in the Economic Analysis (Ref. 4). The costs for this rule are estimated to range from $3.8 to $13.6 million annualized over 20 years at a 3% discount rate and $3.8 to $13.7 million annualized over 20 years at a 7% discount rate. The monetized benefits are estimated to be $3.5 million per year over 20 years at 3% and 7% discount rate. This reflects the benefit to consumers.

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 would not include restrictions on manufacturing, processing, or distribution of methylene chloride for consumer paint and coating removal, but it would prohibit the distribution in commerce of methylene chloride for paint and coating removal in containers with a volume of less than 55 gallons, or 5 gallons for certain formulations. In addition, downstream notification and recordkeeping would be required. The estimated annualized costs of this alternative regulatory action are $5.8 to $16.8 million at 3% and $5.8 to $16.8 million at 7% over 20 years (Ref. 4). The estimated annualized benefits of this alternative regulatory action are $13.0 to $13.1 million at 3% and $12.8 million at 7% over 20 years (Ref. 4). This reflects the $3.5 million per year benefits to consumers noted above and additional benefits to commercial users not targeted by the rule.

The regulatory action finalized today is more cost effective than the primary alternative regulatory action because it achieves the necessary risk reduction for consumers and bystanders with estimated lower costs than the alternative regulatory action. The cost of the alternative regulatory action was estimated to be higher due to the cost of compliance with the container volume requirements which impact commercial users not targeted by the rule. However, the net benefits of the final regulatory action are estimated to be lower than the net benefits of the primary alternative regulatory action, since the primary alternative regulatory action includes benefits from preventing consumer users' exposure to methylene chloride in paint and coating removal, whereas the final regulatory action only includes benefits from eliminating consumer exposures to methylene chloride in paint and coating removal (Ref. 4).

iv. Consideration of alternatives. In addition to the statement of effects and analysis of alternative regulatory actions required under TSCA section 6(c)(2)(A), section 6(c)(2)(C) requires EPA to consider, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use, whether technically and economically feasible alternatives (*e.g.,* substitute chemicals or alternative methods) that benefit health or the environment will be reasonably available as a substitute when the prohibition or restriction takes effect. In the proposed rule, EPA requested comment on the accuracy of its conclusion that identified substitutes for methylene chloride which are reasonably available and technically and economically feasible, and whether its consideration of chemical substitutes and alternative methods met the requirements of TSCA section 6(c)(2)(C). EPA received several comments on this subject. A majority of commenters indicated that effective, safer alternatives are already available for paint and coating removal, and that EPA has amply satisfied TSCA section 6(c)(2)(C) requirements by identifying a number of available, preferable substitutes, including non-chemical substitutes. Some commenters raised concerns regarding alternatives and claimed EPA failed to satisfy the requirements of TSCA section 6(c)(2)(C) because the Agency erroneously concluded that technically and economically feasible alternative paint strippers exist. EPA disagrees with the comments that for consumer users, available alternative formulations are less safe and more expensive than products with methylene chloride, although EPA does recognize that many factors need to be considered when choosing the appropriate alternative. Substitute products currently are available for consumer users of methylene chloride for paint and coating removal, for a variety of coatings on numerous substrates (Refs. 26 and 27). None of the substitute chemicals already available has the level of toxicity associated with methylene chloride (Ref. 24). As EPA stated in the proposed rule, EPA is aware of technically and economically feasible chemical substitutes or alternative methods that are reasonably available to a consumer for almost every situation in

which methylene chloride is used to remove paints or coatings (Ref. 3 at p. 7485). A summary of comments related to substitute products, and EPA's response, is in the docket for this action (Ref. 15).

4. TSCA section 9(a) analysis. Section 9(a) of TSCA describes the steps EPA must take if the EPA Administrator determines in his 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. These steps include submitting a report to the agency administering that other law that describes the risk and the activities that present such risk. EPA has not made such a determination, and, in the proposed rule, EPA explained its reasoning. TSCA section 9(d) further 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. In the proposed rule, EPA described its consultations with CPSC and with OSHA, and letters documenting this consultation are in the docket (Refs. 28 and 29).

CPSC's mission is to protect the public from unreasonable risks of injury or death associated with the use of consumer products under the agency's jurisdiction. CPSC recently updated its guidance on labeling for certain products containing methylene chloride to explain that covered products that do not bear a prominent warning about the risk of death in enclosed spaces are considered misbranded hazardous substances under the Federal Hazardous Substances Act, 15 U.S.C. 1261–1276. One of the specifically-stated purposes for the update was 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). In that guidance, CPSC specifically stated that, "we do not suggest that labeling will address all hazards EPA identified in its proposed rulemaking" regarding methylene chloride use in paint and coating removal products. 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 mitigate the unreasonable risks to consumers identified by EPA so that they are no longer unreasonable.

OSHA's mission is to assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance. OSHA's authority does not address unreasonable risk from methylene chloride in consumer paint and coating removal.

In this final rule, EPA has not used its discretion to make a determination that unreasonable risks from the use of methylene chloride in consumer paint and coating removal may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA, and therefore there is no need to submit a report to CPSC or OSHA under TSCA section 9(a).

More than 20 comments were received regarding issues generally related to TSCA section 9. Some commenters supported EPA's decision to not make a determination and submit a report to another agency under TSCA section 9(a). These commenters agreed with EPA's reasoning on the ability of other authorities to address the unreasonable risks identified by EPA. Other commenters contended that the OSHA regulations and the CPSC labeling guidance were sufficient to address the risks EPA identified, especially given the fact that CPSC was in the process of revising its labeling guidance for methylene chloride. Others thought that, to the extent that EPA had identified risks to consumers and others that were not adequately addressed by the current CPSC guidance or OSHA regulations, a report from EPA under TSCA section 9(a) would have alerted the other agencies to the potential deficiencies.

In this case, EPA disagrees with those commenters who thought that EPA must make a determination that other authorities administered by other agencies could address the unreasonable risks identified by EPA.

5. TSCA section 9(b) analysis. TSCA section 9(b) directs EPA to use other authorities administered by EPA to protect against a risk to health or the environment if EPA determines that such risk could be eliminated or reduced to a sufficient extent by actions taken under those authorities, unless EPA determines that it is in the public interest to protect against such risk by actions taken under TSCA.

Although several EPA statutes have been used to limit methylene chloride exposure, as described in the proposed rule, the acute unreasonable risks EPA has identified could not be addressed through these other statutes.

For this reason, the Administrator is not making a determination that the unreasonable risks of injury to health due to acute human lethality from the use of methylene chloride in consumer paint and coating removal could be eliminated or reduced to a sufficient extent by actions taken under other Federal laws administered in whole or in part by EPA. Another commenter stated that EPA failed to meet its obligations under TSCA section 9(b) because EPA did not compare the estimated costs and efficiencies of acting under TSCA or other statutes administered by EPA. EPA disagrees with this commenter's reading of TSCA section 9(b). The obligation to compare costs and efficiencies only arises after EPA has first determined that the identified unreasonable risks could be adequately addressed through action under another statute administered by EPA, and also determines that it is in the public interest to act under TSCA rather than the other statute. In this case, EPA has made neither of those determinations.

6. TSCA section 26(h) considerations. EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science at the time the risk assessment for methylene chloride was conducted. These information sources supply information relevant to whether the use of methylene chloride in paint and coating removal would present an acute unreasonable risk. For example, the 2014 risk assessment used best available science and methods, was peer reviewed, and went through a public comment process (Ref. 2).

The clarity and completeness of the data, assumptions, methods, quality assurance, and analyses employed in EPA's decision are documented, as applicable and to the extent necessary for purposes of this final rule, in the proposed rule (Ref. 3 at p. 7521) and in the references cited throughout the preamble of the proposed and this final rule. While EPA recognizes, based on the available information, that there is variability and uncertainty with regard to EPA's risk assessment of the use of methylene chloride in paint and coating removal, those uncertainties were identified in the proposed rule (Ref. 3 at p. 7491) and were characterized and documented in the methylene chloride risk assessment (Ref. 2). The extent to which the various information, procedures, measures, methods, protocols, methodologies or models, as applicable, used in EPA's decision 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 EPA's response to comments, is in Docket Number EPA–HQ–OPPT–2012–0725.

EPA received several public comments on the proposed rule relating to the scientific information, technical procedures, measures, methods, protocols, methodologies, and models used by EPA. Commenters disagreed on whether EPA's assessment of methylene chloride was scientifically rigorous, with some praising EPA for a strong scientific underpinning for the regulation and others stating that EPA did not use best available science by incorporating exposure data that were out of date or by not correctly using a weight-of-evidence for some findings. EPA disagrees with commenters that the exposure data should not be used, or that weight-of-evidence was applied incorrectly. This action based on acute unreasonable risks is supported by a risk assessment that underwent peer review and a public comment process. More details on these comments and EPA's response is in the Response to Comments document (Ref. 15).

B. Prohibitions and Requirements

This final rule:

1. Prohibits the manufacturing, processing, and distribution in commerce of methylene chloride for paint and coating removal for all consumer uses;

2. Prohibits the distribution in commerce of methylene chloride in paint and coating removal products to and by retailers. A retailer is any person or business entity that distributes or makes available paint and coating removal products to consumers, including through ecommerce internet sales or distribution. If a person or business entity distributes or makes available any methylene chloride-containing paint or coating removal product to at least one consumer, then it is considered a retailer. For a distributor not to be considered a retailer, he/she must distribute or make available methylene chloride-containing paint and coating removal products solely to commercial or industrial end users or businesses. This additional provision clarifies the proposed regulation and ensures that retailers will not be able to purchase for sale or distribution to consumers, or to make available to consumers, paint and coating removal products containing methylene chloride;

3. Requires manufacturers, processors, and distributors of methylene chloride for any use, excluding retailers, to provide downstream notification of the prohibitions in this final rule through SDSs by adding to sections 1(c) and 15 of the SDS the following language: "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."; and

4. Requires recordkeeping relevant to these prohibitions.

The prohibition on manufacturing, processing, and distribution in commerce of methylene chloride for consumer paint and coating removal, including distribution to and by retailers, will take effect 180 days after the effective date of this final rule. EPA believes this is a reasonable transition period and will not result in additional costs of collecting and disposal of any stranded products. EPA recognizes that some individual retailers might not be as efficient with their inventory management and that could result in stranded products and some additional cost for disposal of such products.

Each person who manufactures, processes, or distributes in commerce methylene chloride is required to provide downstream notification of the restrictions in this rule through SDSs, effective 90 days following the effective date of this final rule. Downstream notification ensures that processors and distributors are aware of the restrictions for methylene chloride in paint and coating removal; enhances the likelihood that the risks associated with this use of methylene chloride are addressed throughout the supply chain; and also streamlines compliance and enhances enforcement, since compliance is improved when rules are clearly and simply communicated (Ref. 30).

After 90 days following the effective date of this final rule, each person who manufactures, processes, or distributes in commerce methylene chloride must retain documentation of the entities to whom methylene chloride was shipped, a copy of the downstream notification provided, and the amount of methylene chloride shipped. The documentation must be retained for 3 years from the date of shipment. Based on a public comment, EPA added to the final rule a provision to keep the required records either at the company's headquarters or at the facility for which the records were generated.

This final rule also includes a definition of retailers and consumer paint and coating removal in order to be responsive to comments received requesting EPA to provide more clarity regarding the regulated distribution to consumers.

C. Downstream Notification

EPA received four comments related to downstream notification of methylene chloride restrictions, one of which took issue with EPA's approach. This commenter stated that EPA lacks the authority to require downstream notification and recordkeeping beyond the scope of the conditions of use identified in its unreasonable risk finding. While EPA recognizes there are companies likely manufacturing, processing, or distributing methylene chloride or products containing methylene chloride for uses that will not be regulated under this final rule, EPA disagrees with the commenter's reading of the statute that section 6(a)(3) downstream notification requirements do not apply to conditions of use other than those for which EPA is addressing the unreasonable risk for a chemical substance.

TSCA section 6(a) requires EPA to impose one or more of the specified requirements to the extent necessary so that a chemical substance no longer presents an unreasonable risk identified by EPA. Here, EPA has determined that the downstream notification provisions are necessary to prevent the identified unreasonable risk. Without downstream notification, manufacturers, processors, and distributors, are likely to be unfamiliar with the prohibitions against distribution of methylene chloride-containing paint and coating removal products to and by retailers. As such, the notification helps ensure that all downstream entities are aware of the prohibitions. Further, notification throughout the supply chain streamlines compliance and enhances enforcement, since compliance can be improved when rules are clearly and simply conveyed. Moreover, under section 6, EPA has authority to require reporting and recordkeeping related to the regulatory requirements imposed by EPA under section 6. See, *e.g.*, 55 FR 222 (EPA's section 6 action on hexavalent chromium in cooling towers).

Some commenters requested more clarity from EPA regarding how to use the SDS for downstream notification. In this final rule, EPA is specifying the changes to the SDS needed for the downstream notification. Specifically, EPA is requiring the addition of the following language to sections 1(c) and 15 of the SDS: "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.''

The effective date of the requirement for this notification and the associated recordkeeping is 90 days after the effective date of this action. The proposed rule would have had these requirements take effect 45 days after the effective date of this final rule. On further reflection, EPA has determined that 90 days is a more reasonable transition period. Regulated entities need only to provide additional information on their SDS, which is routinely produced and updated.

D. Import Certification

Persons who import any chemical substance governed by a final TSCA section 6 rule are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. To comply with the import certification requirements, importers (or their agents) will be required to certify that the shipment of methylene chloride 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 methylene chloride 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.

E. Enforcement

Section 15 of TSCA makes it unlawful to fail or refuse to comply with any provision of a rule promulgated under TSCA section 6. Therefore, any failure to comply with this rule when it becomes effective would be a violation of section 15 of TSCA. In addition, section 15 of TSCA makes it unlawful for any person to: (1) Fail or refuse to establish and maintain records as required by this rule; (2) fail or refuse to permit access to or copying of records, as required by TSCA; or (3) fail or refuse to permit entry or inspection as required by section 11 of TSCA.

Violators may be subject to both civil and criminal liability. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty for each violation. Each day in violation of this final rule, after the effective date could constitute a separate violation. Knowing or willful violations could lead to the imposition of criminal penalties for each day of violation and imprisonment. In addition, other remedies are available to EPA under TSCA.

Individuals, as well as corporations, could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to ''any person'' who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies. In particular, EPA may proceed against individuals who report false information or cause it to be reported.

F. Costs, Benefits, and Impacts

EPA evaluated the costs and benefits of this final action, which is presented in the Economic Analysis (Ref. 4) and summarized in this unit.

1. Overview of public comments. Of the nine comments received related to the Economic Analysis, three comments supported EPA's Economic Analysis. One commenter stated that EPA conducted a thorough cost-benefit analysis, and appropriately provided an in depth qualitative description of health benefits. Other commenters pointed out perceived shortcomings of the Economic Analysis conducted by the Agency, with one commenter calling for the underlying Economic Analysis data to be more comprehensive, accurate, and reflective of current industry practices. These comments, and EPA's response, are in the Response to Comments document in this docket (Ref. 15).

2. Costs. The details of the costs of this final rule are summarized in Unit I.E and discussed in the Economic Analysis (Ref. 4). Under this final rule, costs to users of paint and coating removal products containing methylene chloride are approximately $3.8 to $13.6 million annualized for 20 years at a discount rate of 3% and $3.8 to $13.7 million at a discount rate of 7%. Costs to manufacturers of methylene chloride are $50 and $60 annualized for 20 years at a discount rate of 3% and 7% respectively. Costs for processors, including those associated with reformulation, downstream notification and label changes, on an annualized basis over 20 years are $ 15,000 to $25,000 using 3% and $20,000 to $34,000 using 7% discount rates. Agency costs for enforcement are estimated to be approximately $147,000 and $145,000 annualized over 20 years at 3% and 7%, respectively. Total costs of this final rule are estimated to be approximately $3.8 to $13.6 million annualized over 20 years at 3% and $3.8 to $13.7 million annualized over 20 years at 7%.

3. Benefits. EPA is not fully able to quantify the full monetary benefits that would accrue from preventing all consumer deaths due to methylene chloride in paint and coating removal and the impacts of the substitution effect by switching from methylene chloride to alternative chemicals and methods. Similarly, EPA is not able to monetize the benefits that would accrue from preventing non-fatal and non-cancer effects from exposure to methylene chloride in paint and coating removal. The subset of benefits that can be monetized from mitigating the risks from methylene chloride in paint and coating removal for consumers finalized by this rule are potential avoidance of fatalities and are estimated to be approximately $3.5 million (annualized at 3% and 7% over 20 years) (Ref. 4).

4. Comparison of benefits and costs. The monetized subset of benefits from preventing the risks resulting from methylene chloride in consumer paint and coating removal are less than the estimated monetary costs.

5. Impacts on the national economy, small businesses, technological innovation, the environment, and public health. As summarized in Unit I.E and III.A.3 and described in the Economic Analysis (Ref. 4), EPA considered the anticipated effects of this final rule. With respect to the national economy, as EPA indicated in the proposed rule (Ref. 3 at p. 7489), EPA considered the number of businesses and workers that would be affected and the costs and benefits to those businesses and workers. EPA did not find that there would be a significant impact on the national economy (Ref. 4). In addition, EPA considered the employment impacts of this final rule, and found that the direction of change in employment is uncertain, but EPA expects the short term and longer-term employment effects to be small (Ref. 4). EPA estimates that impacts on small businesses are insignificant; EPA estimates that this final rule would affect approximately 7 small entities, with all small businesses having a cost impact of less than 1% of the annual revenue, (Ref. 4). As EPA indicated in the proposed rule, with respect to this rule's effect on technological innovation, EPA expects this action to spur innovation, not hinder it. A prohibition on the manufacturing, processing, and distribution in commerce of methylene chloride for consumer paint and coating removal is likely to increase demand for alternatives (Ref. 4). This rule is not likely to have significant effects on the environment, though it does present the potential for small reductions in air emissions and soil contamination associated with improper disposal of paint and coating removers containing

methylene chloride. The effects of this rule on public health are estimated to be positive, due to the prevention of deaths and nonlethal adverse health effects due to consumer exposure to methylene chloride when engaging in paint and coating removal (Ref. 3 at p. 7489).

6. Impacts of the final and alternative regulatory actions. The costs of this final rule are estimated to include costs to users of paint and coating removal products containing methylene chloride, product reformulation costs, downstream notification costs, recordkeeping costs, and Agency costs.

The primary alternative regulatory action considered by EPA would not include restrictions on manufacturing, processing, or distribution of methylene chloride for consumer paint and coating removal, but it would require the distribution in commerce of methylene chloride for paint and coating removal in containers with a volume of no less than 55 gallons, or 5 gallons for certain formulations. In addition, downstream notification and recordkeeping would be required. As required under TSCA section 6(c), EPA analyzed the costs and benefits of this primary alternative action and found that this approach would introduce additional burdens to processors and distributors who would bear the cost of ensuring products are in 55- and 5-gallon containers, as appropriate. In addition, the 55-gallon volume restriction would effectively bar most commercial users in the professional contractor, bathtub refinishing, and graffiti removal sectors given the increased cost and, for some users, impracticality of using large containers.

The regulatory action finalized today is more cost effective because it achieves the necessary risk reduction for consumers and bystanders with estimated lower costs than the alternative regulatory action. The cost of the alternative regulatory action was estimated to be higher due to the cost of compliance with the container volume requirements. However, the net benefits of the final regulatory action are estimated to be lower than the net benefits of the primary alternative regulatory action, since the primary alternative regulatory action includes benefits from preventing consumer users' exposure, whereas the final regulatory action only includes benefits from eliminating consumer exposures to methylene chloride in paint and coating removal. A summary of the findings of this analysis are in III.A.3 and in the Economic Analysis (Ref. 4).

IV. References

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

1. EPA. TSCA Work Plan for Chemical Assessments: 2014 Update. *https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf.* Retrieved December 4, 2018.
2. EPA. TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use. CASRN 75–09–2. EPA Document# 740–R1–4003. August 2014. Office of Chemical Safety and Pollution Prevention. Washington, DC *https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf.* Retrieved December 4, 2018.
3. EPA. Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a); Proposed Rule. **Federal Register** (82 FR 7464, January 19, 2017) (FRL–9958–57).
4. EPA. Economic Analysis of Final Rule TSCA Section 6 Action on Methylene Chloride in Paint and Coating Removal (EPA Docket EPA–HQ–OPPT–2016–0231; RIN 2070–AK07). Office of Pollution Prevention and Toxics. Washington, DC.
5. EPA. Toxicological Review of Methylene Chloride (CAS No. 75–09–2). EPA/635/R–10/003F. Integrated Risk Information System, Washington, DC. November 2011.
6. EPA. Public Database 2016 Chemical Data Reporting (May 2017 Release). Washington, DC: US Environmental Protection Agency, Office of Pollution Prevention and Toxics. Retrieved from *https://www.epa.gov/chemical-data-reporting.*
7. EPA. Scope of the Risk Evaluation for Methylene Chloride (Dichloromethane, DCM) EPA–HQ–OPPT–2016–0742–0061. Office of Pollution Prevention and Toxics. Washington, DC. June 2017.
8. OSHA. "Lethal Exposure to Methylene Chloride during Bathtub Refinishing." *OSHA Fatal Facts.* 2016. *https://www.osha.gov/Publications/OSHA3883.pdf.*
9. Centers for Disease Control and Prevention (CDC). "Fatal Exposure to Methylene Chloride Among Bathtub Refinishers—United States, 2000–2011." *Morbidity and Mortality Weekly Report.* February 24, 2012. Vol 61(7), p 119–122.
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11. California Code of Regulations. "*Proposal to List Paint or Varnish Strippers Containing Methylene Chloride as a Priority Product.*" Proposed Regulation Text. November 2017. *https://calsafer.dtsc.ca.gov/cms/commentpackage/?rid=12734.*
12. "Proposition 65 Law and Regulations." Nov 14, 2016. *http://www.oehha.ca.gov/prop65/law/P65law72003.html.*
13. EPA. TSCA Work Plan Chemicals: Methods Document. *http://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf. Retrieved February 25, 2016.*
14. EPA. Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule on the Toxic Substances Control Act (TSCA) Section 6(a) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act for Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint Removers. Office of Chemical Safety and Pollution Prevention. Washington, DC. 2016.
15. EPA. Response to Comments on the Final Methylene Chloride Rule; Regulation of Certain Uses Under TSCA Section 6(a) (EPA Docket EPA–HQ–OPPT–2016–0231). Office of Pollution Prevention and Toxics. Washington, DC.
16. EPA. Outreach Meeting with W. M. Barr and EPA to discuss the Methylene Chloride in Paint and Coating Removal. (EPA Docket EPA–HQ–OPPT–2016–0231). Office of Pollution Prevention and Toxics. Washington, DC.
17. EPA Outreach Meeting with Breast Cancer Prevention Partners (BCPP) and Safer Chemicals Healthy Families (SCHF) and EPA to discuss the Methylene Chloride in Paint and Coating Removal. (EPA Docket EPA–HQ–OPPT–2016–0231) Office of Pollution Prevention and Toxics. Washington, DC.
18. EPA Outreach Meeting with Natural Resources Defense Council and Safer Chemicals Healthy Families (SCHF) and EPA to discuss the Methylene Chloride in Paint and Coating Removal. (EPA Docket EPA–HQ–OPPT–2016–0231) Office of Pollution Prevention and Toxics. Washington, DC.
19. EPA Meeting with families who have lost relatives using methylene chloride in paint removal. (EPA Docket EPA–HQ–OPPT–2016–0231) Office of Pollution Prevention and Toxics. Washington, DC.
20. EPA. Demonstration of Paint Removing products by W.M. Barr. (EPA Docket EPA–HQ–OPPT–2016–0231) Office of Pollution Prevention and Toxics. Washington, DC.
21. EPA. Outreach Meeting with Federal and State Agencies on Recent Methylene Chloride Fatalities. (EPA Docket EPA–HQ–OPPT–2016–0231). Office of Pollution Prevention and Toxics. Washington, DC.
22. "Paint Strippers, Types of Strippers." *PaintPRO,* Vol. 3, No. 3. June 2000. *http://www.paintpro.net/Articles/PP303/PP303_strippers.cfm.*

23. EPA. Trichloroethylene; Regulation of Certain Uses Under TSCA Section 6(a); Proposed Rule. **Federal Register** (81 FR 91592, December 16, 2016) (FRL–9949–86).
24. EPA. Analysis Report of Chemical Alternatives for Use of Methylene Chloride- and N-Methylpyrrolidone-based Paint Removers: Hazard and Exposure Concerns. 2016.
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28. United States Consumer Product Safety Commission (CPSC). Letter to James J. Jones from Patricia H. Adkins. April 19, 2016.
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30. Giles, C. EPA. "Next Generation Compliance." Environmental Forum. October 2013, p 22–26. Washington, DC.
31. EPA. Final Regulatory Flexibility Analysis for Methylene Chloride; Regulation of Certain Uses Under TSCA Section 6(a); Final Rule; RIN 2070–AK07. Office of Chemical Safety and Pollution Prevention. Washington, DC. 2019.
32. EPA. Supporting Statement for an Information Collection Request (ICR) Under the Paperwork Reduction Act (PRA). March 2019.
33. EPA. Section 6(a) Rulemakings under the Toxic Substances Control Act (TSCA) Paint Removers & TCE Rulemakings E.O. 13132: Federalism Consultation. May 13, 2015.
34. EPA. Notification of Consultation and Coordination on Proposed Rulemakings under the Toxic Substances Control Act for 1) Methylene Chloride and n-Methylpyrrolidone in Paint Removers and 2) Trichloroethylene in Certain Uses. April 8, 2015.
35. EPA. Paint Removers: Methylene Chloride and N-Methylpyrrolidone—Community Webinar. May 28, 2015.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

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

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Order 12866 (58 FR 51735, October 4, 1993) and Executive Order 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations 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 summarized in Units I.E., III.A.3., and III.G. (Ref. 4).

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This action is subject to the requirements for regulatory actions specified in Executive Order 13771 (82 FR 9339, February 3, 2017). Details on the estimated costs of this final rule can be found in EPA's analysis (Ref. 4) of the potential costs and benefits associated with this action, which is available in the docket and is summarized in Unit III.F.

C. Paperwork Reduction Act (PRA)

The information collection requirements in this rule have been submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by EPA has been assigned EPA ICR No. 2556.02 and OMB Control No. 2070–0204. You can find a copy of the ICR in the docket for this rule (Ref. 32), and it is briefly summarized here. This rule does not require the regulated entities to submit information to EPA.

The information collection activities required by this rule include a downstream notification requirement and a recordkeeping requirement. The downstream notification would require companies that ship methylene chloride to notify companies downstream in the supply chain through the SDS of the prohibitions described in this final rule. The recordkeeping requirement mandates companies that ship methylene chloride to retain certain information at the company headquarters, or at the facility for which the records were generated, for three years from the date of shipment. These information collection activities are necessary in order to enhance the prohibitions under this rule by ensuring awareness of the prohibitions throughout the methylene chloride supply chain, and to provide EPA with information upon inspection of companies downstream who purchased methylene chloride. This rule does not require confidential or sensitive information to be submitted to EPA or downstream companies. EPA believes that these information collection activities would not significantly impact the regulated entities as the downstream notification requirements is a simple modification to the SDS and recordkeeping requirements include information that is part of the normal course of business.

Respondents/affected entities: Methylene chloride manufacturers, processors, and distributors.

Respondent's obligation to respond: Respondents are not obligated to respond or report to EPA, but must notify downstream users and maintain required records.

Estimated number of respondents: 138.

Frequency of response: On occasion to third parties as needed.

Total estimated annual burden: 69 hours. Burden is defined at 5 CFR 1320.3(b).

Total estimated annual cost: $3,712.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The OMB control numbers for certain EPA regulations are listed in 40 CFR part 9.

D. Regulatory Flexibility Act (RFA)

Pursuant to sections 603 and 609(b) of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) for the proposed rulemaking and convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations from small entity representatives that potentially would be subject to the rule's requirements. Summaries of the IRFA and Panel recommendations are presented in the proposed rulemaking (Ref. 3).

As required by section 604 of the RFA, EPA prepared a final regulatory flexibility analysis (FRFA) for this action (Ref. 31). The FRFA addresses the issues raised by public comments on the IRFA for the proposed rulemaking. The

complete FRFA is available for review in the docket and is summarized here.

1. Statement of need and rule objectives. The purpose of this action is to prevent acute fatalities from the use of methylene chloride in consumer paint and coating removal. Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines 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, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance no longer presents such risk.

With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which a completed risk assessment was published prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (which includes methylene chloride), TSCA section 26(l)(4) (15 U.S.C. 2625(l)(4)) provides that EPA "may publish proposed and final rules" under TSCA section 6(a) that are consistent with the scope of the completed risk assessment and consistent with other applicable requirements of TSCA section 6. EPA is publishing this final rule under TSCA section 6(a) in accordance with that discretionary statutory authority.

Based on EPA's analysis of consumer population exposures to methylene chloride in paint and coating removal, EPA is making a final determination that the use of methylene chloride in consumer paint and coating removal presents an unreasonable risk of injury to health due to acute human lethality. This final rule addresses that unreasonable risk.

EPA believes this rule will be effective in preventing unreasonable risk from the use of methylene chloride in consumer paint and coating removal. This final rule is informed by the TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use, as well as information gathered from the comments on the proposed rulemaking, SBAR panel, and public meetings. For more information on the proposed rulemaking, SBAR panel and outreach efforts for this action, see the docket for this rulemaking (Docket ID Number EPA–HQ–OPPT–2016–0231).

2. Significant comments on the IRFA. EPA received no comments on the IRFA. However, EPA did receive comments related to the regulatory options selected, alternative regulatory actions, and impacts on small businesses. The comments received on the proposed rule and EPA's responses as they relate to this final action are summarized in Unit II.B.3 and in further detail in the Response to Comment Document in the docket (Ref. 15).

3. SBA Office of Advocacy comments and EPA response. EPA received no comments from SBA on the IRFA. SBA, however, did provide comments on the proposed rule. Because EPA is not finalizing the proposed regulations on NMP, EPA is not responding to the comments received regarding NMP at this time and will take them into consideration during the risk evaluation for that chemical. SBA's comments which pertain to methylene chloride consumer paint and coating removal, and EPA's responses, are in the Response to Comments document for this rule (Ref. 15) and in the FRFA (Ref. 31).

4. Estimate of the number of small entities to which the final rule applies. EPA estimates that this final rule would affect approximately 7 small entities, specifically, a small number of formulators of paint and coating removal products that contain methylene chloride (Ref. 32). The cost to these small businesses will be the cost of reformulating products sold to consumer users and the cost of complying with the downstream notification requirements. In addition, cost impacts of a prohibition on sale of paint and coating remover products containing methylene chloride for consumer uses on retailers of such products is not included in this analysis, as EPA is uncertain about the effect of possible increased sales of alternative paint and coatings removal products. Some of the affected retailers may be small businesses and these retailers are not included in this discussion.

Some small business may be negatively affected by the rule. Negative impacts may include increasing production of substitute chemicals to replace some of the production of methylene chloride, or updating SDS sheets, etc. EPA does not expect these impacts to be costly but as they are tasks that will take time, effort, and resources the firms would not otherwise expend in such a manner, EPA sees them as negative impacts on the firms. Another negative impact may include a small business formulator exiting the paint and coating removal product market entirely.

5. Projected reporting, recordkeeping and other compliance requirements of the final rule. i. Compliance requirements. To address the unreasonable risks that EPA has identified for methylene chloride in consumer paint and coating removal, EPA is finalizing under section 6 of TSCA regulations that prohibit the manufacture (including import), processing, and distribution in commerce of methylene chloride for all consumer paint and coating removal. The prohibition on distribution in commerce of methylene chloride in paint and coating removal for all consumer uses includes a prohibition on the distribution of methylene chloride for paint and coating removal to and by retailers. EPA is also requiring manufacturers (including importers), processors, and distributors, except for retailers, of methylene chloride for any use to provide downstream notification of these requirements and prohibitions throughout the supply chain via simple modifications to the SDS; and requiring limited recordkeeping.

ii. Classes of small entities subject to the compliance requirements. The small entities that are potentially directly regulated by this rule are small entities that are formulators of paint and coating removal products that contain methylene chloride.

iii. Professional skills needed to comply. For this rule, complying with the prohibitions, the downstream notification, and the recordkeeping requirements involve no special skills.

6. Steps taken to minimize economic impact to small entities. i. Small Business Advocacy Review Panel. As required by section 609(b) of the RFA, EPA also convened an SBAR Panel during the development of the proposed rule 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. A copy of the full SBAR Panel Report (Ref. 14) is available in the rulemaking docket. The Panel recommended that EPA seek additional information in five specific areas: Exposure information, regulatory options, alternatives, cost information, and risk assessment. The comments received on the proposed rule and EPA's responses as they pertain to consumer paint and coating removal are summarized in Unit II.B.3 and in further detail in the Response to Comments Document in the docket (Ref. 15).

ii. Alternatives considered. EPA considered a wide variety of risk reduction options. The primary alternative regulatory action would not include restrictions on manufacturing, processing, or distribution of methylene chloride for consumer paint and coating

removal, but it would require the distribution in commerce of methylene chloride for paint and coating removal in containers with volumes no less than 55 gallons, or 5 gallons for certain formulations. In addition, downstream notification and recordkeeping would be required. As required under TSCA section 6(c), EPA analyzed the costs and benefits of the alternative regulatory action (Ref. 4). EPA finds that the primary alternative regulatory action would introduce additional burdens to processors and distributors who would bear the costs of ensuring products are in 55 and 5-gallon containers, as appropriate. In addition, the 55-gallon volume restriction would effectively bar most commercial users in the professional contractor, bathtub refinishing, and graffiti removal sectors given the increased cost. The final rule is more cost effective than the primary alternative regulatory action considered. A summary of the findings of this analysis are in III.A.3 and in the Economic Analysis (Ref. 4).

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

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The requirements of this action would primarily affect manufacturers, processors, and distributors of methylene chloride. The total estimated annualized cost of this final rule are $3.8 to $13.6 million and $3.8 to $13.7 million annualized over 20 years at 3% and 7%, respectively (Ref. 4), which does not exceed the inflation-adjusted unfunded mandate threshold of $154 million.

F. Executive Order 13132: Federalism

EPA has concluded that this action does not have federalism implications, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This regulation will not preempt state law. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Neither pause preemption nor permanent preemption apply to the restrictions proposed or to this final regulation, because this TSCA section 6(a) rule is promulgated under TSCA section 26(l)(4). In accordance with section 26(l)(4), this rulemaking is consistent with the scope of the 2014 risk assessment of methylene chloride for paint and coating removal, as well as other applicable requirements of TSCA section 6, and is not based on a risk evaluation conducted under TSCA section 6(b). Therefore, EPA believes that this rule will not preempt a state law or action on methylene chloride for consumer paint and coating removal under either section 18(a)(1)(B) (under which the extent of permanent preemption is "consistent with the scope of the risk evaluation under section (6)(b)(4)(D)") or section 18(b) (under which the extent of pause preemption is tied to the "scope of the risk evaluation pursuant to section 6(b)(4)(D)").

Although this rule does not have federalism implications, 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. EPA invited the following national organizations representing state and local elected officials to a meeting on May 13, 2015, in Washington DC: National Governors Association; National Conference of State Legislatures, Council of State Governments, National League of Cities, U.S. Conference of Mayors, National Association of Counties, International City/County Management Association, National Association of Towns and Townships, County Executives of America, and Environmental Council of States. A summary of the meeting with these organizations, including the views that they expressed, is available in the docket (Ref. 33).

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

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This rulemaking would not have substantial direct effects on tribal government because methylene chloride is not manufactured, processed, or distributed in commerce by tribes. EPA did not receive any information during the public comment period to alter EPA's understanding that this action has no substantial direct effects on tribal governments. Tribes do not regulate methylene chloride, and this rulemaking would not impose substantial direct compliance costs on tribal governments. Thus, E.O. 13175 does not apply to this action. EPA nevertheless consulted with tribal officials during the development of this action, consistent with the EPA Policy on Consultation and Coordination with Indian Tribes (Ref. 34).

H. 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 it is not economically significant as defined in Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessment of exposure by children to methylene chloride in paint and coating removal is contained in the proposed rule (Ref. 3 at pp. 7462, 7476, and 7503). Supporting information on methylene chloride exposures and the health effects of methylene chloride exposure by children is available in the Toxicological Review of Methylene Chloride (Ref. 5) and the methylene chloride risk assessment (Ref. 2).

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

This final rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution in commerce, or use. This rule is intended to protect against risks from methylene chloride in paint and coating removal, and does not affect the use of oil, coal, or electricity.

J. National Technology Transfer and Advancement Act (NTTAA)

This final rule does not involve technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes Federal executive policy on environmental justice. Its main provision 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 health or environmental effects of their programs, policies and activities on minority populations and low-income populations in the U.S. EPA places particular emphasis on the public

health and environmental conditions affecting minority populations, low-income populations, and indigenous peoples. In recognizing that these populations frequently bear a disproportionate burden of environmental harms and risks, EPA works to protect them from adverse public health and environmental effects (Ref. 35).

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 751

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

Dated: March 15, 2019.

Andrew Wheeler,

Administrator.

■ Therefore, add 40 CFR part 751 to read as follows:

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

Subpart A—General Provisions

Sec.
751.1 Purpose.
751.5 Definitions.
751.7 Exports and imports.
751.9 Enforcement and inspections.

Subpart B—Methylene Chloride

751.101 General.
751.103 Definitions.
751.105 Consumer paint and coating removal.
751.107 Downstream notification.
751.109 Recordkeeping.

Subpart C—[Reserved]

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

Subpart A—General Provisions

§751.1 Purpose.

This part sets forth requirements under section 6(a) of the Toxic Substances Control Act, 15 U.S.C. 2605(a), regulating the manufacture (including import), processing, distribution in commerce, use, or disposal of certain chemical substances and mixtures in order to address unreasonable risks to the extent necessary so that the chemical substance or mixture no longer presents such risk.

§751.5 Definitions.

The definitions in section 3 of the Toxic Substances Control Act, 15 U.S.C. 2602, apply to this part except as otherwise established in any subpart under this part.

Act or *TSCA* means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

CASRN means Chemical Abstracts Service Registry Number.

EPA means the U.S. Environmental Protection Agency.

Person means any natural person, firm, company, corporation, joint venture, partnership, sole proprietorship, association, or any other business entity; any State or political subdivision thereof; any municipality; any interstate body; and any department, agency, or instrumentality of the Federal government.

§751.7 Exports and imports.

(a) *Exports.* Persons who intend to export a chemical substance identified in any subpart under this part are subject to the export notification provisions of section 12(b) of the Act. The regulations that interpret section 12(b) appear at 40 CFR part 707, subpart D.

(b) *Imports.* Persons who import a substance identified in any subpart under this part are subject to the import certification requirements under section 13 of the Act, which are codified at 19 CFR 12.118 through 12.127. See also 19 CFR 127.28.

§751.9 Enforcement and inspections.

(a) *Enforcement.* (1) Failure to comply with any provision of this part is a violation of section 15 of the Act (15 U.S.C. 2614).

(2) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(3) Failure or refusal to permit entry or inspection as required by section 11 of the Act (15 U.S.C. 2610) is a violation of section 15 of the Act (15 U.S.C. 2614).

(4) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation.

(b) *Inspections.* EPA may conduct inspections under section 11 of the Act (15 U.S.C. 2610) to ensure compliance with this part.

Subpart B—Methylene Chloride

§751.101 General.

This subpart sets certain restrictions on the manufacture (including import), processing, and distribution in commerce of methylene chloride (CASRN 75–09–2) for consumer paint and coating removal to prevent unreasonable risks of injury to health due to acute human lethality.

§751.103 Definitions.

The definitions in subpart A of this part apply to this subpart unless otherwise specified in this section. In addition, the following definitions apply:

Consumer paint and coating removal means paint and coating removal performed by any natural person who uses a paint and coating removal product for any personal use without receiving remuneration or other form of payment.

Distribute in commerce has the same meaning as in section 3 of the Act, except that the term does not include retailers for purposes of §§ 751.107 and 751.109.

Paint and coating removal means application of a chemical or use of another method to remove, loosen, or deteriorate any paint, varnish, lacquer, graffiti, surface protectants, or other coating from a substrate, including objects, vehicles, architectural features, or structures.

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.

§751.105 Consumer paint and coating removal.

(a) After November 22, 2019, all persons are prohibited from manufacturing, processing and distributing in commerce methylene chloride for consumer paint and coating removal.

(b) After November 22, 2019, all persons are prohibited from distributing in commerce methylene chloride, including any methylene chloride containing products, for paint and coating removal to retailers.

(c) After November 22, 2019, all retailers are prohibited from distributing in commerce methylene chloride, including any methylene chloride containing products, for paint and coating removal.

§751.107 Downstream notification.

Each person who manufactures, processes, or distributes in commerce methylene chloride for any use after August 26, 2019 must, prior to or concurrent with the shipment, notify companies to whom methylene chloride is shipped, in writing, of the restrictions described in this subpart. Notification must occur by inserting the following text in the Safety Data Sheet (SDS) provided with the methylene chloride or with any methylene chloride containing product:

(a) SDS Section 1.(c): "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) SDS Section 15: "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."

§751.109 Recordkeeping.

(a) Each person who manufactures, 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 § 751.107; and

(3) The amount of methylene chloride shipped.

(b) The documentation in paragraph (a) of this section must be retained for 3 years from the date of shipment.

Subpart C—[Reserved]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No.: 181210999–9239–02]

RIN 0648–BI66

Fisheries of the Northeastern United States; Framework Adjustment 30 to the Atlantic Sea Scallop Fishery Management Plan

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS approves and implements the measures of Framework Adjustment 30 to the Atlantic Sea Scallop Fishery Management Plan that establish scallop specifications and other measures for fishing years 2019 and 2020. This action is necessary to respond to updated scientific information, and the intended effect of this rule is to prevent overfishing, improve both yield-per-recruit and the overall management of the Atlantic sea scallop resource, and implement these measures for the 2019 fishing year.

DATES: Effective April 1, 2019.

ADDRESSES: The New England Fishery Management Council developed an environmental assessment (EA) for this action that describes the measures in Framework Adjustment 30 and other considered alternatives and analyzes the impacts of the measures and alternatives. Copies of Framework 30, the EA, the Initial Regulatory Flexibility Analysis (IRFA), and information on the economic impacts of this rulemaking are available upon request from Thomas A. Nies, Executive Director, New England Fishery Management Council, 50 Water Street, Newburyport, MA 01950 and accessible via the internet in documents available at: *https://www.nefmc.org/library/framework-30-1.*

Copies of the small entity compliance guide are available from Michael Pentony, Regional Administrator, NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930–2298, or available on the internet at: *http://www.greateratlantic.fisheries.noaa.gov/sustainable/species/scallop/.*

FOR FURTHER INFORMATION CONTACT: Travis Ford, Fishery Policy Analyst, 978–281–9233.

SUPPLEMENTARY INFORMATION:

Background

The New England Fishery Management Council adopted Framework 30 to the Atlantic Sea Scallop Fishery Management Plan (FMP) on December 5, 2018, and submitted a final EA to NMFS on March 7, 2019, for approval. NMFS published a proposed rule for Framework 30 on February 20, 2019 (84 FR 5035). To help ensure that the final rule would be implemented before April 1, 2019, the start of the fishing year, the proposed rule included a 15-day public comment period that closed on March 7, 2019.

NMFS has approved all of the measures in Framework 30 recommended by the Council, as described below. This final rule implements Framework 30, which establishes scallop specifications and other measures for fishing years 2019 and 2020, including changes to the catch, effort, and quota allocations and adjustments to the rotational area management program for fishing year 2019, and default specifications for fishing year 2020. The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) allows NMFS to approve, partially approve, or disapprove measures proposed by the Council based on whether the measures are consistent with the FMP, the Magnuson-Stevens Act and its National Standards, and other applicable law. NMFS generally defers to the Council's policy choices unless there is a clear inconsistency with the law or the FMP. Details concerning the development of these measures were contained in the preamble of the proposed rule and are not repeated here.

Specification of Scallop Overfishing Limit (OFL), Acceptable Biological Catch (ABC), Annual Catch Limits (ACLs), Annual Catch Targets (ACTs), Annual Projected Landings (APLs) and Set-Asides for the 2019 Fishing Year, and Default Specifications for Fishing Year 2020

The allocations incorporate updated biomass reference points that resulted from the Northeast Fisheries Science Center's most recent scallop stock benchmark assessment that was completed in August 2018. The assessment reviewed and updated the data and models used to assess the scallop stock and ultimately updated the reference points for status determinations. The scallop stock is considered overfished if the biomass is less than half of the biomass at maximum sustainable yield (B_{msy}), and overfishing is occurring if fishing mortality (F) is above the fishing mortality at maximum sustainable yield (F_{msy}). The assessment found that the scallop resource is not overfished and overfishing is not occurring, but the estimates for F_{msy} and B_{msy} have changed. A comparison of the old and new reference points is outlined in Table 1.