ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA–HQ–OPPT–2016–0231; FRL–9958–57]

RIN 2070–AK07

Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Methylene chloride, also called dichloromethane, is a volatile chemical that has a variety of uses, including paint and coating removal. N-methylpyrrolidone (NMP) is a solvent used in a variety of applications, including paint and coating removal. For each of these chemicals, EPA has identified risks of concern associated with their use in paint and coating removal. EPA proposes a determination that these are unreasonable risks. EPA is proposing to prohibit the manufacture (including import), processing, and distribution in commerce of methylene chloride for consumer and most types of commercial paint and coating removal under section 6 of the Toxic Substances Control Act (TSCA). EPA is also proposing to prohibit the use of methylene chloride in these commercial uses; to require manufacturers (including importers), processors, and distributors, except for retailers, of methylene chloride for any use to provide downstream notification of these prohibitions throughout the supply chain; and to require recordkeeping. EPA is proposing an initial ten-year time-limited exemption from these proposed regulations on methylene chloride for coating removal uses critical for national security. First, EPA is proposing to prohibit the manufacture (including import), processing, and distribution in commerce of NMP for all consumer and commercial paint and coating removal; to prohibit the use of NMP for all commercial paint and coating removal; to require, consistent with methylene chloride restrictions, downstream notification of these prohibitions throughout the supply chain; to require recordkeeping; and to provide a time-limited exemption from these proposed regulations on NMP for coating removal uses critical for national security. For NMP, as an alternate proposal, EPA is proposing that (1) commercial users of NMP for paint and coating removal establish a worker protection program for dermal and respiratory protection and not use paint and coating removal products that contain greater than 35 percent NMP by weight (except for product formulations destined to be used by DoD or its contractors performing work only for DOD projects); and (2) processors of products containing NMP for paint and coating removal reformulate products such that these products do not exceed a maximum of 35 percent NMP by weight, identify gloves that provide effective protection for the formulation, and provide warning and instruction labels on the products.

DATES: Comments must be received on or before April 19, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0231, at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods (*e.g.*, mail or hand delivery), the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*.

Docket. Docket number EPA–HQ–OPPT–2016–0231 contains supporting information used in developing the proposed rule, comments on the proposed rule, and additional supporting information. 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:* Ana Corado, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number 202–564–0140; email address: *corado.ana@epa.gov*. *For other information contact:* Niva Kramek, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: 202–564–4830; email address: *kramek.niva@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 proposed action if you manufacture (defined under Toxic Substances Control Act (TSCA) to include import), process, distribute in commerce, or use methylene chloride or NMP for paint and coating removal. Paint and coating removal, also referred to as paint stripping, is the process of removing paint or other coatings from a surface. 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).
- Ship building and repairing (NAICS code 336611)
- Aircraft manufacturing (NAICS code 336411)
- Museums (NAICS code 712110)
- Independent Artists, Writers, and Performers (NAICS code 711510)
- Reupholster and furniture repair (NAICS code 811420)
- Automotive body, paint, and interior repair and maintenance (NAICS code 811121)
- Flooring contractors (NAICS code 238330)
- Painting and wall covering contractors (NAICS code 238320)

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final TSCA section 6(a) rule are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR

12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

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

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

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines after risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements 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)) expressly authorizes EPA to issue rules under TSCA section 6(a) that are consistent with the scope of the completed risk assessment and consistent with the other applicable requirements of TSCA section 6. Methylene chloride and NMP are such chemical substances (Ref. 1). They are listed in the 2014 update to the TSCA Work Plan and the completed risk assessments were published in 2014 and 2015, respectively. The scope of each completed risk assessment includes consumer and commercial paint and coating removal.

C. What action is the Agency taking?

EPA proposes a determination that the uses of methylene chloride or NMP in paint and coating removal present an unreasonable risk of injury to health. Accordingly, for methylene chloride, EPA is proposing under section 6 of TSCA to prohibit the manufacture (including import), processing, and distribution in commerce of methylene chloride for all consumer and for most types of commercial paint and coating removal uses. EPA is also proposing under TSCA section 6 to prohibit the use of methylene chloride for commercial paint and coating removal in the specified sectors, which include painting and decorating, floor refinishing, automotive refinishing, civilian aircraft refinishing, graffiti removal, renovations and contracting, bridge repair and repainting, and marine craft refinishing and repair. EPA is not proposing at this time to regulate the use of methylene chloride in commercial furniture refinishing, also referred to as furniture stripping or refinishing conducted by professionals or commercial workers. EPA is also proposing to exempt certain uses of methylene chloride for coating removal that EPA proposes are critical for national security.

EPA is also proposing to require that any paint or coating removal products containing methylene chloride that continue to be distributed be packaged in containers with a volume no less than 55 gallons, except for formulations specifically manufactured for the Department of Defense, which may be distributed in containers with volumes no less than 5 gallons. EPA is also proposing to require 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; and to require limited recordkeeping. More details on this supply chain approach are in Unit VI.C.3.

EPA intends to issue a separate proposal on methylene chloride in paint and coating removal in commercial furniture refinishing, but plans to issue one final rule covering both this proposal and the future proposed rule on methylene chloride in paint and coating removal in commercial furniture refinishing. More information on such a future proposal that would directly address methylene chloride in paint and coating removal in furniture refinishing is in Unit XI.

For NMP, EPA is co-proposing two different options to reduce the unreasonable risks presented by NMP in paint and coating removal for consumers and commercial users. EPA is co-proposing these two options because the Agency is interested in public consideration of these approaches, and is soliciting comments regarding the extent to which these approaches could reduce the unreasonable risks the Agency has identified.

Under the first approach co-proposed for NMP (option 1), EPA is proposing to prohibit the manufacture (including import), processing, and distribution in commerce of NMP for all consumer and commercial paint and coating removal, with exemptions for certain coating removal uses that EPA proposes are critical to national security. EPA is also proposing to prohibit the commercial use of NMP for paint and coating removal, with exemptions for certain coating removal uses that EPA proposes are critical to national security. These exemptions include the condition that any exempt paint and coating removal products containing NMP be packaged in containers with a volume no less than 5 gallons. Unlike the option proposed for methylene chloride, these exemptions do not include the use of NMP in furniture refinishing. EPA is also proposing to require manufacturers (including importers), processors, and distributors, except for retailers, of NMP for any use to provide downstream notification of these prohibitions throughout the supply chain; and to require limited recordkeeping.

Under the second approach proposed for NMP, EPA is proposing a reformulation, PPE, and labeling approach. This would require product reformulation to limit the concentration of NMP in paint and coating removal products; testing of product formulations to identify specialized gloves that provide protection; relabeling of products to provide additional information to consumers; an occupational dermal and respiratory protection program for commercial use of NMP in paint and coating removal, downstream notification when distributing NMP for other uses, and limited recordkeeping. Under this approach, no exemption is proposed for coating removal identified as critical for national security because paint and coating removal products containing NMP would continue to be available for these national security uses under this option, even without establishing a national security exemption.

EPA is requesting public comment on these proposals.

D. Why is the Agency taking this action?

Based on EPA's analysis of worker and consumer populations' exposures to methylene chloride and NMP in paint and coating removal, EPA proposes a determination that methylene chloride and NMP in paint and coating removal present an unreasonable risk to human

health. For methylene chloride, the health impacts of its use in paint and coating removal include death (due to asphyxiation), liver toxicity, kidney toxicity, reproductive toxicity, specific cognitive impacts, and cancers such as brain cancer, liver cancer, certain lung cancers, non-Hodgkin's lymphoma, and multiple myeloma (Ref. 2). Some of these effects result from a very short, acute exposure; others follow years of occupational exposure. For NMP, these health effects include developmental toxicity (*e.g.*, fetal death or decreased infant birth weight), neurotoxicity, immunotoxicity, liver and kidney toxicity, and reproductive toxicity (Ref. 3).

It is important to note that while both methylene chloride and NMP are used in paint and coating removal, products containing NMP have in recent years become increasingly popular substitutes for users interested in avoiding the health effects or odors known to be associated with products containing methylene chloride. While exposures to these chemicals have been assessed using different health endpoints, EPA proposes a determination that the use of either methylene chloride or NMP in paint and coating removal presents unreasonable risks. For this reason, EPA proposes to address the unreasonable risks presented by both chemicals in one rule.

Although EPA proposes to determine that the identified risks to workers exposed to methylene chloride in commercial furniture refinishing are unreasonable, EPA is not proposing to regulate these risks at this time. EPA intends to issue a separate proposal addressing the use of methylene chloride in paint and coating removal in commercial furniture refinishing. See Unit XI.

As discussed in Unit V.C., EPA is not proposing to prohibit all manufacturing, processing, distribution in commerce, and use of methylene chloride or NMP, of which paint and coating removal is estimated to comprise 25% and 9% of the use of each chemical, respectively (Refs. 2 and 3).

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

EPA proposes to determine that the identified risks from methylene chloride and NMP in paint and coating removal are unreasonable. Apart from that proposed determination, EPA has evaluated the potential costs of the proposed approach of (1) prohibiting the manufacture (including import), processing, and distribution in commerce of methylene chloride for all consumer paint and coating removal in the sectors specified in section I.C of this preamble, exempting specific uses critical to national security; (2) prohibiting the commercial use of methylene chloride for paint and coating removal in the specified sectors; (3) requiring any paint and coating removal products containing methylene chloride to be packaged for distribution in commerce in containers with volumes no less than 55 gallons so as to reduce diversion to restricted uses, except for formulations specifically manufactured for the Department of Defense; (4) requiring manufacturers (including importers), processors, and distributors, except for retailers, to provide downstream notification of these prohibitions throughout the supply chain; and (5) requiring associated recordkeeping requirements. EPA has also evaluated the costs of the two co-proposed options for NMP. Under the first option, this includes (1) prohibiting the manufacture (including import), processing, and distribution in commerce of NMP for all paint and coating removal, exempting specific uses critical to national security; (2) prohibiting the commercial use of NMP for paint and coating removal exempting specific uses critical to national security; (3) requiring any paint and coating removal products containing NMP to be packaged for distribution in commerce in containers with a volume no less than 5 gallons; (4) requiring manufacturers (including importers), processors, and distributors of NMP for any use, except for retailers, to provide downstream notification of these prohibitions throughout the supply chain; and (5) requiring associated recordkeeping requirements. Under the second option, this includes: (1) Prohibiting the manufacture, processing, and distribution in commerce of paint and coating removal products containing more than 35 percent NMP by weight except for products used for critical national security uses; (2) Requiring product formulators to test gloves for the product formulations being processed and distributed in commerce for other than exempt critical national security uses to identify specialized gloves that provide protection for users and keep records relevant to these tests; (3) Requiring product formulators to label products with information for consumers about the risks presented by the products and how to reduce these risks during use, including identifying which specialized gloves provide protection against the specific formulation; (4) Requiring product formulators to provide information for commercial users about reducing risks when using the product, via product labels, SDS, and other methods of hazard communication, and to keep records; (5) Prohibiting the commercial use of paint and coating removal products that contain more than 35 percent by weight of NMP, except for critical national security uses; and (6) Requiring commercial users to establish worker protection programs for dermal and respiratory protection, including hazard communication and training, and to require their employees to wear specialized gloves, impervious clothing that covers most of the body, and a respirator with an assigned protection fact (APF) of 10 or compliance with an alternative air exposure limit.

This analysis, which is available in the docket, is discussed in Units VII.A. and XVII.A., and is briefly summarized here.

Costs of the proposed approach and relevant alternate approaches for each chemical are discussed in Units VII.A. for methylene chloride and XVII.A. for NMP. Costs for the whole proposal follow. Costs to users of methylene chloride or NMP for paint and coating removal under the first co-proposed approach for NMP are $2,517,000 to $50,801,000 annualized for 20 years at a discount rate of 3% and $3,114,000 to $50,916,000 at a discount rate of 7%. Costs to users of methylene chloride or NMP for paint and coating removal under the second co-proposed approach for NMP are $114,164,860 to $124,893,000 annualized for 20 years at a discount rate of 3% and $114,658,000 to $125,438,000 at a discount rate of 7%. As described in more detail in the Economic Analysis (Ref. 4) and supplement to the Economic Analysis (Ref. 127), there are estimated to be approximately 13,000 commercial firms and 2,002,000 consumers who use methylene chloride or NMP in paint and coating removal that would be affected; costs per firm and for each household are estimated to include costs of alternative formulations of paint removal products, additional time spent applying or removing paint with alternative methods or substitute products, and other cost factors. For product processors and formulators, the costs of paint and coating removal product reformulations for methylene chloride and NMP under the first co-proposed approach for NMP are estimated to be approximately $17,000 to $34,000 per year (annualized at 3% over 20 years) and $23,000 to $43,000 (annualized at 7% over 20 years). For product processors and formulators, the costs of paint and coating removal product reformulations for methylene

chloride and NMP under the second co-proposed approach for NMP are estimated to be approximately $25,140 to $41,140 per year (annualized at 3% over 20 years) and $34,160 to $55,160 (annualized at 7% over 20 years). Only 17 firms are estimated to be affected. For manufacturers, processors, and distributors of methylene chloride or NMP under the first co-proposed approach for NMP, the costs of downstream notification and recordkeeping on an annualized basis over 20 years are $140 and $160 using 3% and 7% discount rates respectively. For manufacturers, processors, and distributors of methylene chloride or NMP under the second co-proposed approach for NMP, the costs of downstream notification and recordkeeping on an annualized basis over 20 years are $140 and $160 using 3% and 7% discount rates respectively (the same as under the first co-proposed approach). Approximately 30 firms are estimated to be affected. Agency costs for enforcement for each chemical, under the first co-proposed approach for NMP, are estimated to be approximately $114,401 and $111,718 annualized over 20 years at 3% and 7%, respectively (Ref. 4). Total Agency costs for enforcement, for both chemicals together under the first co-proposed approach for NMP, are estimated to be approximately $228,802 and $223,436 annualized over 20 years at 3% and 7%. Agency costs for enforcement for each chemical, under the second co-proposed approach for NMP, are estimated to be approximately $114,401 and $111,718 annualized over 20 years at 3% and 7%, respectively for methylene chloride and $1,024,144 and $998,711 annualized over 20 years at 3% and 7% respectively for NMP (Ref. 127). Total Agency costs for enforcement, for both chemicals together under the second co-proposed approach for NMP, are estimated to be approximately $1,138,545 and $1,110,429 annualized over 20 years at 3% and 7%.

In summary, total costs of the proposed rule under the first co-proposed approach for NMP are estimated to be $2,763,000 to $51,070,000 annualized over 20 years at 3% and $3,361,000 to $51,163,000 annualized over 20 years at 7% (Ref. 4). Total costs of the proposed rule under the second co-proposed approach for NMP are estimated to be $114,196,000 to $124,893,000 annualized over 20 years at 3% and $114,658,000 to $125,438,000 annualized over 20 years at 7% (Ref. 127).

Although methylene chloride in paint and coating removal can cause a wide range of non-cancer adverse effects, cancer, and death and NMP can cause a variety of developmental non-cancer adverse effects, monetized benefits included only the subset of benefits associated with reducing cancer risks or deaths that occur at a known rate among users or bystanders. Methodological limitations prevent EPA from being able to include a quantification or monetary valuation estimate of the other non-cancer benefits at this time, and thus there is not a quantification or monetary valuation estimate for the overall total benefits. Based on the costs and benefits that EPA can estimate, the monetized benefits for the proposed approach range from approximately $14,354,000 to $14,558,000 on an annualized basis over 20 years at 3% and $13,791,000 to $13,919,000 at 7% (Ref. 4). EPA also considered non-monetized benefits that would result from the prevention of non-cancer adverse effects associated with methylene chloride or NMP in paint and coating removal, including nervous system effects, liver toxicity, kidney toxicity, and reproductive effects from exposure to methylene chloride in paint and coating removal; and developmental toxicity, fetal death, fetal body weight reductions, kidney toxicity, liver toxicity, immunotoxicity, and reproductive toxicity from exposure to NMP in paint and coating removal (Refs. 2 and 3).

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 risk assessments for methylene chloride and NMP, EPA identified risks to children from exposure to methylene chloride and NMP used in paint and coating removal. EPA has also identified women of childbearing age as a potentially exposed or susceptible subpopulation who may be at greater risk than the general population of adverse health effects from exposure to NMP. EPA has identified this subpopulation as relevant to EPA's risk assessment for NMP due to NMP's effects on the developing fetus. Therefore, the risk management standard under Section 6 of TSCA, with respect to NMP, is to reduce the risk posed by NMP so that it no longer presents an unreasonable risk (either to users in the general population or to users who are women of childbearing age). 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 paint removal occurs. These risks include neurological effects such as cognitive impairment, sensory impairment, dizziness, incapacitation, and loss of consciousness (leading to risks of falls, concussion, and other injuries). The supporting non-cancer risk analysis of children as bystanders conducted in the TSCA Work Plan Risk Assessment for methylene chloride meets the 1995 EPA Policy on Evaluating Health Risks to Children. 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 Units VI.C.1. and VI.D.

In the TSCA Work Plan Risk Assessment for NMP, EPA identified developmental toxicity as the most sensitive endpoint for NMP exposure (*i.e.*, fetal death and decreased fetal birth weight) for the most sensitive human life stages (*i.e.*, women of childbearing age between the ages of 16 and 49 years and the fetus) (Ref. 3). The supporting non-cancer risk analysis of children and women of childbearing age conducted in the TSCA Work Plan Risk Assessment for NMP meets the 1995 EPA Policy on Evaluating Health Risks to Children.

II. Overview of Methylene Chloride and Uses Subject to This Proposed Rule

A. What chemical is included in the proposed rule?

This proposed rule would apply to methylene chloride (CASRN 75–09–2) when used in paint and coating removal except for several specified uses, including as part of commercial furniture refinishing and uses critical to national security.

B. What are the uses of methylene chloride?

Methylene chloride is a solvent used in a variety of industrial, commercial and consumer use applications, including (Ref. 2):

- Paint remover
- Adhesive
- Aerosol propellant
- Metal cleaner and degreaser
- Chemical processor for polycarbonate resins and cellulose triacetate (photographic film)
- Feedstock in the production of the refrigerant hydrofluorocarbon-32

Minor uses of methylene chloride include (Ref. 2):

- Extraction solvent for oils, waxes, fats, spices, and hops
- Tablet coating for pharmaceuticals

According to the 2012 Chemical Data Reporting (CDR) information, approximately 260 million pounds of

methylene chloride were produced or imported into the United States that year, with between 80% to 96% produced in the United States (Ref. 2). In terms of environmental releases, 277 facilities reported a total of 3.2 million pounds of releases of methylene chloride to the 2014 Toxics Release Inventory (Ref. 6).

Individuals, including workers, consumers, and the general population, 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).

The use assessed by EPA that is the subject of this proposal, methylene chloride in paint and coating removal, represents about 25% of total use of methylene chloride. This is a decrease from the 1980s, when approximately 50% of the total methylene chloride market was composed of paint removal use (Ref. 2). Paint and coating removal is the application of a chemical or use of another method to remove, loosen, or deteriorate any paint, varnish, lacquer, graffiti, surface protectants, or other coatings from a substrate. Substrates can include objects, vehicles, architectural features, or structures. This use is discussed in detail in Unit VI.B.

Although the TSCA Work Plan Chemical risk assessment for methylene chloride focused on the chemical's use in paint and coating removal, 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). The Agency is proceeding with this proposed rule addressing methylene chloride in paint and coating removal in accordance with TSCA section 26(l) and asks for comment on its decision to pursue risk management for specific conditions of use of methylene chloride while preparing to conduct a risk evaluation of remaining conditions of use of methylene chloride under TSCA section 6(b).

C. What are the potential health effects of methylene chloride?

Methylene chloride is a likely human carcinogen, a neurotoxicant, and acutely lethal. Acute and chronic exposures to methylene chloride are primarily associated with neurological and hepatic effects. 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. Carbon monoxide is one of the metabolic byproducts of methylene chloride, and reversibly binds to hemoglobin as carboxyhemoglobin. Part of the effect of methylene chloride on the central nervous system comes from the accumulation of carboxyhemoglobin in the blood, which can lead to sensory impairment, dizziness, incapacitation, loss of consciousness, heart failure, and death (Ref. 2). Hemoglobin in the fetus has a higher affinity for carbon monoxide than does adult hemoglobin. Thus, 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).

During acute exposures, methylene chloride primarily affects the brain, though effects on lung, liver, and kidney have also been reported in humans following acute exposures. Acute exposures to methylene chloride can be fatal; acute lethality in humans following inhalation exposure is related to central nervous system depressant effects. Effects include loss of consciousness and respiratory depression, resulting in irreversible coma, hypoxia, and eventual death. Acute non-lethal effects in humans are similarly related to the central nervous system and can include incapacitation, loss of consciousness, heart failure, and coma. Other acute non-lethal effects in humans include neurobehavioral deficits measured in psychomotor tasks, such as tests of hand-eye coordination, visual evoked response changes, and auditory vigilance (Ref. 2).

Since 1976, more than 40 deaths have been attributed to methylene chloride when used in paint and coating removal (Ref. 7); in some cases, two or more individuals have died during a single job when air concentrations quickly reached lethal levels, potentially in less than 10 minutes. In other situations, individuals have died when entering rooms or facilities in which paint or coating removal was previously conducted and air concentrations of methylene chloride remained dangerously high (Ref. 7).

Chronic exposures to methylene chloride are associated with cancer and non-cancer hepatic effects. Methylene chloride is likely to be carcinogenic in humans with a mutagenic mode of action. This mutagenic mode of action is supported by the weight of evidence from multiple *in vivo* and *in vitro* studies. There is a risk for some specific cancers, including brain cancer, liver cancer, non-Hodgkin lymphoma, and multiple myeloma. Additionally, several cancer bioassays in animals have identified the liver and lung as the most sensitive target organs for tumor development induced by methylene chloride (Ref. 2).

Non-cancer effects of chronic exposure to methylene chloride are primarily hepatic; the liver is the most sensitive target for non-cancer toxicity. Lifetime exposure in rats dosed with different concentrations is associated with hepatic vacuolation, degeneration, or liver necrosis. Other non-cancer effects of chronic methylene chloride exposure include renal tubular degeneration in rats and mice, testicular atrophy in mice, and ovarian atrophy in mice (Ref. 2).

D. What are the environmental impacts of methylene chloride?

Pursuant to TSCA section 6(c), EPA in this unit describes the effects of methylene chloride on the environment and the magnitude of the exposure of the environment to methylene chloride. The proposed unreasonable risk determination, however, is based solely on risks to human health since these risks are the most serious consequence of use of methylene chloride and are sufficient to support this proposed action.

1. *Environmental effects and impacts.* Methylene chloride is mainly released to the environment in air, and to a lesser extent in water and soil, due to industrial and consumer uses as a solvent, in aerosol products, and in paint and coating removal. Many chemical waste sites contain methylene chloride and these might act as additional sources of environmental contamination through spills, leaks, or evaporation. Because methylene chloride evaporates readily, most releases enter the air. In the air, it is broken down by sunlight and by reaction with other chemicals present in the air. In the air, methylene chloride's half-life is between 53 to 127 days (Ref. 8).

Ecotoxicity studies for methylene chloride have been conducted in fish, aquatic invertebrates, and aquatic plants. Based on available data, in the methylene chloride risk assessment EPA concluded that methylene chloride has low aquatic toxicity for fish, aquatic invertebrates, and aquatic plants (Ref. 2).

While methylene chloride is moderately persistent, given its low bioaccumulation and low hazard for aquatic toxicity, the magnitude of potential environmental impacts on ecological receptors is judged to be low for the environmental releases associated with methylene chloride in paint removal. This should not be misinterpreted to mean that methylene chloride does not pose environmental

concerns. Through other regulations, EPA is addressing methylene chloride releases to air and contamination of groundwater, drinking water, and contaminated soils. While the primary concern with this contamination has been human health, there is potential for methylene chloride exposures to ecological receptors in some cases (Ref. 2). More information about regulations to reduce environmental impacts of methylene chloride is in Unit III.

2. *What is the global warming potential of methylene chloride?* Global warming potential (GWP) measures the potency of a greenhouse gas over a specific period of time, relative to carbon dioxide, which has a high GWP of 1 regardless of the time period used. Due to its volatility, methylene chloride enters the atmosphere where it reacts slowly enough to undergo atmospheric transport and act as a greenhouse gas. Methylene chloride has been reported to the Intergovernmental Panel on Climate Change as a global warming potential chemical with a value of 8.7 GWP, or approximately 8.7 times more heat absorptive than carbon dioxide (Ref. 2).

3. *What is the ozone depletion potential of methylene chloride?* Methylene chloride is not an ozone-depleting substance and is listed as acceptable under the Significant New Alternatives Policy program for metal and electronic cleaning (degreasing), aerosol solvents, foam blowing agents, and other uses (59 FR 13044, March 18, 1994).

4. *Is methylene chloride a volatile organic compound (VOC)?* Though volatile, methylene chloride is exempt from being classified as a VOC as defined at 40 CFR 51.100(c). A VOC is any compound of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions. Because methylene chloride has negligible atmospheric photochemical reactions, it is not classified as a VOC (40 CFR 51.100(s)(1)).

5. *Does methylene chloride persist in the environment and bioaccumulate?* Due to its volatility, methylene chloride does not significantly partition to solid phases. Therefore, releases of methylene chloride to the environment are likely to evaporate to the atmosphere, or if released to soil, migrate to groundwater. Methylene chloride has been shown to biodegrade over a range of rates and environmental conditions. Measured bioconcentration factors for methylene chloride suggest its bioconcentration potential is low (Ref. 2).

III. Regulatory Actions Pertaining to Methylene Chloride

This section summarizes current state, federal, and international regulations and restrictions on methylene chloride, with a focus on its use in paint and coating removal. None of these actions imposes requirements to the extent necessary so that methylene chloride does not present the unreasonable risk described in this proposed rule.

A. Federal Actions Pertaining to Methylene Chloride

Methylene chloride has been the subject of U.S. federal regulations by EPA, the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA). EPA and other agencies have taken actions (see below) to address the serious human health risks from specific sources and routes of methylene chloride exposure, but none of these actions sufficiently mitigate the risks that EPA is proposing to address under TSCA section 6(a).

EPA has issued several final rules and notices pertaining to methylene chloride under EPA's various authorities.

- *Clean Air Act:* Methylene chloride is designated as a hazardous air pollutant (HAP) under the Clean Air Act (42 U.S.C. 7412(b)(1))CAA). EPA issued a final rule in January 2008 that promulgated National Emission Standards for Hazardous Air Pollutants (NESHAP) for area sources engaged in paint stripping, surface coating of motor vehicles and mobile equipment, and miscellaneous surface coating operations. In this NESHAP, EPA listed "Paint Stripping," "Plastic Parts and Products (Surface Coating)," and "Autobody Refinishing Paint Shops" as area sources of HAPs that contribute to the risk to public health in urban areas. The final rule included emissions standards that reflect the generally available control technology or management practices in each of these area source categories, and applies to paint stripping operations using methylene chloride (73 FR 1738, January 9, 2008). In 2014, EPA issued a final rule for Flexible Polyurethane Foam Manufacturing that banned the use of methylene chloride as a foam-blowing agent (79 FR 48073, August 15, 2014). In 2015, EPA issued a final rule for Aerospace Manufacturing and Rework Facilities, which updated a NESHAP from 1995 by adding limitations to reduce organic and inorganic emissions HAPs, including methylene chloride, from specialty coating application operations; and removed exemptions for periods of startup, shutdown and malfunction so that affected units would be subject to the emission standards at all times (80 FR 76152, December 7, 2015).
- *Solid Waste Disposal Act:* Methylene chloride is listed as a hazardous waste under the Resource Conservation and Recovery Act (RCRA) (Code U080) (Ref. 2).
- *Emergency Planning and Community Right-to-Know Act:* Methylene chloride is listed on the Toxics Release Inventory (TRI) pursuant to section 313 of the Emergency Planning and Community Right-to-Know Act (Ref. 2).
- *Safe Drinking Water Act:* The Safe Drinking Water Act (SDWA) requires EPA to determine the level of contaminants in drinking water at which no adverse health effects are likely to occur. EPA has set a maximum contaminant level goal of zero and an enforceable maximum contaminant level for methylene chloride at 0.005 mg/L or 5 parts per billion (57 FR 31776, July 17, 1992).

Regulation of methylene chloride by other agencies includes:

- In 1987, CPSC issued a statement of policy explaining that CPSC considers household products containing methylene chloride to be hazardous substances and providing guidance on labeling of such products. Labels of products containing methylene chloride are required to state that inhalation of methylene chloride vapor has caused cancer in certain laboratory animals, and the labels must specify precautions to be taken during use by consumers (52 FR 34698, September 14, 1987). In 2016, CPSC was petitioned by the Halogenated Solvents Industry Alliance to amend the statement of interpretation and enforcement policy regarding labeling of household products containing methylene chloride; CPSC published that petition for public comments (81 FR 60298, September 1, 2016).
- In 1989, FDA banned methylene chloride as an ingredient in all cosmetic products because of its animal carcinogenicity and likely hazard to human health (21 CFR 700.19). Before 1989, methylene chloride had been used in aerosol cosmetic products, such as hairspray (54 FR 27328 (June 29, 1989)).
- OSHA has taken steps to reduce exposure to methylene chloride in occupational settings. In 1997, OSHA lowered the permissible exposure limit (PEL) for methylene chloride from an eight-hour time-weighted average (TWA) of 500 parts per million (ppm) to an eight-hour TWA of 25 ppm and a 15-minute short-term exposure limit

(STEL) of 125 ppm. This standard also includes provisions for initial exposure monitoring, engineering controls, work practice controls, medical monitoring, employee training, personal protective equipment, and recordkeeping (29 CFR 1910.1052).

• The Department of Housing and Urban Development (HUD) has prohibited methylene chloride and other hazardous chemicals for use in removing lead-based paint by HUD contractors and anyone receiving grants or engaging in the HOME Program, which was created by the National Affordable Housing Act of 1990 (Ref. 9).

• The National Institute for Occupational Safety and Health (NIOSH) considers methylene chloride a potential occupational carcinogen and currently recommends an exposure limit of the "lowest feasible concentration" of methylene chloride (Ref. 10). NIOSH and OSHA in 2013 issued a hazard alert for bathtub refinishing with methylene chloride, warning that methylene-chloride based products are extremely dangerous and that the best way to prevent exposure is to use products that do not contain methylene chloride (Ref. 11).

B. State Actions Pertaining to Methylene Chloride

Several states have taken actions to reduce or make the public aware of risks from methylene chloride. For example, since 2011 methylene chloride has been prohibited from use in graffiti removal in the District of Columbia and 11 states (California, Connecticut, Delaware, Illinois, Indiana, Maine, Maryland, Michigan, New Jersey, New York, and Rhode Island) (Ref.12). Iowa, Indiana, South Carolina, and other states have established detection monitoring regulations for methylene chloride (567 IAC 113.15, 329 IAC 10–21–15, S.C. Code Regs. 16–107.198, Appx. III). In Alaska, methylene chloride is listed as a carcinogenic hazardous substance (18 AAC 75.341). Methylene chloride is listed on California's Safer Consumer Products regulations candidate list of chemicals that exhibit a hazard trait and are on an authoritative list of either chemical hazard traits or potential exposure concerns (Ref. 13). Methylene chloride is also listed on California's Proposition 65 list of chemicals known to cause cancer, birth defects, or reproductive harm (Ref. 13). In Minnesota, it has been found that methylene chloride may negatively affect the nervous system and cause cancer (Minn. R. 4717.8200, Minn. R. 4717.8100). The state of Washington has listed methylene chloride as a human carcinogen and a chemical of high concern to children (WAC 296–62–07473, WAC 173–334–130). In Pennsylvania, it is listed as an environmental and special hazardous substance (34 Pa. Code XIII, Ch. 323.2(a)).

All states have set PELs identical to the OSHA 25 ppm eight-hour time weighted average (TWA) PEL (79 FR 61384, October 10, 2014), however it is worth noting that California, Oregon, and Washington, which have a state PEL identical to the OSHA PEL, have slightly different requirements than OSHA for medical evaluation, fit testing for respirators, and implementation timelines related to methylene chloride (8 CCR 5502, OAR 437–002–1052, WAC 296–62–07470). The OSHA PEL is considerably higher than the levels at which EPA identified risks of concern for methylene chloride in paint and coating removal and would not be protective for the unreasonable risks identified.

C. International Actions Pertaining to Methylene Chloride

Methylene chloride is also regulated internationally and industrial and commercial sectors in certain other countries have moved to alternatives.

In Canada, the Canadian Minister of the Environment published in 2003 a Notice under Part 4 of the "Canadian Environmental Protection Act, 1999" requiring the preparation and implementation of pollution prevention plans for methylene chloride (Ref. 14). This Notice targets persons involved in the use of methylene chloride for the following activities: Aircraft paint stripping; flexible polyurethane foam blowing; pharmaceuticals and chemical intermediates manufacturing and tablet coating; industrial cleaning; and adhesive formulations. Also in 2003, Environment Canada published a Code of Practice for the reduction of methylene chloride emissions from the use of paint and coating removal products in commercial furniture refinishing and other stripping applications (Ref. 14). This Code of Practice was developed by a multi-stakeholder technical working committee, which consisted of industry representatives (*i.e.,* furniture refinishers, auto body shops, formulators of paint and coating removal products, solvent recovery firms), government personnel, and environmental non-governmental organizations.

In the European Union, the European Commission amended its Registration, Evaluation, Authorization, and Restriction of Chemical substances in 2010 to incorporate restrictions for the use of methylene chloride in paint removers. Methylene chloride is banned in the European Union from: (1) Placement on the market in a new product for consumers/professionals after December 2010; (2) placement on the market in any product for consumers/professionals after December 2011; and (3) use by professionals after June 2012. Member States could allow the use of methylene chloride if they have a program to license and train professionals in the following: Awareness; evaluation and management of risks; use of adequate ventilation; and use of appropriate personal protective equipment (Ref. 15). The United Kingdom has issued a derogation to allow professional use of methylene chloride (Ref. 16). In addition, industrial installations using methylene chloride must have effective ventilation, minimize evaporation from tanks, and have measures for safe handling of methylene chloride in tanks, adequate personal protective equipment, and adequate information and training for operators. Paint and coating removers containing methylene chloride in a concentration equal to or greater than 0.1% by weight must include a label: "Restricted to industrial use and to professionals approved in certain EU Member States—verify where use is allowed" (Ref. 15).

IV. Methylene Chloride Risk Assessment and Outreach

In 2013, EPA identified methylene chloride in paint and coating removal as a priority for risk assessment under the TSCA Work Plan. This unit describes the development of the methylene chloride risk assessment and supporting analysis and expert input on the uses that are the subject of this proposed rule. A more detailed discussion of the risks associated with methylene chloride in paint and coating removal can be found in Unit VI.C.1.

A. TSCA Work Plan for Chemical Assessments

In 2012, EPA released the "TSCA Work Plan Chemicals: Methods Document" in which EPA described the process the Agency intended to use to identify potential candidate chemicals for near-term review and assessment under TSCA (Ref. 17). EPA also 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 for further assessment under TSCA 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. 17). Using the TSCA Work Plan chemical prioritization criteria, methylene chloride ranked high for health hazards and exposure potential and was included on the initial list of TSCA Work Plan chemicals for assessment. Methylene chloride appeared in the 2012 TSCA Work Plan for Chemical Assessments and in the 2014 update of the TSCA Work Plan for Chemical Assessments.

B. Methylene Chloride Risk Assessment

EPA finalized a TSCA Work Plan Chemical Risk Assessment for methylene chloride (methylene chloride risk assessment) in August 2014, following the 2013 peer review of the 2012 draft methylene chloride risk assessment. All documents from the 2013 peer review of the draft methylene chloride risk assessment are available in EPA Docket Number EPA–HQ–OPPT–2012–0725. The completed risk assessment is included in that docket.

The methylene chloride risk assessment evaluated health risks to consumers, workers, and bystanders from inhalation exposures to methylene chloride when used in paint and coating removal (Ref. 2). EPA assumes workers and consumers would be adults of both sexes 16 and older, including pregnant women. EPA assumes bystanders in commercial or occupational settings would be worker non-users or adjacent workers, while bystanders in residential settings would be individuals of any age group (*e.g.*, children, adults, the elderly) nearby during product application. During scoping and problem formulation for the risk assessment, EPA focused on paint and coating removal because it was expected to involve frequent or routine use of methylene chloride in high concentrations and/or have high potential for human exposure (Ref. 2). However, this does not mean that EPA found that other uses not included in the methylene chloride risk assessment present low risk.

The methylene chloride risk assessment characterized human health effects associated with paint removal with methylene chloride. Based on the physical-chemical properties of methylene chloride and the paint and coating removal use scenarios described in the assessment, EPA assessed inhalation as the predominant route of exposure to methylene chloride during paint removal. Though highly volatile compounds such as methylene chloride may also be absorbed through the skin, EPA does not have the data nor the methodology to assess methylene chloride dermal exposure during paint removal. As a result, the assessment may underestimate total exposures to methylene chloride during paint removal due to this inability to evaluate dermal exposure (Ref. 2).

The methylene chloride risk assessment identified risks of concern following acute (short-term) and chronic exposures for workers and consumers conducting paint removal with methylene chloride, as well as for exposed bystanders, including residents of homes in which paint removal is conducted and worker non-users adjacent to other workers conducting paint removal. The acute risks identified include death; neurological impacts such as coma, incapacitation, loss of consciousness, and dizziness; and liver effects. The chronic risks identified include brain, liver, lung, and hematopoietic cancers and liver damage (Ref. 2).

Margins of exposure (MOEs) were used in this assessment to estimate non-cancer risks for acute exposures (for consumers and workers) and chronic exposures (for workers). The MOE is the point of departure (an approximation of the no-observed adverse effect level (NOAEL)) for a specific health endpoint divided by the exposure concentration for the specific scenario of concern. The benchmark MOE accounts for the total uncertainty in a point of departure, including: (1) The variation in sensitivity among the members of the human population (*i.e.*, interhuman or intraspecies variability); (2) the uncertainty in extrapolating animal data to humans (*i.e.*, interspecies variability); (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (*i.e.*, extrapolating from subchronic to chronic exposure); and (4) the uncertainty in extrapolating from a lowest observed adverse effect level rather than from a NOAEL (Ref. 18). MOEs provide a non-cancer risk profile by presenting a range of estimates for different non-cancer health effects for different exposure scenarios, and are a widely recognized method for evaluating a range of potential non-cancer health risks from exposure to a chemical. For non-cancer effects EPA estimated exposures that are significantly larger than the point of departure, thus resulting in MOEs that are significantly less than the benchmark MOE (Ref. 2). For methylene chloride, EPA identified acute or chronic non-cancer risks of concern if the MOE estimates were less than the benchmark MOE of 10 (Ref. 2). The health endpoint used for the benchmark MOE for acute exposure to methylene chloride is central nervous system effects, such as dizziness or incapacitation; the health endpoint used for the benchmark MOE for chronic exposure to methylene chloride is liver toxicity. These are the most sensitive adverse health effects from exposure to methylene chloride.

Methylene chloride is a likely human carcinogen; cancer risks determine the estimated incremental increased probability of an individual in an exposed population developing cancer over a lifetime following exposure to the chemical under specified use scenarios. Standard cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk of 1 in 1,000,000 ranging to 1 in 10,000 (*i.e.*, 1×10^{-6} to 1×10^{-4}). For cancer effects, EPA estimated that workers and occupational bystanders exposed to methylene chloride in paint and coating removal have an increase in cancer risk that ranged from 10 times to almost 1,000 times greater than a cancer benchmark of 1 in 1,000,000, depending on the specific way paint or coating removal was conducted with methylene chloride (Ref. 2).

The levels of acute and chronic exposures estimated to present low risk for non-cancer effects also result in low risk for cancer.

The assessment identified the following risks from acute exposures to methylene chloride when used in paint and coating removal (Ref. 2):

- Acute risks of incapacitation, coma, or death in workers exposed to methylene chloride in paint removers when no respiratory protection is used. In some industries with high exposure scenarios, these risks of incapacitation or death are present even when respiratory protection is used.
- Acute risks of neurological effects for most workers. These risks are present even when respiratory protection is used.
- Acute risks of neurological effects for consumer users of methylene chloride as a paint remover.
- Acute risks of neurological effects for bystanders (including children and worker non-users) in the location in which paint removers containing methylene are used by either residents or commercial users. 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.

Based on the risk assessment scenarios, EPA identified the following non-cancer risks from chronic exposures to methylene chloride in paint and coating removal (Ref. 2):

• Non-cancer risks for liver effects for most workers (including worker non-users, or adjacent workers) in industries conducting paint removal.

• Non-cancer risks occur for most workers (including adjacent workers) when exposed to paint removers containing methylene chloride even when wearing respiratory protection in the exposure scenarios that predominantly demonstrate variations in exposure conditions (*i.e.*, exposure frequency and working years) in facilities reporting central tendency or high-end air levels of methylene chloride. Among all the occupational scenarios, the greatest risk of concern is for workers engaging in long-term use of or exposure to methylene chloride as a paint remover (*i.e.*, 250 days/year for 40 years) with no respiratory protection.

The assessment identified the following cancer risks from chronic exposures to methylene chloride when used in paint removal (Ref. 2):

• Cancer risks for workers (including adjacent workers) exposed to methylene chloride as a paint remover in various industries. These cancer risks include liver cancer, lung cancer, brain cancer, non-Hodgkin lymphoma, and multiple myeloma.

• The greatest cancer risks occur for workers exposed to methylene chloride when used as a paint remover who have no respiratory protection and are exposed for an extended period.

C. Supplemental Analysis Consistent With the Methylene Chloride Risk Assessment

Following the methylene chloride risk assessment, EPA conducted supplemental analyses to inform risk management. These analyses are consistent with the scope of the methylene chloride risk assessment and were based on the peer-reviewed methodology used in the methylene chloride risk assessment. They included identification of baseline and central tendency exposure scenarios, impacts of reduced methylene chloride content in paint removers, addition of local exhaust ventilation (LEV), use of personal protective equipment (PPE), additional consumer exposure scenarios, and methods of monitoring to determine workplace exposures. The results of EPA's analyses are available in this rulemaking docket (Refs. 19, 20, and 21). Prior to promulgation of the final rule, EPA will peer review the "Respirator and Glove Specifications for Workers Exposed to Methylene Chloride in Paint and Coating Removal," "Supplemental Consumer Exposure and Risk Estimation Technical Report for Methylene Chloride in Paint and Coating Removal", and "Recommendation for an Existing Chemical Exposure Concentration Limit (ECEL) for Occupational Use of Methylene Chloride and Workplace Air Monitoring Methods for Methylene Chloride" (Refs. 19, 20, 21).

D. Outreach

In addition to the consultations described in Unit XXIII.C., EPA engaged in discussions with experts on and users of paint removers (Ref. 22). The purpose of these discussions was to hear from users, academics, manufacturers, and members of the public health community about practices related to paint removal in various industries and by consumers; the importance of methylene chloride and NMP in paint removal; frequently-used substitute chemicals or alternative paint removal methods; engineering control measures and personal protective equipment currently in use or feasibly adoptable for paint removal; and other risk reduction approaches that may have already been adopted or considered for commercial or consumer paint removal. Informed by these discussions and by industry and other governmental research, EPA has concluded that alternatives to methylene chloride and NMP are available for nearly all paint removal uses.

EPA is continuing to gather information, to the extent practicable, regarding the availability of alternatives to methylene chloride for furniture refinishing. EPA plans to continue to engage stakeholders to identify what methods may be available as alternatives to methylene chloride. After collecting the information, EPA expects to address this use of methylene chloride so that the substance no longer poses an unreasonable risk and intends to issue separately a proposal in the future. Also see Unit XI.

V. Regulatory Approach for Methylene Chloride in Paint and Coating Removal

A. TSCA Section 6(a) Unreasonable Risk Analysis

Under TSCA section 6(a), if the Administrator 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 to the Agency's risk evaluation, 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.

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

• Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances (§ 6(a)(1)).

• Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances for particular uses or for uses in excess of a specified concentration (§ 6(a)(2)).

• Require minimum warning labels and instructions (§ 6(a)(3)).

• Require recordkeeping or testing (§ 6(a)(4)).

• Prohibit or regulate any manner or method of commercial use (§ 6(a)(5)).

• Prohibit or otherwise regulate any manner or method of disposal (§ 6(a)(6)).

• Direct manufacturers and processors to give notice of the determination to distributors and the public and replace or repurchase substances (§ 6(a)(7)).

EPA analyzed a wide range of regulatory options under section 6(a) for each use in order to select the proposed regulatory approach (Refs. 23 and 24). For each use, EPA considered whether a regulatory option (or combination of options) would address the identified unreasonable risks so that the chemical substance no longer presents such risks. EPA found that an option that could reduce exposures such that they would achieve the benchmark MOE for the most sensitive non-cancer endpoint would address the risk of concern for other non-cancer endpoints. Additionally, EPA's assessments for methylene chloride in paint and coating removal found that exposures that meet the benchmark MOE for the most sensitive non-cancer endpoint would also not result in cancer risks of concern.

After the technical analysis, which represents EPA's assessment of the potential for the regulatory options to achieve risk benchmarks based on analysis of exposure scenarios, EPA then considered how reliably the regulatory options would actually reach these benchmarks. For the purposes of this proposal, EPA found that an option addressed the risk so that it was no longer unreasonable if the option could achieve the benchmark MOE or cancer benchmark for the most sensitive endpoint. In considering whether a regulatory option would ensure the chemical no longer presents the unreasonable risk, the Agency considered whether the option could be realistically implemented or whether there were practical limitations on how well the option would mitigate the risks

in relation to the benchmarks, as well as whether the option's protectiveness was influenced by concerns related to environmental justice, children's health, and potentially exposed or susceptible subpopulations identified as relevant to the Agency's risk evaluation.

B. TSCA Section 6(c)(2) Considerations

TSCA section 6(c)(2) requires EPA to consider and publish a statement based on reasonably available information with respect to the:

- Health effects of the chemical substance or mixture (in this case, methylene chloride) and the magnitude of human exposure to methylene chloride;
- Environmental effects of methylene chloride and the magnitude of exposure of the environment to methylene chloride;
- Benefits of methylene chloride for various uses;
- Reasonably ascertainable economic consequences of the rule, including: The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; the costs and benefits of the proposed and final rule and of the one or more primary alternatives that EPA considered; and the cost-effectiveness of the proposed rule and of the one or more primary alternatives that EPA considered.

In addition, in selecting among prohibitions and other restrictions available under TSCA section 6(a), EPA must factor in, to the extent practicable, these considerations. Further, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, EPA must also consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

EPA's analysis of the health effects and magnitude of exposure to methylene chloride can be found in Units IV.B., VI.C.1. and VI.D., which discuss the methylene chloride risk assessment and EPA's regulatory assessment of methylene chloride in paint and coating removal. A discussion of the environmental effects of methylene chloride is in Unit II.D.

With respect to the costs and benefits of this proposal and the alternatives EPA considered, as well as the impacts on small businesses, the full analysis is presented in the Economic Analysis (Ref. 4). To the extent information was reasonably available, EPA considered the benefits realized from risk reductions (including monetized benefits, non-monetized quantified benefits, and qualitative benefits), offsets to benefits from countervailing risks (*e.g.*, risks from chemical substitutions and alternative practices), the relative risk for environmental justice populations and children and other potentially exposed or susceptible subpopulations (as compared to the general population), the cost of regulatory requirements for the various options, and the cost effectiveness of the proposed action and the one or more primary alternate regulatory options. A discussion of the benefits EPA considered can be found in Units VI.D. and VII.B. as well as in the Economic Analysis (Ref. 4).

EPA considered the estimated costs to regulated entities as well as the cost to administer and enforce the options. For example, an option that includes use of a respirator would include inspections to evaluate compliance with all elements of a respiratory protection program (Ref. 25). In understanding the burden, EPA took into account reasonably available information about the functionality and performance efficacy of the regulatory options and the ability to implement the use of chemical substitutes or other alternatives. Reasonably available information included the existence of other Federal, state, or international regulatory requirements associated with each of the regulatory options as well as the commercial history for the options. A discussion of the costs EPA considered and a discussion of the cost-effectiveness of the proposal and the primary alternate regulatory options that EPA considered is in Units VI.F. and VII.A. In addition, a discussion of the impacts on small businesses is in Unit XXIII. and in the Initial Regulatory Flexibility Analysis and Report from the Small Business Advocacy Review Panel (Refs. 26 and 27).

With respect to the anticipated effects of this proposal 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. In addition, EPA considered the employment impacts of this proposal, as discussed in section 9.2 of the Economic Analysis (Ref. 4). EPA found that the direction of change in employment is uncertain, but EPA expects the short term and longer-term employment effects to be small.

The benefits of methylene chloride in paint and coating removal are discussed in Unit VI.B., along with the availability of alternatives. The dates that the proposed restrictions would take effect are discussed in Unit X. The availability of alternatives to methylene chloride in paint and coating removal on those dates is discussed in Unit VI.E.

Finally, with respect to this proposal's effect on technological innovation, EPA expects this action to spur innovation, not hinder it. An impending prohibition on this use of methylene chloride is likely to increase demand for alternatives, which EPA expects would result in the development of new alternatives. See also section 9.3 in the Economic Analysis (Ref. 4).

C. Regulatory Options Receiving Limited Evaluation

EPA analyzed a wide range of regulatory options under TSCA section 6(a). There are a range of regulatory options under TSCA; only those pertaining to these risks were evaluated in detail. An overview of the regulatory options not evaluated in detail follows.

First, EPA reasoned that the TSCA section 6(a)(1) regulatory option to prohibit the manufacture, processing or distribution in commerce of methylene chloride or limit the amount of methylene chloride which may be manufactured, processed or distributed in commerce is not germane because EPA is not proposing to ban or limit the manufacture, processing or distribution in commerce of methylene chloride for uses other than paint and coating removal.

In addition, EPA determined that the TSCA section 6(a)(6) regulatory option to prohibit or otherwise regulate any manner or method of disposal of the chemical is not applicable since EPA did not assess risks associated with methylene chloride disposal.

Another option EPA evaluated would require warning labels and instructions on paint and coating removal products containing methylene chloride, pursuant to TSCA section 6(a)(3) (Ref. 28). However, EPA reasoned that warning labels and instructions alone could not significantly mitigate the unreasonable risks presented by methylene chloride in paint and coating removal. EPA based its reasoning on an analysis of 48 relevant studies or meta-analyses, which found that consumers and professionals do not consistently pay attention to labels for hazardous substances; consumers, particularly those with lower literacy levels, often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers

and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies (Ref. 28). Additionally, workers being exposed may not be in a position to influence their employer's decisions about the type of paint removal method, or ensure that their employer provides appropriate PPE and an adequate respiratory protection program.

These conclusions are based on the weight-of-evidence analysis that EPA conducted of the available literature on the efficacy of labeling and warnings. This analysis indicates that a label's effectiveness at changing user behavior to comply with instructions and warnings depends on the attributes of the label and the user, and how those interact during multiple human information processing stages, including attention, comprehension, judgement, and action (Ref. 28).

Numerous studies have found that product labels and warnings are effective to some degree. However, the extent of the effectiveness has varied considerably across studies and some of the perceived effectiveness may not reflect real-world situations. This is because interactions among labels, users, the environment, and other factors greatly influence the degree of a label's effectiveness at changing user behavior (Ref. 28). In addition, while some studies have shown that certain components of labels and warnings tend to have some influence, it is less clear how effective labels and warnings are likely to be over time, as users become habituated to both the labels and the products.

Presenting information about methylene chloride on a product label would not adequately address the unreasonable risk presented by this use of this chemical because the nature of the information the user would need to read, understand, and act upon is extremely complex. When the precaution or information is simple or uncomplicated (*e.g.*, do not mix this cleaner with bleach or do not mix this cleaner with ammonia), it is more likely the user will successfully understand and follow the direction. In contrast, it would be challenging to most users to follow the complex product label instructions required to explain how to reduce exposures to the extremely low levels needed to minimize the risk from methylene chloride. Rather than a simple message, the label would need to explain a variety of inter-related factors, including but not limited to the use of local exhaust ventilation, respirators and assigned protection factor, and effects to bystanders. Currently, though some paint removers containing methylene chloride are labeled with information about its fatal effects if used without "adequate ventilation" (Ref. 28) and this information appears on the product safety data sheet, deaths continue to occur. It is unlikely that label language changes for this use of methylene chloride will result in widespread, consistent, and successful adoption of risk reduction measures by users.

Any use of labels to promote or regulate safe product use should be considered in the context of other potential risk reduction techniques. As highlighted by a 2014 expert report for the Consumer Product Safety Commission (CPSC), "safety and warnings literature consistently identify warnings as a less effective hazard-control measure than either designing out a hazard or guarding the consumer from a hazard. Warnings are less effective primarily because they do not prevent consumer exposure to the hazard. Instead, they rely on persuading consumers to alter their behavior in some way to avoid the hazard" (Ref. 29). Specifically regarding methylene chloride, effective personal protection resulting in risk reduction would require this altered behavior to include the appropriate use of a supplied-air respirator. Consumer users are particularly unlikely to acquire and correctly use such an apparatus in response to reading a warning label (Ref. 19). Any labeling aiming to reduce risks to consumer or commercial users of these products would need to sufficiently and clearly explain the importance of the supplied-air respirator, and would still leave the user with the problem of obtaining and properly using the supplied-air respirator, which is a particularly expensive piece of equipment (Ref. 4). Further, for the effective use of a respirator, particularly an air-supplied respirator, there would need to be fit-testing of the respirator and training in its use.

While EPA reasons that revised labeling will not address the unreasonable risk presented by methylene chloride in paint and coating removal, as a result of recommendations from the Small Business Advocacy Review (SBAR) Panel to solicit information from the public about the potential efficacy of labeling, following advice from the small entity representatives who participated in the SBAR process (Ref. 27), EPA requests public comments on enhanced labeling requirements for consumer paint and coating removal products containing methylene chloride as a method for reducing exposure to methylene chloride in these products. More information about the SBAR process, the Panel recommendations, and advice from small businesses related to this proposal are in Unit XXIII. and in the Panel Report (Ref. 27).

While this regulatory option alone would not adequately address the unreasonable risks, EPA recognizes that the TSCA section 6(a)(3) warnings and instruction requirement can be an important component of an approach that addresses unreasonable risks associated with a specific use prohibition. EPA has included a downstream notification requirement as part of the proposed rule to ensure that users would be made aware of the prohibition on the use of methylene chloride in paint and coating removal.

An additional regulatory option receiving limited evaluation was a training and certification program for commercial paint and coating removers, similar to the certification process required under EPA's Lead-Based Paint Renovation, Repair, and Painting Rule (73 FR 21692, April 22, 2008). This option was recommended by the small entity representatives as part of the SBAR process (Ref. 27). EPA considered this option as an approach to reducing risks from methylene chloride in paint and coating removal. However, unlike the process for training and certification of commercial workers required under the Lead-Based Paint Renovation, Repair, and Painting Rule, effective risk reduction from commercial use of methylene chloride for paint and coating removal would require additional regulation of distributors of these products. When considering this approach, given the Agency's experience with the training and certification program under the Lead-Based Paint Renovation, Repair, and Painting Rule, EPA viewed the costs and challenges involved in regulating distributors and ensuring that only trained and certified commercial users are able to access these paint and coating removal products as a significant limitation for this approach. EPA seeks public comment on the feasibility of such a program and its potential to reduce risks of exposure to methylene chloride for workers and bystanders so that those risks are no longer unreasonable.

VI. Regulatory Assessment of Methylene Chloride in Paint and Coating Removal

This unit describes the current use of methylene chloride in paint and coating removal, the unreasonable risks presented by this use, and how EPA identified which regulatory options reduce the risks so that they are no longer unreasonable.

A. Methylene Chloride Uses That Are the Focus of This Regulation

The methylene chloride uses that are the focus of this action are:

1. Any consumer use of methylene chloride for paint and coating removal, and

2. Any commercial use of methylene chloride for paint and coating removal except for commercial furniture refinishing, which EPA intends to address in a separate proposal, as described in Unit XI. While EPA proposes to determine that the identified risks from methylene chloride in commercial furniture refinishing are unreasonable, EPA plans to continue public engagement before proposing regulations for methylene chloride in this industry. Additional information is in Unit XI. This is one of the recommendations from SBAR Panel (Ref. 27),

EPA proposes to exempt specific paint and coating removal with methylene chloride from critical corrosion-sensitive components of military aviation and vessels, which the Department of Defense identified as critical for national security purposes. The details of this national security use are in Unit VIII.

B. Methylene Chloride in Paint and Coating Removal

Methylene chloride has been used for decades in paint and coating removal in products intended for both commercial and consumer 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 coatings sometimes referred to as high-performance or specialty coatings; surfaces may be the interior or exterior of buildings, structures, vehicles, aircraft, marine craft, furniture, or other objects. Paint and coating removal can be conducted in occupational or consumer settings. These surfaces, or substrates, include a variety of materials, such as wood, metals, plastics, concrete, and fiberglass. A variety of industries include paint and coating removal in their business activities, including professionals involved in renovations, bathtub refinishing, automotive refinishing, furniture refinishing, art restoration and conservation, aircraft repair, marine craft repair, and graffiti removers (Ref. 3).

Paint and coatings can be removed by chemical, mechanical, or thermal means. Chemical paint removers can include solvents, such as methylene chloride or NMP, caustic chemicals, or other categories of chemicals. Solvents aid in removing paints and coatings by permeating the top of the coating and dissolving the bond between the coating and the substrate (Ref. 30). 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, and spray applications (manually or through automation). Pouring, wiping and rolling are also possible application techniques and application can be manual or automated (Ref. 3).

In the construction trades, methylene chloride is used to remove paint and coatings from walls, trim, architectural features, patios or decks, ceilings, bathtubs, floors, etc. to prepare them for new coatings during residential and commercial building renovation. Methylene chloride is typically applied to the surface using a hand-held brush. It is then left on to soften the old coating (Ref. 4). Once curing has occurred, the old coating is scraped or brushed off and the surface is cleaned. 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). Consumers use methylene chloride in similar ways.

Commercially, methylene chloride is also used to remove paint and coatings from civilian aircraft, marine craft, cars, trucks, railcars, tankers, storage vessels, and other vehicles or their component parts to prepare for new coatings. Similar to the constructions trades, applications in the transportation industry tend to be brushed on and scraped off. More information on specific techniques for commercial paint removal and by consumers are in the methylene chloride risk assessment and supplemental materials (Refs. 2, 19, 20, 21, and 31).

Though many users are switching to substitutes and alternative methods, methylene chloride use persists because it is readily available and works quickly on nearly all coatings without damaging most substrates. In addition, some users may prefer methylene chloride because it is less flammable than some other solvents. However, it 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. Additionally, paint and coating removal products formulated with methylene chloride tend to contain high concentrations of co-solvents that are flammable, reducing one perceived advantage of methylene chloride products.

Chemical products for paint and coating removal are used across several industries as well as by consumers or hobbyists, and products intended for one type of use—such as aircraft renovation—have been used in other situations, such as bathtub refinishing (Refs. 11, 32, and 33). Products intended for one specific type of paint removal project can be easily used in a different setting. Additionally, consumers can easily use products intended for or marketed to professional users since paint removal products are readily available at big box and local hardware stores, as well as paint specialty stores.

EPA has 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. 34). Commercial uses of these products include automotive refinishing, furniture refinishing, art conservation and restoration, pleasure craft building and repair, aircraft paint removal, graffiti removal, bathtub refinishing, and renovations in residences or other buildings. Though the number of workers and consumers exposed to methylene chloride during paint and coating removal is uncertain, EPA has several estimates based on industry data and information gathered for rulemakings promulgated previously under other statutes, such as the Clean Air Act, intended to address different risks. As described in more detail in the Economic Analysis, EPA estimates that 32,600 workers annually are exposed to methylene chloride during paint and coating removal activities (Ref. 4). Of them, 15,000 are estimated to be exposed during furniture refinishing; 17,600 are estimated to be exposed during other commercial paint and coating removal processes (Ref. 4).

Consumer use of methylene chloride in paint and coating removal is similar to commercial use but is carried out by do-it-yourself (DIY) consumers and occurs in consumer settings, such as homes, workshops, basements, garages,

and outdoors. Paint and coating removal products containing methylene chloride are the same as those used in many commercial settings, and the process consumers use is similar to commercial methods of brushing or spraying on the paint and coating removal product, allowing time to pass for the product to penetrate the coating, and then scraping the loosened coating from the surface. Manufacturers and retailers of paint and coating removal products containing methylene chloride frequently sell them to consumers in small containers with marketing language or labeling that state they are easy to use and work on a variety of paints, coatings, and surfaces (Ref. 35). Products intended for consumers containing methylene chloride must meet minimum labeling requirements prescribed by CPSC that the product contains methylene chloride and that it may cause cancer (52 FR 34698, September 14, 1987). Information about risks of death as a result of acute exposure or methods to reduce exposure through personal protective equipment or ventilation are not required and frequently are not present on products containing methylene chloride (Refs. 35 and 36). Paint and coating removers containing methylene chloride are frequently sold at home improvement retailers or automotive supply 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 estimates that a large percentage of users of paint and coating removal products containing methylene chloride are consumers, rather than occupational users. EPA estimates that approximately 1.3 million consumers annually use paint removal products containing methylene chloride (Ref. 4).

C. Analysis of Regulatory Options

In this unit, EPA explains how it evaluated whether the regulatory options considered would address the risks presented by this use as necessary so that the risks are no longer unreasonable. First, EPA characterizes the unreasonable risks associated with the current use of methylene chloride in paint and coating removal. Then, EPA describes its initial analysis of which regulatory options have the potential to achieve standard non-cancer and cancer benchmarks. The levels of acute and chronic exposures estimated to present no risks of concern for non-cancer effects also result in no risks of concern for cancer. Lastly, this section evaluates how well those regulatory options would address the unreasonable risk in practice.

1. *Risks associated with the current use.*

a. General impacts. The methylene chloride risk assessment and supplemental analyses identified acute and chronic risks from inhalation of methylene chloride during paint and coating removal by consumers and bystanders in residences; and commercial users and occupational bystanders in workplaces (individuals not using the paint and coating remover but nearby a user) (Refs. 2 and 19). EPA estimates, having refined the numbers since the risk assessment, that, annually, there are approximately 17,600 direct users at 8,600 commercial operations conducting paint and coating removal with methylene chloride for the uses proposed for regulation that will potentially benefit from the risk reduction resulting from this proposed regulation. EPA estimates that approximately 1.3 million consumers who use paint and coating removal products containing methylene chloride each year that will also potentially benefit from risk reduction resulting from this proposal (Ref. 4).

b. Impacts on minority and other populations. While all consumers and workers using paint and coating removal products containing methylene chloride would benefit from risk reduction, some populations are currently at disproportionate risk for the health effects associated with use of methylene chloride in paint and coating removal. In the construction trades, Hispanic workers (of all races) and foreign-born workers are over-represented (Ref. 4). In the U.S. population, 16% of adults are Hispanic, whereas in the construction trades, 35% of workers are Hispanic (Ref. 4). Due to their overrepresentation in the construction trades, Hispanic workers are disproportionately at risk of exposure to methylene chloride when used in paint and coating removal.

Similarly, foreign-born workers are overrepresented in the construction trades. In the U.S. population overall, 17% of workers in all industries are foreign-born, whereas in the construction trades, 28% of workers are foreign-born (Ref. 4). As a result, they may primarily speak a language other than English and could be characterized as having limited English proficiency. Under Executive Order 13166, EPA and other agencies are charged with examining and identifying the needs of individuals with limited English proficiency (65 FR 50121, August 11, 2000). Like Hispanic workers, foreign-born workers are disproportionately at risk of exposure to methylene chloride when used in paint and coating removal in the construction trades.

EPA's identification of the current disproportionate risks of methylene chloride exposure faced by Hispanic and foreign-born workers in the construction trades is part of the analysis conducted as part of EPA's efforts towards environmental justice. Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice; EPA's compliance with this executive order is detailed in Unit XXIII.

c. Impacts on children. In the methylene chloride risk assessment, EPA examined acute risks for bystanders to consumer use of methylene chloride in paint and coating removal in residential settings. Although EPA expects that users of methylene chloride in paint and coating removal would be adult individuals (16 years old and older), bystanders could be individuals of any age group (*e.g.*, children, adults, and the elderly) who are elsewhere in the house during product application and in the hours following application (Ref. 2). In most scenarios, EPA found acute risks of concern for central nervous system effects for other residents of the house, including children, in which paint and coating removal with methylene chloride was conducted (Ref 2). EPA found risks of concern not only during the application of the product, but also for several hours following (Ref. 2).

Although EPA anticipates that most consumers conducting paint and coating removal with methylene chloride would likely exclude children from the room in which the project was being carried out, it is unclear if they would exclude them from the house overall during and after the product application. Additionally, if the project involved removing the coating from a bathtub, households with only one bathroom would present challenges for bystander exclusion for several hours. As a result, children present in homes where paint and coating removal is being conducted, by family members or by professionals, face acute risks of central nervous system impacts.

EPA was not able to model scenarios in which paint and coating removal was conducted in an apartment building, hotel, or other residence or place in which children may be present other than single-family homes. However, the findings related to bystander exposure suggest risks for children and other

residents of apartments or hotel rooms adjacent to units in which paint and coating removal is being conducted. In these situations, it is even less likely that children would be excluded from all affected areas in order to protect them from acute risks. As a result, methylene chloride is likely to present acute risks to children as bystanders to paint and coating removal with methylene chloride, even if they are excluded from the areas in which work is conducted (Ref. 2).

d. Exposures for this use. Exposures assessed for this use include acute exposures to methylene chloride in paint and coating removal by consumers and residential bystanders, and acute and chronic exposures by commercial workers and occupational bystanders, as described in the methylene chloride risk assessment (Ref. 2). In some cases where commercial paint and coating removal is conducted, such as in workshops or facilities that are within residences (for example, in the case of some small businesses) (Ref. 27), exposed bystanders may include family members, such as children. The exposures assessed included some commercial furniture refinishing, which is not proposed for regulation. Different exposure scenarios were evaluated for workers, occupational bystanders, consumers, and residential bystanders (Ref. 2)

For exposures in commercial settings, EPA assessed acute risks and chronic risks, including cancer risks. For acute risks, EPA assessed four occupational scenarios based on eight-hour TWA exposure concentrations and different variations in exposure conditions, such as presence or absence of respirators and the protection factor of any respirator used. For each commercial use evaluated in the assessment, EPA modeled scenarios using assumed parameters similar to typical use conditions within those industries, such as whether work was conducted indoors or outdoors and what quantity of methylene chloride was estimated to be used. For these acute workplace estimates, the acute methylene chloride exposure concentration evaluated for risk was the eight-hour TWA air concentration in milligrams per cubic meter reported for the various relevant industries. In the risk assessment, EPA assumed that some workers could be rotating tasks and not necessarily carrying out paint and coating removal tasks using methylene chloride on a daily basis. This type of exposure was characterized as acute in this assessment because the worker's body was estimated to have sufficient time to remove methylene chloride and its metabolites before the next encounter with methylene chloride during paint and coating removal (Ref. 2).

For chronic exposure scenarios, EPA varied not only the parameters described above, but also the number of working days exposed to methylene chloride during paint and coating removal (ranging from 125 to 250 days per year) and exposed working years (varying the number of years the worker was assumed to be exposed) (Ref. 2). Overall, EPA evaluated cancer and chronic non-cancer risks for 16 occupational scenarios.

Worker inhalation exposure data were taken from peer-reviewed literature sources, as cited in the risk assessment (Ref. 2). These data sources often did not indicate whether monitored exposure concentrations were for occupational users or bystanders. Therefore, EPA assumed that these exposure concentrations were for a combination of users and bystanders. EPA evaluated scenarios both with and without respirator use and a range of respirator assigned protection factors (APFs), but did not estimate the overall frequency of respirator use because supporting data on the prevalence of respirator use for these commercial uses was unavailable. Similarly, EPA made assumptions about the exposure frequencies and working years because data were not found to characterize these parameters, and estimated various exposure frequencies (125 and 250 days per year) and working years (20 and 40 years). Thus, EPA evaluated occupational risks by developing hypothetical scenarios under the varying exposure conditions described previously (Ref. 2).

It is important to note that EPA relied on monitoring data for these occupational exposure estimates. Many air concentrations reported and used in the risk assessment exceeded the current OSHA PEL of 25 ppm; in some industries where paint and coating removal was conducted by immersion in tanks or vats of methylene chloride, air concentrations were measured at above 7,000 milligrams per cubic meter, or 2,016 ppm. Even in industries with lower expected exposures, air concentrations frequently were reported in excess of 250 milligrams per cubic meter, or 72 ppm, such as during graffiti removal and automotive refinishing (Ref. 2). The risks associated with these dramatically high air concentrations are discussed in Unit VI.C.1.e.

For consumer and residential bystander exposures, EPA assessed exposure scenarios under which the individual user was presumed to work on one of several types of paint and coating removal projects (coffee table, chest of drawers, or bathtub). These scenarios take into account that consumers do not reliably use personal protective equipment (respirators) or have access to engineering controls (*e.g.*, exhaust ventilation), since these methods are costly, technically challenging, and not easily available to consumers (Ref. 2). EPA used product label information to establish the time durations (in minutes) that the user would require to complete each step of the paint or coating removal process. User breaks during wait periods were assumed; the scenarios varied the location of where the user rested (in the work space or elsewhere). In addition, back-to-back projects were modeled because it is likely that the user would take breaks during the wait periods specified on product labels. It was further assumed that the paint scrapings were removed from the house as soon as scraping was completed. In each scenario, the bystander was assumed to be somewhere else in the house, and exposed via inhalation to some of the methylene chloride from the workspace (Ref. 2).

EPA developed seven consumer exposure scenarios for the assessment. Similar to the worker exposure assessment, the following factors were considered in developing the exposure scenarios (Ref. 2):

- The type of application (*i.e.*, brush-on or spray-on), weight fraction of methylene chloride in the paint and coating removal product, application rate by the user, surface area of object from which the paint or coating was being removed, and emission rate of the chemical, which can affect the amount of methylene chloride that ultimately is released to the indoor environment;
- The location where the product is applied, which relates to exposure factors such as the room volume and its air exchange rate with outdoor air;
- The house volume and air exchange rate, for reasons similar to those for the product use location; and
- Precautionary behaviors such as opening windows in the application room, the user leaving the application room during the wait period, related changes to the air exchange rates, and the proximity of the user to the source of methylene chloride emissions.

In the absence of representative air monitoring data for consumer users and residential bystanders using paint and coating removal products containing methylene chloride, EPA used the Multi-Chamber Concentration and Exposure Model to estimate consumer and bystander inhalation exposure concentrations (Ref. 2).

EPA's estimates of the exposures during paint and coating removal with methylene chloride experienced by commercial users and bystanders and consumer users and bystanders were used to assess the risks of this use of methylene chloride. The full exposure estimates and risk findings are described in the methylene chloride risk assessment; risk findings are also summarized in Unit VI.C.1.e.

In addition to estimating likely exposures under current use patterns (baseline exposures), for both commercial and consumer users, EPA assessed a number of exposure scenarios associated with risk reduction options in order to identify variations in methylene chloride exposure during paint and coating removal. All variations in the scenarios were applied to industry-specific exposure inputs and evaluated with exposure parameters that were modified to reflect either a reasonable worst-case scenario (also called the baseline) or a scenario in which exposures were moderated by several factors (also called the central tendency scenario). The risk reduction options that varied between scenarios included engineering controls, use of PPE, and well as combinations of these options (Ref. 19).

- Under the PPE risk reduction option exposure scenarios, EPA evaluated respirators with APF 10 to 10,000 for acute and chronic risks, including cancer risks.
- For the engineering controls risk reduction option exposure scenarios, EPA evaluated exposures using local exhaust ventilation (LEV) to improve ventilation near the activity of workers (using furniture refinishing operations as a model), with an assumed 90% reduction in exposure levels.

Overall, EPA evaluated dozens of distinct exposure scenarios for commercial paint and coating removal with methylene chloride; exposure reductions for consumer users are expected to be similar to the acute risk evaluations for professional contractors or workers in furniture refinishing operations, since these commercial activities are most similar to the types of projects in which consumers would engage (Refs. 19 and 20).

e. Specific risks for this use. The acute inhalation risk assessment used central nervous system effects to evaluate the acute risks for occupational, consumer, and bystander exposure during paint and coating removal with methylene chloride. In the risk assessment, a risk of concern was identified if the MOE estimate was less than the benchmark MOE of 10 for acute central nervous system effects (Ref. 2).

EPA assessed acute risks for central nervous system effects from inhalation for all consumer, occupational, and bystander exposure scenarios of paint and coating removal with methylene chloride. For consumers, EPA identified risks of concern for all scenarios, with some consumer scenarios demonstrating risks within the first hour of product use when paint and coating removal was conducted indoors (such as in a workshop or bathroom), regardless of whether the product formulation was brush or spray. Risks for incapacitating nervous system effects were found in some indoor scenarios (such as in a bathroom) within four hours of product use. MOEs for consumer acute risks from exposures of one hour or less ranged from 1.6 to 0.2; this equates to estimated exposures that are between six and 50 times greater than those that are expected to produce no risks of concern (Ref. 2).

For residential bystanders, EPA identified risks of concern for all scenarios, even assuming that any bystander in the house was not in the room where the paint and coating removal occurred. Depending on the parameters of the scenario, MOEs for acute risks ranged from 2.9 to 0.5, or between three and 20 times greater than those that are expected to produce no risks of concern (Ref. 2).

For commercial users, the occupational scenarios in which acute risks for central nervous system effects were identified included nearly all occupational scenarios, irrespective of the absence or presence of respirators, and in both the central-tendency and worst-case assumed air concentrations of methylene chloride. Additionally, EPA found acute risks for incapacitating central nervous system effects for workers who had no respiratory protection in most industries, or with respirators with APFs of 10 or 25 in the industries with highest likely exposures, such as professional contractors, aircraft refinishers, and workers using immersion methods for paint and coating removal in several industries. MOEs for acute risks ranged from an average of 0.11 (automotive refinishing) to 0.037 (graffiti removal), with a lowest end of 0.0063 (workplaces engaged in paint and coating removal using immersion methods). In general, these workplaces are estimated to present exposure levels between 100 times to greater than 1,000 times more than those that are of concern. Not only workers, but also occupational bystanders, or workers engaged in tasks other than paint and coating removal, would be at acute risk for central nervous system effects (Ref. 2). Therefore, EPA's proposed determination is that acute methylene chloride exposures during paint and coating removal present unreasonable risks.

In the risk assessment, EPA also assessed risks of chronic exposure to methylene chloride during paint and coating removal by commercial users and occupational bystanders (Ref. 2). The methylene chloride risk assessment used liver toxicity as the critical endpoint for chronic exposure. EPA assessed risks for liver toxicity for occupational and bystander exposure scenarios of paint and coating removal with methylene chloride.

Workers and occupational bystanders in most industries evaluated were identified as at risk for non-cancer liver toxicity as a result of chronic exposure to methylene chloride during paint and coating removal under typical exposure scenarios. When workers were exposed repeatedly at facilities they were at risk, even for scenarios evaluated with workers wearing respiratory protection with APF 50 (Ref. 2). The concern is for workers engaging in long-term use of the product (*i.e.*, 250 days/year for 40 years) with no respiratory protection.

For commercial users and bystanders, EPA also assessed cancer risks as a result of chronic exposure to methylene chloride in paint and coating removal. Workers and occupational bystanders showed were estimated to have an excess cancer risk greater than 1 in 1,000,000 for all of the commercial scenarios evaluated if exposed to paint and coating removal with methylene chloride for 250 days per year for 40 years with no respiratory protection. Depending on industry, cancer risks ranged from 6 in 10,000 (graffiti removal) to 2.5 in 1,000 (aircraft refinishing), with a maximum of 4 in 1,000 (workplaces using immersion methods, such as dip tanks for miscellaneous metal items). Workers in all industries showed a relative reduction in cancer risks when estimated to be working for 125 days per year for 20 years with a respirator with APF 50, with cancer risks in some industries estimated to be below benchmark levels in these scenarios. Therefore, EPA's proposed determination is that chronic methylene chloride exposures during paint and coating removal present unreasonable risks.

The SBAR Panel convened in support of this action heard from several SERs who expressed concerns about the underlying methylene chloride risk assessment (Ref. 27). 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.

2. *Initial analysis of potential regulatory options.* Having determined that the risks from methylene chloride in paint and coating removal were unreasonable, EPA evaluated whether regulatory options under section 6(a) could reduce the risk (non-cancer and cancer) so that it is no longer unreasonable.

The results of EPA's assessment of consumer uses, exposures, and risks indicate that regulatory options for consumer uses such as reducing the concentration of methylene chloride or advising the use of respirators could not achieve the target MOE benchmarks for acute exposures (benchmark MOE is 10). Similarly, the results of EPA's evaluation indicate that regulatory options for occupational exposures such as reducing the concentration of methylene chloride in products used for paint and coating removal and using local exhaust ventilation to improve ventilation, in the absence of PPE, could not achieve the target MOE benchmarks (benchmark MOE is 10) for non-cancer endpoints for acute and chronic exposures and common cancer risk benchmarks for chronic exposures (Refs. 19 and 20). The results also demonstrate that all risk reduction options meeting the benchmark MOEs and common cancer benchmarks for methylene chloride in paint and coating removal require the use of a respirator, whether used alone or in conjunction with additional levels of protection or the use of an air exposure limit. Therefore, EPA found the options of setting a maximum concentration of methylene chloride in products under TSCA section 6(a)(2) unable to reduce exposures to the risk benchmarks. Options found not to meet the risk benchmarks and, for the purposes of this proposal, found unable to address the unreasonable risk, are documented in EPA's supplemental technical reports on methylene chloride in paint and coating removal (Refs. 19 and 20).

3. *Assessment of whether regulatory options address the identified unreasonable risk so that methylene chloride in paint and coating removal no longer presents such risk.* As discussed earlier, EPA considered a number of regulatory options under TSCA section 6(a) for methylene chloride in paint and coating removal for the uses proposed for regulation. In assessing these options, EPA considered a wide range of exposure scenarios (Refs. 19, 20, and 38). These include both baseline and risk reduction scenarios involving varying factors such as exposure concentration percentiles, LEV use, respirator use, working lifetimes, etc. As part of this analysis, EPA considered the impacts of regulatory options on consumer users and commercial users separately. However, EPA is proposing to address paint and coating removal with methylene chloride for consumer uses together with many commercial uses, rather than as separate consumer and commercial uses. As described earlier, in Unit VI.B., paint and coating removal products containing methylene chloride frequently are available in the same distribution channels to consumers and professional users. Products are marketed for a variety of projects, and cannot be straightforwardly restricted to a single type of project or user. As highlighted in the investigation into recent deaths among bathtub refinishers using methylene chloride, "ten different products were associated with the 13 deaths [from 2000–2011]. Six of the products were marketed for use in the aircraft industry, the rest for use on wood, metal, glass, and masonry. None of the product labels mentioned bathtub refinishing" (Ref. 33).

The options that had the potential to address the unreasonable risks presented by methylene chloride when used for paint and coating removal by consumers, or within the commercial uses proposed for regulation, or for both consumer and these commercial uses included:

a. A supply-chain approach, which would include prohibiting the manufacturing (including import), processing, and distribution in commerce of methylene chloride for paint and coating removal under TSCA section 6(a)(2) for the consumer and commercial uses proposed for regulation; prohibiting the commercial use of methylene chloride in paint and coating removal under TSCA section 6(a)(5) for the commercial uses proposed for regulation; requiring that all paint and coating removers containing methylene chloride be distributed in volumes no less than 55-gallon containers under TSCA section 6(a)(2); requiring downstream notification when distributing methylene chloride under TSCA section 6(a)(3); and limited recordkeeping under TSCA section 6(a)(4);

b. Variations on such an approach, such as just prohibiting the manufacturing, processing, and distribution in commerce of methylene chloride for paint and coating removal under TSCA section 6(a)(2) for consumer use and for the commercial uses proposed for regulation or just prohibiting the commercial use of methylene chloride for paint and coating removal under TSCA section 6(a)(5) for the commercial uses proposed for regulation;

c. Additional variations on such an approach, such as prohibiting the manufacturing, processing, and distribution in commerce of methylene chloride for paint and coating removal under TSCA section 6(a)(2) for the consumer and commercial uses proposed for regulation and requiring downstream notification (*e.g.*, via a Safety Data Sheet (SDS)) when distributing methylene chloride for other uses under TSCA section 6(a)(3); and

d. Requiring a respiratory protection program, including PPE (a supplied-air respirator with APF 1,000 or 10,000) with an alternative air exposure limit of 1 part per million (ppm) achieved through engineering controls or ventilation alone or in combination with a supplied-air respirator at a lower APF, in commercial facilities where methylene chloride is used for paint and coating removal under TSCA section 6(a)(5) for the commercial uses proposed for regulation.

A discussion of the regulatory options that could potentially reach the risk benchmarks for consumer use, commercial uses proposed for regulation, or both is in this unit, along with EPA's evaluation of how well those regulatory options would address the unreasonable risks in practice.

a. Proposed approach. The proposed regulatory approach for methylene chloride in paint and coating removal for the uses proposed for regulation would prohibit the manufacturing, processing, and distribution in commerce of methylene chloride for paint and coating removal under TSCA section 6(a)(2) for consumer uses and for the commercial uses proposed for regulation; would prohibit the commercial use of methylene chloride for paint and coating removal under TSCA section 6(a)(5) for the uses proposed for regulation; would require any remaining paint and coating removal products containing methylene chloride to be distributed in packaged volumes no less than 55-gallon containers, under TSCA section 6(a)(2); would require manufacturers, processors, and distributors to provide downstream notification of the prohibitions under TSCA section 6(a)(3), and would require recordkeeping relevant to these

prohibitions under TSCA section 6(a)(4).

As discussed in Unit VI.C.1., the risks for exposure to consumers, workers, and bystanders for methylene chloride in paint and coating removal vary. The MOEs for non-cancer endpoints range from 50 to 1,000 times below the benchmark MOEs for central nervous system effects (the acute health impact) or liver toxicity (the chronic health impact). Similarly, the increased risk of cancer (including brain, liver, and lung cancer) in some industries is 100 to nearly 1,000 times greater than common cancer benchmarks (Ref. 2). Under this proposed option, exposures to methylene chloride during paint and coating removal would be completely eliminated. As a result, non-cancer and cancer risks would be eliminated.

The proposed approach would reduce the risks to workers, consumers, and bystanders from methylene chloride in paint and coating removal for the uses proposed for regulation so that those risks are no longer unreasonable. Prohibiting the manufacturing, processing and distribution in commerce of methylene chloride for paint and coating removal for the uses proposed for regulation would minimize the overall availability of methylene chloride for paint and coating removal for these uses. Importantly, this proposed regulation is protective of consumer users. EPA cannot regulate consumer use under TSCA section 6(a)(5). The prohibition of the commercial use of methylene chloride for paint and coating removal in the uses proposed for regulation would reduce commercial demand for methylene chloride paint and coating removal products, reduce the likelihood that other types of products formulated with methylene chloride would be used for paint and coating removal, and significantly reduce the potential for consumer use of commercial paint and coating removal products containing methylene chloride. Workers and occupational bystanders would not be exposed to methylene chloride for paint and coating removal in the uses proposed for regulation, and the risk to consumers and residential bystanders would be minimized because commercial paint and coating removal products containing methylene chloride would not be available in volumes smaller than 55-gallon containers. This large volume requirement would ensure that consumers, who typically buy products in much smaller volumes, would not be able to easily divert products from the supply chain intended for commercial furniture refinishing or uses proposed to be critical to national security. EPA seeks comment on the impact to commercial furniture refinishers of a requirement that paint and coating removal products containing methylene chloride be sold only in 55-gallon containers for commercial paint and coating removal. This request for comment is one of the recommendations of the SBAR Panel, described earlier in Unit V.C. and in more detail in Unit XXIII.C. (Ref. 27). Based on the recommendations from the SBAR Panel, EPA is requesting comment on whether the rule should allow paint and coating removal products containing methylene chloride to be sold in 30-gallon containers, rather than limiting the volume to 55-gallon containers. EPA is also requesting comment on the feasibility of implementing appropriate industrial hygiene controls associated with 30- or 55-gallon containers in order to minimize potential disruptive impacts to those industrial processes where technically feasible substitutes are currently unavailable. The downstream notification of these restrictions ensures that processors and distributors are aware of the manufacturing, processing, distribution in commerce and use restrictions for methylene chloride in paint and coating removal, and enhances the likelihood that the risks associated with this use of methylene chloride are addressed throughout the supply chain. Downstream notification also streamlines compliance and enhances enforcement, since compliance is improved when rules are clearly and simply communicated (Ref. 39). This integrated supply chain proposed approach mitigates the risk to consumers and commercial workers and occupational bystanders in the uses proposed for regulation from methylene chloride in paint and coating removal.

b. Options that are variations of elements of the proposed approach. One variation of the proposed approach would be to prohibit manufacture, processing, and distribution in commerce of methylene chloride for consumer and commercial paint removal for the uses proposed for regulation without the prohibition on commercial use of methylene chloride for paint and coating removal and without the downstream notification of any prohibitions. Without the accompanying prohibition on commercial use and downstream notification that is included in the proposed supply chain approach, this option would leave open the likelihood that commercial users falling within the scope of this proposed rule and consumer users could obtain methylene chloride (which would continue to be available for other uses, such as degreasing or solvent purposes) and use it for paint and coating removal.

Without downstream notification, unsophisticated purchasers in particular are likely to be unfamiliar with the prohibitions regarding this use and mistakenly use methylene chloride for paint and coating removal, thereby exposing themselves and bystanders to unreasonable risks. Thus, under these variations, EPA anticipates that many users would not actually realize the risk benchmarks. Therefore, these variations fail to protect against the unreasonable risks.

Another regulatory option that EPA considered was to prohibit only the commercial use of methylene chloride for paint and coating removal in the uses proposed for regulation. This approach would reduce both non-cancer and cancer risks for commercial settings, but it would not reduce risks to consumers so that they are no longer unreasonable. By prohibiting use in the commercial sector alone, without a prohibition on the manufacture, processing, and distribution in commerce of paint and coating removal products containing methylene chloride for consumer and commercial use in the uses proposed for regulation, this approach would not address consumer risks as distributors of paint and coating removal products containing methylene chloride could continue to distribute to consumers methylene chloride marked as a paint and coating remover, including products labeled and marketed as "professional strength" or "commercial grade" products. Since it is foreseeable that consumers would continue to purchase products labeled and marketed in this fashion, and consumers would continue to be exposed far above the health benchmarks, they would not be protected from the unreasonable risks posed by methylene chloride.

c. Prohibit the manufacturing, processing, and distribution in commerce of methylene chloride for consumer paint and coating removal under TSCA section 6(a)(2) or prohibit the manufacturing, processing, and distribution in commerce of methylene chloride for consumer paint and coating removal under TSCA section 6(a)(2) and require downstream notification when distributing methylene chloride for other uses under TSCA section 6(a)(3). EPA considered prohibiting the manufacturing, processing, and distribution in commerce of methylene chloride for consumer paint and coating removal including an option with a requirement for downstream

notification of such prohibition. If such a prohibition were effective, this option would mitigate the risks to consumers from methylene chloride in paint and coating removal. However, EPA recognizes that consumers can easily obtain products labeled for commercial use. Indeed, for many consumers, identifying a product as being for commercial use may imply greater efficacy. Coupled with the fact that many products identified as commercial or professional are readily obtainable in a variety of venues (*e.g.*, the Internet, general retailers, and specialty stores, such as automotive stores), EPA does not find that this option would protect consumers. In addition, this option alone would not address the risks to workers from methylene chloride in paint and coating removal.

d. Requiring a respiratory protection program, including PPE, air monitoring, and either a supplied-air respirator of APF 1,000 or 10,000 or an air exposure limit of 1 part per million (ppm) achieved through engineering controls or ventilation, in commercial facilities where methylene chloride is used for paint and coating removal under TSCA section 6(a)(5) for the commercial uses proposed for regulation. Another regulatory option that EPA considered for the commercial uses of methylene chloride for paint and coating removal proposed for regulation was to require risk reduction through an occupational respiratory protection program, which would include air monitoring, medical monitoring, and respiratory protection through use of a supplied-air respirator with an APF of 1,000 or 10,000, depending on the methods used for paint and coating removal with methylene chloride and other workplace characteristics, with a performance-based alternative of meeting an air concentration level of 1 ppm as an exposure limit for methylene chloride. A full-facepiece (or helmet/hood) self-contained breathing apparatus (SCBA) when used in the pressure demand mode or other positive pressure mode has an APF of 10,000. EPA's analysis showed that use of a SCBA with an APF of 10,000 would, in all scenarios evaluated, control the exposure of methylene chloride to levels that allow for meeting the benchmarks for non-cancer and cancer risks. Exposures in most workplaces proposed for regulation could be reduced with an APF of 1,000 to exposure levels that reduce risks to benchmark levels (Ref. 19). It is important to note that current OSHA requirements for dermal and eye protection when using methylene chloride in any way would be maintained under this approach, in addition to other requirements for work practices, training, and hazard communication put forth in OSHA's Methylene Chloride Standard (29 CFR 1910.1052). It is also important to note that any respirator used would need to be a supplied-air respirator, since methylene chloride can clog or damage filters or cartridges for air-purifying respirators, rendering them non-protective (Ref. 19).

Although respirators, specifically SCBAs, could reduce exposures to levels that are protective of non-cancer and cancer risks, not all workers may be able to wear respirators. Individuals with impaired lung function due to asthma, emphysema, or chronic obstructive pulmonary disease, for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for tight fitting full-face piece respirators to provide the required protection. Individuals with facial hair, like beards or sideburns that interfere with a proper face-to-respirator seal, cannot wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue, and reduced work efficiency (63 FR 1152, January 8, 1998). According to OSHA, "improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health." (63 FR 1189–1190). Nonetheless, OSHA views respiratory protection as a backup method which is used to protect employees from toxic materials in those situations where feasible engineering controls and work practices are not available or are insufficient to protect employee health (63 FR 1156–1157). The OSHA respiratory protection standard (29 CFR 1910.134) requires employers to establish and implement a respiratory protection program to protect their respirator-wearing employees. This OSHA standard contains several requirements, *e.g.*, for program administration; worksite-specific procedures; respirator selection; employee training; fit testing; medical evaluation; respirator use; respirator cleaning, maintenance, and repair; and other provisions.

In addition, OSHA adopted a hierarchy of controls established by the industrial hygiene community and used to protect employees from hazardous airborne contaminants, such as methylene chloride (29 CFR 1910.1052). According to this hierarchy, substitution of less toxic substances, engineering controls, administrative controls, and work practice controls are the preferred method of compliance for protecting employees from airborne contaminants and are to be implemented first, before respiratory protection is used. OSHA permits respirators to be used where engineering controls are not feasible or during an interim period while such controls are being implemented.

Given equipment costs and the costs of establishing a respiratory protection program, which involves training, respirator fit testing, and the establishment of a medical monitoring program, EPA anticipates that most companies would choose to switch to substitutes instead of adopting a program for this type of PPE to continue using methylene chloride for paint and coating removal because this type of PPE program is not cost-effective. Further, even if cost were not an impediment, there are many limitations to the successful implementation of respirators with an APF of 1,000 or 10,000 in a workplace. As recommended by the SBAR panel, EPA is requesting comment on and information about workplace experience with respiratory protection programs and air monitoring for methylene chloride (Ref. 27). Specifically, EPA seeks comment on whether companies would opt to substitute an alternate chemical or process instead of implementing a worker protection program for PPE. EPA also requests comment on the scientific and technical support used for development of the 1 ppm air exposure limit (Ref. 21) for methylene chloride and the feasibility of implementing and enforcing this performance-based approach. Additionally, EPA is requesting comment on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies.

EPA also considered requiring a combination of local exhaust ventilation and supplied-air respirators with APF of 1,000 or 50, with a performance-based alternative to the respirator of an air exposure limit of 1 ppm as an eight-hour TWA. When properly executed, this option would reduce risks to the health benchmarks for workers and bystanders (Refs. 19, 21, and 38). However, while this option has the benefit of incorporating engineering controls and the use of respirators with a lower APF, the limitations to successful implementation of the use of supplied-air respirators in the workplace discussed previously are still present. EPA is requesting comment on

whether this alternate option of allowing industrial use at specified exposure levels and with appropriate personal protective equipment should be adopted. Specifically, EPA seeks information on whether this alternative approach would incentivize industry to eliminate methylene chloride use in paint and coating removal wherever technically feasible while minimizing disruptive impacts to those processes where technically feasible substitutes are currently unavailable.

Furthermore, neither of the variations of relying upon respiratory protection for commercial paint and coating removal with methylene chloride addresses consumer risks. EPA does not have the authority to require that consumers change use practices or wear PPE. Even if this approach were coupled with a TSCA section 6(a)(2) prohibition on the manufacture, processing and distribution in commerce of methylene chloride for consumer use in paint and coating removal, this would not protect consumers because they would foreseeably continue to buy and use paint and coating removal products containing methylene chloride intended for commercial users, *e.g.,* via the Internet or home improvement or automotive supply retailers. Consumers would continue to be exposed far above the established health benchmarks when using methylene chloride for paint and coating removal (Ref. 20).

Therefore, considering the increased complexity of a respiratory protection program involving supplied-air respirators as well as the general inability to require that consumers adhere to a respiratory protection program resulting in little mitigation of risks to consumers, an option focusing on respiratory protection would not address the unreasonable risks presented by these uses.

D. Adverse Health Effects and Related Impacts That Would Be Prevented by the Proposed Option

The proposed option would prevent exposure to methylene chloride from paint and coating removal and thus would prevent the risks of adverse effects and associated impacts. As discussed in Unit II.C., the range of adverse health effects includes effects on the nervous system, liver, respiratory system, kidneys, and reproductive systems (Ref. 2). These health effects associated with exposure to methylene chloride are serious and can have impacts throughout a lifetime. The following is a discussion of the impacts of significant acute, chronic non-cancer, and cancer effects associated with methylene chloride exposure during paint and coating removal, including the severity of the effect, the manifestation of the effect, and how the effect impacts a person during their lifetime.

1. Nervous system effects—acute exposures. The methylene chloride risk assessment and EPA's 2011 IRIS assessment identified nervous system effects as the critical effect of greatest concern for acute exposure to methylene chloride. Specifically, these assessments identified sensory impairment and incapacitation (loss of consciousness) as the critical effect of acute exposures (Refs. 2 and 5). Exposure to methylene chloride can rapidly cause death as a result of nervous system depression, but even exposures that may in some cases result only in dizziness or fainting can be fatal if the individual who is disoriented or has fainted is alone. Several individuals have died after becoming incapacitated during paint and coating removal with methylene chloride; after losing consciousness, their nervous system is overcome by the continued accumulation of volatile fumes. As described in a recent report on deaths caused by methylene chloride, ". . . the danger posed by methylene chloride is its one-two punch when fumes accumulate. Because it turns into carbon monoxide in the body, it can starve the heart of oxygen and prompt an attack. The chemical also acts as an anesthetic at high doses: Its victims slump over, no longer breathing, because the respiratory centers of their brains switch off." (Ref. 7).

There are increased risks of death and nervous system effects for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated, as well as for the estimated 1.3 million consumers and residential bystanders who use or are exposed to paint and coating removers containing methylene chloride each year (Ref. 4).

Although the fact that deaths occur as a result of exposure to methylene chloride is well documented, the exact number of deaths specifically attributable to methylene exposure is unclear. In 2012, the Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report (MMWR) published results of an investigation into deaths among bathtub refinishers using methylene chloride. The authors of the investigation and the MMWR editors emphasized that the reported number of deaths due to methylene chloride is an underestimate and subject to at least three limitations: A lack of reporting to the OSHA incident database by self-employed individuals, no equivalent database to track consumer incidents and fatalities, and the likelihood that deaths due to methylene chloride exposures are misattributed to heart disease, since the pathology is similar (Ref. 33).

Based on data from OSHA, CPSC, state records, and publicly reported information, EPA has identified 49 fatalities since 1976 resulting from consumer or commercial worker exposure to methylene chloride during paint and coating removal, including for uses not proposed for regulation. However, as described earlier, this is likely an underestimate of the deaths that have occurred. As highlighted in the MMWR report from 2012 and OSHA alert from 2016, health effects from methylene chloride exposure are often misattributed to other causes (Refs. 32 and 33). For example, in several cases, workers were seen in hospital emergency rooms with symptoms of solvent exposure, were not properly diagnosed, and were sent back to the same work that ultimately killed them (Ref. 32).

Thus, EPA is unable to quantify the precise number or frequency of deaths that occur as a result of exposure to methylene chloride during paint and coating removal. However, the sporadically-occurring deaths outside of bathtub refinishing that have been documented as caused by methylene chloride, and the undocumented deaths that have been misattributed to heart disease should not be ignored merely because they cannot be monetized. Death following exposure to methylene chloride during paint and coating removal are characterized by family members as suddenly tragic, particularly when the deceased is young. In 1986 in Colorado, a worker died two hours into his first day on the job using methylene chloride to remove coatings from furniture (Ref. 40). In 2014 in New York, a 20-year old worker died while helping his father with a job refinishing a hotel bathtub (Ref. 41).

Fatalities have also occurred among more experienced workers. In 1990 in Georgia, a worker died while repairing a plastic-coated metal rack; he was found to have fainted and fallen into the tank of methylene chloride the company used to strip rack coatings (Ref. 7). In several instances, pairs of workers were killed while working on the same paint removal project with methylene chloride, such as renovating a squash court or the floor tile of a bathroom in a federal office building (Ref. 40).

In other cases, workers died when helping co-workers in distress. In South Carolina, in 1986, several workers were

killed or hospitalized in one incident: Two workers went to check on a colleague in a basement using a paint remover with methylene chloride; all three died. Five emergency responders arrived at the scene, and three were hospitalized due to inhalation of fumes (Ref. 7).

These sudden, unexpected deaths are not limited to commercial users or occupational bystanders exposed to methylene chloride during paint and coating removal. Consumer fatalities have been recorded, such as the woman who died in her house in 1990 in Ohio after removing paint from furniture with methylene chloride, as reported to the American Association of Poison Control Centers (Ref. 7). Consistent with the underreporting of commercial deaths, EPA estimates there are unreported consumer deaths due to exposure to methylene chloride during paint and coating removal.

These deaths clearly have a significant impact on families, workplaces, and communities, and yet not all of them can be monetized. Similarly, the serious health effects and lifetime impacts on workers who do not die but who are hospitalized with heart failure, coma, or other effects also cannot be quantified or monetized. However, the impacts of these effects should not be ignored. One example is a case in 2012 in California, where one man attempted to save a co-worker who had collapsed while cleaning a paint-mixing tank. The collapsed worker died, and the man attempting to rescue him was incapacitated within several seconds and lost consciousness. Though he survived, he required resuscitation, hospitalization for four days, and lengthy follow-up treatments (Ref. 7). The impacts on workers with severe but non-fatal nervous system impacts include monetary, personal health, and emotional suffering costs that cannot be quantified or monetized, but again, should not be ignored. These severe nervous system impacts can include coma and heart failure (Ref. 2).

Even when less severe, the nervous system effects of acute exposure to methylene chloride can have considerable adverse consequences on an individual, particularly if one is exposed as a bystander who is unaware of why these nervous system effects are occurring. Commercial and consumer users as well as bystanders in workplaces and residences are at risk of dizziness and sensory impairment during most uses of methylene chloride for paint and coating removal. Similarly, chronic exposure to methylene chloride presents risks to the nervous system of commercial users, consumer users, and bystanders exposed to methylene chloride in paint and coating removal.

2. Nervous system effects—chronic exposures. The methylene chloride risk assessment identified nervous system effects as adverse effects of chronic exposure to methylene chloride exposure in paint and coating removal. There are increased health risks for nervous system effects for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

Chronic exposures in occupational settings put users and bystanders at risk of cognitive impairment (affecting eye-hand coordination, tracking tasks, auditory vigilance); adverse effects on autonomic, neuromuscular, and sensorimotor functions (Ref. 2); and long-term effects on specific cognitive-neurological measures (*i.e.,* attention and reaction time) (Ref. 5).

3. Liver toxicity. The methylene chloride risk assessment identified liver toxicity and liver cancer as adverse effects of chronic exposure to methylene chloride exposure in paint and coating removal. There are increased health risks for liver toxicity and liver cancer for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

Specific effects to the liver include hepatic vacuolation and non-alcoholic fatty liver disease (NAFLD) (Ref. 2). Some form of liver disease impacts at least 30 million people, or 1 in 10 Americans. Included in this number is at least 20% of those with NAFLD. NAFLD tends to impact people who are overweight/obese or have diabetes. However, an estimated 25% do not have any risk factors. The danger of NAFLD is that it can cause the liver to swell, which may result in cirrhosis over time and could even lead to liver cancer or failure (Ref. 42). The most common known causes to this disease burden are attributable to alcoholism and viral infections, such as hepatitis A, B, and C. These known environmental risk factors of hepatitis infection may result in increased susceptibility of individuals exposed to organic chemicals such as methylene chloride.

Chronic exposure to methylene chloride can also lead to liver cancers including hepatocellular carcinomas (HCC), hepatocellular adenomas, and biliary tract cancer (Ref. 2). The monetizable benefits associated with reducing the risk of liver cancers associated with methylene chloride exposure are discussed in Unit VII.B. However, the impacts of these cancers should not be measured only as dollar valuations. For example, because HCC is frequently diagnosed only after an individual's health has deteriorated, survival is usually measured in months. As a result, "HCC is responsible for a large proportion of cancer deaths worldwide . . . HCC classically arises and grows in silent fashion, making its discovery challenging prior to the development of later stage disease" (Ref. 43). Recommended treatments are aggressive interventions such as the removal of the tumors or sections of the liver; the life expectancy of patients with HCC is a mean survival rate of 6 to 20 months. Advanced cases can metastasize to any organ system, and tends to spread to bones and lungs. Bone pain related to metastasis is frequently the initial presenting symptom of HCC (Ref. 43).

Additional medical and emotional costs are associated with cancer and non-cancer liver toxicity following chronic exposure to methylene chloride in paint and coating removal, although these costs cannot be quantified. These costs include medical visits and medication costs. In some cases, the ability to work can be affected, which in turn impacts the ability to get proper medical care. Liver toxicity can lead to jaundice, weakness, fatigue, weight loss, nausea, vomiting, abdominal pain, impaired metabolism, and liver disease.

Depending upon the severity of the jaundice, treatments can range significantly. Simple treatment may involve avoiding exposure to methylene chloride and other solvents; however, this may impact an individual's ability to continue to work. In severe cases, liver toxicity can lead to liver failure, which can result in the need for a liver transplant. Even if a donor is available, liver transplantation is expensive (with an estimated cost of $575,000) and there are countervailing risks for this type of treatment (Ref. 44). The mental and emotional toll on an individual and their family as they try to identify the cause of sickness and possibly experience an inability to work, as well as the potential monetary cost of medical treatment required to regain health, are significant.

4. *Hematopoietic cancers.* EPA's 2011 IRIS assessment for methylene chloride found that it is a likely human carcinogen. Chronic inhalation exposure to methylene chloride such as during paint and coating removal has been shown to result in increased risk for non-Hodgkin's lymphoma (NHL) or multiple myeloma in workers (Ref. 5). There are increased risks for NHL or

multiple myeloma for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

NHL is a form of cancer that originates in the lymphatic system. Approximately 19 new cases per 100,000 adults per year are diagnosed, with approximately 6.2 deaths per 100,000 adults annually (Ref. 45). NHL is the seventh most common form of cancer (Ref. 46). Other factors that may increase the risk of NHL are medications that suppress a person's immune system, infection with certain viruses and bacteria, or older age (Ref. 47).

Symptoms of NHL are swollen lymph nodes in the neck, armpits or groin, abdominal pain or swelling, chest pain, coughing or trouble breathing, fatigue, fever, night sweats, and weight loss. Depending on the rate at which the NHL advances, treatment may consist of monitoring, chemotherapy, radiation, stem cell transplant, medications that enhance the immune system's ability to fight cancer, or medications that deliver radiation directly to cancer cells (Ref. 47).

Multiple myeloma is a related hematopoietic cancer, formed by malignant plasma cells. Multiple myeloma is characterized by low blood counts, bone and calcium problems, infections, kidney problems, light chain amyloidosis, and various forms of abnormal plasma cell growth. Often, multiple myeloma has no clinical symptoms until it reaches an advanced stage (Ref. 48).

Treatments for NHL or multiple myeloma result in substantial costs for hospital and doctors' visits in order to treat the cancer. Treatments for NHL or multiple myeloma can also have countervailing risks and can lead to patients' higher susceptibility for secondary malignancies (Refs. 47 and 48). The emotional and mental toll from wondering whether a treatment will be successful, going through the actual treatment, and inability to do normal activities, or work will most likely be high (Ref. 49). This emotional and mental toll could extend to the person's family and friends as they struggle with the diagnosis and success and failure of a treatment regime.

5. Brain cancer. EPA's 2011 IRIS assessment for methylene chloride found that it is a likely human carcinogen. Chronic inhalation exposure to methylene chloride has been shown to result in brain cancer (Ref. 5). There are increased risks for brain cancer for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

Researchers at the National Cancer Institute found that "associations of astrocytic brain cancer were observed with likely exposure to carbon tetrachloride, methylene chloride, tetrachloroethylene, and trichloroethylene, but were strongest for methylene chloride. . . . Risk of astrocytic brain tumors increased with probability and average intensity of exposure, and with duration of employment in jobs considered exposed to methylene chloride . . . These trends could not be explained by exposures to the other solvents" (Ref. 50).

Cancers that originate in the brain, which include astrocytic brain cancers, are relatively rare. Astrocytic brain cancers are estimated to have an incidence of approximately 10 cases per 1 million people per year, depending on how these types of cancers are defined (Ref. 51). Astrocytic tumors are characterized by varying degrees of growth potential and infiltration into nearby tissues. They include tumors that can spread quickly through the brain stem (brain stem gliomas); affect the pineal gland, which controls the sleeping and waking cycle (pineal astrocytic tumors); grow slowly and can be relatively easily cured (pilocytic astrocytoma); grow slowly but often spread into nearby tissues (diffuse astrocytoma); grow quickly and spread into nearby tissues (anaplastic astrocytoma); and grow quickly, spread quickly into nearby tissues, and usually cannot be cured (glioblastoma) (Ref. 51).

For astrocytic brain cancers, like other primary malignant brain tumors, initial clinical symptoms are frequently headaches and seizures. Lower-grade tumors may persist undetected for years, whereas the faster-growing or faster-spreading tumors may rapidly provoke neurological decline. Other symptoms may include nausea, vomiting, headache, and confusion as a result of increased intracranial pressure (Ref. 51).

Treatment for astrocytic brain cancers varies by the type and stage of the tumor; it can include pharmacological treatment (for many patients, this includes steroids and anti-convulsants if they are experiencing seizures), surgery (depending on location of the tumor, they may be removed or separated from the brain), chemotherapy, hormone modulation, or combinations of these treatments (Ref. 51). Like most cancer treatments, these can have countervailing risks. Additionally, the emotional and mental tolls described in earlier sections are relevant to these cancer treatments as well (Ref. 49).

6. Lung cancer. EPA's 2011 IRIS assessment for methylene chloride found that it is a likely human carcinogen. Chronic inhalation exposure to methylene chloride has been shown to result in bronchoalveolar carcinomas (BAC) or bronchoalveolar adenomas, which are forms of lung cancer (Ref. 5). There are increased risks for these lung cancers for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

BAC is a small percent of lung cancers (between 2% to 4%) and has unique characteristics. It is notable for its weak relationship with cigarette smoking; about one-third of patients in the United States with BAC were never smokers. Additionally, because it rarely spreads outside the lungs, it is often initially diagnosed as pneumonia or other lung inflammations (Ref. 52). Most patients do not present clinical symptoms (Ref. 52) and are only diagnosed following radiography or biopsy. Treatment requires surgery (Ref. 52). This has clear countervailing risks, and even if successful in removing any tumors present, the BAC may return.

7. Mammary tumors. Exposure to methylene has been shown to result in significant increases in the incidence of adenomas, fibroadenomas, or fibromas in or near the mammary gland (Refs. 2 and 5). These are largely benign tumors (Ref. 2). Though many benign tumors do not require invasive procedures, doctors recommend removing fibroadenomas. Patients need to undergo a biopsy to identify the carcinogenic risk of the tumor, and have the tumors removed if they continue to grow, change the shape of the breast, or are carcinogenic (Ref. 53). If removal is necessary, the procedure may also require the removal of nearby healthy mammary tissue, resulting in scarring and changed shape and texture of the breast (Ref. 53). Women with fibroadenomas and adenomas also have an increased risk of breast cancer, estimated to be approximately 1.5 to 2.0 times the risk of women with no breast changes (Ref. 54).

8. Reproductive effects. EPA's 2011 IRIS assessment for methylene chloride found that exposure can have reproductive effects that include testicular and ovarian atrophy (Ref. 5). At very high exposures, chronic inhalation of methylene chloride during paint and coating removal can result in these reproductive effects, which are related to decreased fertility (Ref. 55).

There are increased risks for these reproductive effects for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4). Similar to effects discussed previously, while neither the precise reduction in individual risk of developing this disorder from reducing exposure to methylene chloride or the total number of cases avoided can be estimated, EPA still considers their impact.

9. *Kidney toxicity.* EPA's 2011 IRIS assessment for methylene chloride identified kidney effects from exposure to methylene chloride; these effects include renal tubular degeneration (Ref. 5). At very high exposures, chronic inhalation exposure to methylene chloride during paint and coating removal can result in kidney toxicity. There are increased risks for these kidney effects for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

Exposure to methylene chloride can lead to changes in the proximal tubules of the kidney. This damage may result in signs and symptoms of acute kidney failure that include; decreased urine output, although occasionally urine output remains normal; fluid retention, causing swelling in the legs, ankles or feet; drowsiness; shortness of breath; fatigue; confusion; nausea; seizures or coma in severe cases; and chest pain or pressure. Sometimes acute kidney failure causes no signs or symptoms and is detected through lab tests done for another reason.

Kidney toxicity means the kidney has suffered damage that can result in a person being unable to rid their body of excess urine and wastes. In extreme cases where the kidney is impaired over a long period of time, the kidney could be damaged to the point that it no longer functions. When a kidney no longer functions, a person needs dialysis and ideally a kidney transplant. In some cases, a non-functioning kidney can result in death. Kidney dialysis and kidney transplantation are expensive and incur long-term health costs if kidney function fails (Ref. 56).

The monetary cost of kidney toxicity varies depending on the severity of the damage to the kidney. In less severe cases, doctor visits may be limited and hospital stays unnecessary. In more severe cases, a person may need serious medical interventions, such as dialysis or a kidney transplant if a donor is available, which can result in high medical expenses due to numerous hospital and doctor visits for regular dialysis and surgery if a transplant occurs. The costs for hemodialysis, as charged by hospitals, can be upwards of $100,000 per month (Ref. 57).

Depending on the severity of the kidney damage, kidney disease can impact a person's ability to work and live a normal life, which in turn takes a mental and emotional toll on the patient. In less severe cases, the impact on a person's quality of life may be limited while in instances where kidney damage is severe, a person's quality of life and ability to work would be affected. While neither the precise reduction in individual risk of developing kidney toxicity from reducing exposure to methylene chloride during paint or coating removal or the total number of cases avoided can be estimated, these costs must still be considered because they can significantly impact those exposed to methylene chloride.

10. Disproportionate impacts on environmental justice communities. An additional factor that cannot be monetized is the disproportionate impact on environmental justice communities. As described in Unit VI.C.1.b., Hispanic and foreign-born workers, who may have limited English proficiency, are disproportionately over-represented in construction trades (Ref. 4), in which methylene chloride is used for paint and coating removal. Because they are disproportionately over-represented in this industry, these populations are disproportionately exposed to methylene chloride during paint and coating removal, and are disproportionately at risk to the range of adverse health effects described in this unit.

E. Availability of Alternatives

For almost every situation in which methylene chloride is used to remove paints or coatings, EPA is aware of technically and economically feasible chemical substitutes or alternative methods that are reasonably available. The two situations for which EPA does not know of technically and economically feasible alternatives are the uses that EPA proposes are critical for national security, described in more detail in Unit VIII., and commercial furniture refinishing, discussed in more depth in Unit XI. With respect to the specific coating removal uses that EPA proposes are critical for national security, described in Unit VIII., EPA does not believe that technically and economically feasible alternatives are reasonably available at this time. With respect to the furniture refinishing uses described in Unit XI., EPA is still investigating whether economically feasible alternatives are reasonably available.

EPA considered chemical substitutes and alternative methods consistent with the requirements of TSCA section 6(c)(2)(C) and as similarly recommended by the SBAR panel (Ref. 27). A full industry profile characterizing manufacturers, processors and end users of methylene chloride for paint and coating removal and a use and substitutes analysis are included in sections 2 and 3 of EPA's economic assessment (Ref. 4). As described below, EPA proposes that alternatives are technologically feasible, economically feasible, reasonably available, and present fewer hazards to human health than methylene chloride in paint and coating removal. EPA requests comment on whether its conclusion that substitutes for methylene chloride identified are available and technically and economically feasible is accurate and whether its consideration of alternatives was sufficient to satisfy the requirements of TSCA section 6(c)(2)(C).

Research into the efficacy of chemical substitutes has identified products currently available for commercial and consumer users of methylene chloride for paint and coating removal, for a variety of coatings on numerous substrates (Refs. 58 and 59). Research by the European Association for Safer Coating Removal in 2006 found that for every use that was studied of methylene chloride in paint and coating removal, there was a suitable substitute (Ref. 60). Other non-chemical methods of paint removal are also available (Ref. 31). Additionally, in most commercial sectors, users have voluntarily adopted substitute chemicals or methods, either due to financial considerations, customer requests, concern for worker or individual health and safety, decreased discharges to air and water, reduced clean-up costs, or reduced cost of protective equipment and respiratory protection programs (Ref. 22).

Many producers of paint and coating removal products containing methylene chloride also produce paint and coating removal products with substitute chemicals (Ref. 4). This was emphasized by a small business who makes such products (Ref. 22); other small businesses separately described the limitations of many alternatives (Ref. 27). Thus, there is already precedent for producers reformulating products to meet demand from commercial or individual customers. Additionally, methylene chloride is prohibited from use in graffiti removal in California,

Connecticut, Delaware, the District of Columbia, Illinois, Indiana, Maine, Maryland, Massachusetts, Michigan, New York, and Rhode Island (Ref. 12). The fact that 11 states and the District of Columbia have specifically prohibited the use of methylene chloride in graffiti removal supports a finding that it is not critical for this use and that there are efficacious substitutes.

Based on the frequent use of substitute chemicals or alternative methods for paint and coating removal in all industries discussed here, and the formulation and distribution of substitute chemicals for paint and coating removal by all formulators of products containing methylene chloride (Ref. 4), EPA finds that technically and economically feasible alternatives to methylene chloride are reasonably available for all uses proposed for regulation.

Primary chemical substitutes for methylene chloride in paint and coating removal include products formulated with benzyl alcohol; dibasic esters; acetone, toluene, and methanol (collectively ATM); and caustic chemicals. EPA evaluated these products for efficacy, toxicity, relative hazards compared to methylene chloride, and other hazards that might be introduced by use of these products (such as environmental toxicity, increased global warming potential, and increased flammability or other hazards to users). Overall, while the efficacies of the substitutes are comparable to the efficacy of methylene chloride, none of the substitute chemicals already available has the level of toxicity associated with methylene chloride.

Products based on benzyl alcohol formulations have been identified as efficacious paint and coating removers in various industry sectors (Refs. 22 and 27). Consumer products containing benzyl alcohol are available for sale (Refs. 22, 27, 35, 58, 59, and 61). There are fewer hazard concerns compared to methylene chloride-based products, and the levels at which benzyl alcohol causes toxicity are higher than for methylene chloride, suggesting lower toxicity (Ref. 34). The relative inhalation exposure potential is lower for benzyl alcohol than for methylene chloride. The relative dermal exposure potential of benzyl alcohol is similar to methylene chloride (Ref. 34). Benzyl alcohol-based paint removers are expected to result in lower risks than methylene chloride products, primarily due to lower toxicity (Ref. 29).

Dibasic ester products can include dimethyl succinate, dimethyl glutarate and dimethyl adipate. They are generally viewed as efficacious products by commercial users in several sectors, though, because they evaporate slowly, they require a longer dwell time than methylene chloride (Ref. 22, 27). In general, the hazards associated with dibasic esters are less severe and occur at concentrations higher than methylene chloride (Ref. 34). Regarding differential exposures between dibasic esters and methylene chloride, the relative inhalation exposure potential is lower for dibasic esters than for methylene chloride (Ref. 34). The relative dermal exposure potentials of dibasic esters are similar to methylene chloride. Taken together, dibasic ester-based paint removers are expected to result in lower risks than methylene chloride products, primarily due to lower toxicity (Ref. 34).

ATM products contain acetone, toluene, and methanol. Products containing these chemicals may remove coatings very quickly, but may not be effective on every type of coating (Refs. 22 and 27). Acetone, toluene, and methanol evaporate quickly and are very flammable (Ref. 62). However, it is important to note that acetone, toluene, and/or methanol are present in most paint removers that contain methylene chloride, as co-solvents (Ref. 34). As a result, the main difference between paint removers that contain methylene chloride (and typically also contain acetone, toluene, and/or methanol) and ATM products is the absence of methylene chloride. Acetone is readily absorbed via inhalation and the relative inhalation exposure potential is similar to methylene chloride (Ref. 34). Acetone in particular is significantly less toxic than methylene chloride. Toluene and methanol are readily absorbed via inhalation, but the relative inhalation exposure potential is lower than for methylene chloride (Ref. 34). Dermal exposure to acetone, toluene and methanol is slightly less than for methylene chloride (Ref. 34). Taken together, ATM-based paint removers are expected to result in lower cancer risks (Ref. 36).

Products with caustic chemicals typically include calcium hydroxide or magnesium hydroxide. In many uses, they can be effective products, particularly when multiple coatings are being removed from a substrate. Caustic products have been reported to remove up to 30 coats in 24 hours, and in some cases, they have no increased dwell time compared to methylene chloride (Ref. 23). In contrast to methylene chloride-based products, there are no cancer or other repeat dose endpoints of concern associated with caustic products (Ref. 34). Caustic products pose acute concerns due to their physical chemical properties and can cause chemical burns (Ref. 36). It is important to note that products containing methylene chloride may also cause chemical burns. Additionally, the risks associated with caustic-based products are entirely acute, and can be mitigated by appropriate protective equipment more easily than the acute and chronic risks presented by methylene chloride.

In summary, when NMP is excluded from consideration, the most likely chemical substitutes for methylene chloride in paint and coating removal do not pose a risk of cancer to users, generally have lower exposure potential than methylene chloride, and when acute risks are present, as in the case of caustic chemicals, those risks are self-limiting by the nature of the adverse effects (since a user experiencing those effects is likely to take immediate action to mitigate or cease the effect of the caustic chemical). The chemical formulations that seem to present some risks of concern are ATM products, since they contain toluene and methanol. However, these chemicals are also present in most paint removers that contain methylene chloride, as co-solvents. As a result, no additional risks would be introduced were users to substitute a typical methylene chloride product (which would likely contain acetone, toluene, and/or methanol as co-solvents) with ATM products.

In addition to examining toxicity to humans, EPA reviewed available data on the chemicals in the baseline and alternative products for aquatic toxicity, persistence and bioaccumulation data, as a basis for examining potential environmental toxicity. Only one chemical evaluated (citrus terpenes) may have significant impacts on aquatic toxicity, with concern for environmental persistence and/or bioaccumulation. This chemical is contained in NMP-based paint removal products (Ref. 34).

EPA is also mindful of the risks that may be introduced by substitute chemicals or methods to increase global warming, and has examined the global warming potential of the chemical components of likely chemical substitutes for methylene chloride in paint and coating removal. Methylene chloride presents concerns for global warming; it has a GWP of 8.7 (see Unit II.D.2.). The GWP values of likely substitute chemicals in paint and coating removal are: 0 GWP (benzyl alcohol, ATM) or not assessed (caustics, dibasic esters) (Ref. 23). As such, EPA has not identified any increased risk of global warming that would be introduced by use of chemical products

as substitutes for methylene chloride in paint and coating removal.

In addition to human and environmental toxicity, other hazards associated with chemical methods for paint and coating removal are risks of fire due to flammability of the chemical product, and poisoning or acute injury. Risks of fire are serious when using solvents such as paint and coating removal chemicals. The flammability of methylene chloride is lower than some of the substitute organic solvents. However, many paint and coating removal products containing methylene chloride also contain more flammable chemicals as part of the formulation (Ref. 34). Paint and coating removal products sold to consumers that contain methylene chloride frequently have flammability warnings prominently on them (Ref. 35). Other chemical paint and coating removal products, such as those based on benzyl alcohol and dibasic esters, have low flammability and do not present an increased risk of fire from products containing methylene chloride (Ref. 23). Even among products that fall within the same general product composition category, there is meaningful variability in the specific formulations of paint remover products, and thus in their flammability. Furthermore, it is impracticable for EPA to predict the specific product formulations for which use will increase as a result of prohibitions on methylene chloride in paint and coating removal. It is therefore impracticable for EPA to forecast whether the flammability of popular paint and coating removers would generally increase or decrease as a result of the proposed rule.

In addition to using substitute chemical products, non-chemical methods for paint and coating removal are frequently used. These include thermal removal, sanding, hydroblasting, abrasive blasting, and laser removal (Refs. 22 and 31). Acute and chronic physical hazards (*e.g.*, burns, injuries to bodily parts) to workers and consumers can occur, in addition to any lead-related risks that should be considered when using these methods with lead-based paint.

In this overview, when considering alternatives to methylene chloride that would be available, NMP generally was not considered because, under the first co-proposed option for NMP in this proposed rule, this chemical would also be prohibited from use in paint and coating removal. However, under the second co-proposed approach for reducing the risks of NMP in paint and coating removal, products containing NMP would be available for commercial and consumer paint and coating removal, with restrictions. Details of the two co-proposed options are in Unit XVI.3. EPA identified developmental risks following acute exposures for consumers and acute and chronic exposures for commercial users of paint and coating removal products containing NMP following exposure through dermal contact, inhalation, and vapor-through-skin. More information on the risks EPA identified related to NMP are in Unit XVI.B.1.

F. Impacts of the Proposed and Alternative Regulatory Options

This unit describes the estimated costs of the proposed and alternative regulatory actions that EPA considered for methylene chloride in paint and coating removal. More information on the benefits and costs of this proposal as a whole can be found in Unit XXIII.

1. Proposed approach for methylene chloride in paint and coating removal. The costs of the proposed approach are estimated to include product reformulation costs, downstream notification costs, recordkeeping costs, and Agency costs. The costs of paint and coating removal product reformulations are estimated to be approximately $10,000 to $20,000 per year (annualized at 3% over 20 years) and $14,000 to $24,000 (annualized at 7% over 20 years). The cost for reformulation includes a variety of factors such as identifying the appropriate substitute chemical for methylene chloride in the formulation, assessing the efficacy of the new formulation and determining shelf-life. Under the first co-proposed approach for NMP, where the manufacturing, processing, distribution, and commercial use of paint and coating removal products containing NMP would be prohibited, the costs to users of paint and coating removers containing methylene chloride are $4,217,000 to $23,436,000 using a 3% discount rate and $4,592,000 to $23,485,000 at the 7% discount rate (both rates annualized over 20 years). The costs of downstream notification and recordkeeping on an annualized basis over 20 years are $40 and $60 using 3% and 7% discount rates respectively (Ref. 4). Agency costs for enforcement are estimated to be approximately $114,401 and $111,718 annualized over 20 years at 3% and 7%, respectively. The total cost of the proposed approach for paint and coating removers containing methylene chloride under the first co-proposed approach for NMP is estimated to be $4,247,000 to $23,446,000 and $4,612,000 to $23,495,000 annualized over 20 years at 3% and 7%, respectively (Ref. 4). Under the second co-proposed approach for NMP, where paint and coating removal products containing NMP would be available with some restrictions, the costs to users of paint and coating removers containing methylene chloride are $67,087,960 to $68,726,960 using a 3% discount rate and $67,369,940 to $69,006,940 at the 7% discount rate (both rates annualized over 20 years). The costs of downstream notification and recordkeeping on an annualized basis over 20 years are the same as under the first co-proposed approach for NMP. Agency costs for enforcement are estimated to be the same as under the first co-proposed approach for NMP. The total cost of the proposed approach for paint and coating removers containing methylene chloride under the second co-proposed approach for NMP is estimated to be $67,098,000 to $68,747,000 and $67,384,000 to $69,034,000 annualized over 20 years at 3% and 7%, respectively (Refs. 4 and 127).

2. Options that require personal protective equipment for methylene chloride in paint and coating removal. Given equipment costs and the requirements associated with establishing a respiratory protection program which involves training, respirator fit testing and the establishment and maintenance of a medical monitoring program, EPA considers the proposed approach more cost-effective than options that require person protective equipment. This is because EPA anticipates that companies would choose to switch to substitute chemicals instead of adopting a program for PPE, including with a performance-based option of meeting an air concentration level of 1 ppm as an exposure limit for methylene chloride in paint and coating removal. The estimated annualized costs of switching to a respiratory protection program requiring PPE of APF 1,000 are $13,775,000 to $26,535,000 at 3% and $14,202,000 to $26,708,000 at 7% over 20 years (Ref. 4). In addition, there would be higher EPA administration and enforcement costs with a respiratory protection program under the proposed approach.

3. Options that exclude downstream notification. For those options that exclude downstream notification, the options are less effective and more to challenging to implement. The downstream notification (*e.g.*, via SDS) provides additional information on the prohibitions under the proposed option for processors and distributors of methylene chloride or products containing methylene chloride other than paint and coating removers, and

provides an efficient way for those entities to recognize themselves as affected by the regulation, which contributes to a more effective regulation (Ref. 63). In this way, the downstream notification component of the supply chain approach contributes to the use no longer presenting an unreasonable risk because it streamlines and aids in compliance and implementation (Ref. 64).

G. Summary

The proposed approach is necessary so that methylene chloride in paint and coating removal no longer presents an unreasonable risk. It is also more cost effective than other regulatory options the Agency identified as potentially reducing risks so that they are no longer unreasonable, because it achieves the benefits of reducing the unreasonable risks so they are no longer unreasonable for a lower cost than the primary alternative option. For more information, see section 6 in the Economic Analysis (Ref. 4).

As stated previously in this notice, the proposed approach includes:

- Prohibiting manufacturing (including import), processing, and distribution in commerce of methylene chloride for consumer paint and coating removal and commercial paint and coating removal for the uses proposed for regulation;
- Prohibiting commercial use of methylene chloride for paint and coating removal for the uses proposed for regulation;
- Requiring that any products containing methylene chloride intended or used for paint and coating removal be distributed in volumes no less than 55-gallon containers;
- Requiring downstream notification of the prohibition on manufacturing (including import) processing, and distribution of methylene chloride for paint and coating removal for the prohibited uses; and
- Requiring limited recordkeeping.

Technically and economically feasible substitutes to methylene chloride for paint and coating removal are reasonably available for the uses proposed to be regulated. The supply chain approach ensures protection of consumers from the unreasonable risk by precluding the off-label purchase of commercial products by consumers.

The proposed approach is relatively easy to enforce because key requirements are directly placed on a small number of suppliers and because the supply chain approach minimizes to the greatest extent the potential for methylene chloride products to be intentionally or unintentionally misdirected into the prohibited uses. Enforcement under the other options would be much more difficult since the key requirements are directly placed on the large number of product users. As described in a recent article on designing more effective rules and permits, "the government can implement rules more effectively and efficiently when the universes of regulated sources are smaller and better-defined. This is because, other factors being equal, governments can more easily identify, monitor, and enforce against fewer, rather than more, entities" (Ref. 63). Under other options, enforcement activities must target firms that might perform the activity where a use of methylene chloride is restricted or prohibited. Identifying which establishments might use paint and coating removers is difficult because paint and coating removal is not strictly specific to any industry (Ref. 4).

VII. Costs and Monetized Benefits of the Methylene Chloride Component of the Proposed Rule, the Alternatives EPA Considered, and Comparison of Costs and Benefits

EPA proposes that the identified risks from methylene chloride and in paint and coating removal are unreasonable risks. Apart from that proposed determination, EPA has evaluated the potential costs and benefits of the proposed approach and alternative approaches.

A. Costs

The details of the costs of the proposed approach for use of methylene chloride in paint and coating removal by consumers and in commercial uses proposed for regulation are discussed in Unit I.E. and in the Economic Analysis (Ref. 4). Under the proposed option for methylene chloride and the first co-proposed option for NMP, costs to users of paint and coating removal products containing methylene chloride are $4,217,000 to $23,436,000 annualized for 20 years at a discount rate of 3% and $4,592,000 to $23,485,000 at a discount rate of 7%. Costs of paint and coating removal product reformulations are estimated to be approximately $10,000 to $20,000 per year (annualized at 3% over 20 years) and $14,000 to $24,000 (annualized at 7% over 20 years). Costs of downstream notification and recordkeeping on an annualized basis over 20 years are $40 and $60 using 3% and 7% discount rates respectively. Agency costs for enforcement are estimated to be approximately $114,401 and $111,718 annualized over 20 years at 3% and 7%, respectively (Ref. 4).

Total costs of the proposed rule relevant to methylene chloride in paint and coating removal under the first co-proposed option for NMP are estimated to be $4,247,000 to $23,446,000 annualized over 20 years at 3% and $4,612,000 to $23,495,000 annualized over 20 years at 7% (Ref. 4).

Under the proposed option for methylene chloride and the second co-proposed option for NMP, costs to users of paint and coating removal products containing methylene chloride are $67,087,960 to $68,726,960 annualized for 20 years at a discount rate of 3% and $67,369,940 to $69,006,940 at a discount rate of 7%. Costs of paint and coating removal product reformulations, costs of downstream notification, and Agency costs for enforcement are estimated to be the same as under the first co-proposed option for NMP (Refs. 4 and 127).

Total costs of the proposed rule relevant to methylene chloride in paint and coating removal under the second co-proposed option for NMP are estimated to be $67,098,000 to $68,747,000 annualized over 20 years at 3% and $67,384,000 to $69,034,000 annualized over 20 years at 7% (Refs. 4 and 127).

Alternatives that EPA considered include the use of PPE as well as an option that would prohibit the use of methylene chloride in paint and coating removal for consumers and for the commercial uses proposed for regulation without the companion prohibition on manufacture, processing, or distribution in commerce for these uses or the downstream notification requirements. As discussed in Unit VI.C.3., EPA found that PPE options did not address the risks presented by methylene chloride in paint and coating removal so that the risks would no longer be unreasonable. This is because consumers could not be required to adopt PPE, resulting in a significant gap in protection for consumers. In addition, EPA also assumed that no commercial users would adopt PPE because the per-facility costs were prohibitively expensive.

EPA also found that a use prohibition alone without downstream notification requirements would not address the unreasonable risks. EPA estimated the costs of this option to be $4,239,000 to $23,442,000 annualized over 20 years at 3% and $4,604,000 to $23,491,000 annualized over 20 years at 7% (Ref. 4).

B. Benefits

EPA is not fully able to quantify the full monetary benefits that would accrue from preventing all deaths due to methylene chloride in paint and coating

removal. 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 consumer uses and for the commercial uses proposed for regulation are estimated to be $14,363,000 to $14,565,000 (annualized at 3% over 20 years) and $13,796,000 to $13,921,000 (annualized at 7% over 20 years) (Ref. 4). Although the alternatives considered are unlikely to result in the same health benefits as the proposed option, EPA was unable to quantify the differences.

C. Comparison of Benefits and Costs

The monetized subset of benefits for preventing the risks resulting from methylene chloride in paint and coating removal by consumers and by commercial workers for the uses proposed for regulation do not outweigh the estimated monetary costs. EPA believes that the balance of costs and benefits cannot be fairly described without considering the additional, non-monetized benefits of mitigating the non-cancer adverse effects as well as cancer. As discussed previously, the multitude of potential adverse effects associated with methylene chloride in paint and coating removal can profoundly impact an individual's quality of life. Some of the adverse effects associated with methylene chloride exposure can be immediately experienced and can result in sudden death; others can have impacts that are experienced for a shorter portion of life, but are nevertheless significant in nature. While the risk of non-cancer health effects associated with methylene chloride exposure during paint and coating removal cannot all be quantitatively estimated, the qualitative discussion highlights how some of these non-cancer effects may be as severe as cancer and thus just as life altering. These effects include not only medical costs but also personal costs such as emotional and mental stress that are impossible to accurately measure. Considering only monetized benefits would significantly underestimate the impacts of methylene chloride-induced non-cancer adverse outcomes on a person's quality of life.

Thus, considering costs; the subset of benefits that can be monetized (risk of cancer and risk of death in some sectors); and the remaining benefits that cannot be quantified and subsequently monetized (risk of nervous system effects, liver toxicity, reproductive effects, and kidney toxicity), including benefits related to the severity of the effects and the impacts on a person throughout a lifetime in terms of medical costs, effects on earning power and personal costs, emotional and psychological costs, and the disproportionate impacts on Hispanic communities and individuals with limited English proficiency; the benefits of preventing exposure to methylene chloride in paint and coating removal by an estimated 1.3 million consumers and estimated 17,600 commercial workers for the uses proposed for regulation outweigh the costs.

D. Impacts on the National Economy, Small Businesses, Technological Innovation, the Environment, and Public Health

As described in Unit V.B. and in the Economic Analysis, EPA considered the anticipated effects of this proposal on the national economy. While the impacts of this rule as a whole are described in Unit XXIII.C. and the impacts of the methylene chloride component of this proposal are described in more detail in Unit VII.A. and in Section 9.3 of the Economic Analysis (Ref. 4), EPA does not anticipate these impacts having an effect on the overall national economy. EPA anticipates that a majority of small businesses will have cost impacts of less than one percent of the annual revenue, and the majority of small business bathtub refinishing facilities and professional contractors will have cost impacts greater than one percent of annual revenue.

The proposed approach is anticipated to drive technological innovation by formulators of paint and coating removal products containing methylene chloride, as they continue to develop substitute products, and refine such products already available. It is also anticipated to drive technological innovation by formulators of chemical paint and coating removal products with different chemistries as well as manufacturers and retailers of alternative methods of paint and coating removal. See also section 9.3 in the Economic Analysis (Ref. 4).

The proposed approach is anticipated to have a positive impact on public health, as described in Unit VI.D. There is anticipated to be a positive impact on the environment, as a result of decreased use of methylene chloride, which is a hazardous air pollutant, as described in Unit III.A.

VIII. Uses of Methylene Chloride for Paint and Coating Removal Critical for National Security

As part of interagency collaboration with the Department of Defense (DOD) on this proposed rule, EPA is aware that there are specific military uses for which methylene chloride is essential for paint and coating removal and for which there are no technically feasible alternatives currently available. The military readiness of DOD's warfighting capability is paramount to ensuring national security, which includes ensuring the maintenance and preservation of DOD's warfighting assets. DOD has identified mission-critical uses for methylene chloride for ensuring military aviation and vessel readiness. These mission-critical items require the use of methylene chloride for the removal of coatings from mission-critical corrosion-sensitive components on military aviation and vessels, including safety-critical components made of specialty metallic, nonmetallic, and composite materials. As described in this section, EPA proposes to exempt these uses from the regulations proposed on methylene chloride in paint and coating removal. This exemption is proposed for an initial ten-year period from the publication date of a final rule. EPA will engage with DOD to identify any potential extension that may need to be granted, by further rulemaking, after those ten years.

DOD has actively sought to reduce its use of methylene chloride in paint and coating removal since 1990. DOD has replaced most of its usage of methylene chloride for paint and coating removal with mechanical methods, benzyl alcohol products, other solvents, and laser ablation. For instance, the Navy's Fleet Readiness Center Southwest has undertaken a successful 20-year effort and eliminated all but a single use on safety-critical components. In an effort to reduce the use of all HAPs such as methylene chloride, the Army has conducted tests to identify and test the effectiveness of HAP-free paint and coating removers on military high-performance coatings (Ref. 61). In another example, the Air Force in December 2015 significantly reduced the use of methylene chloride for removing coatings on flight control parts and is now using substitute chemical products, primarily those with benzyl alcohol formulations (Ref. 65). This phase-out was driven by worker safety concerns and the destructive impact the methylene chloride product had on the installation's industrial wastewater treatment processes. The Air Force

sought alternatives for this use of methylene chloride for paint and coating removal in this industrial process and was successful at qualifying an alternative that met technical requirements (Ref. 65).

In light of these efforts to identify and adopt alternative chemicals or methods, it is unlikely that DOD has overlooked potential substitutes. DOD continues and will continue to pursue potential substitutes. However, for mission-critical corrosion-sensitive components on military aviation and vessels, including safety-critical components, DOD has found that currently available substitute chemicals for paint and coating removal have one or more technical limitations. In these critical and essential applications, currently available substitute chemicals cannot completely remove specific military high performance or chemical resistant coatings, resulting in improperly applied, incompletely adhering replacement coatings. The impacts of this are early coating failure, corrosion of underlying critical parts, shortened service life for critical components (some of which are no longer manufactured), and reduced availability and mission readiness of military aircraft and vessels.

Substitute chemicals currently available are also incompatible with underlying metallic, nonmetallic and composite materials, resulting in material damage to critical components (*e.g.* hydrogen embrittlement) creating immediate damage or longer-term susceptibility to stress fracturing and corrosion. The impacts of this are shortened service life for critical components (some of which are no longer manufactured), reduced availability and mission readiness of military aircraft and vessels, and an increased risk of catastrophic failure of safety critical parts.

Additionally, substitute chemicals or methods currently available do not support the coating removal requirements of safety inspection, non-destructive inspection, material assessment, or field repair processes. This results in an inability to properly perform safety inspections for critical components, leading to undetected fractures and defects. The impacts of this are increased risk of catastrophic failure of safety critical parts.

Under TSCA section 6(g)(1)(B), EPA may grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture if compliance with the requirement would significantly disrupt the national economy, national security, or critical infrastructure. Based on discussions and information provided by DOD, EPA has analyzed the need for the exemption and concurs with DOD that compliance with the proposed regulations on the use of methylene chloride in paint and coating removal would significantly impact national security. DOD has demonstrated that the reduced mission availability of aircraft and vessels for military missions or, in the worst case, the loss of individual military aircraft and vessels, are potential impacts to military readiness that could result from the proposed prohibition of methylene chloride in paint and coating removal. Due to the importance of these military systems for national security, EPA has determined that these uses of methylene chloride for removal of specialized coatings from military aviation and vessel mission-critical corrosion-sensitive components, including safety-critical components, is critical for national security and the safety of personnel and assets. EPA includes in this exemption corrosion-sensitive military aviation and vessel mission-critical components such as landing gear, gear boxes, turbine engine parts, and other military aircraft and vessel components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and magnesium) and composite materials that not only require their coatings be removed for inspection and maintenance but also would be so negatively affected by the use of technically incompatible, substitute paint removal chemicals or methods that the safe performance of the vessel or aircraft could be compromised.

EPA proposes to grant this exemption for a period of 10 years from the date of promulgation of a final rule, with a potential for extension, by further rulemaking, after review by EPA in consultation with DOD. The conditions for this exemption would be: (1) The use of methylene chloride for coating removal by DOD or its contractors performing this work only for DOD projects is limited to the mission-critical corrosion-sensitive components on military aviation and vessels, including safety-critical components; and (2) this paint and coating removal must be conducted at DOD installations, at Federal industrial facilities, or at DOD contractor facilities performing this work only for DOD projects. This exemption granted under TSCA(6)(g)(1)(B) does not impact or lessen any requirements for compliance with other statutes under which the use, disposal, or emissions of methylene chloride is regulated.

As described in Unit VI.C.3., under the proposed approach, any paint and coating removal products containing methylene chloride would be required to be distributed in packaged volumes no less than 55-gallon containers. As part of the exemption for uses identified as critical for national security, for those formulations specifically manufactured for DOD, suppliers may provide paint and coating removal products containing methylene chloride to DOD in containers with a volume no less than 5 gallons. Allowing selective use for national security purposes does not disrupt the efficacy of the supply chain approach described in Unit VI.C.3.

In addition to the exemption described in this unit, EPA will consider granting additional time-limited exemptions, under the authority of TSCA section 6(g), for a specific condition of use for which EPA can obtain documentation: that the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; that compliance with the proposed rule would significantly disrupt the national economy, national security, or critical infrastructure. To this end, EPA requests comment on a process for receiving and evaluating petitions and requesting EPA promulgate critical-use exemption rules. Under this process, entities who believe that their specific condition of use is a critical or essential use under TSCA section 6(g) would submit a petition for an exemption rulemaking with supporting documentation that they believe demonstrates that the use meets the statutory criteria. EPA would review the petition for completeness and, if the documentation warrants further action, respond to the petition by publishing a proposal in the **Federal Register** inviting comment on a proposed exemption. EPA would consider the comments received, along with any additional information reasonably available, and then take final action on the proposed exemption. EPA requests comment on the specific kinds of documentation that should be required from entities seeking an exemption rulemaking in order to facilitate EPA's and later, the public's review. EPA also requests comment on the appropriate timeframes for EPA action, given that the documentation for any given use could be technical and extensive, and that EPA may also need to develop additional information, such as economic estimates, in order to promulgate an exemption rule under TSCA section 6(g). Finally, members of

the potentially regulated community who believe that their operation is a critical or essential use should provide as much detail as possible to EPA about their operation during this comment period, including information on any evaluations of alternatives, the costs to transition to another chemical or process, and any other relevant information. This would assist EPA in reviewing the specific condition of use, as well as in establishing provisions for future exemption petitions.

IX. Overview of Uncertainties for Methylene Chloride in Paint and Coating Removal

A discussion of the uncertainties associated with this proposed rule can be found in the methylene chloride risk assessment (Ref. 2) and in the additional analyses for methylene chloride in commercial and consumer paint and coating removal (Refs. 19, 20, and 38). A summary of these uncertainties follows.

EPA used a number of assumptions in the methylene chloride risk assessment and supporting analysis to develop estimates for occupational and consumer exposure scenarios and to develop the hazard/dose-response and risk characterization. EPA recognizes that the uncertainties may underestimate or overestimate actual risks. These uncertainties include the likelihood that releases of and exposures to methylene chloride vary from one paint and coating removal project to the next. EPA attempted to quantify this uncertainty by evaluating multiple scenarios to establish a range of releases and exposures. In estimating the risk from methylene chloride in paint and coating removal, there are uncertainties in the number of workers, bystanders, and consumers exposed to methylene chloride and in the inputs to the models used to estimate exposures.

In addition to the uncertainties in the risks, there are uncertainties in the cost and benefits. The uncertainties in the benefits are most pronounced in estimating the benefits from preventing deaths due to methylene chloride that have been underreported in most commercial sectors. Additional significant uncertainties in benefits include the entirety of prevention of the non-cancer adverse effects, including underreported deaths (described in Unit VI.E.), because these benefits generally cannot be monetized due to the lack of concentration response functions in humans leading to the ability to estimate the number of population-level non-cancer cases and limitations in established economic methodologies. Additional uncertainties in benefit calculations arose from EPA's use of a forecast from an industry expert to estimate the categories of alternatives that users might choose to adopt and the potential risks for adverse health effects that the alternatives may pose. While there are no products or methods that have comparable cancer or lethal risks, these substitute products and alternative methods do present hazards. Without information on what alternative methods or chemicals users of methylene chloride for paint and coating removal are likely to switch to, and estimates of the exposures for those alternatives, EPA is unable to quantitatively estimate any change in non-cancer risks due to use of substitute chemicals or alternative methods instead of using methylene chloride for commercial or consumer paint and coating removal.

Additional uncertainties include any benefits accrued by commercial users of methylene chloride for paint and coating removal who would benefit from using substitute chemicals and alternative processes. These users would be able to reduce or eliminate costs incurred for emissions control, hazardous waste disposal, or wastewater treatment, which are all required for commercial users of methylene chloride for any purpose.

In addition to these uncertainties related to benefits, there are uncertainties related to the cost estimates. As noted earlier, there is uncertainty in EPA's estimates of which chemical substitutes or alternative methods users may adopt instead of methylene chloride for paint and coating removal, which in turn produces uncertainty as to the cost of those substitutes or methods. EPA has estimated the cost of substitute chemicals, and, in some sectors, some increase in costs due to increased labor required by some substitute methods, but is not able to fully characterize the total costs to all sectors for using substitute chemicals or alternative products. It is possible that some users with paint removal projects that require removing multiple layers of coatings may ultimately save time by switching to a substitute chemical that is more effective than methylene chloride for this particular use. However, changes in time gained or lost during paint and coating removal projects cannot be estimated for all users potentially affected by this proposed rule. In addition, under certain assumptions EPA's economic analysis estimates that some users of methylene chloride for paint and coating removal will see a cost savings when switching to substitutes. Standard economic theory suggests that financially rational companies would choose technologies that maximize profits so that regulatory outcomes would not typically result in a cost savings for the regulated facilities. There could be several reasons that cost savings might occur in the real world. Potential reasons include lack of complete information or barriers to obtaining information on the cost savings associated with alternatives as well as investment barriers or higher interest rates faced by firms. Additionally, there may be costs associated with these alternatives that are not adequately accounted for in the analysis. To evaluate the effect of this uncertainty, EPA has included a sensitivity analysis that sets the cost savings to zero for these compliance alternatives (Ref. 4 at Section 7). EPA also recognizes that these firms might experience positive costs of compliance rather than zero costs, so that the actual total costs could be higher than those in the sensitivity analysis. However, EPA has no current basis to estimate these potentially higher costs, since the available data appear to show that there are lower cost substitutes available. EPA requests comments on these assumptions.

Additionally, there are uncertainties due to the estimates of the number of affected commercial and consumer users, and for numbers of processors and distributors of methylene chloride-containing products not prohibited by the proposed rule who are required to provide downstream notification and/or maintain records.

EPA will consider additional information received during the public comment period. This includes scientific publications and other input submitted to EPA during the comment period.

X. Major Provisions and Enforcement of the Proposed Rule for Methylene Chloride in Paint and Coating Removal

This proposal relies on general provisions in the proposed Part 751, Subpart A, which can be found at 81 FR 91592 (December 16, 2016).

A. Prohibitions and Requirements

The rule, when final, would (1) prohibit the manufacturing, processing, and distribution in commerce of methylene chloride for paint and coating removal for consumer uses and for all commercial uses excluding for commercial furniture refinishing (see Unit XI.) and exempting those defined as critical for national security (see Unit VIII.); (2) prohibit commercial use of methylene chloride for paint and coating removal except for commercial

furniture refinishing and for uses defined as critical for national security; (3) require any paint and coating removal products containing methylene chloride to be distributed in containers with a volume no less than 55-gallons, except for formulations manufactured specifically for the Department of Defense; (4) require manufacturers, processors, and distributors of methylene chloride and all products containing methylene chloride, excluding retailers, to provide downstream notification of the prohibitions; and (5) require recordkeeping relevant to these prohibitions. As described in Unit XI., EPA intends to issue separately a proposal to regulate the risks presented by methylene chloride in commercial furniture refinishing so that those risks are no longer unreasonable; EPA intends to finalize that separate proposal and this proposal together.

The prohibition on manufacturing, processing, and distributing in commerce methylene chloride for consumer paint and coating removal would take effect 180 days after publication of a final rule. Similarly, the prohibition on manufacturing, processing, and distributing in commerce methylene chloride for any non-prohibited paint and coating removal commercial uses in containers with volumes less than 55 gallons would take effect 180 days after publication of a final rule. The prohibition on commercial use of methylene chloride for paint and coating removal except in furniture refinishing or for critical national security uses would take effect 270 days after publication of a final rule. These are reasonable transition periods because, as noted in Unit VI.E. and by the small businesses participating in the SBAR process, many formulators of paint and coating removers containing methylene chloride also manufacture products for this use that do not contain methylene chloride (Ref. 27). In addition, alternative paint removal products exist at comparable expense for users to purchase. Six months from publication of the final rule is sufficient time to allow for existing stocks to move through the market place and to allow manufacturers, processers and distributors and users to plan for and implement product substitution strategies.

B. Downstream Notification

EPA has authority under TSCA section 6 to require that a substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. Many manufacturers and processors of methylene chloride are likely to manufacture or process methylene chloride or products containing methylene chloride for other uses that would not be regulated under this proposed rule. Other companies may be strictly engaged in distribution in commerce of methylene chloride, without any manufacturing or processing activities, to customers for uses that are not regulated. EPA is proposing a requirement for downstream notification by manufacturers, processors, and distributors of methylene chloride for any use to ensure compliance with the prohibition on manufacture, processing, distribution in commerce, and commercial use of methylene chloride for the uses proposed for regulation. Downstream notification is necessary for effective enforcement of the rule because it provides a record, in writing, of notification on use restrictions throughout the supply chain, likely via modifications to the Safety Data Sheet. Downstream notification also increases awareness of restrictions on the use of methylene chloride for paint and coating removal, which is likely to decrease unintentional uses of methylene chloride by these entities. Downstream notification represents minimal burden and is necessary for effective enforcement of the rule. The estimated cost of downstream notification on an annualized basis over 20 years is $40 and $60 using 3% and 7% discount rates respectively (Ref. 4).

The effective date of the requirement for this notification would be 45 days after publication of the final rule. This is a reasonable transition period because regulated entities would only need to provide additional information on their SDS, which are routinely produced and updated.

C. 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 proposed 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 proposed rule when it becomes effective could constitute a separate violation. Knowing or willful violations of this proposed rule when it becomes effective 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.

XI. Furniture Refinishing (Methylene Chloride)

At this time, following input from small entity representatives received during the SBAR process, and based on the SBAR panel recommendations, EPA is not proposing to regulate methylene chloride when used in paint and coating removal in commercial furniture refinishing, also referred to as professional furniture refinishing (Ref. 27). Although EPA proposes to determine that risks to workers using methylene chloride for commercial furniture refinishing are unreasonable, EPA is seeking additional information about this industry to inform development of future proposed restrictions on methylene chloride in commercial furniture refinishing.

A. Description of Commercial Furniture Refinishing

Commercial furniture refinishing consists of several processes, including but not limited to repair, reupholstery, repainting, and depainting or removing paints and coatings, sometimes referred to as furniture stripping. EPA has defined furniture stripping as paint and coating removal from furniture; it includes 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 wood, metal, or other types of furniture, doors, radiators, or cabinets. Furniture stripping can be conducted separately or as a part of furniture refinishing. EPA has defined commercial furniture stripping as furniture stripping conducted in a commercial facility performed by an

individual, government entity, or company for which an individual, government entity, or company receives remuneration or other form of payment.

As described in the methylene chloride risk assessment, to carry out furniture stripping, or to remove paint, lacquer, varnish, or other coatings from wood or metal furniture (or similar items such as doors, radiators, and cabinets), chemical paint and coating removal products may be applied to the furniture by either dipping the furniture in an open tank containing the chemicals, brushing or spraying the product onto the furniture surface, or manually applying the chemical product with a brush, rag, or aerosol spray. Larger furniture refinishing facilities conducting furniture stripping may pump the chemical product through a brush. The application method depends on the size and structure of the furniture as well as the capabilities of the facility (Ref. 2). Some firms may use alternative methods of paint and coating removal, such as sanding or heat/thermal guns, but EPA's information to date indicates that paint and coating removal on furniture is primarily conducted with chemical removers (Refs. 22, 27, 31, 66 and 27).

The area where furniture refinishing workers conducting furniture stripping apply paint and coating removal chemicals typically has a sloped surface to allow for collection and recycling of unused chemical product. Larger facilities use a flow tray to apply the paint and coating removal product or chemical to parts. The flow tray is a sloped, shallow tank with a drain at the lower end. Some facilities may use a dip tank to immerse whole pieces or parts of furniture in the chemical product (Refs. 2 and 22).

After a worker applies the chemical product or immerses the piece of furniture in it, the paint and coating remover is left to soak, or "dwell," on the furniture surface to soften the paint, coating, or varnish. Once soaking is complete, a worker manually scrapes or brushes the unwanted coating from the furniture surface. The worker then transfers the furniture to a washing area where they wash the waste chemical and paint or coating sludge from the furniture. Workers can wash the treated furniture with low-pressure washing operations or high-pressure water jets or high-pressure wands. Wash water may contain oxalic acid to brighten the wood surface. Wash water is collected and either recycled or disposed of as waste. After washing, the worker transfers the furniture to a drying area where it is allowed to dry before being transferred to other refinishing processes (*e.g.*, sanding, painting, reupholstery) (Ref. 2).

Based on industry research and discussions with stakeholders, EPA is aware that most commercial furniture refinishing firms primarily use chemical methods for paint and coating removal, and that methylene chloride or methylene chloride-based products are the types of chemical paint removers primarily and, in some firms, exclusively, used. Some commercial furniture refinishers, including some small businesses participating in the SBAR process, have said that although they make limited use of acetone for some types of furniture, they have not found any workable substitutes for methylene chloride as a primary paint and coating removal method (Refs. 22 and 27). More information on the potential use of substitutes for furniture refinishing is provided in Unit XI.E.

B. Risks Associated With Furniture Refinishing

The methylene chloride risk assessment and additional supplemental analyses identified acute and chronic risks from inhalation of methylene chloride during paint and coating removal by consumers, commercial users, and bystanders in residences or workplaces (individuals not using the paint and coating remover but nearby a user) (Refs. 2, 19, 20, and 38). This includes an assessment of the risks from methylene chloride when used in commercial furniture refinishing. EPA estimates that, annually, there are approximately 15,000 workers at 4,900 commercial refinishing operations conducting paint and coating removal with methylene chloride (Ref. 4).

1. Exposures assessed to methylene chloride during commercial furniture refinishing and immersion stripping. Exposures assessed for workers in commercial furniture refinishing include acute and chronic exposures to methylene chloride for paint and coating removal, as described in the methylene chloride risk assessment (Ref. 2). The exposure pathways of interest included dermal contact and inhalation, but, due to limitations described in the risk assessment, the assessment was based only on the inhalation route of exposure. Different exposure scenarios were evaluated for workers, occupational bystanders, consumers, and residential bystanders (Ref. 2). Not included in the assessment but important to note are bystanders in commercial refinishing operations that are located in workshops or other parts of residences; here, the bystanders may include not only workers but also children and occupants of the home.

In addition to estimating likely exposures under current use patterns, for both commercial and consumer users, EPA assessed a number of exposure scenarios associated with risk reduction options in order to identify variations in methylene chloride exposure during paint and coating removal. All variations in the scenarios were applied to industry-specific exposure inputs and evaluated with exposure parameters that were modified to reflect either a reasonable worst-case scenario (also called the baseline) or a scenario in which exposures were moderated by several factors (also called the central tendency scenario). The risk reduction options varied between scenarios and included engineering controls and use of personal protective equipment (PPE), as well as combinations of these options (Ref. 19).

- Under the PPE risk reduction option exposure scenarios, EPA evaluated respirators with APF 10 to 10,000 for acute and chronic risks, including cancer risks.
- For the engineering controls risk reduction option exposure scenarios, EPA evaluated using local exhaust ventilation (LEV) to improve ventilation near the activity of workers in furniture refinishing operations, with an assumed 90% reduction in exposure levels.

Overall, EPA evaluated several distinct exposure scenarios for paint and coating removal with methylene chloride for commercial furniture refinishing. Additionally, EPA evaluated several distinct exposure scenarios for miscellaneous paint and coating removal conducted by immersion of the object in vats or tanks of methylene chloride (dip methods), since this has been reported as a method of paint and coating removal during furniture refinishing (Refs. 19 and 27).

The results of these evaluations of exposure scenarios demonstrate that the scenarios meeting all relevant health benchmarks for all scenarios of methylene chloride in paint and coating removal in commercial furniture refinishing requires: (1) A respiratory protection program using a supplied-air respirator with APF of 1,000 or 10,000, depending on type of method used for applying methylene chloride or workplace characteristics, such as the size of the facility; (2) reducing exposures with LEV that can achieve 90% efficiency in air flow plus worker respiratory protection with APF 1,000; or (3) elimination of exposure to methylene chloride by using an alternative method of paint and coating removal (Ref. 19). Although non-cancer risks and cancer risks were estimated using separate measures, exposure

reduction that is protective against non-cancer risks from methylene chloride is also protective against cancer risks.

2. Risks assessed from methylene chloride during commercial furniture refinishing and immersion methods. Exposure to methylene chloride is associated with death, neurotoxicity, liver toxicity, and cancer in humans and animals. To estimate non-cancer risks for acute and chronic exposures, the methylene chloride risk assessment used MOEs. Exposure scenarios with MOEs below the benchmark MOE have risks of concern, as explained in detail in the methylene chloride risk assessment. For acute and chronic exposure scenarios, the benchmark MOE is 10 (Ref. 2). The benchmark MOE identifies a risk of concern for a given endpoint; it is obtained by multiplying the total uncertainty factors associated with each health endpoint's point of departure. For more information on uncertainty factors, see Unit IV.B.

The acute inhalation risk assessment used central nervous system effects to evaluate the acute risks for occupational, consumer, and bystander exposure during paint and coating removal with methylene chloride. A risk of concern was identified if the MOE estimate was less than the benchmark MOE of 10 (Ref. 2).

EPA assessed acute risks for central nervous system effects from inhalation for workers using methylene chloride for commercial furniture refinishing and for immersion methods of paint and coating removal for various objects, including furniture. Acute risks were estimated in this sector, even in the presence of respirators with APF 10 or APF 25. MOEs for acute risks in commercial furniture refinishing ranged from a central tendency of 0.08 to 0.035, with a high end of 0.0063 (workplaces engaged in paint and coating removal using immersion methods). In general, these workplaces are estimated to present exposure levels between 125 times to greater than 1,500 times more than those that are expected to produce no risks of concern. Not only workers, but also occupational bystanders, or workers engaged in tasks other than paint and coating removal, would be at acute risk for central nervous system effects.

EPA also assessed risks of chronic exposure to workers using methylene chloride for commercial furniture refinishing. The methylene chloride risk assessment used liver toxicity as the critical endpoint for chronic exposure. The selected exposure scenarios represented inhalation exposures with a range of conservative assumptions. As described earlier, the assumptions were then varied, such as use of PPE (supplied-air or other respirator) and duration of time spent in contact with the product (days and years). EPA assessed risks for liver toxicity (with effects that include vacuolation and fatty liver) for occupational and bystander exposure scenarios of paint and coating removal with methylene chloride.

Workers and occupational bystanders in this industry were estimated to be at risk of non-cancer liver toxicity as a result of chronic exposure to methylene chloride during paint and coating removal under typical exposure scenarios. When workers' exposures were estimated at facilities repeatedly reporting moderate or high methylene chloride air concentration levels, EPA estimated that there were risks of concern for these workers, even for scenarios evaluated with workers wearing respiratory protection with APF 50. Among all of the occupational scenarios, the greatest risk of concern is for workers engaging in long-term use of the product (*i.e.,* 250 days/year for 40 years) with no respiratory protection. For those workers, MOEs for chronic exposures were 0.025, or reflective of risks 400 times greater than the benchmark. Even for workers assumed to have lower exposure, MOEs did not reach 10. In most workplaces engaged in commercial furniture refinishing, MOEs for chronic exposure ranged from a central tendency of 0.60 to 0.3. Additionally, in EPA's risk assessment scenarios, which are not necessarily reflective of industry-wide work practices, for workers and bystanders assumed to have the lowest exposure (respirator APF 50, limited exposure duration, and moderate air concentration), MOEs for chronic exposure were 5, or one-half of the benchmark (Ref. 2).

For commercial users and bystanders, EPA also assessed cancer risks as a result of chronic exposure to methylene chloride in paint and coating removal in commercial furniture refinishing. Methylene chloride is a likely human carcinogen; cancer risks determine the incremental increased probability of an individual in an exposed population developing cancer over a lifetime following exposure to the chemical under specified use scenarios. Common cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk of one in one million or one in ten thousand (*i.e.,* 1×10^{-6} or 1×10^{-4}). Estimates of cancer risk should be interpreted as the incremental increased probability of an individual in an exposed population developing cancer over a lifetime as a result of exposure to the potential carcinogen (*i.e.,* incremental or excess individual lifetime cancer risk) (Ref. 2).

In the methylene chloride risk assessment, when exposure for workers and occupational bystanders was estimated in facilities conducting commercial furniture refinishing, EPA identified excess cancer risks if these workers and bystanders were exposed to paint and coating removal with methylene chloride for 250 days per year for 40 years with no respiratory protection. Cancer risks ranged from 2 in 10,000 to 8 in 10,000, with a maximum of 5 in 1,000 (workplaces using immersion methods) (Ref. 2).

For commercial users and occupational bystanders in commercial furniture refinishing, acute and chronic risks were assessed based on the typical occupational exposure parameters, which may include several hours per day of exposure over several years of work. For these reasons, any risk mitigation measures must address not only acute risks, but also chronic risks, including both cancer and non-cancer effects. For these reasons, the most sensitive endpoint for risk mitigation must be considered, whether it derives from acute or chronic exposure.

3. Impacts of the exposures. As discussed for other commercial uses in Unit VI.E., exposure to methylene chloride in paint and coating removal, when conducted in commercial furniture refinishing and for other purposes, is associated with a range of adverse health effects, which include impacts on the nervous system, liver, respiratory system, kidneys, and reproductive systems. In some instances, these effects may appear relatively mild, such as dizziness, which occurs early in exposure and at low exposure levels. However, with increasing levels of exposure or increasing duration, these effects can take the form of generally irreversible health effects such as cognitive impairment, sensory impairment, coma, heart failure, liver toxicity, brain cancer, liver cancer, non-Hodgkin lymphoma, and multiple myeloma.

Acute exposure to methylene chloride during paint and coating removal can be fatal; since 1980, at least seven workers have died while using methylene chloride for commercial furniture refinishing. Data from OSHA indicate that the circumstances of death vary. For example, some workers collapse while conducting paint and coating removal over or near dip tanks, frequently falling into the tanks and subsequently dying. This was the case in 1985 in Pennsylvania, 1986 in Colorado, 1990 in Connecticut, and

2000 in Pennsylvania (Ref. 7). The worker in Connecticut earlier complained that the vapors were making him dizzy, and shortly after slumped into the dip tank and died; the worker in 2000 in Pennsylvania was found face-down in the dip tank next to the shutters from which he was attempting to remove paint (Ref. 7). Other workers in commercial furniture refinishing facilities lose consciousness at their workplace, but die sometime later, such as a worker in 1991 in Colorado, and in 1999 in Tennessee (Ref. 68).

These are likely not the only deaths in commercial furniture refinishing due to methylene chloride; as discussed in Unit VI.E., many deaths due to methylene chloride have not been recorded due to a lack of reporting to the OSHA incident database by self-employed individuals and the likelihood that deaths due to methylene chloride exposures are misattributed to heart disease, since the pathology is similar (Ref. 33).

In addition to fatalities, methylene chloride exposure during commercial wood refinishing has caused acute effects, such as the 1996 case of a cabinet manufacturer employee who experienced chronic headaches found to be due to methylene chloride exposure when the doors at his facility were closed in the winter months (Ref. 69).

In most commercial furniture refinishing facilities using methylene chloride for paint and coating removal, worker and occupational bystander exposure concentrations are orders of magnitude above what would be necessary to achieve the benchmark MOE of 10 for acute and chronic non-cancer effects. For acute health effects such as nervous system impacts, EPA estimated an MOE of 0.08 for workers in commercial furniture refinishing. For chronic non-cancer health effects such as liver toxicity, workers in this industry have an MOE of 0.6 to 0.3 (Ref. 2). For a description of MOEs and their use in risk assessment, see Unit IV.B.

In each case, workers in commercial furniture refinishing using methylene chloride for paint and coating removal are exposed at a level that is generally 125 to 1,500 times higher than what EPA has found to be a level that would not present acute or chronic non-cancer risks of concern. These risks of concern are for effects such as death, multiple adverse chronic health effects, and the subsequent lifetime impacts from these effects. Additionally, individuals occupationally exposed to methylene chloride in paint and coating removal may also be impacted by an increased risk for several types of cancer. The cancer risks to workers in commercial furniture refinishing using methylene chloride for paint and coating removal range from 8 cases in 10,000 people to 5 cases in 1,000 people (workplaces using immersion methods) (Ref. 2).

EPA's risk estimates are corroborated by research conducted independently investigating working conditions at commercial furniture refinishing and OSHA enforcement of their methylene chloride standard. In 1990, as a result of several cases of methylene chloride poisoning during paint and coating removal in commercial furniture refinishing in Colorado, occupational medicine specialists from the University of Colorado surveyed the 21 small shops in the Denver area engaged in commercial furniture refinishing. These researchers found that of the 21 shops, no workers wore respirators at all in seven shops, and in 14 facilities, workers occasionally wore half-face respirators with organic vapor cartridges (which do not provide respiratory or eye protection from methylene chloride). In ten of the 21 shops, workers experienced acute nervous system effects, such as dizziness or nausea while working to remove coatings from furniture. The researchers concluded that "current safety practices in small-scale furniture-stripping shops may be inadequate to keep methylene chloride exposure levels in compliance with latest recommendations, and serious or fatal overexposure can occur" (Ref. 70).

When considering the benefits of preventing exposure to methylene chloride in paint and coating removal in commercial furniture refinishing, EPA considered the type of effect, the severity of the effect, the duration of the effect, and costs and other impacts of the health endpoint. The health endpoints associated with exposure to methylene chloride are serious. Unit VI.E. presents a detailed discussion of the impacts of the most significant acute, chronic non-cancer, and cancer effects associated with methylene chloride exposure during paint and coating removal, including the severity of the effect, the manifestation of the effect, and how the effect impacts a person during their lifetime. These effects include nervous system effects resulting from acute exposures, such as sensory impairment, incapacitation (loss of consciousness), and death; and effects resulting from chronic, occupational exposures including liver toxicity and liver cancer, hematopoietic cancers, brain cancer, lung cancer, reproductive effects, and kidney toxicity.

There are increased risks of death, nervous system effects, and liver, lung, brain, reproductive, and kidney effects for the approximately 15,000 workers in 4,900 commercial facilities or companies that use methylene chloride for paint and coating removal during commercial furniture refinishing each year (Ref. 4).

C. Approaches That Could Reduce the Risks of Methylene Chloride Used in Furniture Refinishing to Benchmark Levels

Although EPA is not proposing to regulate the use of methylene chloride in paint and coating removal for commercial furniture refinishing, EPA has identified potential requirements for methylene chloride in paint and coating removal for commercial furniture refinishing that could reduce exposures so that the risks presented would no longer be unreasonable. EPA is providing advanced notice of these potential approaches and is seeking comment on them.

1. Prohibition on manufacturing, processing, distribution, and use of methylene chloride in commercial furniture refinishing. Similar to the approach proposed for regulation of methylene chloride in other commercial paint and coating removal (see Unit V.), EPA has identified a prohibition on manufacturing, processing, distribution, and use of methylene chloride in commercial furniture refinishing as an option for reducing risks in this industry to benchmark levels, under TSCA sections 6(a)(2) and 6(a)(5). This approach could also require manufacturers, processors, and distributors to provide downstream notification of the prohibitions under TSCA section 6(a)(3), and could require recordkeeping relevant to these prohibitions under TSCA section 6(a)(4).

Under this approach, exposures to methylene chloride during paint and coating removal in commercial furniture refinishing would be completely eliminated. As a result, not only non-cancer risks, but also cancer risks would be eliminated.

2. Requiring a respiratory protection program, including PPE, air monitoring, and either a supplied-air respirator of APF 1,000 or 10,000 or an air exposure limit of 1 part per million (ppm) achieved through engineering controls or ventilation, in commercial facilities for furniture refinishing using methylene chloride for paint and coating removal under TSCA section 6(a)(5). Another regulatory approach that EPA has considered for the use of methylene chloride for paint and coating removal in commercial furniture refinishing would be to require risk reduction through an occupational respiratory

protection program, which would include air monitoring, medical monitoring, and respiratory protection through use of a supplied-air respirator with an APF of 1,000 or 10,000, depending on the methods used for paint and coating removal with methylene chloride and other workplace characteristics, with a performance-based option of meeting an air concentration level of 1 ppm as an exposure limit for methylene chloride.

A full-face (or helmet/hood) self-contained breathing apparatus (SCBA) when used in the pressure demand mode or other positive pressure mode has an APF of 10,000. EPA's analysis found that use of a SCBA with an APF of 10,000 would, in all scenarios evaluated, control the methylene chloride exposure to levels that allow for meeting the benchmarks for non-cancer and cancer risks. In some commercial furniture refinishing facilities using methylene chloride for paint and coating removal, workers with a supplied-air respirator with an APF of 1,000 would experience reduced exposures to methylene chloride such that their risks would be reduced to benchmark levels (Ref. 19). It is important to note that current OSHA requirements for dermal and eye protection when using methylene chloride in any way would be maintained under this approach, in addition to other requirements for work practices, training, and hazard communication put forth in OSHA's Methylene Chloride Standard (29 CFR 1910.1052).

EPA seeks comment on whether commercial furniture refinishing operations have these types of respiratory protection programs in place, any experiences in complying with the current OSHA methylene chloride standard, methods of reducing costs associated with these programs, and recommended approaches for small businesses considering a respiratory protection program that would include supplied-air respirators.

EPA also considered requiring a combination of local exhaust ventilation and respirators with APF of 1,000 or 50, with a performance-based option of an air exposure limit of 1 ppm as an eight-hour TWA. When properly executed, this option would reduce risks to the health benchmarks for workers and bystanders (Refs. 19 and 38). However, while this option has the benefit of incorporating engineering controls and the use respirators with a lower APF, the limitations to successful implementation of the use of supplied-air respirators in the workplace discussed previously are still present.

Further, this option would also require the use of prescriptive and expensive engineering controls to ensure that the exposures are below the benchmark cancer risks (Ref. 19). In an examination of the impacts of its methylene chloride standard, OSHA in 2010 found that furniture refinishing facilities in particular have not installed ventilation systems that would lower worker exposures to methylene chloride (Ref. 68). OSHA's assessment found that this is largely due the fact that most of these facilities are part of small businesses, and they tend to be less able to have sufficient capital to purchase the ventilation systems. Additionally, this type of ventilation requires make-up air systems, which have an additional cost and which, in cold climates, would need to heat the air and thus increase energy costs (Ref. 68).

Even if these engineering controls were installed, research conducted by the National Institutes of Occupational Safety and Health (NIOSH), as well as independent researchers, has indicated that ventilation alone is generally not able to reduce methylene chloride exposures below 25 ppm (Refs. 68 and 71), and there is no indication that a level close to 1 ppm (an acceptable exposure limit) could be reached.

3. Approaches that do not mitigate the risks of methylene chloride in commercial furniture refinishing to benchmark levels. As described in Units IV.B. and IV.C., EPA evaluated dozens of distinct exposure scenarios across consumer and commercial uses of methylene chloride for paint and coating removal, including in commercial furniture refinishing. The results of EPA's evaluation indicate that regulatory approaches for occupational exposures in commercial furniture refinishing such as reducing the concentration of methylene chloride in products used for paint and coating removal and using local exhaust ventilation to improve ventilation, in the absence of PPE, could not achieve the target MOE benchmarks for non-cancer endpoints for acute and chronic exposures and standard cancer risk benchmarks for chronic exposures (Refs. 26 and 29). The results also demonstrate that all risk reduction options meeting the benchmark MOEs and cancer benchmarks for methylene chloride in paint and coating removal in commercial furniture refinishing require the use of a supplied-air respirator, whether used alone or in conjunction with additional levels of protection. Therefore, EPA found that setting a maximum concentration of methylene chloride in products under section 6(a)(2) could not reduce exposures so that risks from paint and coating removal with methylene chloride in commercial furniture refinishing would be reduced to benchmark levels. Options found not to meet the risk benchmarks are documented in EPA's supplemental technical reports on methylene chloride in paint and coating removal (Refs. 19, 20, 21, and 38).

D. Costs of EPA's Potential Approach for Regulation

EPA is at this time seeking additional information to inform its consideration of the reasonably ascertainable economic consequences of an action that would address the risks of commercial furniture refinishing so that they are no longer unreasonable, as required under TSCA section 6(c)(2)(A)(iv). This section presents the information EPA currently has and identifies the information that EPA is seeking. While the costs of potential risk management actions are not a legally permissible basis for EPA to reassess its proposed unreasonable risk determination, see TSCA section 6(b)(4)(A), costs are relevant to deciding among alternative risk management approaches that reduce risk so that a chemical substance no longer presents unreasonable risk and in establishing compliance dates for a risk management approach that is ultimately selected.

1. Information available to EPA. Based on industry research and information provided by stakeholders, including during informal discussions and more formally from small entity representatives participating in the SBAR process (described in more detail in Unit XXIII.), EPA has learned that there may not be any substitute chemicals or alternative practices frequently in use for paint and coating removal in commercial furniture refinishing other than chemical paint and coating removal with methylene chloride (Refs. 22 and 27).

Primary chemical substitutes for methylene chloride in commercial paint and coating removal more generally include products formulated with benzyl alcohol; dibasic esters; acetone, toluene, and methanol (ATM); and caustic chemicals. These substitute chemicals, their hazards, and their environmental impacts are described in more detail in Unit VI.E. EPA has learned that these chemicals are generally not suitable for paint and coating removal in furniture refinishing since they either are ineffective at removing particular coatings frequently found on furniture (such as varnish, lacquer, or older paint formulations in multiple layers); are formulated to include large amounts of water and thus

incompatible with wood objects that can become saturated and damaged (as is the case with many products containing benzyl alcohol); or are chemically incompatible with wood and can result in damage or raising the grain on the object (as is the case with caustic paint and coating removal products) (Refs. 22 and 27). Products that may be chemically compatible with wood substrates or the paints, varnishes, or lacquers to be removed were described by stakeholders as requiring too long a dwell time to be efficacious for their business and thus are not used (Refs. 22 and 27). Other than two commercial furniture refinishers who remove paints and coatings on some solid wood objects with either immersion in 100% acetone or an acetone-toluene-methanol blend, no commercial wood finishing firms reported using substitute chemicals routinely for paint and coating removal, and none felt they were able to completely eliminate use of methylene chloride, despite being aware of the worker health and environmental impacts (Refs. 22 and 27).

In addition to substitute chemical products, EPA has identified non-chemical methods for commercial paint and coating removal that can be used more generally as alternatives to methylene chloride. Frequently-used alternative methods to chemical paint and coating removal include thermal removal, sanding, hydroblasting, abrasive blasting, and laser removal (Refs. 22 and 27). These methods are already frequently in use in various industries for paint and coating removal (Refs. 22, 27, and 31); they and their acute and chronic hazards to workers are described in more detail in Unit VI.E.

For commercial furniture refinishing, EPA has learned that all firms engage in varying amounts of mechanical or hand-sanding but do not consider it a primary method of paint and coating removal (Refs. 22 and 27). Additionally, despite the hand scraping or brushing that is required to remove waste paint from furniture and other objects for which methylene chloride has been used to remove paint or coatings, most stakeholders described sanding as too time consuming or labor intensive to use routinely as a primary method of paint and coating removal. Additionally, though many other commercial sectors have adopted various soft media blasting techniques for delicate substrates, such as using soda blasting on fiberglass vehicle parts, EPA has not found this to be a practice used in commercial furniture refinishing (Refs. 22 and 27).

EPA is seeking additional information to inform its consideration of the impacts on commercial furniture refinishing if use of methylene chloride as a paint and coating remover were prohibited or restricted.

2. Information sought. To aid in identifying the economic impacts on commercial furniture refinishers of any potential prohibition or restriction on methylene chloride for paint and coating removal, EPA is seeking the following information related to the approach that would prohibit the use of methylene chloride for paint and coating removal in furniture refinishing:

- What percent of business for firms in this sector is paint and coating removal, versus furniture repair, reupholstery, or other furniture refinishing functions?
- How likely is it that firms in this sector would close if methylene chloride were prohibited from use in paint and coating removal in this sector?
- What would the impact be on this sector if all firms were prohibited from using methylene chloride for paint and coating removal, and thus any changes in work processes or dwell time would be universally experienced?
- Have firms had any success with substitute chemicals or alternative methods of paint and coating removal? If not, which aspects of the chemical or method renders the substitute or alternative ineffective?

Related to the approach that would require a respiratory protection program, including either a supplied-air respirator with either APF 1,000 or APF 10,000, or engineering controls or ventilation to reach an exposure limit of 1 ppm:

- What is the current experience of firms in this sector with supplied-air respirators and/or engineering controls?
- What is the current experience of firms in this sector with ventilation systems, makeup-air systems, and other engineering controls?
- What types of exposures do workers in firms in these sectors currently experience?

EPA has found that commercial furniture refinishing primarily uses methylene chloride for paint and coating removal and that no current chemical substitutes are seen as useful alternatives. However, in recent decades, substitute products have been developed for other types of paint and coating removal, and it is possible that new substitute chemicals or products could be developed to address the special coatings or substrates involved in commercial furniture refinishing. Several formulators and research organizations are exploring possibilities for efficacious and cost-effective substitute chemicals.

Additionally, outside of the United States, commercial furniture refinishers have adopted methods that are alternatives to chemical paint and coating removal. For example, most paint and coating removal in Sweden is conducted by thermal methods, such as heat guns or heat lamps, including for commercial furniture refinishing (Ref. 72). In Denmark, firms engaging in commercial furniture refinishing are reported to use large microwave furnaces, which can hold large pieces of furniture (Ref. 73).

These alternative methods and the research into substitute chemicals indicate that it is now and in the future may increasingly be possible to remove paint and coatings from furniture without methylene chloride. If that were the case, EPA would be able to more straightforwardly identify the costs and impacts of any proposed regulation of methylene chloride for paint and coating removal in commercial furniture refinishing. EPA is seeking additional information on the use and development of substitute chemicals and alternative methods that would be useful in commercial paint and coating removal on furniture, including information on:

- What are the current considerations when selecting a paint and coating removal chemical for furniture refinishing or refinishing of other wood objects or surfaces?
- What are the current considerations when selecting a paint and coating removal method for furniture refinishing or refinishing of other wood objects or surfaces?
- Are there substitute chemicals or alternative methods in use beyond what EPA has identified in this notice?
- Are any new paint and coating removal product formulations or chemistries under development?
- Are any new paint and coating removal methods in development for furniture refinishing, or refinishing of other wood objects or surfaces?

E. Public Engagement To Identify Impacts and Alternatives

To learn more about paint and coating removal in furniture refinishing, foreseeable impacts of any proposed regulations, and alternatives to methylene chloride, EPA plans to hold a series of stakeholder meetings. These meetings will focus on current practices related to methylene chloride for paint and coating removal in commercial furniture refinishing; any substitute chemicals or alternative methods currently in use or under development;

and current and best practices related to respiratory protection programs and exposure reduction.

EPA will announce dates and locations of these meetings in a future notice in the **Federal Register** as well as on EPA's Web site. EPA will provide some of these meetings electronically by Webinar to maximize public participation.

F. Next Steps

EPA views this section as an Advanced Notice of Proposed Rulemaking, and intends to issue a Notice of Proposed Rulemaking following the series of stakeholder meetings and further analysis on the cost impacts of regulatory action on this industry. Following that proposal and public comment period, EPA intends to finalize together the regulations proposed and the future proposal related methylene chloride in commercial furniture refinishing.

XII. Overview of NMP and Uses Subject to This Proposed Rule

A. What chemical is included in the proposed rule?

This proposed rule would apply to N-methylpyrrolidone (Chemical Abstract Services Registry Number (CASRN) 872–50–4) when used in paint and coating removal.

B. What are the uses of NMP and how can people be exposed?

NMP is a solvent used in a variety of industrial, commercial and consumer use applications, including (Ref. 3):

- Petrochemical processing, acetylene recovery from cracked gas, extraction of aromatics and butadiene, gas purification, lube oil extraction;
- Plastics engineering, as a reaction medium for the production of high-temperature polymers such as polyethersulfones, polyamideimides and polyaramids;
- Use in coatings, as a solvent for acrylic and epoxy resins, polyurethane paints, waterborne paints or finishes, printing inks, synthesis/diluent of wire enamels, coalescing agent;
- Production of agricultural chemicals: Solvent and/or co-solvent for liquid formulations;
- Electronics cleaning: Cleaning agent for silicon wafers, photoresist stripper, auxiliary in printed circuit board technology; and
- Industrial and domestic cleaning, including as a component in degreasers and paint removers.

According to the 2012 CDR information, approximately 180 million pounds of NMP were produced or imported into the U.S. that year (Ref. 3).

Individuals, including workers, consumers, and the general population are exposed to NMP from industrial/commercial and consumer sources, in different settings such as homes and workplaces, and through multiple routes (inhalation, dermal, and vapor-through-skin).

According to data in the 2014 TRI, 386 facilities reported releases or transfers of NMP and the top 100 facilities disposed of or released a total of 10.2 million pounds of NMP (Ref. 6).

The use assessed by EPA that is the subject of this proposal, NMP in paint and coating removal, represents about 9% of total use of NMP (Ref. 3). Paint and coating removal is the 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. Substrates can include objects, vehicles, architectural features, or structures. This use is discussed in detail in Unit XVI.A.

Although the TSCA Work Plan Chemical risk assessment for NMP focused on the chemical's use in paint and coating removal, EPA announced in December 2016 its designation of NMP as one of the ten chemical substances that will undergo risk evaluation pursuant to TSCA section 6(b)(2)(A) (81 FR 91927). The Agency is proceeding with this proposed rule addressing NMP in paint and coating removal in accordance with TSCA section 26(l) and asks for comment on its decision to pursue risk management for specific conditions of use of NMP while preparing to conduct a risk evaluation of remaining NMP conditions of use under TSCA section 6(b).

C. What are the potential health effects of NMP?

NMP is a developmental toxicant (Ref. 3). A broad set of relevant studies including animal bioassays in rats, mice, and rabbits show that maternal NMP exposure is associated with dose-dependent adverse developmental impacts on the fetus (including body weight reductions and fetal death). Developmental toxicity is the most sensitive endpoint. Other adverse impacts resulting from NMP exposure include effects on maternal body weight; alterations in blood cell counts; liver, kidney, splenic, thymus, and testicular effects; and neurotoxicity.

Nearly every study that evaluated developmental toxicity of NMP exposure identified some type of adverse effect depending on the route of exposure and the internal dose achieved. Moreover, a review of effect levels reveals that these effects are observed within a comparable dose range when administered doses are converted to internal doses for a series of gestational exposure studies in rats. The NOAELs for these comparable developmental studies typically ranged from 100 to 200 mg/kg/day for oral exposure, 237 mg/kg/day for dermal exposure, and 479 to 612 mg/m^3 for inhalation exposure. EPA applied a physiologically-based pharmacokinetic model to derive internal doses for these exposure scenarios to compare across routes and aggregate exposures. Specifically, EPA identified a number of biologically relevant, consistent, and sensitive effects, representing a continuum of reproductive and developmental effects for consideration in assessing human health risks, including decreased fetal and postnatal body weight, delayed ossification, skeletal malformations, and increased fetal and postnatal mortality. EPA identified a point of departure for decreased fetal body weight based on the average blood concentration of 411 mg/L. Studies have shown acute effects of NMP exposure to include fetal mortality and indications of fetal resorptions in rodents and a point of departure based on maximum blood concentration of 216 mg/L. Fetal and postnatal mortality have also been observed in oral and dermal studies (Ref. 3).

Chronic effects of NMP exposure include fetal body weight decreases. These effects were consistent among multiple studies with different dosing regimens and across exposure routes. Reduced fetal body weight is a sensitive endpoint that is considered a marker for fetal growth restriction, which is often assumed to be representative of chronic exposures. Decreases in fetal and postnatal body weights occur at similar dose levels (Ref. 3).

There is one case report of the fetus of a pregnant woman dying in utero at week 31 of pregnancy. The worker was exposed throughout pregnancy to NMP by inhalation and dermal exposure, but the exposure levels were unknown. The worker's tasks involved other chemicals, including acetone and methanol. During week 16 of the pregnancy, the worker cleaned up a spill of NMP using latex gloves that dissolved in the NMP. She was ill for the next 4 days and experienced malaise, headache, nausea and vomiting. While this study provides some evidence that NMP may be fetotoxic, the lack of quantitative exposure data precluded its use in the TSCA Work Plan Chemical Risk Assessment for NMP (Ref. 3).

Chronic effects of NMP exposure include systemic effects following

maternal exposure, which include body weight reductions, alterations in clinical chemistry and blood cell counts, liver and kidney toxicity, neurotoxicity and thymic atrophy, with highly variable dose levels where no observed adverse effects occurred (Ref. 3).

An additional effect of chronic NMP exposure is reproductive toxicity, though these findings are significantly less frequent or consistent than the occurrence of developmental effects. When observed, reproductive effects were variable in occurrence and dose effect range. Several rat studies identified some type of testicular effect, including testicular lesions, atrophy or smaller testes. Similarly, a small number of rat studies noted some effects related to developmental neurotoxicity in postnatal development and behavior following maternal exposure (Ref. 3).

In addition to developmental toxicity, exposure to NMP presents other acute and chronic toxicity concerns. Acute effects include skin, eye, and possible respiratory irritation. Human volunteer chamber studies revealed some discomfort during exposure. Prolonged exposures to neat (*i.e.,* pure) NMP increases the permeability of the skin (Ref. 3).

D. What are the environmental impacts of NMP?

Section 6(c) of TSCA requires that EPA state the effects of NMP on the environment and the magnitude of the exposure of the environment to NMP. The proposed unreasonable risk determination, however, is based solely on risks to human health since these risks are the most serious consequence of use of NMP and are sufficient to support this proposed action.

1. *Environmental effects and impacts.* Ecotoxicity studies for NMP have been conducted in fish, aquatic invertebrates, aquatic plants and birds. There were no acceptable studies identified for sediment or soil dwelling organisms. Based on available data in the NMP risk assessment, EPA concluded that NMP has low acute and chronic toxicity to aquatic organisms (including plants) and birds (Ref. 3). Based on NMP's low persistence, low bioaccumulation, and low hazard for environmental toxicity, the magnitude of potential environmental impacts on ecological receptors are judged to be low for the environmental releases associated with the use of NMP in paint and coating removal.

2. *What is the global warming potential of NMP?* Global warming potential (GWP) measures the potency of a greenhouse gas over a specific period of time, relative to carbon dioxide, which has a GWP of 1 regardless of the time period used. No GWP has been developed for NMP because of its very short atmospheric lifetime. Based on its very short half-life, its GWP is expected to be very low (Ref. 3).

3. *What is the ozone depletion potential of NMP?* NMP is not an ozone-depleting substance and is listed as acceptable under the Significant New Alternatives Policy (SNAP) program for degreasing and aerosols (Ref. 9).

4. *Is NMP a volatile organic compound (VOC)?* NMP is not a VOC as defined at 40 CFR 51.100(c). A VOC is any compound of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions.

5. *Does NMP persist in the environment and bioaccumulate?* NMP is not persistent or bioaccumulative. Biodegradation studies have consistently shown NMP to be readily biodegradable. Based on its vapor pressure, NMP released to the atmosphere is expected to exist solely in the vapor-phase. Vapor-phase NMP is degraded in air by reaction with photochemically-produced hydroxyl radicals. The half-life of this reaction is approximately 5.8 hours, assuming a hydroxyl radical concentration of 1.5×10^6 hydroxyl radicals/cm^3 air over a 12-hr day. NMP in the atmosphere can be expected to dissolve into water droplets, where it will be removed by condensation or further reactions with hydroxyl radicals (Ref. 3).

When released to water, NMP is not expected to adsorb to suspended solids or sediment in the water column based upon its Koc value. Based on its low soil organic carbon partitioning coefficient (log Koc = 0.9), NMP is expected to possess high mobility in soil; releases of NMP to soil may volatilize from soil surfaces or migrate through soil and contaminate groundwater (Ref. 3).

EPA was not able to locate measured bioconcentration studies for NMP; however, the estimated bioaccumulation factor of 0.9 and estimated bioconcentration factor of 3.16 suggest that bioaccumulation and bioconcentration in aquatic organisms is low. Based on the available environmental fate data, NMP is expected to have low bioaccumulation potential and low persistence (Ref. 3).

XIII. Regulatory Actions Pertaining to NMP

This section summarizes current state, federal, and international regulations and restrictions on NMP, with a focus on its use in paint and coating removal. None of these actions imposes requirements to the extent necessary so that NMP does not present the unreasonable risk described in this proposed rule.

A. Federal Actions Pertaining to NMP

While many of the statutes that EPA is charged with administering provide statutory authority to address specific sources and routes of NMP exposure, none of these can address the serious human health risks from NMP exposure that EPA is proposing to address under TSCA section 6(a).

- NMP is listed on the Toxics Release Inventory (TRI) and is therefore subject to reporting pursuant to Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) (Ref. 6).
- NMP is on The Clean Air Act (CAA) Section 111, Standards of Performance for New Stationary Sources of Air Pollutants—Equipment Leaks Chemical List (40 CFR 68.130)
- NMP is currently approved for use by EPA as a solvent and co-solvent inert ingredient in pesticide formulations for both food and non-food uses and is exempt from the requirements of a tolerance limit (Ref. 74).

In 2013, the Consumer Product Safety Commission issued a fact sheet warning the public about hazards of paint sand coating removal products, including those containing NMP, and included recommendations for PPE when using products containing this chemical (Ref. 62).

B. State Actions Pertaining to NMP

Several states have taken actions to reduce or make the public aware of risks from NMP. California has set worker protection regulations that require workers to wear gloves when using NMP, and workplace to meet a permissible exposure limit of 1 ppm as an eight-hour time-weighted average (TWA) (Ref. 3). Additionally, NMP is listed as an informational candidate on California's Safer Consumer Products regulations candidate list of chemicals that exhibit a hazard trait and are on an authoritative list and is also listed on California's Proposition 65 list of chemicals known to cause cancer or birth defects or other reproductive harm (Ref. 3).

In Washington, NMP is listed as a chemical of high concern under the Children's Safe Product Act (Ref. 3). Minnesota classifies NMP as a chemical of high concern and several other states have placed NMP on similar chemical listings. Additional states have

recognized NMP as an air pollutant (Ref. 3).

C. International Actions Pertaining to NMP

NMP is currently on the candidate list of substances of very high concern for authorization in the European Union. In August 2013, the Dutch National Institute for Public Health and the Environment submitted a proposal for the restriction of NMP to the European Chemicals Agency under the Registration, Evaluation, Authorisation and Restriction regulation. The Risk Assessment Committee modified the restriction proposal and the combined opinion will be sent to the European Commission for final decision. The Risk Assessment Committee recommended using long-term exposure Derived No Effect Levels for pregnant workers (the most sensitive population) for both inhalation and dermal exposure (Ref. 3).

Other countries have also recognized the risks of NMP. When Canada conducted a categorization of the Domestic Substances List for its Chemicals Management Plan in 2006, NMP met Canada's human health categorization criteria. NMP has been the subject of a Tier II health risk assessment in Australia under that country's Inventory Multi-tiered Assessment and Prioritisation. It is currently subject to labeling and related requirements based on concern for skin, eye and respiratory irritation and for reproductive toxicity. These government assessments consider NMP to be of low environmental concern (Ref. 3). Australia concluded that further risk management is required and additional assessment (Tier III) is needed to determine if current exposure controls are adequate to protect workers and the public when NMP is used in domestic products (Ref. 3).

XIV. NMP Risk Assessment and Outreach

In 2013, EPA identified NMP in paint and coating removal as a priority for risk assessment under the TSCA Work Plan. This unit describes the development of the NMP risk assessment and supporting analysis and expert input on the uses that are the subject of this proposed rule. A more detailed discussion of the risks associated with NMP in paint and coating removal can be found in Units XVI.B.1. and XVI.D.

A. TSCA Work Plan for Chemical Assessments

Using the TSCA Work Plan chemical prioritization criteria, discussed in Unit IV.A., NMP ranked high for health hazards and exposure potential and was included on the initial list of TSCA Work Plan chemicals for assessment. NMP appeared in the 2012 TSCA Work Plan for Chemical Assessments and in the 2014 update of the TSCA Work Plan for Chemical Assessments.

B. NMP Risk Assessment

EPA finalized a TSCA Work Plan Chemical Risk Assessment for NMP (NMP risk assessment) in 2015, following the 2013 peer review of the 2012 draft NMP risk assessment. All documents from the 2013 peer review of the draft NMP risk assessment are available in EPA Docket Number EPA–HQ–OPPT–2012–0725. The completed risk assessment is included in that docket.

The NMP risk assessment evaluated health risks to consumers, workers, and bystanders from dermal and inhalation exposures to NMP when used in paint and coating removal (Ref. 3). EPA assumes workers and consumers would be adults of both sexes 16 years and older, including pregnant women. EPA assumes bystanders in residential settings would be individuals of any age group (*e.g.*, children, adults, and the elderly) nearby during product application. During scoping and problem formulation for the risk assessment, EPA focused on occupational and consumer paint and coating removal because of high NMP content in products and potential high exposure to workers and consumers. EPA selected these uses for the NMP risk assessment because they were expected to involve frequent or routine use of NMP in high concentrations and/or have high potential for human exposure (Ref. 3). However, this does not mean that EPA determined that other uses not included in the NMP risk assessment present low risk.

The NMP risk assessment characterized human health effects associated with paint removal with NMP. Based on the physical-chemical properties of NMP and the paint stripping use scenarios described in the assessment, EPA views dermal exposure as the predominant route of exposure to NMP during paint removal, including absorption of vapor-through-skin.

The NMP risk assessment identified developmental risks of concern following acute (short-term) and chronic (repeated) exposures for workers conducting paint removal with NMP. Specifically, these developmental effects include increased fetal resorptions (fetal death) from acute exposures and decreased fetal body weight from chronic exposures (Ref. 3). EPA identified acute risks of concern for consumers using NMP for paint and coating removal in the more complete array of scenarios described in the supplemental analyses, which used the same modeling methods as the risk assessment (Refs. 75 and 76).

Margins of exposure (MOEs) were used in the risk assessment and supplemental analyses to estimate non-cancer risks for acute and chronic exposures. For an explanation of MOEs, see Unit IV.B. For NMP, EPA identified acute or chronic non-cancer risks of concern if the MOE estimates were less than the benchmark MOE of 30 (Ref. 3). The health endpoint used for the benchmark MOE for acute exposure to NMP is fetal death; the health endpoint used for the benchmark MOE for chronic exposure to NMP is decreased infant birth weight. These are the most sensitive adverse health effects from exposure to NMP.

The NMP risk assessment and supplemental analyses estimated acute risks of fetal death for consumers from the use of paint and coating removers containing NMP, and acute and chronic non-cancer risks of decreased infant birth weight for workers from the use of paint and coating removers containing NMP. Exposure scenarios with MOEs below the benchmark MOE present risks of concern. Typically, non-cancer adverse effects are more likely to result from exposure scenarios with MOEs multiple orders of magnitude below the benchmark MOE. For non-cancer effects, EPA estimated exposures that are significantly larger than the point of departure (Ref. 3). Specifically, the assessment identified risks of fetal death from acute exposures of:

- Four or fewer hours per day, when gloves were not used.
- Greater than 4 hours per day, and risks were not mitigated by personal protective equipment such as respirators or gloves.

The assessment identified risks of decreased infant birth weight from chronic (repeated) exposures of:

- Four or fewer hours per day, when gloves were not used.
- Greater than 4 hours per day, and risks were not mitigated by personal protective equipment such as respirators or gloves.
- Over the course of a work-week (5 days)

Given the risks identified in the NMP risk assessment, the agency undertook further analysis to consider whether that use of NMP in paint and coating removal poses an unreasonable risk.

C. Supplemental Analysis Consistent With the NMP Risk Assessment

Following the NMP risk assessment, EPA conducted supplemental analyses

to inform risk management and to expand on the consumer exposure scenarios. These analyses are consistent with the scope of the NMP risk assessment and were based on the peer-reviewed methodology used in the NMP risk assessment. They included identification of baseline and central tendency exposure scenarios, impacts of reduced NMP content in paint removers, addition of local exhaust ventilation (LEV), use of personally protective equipment (PPE), and methods of monitoring to ascertain workplace exposures. The results of EPA's analyses are available in this rulemaking docket (Refs. 37, 75, and 76). Prior to promulgation of the final rule, EPA will peer review the "Recommendation for an Existing Chemical Exposure Limit (ECEL) for Occupational Use of NMP and Workplace Air Monitoring Methods for NMP," "Respirator and Glove Specifications for Workers and Consumers Exposed to N-methylpyrrolidone (NMP) in Paint and Coating Removal and Estimated Fractions of Worker Population Vulnerable to the Acute Health Effect," and "Supplemental Consumer Exposure and Risk Estimation Technical Report for NMP in Paint and Coating Removal" (Refs. 37, 75, and 76).

D. Outreach

In addition to the consultations described in Unit XXIII., EPA initiated discussions with experts on and users of paint removers (Ref. 22). For more information on these discussions, see Unit IV.D.

XV. Regulatory Approach for NMP in Paint and Coating Removal

A. TSCA Section 6(a) Unreasonable Risk Analysis

Under TSCA section 6(a), if the Administrator 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 to EPA's risk evaluation, 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.

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

- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances (§ 6(a)(1)).
- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances for particular uses or for uses in excess of a specified concentration (§ 6(a)(2)).
- Require minimum warning labels and instructions (§ 6(a)(3)).
- Require recordkeeping or testing (§ 6(a)(4)).
- Prohibit or regulate any manner or method of commercial use (§ 6(a)(5)).
- Prohibit or otherwise regulate any manner or method of disposal (§ 6(a)(6)).
- Direct manufacturers and processors to give notice of the determination to distributors and the public and replace or repurchase substances (§ 6(a)(7)).

EPA analyzed a wide range of regulatory options under section 6(a) for each use in order to select the proposed regulatory approach (Refs. 23 and 24). For each use, EPA considered whether a regulatory option (or combination of options) would address the unreasonable risk so that it no longer presents such risk. To do so, EPA initially analyzed whether the regulatory options could reduce risks to levels below those of concern, based on EPA's technical analysis of exposure scenarios.

After the technical analysis, which represents EPA's assessment of the potential for the regulatory options to achieve risk benchmarks based on analysis of exposure scenarios, EPA then considered how reliably the regulatory options would actually reach these benchmarks. For the purposes of this proposal, EPA found that an option addressed the risk so that it was no longer unreasonable if the option could achieve the benchmark MOE or cancer benchmark for the most sensitive endpoint. In considering whether a regulatory option would ensure the chemical no longer presents the unreasonable risk, EPA considered whether the option could be realistically implemented or whether there were practical limitations on how well the option would mitigate the risks in relation to the benchmarks, as well as whether the option's protectiveness was impacted by environmental justice or children's health concerns.

B. TSCA Section 6(c)(2) Considerations

As noted previously, TSCA section 6(c)(2) requires EPA to consider and publish a statement based on reasonably available information with respect to the:

- Health effects of the chemical substance or mixture (in this case, NMP) and the magnitude of human exposure to NMP;
- Environmental effects of NMP and the magnitude of exposure of the environment to NMP;
- Benefits of NMP for various uses;
- Reasonably ascertainable economic consequences of the rule, including: The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; the costs and benefits of the proposed and final rule and of the one or more primary alternatives that EPA considered; and the cost-effectiveness of the proposed rule and of the one or more primary alternatives that EPA considered.

In addition, in selecting among prohibitions and other restrictions available under TSCA section 6(a), EPA must factor in, to the extent practicable, these considerations. Further, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, EPA must also consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

EPA's analysis of health effects and magnitude of exposure to NMP can be found in Units XIV.B., XVI.B. and XVI.C., which discuss the NMP risk assessment and EPA's regulatory assessment of the use of NMP in paint and coating removal. A discussion of the environmental effects of NMP is in Unit XII.D.

With respect to the costs and benefits of this proposal and the alternatives EPA considered, as well as the impacts on small businesses, the full analysis is presented in the Economic Analysis (Ref. 4). The regulatory options and consideration of TSCA section 6(c)(2) factors are discussed in more detail in Unit V for methylene chloride in paint and coating removal and in Unit XV. for NMP in paint and coating removal.

To the extent information was reasonably available, EPA considered the benefits realized from risk reductions (including monetized benefits, non-monetized quantified benefits, and qualitative benefits), offsets to benefits from countervailing risks (*e.g.*, residual risk risks from chemical substitutions and alternative practices), the relative risk for environmental justice populations and children and other potentially exposed or susceptible subpopulations (as compared to the general population), the cost of regulatory requirements for

the various options, and the cost effectiveness of the proposed action and the one or more primary alternate regulatory options. A discussion of the benefits EPA considered can be found in Units XVI.C. and XVII.B. as well as in the Economic Analysis (Ref. 4).

EPA considered the estimated costs to regulated entities as well as the cost to administer and enforce the options. For example, an option that includes use of a respirator would include inspections to evaluate compliance with all elements of a respiratory protection program (Ref. 25). In understanding the burden, EPA took into account the reasonably available information about the functionality and performance efficacy of the regulatory options and the ability to implement the use of chemical substitutes or other alternatives. Reasonably available information included the existence of other Federal, state, or international regulatory requirements associated with each of the regulatory options as well as the commercial history for the options. A discussion of the costs EPA considered and a discussion of the cost-effectiveness of the proposal and the primary alternate regulatory options that EPA considered is in Units XVI.E. and XVII.A. In addition, a discussion of the impacts on small businesses is in Unit XXIII. and in the Initial Regulatory Flexibility Analysis and Report from the Small Business Advocacy Review Panel (Refs. 26 and 27).

With respect to the anticipated effects of this proposal 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. In addition, EPA considered the employment impacts of this proposal, as discussed in the Economic Analysis (Ref. 4). EPA found that the direction of change in employment is uncertain, but EPA expects the short term and longer-term employment effects to be small.

The benefits of NMP in paint and coating removal are discussed in Unit XVI.A., along with the availability of alternatives. The dates that the proposed restrictions would take effect are discussed in Unit XX. The availability of alternatives to methylene chloride in paint and coating removal on those dates is discussed in Unit XVI.D.

Finally, with respect to this proposal's effect on technological innovation, EPA expects this action to spur innovation, not hinder it. An impending prohibition on this use of NMP is likely to increase demand for alternatives, which EPA expects would result in the development of new alternatives. See section 9.3 in the Economic Analysis (Ref. 4).

C. Regulatory Options Receiving Limited Evaluation

EPA analyzed a wide range of regulatory options under TSCA section 6(a). There are a range of regulatory options under TSCA; only those pertaining to these risks were evaluated in detail. An overview of the regulatory options not evaluated in detail follows.

First, EPA reasoned that the TSCA section 6(a)(1) regulatory option to prohibit the manufacture, processing or distribution in commerce of NMP or limit the amount of NMP which may be manufactured, processed or distributed in commerce is not applicable because EPA is not proposing to ban or limit the manufacture, processing or distribution in commerce of NMP for uses other than paint and coating removal.

In addition, EPA reasoned that the TSCA section 6(a)(6) regulatory option to prohibit or otherwise regulate any manner or method of disposal of the chemical is not applicable since EPA did not assess risks associated with NMP disposal.

Another option EPA evaluated would be to only require warning labels and instructions on paint and coating removal products containing NMP, pursuant to section 6(a)(3) (Ref. 30). EPA reasoned that warning labels and instructions alone could not mitigate the risks as necessary so that NMP no longer presents an unreasonable risk (either to users in the general population or to users who are women of childbearing age). For a further discussion of why EPA believes that labeling alone will not effectively mitigate the unreasonable risks, see Unit V.C. EPA's general observations about labeling, described in that unit, are also applicable in the case of NMP. Specifically regarding NMP, effective personal protection resulting in risk reduction would require not only the appropriate donning and doffing of specialized gloves that are not easily available to consumers, but also identification of which type of glove is protective against particular formulations of paint and coating removal products containing NMP (Ref. 75). Any labeling aiming to reduce risks to consumer or commercial users of these products would need to sufficiently and clearly explain this, and would still leave the user with the problem of obtaining and properly using the appropriate gloves and (in the case of commercial users or consumers using the product for several days at a time) the appropriate respirator. With respect to consumer risks in particular, a label on a product that is easily available to consumers, that directs the user to obtain and use safety equipment that is not easily available to consumers, is especially unlikely to be correctly followed.

A regulatory option receiving limited evaluation was a training and certification program for commercial paint and coating removers, similar to the certification process required under EPA's Lead Renovation, Repair, and Painting Rule (73 FR 21692, April 22, 2008). This option was recommended by the small entity representatives as part of the SBAR process (Ref. 27). EPA considered this option as an approach to reducing risks from NMP in paint and coating removal. However, unlike the process for training and certification of commercial workers required under the Lead Renovation, Repair, and Paint Rule, effective risk reduction from commercial use of NMP for paint and coating removal would require additional regulation of distributors of these products. When considering this approach, given the Agency's experience with the training and certification program under the Lead Renovation, Repair, and Paint Rule, EPA viewed the costs and challenges involved in regulating distributors and ensuring that only trained and certified commercial users are able to access these paint and coating removal products as a significant limitation for this approach. EPA seeks public comment on the feasibility of such a program and its potential to reduce risks of exposure to NMP for workers so that those risks are no longer unreasonable.

XVI. Regulatory Assessment of NMP in Paint and Coating Removal

This unit describes the current use of NMP in paint and coating removal, the unreasonable risks presented by this use, and how EPA identified which regulatory options reduce the risks so that they are no longer unreasonable.

A. NMP in Paint and Coating Removal

As described previously in Units I.A. and VI.B., paint and coating removal, also referred to as paint stripping, is the process of removing paint or other coatings from a surface of a substrate, such as an object or structure (Ref. 3). More information on specific techniques for paint removal in each industry and by consumers are in the NMP risk assessment and supplemental materials (Refs. 3, 75, and 76).

Chemical products for paint and coating removal are used across several industries as well as by consumers or hobbyists, and products intended for one type of use—such as aircraft renovation—have been used in other

situations, such as bathtub refinishing (Refs. 11, 32, and 33). There are no restrictions on using products intended for one specific type of paint removal project in a different setting. Additionally, consumers face no restrictions when using products intended for or marketed to professional users.

EPA has identified 64 different products for paint and coating removal that contain NMP, formulated by 21 different firms. This is approximately 59% of the total number of paint and coating removal products EPA identified (109 products) (Ref. 34). Though the number of workers and consumers exposed to NMP during paint and coating removal is uncertain, EPA has several estimates based on industry data. As described in Unit VI.B., commercial uses include automotive refinishing, furniture refinishing, art conservation and restoration, pleasure craft building and repair, aircraft paint removal, graffiti removal, bathtub refinishing, and renovations in residences or other buildings. As described in more detail in the Economic Analysis, EPA estimates that 30,300 workers annually are exposed to NMP during paint and coating removal activities (Ref. 4).

Consumer use of NMP in paint and coating removal is similar to commercial use, but occurs in consumer settings, such as homes, workshops, basements, garages, and outdoors. Paint and coating removal products containing NMP are the same as those used in many commercial settings, and the process consumers use is similar to commercial methods of brushing or spraying on the paint and coating removal product, allowing time to pass for the product to penetrate the coating, and then scraping the loosened coating from the surface.

When consumers interested in DIY paint and coating removal choose to use chemical paint removers (Ref. 77), they frequently receive advice to use products that contain NMP, without any reference to the risks presented by NMP or even solvents in general (Refs. 78 and 79). Manufacturers and retailers of paint and coating removal products containing NMP frequently sell them to consumers in small containers with marketing language or labeling that state they are biodegradable, 'plant-based', or contain 'no harsh fumes' and implies they are 'green' or 'safe' (Ref. 35). Products containing NMP are not required to be labeled with that information or any information about personal protection or risk reduction. These products are frequently sold at home improvement retailers or automotive supply stores that sell products to consumers as well as professional users (Ref. 35). Additionally, due to the wide availability of products available on the Internet and through various additional suppliers that serve commercial and consumer customers, consumers are able to purchase a variety of paint and coating removal products containing NMP. EPA estimates that the majority of users of paint and coating removal products containing NMP are consumers, rather than occupational users. EPA estimates that approximately 732,000 consumers annually use paint removal products containing NMP (Ref. 4).

B. Analysis of Regulatory Options

In this section, EPA explains how it evaluated whether the regulatory options considered would address the unreasonable risks presented by the use of NMP in paint and coating removal. First, EPA characterizes the unreasonable risks associated with the current use of NMP in paint and coating removal. Then, EPA describes its initial analysis of which regulatory options have the potential to achieve non-cancer benchmarks. Lastly, this section evaluates how well those regulatory options would address the unreasonable risk in practice.

1. Risks associated with the current use. a. General impacts. The NMP risk assessment and additional supplemental analyses identified acute and chronic risks for consumers and commercial users of paint and coating removal products containing NMP following exposure through dermal contact, inhalation, and vapor-through-skin (Refs. 3, 75, and 76). EPA did not find risks for occupational or residential bystanders (individuals not using the paint and coating remover, but near someone who is). EPA estimates, having refined the numbers since the risk assessment that, annually, there are approximately 30,300 workers at 4,300 commercial operations conducting paint and coating removal with NMP, and approximately 732,000 consumers who use paint and coating removal products containing NMP each year (Ref. 4).

b. Impacts on minority and other populations. While all consumers and workers using paint and coating removal products containing NMP would benefit from risk reduction, some populations are currently at disproportionate risk for the health effects associated with NMP in paint and coating removal. These are the same populations at disproportionate risk for the health effects associated with methylene chloride in paint and coating removal, and are described in Unit VI.C.1.b.

c. Impacts on children. EPA has concerns for effects on the developing fetus from acute and chronic worker and consumer maternal exposures to NMP. The risk estimates focus on the most susceptible life stages, which for NMP are women of childbearing age and their developing fetus. However, because women may not know that they are pregnant (Refs. 80 and 81) and short-term exposure to NMP may adversely impact fetal development during a single day or single week of exposure, the life stages of concern for risk assessment include all women of childbearing age (*i.e.,* women between the ages of 16 and 49 years) and the developing fetus. The impacts to children derive from the pre-natal or maternal exposure; these impacts include decreased fetal weight, decreased birth (post-natal) weight, and fetal death. Details on the impacts of these health effects are described in Unit XVI.C.

EPA assumed that consumer and commercial users would generally be adults of both sexes (16 years old and older, including women of childbearing age), although exposures by teenagers and even younger individuals may be possible in consumer settings. However, risk estimates focused on the most susceptible life stage, which are pregnant women and their developing fetus, because developmental toxicity is one of the most sensitive health effects associated with NMP exposure (Ref. 3).

d. Exposures for this use. Exposures assessed for this in the risk assessment and supplemental analyses use include acute and chronic (or repeat-dose) exposures by commercial workers and acute exposures by consumers engaging in paint and coating removal with NMP, as described in the NMP risk assessment and additional analyses (Refs. 3 and 76). The exposure pathways of interest included dermal contact, vapor-through-skin, and inhalation. Acute scenarios assumed one day, or up to eight hours, of exposure; chronic, or repeat-dose, scenarios assumed five days of exposure per week, or one work week, with up to eight hours per day of exposure (Refs. 3 and 76).

For exposures in commercial settings, EPA assessed exposure scenarios under which the worker was presumed to work on either an indoor project (such as work by professional contractors, furniture stripping and other settings) or an outdoor or semi-enclosed space (such as graffiti removal on the exterior of a building, outdoor escalator, or elevator).

In the NMP risk assessment, EPA developed six occupational user

exposure scenarios for assessment. The following factors were considered in developing the exposure scenarios (Ref. 3):

• The weight fraction of NMP in the paint and coating removal product;

• Skin surface area of the worker in contact with the paint removal product; and

• Duration of contact (in hours) with the paint removal product.

Within each of the six workplace scenarios, EPA evaluated five permutations, by modifying the parameters of the scenario to include different combinations of personal protective equipment (PPE). These permutations were (1) respirator with assigned protection factor (APF) of 10, and gloves; (2) respirator APF 10 only; (3) gloves only; (4) neither respirator nor gloves; and (5) not directly using the product (nearby worker) (Ref. 3).

EPA used air concentration data and estimates found in literature sources to serve as inhalation exposure concentration inputs to the physiologically-based pharmacokinetic modeling for occupational exposures to NMP. This modeling was used to derive internal dose estimates for acute and chronic occupational exposures, and predicted absorption of liquid or vapor by the individual in the scenario when using the paint and coating removal product containing NMP (Ref. 3).

For consumer exposures, EPA assessed exposure scenarios under which the individual was presumed to work on one of several types of paint and coating removal projects (table and chairs, chest of drawers, or bathtub), with inputs reflecting that consumers do not reliably use personal protective equipment (effective gloves) or have access to engineering controls (*e.g.*, ventilation fan). In each scenario, the consumer would be exposed via inhalation, dermal contact, and vapor-through-skin (Ref. 3).

EPA developed seven consumer exposure scenarios for the assessment. Similar to the worker exposure assessment, the following factors were considered in developing the exposure scenarios (Ref. 3):

• The type of application (*i.e.*, brush-on or spray-on), weight fraction of NMP in the paint and coating removal product, application rate by the user, surface area of object from which the paint or coating was being removed, and emission rate of the chemical, which can affect the amount of NMP that ultimately is released to the indoor environment;

• The location where the product is applied, which relates to exposure factors such as the room volume and its air exchange rate with outdoor air;

• The house volume and air exchange rate, for reasons similar to those for the product use location; and

• Precautionary behaviors such as opening windows in the application room, the user leaving the application room during the wait period, related changes to the air exchange rates, and the proximity of the user to the source of NMP emissions.

In the absence of representative air monitoring data for consumers using paint and coating removal products containing NMP, EPA used the Multi-Chamber Concentration and Exposure Model to estimate consumer inhalation exposure concentrations. The predicted air concentrations from the exposure modeling for users and non-users were inputs to the physiologically-based pharmacokinetic modeling software and used to define consumers' moment-by-moment air concentration inhaled and in contact with unobstructed skin. The parameters and data sources for the model are described in the NMP risk assessment (Ref. 3).

EPA's estimates of the exposures individuals experienced during the acute and chronic scenarios of commercial or consumer use of paint and coating removal products containing NMP were used to assess the risks of these uses of NMP. The full exposure estimates and risk findings are described in the NMP risk assessment; risk findings are also summarized in Unit XVI.B.1.a.

In addition to estimating likely exposures under current use patterns, for both commercial and consumer users, EPA assessed a number of exposure scenarios associated with risk reduction options in order to identify variations in NMP exposure. All variations in the scenarios were evaluated with exposure parameters that were modified to reflect either a reasonable worst-case scenario (also called the baseline) or a scenario in which exposures were moderated by several factors (also called the central tendency scenario). The risk reduction options that were varied between scenarios included material substitution, duration of use, engineering controls, and use of PPE, as well as combinations of these options (Refs. 37, 75, and 76), as follows:

• The material substitution scenarios involved reducing the concentration of NMP in the paint and coating removal product, with concentrations varying from 5, 10, 25, 30, 35, 40, 62.5 and 100% by weight in the product.

• The duration of use scenarios involved, for consumers, variations in the type of activity during which paint removal would be conducted (for example, 7 hours of exposure to NMP when removing paint from a table and 8 chairs; 0.5 hours of exposure to NMP when removing paint from a coffee table). For commercial users, duration of exposure to NMP in paint and coating removers was assessed as job time during a work day (1 to 8 hours).

• Under the PPE risk reduction option exposure scenarios, EPA evaluated consumers wearing specialized gloves, and workers wearing specialized gloves and/or respirators with APF 10.

• For the engineering controls risk reduction option exposure scenarios, EPA evaluated using LEV to improve ventilation near the activity of workers in furniture refinishing operations, with an assumed 90% reduction in exposure levels.

Additionally, EPA evaluated combinations of the options. For consumers, this included material substitution, duration of exposure, and PPE; for workers, this included material substitution, duration of exposure, PPE, and LEV. Engineering controls are not assumed to be practical for consumers as a method of exposure reduction. Overall, EPA evaluated dozens of distinct exposure scenarios for both consumer and commercial paint and coating removal with NMP.

e. Specific risks for this use. The assessment of acute risks used developmental toxicity data to evaluate the acute risks for paint and coating removal with NMP. EPA based its assessment of acute risks on the endpoint most protective of health (*i.e.*, fetal death (Ref. 3)), representing the most sensitive human life stage (*i.e.*, women of childbearing age (greater than 16 years) and the fetus). Because fetal effects were selected as key endpoints, risks were calculated for pregnant women and women of childbearing age who may become pregnant. As described in the risk assessment, exposures that do not result in risks of concern for these particular lifestages are also found to be protective of children and adult males. A risk of concern was identified if the MOE estimate was less than the benchmark MOE of 30 (Ref. 3).

In the risk assessment and supplemental analyses, EPA evaluated risks for fetal death from dermal contact, inhalation, and vapor-through-skin for all consumer, occupational, and bystander exposure scenarios of paint and coating removal with NMP. No risks were identified for occupational or residential bystanders. Acute risks of fetal death were identified for the

consumer and commercial users of NMP for paint and coating removal in several, although not all, scenarios. To identify what, if any, risks may be present for consumers in different scenarios, EPA conducted additional analyses consistent with the risk assessment to provide an expanded understanding of consumer exposures (Ref. 76). Additionally, it appears that consumers could engage in patterns of use comparable to worker exposures that present risk; for example, any consumers engaging in paint and coating removal with NMP for longer than four hours in one day could be subject to the acute occupational risks identified (Ref. 3).

For commercial users, the occupational scenarios in which acute risks were identified included four hours of paint removal in one day with no gloves, with or without a respirator, indoors or outdoors, assuming mid-range of the exposure parameters described earlier, such as concentration of NMP in the product (MOEs range from 12 to 15); and four hours of paint removal in one day with or without a respirator and gloves, indoors or outdoors, assuming the higher exposure parameters described earlier (MOEs range from 0.7 to 11.8) (Ref. 3). These risks are present whether the worker is indoors or outdoors, and may be present even in the presence of PPE or ventilation, depending on the duration of use and the concentration of NMP in the product. Therefore, EPA's proposed determination is that acute NMP exposures during paint and coating removal present unreasonable risks.

EPA also assessed risks of chronic exposure to NMP by commercial users, with a short-term chronic exposure that can be defined as a repeat-dose scenario in which the individual is exposed over the course of a work week, rather than over a lifetime. This chronic assessment used decreased fetal body weight as the critical endpoint. EPA assessed risks for decreased birth weight for occupational and bystander exposure scenarios of paint and coating removal with NMP. In the risk assessment, a risk of concern was identified if the MOE estimate was less than the benchmark MOE of 30 for decreased birth weight (Ref. 3).

Risk of decreased birth weight was identified for commercial users of NMP for paint and coating removal in several scenarios, including four hours of paint removal during each day in a work week without gloves, with or without a respirator, indoors or outdoors, assuming the mid-range of the exposure parameters described earlier, such as concentration of NMP in the product (MOEs range from 5.4 to 6.1); and eight hours of paint removal during each day in a work week, with or without a respirator or gloves, indoors or outdoors, assuming the higher exposure parameters described earlier (MOEs range from 0.1 to 3.2) (Ref. 3). Though no risks were identified for occupational bystanders, for workers, these risks are present whether the worker is indoors or outdoors, and may be present even if PPE or ventilation is used, depending on the duration of use and the concentration of NMP in the product (Ref. 3). In some scenarios, this equates to estimated exposures that are more than 10 times greater than those that would produce the benchmark MOE for this endpoint, which assesses risks for fetal death and decreased birth weight. Therefore, EPA's proposed determination is that chronic NMP exposures during paint and coating removal also present unreasonable risks.

The SBAR Panel convened in support of this action heard from several SERs who expressed concerns about the underlying NMP risk assessment (Ref. 27). Many of the concerns expressed by these SERs were already expressed in the public comments and the peer review comments on the NMP 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.

2. Initial analysis of potential regulatory options. Having determined that the risks from NMP in paint and coating removal were unreasonable, EPA evaluated how regulatory options under section 6(a) might reduce the risks so that they are no longer unreasonable.

The results of EPA's assessment of consumer uses, exposures, and risks indicate that regulatory options for consumer uses such as reducing the concentration of NMP in a product or advising the use of specialized gloves or respirators individually could not achieve the target MOE benchmarks for acute exposures (Ref. 76). Similarly, the results of EPA's evaluation indicate that regulatory options for occupational exposures such as reducing the concentration of NMP in products used for paint and coating removal and using local exhaust ventilation to improve ventilation, in the absence of PPE, could not achieve the target MOE benchmarks for non-cancer endpoints for acute and chronic exposures (Refs. 37 and 75). The results also demonstrate that all risk reduction options meeting the benchmark MOEs for NMP in paint and coating removal require the use of specialized gloves, whether used alone or in conjunction with additional levels of respiratory protection such as a respirator of APF 10 or the use of an air exposure limit, even when the concentration of NMP in a product was limited to 25 percent. Therefore, EPA found setting a maximum concentration of NMP in products under TSCA section 6(a)(2) alone would not reduce exposures to levels at which risks would be at or below the risk benchmarks. Further, EPA's analysis found that even with specialized gloves and a respirator, workers would be at risk of NMP exposure if they used products with more than 25 percent NMP. Additional exposure level estimates for various scenarios are available in the supplemental analyses, which also document options that did not meet the risk benchmarks and which do not, for purposes of this proposal, address the identified unreasonable risks (Refs. 37, 75, and 76).

3. Assessment of whether regulatory options address the identified unreasonable risks to the extent necessary so that NMP in paint and coating removal no longer presents such risk. As discussed earlier, EPA considered a number of regulatory options under TSCA section 6(a) for NMP in paint and coating removal, which are reflected in EPA's supporting analysis (Ref. 30). In assessing these options, EPA considered a wide range of exposure scenarios (Refs. 75 and 76). These include both baseline and risk reduction scenarios involving varying factors such as concentration of NMP in paint and coating removal products, LEV use, respirator and glove use, and duration of use. As part of this analysis, EPA considered the impacts of regulatory options on consumer users and commercial users separately. However, EPA is proposing to address the use of NMP in paint and coating removal as a whole rather than as separate consumer and commercial uses. As described earlier in Unit XVI.A., paint and coating removal products containing NMP frequently are available in the same distribution channels to consumers and professional users. Products are marketed for a variety of projects, and cannot be straightforwardly restricted to a single type of project or user.

The Agency examined two main alternative approaches to addressing the unreasonable risk from NMP in paint and coating removal under current conditions of use by consumers and commercial users. These two approaches are the supply chain approach (and its two primary variations) and the reformulation, labeling, and PPE approach. These

regulatory alternatives are the options that have the potential to address the unreasonable risks presented by NMP when used for paint and coating removal by consumers, commercial users, or for both. The two options and their variations are described below.

(a) The first co-proposed approach (option 1) is a supply-chain approach, which would include prohibiting the manufacturing, processing, and distribution in commerce of NMP for paint and coating removal under TSCA section 6(a)(2) except for certain uses critical to national security; prohibiting the commercial use of NMP in paint and coating removal under TSCA section 6(a)(5) except for certain uses critical to national security; requiring that all paint and coating removers containing NMP be distributed in containers with volumes no less than 5 gallons under TSCA section 6(a)(2); requiring downstream notification when distributing NMP for other uses under TSCA section 6(a)(3); and limited recordkeeping under TSCA section 6(a)(4);

(b) Variations on such a supply-chain approach, such as just prohibiting the manufacturing, processing, and distribution in commerce of NMP for paint and coating removal under TSCA section 6(a)(2) for consumer and commercial use or just prohibiting the commercial use of NMP for paint and coating removal under TSCA section 6(a)(5);

(c) Additional variations on such a supply-chain approach, such as prohibiting the manufacturing, processing, and distribution in commerce of NMP for paint and coating removal under TSCA section 6(a)(2) for consumer and commercial use and requiring downstream notification (*e.g.*, via SDS) when distributing NMP for other uses under TSCA section 6(a)(3); and

(d) The second co-proposed approach (option 2), a reformulation, PPE, and labeling approach, which would require (1) product reformulation to limit the concentration of NMP in paint and coating removal products under section 6(a)(2); (2) testing of product formulations to identify specialized gloves that provide protection for users and relevant recordkeeping under section 6(a)(4); (3) relabeling of products intended for consumer use to provide additional information to consumers under section 6(a)(3); (4) an occupational dermal and respiratory protection program for commercial use of NMP in paint and coating removal, including a requirement for hazard communication, specialized gloves and an air exposure limit or respirator under section 6(a)(5); (5) a prohibition on use of NMP above a concentration of 35 percent for commercial paint and coating removal under 6(a)(5); (6) downstream notification when distributing NMP for other uses under TSCA section 6(a)(3); and (7) limited recordkeeping under TSCA section 6(a)(4). Under this co-proposed approach, EPA is not proposing an exemption for coating removal uses identified as critical to national security because paint and coating removal products containing NMP would continue to be available for these national security uses under this option, even without establishing a national security exemption.

A discussion of the regulatory options that could reach the risk benchmarks for consumer use, commercial use, or both is in this unit, along with EPA's evaluation of how well those regulatory options would address the unreasonable risks EPA has identified. EPA requests comment on the two co-proposed regulatory options addressing the use of NMP in paint and coating removal, particularly with regard to the advantages and disadvantages of the different approaches, their potential associated benefits, and whether such approaches would be consistent with EPA's obligation under TSCA to address risks identified as unreasonable.

a. First co-proposed approach: Supply-chain (option 1). The proposed regulatory approach for NMP in consumer and commercial paint and coating removal would prohibit the manufacturing, processing, and distribution in commerce of NMP for consumer and commercial paint and coating removal under TSCA section 6(a)(2), except for certain uses critical to national security; would prohibit the commercial use of NMP for paint and coating removal under TSCA section 6(a)(5), except for certain uses critical to national security; would require any remaining paint and coating removal products containing NMP to be distributed in containers with a volume no less than 5 gallons, under TSCA section 6(a)(2); would require manufacturers, processors, and distributors of NMP to provide downstream notification of the prohibitions under TSCA section 6(a)(3), and would require recordkeeping relevant to these prohibitions under TSCA section 6(a)(4).

As discussed earlier, a risk of concern was identified if the MOE estimate was less than the benchmark MOE of 30. As described in Unit XVI.B.1., the baseline risks for workers and consumers from paint and coating removal with NMP were identified as ranging from two to 10 times below the benchmark MOEs of 30 for fetal death (the acute health impact) or low birth weight (the chronic health impact). Under this proposed option, exposures to NMP during paint and coating removal would be eliminated for consumers and workers. As a result, acute and chronic risks would be eliminated.

The first co-proposed approach would ensure that workers and consumers from the general population (as well as workers and consumers who are women of childbearing age) are no longer exposed to unreasonable risks from NMP exposure during paint and coating removal. Prohibiting the manufacturing, processing and distribution in commerce of NMP for paint and coating removal would minimize the overall availability of NMP for paint and coating removal. Importantly, this proposed regulation is protective of consumer users. EPA cannot regulate consumer use under TSCA section 6(a)(5). The prohibition of the commercial use of NMP for paint and coating removal would reduce commercial demand for NMP paint and coating removal products, reduce the likelihood that other types of products formulated with NMP would be used for paint and coating removal, and significantly reduce the potential for consumer use of commercial paint and coating removal products containing NMP. Workers would not be exposed to NMP for paint and coating removal, except for those uses that are proposed to be exempt because they are critical to national security. The risk to consumers would be minimized because commercial paint and coating removal products containing NMP would not be available outside of those directly supplied to DOD for uses identified as critical to national security.

The downstream notification of these restrictions ensures that processors and distributors are aware of the manufacturing, processing, distribution in commerce and use restrictions for NMP in paint and coating removal, and enhances the likelihood that the risks associated with this use of NMP are addressed throughout the supply chain. Downstream notification also streamlines compliance and enhances enforcement, since compliance is improved when rules are clearly and simply communicated (Ref. 39). This integrated supply chain proposed approach completely mitigates the risk to consumers and workers from NMP in paint and coating removal.

b. Options that are variations of elements of the co-proposed supply-chain approach (option 2). One

variation of the proposed approach would be to prohibit manufacture, processing, and distribution in commerce of NMP for consumer and commercial paint removal for the uses proposed for regulation this without the prohibition on commercial use of NMP for paint and coating removal and without the downstream notification of any prohibitions. Without the accompanying prohibition on commercial use and downstream notification that is included in the proposed supply chain approach, this option would leave open the likelihood that commercial and consumer users could obtain NMP (which would continue to be available for other uses, such as degreasing or solvent purposes) and use it for paint and coating removal.

Without downstream notification, unsophisticated purchasers in particular are likely to be unfamiliar with the prohibitions regarding this use and mistakenly use NMP for paint and coating removal, thereby exposing themselves and bystanders to unreasonable risks. Thus, under these variations, EPA anticipates that many users would not actually realize the risk benchmarks. Therefore, these variations fail to protect against the unreasonable risks. EPA requests comment on its consideration of and conclusions regarding this option.

Another regulatory option that EPA considered was to prohibit only the commercial use of NMP for paint and coating removal. This approach would reduce risks for commercial settings, but it would not reduce risks to consumers so that they are no longer unreasonable. By prohibiting use in the commercial sector alone, without a prohibition on the manufacture, processing, and distribution in commerce of paint and coating removal products containing NMP for consumer and commercial use, this approach would not address consumer risks as distributors of paint and coating removal products containing NMP could continue to distribute to consumers NMP marked as a paint and coating remover, including products labeled and marketed as "professional strength" or "commercial grade" products. Since it is foreseeable that consumers would continue to purchase products labeled and marketed in this fashion, consumers would continue to be exposed far above the health benchmarks and would not be protected from the unreasonable risks posed by NMP. EPA requests comment on its consideration of and conclusions regarding this option.

c. Prohibit the manufacturing, processing, and distribution in commerce of NMP for consumer paint and coating removal under TSCA section 6(a)(2) or prohibit the manufacturing, processing, and distribution in commerce of NMP for consumer paint and coating removal under TSCA section 6(a)(2) and require downstream notification when distributing NMP for other uses under TSCA section 6(a)(3). EPA considered prohibiting the manufacturing, processing, and distribution in commerce of NMP only for consumer paint and coating removal, including an option with a requirement for downstream notification of such prohibition. If such a prohibition were effective, this option would mitigate the risks to consumers from NMP in paint and coating removal. However, consumers can easily obtain products labeled for commercial use. Indeed, for many consumers, identifying a product as being for commercial use may imply greater efficacy. Coupled with the fact that many products identified as commercial or professional are readily obtainable in a variety of venues (*e.g.*, the Internet, general retailers, and specialty stores, such as automotive stores), EPA does not find that this option would protect consumers. In addition, this option alone would not address the risks to workers from NMP in paint and coating removal. EPA requests comment on its consideration of and conclusions regarding this option.

d. Second co-proposed approach: Reformulation, labeling, and PPE approach. EPA is co-proposing two regulatory options for NMP. The second co-proposed option would involve product reformulation, glove testing, labeling, and worker protection. This approach has the potential to reduce the risks presented by NMP during paint and coating removal. EPA currently believes this potential is greater for workers than for consumers. potential is greater for workers than for consumers. EPA is considering this co-proposed regulatory option, and may adopt it in the final rule; the Agency therefore solicits comment on the option, as described below.

i. Description of second co-proposed approach. The second co-proposed approach for NMP in commercial and consumer paint and coating removal requires actions from commercial users and product formulators. Under this approach, under section 6(a)(5), commercial users of NMP for paint and coating removal would be required to establish a worker protection program for dermal and respiratory protection, including hazard communication, training, and requirements that workers wear clothing covering most of the body, *i.e.*, impervious long pants and shirts with long sleeves, use gloves specified by product formulators (described under formulator requirements below) and a respirator with APF 10, with an alternative air exposure limit of 5 ppm achieved through engineering controls or ventilation. Also under this approach, formulators of products for either commercial or consumer use would be required to (1) Reformulate products such that paint and coating removal products containing NMP do not exceed a maximum of 35 percent NMP by weight in product formulations under section 6(a)(2) (except for product formulations destined to be used by DOD or its contractors performing work only for DOD projects identified in Unit XVIII.); (2) Test gloves for the product formulations being processed and distributed in commerce to identify specialized gloves that provide protection for users under section 6(a)(4); (3) Label products with information for consumers about reducing risks when using the products, including identifying which specialized gloves provide protection against their specific formulation; and (4) Provide information for commercial users about reducing risks when using the product, via product labels, SDS, and other methods of hazard communication. Variations of more than 1% in any component of a paint and coating removal product containing NMP would be considered a separate formulation.

Specifically, for labeling targeted to consumers under section 6(a)(3) formulators would be required to provide the following information to consumers on product labels: A warning that irreversible health effects such as fetal death may occur as a result of using the product; instructions to not use the product without a new (*i.e.*, replaced each time the product is used) pair of the formulation-specific gloves identified on the label; instructions to either use the product outdoors or to adequately ventilate the workspace by opening windows and adding fans; instructions to not spray-apply the product; instructions to wear clothing that covers exposed skin; and instructions to use a respirator of APF 10, such as a NIOSH-certified air-purifying elastomeric half-mask respirator equipped with N100, R100, or P100 filters. The labeling requirement would also include appropriate placement and font size for the label information.

EPA requests comments on the components of this co-proposal, particularly on the maximum percent concentration that would be permitted

in paint and coating removal products containing NMP. EPA notes that the air exposure limit described earlier correlates with the concentration of NMP in the product, and would necessarily change with any corresponding change in NMP concentration (Ref. 37). EPA's calculations for the estimated exposures from products at various concentrations is in Ref. 75.

EPA also requests comment on the scientific and technical support used for development of the 5 ppm air exposure limit (Ref. 37) for NMP and the feasibility of implementing and enforcing this performance-based approach. Additionally, EPA is requesting comment on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies. EPA is requesting comment on whether this alternate option of allowing industrial use at specified exposure levels and with appropriate personal protective equipment should be adopted. Specifically, EPA seeks information on whether this alternative approach would incentivize industry to eliminate NMP use in paint and coating removal wherever technically feasible while minimizing disruptive impacts to those processes where technically feasible substitutes are currently unavailable. EPA also requests comment on whether there should be a phase-in period, *e.g.*, 3 years for formulators to develop the new formulations of products containing NMP at 35 percent. This would also allow users to make the transition. EPA also requests comment on whether the 35% limit on the concentration of NMP in the formulation is appropriate; whether EPA should specify a higher, lower or no limit; and why. Finally, EPA requests comment on the specific regulatory requirements for glove testing and for personal protective equipment programs. EPA has identified two ASTM International standards that are pertinent to glove testing, ASTM F739, "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact," and ASTM F1194–99, "Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing Materials." EPA requests comment on whether these standards should govern the mandatory glove testing, or whether there are other standards or requirements that should be imposed. In addition, EPA is proposing to require employers whose employees are exposed to NMP in paint and coating removal products to develop and institute personal protective equipment programs. These programs must be in writing, specific to the affected workplace, and include provisions relating to the proper selection, use, and maintenance of equipment. EPA requests comment on whether the proposed requirements for personal protective equipment programs are appropriate and complete, whether less burdensome requirements would similarly allow risk to be reduced so that it is no longer unreasonable, or whether EPA should cross reference the OSHA regulations on personal protective equipment, specifically 29 CFR 1910.132–134 and 29 CFR 1910.138.

ii. Risk reduction of second co-proposed approach. Reducing risks to workers so that they would not be unreasonable requires a combination of a concentration limitation and worker protection programs that include PPE and hazard communication because concentration limits or a worker protection program alone would not be sufficient to reduce the risks to workers so that they are no longer unreasonable. For this reason, the second co-proposal aims to reduce the risks to workers by placing requirements on product formulators and commercial users.

Reducing exposure to NMP requires consideration of routes of exposure as well as user behaviors, such as wearing appropriate PPE (*i.e.*, specialized gloves that are effective for the specific formulation used, impervious clothing and a respirator). The dermal route is the primary contributor to exposures from NMP; however, vapor deposition and subsequent absorption through skin and inhalation are also important exposure pathways that must be considered in determining a person's exposure to NMP. Even when wearing specialized gloves, dermal absorption of NMP from the vapor phase typically contributes significantly to human exposure. EPA's calculations for dermal exposure are based on a person having up to 25 percent of exposed skin surface (*e.g.*, arms, head and neck), providing significant exposure to NMP even with impervious glove use (Ref. 3). Thus, the use of impervious long pants and shirts is needed to minimize the area of exposed skin and thus reduce the risk associated with using NMP for paint and coating removal. To address the exposures to NMP use in paint and coating removal via dermal exposure from both direct contact and vapor deposition, and via inhalation exposure, the following combination is required: Specialized gloves that are effective for the specific formulation used; a respirator with an APF of 10; and impervious clothing covering the body. This combination, as part of a worker protection program, will reduce occupational exposures so that the benchmark MOE is exceeded, provided that the concentration of NMP in the formulations used in paint and coating removals does not exceed 35 percent (Ref. 75). Therefore, EPA believes that any remaining occupational risks would not be unreasonable.

Specialized gloves are an important component of reducing exposure and, thus, must be effective. The presence of co-solvents in the paint and coating removal product containing NMP can result in inadvertent exposure to NMP. Most paint and coating removal products containing NMP contain co-solvents (Ref. 34). Gloves proven to resist permeation or breakthrough from pure NMP have been shown to experience degradation and permeation with these co-solvents especially those that are small-molecule, volatile solvents. For this reason, it is not possible to know which type of glove provides adequate protection from products containing NMP with any co-solvents without testing the formulation of each product for glove breakthrough and permeation. When working with formulated products, the chemical component with the shortest break-through time must be considered when selecting the appropriate glove type for protection against chemical hazards unless glove-specific test data are available (Ref. 82). Risks may not be reduced if the appropriate gloves are not identified through testing.

Consumers could have access to NMP formulations identical to those available to commercial users. This co-proposed approach would attempt to address the unreasonable risk to consumers through the combination of labeling and product reformulation. The product reformulation would be as discussed previously. If consumers using NMP formulations which did not exceed 35% of NMP were to consistently follow *all* the warnings on the label (specifically, if the consumer were to use a new pair of the formulation-specific gloves identified on the label each time the product is used; and were to adequately ventilate the workspace; and not spray-apply the product; and if they were to wear clothing that covers exposed skin; and properly fit and use a respirator of APF 10, such as a NIOSH-certified air-purifying elastomeric half-mask respirator equipped with N100, R100, or P100 filters) then the consumer exposures to NMP would be expected to result in MOEs that approach the benchmark MOE of 30 (Ref. 76).

Under real-world conditions, EPA expects that not all consumers will adequately follow the label to reduce risk to a level above the benchmark MOE. The Agency is requesting comment on whether incomplete adherence to the label might still suffice to reduce risks presented by NMP in paint and coating removal so that those risks are no longer unreasonable. EPA also requests comment on whether the voluntary nature of consumer use and the information provided on the label that would allow consumers to avoid risk below the benchmark MOE if label directions were followed should be a factor in determining whether any remaining risk associated with this exposure scenario is unreasonable, and if so, how.

EPA is also requesting comment on how labels may be constructed to effectively communicate risk and instructions on how to use the product, such as information on label content, placement of information, pictures, and font size and color; how to construct a label to effectively communicate and improve the user's understanding of risk and protective measures. EPA requests that this be supported by data demonstrating the effectiveness of a label approach, particularly as it pertains to susceptible sub-populations or individuals with limited English proficiency or low literacy in any language.

EPA requests comment on the efficacy of this co-proposed option, including on individual components.

iii. Concerns regarding second co-proposed approach. EPA has identified several concerns regarding this co-proposed option related to risk reduction for commercial users and for consumers. For commercial users, many of these concerns relate to the use of PPE. Although respirators in conjunction with the use of appropriate formulation-tested gloves could reduce exposures to levels that are protective of acute and chronic risks, respirators are not EPA's preferred approach to decrease exposures. Not all workers may be able to wear respirators, even those with a lower APF. For a discussion of the use of respirators and the associated respiratory protection program, see Unit VI.C. Given equipment costs and the costs of establishing a worker protection program, which involves training, respirator fit testing and the establishment of a medical monitoring program, EPA anticipates that most companies would choose to switch to substitutes instead of adopting a program for this type of PPE to continue using NMP in paint and coating removal. As recommended by the SBAR panel, EPA is requesting comment on and information about workplace experience with worker protection programs and air monitoring for NMP (Ref. 27). Specifically, EPA seeks comment on whether companies would opt to substitute an alternate chemical or process instead of implementing a worker protection program for PPE. Additionally, EPA is requesting comment on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies.

Under this approach, risks to consumers are only addressed to the extent that consumers understand and follow the required label information. While the Agency expects that some number of consumers who read the labels of paint and coating removal products containing NMP would understand this information and take appropriate steps to reduce their risks based on label information, as noted in Unit V.C., studies have shown that consumers do not consistently pay attention to labels for hazardous substances; consumers, particularly those with lower literacy levels, often do not understand label information; consumers often base a decision to follow label information on previous experience and perceptions of risk; even if consumers have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers have varying behavioral responses to warning labels.

Even for those consumers who understand and follow the label, EPA expects some number will not follow the label instructions precisely or may be unable to readily locate the specialized gloves or the respirator indicated on the label (Ref. 28). Further, it is unlikely that consumers would have the fit of their respirator tested, which is important part of the proper use, and thus effectiveness, of a respirator, or that they would wear a new pair of specialized gloves for each use of the product containing NMP. EPA emphasizes that product labels are not equivalent to worker protection programs in which risks are reduced through, among other things, training programs, requirements that include proper testing and use of respirators, and requirements to use specialized gloves each time the product is used.

EPA is unable to determine how many consumers would read and take *all* appropriate action based on label information, and to what extent they could effectively carry out those actions such that their exposure would be reduced.

As under the first co-proposed approach, manufacturers, processors, and distributors would be required to provide downstream notification of these requirements under TSCA section 6(a)(3), and limited recordkeeping would be required under TSCA section 6(a)(4).

C. Adverse Health Effects and Related Impacts That Would Be Prevented by the Proposed Options

EPA is co-proposing these options to prevent exposure to NMP from paint and coating removal and thus prevent the risks of adverse effects and associated impacts. As discussed in Unit XII.C., the range of adverse health effects from NMP includes developmental toxicity resulting in decreased birth weight or fetal death, kidney toxicity, liver toxicity, immunotoxicity, and reproductive toxicity (Ref. 3). These health effects associated with exposure to NMP are serious and can have impacts throughout a lifetime. The following is a discussion of the impacts of significant acute and chronic non-cancer effects associated with NMP exposure during paint and coating removal, including the severity of the effect, the manifestation of the effect, and how the effect impacts a person during their lifetime.

1. Developmental effects—acute exposures. The NMP risk assessment identified developmental effects as the most sensitive endpoint for acute exposure to NMP. Specifically, this assessment identified fetal death as the critical effect of acute exposures over the course of a day. Fetal death or fetal mortality includes miscarriage, spontaneous abortion, or stillbirth, depending on when in the pregnancy it occurs. Fetal death may result from a single maternal exposure to NMP at a developmentally critical period (Ref. 3). There are increased risks of fetal death for pregnant women who use NMP for paint and coating removal as consumers. EPA estimates that 732,000 consumers use NMP for paint and coating removal each year; of them, approximately 38,000 are estimated to be pregnant women. EPA estimates that approximately 11,300 of these pregnant women are estimated to experience acute exposure to NMP at levels that would result in an MOE below the benchmark of 30. Additionally, there are increased risks of fetal death for a subset of pregnant women among the approximately 8,800 female workers in 4,300 commercial facilities or companies that use NMP for paint and

coating removal. Of these female workers, approximately 500 are estimated to be pregnant, and, of them, approximately 160 are estimated to have acute exposure to NMP at levels that would result in an MOE below the benchmark of 30 for fetal death (Ref. 4). The basis for these calculations are shown in section 5.2.1 of the Economic Analysis (Ref. 4).

Researchers aiming to improve early childhood health outcomes have identified the most sensitive time in a pregnancy as the first few weeks following conception, before a woman may be aware she is pregnant. In the context of maternal welfare and risk reduction, "women often delay assessing and improving their health until after confirmation of pregnancy, putting their baby at risk during the critical early developmental stages" (Ref. 81). Approximately 35% of pregnancies in the United States are unplanned (Ref. 83); consequently, many women who are pregnant may not have taken or be prepared to take steps to reduce risks to the developing fetus during early stages of pregnancy. Maternal exposure to NMP in paint and coating removal may occur before a woman realizes she is pregnant. As such, even if she is aware of the risks of exposure to NMP, she may not take steps to reduce risks of fetal death.

Even if they are aware of their pregnancy, women may not wish to disclose this fact to their employers; although legal protections are in place, many women "feel they may lose their job, may not be considered for a promotion, or may have a promotion taken away if they announce they are pregnant" (Ref. 81). Similarly, the American College of Occupational and Environmental Medicine has found that "while it is illegal for an employer to terminate a worker because of pregnancy, such fears may not be groundless for some workers" (Ref. 83). Consequently, pregnant women may attempt to "minimize their pregnancy" (Ref. 81) and may not be vocal in their workplace about reducing risks to their pregnancy. This could increase chances of exposure to chemicals such as NMP that present a risk of fetal death.

Exposure to NMP in paint and coating removal during a single day (over 8 hours) was found to present risks of fetal death (Ref. 3). The impacts of fetal death, including miscarriage or stillbirth, include emotional impacts on the woman experiencing the death of a fetus, and also present significant emotional impacts for partners and spouses.

Emotional impacts and other mental health effects of miscarriage or stillbirth can include depression, anxiety, grief, and guilt. Mental health research has consistently identified both miscarriage (defined as fetal death occurring before the 20th week of gestation) and stillbirth (defined as fetal death occurring after the 20th week of gestation) as a significant emotional burden that can persist for more than a year and sometimes up to three years following the event of fetal death (Ref. 84). Compared with their peers, women who have experienced fetal death "exhibit significantly elevated levels of depression and anxiety in the weeks and months following the loss, compared with samples of pregnant, community or postpartum women" (Ref. 85). Psychologists see miscarriage and stillbirth as "an unanticipated, often physically as well as psychologically traumatic event representing the death of a future child and disruption of reproductive plans. Physiologically, it marks the end of a pregnancy, and psychologically it may produce doubts about procreative competence" (Ref. 86). Other descriptions of fetal death similarly characterize it as "a significant psychosocial stressor that results in a high level of dysphoria and grief" (Ref. 87). Consequently, women who experience the death of a fetus are at increased risk for depression, anxiety, and other psychiatric disorders (Ref. 86).

Major depressive disorder has been identified in between 10% to 50% of women after a miscarriage, depending on the measures used (Refs. 88 and 89). According to the National Institutes of Mental Health, persistent depressive disorder is a depressed mood that lasts for at least two years. Symptoms can include difficulty concentrating, sleep pattern disruptions, appetite or weight change, thoughts of suicide or suicide attempts, loss of interest in hobbies or activities, decreased energy, and aches, headaches, or digestive problems without a clear physical cause and that do not ease even with treatment (Ref. 90). Depression can affect an individual's physical health and their ability to work. Additionally, depression in one family member can also result in increased instance of illness or morbidity in other family members (Ref. 91). Treatment can require several types of attempted pharmaceutical or psychological therapies, and, in the case of depression following fetal death, can persist for years (Ref. 89).

Depression is not the only emotional impact of fetal death; many women also experience intense and persistent anxiety. Researchers have found that "a significant percentage of women experience elevated levels of anxiety after a miscarriage up until about 6 months post-miscarriage, and they are at increased risk for obsessive-compulsive and posttraumatic stress disorder" (Ref. 89).

In addition to depression and anxiety, a primary component of the emotional burdens presented by fetal death is guilt. As one researcher explained, women search for answers to what they perceive as an inexplicable trauma: "They will spend enormous amounts of emotional energy trying to explain why it happened . . .. They often blame themselves, even when it is inaccurate, to help make sense of it. Women may torment themselves with guilt and blame, rewriting the story, so to speak: 'If I hadn't gone to the grocery store' or 'If I didn't stay up so late.' It's a way of coping with the loss" (Ref. 92).

Related to these emotional impacts, one study found that "the mean annual suicide rate within one year after miscarriage was significantly higher (18.1 per 100.000) than the suicide rates both for women who gave birth (5.9) and for women in the general population (11.3) in Finland between 1987 and 1994" (Ref. 86).

Women experiencing miscarriages or stillbirths are not the only individuals affected by fetal death. Researchers have also documented the ways in which the woman's partners are affected by the loss (Ref. 86). Recent research has found that male partners experience more grief over miscarriages than previously assumed (Ref. 92) and that in 25% of the cases studied, the intensity of fathers' grief exceeded that of the mothers' (Ref. 93).

Additional burdens from fetal death can be felt throughout the affected family, including by subsequent children, since the depression, anxiety, and guilt initiated by fetal death may persist during and after any subsequent successful pregnancy (Ref. 92). As a result, future pregnancies and children can be adversely affected by fetal death during the mother's previous pregnancies due to persistent psychological impacts leading to maternal stress or depression that can last up to three years (Refs. 94 and 85). As a result of this stress or depression, complications during subsequent pregnancies can occur. Maternal anxiety or depression during pregnancy is associated with pre-term birth, decreased birth weight, and impacts on fetal brain development as a result of abnormal uterine blood flow and increased maternal cortisol levels (Ref. 94). Maternal anxiety and depression, including that initiated by fetal death during a previous pregnancy, is also

associated with a higher risk of maternal postpartum depression (Ref. 85), which can lead to poor infant care, and infant cognitive delay (Ref. 94). For some children born to women who previously experienced the death of a fetus, there may be disorganized or insecure maternal attachment or bonding (Ref. 95), and maternal perinatal mood symptoms that may alter a child's emotional or health outcomes (Refs. 85 and 86). For example, available data indicate that "12-month-old infants born following prenatal loss were reported to show higher rates of disorganized attachment patterns to their mothers than children born into families without a loss history. Thus, even if there is no persistence of mood disturbance into the postnatal period, there may still be adverse effects of a previous prenatal loss on the parent-child relationship and child outcomes" (Ref. 85). Similarly, maternal post-partum depression or anxiety has been found to have "deleterious effects on maternal-child attachment, child behavior, and cognitive and neuroendocrine outcomes that persist into adolescence" (Ref. 85). In this way, a single instance of fetal death may result in years of emotional impacts for the mother and may potentially affect the health and well-being of future children. In addition to depression and anxiety, emotional impacts can take the form of grief, envy, or isolation.

Similarly, a woman's attitude towards a pregnancy does not necessarily correlate with the emotional impact resulting from fetal death. Although ambivalence toward pregnancy was associated with different emotional impacts (greater association with depressive symptoms, rather than grief), they were found to be as intense as in women who were not ambivalent about their pregnancy (Ref. 86).

As a result, fetal death at any stage of a pregnancy, even when experienced by a woman who is ambivalent about that pregnancy, may result in intense emotional impacts and psychological morbidities, for both the mother and other family members; these impacts can include depression and anxiety and, in many cases, could persist and potentially impact future pregnancies and children.

Additionally, it is important to note that fetal death can present health risks to the woman; in some cases, maternal death can result. From 1981 to 1991, the Centers for Disease Control and Prevention (CDC) recorded 62 cases of maternal mortality following spontaneous abortion at or before 20 weeks of fetal gestational age (an overall case fatality rate of 0.7 per 100,000 spontaneous abortions) (Ref. 96). Leading causes of maternal mortality during these incidents of fetal death were infection, hemorrhage, or embolism (Ref. 96). The CDC has noted that this case fatality rate is likely the result of underreporting, and that "the true number of deaths related to pregnancy might increase from 30% to 150% with active surveillance" (Ref. 97).

Even when the effects of fetal death are less severe, a miscarriage or stillbirth can have considerable adverse consequences on an individual, family, or community. Commercial and consumer users of NMP in paint and coating removal are at risk of fetal death from typical use of products containing NMP; although EPA is unable to quantify the precise number or frequency of fetal deaths that may occur as a result of exposure to NMP during paint and coating removal, reducing the risks of exposure would benefit women, their families, and the public at large by reducing risks of fetal death in a population of approximately 12,000 pregnant individuals (consumers and workers) likely to experience acute exposures that present risks of fetal death. Details on how EPA estimated the number of individuals is in section 5.2.1 of the Economic Analysis (Ref. 4).

2. Developmental effects—chronic exposures. The NMP risk assessment identified developmental effects as the most sensitive endpoint for chronic exposure to NMP. Specifically, the assessment selected decreased birth weight as the critical effect resulting from repeated exposures to women of child-bearing age. It is not known if there is a window of exposure that may pose greater risks to the fetus; therefore, any repeated exposure to NMP could increase risks to the fetus for developmental effects.

Rather than accumulating over a lifetime, risks were found for workers exposed to NMP during paint and coating removal over the course of a workweek, or five days. Even when maternal exposure ceased, the decreased fetal body weight was found to be a persistent adverse effect (Ref. 3); consequently, a relatively brief period of maternal repeated exposure to NMP in typical paint and coating removal can cause fetal weight decreases, resulting in life-long impacts. There are increased risks of decreased fetal weight for the subset of pregnant women among the approximately 8,800 female workers in 4,300 commercial facilities or companies that use NMP for paint and coating removal. EPA estimates that there are approximately 500 pregnant women working in these commercial facilities (Ref. 4). A subset of these 500 pregnant would have chronic exposure to NMP at levels that would result in an MOE below the benchmark of 30 for decreased fetal weight (Ref. 3).

Decreased fetal weight can lead to reduced or low birth weight, which can have lifelong effects on a person and their family. Most cases of reduced or low birth weight are pre-term or premature birth; as a result, until recently, health impacts of reduced or low birth weight have been difficult to separate from the effects due to premature birth or gestational age. However, epidemiological, social, and medical research in the past several decades has isolated several health effects of reduced or low birth weight separate from gestational age at birth. Full-term babies may be born at low or reduced birth weights as a result of fetal growth restriction; these infants are usually referred to as small for gestational age, and "may have low birth weight because something slowed or stopped their growth in the womb" (Ref. 98). Low birth weight is typically defined as birth weight of less than 5.5 pounds, or 2,500 grams. Very low birth weight is typically defined as less than 1,500 grams (Ref. 99).

Low birth weight can have significant impacts on childhood development and the incidence of future diseases (Ref. 100); reduced birth weight can cause serious health problems for some children (Ref. 98), as well as long-term impacts on their lives as adults (Ref. 101).

Health impacts of low or reduced birth weight can begin at birth. According to the CDC, low birth weight infants may be more at risk for many health problems as neonates (Ref. 99); other medical authorities report that health impacts for infants with low birth weight include low oxygen levels at birth, inability to maintain body temperature; difficulty feeding and gaining weight; infection; breathing problems such as respiratory distress syndrome; neurologic problems, such as intraventricular hemorrhage (bleeding inside the brain); gastrointestinal problems such as necrotizing enterocolitis (a serious disease of the intestine), and a greater risk of Sudden Infant Death Syndrome (Ref. 102). These effects and health impacts have clear implications for the infant's future health and survival, and can cause emotional stress and anguish for families of the infant.

Effects of reduced or low birth weight can persist beyond infancy. It can affect growth: Low birth weight has been found to be "a major risk factor for children's physical growth in the early

years and there is no evidence of catch-up by age 2" (Ref. 103). In populations that may already be at risk for poor health outcomes, children with reduced birth weight or who were small for gestational age continued to be significantly smaller in all measures (height, weight, and head circumference) than their normal birth weight counterparts at age 3 (Refs. 104 and 105), and generally smaller between ages 4 through 7 (although the differences were small) (Ref. 104).

A child's size is not the only potential effect of reduced or low birth weight. Many studies have identified increased risk of cognitive, behavioral, and neurological problems in children and adolescents who had low birth weight or who were small for gestational age (Refs. 106 and 107). A large cohort study that followed infants born at full term with reduced birth weight (small for gestational age) found that "children of both genders who were born [small for gestational age] are at higher risk of learning difficulties" (Ref. 106), with girls with the lowest birth weight experiencing an increased risk of attention problems (Ref. 106).

Other studies have confirmed the impact of reduced or low birth weight on academic success in childhood; researchers note that compared to their normal birth weight siblings, low birth weight children are less likely to be in excellent or very good health in childhood. They also score significantly lower on reading, passage comprehension, and math achievement tests. Low birth-weight children are roughly one-third more likely to drop out of high school relative to other children (Ref. 100).

After childhood, the health, social, and financial impacts of reduced or low birth weight can continue. In many cases, an individual's size may continue to be affected. The difference in growth during adolescence and early adulthood varies by sex. Female adults who were very low birth weight infants tend to be the same size as their peers of average birth weight by age 20, while male adults "remain significantly shorter and lighter than controls" (Ref. 109). However, this may have its own risks: "Since catch-up growth may be associated with metabolic and cardiovascular risk later in life, these findings may have implications for the future adult health of [very low birth weight] survivors" (Ref. 109).

In terms of health effects, low birth weight can continue to have significant negative effects on adults. Researchers have found that low birth weight increases the probability of being in fair or poor health as an adult. Specifically, "low birth weight children are nearly twice as likely as their normal birth-weight siblings to be in problematic health by ages 37–52 (23% versus 12%) (Ref. 100). Specific risks associated with low birth weight (separate from pre-term birth or gestational age) include increased risk of renal disease (Ref. 110); increased risk of asthma, diabetes, stroke, heart attack, or heart disease by age 50 (compared to average weight siblings) (Ref. 100); and increased risk of clinically verified hyperkinetic disorder, including attention deficit hyperactivity disorder (Ref. 111). Adults who were low birth weight babies may be more likely to have certain health issues such as diabetes, heart disease, high blood pressure, metabolic syndrome, and obesity (Ref. 98).

Additionally, there are financial implications for adults who were low birth weight; low birth weight has been found to lower labor force participation and labor market earnings over an individual's lifetime (Ref. 100). Specifically, "low birth weight is linked to a 10% reduction in hourly wages from ages 18–26, compared to the wages of normal birth-weight siblings, but a 22% reduction in wages from ages 37–52. Low birth-weight children, relative to their normal birth-weight siblings, work 7.4% fewer hours in adulthood" (Ref. 100).

Decreased fetal weight and low birth weight are strongly associated with a number of adverse health effects in adults. The Barker Hypothesis (Ref. 112) was among the first to identify a pattern between neonatal health and cardiovascular disease. Subsequent research in laboratory animals and in human epidemiological studies confirmed this pattern and extended the observations to include the relationship between delayed fetal growth, low birth weight and metabolic syndrome, which encompasses a host of adverse outcomes, such as hypertension, insulin resistance, obesity and type 2 diabetes mellitus (Refs. 113, 114, and 115). Diseases such as cardiovascular disease, hypertension, obesity and diabetes mellitus have a tremendous impact on public health. For example, according to the CDC, heart disease remains the nation's leading cause of death (Ref. 116). In addition to causing premature mortality, the monetary costs of cardiovascular disease were estimated at $209.3 billion in direct costs and $142.5 billion in indirect costs, for a total of $351.8 billion (Ref. 116). A number of health disparities are associated with cardiovascular disease. Cardiovascular disease causes more deaths in women than men, and in black Americans, compared to white (Ref. 116). Years of potential life lost before age 75 from heart disease is nearly double for Black or African Americans relative to White, Non-Hispanic Americans (Ref. 116).

Several of these health effects associated with reduced fetal growth and low birth weight fall within the definition of metabolic syndrome, which is generally defined as the presence of 3 or more of the following: Abdominal obesity (waist circumference ≥88 cm in women or ≥102 cm in men); low HDL cholesterol (<50 mg/dL in women or <40 mg/dL in men); elevated triglycerides (≥150 mg/dL); elevated fasting blood glucose (≥100 mg/dL or use of oral hypoglycemic medication or insulin or both); or elevated blood pressure (at least 1 of the following: Systolic ≥130 mmHg, diastolic ≥85 mmHg, or use of antihypertensive medication). Epidemiological studies indicate a strong, consistent association between low birth weight and metabolic syndrome (Ref. 113). The symptoms associated with metabolic syndrome are in turn associated with increased risk of cardiovascular disease and diabetes (Ref. 117).

Collectively, the sign, symptoms and diseases associated with delayed fetal growth and small birth weight present an enormous burden on public health. The extent that the development of adult disease is rooted in reductions in fetal and neonatal growth could limit the success of adult lifestyle changes in modifying these effects. Therefore, prevention must be focused on assuring fetal and neonatal health and preventing adverse impacts on growth rates.

Researchers highlight the fact that low birth weight can occur in every demographic group, and that even though most babies with low birth weight have normal outcomes, as a whole, infants with low birth weight "generally have higher rates of subnormal growth, illnesses, and neurodevelopmental problems. These problems increase as the child's birth weight decreases" (Ref. 118). Additionally, by using sibling comparisons and cohort studies, the effects of low birth weight have been found to persist even when accounting for "the independent effects of birth order, mother's age at birth, birth year cohort, race/ethnicity, family structure, parental income, and parental fertility timing" (Ref. 100).

Though most research has focused on infants with low or very low birth weight, it is important to note that children with reduced, but clinically normal, birth weights (2,500 to 2,999 grams) are also at increased risk from the health, academic, social, and financial effects described.

In this way, reduced or low birth weight resulting from maternal exposure to NMP during paint and coating removal can have serious and life-long impacts on individuals and their families, including their future family members. Even when birth weight is not reduced to the clinical definition of low, the decrease in fetal weight can have significant impacts. Additionally, it is important to note that the impacts of low birth weight go beyond affected individuals and their families; reduced and low birth weight "results in substantial costs to the health sector and imposes a significant burden on society as a whole" (Ref. 101).

3. Body weight reductions—chronic exposures. While the impact of decreased body weights in adult animals may be minimal, decreased body weight gain in pregnant females, in particular, may contribute to negative developmental outcomes as well as impacts on adult health (Refs. 119 and 120).

4. Kidney toxicity—chronic exposures. There are increased health risks for liver toxicity for many of the approximately 30,300 workers in 4,300 commercial facilities or companies that use NMP for paint and coating removal (Ref. 4). Exposure to NMP can cause kidney damage. This damage may result in signs and symptoms of acute kidney failure that include; decreased urine output, although occasionally urine output remains normal; fluid retention, causing swelling in the legs, ankles or feet; drowsiness; shortness of breath; fatigue; confusion; nausea; seizures or coma in severe cases; and chest pain or pressure. Sometimes acute kidney failure causes no signs or symptoms and is detected through lab tests done for another reason.

Kidney toxicity means the kidney has suffered damage that can result in a person being unable to rid their body of excess urine and wastes. In extreme cases where the kidney is impaired over a long period of time, the kidney could be damaged to the point that it no longer functions. When a kidney no longer functions, a person needs dialysis and ideally a kidney transplant. In some cases, a non-functioning kidney can result in death. Kidney dialysis and kidney transplantation are expensive and incur long-term health costs if kidney function fails (Ref. 56).

The monetary cost of kidney toxicity varies depending on the severity of the damage to the kidney. In less severe cases, doctor visits may be limited and hospital stays unnecessary. In more severe cases, a person may need serious medical interventions, such as dialysis or a kidney transplant if a donor is available, which can result in high medical expenses due to numerous hospital and doctor visits for regular dialysis and surgery if a transplant occurs. The costs for hemodialysis, as charged by hospitals, can be upwards of $100,000 per month (Ref. 57).

Depending on the severity of the kidney damage, kidney disease can impact a person's ability to work and live a normal life, which in turn takes a mental and emotional toll on the patient. In less severe cases, the impact on a person's quality of life may be limited while in instances where kidney damage is severe, a person's quality of life and ability to work would be affected. While neither the precise reduction in individual risk of developing kidney toxicity from reducing exposure to NMP during paint or coating removal or the total number of cases avoided can be estimated, these costs must still be considered because they can significantly impact those exposed to NMP.

5. Liver toxicity—chronic exposures. There are increased health risks for liver toxicity for many of the approximately 30,300 workers in 4,300 commercial facilities or companies that use NMP for paint and coating removal (Ref. 4).

Some form of liver disease impacts at least 30 million people, or 1 in 10 Americans. Included in this number is at least 20% of those with NAFLD. NAFLD tends to impact people who are overweight/obese or have diabetes. However, an estimated 25% do not have any risk factors. The danger of NAFLD is that it can cause the liver to swell, which may result in cirrhosis over time and could even lead to liver cancer or failure (Ref. 42). The most common known causes to this disease burden are attributable to alcoholism and viral infections, such as hepatitis A, B, and C. These known environmental risk factors of hepatitis infection may result in increased susceptibility of individuals exposed to organic chemicals such as NMP.

Additional medical and emotional costs are associated with liver toxicity following chronic exposure to NMP in paint and coating removal, although these costs cannot be quantified. These costs include medical visits and medication costs. In some cases, the ability to work can be affected, which in turn impacts the ability to get proper medical care. Liver toxicity can lead to jaundice, weakness, fatigue, weight loss, nausea, vomiting, abdominal pain, impaired metabolism, and liver disease.

Depending upon the severity of the jaundice, treatments can range significantly. Simple treatment may involve avoiding exposure to NMP and other solvents; however, this may impact an individual's ability to continue to work. In severe cases, liver toxicity can lead to liver failure, which can result in the need for a liver transplant. Even if a donor is available, liver transplantation is expensive (with an estimated cost of $575,000) and there are countervailing risks for this type of treatment (Ref. 44). The mental and emotional toll on an individual and their family as they try to identify the cause of sickness and possibly experience an inability to work, as well as the potential monetary cost of medical treatment required to regain health, are significant.

6. Reproductive toxicity. There are increased risks for these reproductive effects for many of the approximately 30,300 workers in 4,300 commercial facilities or companies that use NMP for paint and coating removal (Ref. 4). Similar to effects discussed previously, while neither the precise reduction in individual risk of developing this disorder from reducing exposure to NMP or the total number of cases avoided can be estimated, EPA still considers their impact.

7. Disproportionate impacts on environmental justice communities. An additional factor that cannot be monetized is the disproportionate impact on environmental justice communities. As described in Units VI.C.1.b. and XVI.B.1.b, Hispanic and foreign-born workers, who may have limited English proficiency, are disproportionately over-represented in construction trades (Ref. 4), in which NMP is used for paint and coating removal. Because they are disproportionately over-represented in this industry, these populations are disproportionately exposed to NMP during paint and coating removal, and are disproportionately at risk to the range of adverse health effects described here.

D. Availability of Alternatives

For almost every situation in which NMP is used to remove paints or coatings, EPA is aware of a cost-effective, economically feasible chemical substitutes or alternative methods. The exception is for critical corrosion-sensitive components of military aviation and vessels, for which EPA proposes are critical for national security, and for which EPA proposes an exemption, described in more detail in Unit XVIII.

EPA considered chemical substitutes and alternative methods consistent with the requirements of TSCA Section 6(c)(2)(C) and as similarly recommended by the SBAR panel (Ref.

27). A full industry profile characterizing manufacturers, processors, and end users of NMP for paint and coating removal and a use and substitutes analysis are included in section 2 and 3 of EPA's economic assessment. (Ref. 4). As described below, EPA proposes that alternatives are technologically and economically feasible, reasonably available, and present fewer hazards to human health than NMP in paint and coating removal. EPA requests comment on whether its conclusion that substitutes for NMP are available and technically and economically feasible is accurate and whether its consideration of alternatives was sufficient to satisfy the requirements of TSCA section 6(c)(2)(C).

Research into the efficacy of chemical substitutes has identified products currently available for commercial and consumer users of NMP for paint and coating removal, for a variety of coatings on numerous substrates (Refs. 58 and 59). Additionally, in most commercial sectors, NMP is not in widespread use; most sectors use substitute chemicals or methods, either due to financial considerations, problems with the efficacy of products containing NMP, or concern for worker or individual health and safety (Ref. 22). This was emphasized by a small business that manufactures such products (Ref. 22).

Many producers of paint and coating removal products containing NMP also produce paint and coating removal products with substitute chemicals (Ref. 4). This was emphasized by small businesses participating in the SBAR process (Ref. 27). Thus, there is already precedent for producers reformulating products to meet demand from commercial or individual customers.

Based on the frequent use of substitute chemicals or alternative methods for paint and coating removal in all industries discussed here, and the formulation and distribution of substitute chemicals for paint and coating removal by all formulators of products containing NMP (Ref. 4), EPA found that economically feasible alternatives to NMP are reasonably available for all paint and coating removal uses. Primary chemical substitutes for NMP in paint and coating removal include products formulated with benzyl alcohol; dibasic esters; acetone, toluene, and methanol (ATM); and caustic chemicals. EPA evaluated these products for efficacy, toxicity, relative hazards compared to NMP, and other hazards that might be introduced by use of these products (such as environmental toxicity, increased global warming potential, and increased flammability or other hazards to users).

EPA's analysis compared the hazard and exposure characteristics of the chemical paint and coating removal chemicals and products presumed to be already in use to NMP, to aid in ascertaining the impact on users of moving to alternative products. EPA used authoritative sources to characterize efficacy, hazard endpoints and identify effect and no effect levels. Relative exposure potential was assessed based on physical chemical parameters and concentrations in formulations, and exposure potential was considered to be similar to NMP within an order of magnitude. Product composition was based on publicly available Safety Data Sheets for products advertised for paint and coating removal (Ref. 36).

Products based on benzyl alcohol formulations have been identified as efficacious paint and coating removers in various industry sectors (Refs. 22 and 27). Consumer products containing benzyl alcohol are available for sale (Refs. 22, 27, 35, 58, 59, and 61). Regarding differential hazards between benzyl alcohol and NMP, there are fewer hazard concerns compared to NMP-based products, and the benzyl alcohol NOAELs are higher than for NMP, suggesting lower toxicity (Ref. 34). Regarding differential exposures between benzyl alcohol and NMP, the relative inhalation and dermal exposure potentials are similar to NMP (Ref. 34). Taken together, benzyl alcohol-based paint removers are expected to result in lower risks, primarily due to lower toxicity.

Dibasic ester products can include dimethyl succinate, dimethyl glutarate and dimethyl adipate. Many NMP products contain dibasic esters, and given the efficacy of these products users of these products would not experience much inconvenience if switched to substitute products that contain solely formulations based on dibasic esters, without NMP (Ref. 34). Regarding differential hazards between dibasic esters and NMP, in general, the hazards associated with dibasic esters are less severe and occur at concentrations suggesting lower toxicity (Ref. 34). Regarding differential exposures between dibasic esters and NMP, the relative inhalation exposure potential is similar to NMP. The relative dermal exposure potential for dibasic esters is lower, but similar to, NMP (Ref. 34). Taken together, dibasic ester-based paint removers are expected to result in lower risks, primarily due to lower toxicity.

ATM products contain acetone, toluene, and methanol. Products containing these chemicals may remove coatings very quickly, but may not be effective on every type of coating (Ref. 27). ATM-based products are composed of chemicals that exhibit a range of hazard characteristics. Taken together, the components of ATM-based formulations have comparable hazard concerns to NMP. Regarding differential exposures between ATM and NMP, the relative inhalation exposure potentials for acetone, toluene and methanol are higher than NMP. The relative dermal exposure potentials for acetone, toluene and methanol are lower, but similar to, NMP (Ref. 34).

Products with caustic chemicals typically include calcium hydroxide or magnesium hydroxide. In many uses, they can be an effective product, particularly when multiple coatings are being removed from a substrate. In contrast to NMP-based products, there are no developmental or other repeat dose endpoints of concern associated with caustic products (Ref. 34). Caustic products pose acute concerns due to their physical chemical properties and can cause chemical burns (Ref. 34). The risks associated with caustic-based products are acute, and may be mitigated by appropriate and familiar protective equipment. The risks associated with NMP-based products are both acute and long term (Ref. 3).

In summary, when methylene chloride is excluded from consideration, the most likely chemical substitutes for NMP in paint and coating removal do not pose a risk of acute or chronic developmental effects, generally have lower or similar exposure potential than NMP, and when acute risks are present, as in the case of caustic chemicals, those risks are self-limiting by the nature of the adverse effects. The chemical formulations that seem to present some risks of concern contain toluene and methanol; however, risks from these chemicals can be mitigated by the user more easily than risks presented by NMP. Overall, exclusive use of substitute chemical products for paint and coating removal instead of NMP would remove the risks of chronic effects and acute developmental effects without introducing additional substantial risks to human health.

In addition to examining toxicity to humans, EPA reviewed available data on the chemicals in the baseline and alternative products for aquatic toxicity, persistence and bioaccumulation, as a basis for examining potential environmental toxicity. Only one chemical evaluated may have significant impacts on aquatic toxicity, with concern for environmental persistence and/or bioaccumulation. This chemical is contained in NMP-based paint

removal products and thus is not considered further.

EPA is also mindful of the risks that may be introduced by substitute chemicals or methods that increase global warming, and has examined the global warming potential of the chemical components of likely chemical substitutes for NMP in paint and coating removal. NMP does not present concerns for global warming and has a global warming potential (GWP) of 0 (Ref. 3). Similarly, the GWP values of likely substitute chemicals in paint and coating removal are: 0 GWP (benzyl alcohol, ATM) or not assessed (caustics, dibasic esters) (Ref. 24). As such, EPA has not identified any increased risk of global warming that would be introduced by use of chemical products as substitutes for NMP in paint and coating removal.

In addition to human and environmental toxicity, other hazards associated with chemical methods for paint and coating removal are risks of fire due to flammability of the chemical product, and poisoning or acute injury. Risks of fire are serious when using solvents such as paint and coating removal chemicals. Even among products that fall within the same general product composition category, there is meaningful variability in the specific formulations of paint remover products, and thus in their flammability. Furthermore, it is impracticable for EPA to predict the specific product formulations for which use will increase as a result of prohibitions on NMP in paint and coating removal. It is therefore impracticable for EPA to forecast whether the flammability of popular paint and coating removers would generally increase or decrease as a result of the proposed rule.

In addition to using substitute chemical products, EPA has identified non-chemical methods for paint and coating removal that can be used as alternatives to NMP. These methods are already frequently in use in various industries or by consumers for paint and coating removal, and are described in more detail in Unit VI.E.

EPA recognizes that all methods of paint and coating removal can present some hazards. Most of these alternative methods are already in frequent use, including by consumers and workers who currently use NMP or other chemicals for some paint and coating removal. The risks associated with each of these methods, while serious, are generally acute, related to injury, and can be mitigated through readily available and easy-to-implement standard safety practices; in contrast, the acute risks presented by NMP, such as fetal death, require specialized gloves and are not the type of hazard frequently encountered when using household products.

E. Impacts of the Proposed and Alternative Regulatory Options

1. First co-proposed approach: Supply-chain approach. The costs of the first co-proposed approach are estimated to include product reformulation costs, downstream notification costs, recordkeeping costs, and Agency costs. The costs of paint and coating removal product reformulations are estimated to be approximately $7,000 to $14,000 per year (annualized at 3% over 20 years) and $9,000 to $19,000 (annualized at 7% over 20 years). The cost for reformulation includes a variety of factors such as identifying the appropriate substitute chemical for NMP in the formulation, assessing the efficacy of the new formulation and determining shelf life. The costs to users of paint and coating removers containing NMP are (−$1,477,000) to $27,617,000 at a discount rate of 3% and (−$1,231,000) to $27,638,000 at a discount rate of 7% (Ref. 4). The costs of downstream notification and recordkeeping on an annualized basis over 20 years are $100 and $100 using 3% and 7% discount rates respectively (Ref. 4). Agency costs for enforcement are estimated to be approximately $114,401 and $111,718 annualized over 20 years at 3% and 7%, respectively. The total cost of the proposed approach for paint and coating removers containing NMP is estimated to be (−$1,484,000) to $27,624,000 and (−$1,251,000) to $27,668,000 annualized over 20 years at 3% and 7%, respectively (Ref. 4).

2. Second co-proposed approach: Reformulation, labeling, and PPE approach. Reformulation costs are estimated to have less of an impact than those associated with adoption of worker protection programs. Given equipment costs and the requirements associated with establishing a dermal and respiratory protection program which involves training, purchase of specialized gloves, respirator fit testing and the establishment and maintenance of a medical monitoring program, EPA anticipates that companies would choose to switch to substitute chemicals instead of adopting a program for PPE, including with a performance-based option of meeting an air concentration level of 5 ppm as an exposure limit for NMP in paint and coating removal, when these products have a maximum concentration of 35% NMP by weight. The estimated annualized costs to commercial and consumer users of switching to this type of dermal and respiratory protection program are $47,076,900 to $56,130,900 at 3% and $47,245,900 to $56,383,900 at 7% over 20 years. In addition, there would be higher EPA administration and enforcement costs under the second co-proposed approach than there would be with an enforcement program under the first co-proposed approach. Finally, this option requires that formulators of paint and coating removal products containing NMP identify which gloves are non-penetrable by NMP if used for an eight-hour shift; this requires that the formulators or processors conduct testing, which can have costs of $15,786 per product (Refs. 4 and 127).

3. Options that exclude downstream notification. For those options that exclude downstream notification, the options are less effective and more to challenging to implement. The downstream notification (*e.g.*, via SDS) provides additional information on the prohibitions under the proposed option for processors and distributors of NMP or products containing NMP other than paint and coating removers, and provides an efficient way for those entities to recognize themselves as affected by the regulation, which contributes to a more effective regulation (Ref. 63). In this way, the downstream notification component of the supply chain approach contributes to the use no longer presenting an unreasonable risk because it streamlines and aids in compliance and implementation (Ref. 64).

F. Summary

EPA is co-proposing these two options because the Agency believes both deserve consideration by commenters. The first co-proposed approach is necessary so that NMP in paint and coating removal no longer presents an unreasonable risk to the general population or to women of childbearing age. It is more cost effective than other regulatory options EPA identified as potentially reducing risks so that they are no longer unreasonable, because the proposed option achieves the benefits of reducing the unreasonable risks so they are no longer unreasonable for a lower cost than the second co-proposed approach. For more information, see Section 6 in the Economic Analysis (Ref. 4). As stated previously in this notice, the first co-proposed approach includes:

- Prohibiting manufacturing (including import), processing, and distribution in commerce of NMP for use in consumer and commercial paint

and coating removal, except for specified uses critical to national security;

- Prohibiting commercial use of NMP for paint and coating removal, except for specified uses critical to national security;
- Requiring that any products containing NMP intended or used for paint and coating removal be distributed in containers with a volume no less than 5 gallons;
- Requiring downstream notification of the prohibition on manufacturing (including import), processing, and distribution of NMP for the prohibited uses; and
- Requiring limited recordkeeping.

Technically and economically feasible alternatives to NMP for paint and coating removal are reasonably available. The supply chain approach ensures protection of consumers from the unreasonable risk by precluding the off-label purchase of commercial products by consumers.

The first co-proposed approach is relatively easy to enforce because key requirements are directly placed on a small number of suppliers and because the supply chain approach minimizes to the greatest extent the potential for NMP products to be intentionally or unintentionally misdirected into the prohibited uses. Enforcement under the other options would be much more difficult since the key requirements are directly placed on the large number of product users. As described in a recent article on designing more effective rules and permits, "the government can implement rules more effectively and efficiently when the universes of regulated sources are smaller and better-defined. This is because, other factors being equal, governments can more easily identify, monitor, and enforce against fewer, rather than more, entities" (Ref. 63). Under other options, enforcement activities must target firms that might perform the activity where a use of NMP is restricted or prohibited. Identifying which establishments might use paint and coating removers is difficult because paint and coating removal is not strictly specific to any industry (Ref. 4).

The second co-proposed approach would allow the continued use of NMP in commercial and consumer paint and coating removal at up to 35 percent NMP by weight, except for exempt critical national security uses which can be at any concentration, provided that commercial users of NMP for paint and coating removal establish a worker protection program for dermal and respiratory protection.

In addition, the co-proposed approach would require formulators of products for either commercial or consumer uses other than critical national security uses to: Reformulate products such that paint and coating products containing NMP do not exceed a maximum of 35 percent NMP by weight in product formulations; test gloves for the product formulations being processed and distributed in commerce to identify specialized gloves that provide protection for users; label products with information for consumers and provide information for commercial users about reducing risks when using the product. This approach would effectively reduce risk for workers. EPA is requesting comment on whether this co-proposed approach would be effective at reducing risks for consumers so that the risks are no longer unreasonable.

XVII. Costs and Monetized Benefits of the NMP Component of the Proposed Rule, the Alternatives EPA Considered, and Comparison of Costs and Benefits

EPA proposes that the identified risks from NMP in paint and coating removal are unreasonable. Apart from that proposed determination, EPA has evaluated the potential costs and benefits of the two co-proposed approach and their variations.

A. Costs of the First Co-Proposed Approach

The details of the costs of the first co-proposed approach for NMP in commercial and consumer paint and coating removal are discussed in Unit I.E. and in the Economic Analysis (Ref. 4). Under the first co-proposed option, costs to users of paint and coating removal products containing NMP are (−$1,477,000) to $27,617,000 at a discount rate of 3% and (−$1,231,000) to $27,638,000 at a discount rate of 7%. Costs of paint and coating removal product reformulations are estimated to be approximately $7,000 to $14,000 per year (annualized at 3% over 20 years) and $9,000 to $19,000 (annualized at 7% over 20 years). Costs of downstream notification and recordkeeping on an annualized basis over 20 years are $100 and $100 using 3% and 7% discount rates respectively. Agency costs for enforcement are estimated to be approximately $114,401 to $111,718 annualized over 20 years at 3% and 7%, respectively (Ref. 4). Under the first proposed approach, total costs of the proposed rule relevant to NMP in paint and coating removal are estimated to be (−$1,484,000) to $27,624,000 and (−$1,251,000) to $27,668,000 annualized over 20 years at 3% and 7% respectively (Ref. 4).

EPA also found that a use prohibition alone without downstream notification requirements would not address the unreasonable risks. EPA estimated the costs of this option to be $5,164,000 to $30,702,000 annualized over 20 years at 3% and $5,409,000 to $30,839,000 annualized over 20 years at 7% (Ref. 4).

B. Benefits of the First Co-Proposed Approach

As described in Unit XVII.B., there are no monetizable benefits from mitigating the risks from NMP in consumer and commercial paint and coating removal. Although the alternatives considered are unlikely to result in the same health benefits as the first co-proposed option, EPA was unable to quantify the differences.

C. Comparison of Benefits and Costs of the First Co-Proposed Approach

Based on the costs and benefits EPA can estimate, the monetized subset of benefits for preventing the risks resulting from NMP in consumer and commercial paint and coating removal do not outweigh the estimated monetary costs. However, EPA believes that the balance of costs and benefits of the proposed regulation of NMP cannot be fairly described without considering the additional, substantial, non-monetized benefits of mitigating the non-cancer adverse effects. As discussed previously, the multitude of potential adverse effects associated with NMP in paint and coating removal can profoundly impact an individual's quality of life. Some of the adverse effects associated with NMP exposure can be immediately experienced and can affect a person from childhood throughout a lifetime (*e.g.*, low birth weight and associated impacts). Other adverse effects (*e.g.*, adult immunotoxicity, kidney and liver failure, or fetal death) can have impacts that are experienced for a shorter portion of life, but are nevertheless significant in nature.

While the benefits associated with avoiding the health effects associated with NMP exposure during paint and coating removal cannot be monetized or quantitatively estimated, the qualitative discussion highlights how some of these effects may be as severe as more traditionally monetizable effects and thus just as life-altering; therefore the benefits of avoiding these effects are substantial. These effects include not only medical costs but also personal costs such as emotional and mental stress that are impossible to accurately measure. Considering only monetized benefits would significantly underestimate the benefits of avoiding

NMP-induced adverse outcomes on a person's quality of life.

Thus, considering costs and the benefits that cannot be quantified and subsequently monetized (developmental effects, fetal death, adult body weight reductions, kidney toxicity, liver toxicity, and immunotoxicity), including benefits related to the severity of the effects and the impacts on a person throughout a lifetime in terms of medical costs, effects on earning power and personal costs, emotional and psychological costs, and the disproportionate impacts on Hispanic communities and individuals with limited English proficiency, the benefits of preventing exposure to NMP in paint and coating removal by an estimated 732,000 consumers and an estimated 30,300 commercial workers outweigh the costs.

D. Impacts on the National Economy, Small Businesses, Technological Innovation, the Environment, and Public Health of the First Co-Proposed Approach

As described in Unit V.B. and in the Economic Analysis, EPA considered the anticipated effects of this proposal on the national economy. While the impacts of this rule as a whole are described in Unit XXIII.C. and the impacts of the NMP component of this proposal are described in more detail in Unit XVII.A. and in Section 9.3 of the Economic Analysis (Ref. 4), EPA does not anticipate these impacts having an effect on the overall national economy. EPA anticipates that a majority of small businesses will have cost impacts of less than one percent of the annual revenue, and the majority of small business bathtub refinishing facilities and professional contractors will have cost impacts greater than one percent of annual revenue.

The first co-proposed approach is anticipated to drive technological innovation by formulators of paint and coating removal products containing NMP, as they continue to develop substitute products, and refine such products already available. It is also anticipated to drive technological innovation by formulators of chemical paint and coating removal products with different chemistries as well as manufacturers and retailers of alternative methods of paint and coating removal, particularly those with interest in appealing to the consumer uses. See section 9.3 in the Economic Analysis (Ref. 4).

The first co-proposed approach is anticipated to have a positive impact on public health, as described in Unit XVI.C. There is not anticipated to be a significant impact on the environment, for the reasons described in Unit XII.D.

E. Costs of the Second Co-Proposed Approach

The details of the costs of the second co-proposed approach for NMP in commercial and consumer paint and coating removal are discussed in Unit I.E. and in the supplement to the Economic Analysis (Ref. 127).

Under the second co-proposed option, costs to users of paint and coating removal products containing NMP are $47,076,900 to $56,130,900 (annualized at 3% over 20 years) and $47,245,900 to $56,383,900 (annualized at 7% over 20 years). Costs of paint and coating removal product reformulations are estimated to be approximately $15,100 to $21,100 per year (annualized at 3% over 20 years) and $20,100 to $28,100 (annualized at 7% over 20 years). Agency costs for enforcement are estimated to be approximately $1,024,144 and $998,711 annualized over 20 years at 3% and 7% respectively. Under the second proposed approach, total costs of the proposed rule relevant to NMP in paint and coating removal are estimated to be $47,098,000 to $56,146,000 and $47,274,000 to $56,404,000 annualized over 20 years at 3% and 7% respectively (Ref. 127).

F. Benefits of the Second Co-Proposed Approach

As described in Unit XVII.B., there are no monetizable benefits from mitigating the risks from NMP in consumer and commercial paint and coating removal. Although the second co-proposed option is unlikely to result in the same health benefits as the first co-proposed option, EPA was unable to quantify the differences.

G. Comparison of Benefits and Costs of the Second Co-Proposed Approach

Based on the costs and benefits EPA can estimate, the monetized subset of benefits for preventing the risks resulting from NMP in consumer and commercial paint and coating removal do not outweigh the estimated monetary costs. However, EPA believes that the balance of costs and benefits of the proposed regulation of NMP cannot be fairly described without considering the additional, substantial, non-monetized benefits of mitigating the non-cancer adverse effects. As discussed previously, the multitude of potential adverse effects associated with NMP in paint and coating removal can profoundly impact an individual's quality of life. Considering only monetized benefits would significantly underestimate the benefits of avoiding NMP-induced adverse outcomes on a person's quality of life.

H. Impacts on the National Economy, Small Businesses, Technological Innovation, the Environment, and Public Health of the Second Co-Proposed Approach

As described in Unit V.B. and in the Economic Analysis, EPA considered the anticipated effects of this proposal on the national economy. While the impacts of this rule as a whole are described in Unit XXIII.C. and the impacts of the NMP component of this proposal are described in more detail in Unit XVII.A. and in the supplement to the Economic Analysis (Ref. 127), EPA does not anticipate these impacts having an effect on the overall national economy.

The second co-proposed approach is anticipated to drive technological innovation by formulators of paint and coating removal products containing NMP, as they continue to develop substitute products, and refine such products already available. It is also anticipated to drive technological innovation by formulators of chemical paint and coating removal products with different chemistries as well as manufacturers and retailers of alternative methods of paint and coating removal, particularly those with interest in appealing to the consumer uses. See the supplement to the Economic Analysis (Ref. 127).

The second co-proposed approach is anticipated to have a positive impact on public health, as described in Unit XVI.C. There is not anticipated to be a significant impact on the environment, for the reasons described in Unit XII.D.

XVIII. Uses of NMP for Paint and Coating Removal Critical for National Security

As part of interagency collaboration with the Department of Defense (DOD) on this proposed rule, EPA is aware that there are specific military uses for which NMP is essential for paint and coating removal and for which there are no technically feasible alternatives currently available. The military readiness of DOD's warfighting capability is paramount to ensuring national security, which includes ensuring the maintenance and preservation of DOD's warfighting assets. DOD has identified mission-critical uses for NMP for ensuring military aviation and vessel readiness. These mission-critical items require the use of NMP for the removal of coatings from mission-critical corrosion-sensitive components on military aviation and

vessels, including safety-critical components made of specialty metallic, nonmetallic, and composite materials. As described in this section, EPA proposes to exempt these uses from the regulations proposed on NMP in paint and coating removal. This exemption is proposed for an initial ten-year period from the publication date of a final rule. EPA will engage with DOD to identify any potential extension that may need to be granted, by further rulemaking, after those ten years.

DOD continues and will continue to pursue potential substitutes for NMP in paint and coating removal. However, for mission-critical corrosion-sensitive components on military aviation and vessels, including safety-critical components, DOD has found that currently available substitute chemicals for paint and coating removal have one or more technical limitations. These are the same technical limitations described in Unit VIII., which outlines the proposed exemption for methylene chloride for similar uses critical to national security.

Under TSCA section 6(g)(1)(B), EPA may grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture if compliance with the requirement would significantly disrupt the national economy, national security, or critical infrastructure. Based on discussions and information provided by DOD, EPA has analyzed the need for the exemption and concurs with DOD that compliance with the proposed regulations on the use of NMP in paint and coating removal would significantly impact national security. DOD has demonstrated that the reduced mission availability of aircraft and vessels for military missions or, in the worst case, the loss of individual military aircraft and vessels, are potential impacts to military readiness that could result from the proposed prohibition of NMP in paint and coating removal. Due to the importance of these military systems for national security, EPA has determined that these uses of NMP for removal of specialized coatings from military aviation and vessel mission-critical corrosion-sensitive components, including safety-critical components, is critical for national security and the safety of personnel and assets. EPA includes in this exemption corrosion-sensitive military aviation and vessel mission-critical components such as landing gear, gear boxes, turbine engine parts, and other military aircraft and vessel components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and magnesium) and composite materials that not only require their coatings be removed for inspection and maintenance but also would be so negatively affected by the use of technically incompatible, substitute paint removal chemicals or methods that the safe performance of the vessel or aircraft could be compromised.

EPA proposes to grant this exemption for a period of ten years from the date of promulgation of a final rule, with a potential for extension, by further rulemaking, after review by EPA in consultation with DOD. The conditions for this exemption would be: (1) The use of NMP at any concentration for coating removal by DOD or its contractors performing this work only for DOD projects is limited to the mission-critical corrosion-sensitive components on military aviation and vessels, including safety-critical components; (2) this paint and coating removal must be conducted at DOD installations, or at Federal industrial facilities, or at DOD contractor facilities performing this work only for DOD projects.

This exemption granted under TSCA(6)(g)(1)(B) does not impact or lessen any requirements for compliance with other statutes under which the use, disposal, or emissions of NMP is regulated.

As described in Unit XVI.B.3., under the proposed approach, any paint and coating removal products containing NMP would be required to be distributed in containers with a volume no less than 5 gallons, as part of the exemption for uses identified as critical for national security. Allowing selective use for national security purposes does not disrupt the efficacy of the supply chain approach described in Unit XVI.B.3.

In addition to the exemption described in this unit, EPA will consider granting additional time-limited exemptions, under the authority of TSCA section 6(g). Details of EPA's request for comment on such exemption are described in Unit VIII.

XIX. Overview of Uncertainties for NMP in Paint and Coating Removal

A discussion of the uncertainties associated with this proposed rule can be found in the NMP risk assessment (Ref. 3) and in the additional analyses for NMP in commercial and consumer paint and coating removal (Refs. 75 and 76). A summary of these uncertainties follows.

EPA used a number of assumptions in the NMP risk assessment and supporting analysis to develop estimates for occupational and consumer exposure scenarios and to develop the hazard/dose-response and risk characterization. EPA recognizes that the uncertainties may underestimate or overestimate actual risks. These uncertainties include the likelihood that exposures to NMP vary from one paint and coating removal project to the next. EPA attempted to quantify this uncertainty by evaluating multiple scenarios to establish a range of releases and exposures. In estimating the risk from NMP in paint and coating removal, there are uncertainties in the number of workers and consumers exposed to NMP and in the model inputs and algorithms used to estimate exposures.

In addition to the uncertainties in the risks, there are uncertainties in the cost and benefits. The uncertainties in the benefits are most pronounced in estimating the benefits from preventing the entirety of the adverse effects (described in Unit XIV.C.) because these non-cancer benefits generally cannot be monetized due to the lack of concentration response functions in humans leading to the ability to estimate the number of population-level non-cancer cases and limitations in established economic methodologies. Additional uncertainties in benefit calculations arose from EPA's use of a forecast from an industry expert to estimate the categories of alternatives that users might choose to adopt and the potential risks for adverse health effects that the alternatives may pose. While there are no products or methods that have comparable developmental or similar risks, these substitute products and alternative methods do present hazards. Without information on what alternative methods or chemicals users of NMP for paint and coating removal are likely to switch to, and estimates of the exposures for those alternatives. EPA is unable to quantitatively estimate any change in non-cancer risks due to use of substitute chemicals or alternative methods instead of using NMP for commercial or consumer paint and coating removal.

In addition to these uncertainties related to benefits, there are uncertainties related to the cost estimates. As noted earlier, there is uncertainty in EPA's estimates of which chemical substitutes or alternative methods users may adopt instead of NMP for paint and coating removal, which in turn produces uncertainty as to the cost of those substitutes or methods. EPA has estimated the cost of substitute chemicals, but is not able to fully characterize or quantify the total costs to all sectors for using substitute chemicals or alternative products. In addition, under certain assumptions EPA's economic analysis estimates that

some users of NMP for paint and coating removal will see a cost savings when switching to substitutes. Standard economic theory suggests that financially rational companies would choose technologies that maximize profits so that regulatory outcomes would not typically result in a cost savings for the regulated facilities. There could be several reasons that cost savings might occur in the real world. Potential reasons include lack of complete information or barriers to obtaining information on the cost savings associated with alternatives as well as investment barriers or higher interest rates faced by firms. Additionally, there may be costs associated with these alternatives that are not adequately accounted for in the analysis. To evaluate the effect of this uncertainty, EPA has included a sensitivity analysis that sets the cost savings to zero for these compliance alternatives (Ref. 4 at Section 7). EPA also recognizes that these firms might experience positive costs of compliance rather than zero costs, so that the actual total costs could be higher than those in the sensitivity analysis. However, EPA has no current basis to estimate these potentially higher costs, since the available data appear to show that there are lower cost substitutes available. EPA requests comments on these assumptions.

Additionally, there are uncertainties due to in the estimates of the number of affected commercial and consumer users, and for numbers of processors and distributors of NMP-containing products not prohibited by the proposed rule who are required to provide downstream notification and/or maintain records.

EPA will consider additional information received during the public comment period. This includes scientific publications and other input submitted to EPA during the comment period.

XX. Major Provisions and Enforcement of the Proposed Rule for NMP in Paint and Coating Removal

This proposal relies on general provisions in the proposed Part 751, Subpart A, which can be found at 81 FR 91592 (December 16, 2016).

A. Prohibitions and Requirements

Under the first co-proposed approach, the rule, when final, would (1) prohibit the manufacturing, processing, and distribution in commerce of NMP for consumer and commercial paint and coating removal, exempting uses defined as critical for national security (see Unit XVIII.); (2) prohibit the commercial use of NMP for paint and coating removal, exempting for uses defined as critical for national security; (3) require any paint and coating removal products containing NMP to be distributed in containers with a volume no less than 5 gallons; (4) require that any commercial use of NMP for paint and coating removal for uses critical to national security include specific worker protections; (5) require manufacturers, processors, and distributors of NMP and all products containing NMP, excluding retailers, to provide downstream notification of the prohibitions; (6) and require recordkeeping relevant to these prohibitions. The prohibition on manufacturing, processing, and distributing in commerce of NMP for all consumer paint and coating removal would take effect 180 days after publication of a final rule. Similarly, the prohibition on manufacturing, processing, and distributing in commerce of NMP for any paint and coating removal for uses other than those exempted as critical for national security in volumes less than 5-gallon containers would take effect 180 days after publication of a final rule. The prohibition on commercial use of NMP for paint and coating removal except for the exempted critical national security uses would take effect 270 days after publication of a final rule. These are reasonable transition periods because, as noted in Unit XVI.D. and by the small businesses participating in the SBAR process, many formulators of paint and coating removers containing NMP also manufacture products for this use that do not contain NMP (Ref. 27). In addition, alternative paint removal products exist at comparable expense for users to purchase. Six months from publication of the final rule is sufficient time to allow for existing stocks to move through the market place and to allow manufacturers, processers and distributors and users to plan for and implement product substitution strategies.

Under the second co-proposed approach, formulators of paint and coating removal products for either commercial or consumer use would be required to: (1) Ensure that their paint and coating removal products containing NMP do not exceed a maximum of 35 percent NMP by weight in product formulations exempting products used for critical national security uses (see Unit XVIII.); (2) Test gloves for the product formulations being processed and distributed in commerce for other than exempt critical national security uses to identify specialized gloves that provide protection for users and keep records relevant to these tests; (3) Label products with information for consumers about the risks presented by products that contain NMP and how to reduce these risks when using the products, including identifying which specialized gloves provide protection against the specific formulation; and (4) Provide information for commercial users about reducing risks when using the product, via product labels, SDS, and other methods of hazard communication. Variations of more than 1% in any component of a paint and coating removal product containing NMP would be considered a separate formulation.

Under this co-proposal, commercial users of NMP for paint and coating removal other than exempt critical national security uses would be prohibited from using paint and coating removal products or formulations that contain more than 35 percent by weight of NMP. They would also be required to establish a worker protection program for dermal and respiratory protection, including hazard communication, training, and requirements that workers wear clothing covering most of the body, *i.e.*, impervious long pants and shirts with long sleeves, use gloves specified by product formulators (described under formulator requirements below) and a respirator with APF 10, with an alternative air exposure limit of 5 ppm achieved through engineering controls or ventilation.

B. Downstream Notification

EPA has authority under TSCA section 6 of TSCA to require that a substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. Many manufacturers and processors of NMP are likely to manufacture or process NMP or products containing NMP for other uses that would not be regulated under this proposed rule. Other companies may be strictly engaged in distribution in commerce of NMP, without any manufacturing or processing activities, to customers for uses that are not regulated. Under both co-proposed approaches, EPA is proposing a requirement for downstream notification by manufacturers, processors, and distributors of NMP for any use to ensure compliance with the prohibition on manufacture, processing,

distribution in commerce, and commercial use of NMP for the uses proposed for regulation. Downstream notification is necessary for effective enforcement of the rule because it provides a record, in writing, of notification on use restrictions throughout the supply chain, likely via modifications to the Safety Data Sheet. Downstream notification also increases awareness of restrictions on the use of NMP for paint and coating removal, which is likely to decrease unintentional uses of NMP by these entities. Downstream notification represents minimal burden and is necessary for effective enforcement of the rule. The estimated cost of downstream notification on an annualized basis over 20 years is $100 and $100 using 3% and 7% discount rates respectively (Ref. 4).

The effective date of the requirement for this notification would be 45 days after publication of the final rule. This is a reasonable transition period because regulated entities would only need to provide additional information on their SDS, which are routinely produced and updated.

C. 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 proposed 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 of operation in violation of this proposed rule when it becomes effective could constitute a separate violation. Knowing or willful violations of this proposed rule when it becomes effective 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.

XXI. Analysis for Methylene Chloride and NMP in Paint and Coating Removal under TSCA Section 9 and Section 26(h) Considerations

A. TSCA Section 9(a) Analysis

Section 9(a) of TSCA provides that, if the Administrator determines in her discretion that an unreasonable risk may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA, the Administrator must submit a report to the agency administering that other law that describes the risk and the activities that present such risk. If the other agency responds by declaring that the activities described do not present an unreasonable risk or if that agency initiates action under its own law to protect against the risk within the timeframes specified by TSCA section 9(a), EPA is precluded from acting against the risk under sections 6(a) or 7 of TSCA.

TSCA section 9(d) instructs the Administrator to consult and coordinate TSCA activities with other Federal agencies for the purpose of achieving the maximum enforcement of TSCA while imposing the least burden of duplicative requirements. For this proposed rule, EPA has consulted with OSHA and with CPSC. Both CPSC and OHSA have provided letters documenting this consultation (Refs. 121 and 122).

CPSC protects the public from unreasonable risks of injury or death associated with the use of consumer products under the agency's jurisdiction. Though CPSC has provided guidance to consumers when using products containing NMP, there are no CPSC regulations regarding NMP in paint and coating removal. CPSC currently requires that household products that can expose consumers to methylene chloride vapors must bear appropriate warning labels (52 FR 34698, September 14, 1987). In a letter regarding EPA's proposed rulemaking, CPSC stated that "Some paint removers are distributed for sale to, and use by, consumers and thus would likely fall within CPSC's jurisdiction. However, because TSCA gives EPA the ability to reach both occupational and consumer uses, we recognize that EPA may address risks associated with these chemicals in a more cohesive and coordinated manner given that CPSC lacks authority to address occupational hazards" (Ref. 121).

OSHA assures 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 methylene chloride standard, 29 CFR 1910.1052, was issued in 1997 and applies to general industry, construction, and shipyard employment. It sets the PEL for airborne methylene chloride to an eight-hour TWA of 25 parts per ppm. OSHA has not set a standard for NMP. OSHA recently published a Request for Information on approaches to updating PELs and other strategies to managing chemicals in the workplace (79 FR 61384, October 10, 2014). OSHA's current regulatory agenda does not include revision to the methylene chloride PEL, establishment of a PEL for NMP, or other regulations addressing the risks EPA has identified when methylene chloride or NMP are used in paint and coating removal (Ref. 122).

This proposed rule addresses risk from exposure to methylene chloride and NMP during paint and coating removal in both workplace and consumer settings. With the exception of TSCA, there is no Federal law that provides authority to prevent or sufficiently reduce these cross-cutting exposures. No other Federal regulatory authority, when considering the exposures to the populations and within the situations in its purview, can evaluate and address the totality of the risk that EPA is addressing in this proposal and the prior proposal on TCE uses (Ref. 1). For example, OSHA may set exposure limits for workers but its authority is limited to the workplace and does not extend to consumer uses of hazardous chemicals. Further, OSHA does not have direct authority over state and local employees, and it has no authority at all over the working conditions of state and local employees in states that have no OSHA-approved State Plan under 29 U.S.C. 667. Other Federal regulatory authorities, such as CPSC, have the authority to only regulate pieces of the risks posed by methylene chloride and NMP, such as when used in consumer products.

Moreover, recent amendments to TSCA, Public Law 114–182, alter both the manner of identifying unreasonable risk under TSCA and EPA's authority to address unreasonable risk under TSCA, such that risk management under TSCA is increasingly distinct from analogous provisions of the Consumer Product Safety Act (CPSA), the Federal Hazardous Substances Act (FHSA), or the OSH Act. These changes to TSCA reduce the likelihood that an action under the CPSA, FHSA, or the OSH Act

would reduce the risk of methylene chloride and NMP in paint and coating removal so that the risks are no longer unreasonable under TSCA. Whereas (in a TSCA section 6 rule) an unreasonable risk determination sets the objective of the rule in a manner that excludes cost considerations, 15 U.S.C. 2605(a)(b)(4)(A), subject to time-limited conditional exemptions for critical chemical uses and the like, 15 U.S.C. 2605(g), a consumer product safety rule under the CPSA must include a finding that "the benefits expected from the rule bear a reasonable relationship to its costs." 15 U.S.C. 2058(f)(3)(E). Additionally, recent amendments to TSCA reflect Congressional intent to "delete the paralyzing 'least burdensome' requirement," 162 Cong. Rec. S3517 (June 7, 2016). However, a consumer product safety rule under the CPSA must impose "the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated." 15 U.S.C. 2058(f)(3)(F). Analogous requirements, also at variance with recent revisions to TSCA, affect the availability of action under the FHSA relative to action under TSCA. 15 U.S.C. 1262. Gaps also exist between OSHA's authority to set workplace standards under the OSH Act and EPA's amended obligations to sufficiently address chemical risks under TSCA. To set PELs for chemical exposure, OSHA must first establish that the new standards are economically feasible and technologically feasible. 79 FR 61387 (2014). But under TSCA, EPA's substantive burden under TSCA section 6(a) is to demonstrate that, as regulated, the chemical substance no longer presents an unreasonable risk, with unreasonable risk being determined without consideration of cost or other non-risk factors.

TSCA is the only regulatory authority able to prevent or reduce risks of methylene chloride or NMP exposure to a sufficient extent across the range of uses and exposures of concern. In addition, these risks can be addressed in a more coordinated, efficient and effective manner under TSCA than under two or more different laws implemented by different agencies. Furthermore, there are key differences between the newly amended finding requirements of TSCA and those of the OSH Act, CPSA, and the FHSA. For these reasons, in her discretion, the Administrator does not determine that unreasonable risks from the use of methylene chloride and NMP in 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. However, EPA is requesting public comment on this issue (*i.e.,* the sufficiency of an action taken under a Federal law not administered by EPA).

B. TSCA Section 9(b) Analysis

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

Although several EPA statutes have been used to limit methylene chloride or NMP exposure (Units III.A. and XII.A.), regulations under these EPA statutes have limitations because they largely regulate releases to the environment, rather than direct human exposure. SDWA only applies to drinking water. CAA does not apply directly to worker exposures or consumer settings where methylene chloride or NMP are used. Under RCRA, methylene chloride that is discarded may be considered a hazardous waste and subject to requirements designed to reduce exposure from the disposal of methylene chloride to air, land and water. RCRA does not address exposures during use of products containing methylene chloride or NMP. Only TSCA provides EPA the authority to regulate the manufacture (including import), processing, and distribution in commerce, and use of chemicals substances.

For these reasons, the Administrator does not determine that unreasonable risks from the use of methylene chloride and NMP in 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.

C. Section 26(h) Considerations

EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science. For example, EPA based its proposed determination of unreasonable risk presented by the use of methylene chloride and NMP in paint and coating removal on the completed risk assessments, which each followed a peer review and public comment process, as well as using best available science and methods (Refs. 2 and 3). Supplemental analyses were performed to better characterize the exposed populations and estimate the effects of various control options. These supplemental analyses were consistent with the methods and models used in the risk assessment. These analyses were developed for the purpose of supporting a future regulatory determination: To determine either that particular risks are not unreasonable or that those are risks are unreasonable. They were also developed to support risk reduction by regulation under section 6 of TSCA, to the extent risks were determined to be unreasonable. It is reasonable and consistent to consider these supplemental analyses in this rulemaking for such relevant purposes.

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 the Agency's response to comments, can be found on EPA's Assessments for TSCA Work Plan Chemicals Web page at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals.*

XXII. 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.**

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XXIII. 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 an economically significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Order 12866 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., VII.B., and XVII.B. (Refs. 4 and 127).

B. Paperwork Reduction Act (PRA)

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by the EPA has been assigned the EPA ICR number 2556.01. You can find a copy of the ICR in the docket for this proposed rule (Ref. 123), and it is briefly summarized here.

Under the proposed approach for methylene chloride and both co-proposed approaches for NMP, the information collection activities required under the proposed rule include a downstream notification requirement and a recordkeeping requirement. The downstream notification would require companies that ship methylene chloride or NMP to notify companies downstream in the supply chain of the prohibitions of methylene chloride or NMP in the proposed rule. The proposed rule does not require the regulated entities to submit information to EPA. The proposed rule also does not require confidential or sensitive information to be submitted to EPA or downstream companies. The recordkeeping requirement mandates companies that ship methylene chloride or NMP to retain certain information at the company headquarters for three years from the date of shipment. These information collection activities are necessary in order to enhance the prohibitions under the proposed rule by ensuring awareness of the prohibitions throughout the methylene chloride or NMP supply chain, and to provide EPA with information upon inspection of companies downstream who purchased methylene chloride or NMP. EPA believes that these information collection activities would not significantly impact the regulated entities.

Under the second co-proposed approach for NMP, processors of paint and coating removal products containing NMP must test gloves for permeability for each formulation they process. One type of gloves may not be appropriate for all NMP paint remover formulations because the permeability of the product will vary based on the other solvents and chemicals used in the formulation. The testing requirements for glove permeability and the labeling requirements mandate that processors paint removers containing perform glove permeability testing on each paint remover product containing NMP and update their current product labels to contain warnings and instructions for consumers on how to reduce exposures to NMP. Without the reporting requirements, processors of these products might not provide information about the specific types of protective gloves to users. Requiring that labels of paint and coating removal products containing NMP include information about which specific types of gloves provide dermal protection from the specific product formulation provides information that is essential for knowing how to reduce exposures while carrying out paint and coating removal with NMP. Requiring additional warnings and instructions to consumers provides information about the risks presented by the product and how those risks can be reduced. EPA believes that these information collection activities would not significantly impact the regulated entities.

Respondents/Affected Entities: Methylene chloride and NMP manufacturers, processors, and distributors; commercial users of NMP for paint and coating removal.

Respondent's Obligation to Respond: Respondents are not obligated to respond or report to EPA.

Estimated Number of Respondents for the Proposed Approach for Methylene Chloride and the First Co-Proposed Approach for NMP: 327.

Estimated Total Number of Potential Respondents for the Proposed Approach for Methylene Chloride and the Second Co-Proposed Approach for NMP: 327

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

Total Estimated Burden for the Proposed Approach for Methylene Chloride and the First Co-Proposed Approach for NMP: 163.5

Estimated Total Annual Burden for the Proposed Approach for Methylene Chloride and the Second Co-Proposed Approach for NMP: 1,084 hours.

Total Estimated Cost for the Proposed Approach for Methylene Chloride and the First Co-Proposed Approach for NMP: $7,904 (per year).

Estimated Total Annual Costs for the Proposed Approach for Methylene Chloride and the Second Co-Proposed Approach for NMP: $924,890 (per year).

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *oira_submission@omb.eop.gov*, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than February 21, 2017. The EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 603 of the RFA, 5 U.S.C. 601 *et seq.*, EPA prepared an initial regulatory flexibility analysis (IRFA) (Ref. 26) that examines the impact of the proposed rule on small entities along with regulatory alternatives that could minimize that impact. The complete IRFA is available for review in the docket and is summarized here.

1. Need for the rule. Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA

determines that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk. Based on EPA's risk assessments of methylene chloride (Ref. 2) and NMP (Ref. 3), EPA proposes a determination that the use of methylene chloride and NMP in paint and coating removal presents an unreasonable risk of injury to human health. The provisions of this proposal are necessary to address the risk so that it is no longer unreasonable.

2. *Objectives and legal basis.* In part, the legal basis for this proposal is TSCA section 6(a), which provides authority for the Administrator to apply requirements to the extent necessary so that a chemical substance or mixture no longer presents an unreasonable risk of injury to health or the environment. Additional legal basis for the proposal is found at TSCA section 26(l)(4). With respect to chemical substances such as methylene chloride and NMP (which are listed in the 2014 update to the TSCA Work Plan for Chemical Assessments and for which completed risk assessments were published prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) TSCA section 26(l)(4) expressly authorizes EPA to issue rules under TSCA section 6(a) that are consistent with the scope of the completed risk assessment and consistent with the other applicable requirements of TSCA section 6.

3. *Small entities covered by this proposal.* EPA estimates that the proposal would affect approximately 10,300 small entities. The majority of these entities are commercial users of methylene chloride or NMP in paint and coating removal in a variety of occupational settings such as bathtub refinishing, graffiti removal, autobody repair, and residential renovations. This also includes a small number of formulators of paint and coating removal products that contain methylene chloride and NMP, for commercial or consumer uses (Refs. 4, 26, and 127).

4. *Compliance requirements and the professional skills needed.* For methylene chloride, EPA is proposing under TSCA section 6 to prohibit the manufacture (including import), processing, and distribution in commerce of methylene chloride for all consumer and many types or uses of commercial paint and coating removal, as described in the proposed rule. EPA is also proposing under TSCA section 6 to prohibit the use of methylene chloride for commercial paint and coating removal in these several specified sectors. Additionally, EPA is proposing to require that any paint or coating removal products containing methylene chloride that continue to be distributed be packaged in volumes no less than 55-gallon containers, except for formulations produced specifically for DOD. EPA is also proposing to require 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; and to require limited recordkeeping. More details on this supply chain approach are in Unit VI.C.3.

For NMP, EPA is co-proposing two approaches. Under the first co-proposed approach, EPA is proposing to prohibit the manufacture (including import), processing, and distribution in commerce of NMP for all consumer and commercial paint and coating removal, exempting uses identified in the proposed rule as critical to national security; and to prohibit the commercial use of NMP for paint and coating removal, exempting uses identified as critical to national security. EPA is proposing to require that any paint or coating removal products containing NMP that continue to be distributed be packaged in no less than 5-gallon containers. EPA is also proposing to require manufacturers (including importers), processors, and distributors, except for retailers, of NMP for any use to provide downstream notification of these prohibitions throughout the supply chain; and to require limited recordkeeping. For the second co-proposed approach for NMP, commercial users would be required to implement and maintain a detailed program for worker protection, including dermal and respiratory protection. Additionally, product processors would be required to carry out testing to identify gloves that are protective against each product formulation, labeling product with that information, and provide additional information on the label to consumers regarding risks of using the product and instructions on how to reduce those risks. As in the first co-proposal, EPA is also proposing to require manufacturers (including importers), processors, and distributors, except for retailers, of NMP for any use to provide downstream notification of these prohibitions throughout the supply chain; and to require limited recordkeeping. More details on these two co-proposals are in Unit XVI.B.3.

Under the proposed approach for methylene chloride and first co-proposed approach for NMP, complying with the prohibitions, the downstream notification, and the recordkeeping requirements involve no special skills. However, implementing the use of substitute chemicals or alternative paint and coating removal processes may involve special skills or expertise in the sector in which the paint and coating removal is conducted.

For the second co-proposed approach for NMP, commercial users would be required to implement and maintain a detailed program for worker protection, which would involve special skills or expertise in industrial hygiene. Similarly, product processors would be required to carry out testing to identify gloves that are protective against each product formulation, could involve special skills or expertise. Labeling products to comply with new requirements would not involve special skill, particularly since EPA proposes to identify specific information for labels of paint and coating removal products containing NMP. As in the first co-proposal for NMP, the downstream notification and the recordkeeping requirements require no special skills.

5. *Other Federal regulations.* Other Federal regulations that affect the use of methylene chloride or NMP in paint and coating removal are discussed in Units III.A. and XIII.A. While many of the statutes that EPA and other agencies are charged with administering provide statutory authority to address specific sources and routes of methylene chloride exposure, none of these can address the serious human health risks from methylene chloride exposure that EPA is proposing to address under TSCA section 6(a). Regarding methylene chloride, because the methylene chloride NESHAPs were developed only to regulate emissions from certain types of paint and coating removal operations, not to address worker or consumer exposures, they are not duplicative with this proposal. Similarly, regulations addressing methylene chloride disposal or water contamination do not address worker or consumer exposures when conducting paint and coating removal. This proposed rule does not conflict with the NESHAP (or regulations addressing methylene chloride disposal or water contamination): it neither prohibits any action required by such

rules, nor requires any action prohibited by such rules.

OSHA's methylene chloride standard, 29 CFR 1910.1052, was issued in 1997 and applies to general industry, construction, and shipyard employment. This proposal does not duplicate OSHA's methylene chloride standard. Nor does the proposed rule conflict with the OSHA standard: it would not prohibit actions required to meet OSHA's methylene chloride standard and it would not require actions in violation OSHA's methylene chloride standard.

CPSC requires that consumer products that contain methylene chloride be labeled with a statement regarding the cancer risks presented by inhalation of methylene chloride fumes. This proposal does not impose requirements that would duplicate or conflict with CPSC's labeling requirements for methylene chloride.

Regarding NMP, there are no OSHA or CPSC regulations. EPA's proposal is not duplicative of other Federal rules nor does it conflict with other Federal rules.

6. *Regulatory alternatives considered.* As described in Units V.C., VI.C., XV.C., and XVI.B., EPA considered a wide variety of risk reduction options. The Economic Analysis (Ref. 4) examined several alternative analytical options. However, most of the alternatives did not address the risks presented by methylene chloride and NMP in paint and coating removal as necessary so that they would no longer be unreasonable, either to the general population or (in the case of NMP) to women of childbearing age.

The primary alternative considered by EPA for methylene chloride in paint and coating removal was to allow the commercial use of methylene chloride in paint and coating removal and require a respiratory protection program, including PPE, air monitoring, and either a supplied-air respirator of APF 1,000 or 10,000 or an air exposure limit achieved through engineering controls or ventilation in commercial facilities where methylene chloride is used for paint and coating removal. Depending on air concentrations and proximity to the paint and coating removal, other employees in the area would also need to wear respiratory protection equipment. While this option would address the risks presented by methylene chloride in paint and coating removal, so that they would no longer be unreasonable, the Economic Analysis indicates that this option is more expensive than switching to a substitute chemical or alternative paint and coating removal method (Ref. 4). However, as recommended by the SBAR panel, EPA is seeking comment on and additional information about air monitoring and the use of supplied-air respirators in firms conducting paint and coating removal with methylene chloride (Ref. 27).

EPA is co-proposing two approaches to address risks presented by NMP in commercial and consumer paint and coating removal. Those approaches are described above. EPA considers both of these approaches to be primary regulatory alternatives.

As required by section 609(b) of the RFA, EPA also convened a SBAR Panel to obtain advice and recommendations from small entity representatives that potentially would be subject to the rule's requirements. The SBAR Panel evaluated the assembled materials and small-entity comments on issues related to elements of an IRFA. A copy of the full SBAR Panel Report (Ref. 27) 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. Specifically, the Panel recommendations were: (1) Exposure information: EPA should request workplace monitoring information during the comment period for worker exposure levels from companies for methylene chloride and NMP in paint and coating removal. EPA should request additional information regarding the frequency of use currently of PPE, and consider that information when weighing alternative options in the proposed rulemaking for methylene chloride and NMP in paint and coating removal. (2) Regulatory options: EPA should consider and seek public comments on enhanced labeling requirements for consumer paint removal products containing methylene chloride or NMP to reduce exposure to methylene chloride and NMP. EPA should consider and seek public comments on a control option such as a certification program similar to the Lead Renovation, Repair and Painting program with increased training and education for commercial users of paint removers. EPA should delay any proposed regulatory action on methylene chloride for the commercial furniture refinishing industry while it gathers additional information to characterize the impacts on this industry of restrictions on use of methylene chloride in paint and coating removal. EPA should request comment on current practices in the furniture refinishing industry on limiting exposure to methylene chloride used in paint and coating removal. EPA should request comment on the feasibility of methylene chloride only being sold in 30–55- gallon drums. EPA should address the proposed regulatory actions as distinctly as possible in the one proposed rulemaking addressing both methylene chloride and NMP in paint and coating removal. (3) Alternatives: EPA should ensure that its analysis of the available alternatives to methylene chloride and NMP in paint and coating removal comply with the requirements of TSCA section 6(c)(2)(C) and include consideration, to the extent legally permissible and practicable, of whether technically and economically feasible alternatives that benefit health or the environment, compared to the use being prohibited or restricted, will be reasonably available as a substitute when the proposed requirements would take effect. Specifically, EPA should evaluate the feasibility of using alternatives, including the cost, relative safety, and other barriers; and take into consideration the current and future planned regulation of compounds the agency has listed as alternatives. (4) Cost information: EPA should request additional information on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies. (5) Risk assessments: EPA should recognize the concerns that the SERs had on the risk assessments by referring readers to the risk assessments and the Agency's Summary of External Peer Review and Public Comments and Disposition document for each risk assessment, which addresses those concerns, in the preamble of the proposed rulemaking.

Throughout this preamble, EPA has requested information with respect to these and other topics.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The requirements of this action would primarily affect manufacturers, processors, and distributors of methylene chloride or NMP. The total estimated annualized cost of the proposed rule under the first co-proposed approach for NMP is $4,185,000 to $23,423,000 and $4,550,000 to $23,472,000 annualized over 20 years at 3% and 7%, respectively (Ref. 4). The total estimated annualized cost of the proposed rule under the second co-proposed approach for NMP is $114,196,000 to $125,893,000 and $114,658,000 to $125,438,000 annualized over 20 years

at 3% and 7%, respectively (Ref. 127), which does not exceed the inflation-adjusted unfunded mandate threshold of $154 million.

E. Executive Order 13132: Federalism

The EPA has concluded that this action has federalism implications, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because regulation under TSCA section 6(a) may preempt state law. EPA provides the following federalism summary impact statement. The Agency consulted with state and local officials early in the process of developing the proposed action to permit them to have meaningful and timely input into its development. 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. 124). Although EPA provided these organizations an opportunity to provide follow-up comments in writing, EPA received no written follow-up.

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

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This rulemaking would not have substantial direct effects on tribal government because methylene chloride or NMP are not manufactured, processed, or distributed in commerce by tribes. Tribes do not regulate methylene chloride or NMP, and this rulemaking would not impose substantial direct compliance costs on tribal governments. Thus, EO 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.

EPA met with tribal officials in a national informational webinar held on May 12, 2015 concerning the prospective regulation of methylene chloride and NMP in paint and coating removal under TSCA section 6, and in another teleconference with tribal officials on May 27, 2015 (Ref. 125). EPA also met with the National Tribal Toxics Council (NTTC) in Washington, DC and via teleconference on April 22, 2015 (Ref. 125). In those meetings, EPA provided background information on the proposed rule and a summary of issues EPA explored. These officials expressed support for EPA regulation to reduce the risks presented by methylene chloride and NMP in paint and coating removal.

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

This action is subject to Executive Order 13045 because it is an economically significant regulatory action as defined by Executive Order 12866, and the EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children, specifically on the developing fetus. Accordingly, we have evaluated the environmental health or safety effects of methylene chloride and NMP in paint and coating removal on children. This action's health and risk assessment of exposure by children to methylene chloride and NMP in paint and coating removal are contained in Units I.F., VI.C.1.c., and XVI.B.1.c. of this preamble. Supporting information on methylene chloride and NMP exposures and the health effects of methylene chloride or NMP exposure by children is available in the Toxicological Review of Methylene Chloride (Ref. 5), the NMP risk assessment (Ref. 3), and the methylene chloride risk assessment (Ref. 2).

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

This proposed 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 rulemaking is intended to protect against risks from methylene chloride and NMP in paint and coating removal, and does not affect the use of oil, coal, or electricity.

I. National Technology Transfer and Advancement Act (NTTAA)

This proposed rulemaking does not involve technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272 note. However, under one of the co-proposals for NMP discussed in Unit XVI, EPA is proposing to require processors of paint and coating removal products that contain NMP to identify, through testing, gloves that provide an impervious barrier to dermal exposure during normal and expected duration and conditions of exposure. EPA has identified two potentially-applicable voluntary consensus standards for this process: ASTM International Standard F739, "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact," and ASTM International F1194–99, "Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing Materials." EPA is not proposing specific provisions for conducting and documenting glove testing, nor is EPA proposing to incorporate these voluntary consensus standards by reference. EPA requests comment on whether the regulation should include additional requirements on glove testing for processors and, if so, how that should be accomplished.

J. 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. Units VI.C.1.b.,VI.D.10., XVI.B.1.b., and XVI.C.6. of this preamble address public health impacts from methylene chloride and NMP in paint and coating removal. This proposed rule would address the current disproportionate risk to Hispanic workers (of all races) and foreign-born workers in the construction trades, where these two populations are overrepresented compared to the general U.S. adult population (Ref. 4). Though this proposed rule would eliminate risks of exposure to NMP and methylene chloride when used in paint and coating removal in the construction trades, because workers in these two populations currently are overrepresented in this trade, these populations would disproportionately benefit from this risk reduction. The 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. 126).

List of Subjects in 40 CFR Part 751

Environmental protection, Chemicals, Export notification, Hazardous substances, Import certification, Recordkeeping.

Dated: January 12, 2017.

Gina McCarthy,

Administrator.

Therefore, 40 CFR part 751, as proposed to be added at 81 FR 91592 (December 16, 2016), is proposed to be further amended as follows:

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

■ 1. The authority citation for part 751 is revised to read as follows:

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

■ 2. Add Subpart B to read as follows:

Subpart B—Methylene Chloride

Sec.
751.101 General.
751.103 Definitions.
751.105 Consumer Paint and Coating Removal.
751.107 Commercial Paint and Coating Removal in Specified Industries or for Specified Uses.
751.109 Downstream Notification.
751.111 Recordkeeping.

Subpart B—Methylene Chloride

§ 751.101 General.

This subpart sets certain restrictions on the manufacture (including import), processing, distribution in commerce, and uses of methylene chloride (CASRN 75–09–2) to prevent unreasonable risks to health associated with human exposure to methylene chloride for the specified uses.

§ 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:

Commercial furniture stripping means furniture stripping conducted in a commercial facility performed by an individual, government entity, or company for which an individual, government entity, or company receives remuneration or other form of payment.

Commercial paint and coating removal means paint and coating removal performed by an individual, government entity, or company, for which an individual, government entity, or company receives remuneration or other form of payment.

Critical corrosion-sensitive components of military aviation and vessels means parts that directly enable or support warfighting assets of the Department of Defense (DOD) and include "safety critical items" identified by DOD in accordance with DOD policies and requirements for ensuring safety and performance. These include corrosion-sensitive aviation and vessel safety-critical components such as landing gear, gear boxes, turbine engine parts, and other military aircraft and vessel components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and magnesium) and composite materials that not only require their coatings be removed for inspection and maintenance but also would be so negatively affected by the use of paint removal chemicals or methods other than methylene chloride that the safety of the system could be compromised.

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 § 751.109 and § 751.111.

Furniture stripping means paint and coating removal from furniture and includes 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 wood, metal, or other types of furniture, doors, radiators, or cabinets. Furniture stripping includes paint and coating removal from furniture that occurs separately from or as part of furniture refinishing.

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 or business who distributes in commerce a chemical substance, mixture, or article to consumer end users.

§ 751.105 Consumer Paint and Coating Removal.

After [*date 180 calendar days after the date of publication of the final rule*], all persons are prohibited from manufacturing, processing, and distributing in commerce methylene chloride for consumer paint and coating removal.

§ 751.107 Commercial Paint and Coating Removal in Specified Industries or for Specified Uses.

(a) After [*date 180 calendar days after the date of publication of the final rule*], all persons are prohibited from manufacturing, processing, and distributing in commerce methylene chloride for commercial paint and coating removal except for commercial furniture stripping or for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.103. After [*date 10 years after the date of publication of the final rule*], all persons are prohibited from manufacturing, processing, and distributing in commerce methylene chloride for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels.

(b) After [*date 180 calendar days after the date of publication of the final rule*], all persons are prohibited from distributing in commerce methylene chloride for paint and coating removal in containers with a volume less than 55 gallons except for formulations specifically manufactured for the Department of Defense, which may be distributed in commerce in containers with a volume no less than 5 gallons.

(c) After [*date 270 calendar days after the date of publication of the final rule*], all persons are prohibited from commercial use of methylene chloride for paint and coating removal except for commercial furniture stripping or for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.103. After [*date 10 years after the date of publication of the final rule*], all persons are prohibited from commercial use of methylene chloride for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels.

(d) Any paint and coating removal from critical corrosion-sensitive components of military aviation and vessels must be conducted under the following restrictions:

(1) All paint and coating removal from critical corrosion-sensitive components of military aviation and vessels using methylene chloride must be conducted at DOD installations, or at deployed locations under the control of DOD organizations, or at locations of DOD contractors performing coating removal work from corrosion-sensitive components of military aviation and vessels for DOD.

§ 751.109 Downstream Notification.

Each person who manufactures, processes, or distributes in commerce methylene chloride for any use after [*date 45 calendar days after the date of publication of the final rule*] 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.

§ 751.111 Recordkeeping.

(a) Each person who manufactures, processes, or distributes in commerce any methylene chloride after [*date 45 calendar days after the date of publication of final rule*] must retain in one location at the headquarters of the company 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 § 751.109; and

(3) The amount of methylene chloride shipped.

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

■ 3. Add Subpart C as follows:

Subpart C—N-Methylpyrrolidone.

Sec.
751.201 General.
751.203 Definitions. [option 1]
751.205 Manufacture, processing, and distribution of NMP for consumer paint and coating removal.
751.207 Manufacture, Processing, and Distribution of NMP for Commercial Paint and Coating Removal
751.209 Downstream Notification.
751.211 Recordkeeping. [option 2]
751.205 Paint and Coating Removal for Specified Uses.
751.209 Downstream Notification.
751.211 Recordkeeping.

Subpart C—N-Methylpyrrolidone

§ 751.201 General.

This subpart sets certain restrictions on the manufacture (including import), processing, distribution in commerce, and uses of N-methylpyrrolidone (NMP) (CASRN 872–50–4) to prevent unreasonable risks to health associated with human exposure to NMP for the specified uses.

§ 751.203 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:

Commercial paint and coating removal means paint and coating removal performed by an individual, government entity, or company, for which an individual, government entity, or company receives remuneration or other form of payment.

Critical corrosion-sensitive components of military aviation and vessels means parts that directly enable or support warfighting assets of the Department of Defense (DOD) and include "safety critical items" identified by DOD in accordance with DOD policies and requirements for ensuring safety and performance. These include corrosion-sensitive aviation and vessel safety-critical components such as landing gear, gear boxes, turbine engine parts, and other military aircraft and vessel components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and magnesium) and composite materials that not only require their coatings be removed for inspection and maintenance but also would be so negatively affected by the use of paint removal chemicals or methods other than NMP that the safety of the system could be compromised.

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 § 751.209 and § 751.211.

Formulation is a mixture of active and other ingredients.

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

Retailer means a person or business who distributes in commerce a chemical substance, mixture, or article to consumer end users.

[OPTION 1 PROPOSED REGULATORY TEXT FOR §§ 751.205, 751.207, 751.209, and 751.211: Co-Proposal 1: NMP—Banning the Manufacture, Processing, Distribution, and Use Except for a Critical Use Exemption]

§ 751.205 Manufacture, Processing, and Distribution of NMP for Consumer Paint and Coating Removal.

After [*date 180 calendar days after the date of publication of the final rule*], all persons are prohibited from manufacturing, processing, and distributing in commerce NMP for consumer paint and coating removal.

§ 751.207 Manufacture, Processing, and Distribution of NMP for Commercial Paint and Coating Removal.

(a) After [*date 180 calendar days after the date of publication of the final rule*], all persons are prohibited from manufacturing, processing, and distributing in commerce NMP for commercial paint and coating removal except for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.203. After [*date 10 years after the date of publication of the final rule*], all persons are prohibited from manufacturing, processing, and distributing in commerce NMP for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels.

(b) After [*date 180 calendar days after the date of publication of the final rule*], all persons are prohibited from distributing in commerce NMP for paint and coating removal in containers with a volume less than 55 gallons except for formulations specifically manufactured for the Department of Defense, which may be distributed in commerce in containers with a volume no less than 5 gallons.

(c) After [*date 270 calendar days after the date of publication of the final rule*], all persons are prohibited from commercial use of NMP for paint and coating removal except for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.203. After [*date 10 years after the date of publication of the final rule*], all persons are prohibited from commercial use of NMP for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels.

(d) Any paint and coating removal from critical corrosion-sensitive components of military aviation and vessels must be conducted under the following restrictions:

(1) All paint and coating removal from critical corrosion-sensitive components of military aviation and vessels using NMP must be conducted at DOD installations; DOD owned, contractor operated locations; or contractor owned, contractor operated locations performing paint and coating removal from critical corrosion-sensitive components of military aviation and vessels for DOD.

(2) [Reserved].

§ 751.209 Downstream notification.

Each person who manufactures, processes, or distributes in commerce NMP for any use after [*date 45 calendar days after the date of publication of the final rule*] must, prior to or concurrent with the shipment, notify companies to whom NMP is shipped, in writing, of the restrictions described in this subpart.

§ 751.211 Recordkeeping.

(a) Each person who manufactures, processes, or distributes in commerce any NMP after [*date 45 calendar days after the date of publication of final rule*] must retain in one location at the headquarters of the company documentation showing:

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

(2) A copy of the notification provided under § 751.209; and

(3) The amount of NMP shipped.

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

[OPTION 2 PROPOSED REGULATORY TEXT FOR §§ 751.205, 751.209, and 751.211: Co-Proposal 2: NMP—Continued Use with Requirements for Product Reformulation, Labeling, and PPE]

§ 751.205 Paint and Coating Removal for Specified Uses.

(a) *Processors.* (1) Formulations of NMP for paint and coating removal that contain more than 35 percent by weight of NMP must not be manufactured, processed, or distributed in commerce after [*date 180 calendar days after the date of publication of the final rule*], except for product formulations destined to be used by DOD or contractors performing work only on DOD projects for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.203 and subsection (b)(1).

(2) Conduct glove testing for each separate formulation of NMP, with a variation of more than 1 percent in any component of a paint and coating removal product containing NMP considered a separate formulation.

(i) The processor must be able to demonstrate that the gloves provide an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure.

(ii) The processor must subject the gloves to the expected conditions of exposure, including the likely combinations of chemical substances to which the gloves may be exposed in the work area.

(3) Provide a label securely attached to each NMP paint and coating removal product and not in the form of a booklet or other pull off type labeling. Label information must be prominently displayed and in an easily readable font size. Each separate NMP paint and coating removal product must be labeled with the following information:

(i) A notice that 40 CFR 751.205 requires commercial users of NMP paint and coating removal products to establish an occupational dermal and respiratory protection program, including the use of specialized gloves and an air exposure limit or respirator.

(ii) A warning to consumers that fetal death and other irreversible health effects may occur as a result of using the NMP product;

(iii) An identification of the formulation-specific gloves that will provide protection from the NMP product and a direction to use a new pair of those gloves for each time the NMP product is used;

(iv) A direction for consumers to either use the product outdoors or adequately ventilate the workspace by opening windows and adding fans;

(v) A warning for consumers to not apply the product as a spray;

(vi) A direction to wear clothing that covers exposed skin;

(vii) A direction to use a respirator with an Assigned Protection Factor (APF) of 10. Refer to § 751.205(c)(3)(ii) for respirators having an APF of 10 or greater;

(b) *Commercial users.* Each person or company engaged in any commercial NMP paint and coating removal activities [*date 180 calendar days after the date of publication of the final rule*] is prohibited from using paint and coating removal products or formulations that contain more than 35 percent by weight of NMP and must institute a worker protection program that includes the requirements of § 751.205(c) and (e) except for product formulations destined to be used for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.203. After [*date 10 years after the date of publication of the final rule*], all persons are prohibited from using paint and coating removal products or formulations that contain more than 35 percent by weight of NMP and must institute a worker protection program that includes the requirements of § 751.205(c) and (e).

(1) Any paint and coating removal from critical corrosion-sensitive components of military aviation and vessels must be conducted under the following restrictions:

(i) All paint and coating removal from critical corrosion-sensitive components of military aviation and vessels using NMP must be conducted at DOD installations; or at government owned, contractor operated locations; or at contractor owned and contractor operated locations performing paint and coating removal from critical corrosion-sensitive components of military aviation and vessels for DOD.

(ii) [Reserved].

(2) [Reserved].

(c) *Personal protective equipment (PPE).*

(1) *General.* (i) Protective equipment that is of safe design and construction for the work to be performed must be provided, used, and maintained in a sanitary, reliable, and undamaged condition. The employer must select PPE that properly fits each affected employee and communicate PPE selections to each affected employee.

(ii) *Training.* The employer must provide training to each employee required to use PPE.

(A) Each affected employee must be trained to know at least the following:

(*1*) When PPE is necessary.

(*2*) What PPE is necessary.

(*3*) How to properly don, doff, adjust, and wear PPE.

(*4*) The limitations of the PPE.

(*5*) The proper care, maintenance, useful life and disposal of the PPE.

(B) Each affected employee must demonstrate an understanding of these elements and the ability to use PPE properly before being allowed to perform work requiring the use of PPE.

(C) Retraining is required when previous training is rendered obsolete, whether due to changes in the workplace or the type of PPE, or when the employer has reason to believe that a previously-trained employee does not have the understanding and skill required by this subparagraph.

(2) *Dermal protective equipment.* (i) *General.* Each person who is reasonably likely to be dermally exposed in the work area to an NMP paint and coating removal product through direct handling of the substance or through contact with equipment or materials on which the substance may exist, or because the substance becomes airborne must be provided with, and required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use.

(ii) *Specific dermal protective equipment.* The required dermal protective equipment includes, but is not limited to, the following items:

(A) Formulation-specific gloves as indicated on the NMP paint and coating removal product label. A new pair must be supplied and worn each time the NMP product is used.

(B) Impervious clothing covering the exposed areas of the body (*e.g.* long pants, long shirt).

(iii) *Demonstration of imperviousness.* The employer must demonstrate that each item of chemical protective clothing selected provides an impervious barrier to prevent dermal exposure during normal and expected

duration and conditions of exposure within the work area by any one or a combination of the following:

(A) Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area.

(B) Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the chemical substance alone and in likely combination with other chemical substances in the work area.

(3) *Respiratory protection.* (i) *General.* Each person who is reasonably likely to be exposed in the workplace to the use of NMP in paint and coating removal products must be provided with and is required to wear, at a minimum, a NIOSH-certified respirator with an APF of 10. All respirators must be issued, used, and maintained in accordance with an appropriate written respiratory protection program that is specific to the workplace and that includes the following:

(A) Procedures for selecting respirators for use in the workplace.

(B) Medical evaluations of employees required to use respirators.

(C) Fit testing procedures.

(D) Procedures for proper use of respirators.

(E) Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators.

(F) Procedures to ensure adequate air quality, quantity, and flow of breathing air for atmosphere-supplying respirators.

(G) Procedures for regularly evaluating the effectiveness of the program.

(H) Recordkeeping.

(ii) *Authorized respirators.* The following NIOSH-certified respirators meet the minimum requirements of this section:

(A) Any NIOSH-certified air-purifying elastomeric half-mask respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) Any appropriate NIOSH-certified N100 (if oil aerosols absent), R100, or P100 filtering facepiece respirator;

(C) Any NIOSH-certified air-purifying full facepiece respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. A full facepiece air-purifying respirator, although it has a higher APF of 50, is required to provide full face protection because the PMN substance presents significant exposure concern for mucous membranes, eyes, or skin;

(D) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a half-mask; or

(E) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half mask.

(d) *Alternative to respirator requirement.* Commercial users of NMP products for paint and coating removal may use an existing chemical exposure limit (ECEL) as a means of controlling inhalation exposures whenever practicable rather than respirators.

(1) *Existing Chemical Exposure Limit (ECEL).* The employer must ensure that no person is exposed to an airborne concentration of NMP in excess of 20 mg/m^3 (the ECEL) as an 8-hour time-weighted average (TWA) without using a respirator. For non-8-hour work-shifts, the ECEL for that work-shift (ECELn) must be determined by the following equation: ECELn = ECEL x (8/n) x [(24-n)/16], where n = the number of hours in the actual work-shift.

(2) *Verification of method validity.* An independent accredited reference laboratory must verify the validity of the analytical method for NMP in paint and coating removal products. The sampling and analytical method, and all exposure monitoring data relied on by the employer, must be accurate to within 25% at a 95% confidence level for concentrations of NMP ranging from one half the ECEL to twice the ECEL.

(3) *Exposure monitoring.* The employer must collect samples that are representative of the potential exposure of each person who is reasonably likely to be exposed to airborne concentrations of NMP.

(i) *Initial monitoring.* Before the employer may deviate from the respirator requirements in subsection (d) of this section, the employer must conduct initial exposure monitoring to accurately determine the airborne concentration of NMP for each exposure group in which persons are reasonably likely to be exposed.

(ii) *Results.* (A) Employees whose exposures are represented by initial monitoring results below the ECEL need not wear the respirators required in subsection (d) of this section.

(B) Employees whose exposures are represented by initial monitoring results above the ECEL must continue to wear the respirators required in subsection (d) of this section until such time as two monitoring results below the ECEL, sampled at least 24 hours apart, are obtained.

(C) Within 15 days of the date exposure monitoring results are received, the employer must provide the results to each person whose exposure is represented by the monitoring. If the result is above the ECEL, the employer must also provide the employee with information on the actions the employer will take to reduce employee exposures to the ECEL or below.

(iii) *Periodic monitoring.* The employer must repeat exposure monitoring:

(A) Every 6 months for those employees whose initial monitoring results are between 0.5 ECEL and the ECEL, until such time as 2 results below 0.5 ECEL, from samples collected at least 24 hours apart, are obtained,

(B) Every 3 months for those employees whose initial monitoring results are at or above the ECEL. If 2 results below the ECEL, from samples collected at least 24 hours apart, are obtained, then frequency may be reduced to every 6 months. If 2 results below 0.5 ECEL, from samples collected at least 24 hours apart, are obtained, then exposure monitoring under this subsection need not be repeated unless there is a process, equipment, environment, or personnel change.

(C) At any time when process, equipment, environment, or personnel changes may reasonably cause new or additional exposures to NMP.

(e) *Hazard communication program.* Each employer that performs commercial NMP paint and coating removal activities must develop and implement a written hazard communication program for the substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, SDSs, other forms of warning material, and employee information and training will be satisfied. The employer must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The employer may rely on an existing hazard communication program that satisfies the requirements of this paragraph.

(1) *General.* The written program must include the following:

(i) A list of each NMP paint and coating removal product present in the work area. The list must be maintained in the work area and must use the identity provided on the appropriate

SDS. The list may be compiled for the workplace or for individual work areas.

(ii) The methods the employer will use to inform contractors of the presence of NMP paint and coating removal products in the employer's workplace and of the provisions of this part applicable to the NMP products if employees of the contractor work in the employer's workplace and are reasonably likely to be exposed to the NMP products while in the employer's workplace.

(2) *Employee information and training.* Each employer must ensure that employees are provided with information and training on NMP paint and coating removal products. This information and training must be provided at the time of each employee's initial assignment to using an NMP paint and coating removal product.

(i) Information provided to employees under this paragraph must include:

(A) The requirements of this section.

(B) The location and availability of the written hazard communication program.

(ii) Training provided to employees must include:

(A) The potential human health hazards of the NMP paint and coating removal products as specified on the label.

(B) The measures employees can take to protect themselves from the NMP paint and coating removal products, including specific procedures the employer has implemented to protect employees from exposure to the substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure.

(3) *Existing hazard communication program.* The employer need not take additional actions if existing programs and procedures satisfy the requirements of this section.

§ 751.209 Downstream notification.

Each person who manufactures, processes, or distributes in commerce NMP for any use after [*date 45 calendar days after the date of publication of the final rule*] must, prior to or concurrent with the shipment, notify companies to whom NMP is shipped, in writing, of the restrictions described in this subpart.

§ 751.211 Recordkeeping.

(a) Each person who manufactures, processes, or distributes in commerce any NMP after [*date 45 calendar days after the date of publication of final rule*] must retain in one location at the headquarters of the company documentation showing:

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

(2) A copy of the notification provided under § 751.209; and

(3) The amount of NMP shipped.

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

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EPA'S OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION (OCSPP)

Briefing Materials for Mike Dourson, Nominee for Assistant Administrator

ED_004886_00002644-00001

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About the Office of Chemical Safety and Pollution Prevention (OCSPP)

What We Do

Using sound science as a compass, OCSPP's mission is to protect you, your family, and the environment from potential risks from pesticides and toxic chemicals. Through innovative partnerships and collaboration, we also work to prevent pollution before it begins. This reduces waste, saves energy and natural resources, and leaves our homes, schools and workplaces cleaner and safer. OCSPP implements the:

- [HYPERLINK "https://www.epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act"]
- [HYPERLINK "https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act"]
- [HYPERLINK "https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act"]
- [HYPERLINK "https://www.epa.gov/laws-regulations/summary-pollution-prevention-act"].

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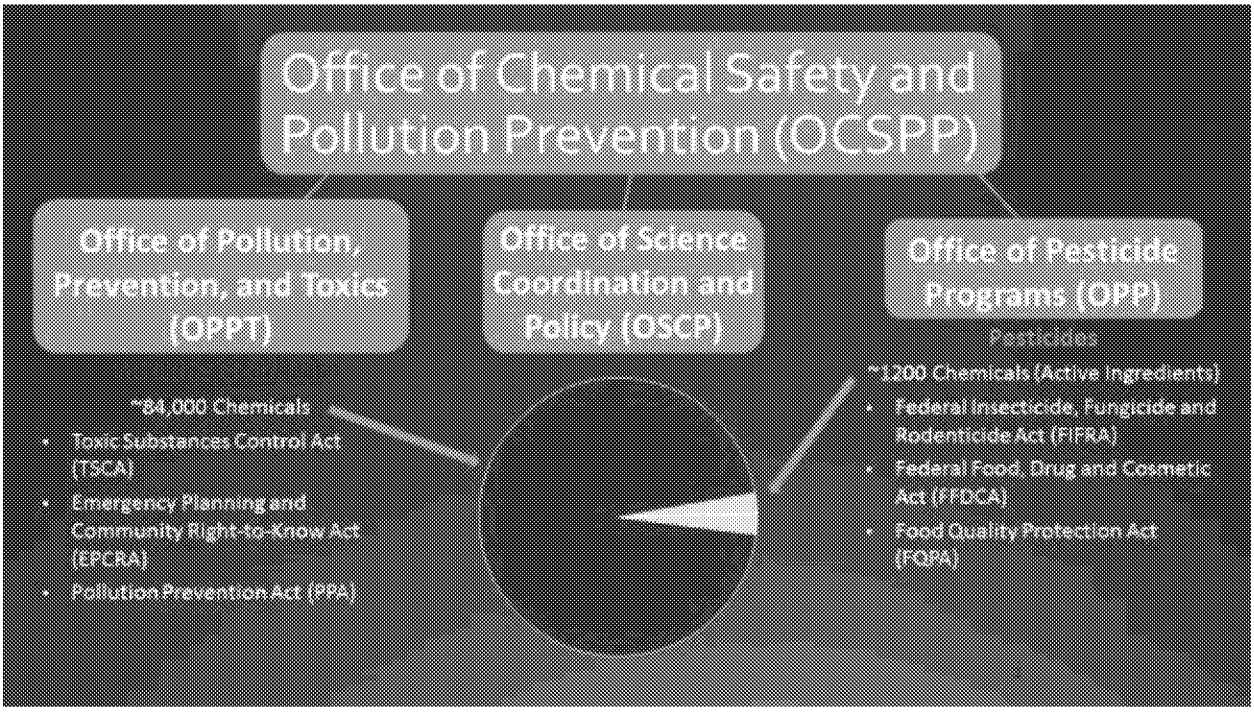
Overview of Offices, Function and Scope of Authority

Organization

The Office of Chemical Safety and Pollution Prevention includes the following three offices:

- [HYPERLINK "https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp" \l "opp"]
- [HYPERLINK "https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp" \l "oppt"]
- [HYPERLINK "https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp" \l "oscp"]



Office of Pesticide Programs (OPP)

OPP regulates the manufacture and use of all pesticides (including insecticides, herbicides, rodenticides, disinfectants, sanitizers and more) in the United States and establishes maximum levels for pesticide residues in food, thereby safeguarding the nation's food supply. EPA has expanded public access to information about risk assessment and risk management actions to help increase transparency of decision making and facilitate consultation with the public and affected stakeholders.

In addition to our regulatory functions, we provide information and coordinate with partners and stakeholders on issues ranging from worker protection to misuse of pesticides. We participate in a variety of partnerships related to pesticide use, including the Pesticide Environmental Stewardship Program, a voluntary private and public partnership dedicated to reducing pesticide use and risk, and Integrated Pest Management in Schools.

OPP implements the [HYPERLINK "https://www.epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act"], the [HYPERLINK "https://www.epa.gov/pria-fees"], and key parts of the [HYPERLINK "https://www.epa.gov/laws-regulations/summary-food-quality-protection-act"], [HYPERLINK "https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act"], and [HYPERLINK "https://www.epa.gov/laws-regulations/summary-endangered-species-act"].

Programs and projects managed by the Office of Pesticide Programs

- [HYPERLINK "https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks"]
- [HYPERLINK "https://www.epa.gov/bedbugs"]
- [HYPERLINK "https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/epas-regulation-biotechnology-use-pest-management"]
- [HYPERLINK "https://www.epa.gov/endangered-species"]
- [HYPERLINK "https://www.epa.gov/ingredients-used-pesticide-products"]
- [HYPERLINK "https://www.epa.gov/insect-repellents"]
- [HYPERLINK "https://www.epa.gov/managing-pests-schools"]
- [HYPERLINK "https://www.epa.gov/mosquitocontrol"]
- [HYPERLINK "https://www.epa.gov/pesticide-labels"]
- [HYPERLINK "https://www.epa.gov/pesticide-registration"]
- [HYPERLINK "https://www.epa.gov/pesticide-reevaluation"]
- [HYPERLINK "https://www.epa.gov/pesticide-tolerances"]
- [HYPERLINK "https://www.epa.gov/pesp"]
- [HYPERLINK "https://www.epa.gov/pets"]
- [HYPERLINK "https://www.epa.gov/pollinator-protection"]
- [HYPERLINK "https://www.epa.gov/reducing-pesticide-drift"]
- [HYPERLINK "https://www.epa.gov/pesticide-worker-safety"]

[HYPERLINK "https://www.epa.gov/pesticide-contacts/organization-chartcurrent-headquarters-leadership-epa-pesticide-programs"]
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Office of Pollution Prevention and Toxics (OPPT)

OPPT manages programs under the Toxic Substances Control Act and the Pollution Prevention Act. Under these laws, EPA evaluates new and existing chemicals and their risks, and finds ways to prevent or reduce pollution before it gets into the environment. We also manage a variety of environmental stewardship programs that encourage companies to reduce and prevent pollution. OPPT implements the [HYPERLINK "https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act"], the [HYPERLINK "https://www.epa.gov/laws-regulations/summary-pollution-prevention-act"] and [HYPERLINK "https://www.epa.gov/regulatory-information-topic/regulatory-information-topic-toxic-substances" \l "tri"] of the [HYPERLINK "https://www.epa.gov/epcra/what-epcra"].

[HYPERLINK "https://www.epa.gov/chemicals-under-tsca"]

Programs and projects managed by the Office of Pollution Prevention and Toxics

- [HYPERLINK "https://www.epa.gov/aegl"]
- [HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca"]
- [HYPERLINK "https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/overview-biotechnology-under-tsca"]
- [HYPERLINK "https://www.epa.gov/chemical-data-reporting"]
- [HYPERLINK "https://www.epa.gov/e3"]
- [HYPERLINK "https://www.epa.gov/greenchemistry"]
- [HYPERLINK "https://www.epa.gov/green-engineering"]
- [HYPERLINK "https://www.epa.gov/green-sports"]
- [HYPERLINK "https://www.epa.gov/greenerproducts"]
- [HYPERLINK "https://www.epa.gov/tsca-import-export-requirements"]
- [HYPERLINK "https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca"]
- [HYPERLINK "https://www.epa.gov/p2"]
- [HYPERLINK "https://www.epa.gov/tsca-screening-tools"]
- [HYPERLINK "https://www.epa.gov/tsca-cbi"]
- [HYPERLINK "https://www.epa.gov/saferchoice"] (formerly Design for the Environment)
- [HYPERLINK "https://www.epa.gov/sustainable-futures"]
- [HYPERLINK "https://www.epa.gov/toxics-release-inventory-tri-program"]
- [HYPERLINK "https://www.epa.gov/tsca-inventory"]

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Office of Science Coordination and Policy (OSCP)

OSCP provides coordination, leadership, peer review, and synthesis of science and science policy within OCSPP. We aim to assure sound scientific decisions are made regarding safe pesticide and chemical management through the leadership of the Scientific Advisory Panel. We also coordinate emerging exposure and hazard assessment topics such as endocrine disruptors.

Programs and projects managed by the Office of Science Coordination and Policy

- [HYPERLINK "https://www.epa.gov/endocrine-disruption"]
- [HYPERLINK "https://www.epa.gov/sap"]
- TSCA Peer Review Committees
  - [HYPERLINK "https://www.epa.gov/tsca-peer-review"]
  - Science Advisory Committee on Chemicals (SACC) - [HYPERLINK "https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0474-0001"]

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OCSPP BUDGET OVERVIEW

OCSPP's budget is comprised of multiple "Program Projects," which are the programmatic elements that the Agency requests and receives funding from Congress. OCSPP has 12 Program Projects across the Pesticides, Toxics, and Science Policy program offices.

OCSPP receives funding for these Program Projects in three Congressional Appropriation Accounts:

- Environmental Programs & Management (EPM) – Primarily Operating funds and Payroll
- Science & Technology (S&T) – Primarily funds OCSPP Labs
- State and Tribal Assistance Grants (STAG) – Grants to States and Tribes

OCSPP is authorized to collect and spend fees under the FIFRA, PRIA, and TSCA:

- FIFRA – Maintenance Fees for Pesticide Re-registrations
- PRIA – Registration Fees for new Pesticide Registrations
    - Authority to collect expiring at end of FY 2017, reauthorization currently on the Hill
- TSCA – Fees for implementing specific TSCA sections
    - Not currently collecting fees, developing rule to collect fees

A majority of OCSPP funding is housed in Headquarters, there is a small presence in the EPA Regions for the Pesticides and Toxics Programs. The primary Regional funding is from the State and Tribal Assistance Grants (STAG) for Pesticides, Lead, and Pollution Prevention. Regions provide technical assistance, direct implementation, outreach, and administer OCSPP's Categorical Grants.

OCSPP FY 2017 Full Time Equivalent Ceiling by Program Office

OCSPP Program Office	FY 17 FTE Ceiling
AA/Immediate Office	35.8
Office of Pesticide Programs	635.9
Office of Pollution Prevention and Toxics	311.1
Office of Science Coordination and Policy	19.0
Regional Resources	154.2
Total OCSPP FTE	**1,156.0**

Total OCSPP Related Program Funding: FY 2016 Enacted – FY 2018 President's Budget

	FY 2016		FY 2017		FY 2018	
Program Project	**Dollars**	**FTE**	**Dollars**	**FTE**	**Dollars**	**FTE**
Pollution Prevention Program	$13,140.0	58.1	$12,091.0	58.1	$0.0	0.0
TRI / Right to Know (Includes OEI)	$13,882.0	43.5	$13,932.0	43.5	$8,680.0	28.4
Toxic Substances: Chemical Risk Review and Reduction	$58,554.0	238.7	$59,398.0	238.7	$65,036.0	240.7
Toxic Substances: Lead Risk Reduction Program	$13,275.0	72.8	$13,175.0	72.8	$0.0	0.0
Science Policy and Biotechnology	$1,174.0	5.4	$1,468.0	5.4	$0.0	0.0
Endocrine Disruptors	$7,553.0	8.9	$7,260.0	8.9	$0.0	0.0
Pesticides: Protect Human Health from Pesticide Risk	$60,937.0	418.7	$58,825.0	418.7	$50,842.0	416.5
Pesticides: Protect the Environment from Pesticide Risk	$39,621.0	269.3	$40,673.0	269.3	$34,125.0	268.4
Pesticides: Realize the Value of Pesticide Availability	$6,657.0	46.5	$6,728.0	46.5	$5,555.0	46.3
Categorical Grant: Pollution Prevention	$4,765.0	0.0	$4,682.0	0.0	$0.0	0.0
Categorical Grant: Pesticides Program Implementation	$12,701.0	0.0	$12,481.0	0.0	$8,874.0	0.0
Categorical Grant: Lead	$14,049.0	0.0	$13,805.0	0.0	$0.0	0.0
Total OCSPP Programs	**$246,308.0**	**1,161.9**	**$244,518.0**	**1,161.9**	**$173,112.0**	**1,000.3**

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CHLORPYRIFOS

SUMMARY:

On March 29, 2017, EPA issued an order denying a petition from the Pesticide Action Network of North America (PANNA) and Natural Resources Defense Council (NRDC), requesting that the EPA revoke all tolerances (maximum residue levels) in food for the pesticide chlorpyrifos under the Federal Food, Drug, and Cosmetic Act (FFDCA) and cancel all chlorpyrifos registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). USDA scientists supported this determination. The EPA intends to complete the registration review of chlorpyrifos by October 1, 2022. In completing the registration review for chlorpyrifos, the EPA will further evaluate the neurodevelopmental effects reported in epidemiological studies and consider these reports in the context of the animal toxicity data available on chlorpyrifos. Regarding potential ecological concerns, the draft Biological Opinion for chlorpyrifos (as well as malathion and diazinon) is expected from the Services this summer. The Final Biological Opinions are currently due in December 2017.

BACKGROUND:

- In September 2007, PANNA and NRDC submitted a petition seeking revocation of all tolerances and cancellation of all Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registrations of products containing the insecticide chlorpyrifos.
- Through the pesticide re-evaluation program, the EPA conducted risk assessments in 2011 (preliminary), 2014 (revised after public comment), and 2015 (part of the proposed rule) that incorporated methodologies as the science has advanced. In October 2015, the EPA proposed to revoke all food residue tolerances for chlorpyrifos.
- The EPA took most of the complex and novel science questions raised in the petition to the FIFRA Scientific Advisory Panel (SAP) for review several times. Specifically, the EPA requested the SAP to review new worker and non-occupational exposure methods, experimental toxicology and epidemiology, risk assessment approaches for semi-volatile pesticides, and the evaluation of a pharmacokinetic-pharmacodynamic model.
- In November 2017, after consideration of the advice received from the FIFRA SAP, EPA issued a revised risk assessment. EPA is currently considering all of the comments received on the draft risk assessments.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- Considering SAP's recommendations, the EPA issued a Notice of Data Availability in November 2016 on a revised human health risk assessment.
- The EPA issued the order denying the PANNA-NRDC petition on March 29, 2017, based on scientific uncertainty.
- In January 2017, the EPA initiated formal consultation under the Endangered Species Act with the US Fish and Wildlife Service and the National Marine Fisheries Service.

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HOT ISSUES:

Congressional Inquiry: Date: June 29, 2017; **Congressperson:** U.S. Senator Tom Udall
Summary of Inquiry: The letter expressed concern over the recent petition denial and requested information presented to the Administrator that resulted in the decision to deny the chlorpyrifos petition.

Press Inquiries: Date: July 18, 2017; **Media Outlets:** Bloomberg BNA and The Hill (web)
Questions: Reporter seeking comment on court's final opinion of the chlorpyrifos case.

Date: June 27, 2017; **Media outlet**: Bloomberg BNA (web)
Question: Reporter asked about the timing of chlorpyrifos registration review.

LEAD OFFICE/REGION:

OCSPP

OTHER KEY OFFICES/REGIONS:

DICAMBA

SUMMARY:

Dicamba is an active ingredient registered for pesticide use as an herbicide. In late 2016, EPA registered a dicamba product designed to control weeds in cotton and soybean plants that have been genetically engineered to resist dicamba (also known as dicamba-resistant corn and soybeans). Monsanto, BASF and DuPont have dicamba end-use products. Since June 2017, the EPA has been receiving reports regarding a high number of crop damage incidents involving dicamba.

BACKGROUND:

- Reports of crop damage began June 13, 2017. Initial reports came from Arkansas, Missouri, Mississippi, and Tennessee. As the growing/use season proceeds, recent reports have been expanding into more northern states (Iowa, Nebraska, and Kansas).
- The underlying causes of the various damage incidents are not yet clear. EPA is currently reviewing the available information.
- When the product was registered in 2016, EPA estimated exposure to non-target crops from pesticide drift/movement. To help prevent drift/movement, EPA required precautions and product use limitations.
- EPA also limited the registration to two years to allow for opportunity to reassess use and either let it expire or easily make necessary changes in the registration if there are problems with resistant weeds or pesticide drift.
- Despite approval of new dicamba products with drift reduction agents and further use restrictions, which were set in place prior to the 2017 growing season, many states have reported high numbers of dicamba complaints.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- The Office of Pesticide Programs (OPP) has met with state lead agency representatives, extension service experts, and the registrants to learn more about the scope and source(s) of the damage, participation of growers in training programs prior to application, and to identify potential measures that could be used to prevent damage. We will continue to work with effected stakeholders.
- On July 28, OPP held a teleconference with Extension Service experts and State Lead Agency representatives.
- On July 13, OPP held a teleconference with state experts from Arkansas, Georgia, Indiana, Mississippi, Missouri, Nebraska, and Tennessee to discuss the observed crop damage.
- In response to the incidents reported, three states (Arkansas, Missouri, and Tennessee) have taken additional steps to further restrict the use of dicamba.

HOT ISSUES:

Press Inquiry: Date: July 24, 2017; **Media Outlet**: Bloomberg BNA (web)
Summary: Off-target plant damage (did EPA adequately assess risks?). Since June 2017, there have been 6 press inquiries on dicamba incidents.

LEAD OFFICE/REGION: OCSPP/OPP OTHER KEY OFFICES/REGIONS: N/A

GLYPHOSATE

SUMMARY:

Glyphosate is a widely used herbicide that controls broadleaf weeds and grasses. EPA is currently re-evaluating the safety of glyphosate through our registration review program. This re-evaluation process occurs every 15 years and is mandated by federal law. In December 2016, EPA convened its FIFRA Scientific Advisory Panel (SAP) to review and solicit comments on our findings that glyphosate is not likely to be carcinogenic to humans at doses relevant for human health risk assessment. Once EPA has reviewed the SAP report and made any appropriate changes to our risk assessment, we intend to release the draft human health and ecological risk assessments for a 60-day public comment period in the Federal Register.

EPA is currently scheduled to complete the draft risk assessments no later than 2017. After consideration of the public comments on the draft risk assessments, EPA will determine whether any risk management is needed. We intend to complete our evaluation, consistent with the statutory deadline for registration review.

BACKGROUND:

- The EPA initiated registration review for glyphosate in 2009. The agency is in the process of completing the draft risk assessments supporting this review. The upcoming draft risk assessments will incorporate the results of endocrine screening analysis and the potential effects on monarch butterflies, as well as consider the 2015 International Agency for Research on Cancer (IARC) report classifying glyphosate as a probable cancer causing agent.
- Subsequent to IARC's 2015 report, various international regulatory agencies have concluded that glyphosate does not cause cancer. In April 2016, the EPA inadvertently published (to the public docket) a memorandum from its Cancer Assessment Review Committee (CARC), which classified glyphosate as "not likely to be carcinogenic to humans." This report was later redacted from the docket because the risk assessment was incomplete (EPA is currently working to complete the assessment).
- In December 2016, the EPA held a FIFRA Scientific Advisory Panel (SAP) meeting to discuss the carcinogenic potential of glyphosate. The agency proposed to classify glyphosate as "not likely to be carcinogenic to humans." The EPA received SAP's recommendations in March 2017, and is currently reviewing the report.
- Although the 2015 IARC reached the conclusion that glyphosate is a probable cancer causing agent, the European Food Safety Authority concluded in November 2015 that glyphosate is unlikely to pose a carcinogenic hazard to humans. In May 2016, the Joint Food and Agriculture Organization Meeting on Pesticide Residues (JMPR) also concluded that glyphosate was unlikely to pose a carcinogenic risk to humans from exposure through the diet. Similar decisions have been made by regulatory agencies in numerous countries including Canada, Germany, Japan, New Zealand, and Australia.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

None

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HOT ISSUES:

Congressional Inquiry: Date: July 07, 2017; **Congressperson**: U.S. Senator Martin Heinrich
Summary: Requests for status of glyphosate's registration review and public comment opportunities.

Press Inquiries: Date: July 11, 2017; **Media Outlet**: New York Times (print/ web)
Question: Background on the 2013 action on glyphosate's tolerances.

Date: June 6, 2017; **Outlet**: Québec Science (print/web)
Question: Status of glyphosate's registration review and its deadline.

LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP	ORD

FIFRA AND ENDANGRED SPECIES ACT

SUMMARY:

The EPA is collaborating with the Services to develop interim scientific approaches and create a sustainable process for completing consultations that meet requirements of both statutes. The EPA aims to streamline the process to a point where it is protective of species, timely for FIFRA registration review decisions, feasible within the agencies' resource constraints, and transparent to the public.

BACKGROUND:

- Historically, the EPA and the Services (Fish and Wildlife Service (FWS) and National Marine Fisheries Service (NMFS)), have been unable to reach consensus on a risk assessment approach.
- In an April 2013 report, the National Academy of Sciences (NAS) provided recommendations to the EPA, the Services, and USDA on a common approach for assessing the risks of pesticides to endangered species.
- EPA's biological evaluations (BEs) implementing these methods are the first step in the consultation process. The Services may then adopt, modify, or reject EPA's conclusions when developing biological opinions (BiOps) to determine if species are jeopardized. The EPA may then take regulatory action to address such risks.
- EPA and the Services have entered into settlement agreements, resolving 4 lawsuits and allowing the agencies to focus on nationwide consultations for 5 pesticides (chlorpyrifos, diazinon, malathion, carbaryl, and methomyl). Final BiOps for chlorpyrifos, diazinon and malathion are due in December 2017. Final BiOps for carbaryl and methomyl are due in December 2018. EPA and FWS have also set schedules for the next 4 nationwide pesticide consultations (atrazine, glyphosate, simazine, and propazine). EPA plans to complete final BEs in June 2020. FWS will complete final BiOps in June 2022.
- Several additional ESA lawsuits are pending against EPA, including challenging new chemical registration decisions (cyantraniliprole, flupyridifurone, bicyclopyrone, benzovindiflupyr, and coupron couprous iodide); Ellis v. Keigwin (clothianidin and thiamethoxam) and the Megasuit. There was a recent ruling for cyantraniliprole, remanding the registration without vacatur to EPA to initiate consultation under the ESA.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

In January 2017, the EPA issued the first ever nation-wide draft BEs for chlorpyrifos, diazinon, and malathion. On April 13, 2017, registrants for these pesticides sent letters to the political leadership of the EPA and the Services requesting the EPA withdraw the BEs, the Services stop work on their BiOps, and modify the settlement agreements to allow more time to complete consultation. The EPA is considering the request.

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HOT ISSUES:

Congressional Inquiries: The House Committees on Natural Resources and Agriculture and the Senate Committees on Agriculture and Environment and Public Works have previously expressed interest in the EPA's progress towards implementing the NAS report recommendations and completion of the BiOps. Under court-ordered settlements, the Services are to issue BiOps for chlorpyrifos, diazinon, and malathion by December 2017, and for carbaryl and methomyl by December 2018. For the Services to meet these settlement dates the EPA initiated consultation in January 2017, by issuing BEs for the first three pesticides.

LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP

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POLLINATORS

SUMMARY:

Pollinator protection is a priority for the EPA, given that bee pollination and insect control are essential to the success of agriculture. A complex set of stressors has been associated with honey bee declines, including loss of habitat, parasites and disease, genetics, poor nutrition, bee management practices, and pesticide exposure. No single factor has been identified as the cause. The EPA has been working to protect bees and other pollinators from pesticide exposures, while continuing to make regulatory decisions under the risk-benefit parameters of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

BACKGROUND:

- Pollinators are critical to our nation's economy, food security, and environmental health. Bee pollination and insect control are essential to the success of agriculture. Honey bee pollination alone adds more than $15 billion in value to agricultural crops each year.

- In January 2016, the EPA, in collaboration with our regulatory partners in Canada and California, released for public comment, our preliminary pollinator risk assessment for imidacloprid, a neonicotinoid pesticide. This assessment followed guidance describing a tiered process for assessing risk to bees from pesticides that EPA developed with Canada's PMRA input and issued in 2014. Additional assessments for the neonicotinoids, clothianidin, dinotefuran and thiamethoxam, using this same guidance and also in collaboration with our regulatory partners, were released in January 2017. EPA is continuing its review of the data to determine the likelihood of adverse effects to honey bee colonies and plans to complete reviews of these neonicotinoids in 2018.

- In January 2017, the EPA announced a policy that all chemicals that are acutely toxic to pollinators and are labeled for use on crops that may use contract pollination services, applications at bloom are prohibited if the application rates exceed the EPA's level of concern.

- In January 2017, the EPA hosted an international workshop on assessing exposure to native pollinators to determine if our conservative assessments are adequately protective.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

None

HOT ISSUES:

Lawsuits and petitions brought by the Center for Food Safety (CFS) and others have been filed regarding the registration of the neonicotinoids and, more recently, over seeds that are coated with neonicotinoid pesticides. These petitions are currently in review.

LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP/OPP	CA DPR; Canada's PMRA

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CONTROLING CEROSPORA IN SUGAR BEETS

SUMMARY:

In late March and early April 2017, the states of Michigan, Minnesota, and North Dakota submitted to EPA emergency exemption (FIFRA Section 18) requests for the use of the fungicide chlorothalonil to control Cercospora in sugar beets. In July 2017, EPA informed the states that the agency was unable to make a safety finding for the use of chlorothalonil on this crop and denied the emergency exemption requests.

BACKGROUND:

- EPA is currently re-evaluating the safety of chlorothalonil as part of the statutorily-mandated registration review program. As part of this re-evaluation, in March 2012, EPA identified several data gaps which preclude the Agency from being able to make the required safety finding under the FFDCA to set a tolerance for the use of chlorothalonil on sugar beets.

- The registrants for chlorothalonil are in the process of generating the necessary data to support the continued registration of this fungicide. EPA expects to receive the required studies later in 2017. EPA will review these data to determine if a different determination can be made for the 2018 growing season.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- EPA has had several conversations with state agricultural agencies and cooperative extensions to try to identify potential alternatives to meet the pest control needs of sugar beet growers for the 2017 growing season.

HOT ISSUES:

Congressional Inquiries:
Date: May 09, 2017; **Congressperson:** U.S. Representative Kevin Cramer
Date: May 11, 2017; **Congressperson:** U.S. Representative John Moolenaar; U.S. Representative Collin Peterson; U.S. Representative Kevin Cramer; U.S. Representative Paul Mitchell; U.S. Representative Dan Kildee
Summary: Letters in strong support of the Section 18 requests made by the North Dakota Department of Agriculture, Minnesota Department of Agriculture, Michigan Department of Agriculture for the emergency use of chlorothalonil on sugar beets.

Date: May 2017, **Congressperson**: Senator Stabenow's staff
Summary: Briefing on status of the section 18 requests and the Agency's inability to make the required safety finding for these requests.

LEAD OFFICE/REGION: | OTHER KEY OFFICES/REGIONS:

OCSPP

WORKER PROTECTION STANDARD RULE

SUMMARY:

In February 2017, the National Association of State Departments of Agriculture (NASDA) petitioned the EPA to extend the implementation of all revised provisions of the Worker Protection Standard Rule (WPS) until at least January 2018. After careful evaluation, the agency believes it appropriate to grant the request to extend the implementation of all revised provisions of the WPS until the necessary guidance and training have been completed to allow state lead pesticide agencies time to successfully implement the rule changes. The EPA will soon begin the regulatory process to formally extend the compliance date for all revised provisions of the WPS.

BACKGROUND:

- The Worker Protection Standard seeks to protect and reduce the risks of injury or illness to agricultural workers (those who perform hand-labor tasks in pesticide-treated crops, such as harvesting, thinning, pruning) and pesticide handlers (those who mix, load and apply pesticides), resulting from use and contact with pesticides on farms, forests, nurseries and greenhouses.

- The EPA issued the final rule in November 2015, establishing staggered compliance dates for implementation of the changes to the Agricultural Worker Protection Standard. The majority of the new requirements went into effect on January 2, 2017; the remaining requirements are scheduled to go into effect on January 2, 2018.

- In late 2016, NASDA and the American Farm Bureau Federation filed a petition seeking a delay in the implementation of the revised Worker Protection Standard. In January 2017, the EPA denied the petition.

- In February 2017, the National Association of State Departments of Agriculture (NASDA) submitted a new petition requesting EPA postpone the compliance date to at least January 2, 2018 or until adequate compliance tools have been completed and states have the necessary tools, time and resources to implement the rule changes and provide compliance assistance to the regulated community.

- On May 11, 2017, EPA granted the petition and committed to beginning the regulatory process to formally extend the compliance date for all revised provisions of the WPS. This regulation is needed to adjust the compliance date.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

None

LEAD OFFICE/REGION:

OCSPP

OTHER KEY OFFICES/REGIONS:

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PESTICIDE APPLICATOR CERTIFICATION AND TRAINING RULE

SUMMARY:

Certification and training programs, approved by the EPA, are administered by the states and ensure that applicators are properly trained and competent to apply restricted use pesticides, the most acutely toxic pesticides registered by the EPA. The EPA issued the final rule on January 4, 2017. Since its issuance, the agency has delayed the effective date of the rule to May 22, 2018, in order to consider whether further revisions should be made before the rule becomes effective. The EPA understands the critical role that states play in implementing the C&T program and are committed to working with our state partners to ensure a protective, yet flexible, certification and training standard.

BACKGROUND:

- January 4, 2017, EPA published the final rule revising the certification rule, with a multi-year process for state plans development and EPA approvals - effective date March 6, 2017.
- Several organizations, including the National Association of State Departments of Agriculture, the Association of American Pesticide Control Officials, National Pest Management Association, and National Agricultural Aviation Association, have expressed support for the final rule.
- Notwithstanding this overall support and appreciation for the changes the EPA made in the final rule, many of these organizations have requested that the EPA extend the effective date of the rule until the EPA has:
    - Delivered adequate enforcement guidance, educational materials, and training materials;
    - Provided resources necessary to implement the revised rule; and
    - Made revisions to address concerns about the minimum age restrictions.
- January 20, 2017, "Regulatory Freeze Pending Review" has issued to give newly arrived Agency officials the opportunity to conduct a substantive review of certification rule – effective date moved several times to May 22, 2018.
- Executive Order on Regulatory Reform activity raised general and specific issues regarding the rule

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- On June 2, 2017, EPA extended the effective date of the rule to May 22, 2018.
- A group of farmworker advocacy groups have sued EPA in District court for alleged violations of the Administrative Procedure Act during the rulemaking that postponed the effective date of the certification rule until May 2018.

HOT ISSUES:

- Consortium of worker advocate groups sued EPA Administrator in 9th Circuit Court and in District Court for administrative procedures act violations.

LEAD OFFICE/REGION: OCSPP/OPP OTHER KEY OFFICES/REGIONS:

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PRIA 4

SUMMARY:

The EPA strongly supports the Pesticide Registration Improvement Act (PRIA) 4 and anticipates immediate implementation of the amended law. PRIA 4 brings together a coalition of divergent interests that permits market access of pesticides, benefitting both the pesticides and agricultural industries, while safeguarding the environment and human health. If PRIA 4 is not passed by September 30, 2017, when PRIA 3 sunsets, pesticide applications will no longer be subject to decision time periods. The two-year sunset provision specifies fees be reduced in the first year by 40% below the levels in effect during FY2017, and by 70% in the second year. After two years, fee requirements are terminated. In addition, EPA would no longer be able to collect maintenance fees to support the statutorily-mandated registration review program.

BACKGROUND:

- PRIA has benefitted from a broad coalition of stakeholder groups representing seven pesticide industry trade groups and two non-governmental organizations. This stakeholder support has paved the way to expedited approval processes in Congress to pass the original law and its amendments to extend.
- PRIA establishes a fee for service framework that charges applicants based on the type and complexity of the activity requested. It also holds the EPA to mandatory time frames for reviewing and making decisions on these actions.
- The fees fund a portion of the EPA's pesticides registration and registration review activities. PRIA 4 is estimated to bring in $17 million per year on average, which helps support staff plus other expenses related to pesticide registration.
- PRIA 4 extends the authorization to collect maintenance fees, at $31M/yr through FY'20. These fees supplement pesticide reevaluation activities, review of substantially similar new registrations and amendments, and review of inert clearances. There are two set-asides specified: one for Good Laboratory Practice (GLP) inspections and the other for development of product performance guidance and rulemaking for invertebrate pests of significant public health importance.
- PRIA allows partial fee waivers for small businesses and exempts federal and state government entities from fee requirements. Applications supported by the IR-4 Project, a USDA-funded program which supports the availability of pest management tools for growers of minor use crops, are likewise exempt from fee requirements. Since PRIA initially became law in March 2004, the EPA has approved over 20,000 pesticide applications, meeting or beating mandated due dates for over 98% of those actions.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- H.R. 1029 was introduced in February, 2017 and was unanimously passed in the House on March 20, 2017. On June 29, 2017, the Senate Agriculture Committee unanimously voted in favor of extending authorization of PRIA for an additional 3 years.

LEAD OFFICE/REGION: OCSPP/OPP OTHER KEY OFFICES/REGIONS:

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ACTIONS TO CONTROL ZIKA

SUMMARY:

The spread of the Zika virus, mainly through mosquitoes, throughout the continental U.S. and territories, is an ongoing and highly visible public health emergency. Through proper mosquito prevention, control and integrated pest management (IPM) at the federal, state, local and household levels, the spread of the Zika virus can be slowed in the U.S.

EPA is continuing to work on the evaluation of pesticides that are approved for use in mosquito control. These evaluations are part of EPA's regular pesticide registration review process. Naled and malathion are two pesticides currently undergoing this evaluation process and both are used by mosquito control districts for aerial and ground spraying to control adult mosquitos.

BACKGROUND:

- The Zika virus has had the biggest impact in Puerto Rico and other island territories to date. Travel related cases have now been identified in 49 states (none in Alaska).
- The Centers for Disease Control and Prevention is the lead federal agency for responding to the Zika virus. EPA supports CDC, providing expertise in integrated pest management, pesticide registration and use, and cleanup of environmental contamination in indoor and outdoor areas. EPA is focused on appropriate pesticide use, including technical assistance on wide-area spraying, residential treatments, and any potential new product registrations or emergency exemptions. In order to address public health concerns, EPA is providing technical assistance and communications support to prevent pesticide misuse and overuse.
- EPA has approved five emergency exemptions for pesticide products to be used for vector control: Four were issued to CDC to help control mosquito populations. One was issued to the Department of Defense to help them comply with other countries' requirements to disinfect aircrafts coming from countries with Zika transmission.
- EPA conducted a comprehensive review of naled in 2002, as part of its reregistration process. This re-evaluation relied on a wealth of naled-specific toxicity and exposure data, which were used to assess potential dietary, drinking water, occupational and residential risks. Since that time, additional toxicity and exposure studies specific to the naled mosquito-control uses have been conducted. These data are currently under EPA review and will be incorporated into a revised risk assessment, which is being developed as part of the agency's routine registration review process. EPA plans to release for public comment an updated naled mosquito assessment before the end of 2017.
- In 2016, EPA made available for public comment the draft malathion human health risk assessment because the draft risk assessment indicated a potential risk for children when malathion is applied aerially to kill mosquitos. EPA provided mosquito control professionals with advice on how to reduce exposures to protect human health when using malathion as an aerial spray. After consideration of public comments, EPA will propose any necessary risk mitigation decisions and associated label changes. The agency expects to reach a decision in 2017.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

None

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HOT ISSUES:

Congressional Inquiry: Date: July 6, 2017; **Congressperson**: U.S. Senator Marco Rubio
Summary: How safe is naled, considering it has been recommended for use by Miami-Dade County's to prevent the spread of Zika and what is EPA's role in approving the use of naled.

Press Inquiries: Date: June 28, 2017; **Media Outlet**: WLRN/Miami Herald News (radio)
Question: Provide existing agency research on naled.

Date: June 9, 2017**; Media Outlet**: CNN (web)
Question: Agency response to University of Michigan naled study.

LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP	Regions 2 and 4, OITA, OEJ

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EMERGINING BIOTECHNOLOGY TO CONTROL MOSQUITOS

SUMMARY:

The EPA is currently reviewing registration requests submitted by MosquitoMate for Wolbachia mosquitos. The EPA is also involved in discussions with the registrant, Oxitec, and the FDA regarding oxitec mosquitos. Oxitec's genetically engineered mosquitos and MosquitoMate's Wolbachia mosquitoes are emerging biotechnology pesticides that could be used to combat the spread of mosquito-borne diseases, such as Zika.

BACKGROUND:

- The EPA registers biopesticides, which include alterations of mosquito species to reduce mosquito populations. Two technologies (one action pending with EPA, the other is anticipated) involve release of sterilized male mosquitos. When the altered mosquitos are released and mate with wild female mosquitos, the offspring are not viable.

- One technique introduces Wolbachia bacteria, found naturally in many insect species, into male mosquitos. The EPA is reviewing MosquitoMate's Wolbachia ZAP *Aedes albopictus* pesticide registration application and intends to make a decision in late FY17 or early FY18.

- Another technique involves genetically engineered *Aedes aegypti* mosquitoes. "Oxitec" mosquito is currently regulated by the FDA as a new animal drug under the Federal Food, Drug, and Cosmetic Act and has yet to be approved for general use. FDA has proposed to transfer jurisdiction to the EPA through a published draft guidance document. While awaiting the anticipated jurisdiction change, the EPA can accept an Oxitec application for a pesticide experimental use permit and for an emergency exemption (Section 18).

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- In June 2017, EPA extended the time and added test sites for an existing experimental use permit (EUP) to evaluate the *Wolbachia* bacteria's effectiveness in suppressing *Aedes aegypti* mosquitoes. This permit allows MosquitoMate, Inc., to test a potential new tool to fight mosquitoes at sites in Fresno and Orange Counties in California, Monroe, Lee, and Miami-Dade Counties in Florida, and Harris County in Texas.

- The EUP, originally issued to the University of Kentucky's Department of Entomology in October 2015 for limited testing in Fresno County, California, was extended in September 2016 to add testing in Lee County in Florida. The current permit will allow MosquitoMate, Inc., to continue the development of this new tool.

HOT ISSUES:

Press Inquiry: Date: July 6, 2017, **Media Outlet:** WINK News (TV), **Questions summary:** Asked for clarification about the approval process of an Oxitec mosquito control trial in Florida.

LEAD OFFICE/REGION: OCSPP/OPP OTHER KEY OFFICES/REGIONS:

CITRUS GREENING

SUMMARY:

The EPA is committed to supporting researchers, producers and state personnel in efforts to help control citrus greening, a devastating crop disease. In 2017, the EPA responded to the state of Florida on their FIFRA Section 18 emergency use requests by re-authorizing the use of oxytetracycline and streptomycin products on citrus trees for this season. The EPA also re-authorized the emergency use of clothianidin, an insecticide that can help control the insect vector of this disease. In the past years, the EPA has prioritized and registered several new insecticides for citrus (i.e., flupyradifurone and cyantraniliprole) and has approved and supported a number of state registration actions from Florida under the FIFRA Section 24(c) program.

BACKGROUND:

- Citrus Greening, also known as Huanglongbing (HLB), is caused by a bacterial pathogen transferred from an infected plant during the feeding activities of an insect pest called the Asian citrus psyllid. HLB was first identified in Florida in 2005. By 2007, the disease had spread through all 34 citrus-producing counties in the state. The onset of symptoms from HLB occur over time and are progressive, starting with reduced fruit yield and quality, and leading eventually to the tree's death. HLB is considered the most serious citrus disease worldwide.

- Florida's citrus supply is critically low and may become insufficient to sustain its juice-processing infrastructure. Orange production has declined from 226.2 million boxes in 1996-1997 to 96.7 million boxes in 2014-2015. Further declines are expected. HLB is believed to cost the Florida citrus industry approximately $300 million/year.

- In July 2017, the California Department of Food and Agriculture and the United States Department of Agriculture confirmed the detection of citrus greening in Riverside County, California.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- The EPA is participating in an important research initiative run by USDA on HLB known as the Multi-Agency Coordination System, a program that funds research to develop tools to control HLB The EPA issued experimental use permits (EUPs) to investigate the efficacy of pinach defensin antimicrobial peptides in targeting the bacterial pathogen causing HLB.

- The EPA continues to coordinate with USDA/APHIS on these field tests as well as other smaller-scale biotech field tests investigating control methods for citrus greening.

HOT ISSUES:

None

LEAD OFFICE/REGION: OCSPP/OPP OTHER KEY OFFICES/REGIONS:

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RNAi

SUMMARY:

"RNAi corn" is an emerging technology that provides an important tool for farmers to help combat corn rootworm resistance in crops altered with Bacillus thuringiensis (Bt). Corn rootworm is a devastating corn pest that has developed resistance to several other pesticides. Corn growers are facing problems of resistance to corn rootworm in some of their Bt-treated crops. RNAi corn provides a new tool for corn growers to fight the corn rootworm and has undergone independent scientific peer review.

BACKGROUND:

- RNAi, which refers to interference of RNA genes, works as a pesticide by silencing the activity of a targeted gene. Commercial registrations of RNAi-based plant-incorporated protectant (PIP) crops to date have targeted plant pathogens, such as the plum pox virus. MON 87411 is the first RNAi-based PIP to target an insect pest.
- Controlling corn rootworm is a major challenge for many corn growers, and infestations frequently result in significant yield losses to corn crops. Corn rootworm has been referred to as the "billion-dollar pest" because the U.S. Department of Agriculture estimated that the insect can collectively cost corn growers in the United States over a billion dollars in terms of control costs and yield losses.
- PIPs are plants that have genes inserted causing the plants to produce a pesticide inside their own tissue. When plants are genetically modified to produce pesticides in this manner they are regulated by the EPA.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- In June 2017, EPA registered four products containing a new and innovative plant-incorporated protectant (PIP) called SMARTSTAX PRO that will help U.S. farmers control corn rootworm.

HOT ISSUES:

None

LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP

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OFFICE OF PESTICIDE PROGRAMS' LABORATORIES

SUMMARY:

The Office of Pesticide Programs operates two laboratories at the EPA's Environmental Science Center in Fort Meade, Maryland. These laboratories provide essential support for the registration and re-evaluation of conventional and public health pesticides and expertise in the event of emerging threats.

BACKGROUND:

- The Office of Pesticide Programs operates a microbiology lab and a chemistry lab. Both of these laboratories ensure that registrants have standardized methods to register their products, opening the door for market access.
- The microbiology lab is the only federal lab that develops and standardizes test methods to measure the efficacy of antimicrobial pesticides (disinfectants) against human and animal pathogens. The microbiology lab also provides technical expertise to other federal agencies and states when emerging pathogens arise, for example Ebola, avian flu and *Candida auris*.
- The microbiology lab is the only EPA laboratory with a Biosafety Level 3 certification under the Federal Select Agent program, which enables the lab to analyze for anthrax during an emergency and to evaluate the efficacy of products for decontamination and remediation.
- The chemistry lab reviews tarp fumigant packages for manufacturers so growers can have buffer zone credits and bystanders can be protected from exposure to volatile pesticides. The chemistry lab also collects and maintains reference standards for registered pesticides and their metabolites and degradates that are legally required.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

None

HOT ISSUES:

None

LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP

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2016 AMENDMENTS TO THE TOXIC SUBSTANCES CONTROL ACT (TSCA)

ISSUE/TOPIC:

What changes were made to TSCA in the 2016 amendments?

BACKGROUND:

The following provides a brief overview of the key provisions in the Frank R. Lautenberg Chemical Safety for the 21st Century Act for:

- Existing chemicals;
- New chemicals;
- Confidential business information;
- Source of sustained funding;
- Federal-state partnership; and
- Mercury export and disposal.

EXISTING CHEMICALS

- Chemical Assessments
  - Prioritization
    - EPA must establish a risk-based process to determine which chemicals it will prioritize for assessment, identifying them as either "high" or low" priority substances.
      - High priority – the chemical may present an unreasonable risk of injury to health or the environment due to potential hazard and route of exposure, including to susceptible subpopulations
      - Low priority – the chemical use does not meet the standard for high-priority
  - Risk Evaluations
    - High priority designation triggers a requirement and deadline for EPA to complete a risk evaluation on that chemical to determine its safety
    - Low priority designation does not require further action, although the chemical can move to high-priority based on new information
    - Assessment pipeline
      - First 180 days – EPA must have 10 ongoing risk evaluations
      - Within 3.5 years – EPA must have 20 ongoing risk evaluations
  - New Risk-Based Safety Standard
    - Chemicals are evaluated against a new risk-based safety standard to determine whether a chemical use poses an "unreasonable risk"
      - Risk evaluation excludes consideration of costs or non-risk factors
      - Must consider risks to susceptible and highly exposed populations
  - Action to address unreasonable risks
    - When unreasonable risks are identified, EPA must take final risk management action within two years, or four years if extension needed
    - Costs and availability of alternatives considered when determining appropriate action to address risks

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        - Action, including bans and phase-outs, must begin as quickly as possible but no later than five years after the final regulation
    - Manufacturer-requested assessments
        - Manufacturers can request that EPA evaluate specific chemicals, and pay the associated costs as follows:
            - If on the TSCA Workplan, manufacturers pay 50% of costs
            - If not on the TSCA Workplan, manufacturers pay 100% of costs
        - These assessments must account for between 25-50% of the number of ongoing risk evaluations for high-priority chemicals, but do not count towards the minimum 20 ongoing risk evaluation requirement
- Chemical Testing Authority
    - Expands authority to obtain testing information for prioritizing or conducting risk evaluations on a chemical, and expedites the process with new order and consent agreement authorities
    - Promotes the use of non-animal alternative testing methodologies
- Persistent, Bioaccumulative, and Toxic (PBT) Chemicals
    - New fast-track process to address certain PBT chemicals on the TSCA Workplan
        - Risk evaluation not needed, only use and exposure to chemical needed
        - Action to reduce exposure to extent practicable must be proposed no later than three years after the new law and finalized 18 months later.
        - Additional requirements for PBTs in the prioritization process for assessments

NEW CHEMICALS

- Pre-Market Review of New Chemicals
    - New requirement that EPA must make an affirmative finding on the safety of a new chemical or significant new use of an existing chemical before it is allowed into the marketplace
        - EPA can still take a range of actions to address potential concerns including ban, limitations, and additional testing on the chemical

CONFIDENTIAL BUSINESS INFORMATION

- Establishes new substantiation requirements for certain types of confidentiality claims from companies
- Requires that EPA review and make determinations on all new confidentiality claims for the identity of chemicals and a subset of other types of confidentiality claims
- EPA must review past confidentiality claims for chemical identity to determine if still warranted

SOURCE OF SUSTAINED FUNDING

- Allows EPA to collect up to $25 million annually in user fees from chemical manufacturers and processors when they:
    - Submit test data for EPA review
    - Submit a premanufacture notice for a new chemicals or a notice of new use
    - Manufacture or process a chemical substance that is the subject of a risk evaluation; or
    - Request that EPA conduct a chemical risk evaluation

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- New fees will defray costs for new chemical reviews and a range of TSCA implementation activities for existing chemicals

FEDERAL-STATE PARTNERSHIP

- Preservation of State Laws
  - States can continue to act on any chemical, or particular uses or risks from a chemical, that EPA has not yet addressed
  - Existing state requirements (prior to April 22, 2016) are grandfathered
  - Existing and new state requirements under state laws in effect on August 31, 2003, are preserved
  - Preserves states environmental authorities related to air, water, waste disposal and treatment
  - States and federal government can co-enforce identical regulations
- Preemption of State Laws
  - State action on a chemical is preempted when:
    - EPA finds (through a risk evaluation) that the chemical is safe, or
    - EPA takes final action to address the chemical's risks
  - State action on a chemical is temporarily "paused" when EPA's risk evaluation on the chemical is underway, but lifted when EPA:
    - completes the risk evaluation, or
    - misses the deadline to complete the risk evaluation
- Exemptions
  - States can apply for waivers from both general and "pause" preemption
  - If certain conditions are met, EPA MAY grant an exemption from general preemption, and MUST grant an exemption from pause preemption

MERCURY EXPORT AND DISPOSAL

- Amends requirements of the Mercury Export Ban Act (MEBA) and addresses Dept. of Energy's (DOE) responsibility to designate a long-term storage facility
  - If the facility is not operational by 1/1/2020, DOE must accept title to and pay for permitting and storage costs for mercury accumulated in accordance with MEBA prior to that date
- Requires that EPA create an inventory of supply, use, and trade of mercury and mercury compounds; and prohibits export of certain mercury compounds

LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP/OPPT	

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TSCA IMPLEMENTATION ACTIVITIES

ISSUE/TOPIC:

EPA's Implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act

BACKGROUND:

- The Frank R. Lautenberg Chemical Safety for the 21st Century Act, signed into law on June 22, 2016, made a host of transformative changes to the Toxic Substances Control Act (TSCA) that strengthen the EPA's ability to identify and address chemical risks. The EPA promptly began the work of implementing the new law, which became immediately effective, and is continuing to make significant progress in carrying out its requirements.
- The EPA is implementing the numerous new and expanded requirements under TSCA enacted and made immediately effective by the Lautenberg Act. The agency has met and continues to be on track for meeting critical initial statutory deadlines, including the framework rules and the first 10 risk evaluations.
- The EPA is working aggressively to address the new chemicals backlog, including increased staffing and policy changes. Throughput rates are expected to return to normal by August 2017.
- The EPA will continue to seek input from stakeholders on critical implementation elements of TSCA as amended. Since June 2016, EPA has held an unprecedented number of public meetings seeking to hear from affected entities. Input from these meetings and other stakeholder discussions has helped shape the agency considerations.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- Final Active/Inactive Inventory Reporting Rule required by June 2017
  - ✓ Final Rule Published June 22, 2017

- Final Prioritization Process Rule required by June 2017
  - ✓ Final Rule Published June 22, 2017

- Final Risk Evaluation Process Rule required by June 2017
  - ✓ Final Rule Published June 22, 2017

- Initial 10 Risk Evaluations
  - ✓ Identified First 10 Chemicals for Risk Evaluation
  - ✓ Final Scopes Published June 22, 2017

-Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations
  - ✓ Guidance Published June 22, 2017

-Science Advisory Committee established by June 2017
  - ✓ Charter established, 18 members appointed

UPCOMING/ONGOING ACTIVITIES:

NEW CHEMICALS

- Continuing work to eliminate the backlog of new chemical submissions
- Development of "Points to Consider" document to increase quality of submissions and efficiency of EPA review

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- Public meeting to get additional feedback planned for Fall 2017

"PRE-PRIORITIZATION"

- Proposed a phase for gathering/developing chemical information and identifying potential candidates for prioritization before initiating the prioritization process for a particular chemical
- Based on public comments received, this phase was excluded from the final rule
- OCSPP committed to further public discussion beginning Fall 2017

PRIORITIZATION

- EPA must designate at least 20 High-Priority chemicals and 20 Low-Priority chemicals by end of 2019
- Prioritization rule established process to designate a chemical as High or Low-Priority for further evaluation
- High-Priority chemicals immediately move to risk evaluation
- Low-Priority chemicals do not move to risk evaluation
- For each EPA-initiated risk evaluation completed, EPA must designate another High-Priority chemical to take its place
- By law, process must take between 9 and 12 months

RISK EVALUATIONS

- For the first 10 chemical risk evaluations, EPA will be issuing "Problem Formulation" documents that further refine the "Scope" documents published on June 22, 2017
- Pursuant to the Risk Evaluation procedural rule, EPA will issue draft risk evaluations and take public comment before finalizing
- Final risk evaluations must be issued 3 years following initiation, or late Fall 2019 for the "first 10" chemicals

SECTION 6 RULEMAKING ACTIVITIES

- Evaluating comment on proposed rules for three chemicals used in degreasing (TCE) and paint removing applications (MC and NMP)

FEES RULEMAKING

- Propose and finalize rule; will help defray implementation costs

TSCA ACTIVE/INACTIVE INVENTORY

- Reporting to begin shortly; EPA will use information to determine whether a chemical is active or inactive in commerce

SECTION 4 TEST ORDERS

- Evaluate use of new authority to issue orders requiring development of information
- Strategic Plan for advancing use of non-animal testing approaches
- Deadline June 2018

MERCURY REPORTING RULE

- Proposed rule expected late 2017 and final rule deadline 2018; will help inform future versions of the Mercury Inventory

PBT CHEMICALS

- Expedited rulemaking to reduce exposures; required in section 6(h) of TSCA

HOT ISSUES:	
• New Chemicals – EPA commitment to clear "backlog" by end of July; public meeting in Fall 2017 on process/policy changes resulting from TSCA amendments • Risk Evaluation Scoping – questions from public, press, and Congress on approach to "conditions of use"; evaluation of "legacy" uses; next steps for the First 10 risk evaluations • Section 6 Rules – questions from public, press and Congress on status of proposed rules	
LEAD OFFICE/REGION:	**OTHER KEY OFFICES/REGIONS:**
OCSPP/OPPT	ORD, OLEM, OW, OECA, OCHP, R5, OP, OGC

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ACTIVE/INACTIVE INVENTORY RULE

ISSUE/TOPIC:

Final "framework" rule requiring reporting by chemical manufacturers to help determine which chemicals on the TSCA Inventory are still actively manufactured or processed.

BACKGROUND:

- There are over 85,000 chemical substances listed on the TSCA Inventory.
- It is probable that only a subset of those chemicals are still actively manufactured or processed.
- The Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, requires EPA to designate chemical substances on the TSCA Chemical Substance Inventory as either "active" or "inactive" in U.S. commerce.
- To accomplish that, EPA finalized a rule requiring industry reporting of chemicals manufactured (including imported) or processed in the U.S. over the past 10 years, ending on June 21, 2016.
- Reporting will be used to identify which chemical substances on the TSCA Inventory are active in U.S. commerce and will help inform the prioritization of chemicals for risk evaluation.
- Additionally, active and inactive designations for each chemical substance will be included as part of the Agency's regular publications of the TSCA Inventory.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- ✓ Final rule singed on June 22, 2017
- ✓ Reporting under the final rule is expected to begin in August

HOT ISSUES:

N/A

LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP/OPPT	OGC

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PRIORITIZATION RULE

ISSUE/TOPIC:

Final procedural "framework" rule for prioritizing chemical substances for risk evaluation.

BACKGROUND:

- TSCA required EPA to establish, by rule, the process and criteria for prioritizing chemical substances for risk evaluation. See TSCA section 6(b)(1)
- High-Priority substances move immediately to risk evaluation, whereas substances designated as Low-Priority do not receive further evaluation at the time.
- TSCA provided some specificity on both the process and criteria, including preferences for certain chemical substances that EPA must apply, the procedural steps, definitions of High-Priority Substances and Low-Priority Substances, and screening criteria that EPA must consider in designating a chemical substance as either High-Priority Substances or Low-Priority Substances.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

SUMMARY OF PRIORITIZATION PROCESS:

✓ Final Rule Published on June 22, 2017

1. Initiation. Announcement of candidate chemical, followed by 90-day public comment
2. Proposed Designation. Based on screening review, proposed as either High- or Low-Priority, followed by 90-day public comment
3. Final Designation. Chemical finalized as either High- or Low-Priority Substance, with High-Priority substances immediately moving to risk evaluation.

***By law, process must take between 9-12 months from Initiation to Final Designation

HOT ISSUES:

"PRE-PRIORITIZATION":

EPA initially proposed a phase for information gathering and identification of potential candidates that would occur *prior to* the official start of prioritization, but deferred final action on this regulatory provision based on public comments. Additional stakeholder meetings planned for Fall 2017.

LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP/OPPT	ORD, OLEM, OW, OECA, OCHP, R5, OP, OGC

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RISK EVALUATION RULE

ISSUE/TOPIC:

Under TSCA section 6(b)(4), EPA was required to issue a rule to establish a process for conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use.

BACKGROUND:

- The final rule was published on June 22, 2017, meeting the statutory 1-year deadline.
- The proposed rule was published on January 19, 2017, followed by a 60-day public comment period.
- This process incorporates the science requirements of the amended statute, including best available science and weight of the scientific evidence.
- Risk evaluation is the second step, after Prioritization, in a new process of existing chemical substance review and management established under recent amendments to TSCA.
- This rule identifies the steps of a risk evaluation process including: scope, hazard assessment, exposure assessment, risk characterization, and finally a risk determination.
- Chemical substances designated as High-Priority Substances during the prioritization process and those chemical substances for which EPA has initiated a risk evaluation in response to a manufacturer request, will always be subject to this process.
- The final rule also includes the required "form and criteria" applicable to such manufacturer requests.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- To the extent practicable, this process will be used for the first ten chemical substances undergoing evaluation

HOT ISSUES:

- The changes made from the proposed rule (January, 19, 2017) to the final rule has drawn a mixed response and Congressional interest.
- Senator Udall has publically commented on this rule, expressing concern that the rule preferentially benefits industry at the expense of public safety.
- Representative Pallone has expressed interest in seeing the changes from the proposed to the final rule.
- The major points of contention of this rule are:
  - The Agency's implementation of the statutory requirement to evaluate the chemical under the 'conditions of use'. In the proposed rule, the Agency proposed the consideration of 'all' conditions of use, while the final rule more discretion to evaluate the riskiest uses.
  - The codification of definitions for 'weight of scientific evidence' and 'best available science,' which were not defined in the proposed rule. Many environmental NGOs feel strongly these terms should not be defined in the rule, as they are not statutorily defined and will tie the hands of the Agency in the future.
  - The form and manner for which manufacturers can request a chemical they manufacturer undergo risk evaluation. In the proposed rule the requestor had to submit all the information for all conditions of use, and in the final rule they are able to submit just the information for the use(s) of interest.

LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT

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TSCA FEE RULES

ISSUE/TOPIC:

Collection of fees from chemical manufacturers and processors, as authorized under the 2016 amendments to TSCA

BACKGROUND:

- The 2016 amendments to TSCA significantly increased EPA's authority to collect fees from chemical manufacturers and processors, and once established, will defray some of the costs of implementing the Agency's new responsibilities under the law.
- Prior to the amendments, the Agency had authority to require, by rule, the payment of fees by person required to submit data under TSCA sections 4 and 5. Although authorized under the statue, the Agency has not collected fees for data submitted under TSCA section 4 and no TSCA section 4 rule was ever promulgated by the EPA. Section 5 fees were capped by statute at $2,500 per submission ($100 for small businesses). Since 1988, fees collected under TSCA have gone to the U.S. Treasury General Fund, and have not directly supported TSCA implementation.
- The EPA will now be able use user fees collected from chemical manufacturers and processors to defray 25 percent of its costs for administering Sections 4, 5, 6 and 14 of TSCA as amended, or up to $25 million a year for the first three years, whichever is less. Fees collected will now be deposited into a new "TSCA Service Fee Fund" which will directly support implementation activities.
- The EPA intends to propose increased fees for PMN review and to add fee categories for activities conducted under TSCA sections 4 (*e.g.*, test rules, test orders and enforceable consent agreements) and 6 (*e.g.*, risk evaluations).
- Before collecting new fees to supplement appropriations and help pay for implementation of the amended law, the EPA must develop a final rule governing the collection and administration of those fees.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

✓ The EPA engaged with members of the public potentially subject to the fees on the following: public meeting and webinar held on August 11, 2016; industry-specific consultation meeting and webinar held on September 13, 2016; and dockets opened to collect written comments from stakeholders.

✓ A draft of the proposed TSCA User Fee Rule is currently under development.

HOT ISSUES:

- Manufacturer-requested risk evaluations cannot be accepted until the Fees Rule has been finalized.
- Reduced fees for small businesses.
- The FY 2018 President's Budget anticipated fee collections would begin in Q2 of FY 2018 and shifts $8.6M and 53.6 FTE from annual CRRR appropriations to new TSCA fee collections.

LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP/OPPT	OCFO, OGC, OP, ORD, OLEM, OW, OCHP

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FIRST 10 CHEMICAL RISK EVALUATIONS

SUMMARY:

As required under section 6(b)(4) of the Toxic Substances Control Act (TSCA) as recently revised, EPA must conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use. TSCA instructs the Agency to identify the first 10 chemicals to undergo risk evaluation from the 2014 TSCA Work Plan, initiating a pipeline of chemical risk evaluations subject to statutory deadlines, minimum throughput and re-population requirements.

BACKGROUND:

- The first 10 chemicals to undergo risk evaluation were announced in December 2016:

1,4-Dioxane	Methylene Chloride
1-Bromopropane	N-methylpyrrolidone (NMP)
Asbestos	Pigment Violet 29
Carbon Tetrachloride	Trichloroethylene (TCE)
Cyclic Aliphatic Bromide Cluster (HBCD)	Tetrachloroethylene (PERC)

- These chemicals were drawn from EPA's 2014 TSCA Work Plan, a list of 90 chemicals selected based on their potential for high hazard and exposure as well as other considerations.
- Announcement of the first 10 chemicals triggered a statutory deadline to complete risk evaluation for these chemicals within three years.
- Under the newly amended law, EPA was required to release a scoping document within six months for each chemical. This includes the hazard(s), exposure(s), conditions of use, and the potentially exposed or susceptible subpopulation(s) the agency plans to consider for the evaluation.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- On June 22, 2017 and meeting the statutory deadline, EPA published the scopes of these first 10 chemicals, which include hazards, exposure, conditions of use, and potentially exposed or susceptible subpopulations considered in the risk evaluation.
- Because there was insufficient time for EPA to provide an opportunity for public comment on a draft the scope documents, EPA will publish and take public comment problem formulation documents.
- The problem formulation documents will refine the current scopes, and are expected to be published in December 2017-January 2018.

HOT ISSUES:

- EPA's decision to not include legacy uses as a 'condition of use' that will be evaluated in the risk evaluations, has received some negative attention, particularly for asbestos. This would include, for example, products that contain asbestos that are no longer being manufactured, but may be in a person's home.

LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT

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GUIDANCE TO ASSIST INTRESTED PERSONS IN DEVELOPING RISK EVALUATIONS

SUMMARY:

Within the first year after amended TSCA was signed into law, EPA was required to develop guidance to assist interested persons in submitting draft risk evaluations on chemical substances to be considered by the Agency.

BACKGROUND:

- In accordance with TSCA section 26(l)(5), no later than one year after the date of enactment, EPA shall develop guidance to assist interested persons in developing and submitting draft risk evaluations that shall be considered by the Agency.
- The guidance addresses the quality of the information submitted and the process to be followed in developing draft risk evaluations for consideration.
- The process covered in this guidance addresses the minimum components of a risk evaluation as enumerated in TSCA section 6(b), as well as the process codified in the Risk Evaluation Rule.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- The 'Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluation Under the Toxic Substances Control Act' was released on June 22, 2017, meeting the statutory deadline.
- The Agency is uncertain at this time of the public interest in this provision, and has not yet received any submitted draft risk evaluations.
- EPA welcomes and will review and consider submitted draft risk evaluations, and in general they will be treated as additional information to information Agency actions or decision making.

HOT ISSUES:

- EPA did not provide an opportunity for a formal public comment on this document, but did open a docket to accept any comment or questions.
- EPA will consider updating this document in the future as the Agency and public become more familiar with the risk evaluation process.

LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT

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PERSISTENT, BIOACCUMULATIVE AND TOXIC (PBT) CHEMICALS – EXPIDATED RULE MAKING

SUMMARY:

Certain persistent, bioaccumulative, and toxic (PBT) chemicals have been specifically identified as a priority for action under TSCA section 6(h), which requires EPA to take expedited regulatory action to address risks from such chemicals.

BACKGROUND:

- TSCA section 6(h) requires EPA to take expedited regulatory action under section 6(a) for certain PBT chemicals from the 2014 update of the TSCA Work Plan for Chemical Assessments without a risk evaluation, and to meet a statutory deadline of June 2019 for a proposed rule, with a final rule to follow no more than 18 months later. This directive is separate from the process outlined in the statute for the initial ten chemicals selected for risk evaluation.
- As a first step in the TSCA section 6(h) process, five PBT chemicals were identified for action in keeping with the statutory criteria
    - Decabromodiphenyl ethers (DecaBDE), used as a flame retardant in textiles, plastics, wiring insulation, and building and construction materials;
    - Hexachlorobutadiene (HCBD), used as a solvent in the manufacture of rubber compounds and as hydraulic, heat transfer or transformer fluid;
    - Pentachlorothiophenol (PCTP), used as a mercaptan (sulfur) cross-linking agent to make rubber more pliable in industrial uses;
    - Phenol, isopropylated, phosphate (3:1), used as a flame retardant in consumer products and as lubricant, hydraulic fluid, and other industrial uses; and
    - 2,4,6-Tris(tert-butyl) phenol, an antioxidant that can be used as a fuel, oil, gasoline or lubricant additive.
- Two additional PBT chemicals met the TSCA section 6(h) criteria; however, manufacturers for these substances submitted timely requests to EPA for risk evaluations pursuant to section 6(h)(5) and are therefore not subject to the rulemaking effort. As a result of the requests, Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl) and Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl are excluded from the expedited action requirements under TSCA section 6(h).

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

EPA has established public dockets for each of the five PBT chemicals to facilitate receipt of information on exposure and use which may be useful to the Agency's rulemaking effort. EPA is requesting that any information be submitted to the docket by December 2017 so that the information can inform any regulatory action.

HOT ISSUES:

To date, this rulemaking has not received significant public attention, though manufacturers of these chemicals have initiated discussions with EPA. Issues expected to be addressed in the near future include identifying the conditions of use for each of the chemicals and exposures to the general population, potentially exposed or susceptible subpopulations, and the environment.

LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP/OPPT, with a cross-agency workgroup formed as part of the rulemaking process (including OLEM, ORD, OECA, OGC, and OP).	

NEW CHEMICAL REVIEWS

ISSUE/TOPIC:

The 2016 TSCA amendments resulted in changes to EPA's new chemicals program. TSCA section 5 now requires EPA to review a new chemical (or significant new use of an existing chemical) and make affirmative determinations relating to safety of chemicals before those chemicals can proceed to market.

BACKGROUND:

- The EPA typically receives approximately 1,000 new chemicals submissions per year and, by law, must generally conclude review of each submission within 90 days.
- EPA generally has approximately 300-350 cases under review at any given time.
- The amendments to TSCA, including the new affirmative determination mandate for new chemicals, went into effect immediately on June 22, 2016. New chemical submissions that were in the "queue" on that date were also subject to the new requirement.
- As a result of these changes, and given the need for EPA to revise processes to respond to the new requirements of TSCA, the throughput rate on determinations temporarily slowed and the number of cases undergoing review roughly doubled. This has been referred to as the new chemicals "backlog."

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

✓ EPA has worked expeditiously to adjust its review process to meet the new requirements in TSCA, and has significantly reduced the backlog from roughly 350 to 100 cases. OCSPP remains committed to eliminating the backlog entirely, and continuing to improve the efficiency and effectiveness of its new chemicals program. OCSPP has already instituted a number of program changes, including increased staffing and process/policy changes.

HOT ISSUES:

- Congressional Inquiries. Members in both the Senate Environment and Public Works Committee and the House Energy and Commerce Committee continue to express interest in EPA's efforts to eliminate the new chemicals "backlog." OCSPP has responded to a number of requests for information and briefings on this topic.

LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP/OPPT	OGC

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TSCA CONFIDENTIAL BUSINESS INFORMATION (CBI)

SUMMARY:

Section 14(a) of the Toxic Substances Control Act (TSCA) provides that submitters may claim information submitted to EPA under TSCA as confidential business information (CBI). EPA is working to implement significant changes to TSCA section 14 made by the Frank R. Lautenberg Chemical Safety for the 21St Century Act.

BACKGROUND:

The Frank R. Lautenberg Chemical Safety for the 21St Century Act introduced new requirements relating to the submission of CBI, its management, and periodic reviews of CBI claims, including expiration of CBI claims.

All CBI claims must be substantiated at the time the information claimed as CBI is submitted to EPA, except for those types of information exempt under TSCA section 14(c)(2). The law requires that the submitter provide a statement concerning the need for the CBI claim and a certification that the statement of need is true and correct. EPA has collapsed the two requirements into a single certification statement. There is also a requirement that when a chemical identity is claimed as CBI, a non-CBI structurally descriptive generic name be provided.

EPA must, with limited exceptions, review all CBI claims for chemical identity, as well as a representative sample of at least 25% of other claims within 90 days of receipt. Other CBI claims may also be reviewed by the Agency based on specific events, such as pursuant to a Freedom of Information Act (FOIA) request, when a substance is designated as a high priority or active substance, or when the Agency believes that disclosure would be important in implementation of TSCA section 6. Most CBI claims expire after 10 years unless the information submitter reasserts and re-substantiates the CBI claim. When EPA approves a CBI claim for chemical identity, the Agency must develop a unique identifier for the chemical and apply the unique identifier to all information relevant to the applicable chemical substance. TSCA CBI may also be shared with non-federal authorities including states, subdivisions of states, tribes, emergency responders, and health care professionals if, certain requirements are met.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- January 19, 2017, Federal Register Notice announcing interpretation of statute as requiring substantiation of TSCA CBI claims at the time the information is submitted to EPA.
- May 8, 2017, Federal Register Notice requesting comment on the Assignment and Application of the "Unique Identifier" Under TSCA Section 14 and Public Meeting held on May 24, 2017.

HOT ISSUES:

OPPT is expecting to announce its approach for implementing a unique identifier approach by the end of September.

LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP/OPPT	OGC

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ALTERNATIVE TESTING STRATEGIC PLAN

SUMMARY:

The 2016 amendments to TSCA require the Administrator to "…reduce and replace, to the extent practicable, scientifically justified and consistent with the policies of this title, the use of vertebrate animals in the testing of chemical substances or mixtures…" (TSCA §4(h)(1))

BACKGROUND:

- Section 4 of TSCA authorizes and provides specific requirements related to testing chemical substances and mixtures
- Subsection (h) is an amendment to TSCA provided in the Lautenberg Chemical Safety Act; it did not exist in original TSCA
- Agency requests for testing (and voluntary testing by stakeholders) must encourage and facilitate methods and approaches to reduce/replace the use of vertebrate animals
- Section 4(h)(2)(A) requires the Administrator to "…develop a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing and provide information of equivalent or better scientific quality…"
- This plan must be published by June 22, 2018, and not later than June 22, 2021 and every five years thereafter EPA must report to congress on progress implementing the plan and goals for future implementation

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- OPPT is on track to publish the initial Strategic Plan by June of 2018
- February: OPPT began more active participation in the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM, a permanent committee of the National Institute of Environmental Health Sciences [NIEHS] established by law in 2000. It is composed of representatives from 16 U.S. federal agencies and is charged with establishing, where feasible, "…guidelines, recommendations, and regulations that promote the regulatory acceptance of new or revised…tests…while reducing, refining or replacing animal tests…")
- March: OPPT conducted outreach to scientific community by providing an overview of the new requirements to the Annual Society of Toxicology (SOT) meeting
- April: OPPT began substantive intra-agency discussions with EPA offices with equities and expertise to contribute to the strategy, e.g., OCSPP's Office of Pesticide Programs and Endocrine Disruptor Program and ORD's National Center for Computational Toxicology; all of which have developed and/or tested use of alternative test methods in the context of conducting risk assessment
- May: OPPT conducted outreach to the international chemical's management community by providing an overview of new requirements to the Organization for Economic Cooperation and Development's Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology; follow-up conference call with parties (25 lines were open, multiple government authorities from various countries and some stakeholders; participant list not yet circulated) with past experience and interest in collaboration in July
- June: conducted outreach to the scientific community by presenting progress to date to the Society of Toxicology's Specialty Section on In Vitro Methods

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- July-September: working on developing a substantive outline for stakeholder workshop to be held likely in November

HOT ISSUES:

There has been some attention by certain non-governmental organizations (NGOs) and industry stakeholders on this topic/project. OPPT is getting inquiries by stakeholders (in and outside the agency) as interested parties become more aware of this section of the amended TSCA and as the June 2018 deadline draws near.

LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP/OPPT ORD/NCCT	OCSPP/OPP; OCSPP/OSCP-EDSP;

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MERCURY

SUMMARY:

OCSPP addresses environmental release and exposure to mercury by working to reduce its use in favor of safer alternatives.

BACKGROUND:

- Mercury is an element found in the earth's crust
- In the environment, mercury is a persistent, bioaccumulative neurotoxicant
- People can be exposed to mercury from both natural and man-made sources, including volcanic release, burning of coal, and use in products and processes
- Although mercury use has declined substantially, it continues despite the availability of cost-effective substitutes for some uses
- Responsibility for implementing a federal ban on export of mercury lies with OCSPP

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

As required by the 2016 amendment to the Toxic Substances Control Act (TSCA), OCSPP has met two statutory deadlines:

1. published a notification of the mercury compound export ban in the Federal Register on August 26, 2016,
2. published the initial mercury inventory (based on publicly available information) in the Federal Register on March 29, 2017.

To implement another provision in the 2016 amendment to TSCA, OCSPP is developing a triennial inventory of supply, use, and trade. The law directs EPA to promulgate a regulation to collect information from manufacturers to assist in preparing the inventory. Three groups of manufacturers are identified for reporting: mercury manufacturers, manufacturers of mercury-added products, and manufacturers who otherwise intentionally use mercury. In carrying out the inventory, EPA must identify any manufacturing process or product and recommend actions including regulations to achieve reduction in mercury use. The final rule deadline is June 22, 2018, and OCSPP is currently developing the proposed rule for publication and comment.

HOT ISSUES:

Congressional interest in mercury is reflected in provisions of the 2016 amendment to the Toxic Substances Control Act (TSCA) that OCSPP implements as described above.

LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT

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TOXICS RELEASE INVENTORY (TRI)

SUMMARY:

The Toxics Release Inventory (TRI) is an information disclosure program covering toxic chemical releases and other waste management (e.g., recycling) quantities by industrial facilities. The TRI program was established by section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986 and later expanded by section 6607 of the Pollution Prevention Act (PPA) of 1990.

BACKGROUND:

- By July 1 of each year, more than 20,000 facilities across the United States in the manufacturing, electricity generation (oil and/or coal-fired), mining, solvent recovery, and other sectors, report electronically to EPA's TRI Program each facility's prior calendar year releases, other waste management (recycling, energy recovery, treatment) quantities, and source reduction on more than 650 TRI-listed toxic chemicals.
- EPCRA requires the manufacturing sectors to report to TRI. In a 1997 final rule, the Agency added seven additional sectors to TRI, including mining and electricity generation.
- The Agency receives more than 80,000 TRI reports each year from the 20,000+ facilities reporting to TRI.
- Pursuant to the statute, the EPA makes the TRI data publicly accessible; first publishing, in user-friendly electronic formats, the Preliminary TRI Data in July, within three weeks of the July 1 submission deadline and then publishing an updated, "frozen" National Analysis dataset, in the fall. This latter dataset is the snapshot of TRI reporting that is used by EPA to develop the annual TRI National Analysis, which is the Agency's interpretation of the TRI data as evaluated by trends and "data cuts" focused on specific chemicals, sectors, parent company, and other variables. The TRI National Analysis is published as an interactive website in January of each year.
- The TRI data is used by a wide range of internal and external stakeholders including government (including EPA program offices), academia, industry, community organizations, the media, concerned citizens, and the financial community, to assist with research, policy decisions, informed dialogue, and many other uses.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- In October 2016, the TRI marked its 30th anniversary as the Agency's premier, multi-media right-to-know program.
- In January 2017, the TRI Program published the TRI National Analysis for the 2015 TRI dataset. The National Analysis showed that total TRI-reported releases decreased by 15% and total TRI-reported waste decreased by 3% between 2014 and 2015.
- On July 19, 2017, the Agency published the 2016 calendar year Preliminary Data submitted by industry to EPA by July 1, 2017.
- The TRI continues to serve as an invaluable data source for TSCA implementation and TSCA and other priority chemicals are being considered for inclusion on the TRI Chemical List.

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HOT ISSUES:

- As part of the Agency's Regulatory Reform docket, comments from the National Mining Association (NMA), other mining associations, and specific mining companies have requested regulatory relief from the TRI reporting requirements, either in full or at least with regard to naturally occurring chemicals mined from the earth. OCSPP is currently evaluating these comments and considering options for burden relief and for additional ways to place mining data reported to TRI in context to avoid misuse or misunderstandings of the TRI data.
- The Agency has placed the Proposed Rule to Add Natural Gas Processing (NGP) Facilities to TRI on the 2017 Inactive Actions List of the Regulatory Agenda.

LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT

While the TRI Program is located in OCSPP, the TRI Information Technology (IT) systems and tools are managed by the Office of Environmental Information (OEI). Each Region has a Regional TRI Coordinator.

SAFER CHOICE PROGRAM

SUMMARY:

Safer Choice is a voluntary, stakeholder-driven program designed to recognize and partner with industry by developing products and chemicals that benefit people and the environment; the Safer Chemical Ingredients List (SCIL) includes chemicals used in Safer Choice-labeled products.

BACKGROUND:

Safer Choice Program [HYPERLINK "http://www.epa.gov/saferchoice"]

- Formerly the Design for the Environment (DfE) Program, redesigned to Safer Choice in 2015
- Developed with a broad cross-section of stakeholders
- Allows use of the Safer Choice label on cleaning and other products that meet human health and environmental criteria
- About 2,000 products from 500 American manufacturing partners
    - Many Safer Choice partner companies are small businesses
- Program participants include:
    - Chemical manufacturers (e.g., AkzoNobel, BASF, Dow, Eastman, Milliken, Novozymes, Stepan)
    - Product manufacturers
        - Large companies: BISSELL, Clorox, Church & Dwight, Ecolab, GOJO, Proctor & Gamble, RB, WD-40, others
        - Small businesses: Berkley Green, Clean Control, Earth Friendly Products, Honest Company, Jelmar (CLR), Seventh Generation, State Industrial, Sun Products, Wexford Labs, others
    - Retailers (e.g., Albertsons/Safeway, Amazon, Brandless, Costco, Home Depot, Office Depot/Office Max, Sears, Staples, Target, Walmart, Wegmans)

Safer Chemical Ingredients List (SCIL) [HYPERLINK "http://www.epa.gov/saferchoice/safer-ingredients"]

- Created to meet stakeholder demand for a list of chemicals that meet Safer Choice criteria for use in Safer Choice labeled products
    - Chemical manufacturers can identify and target opportunities for chemical innovation
    - Product manufacturers can select chemicals
- SCIL highlights green chemistry innovations by the chemical industry
- SCIL is a living list of 870 chemicals that meet Safer Choice's Criteria for Safer Chemical Ingredients
    - Chemicals are organized by functional-use categories (e.g., solvents, surfactants, chelants)

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HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

Safer Choice label

- 33 companies and organizations named 2017 Safer Choice Partners of the Year
- EPA supported online survey of 2,000+ adult U.S. residents in February 2016:
  - 35% say they have seen the Safer Choice label in stores
  - 76% of consumers–83% of parents and 86% of millennials–responded that they would use the Safer Choice label to inform purchasing decisions
- 320 partnership products added or renewed in FY17

Safer Choice Summit

- Almost 200 company and organization attendees provided input for program enhancement

Safer Chemical Ingredients List (SCIL)

- 48 chemicals added to date in FY17

HOT ISSUES:

The SCIL may provide a source of candidate Low Priority Substances under TSCA

LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT

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NANOTECHNOLOGY

SUMMARY:

Nanotechnology is the understanding and control of matter at dimensions of roughly 1-100 nanometers

BACKGROUND:

- Many nanoscale materials are regarded as "chemical substances" under the Toxic Substances Control Act.
- Chemical substances that have structures with dimensions at the nanoscale -- approximately 1-100 nanometers (nm) -- are commonly referred to as nanoscale materials or nanomaterials
- EPA is moving expeditiously ensuring appropriate oversight of nanotechnology, while not unduly impeding its development.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

Since 2005, EPA has received and reviewed over 190 new chemical notices under TSCA for nanoscale materials.

EPA has approved nearly all of them for commercialization, in most cases allowing the manufacture of new chemical nanoscale materials under the terms of certain regulatory exemptions, but only in circumstances where exposures were tightly controlled to protect against unreasonable risks (using, for example, the exposure and environmental release limitations discussed above).

On January 12, 2017, as part of the Agency's effort to ensure a more comprehensive understanding of nanoscale materials in commerce, EPA issued a final regulation requiring one-time reporting and recordkeeping of existing exposure and health and safety information on nanoscale materials produced from substances already on the TSCA Inventory.

On May 12, 2017, EPA extended the effective date of the rule to August 14, 2017.
On May 15, 2017, EPA issued draft guidance for the rule asking for additional public comment. EPA will finalize its guidance by the August 14 effective date.

HOT ISSUES:

Concerns about the reporting rule were raised in public comment on the regulatory reform activity.

LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT

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POLLUTION PREVENTION (P2) PROGRAM

SUMMARY:

The EPA's Pollution Prevention (P2) Program complements EPA's regulatory programs by working with businesses, states, and other partners to encourage and facilitate adoption of source reduction approaches through: (a) the development and delivery of P2 information and tools; (b) technical assistance; (c) the funding and facilitation of P2 innovations; and (d) the sharing and amplification of those innovations so that others can replicate approaches and outcomes.

BACKGROUND:

Pollution prevention (P2), also called "source reduction," is any practice that reduces, eliminates, or prevents pollution at its source before it is generated. The EPA P2 Program:

- Provides P2 Information, Training and Technical Assistance to Businesses: As required by the P2 Act of 1990, EPA makes **grants** available to **states and tribes** to promote adoption of pollution prevention by businesses. These grants fund outreach efforts by states and tribes to provide direct P2 technical assistance and training for businesses, aid in development and adoption of P2 solutions and innovations, and sharing those innovations across state and regional boundaries so that others can benefit from and replicate P2 approaches and outcomes.

- Supports Markets with Information:
  - The EPA **Environmentally Preferable Purchasing (EPP) Program** maintains Recommendations of Specifications, Standards, and Ecolabels in order to provide clear information to federal procurement officials -- and manufacturers and service providers -- about which of the many private sector standards and ecolabels demonstrate effective environmental performance of products and service. This work also supports the P2 Act requirement that EPA identify opportunities to use Federal procurement to encourage pollution prevention.
  - The EPP Program also works with a variety of non-governmental standards development organizations to promote development of voluntary consensus standards for environmentally preferable goods and services.

- The Presidential Green Chemistry Challenge Awards: A recognition program for innovative, green chemistry technologies.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

P2 Technical Assistance and Information for Business: Between 2011-2015, the EPA's P2 program issued 281 assistance grants for $31.6 million, which resulted in four-year rolling benefits estimated at:

- $1.1 billion in savings
- 401 million pounds of hazardous materials reduced
- 23.6 billion gallons of water saved
- 10.8 million tons of greenhouse gases eliminated
- 15.38 billion kilowatt hours of energy savings

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Supporting Markets with Information (EPP): In September 2015, in accordance with Executive Order 13693 and the OMB implementing instructions, EPA, in consultation with OMB and the White House Council on Environmental Quality (CEQ), issued interim recommendations for standards and ecolabels for federal procurement. In December 2016, EPA completed a pilot using multi-stakeholder developed Guidelines to assess approximately 50 standards and ecolabels from 20 organizations from the furniture, flooring and paints/coatings product sectors. The EPA recommendations for these product categories were updated based on the results of this pilot.

Green Chemistry: During the 22 years of the Green Chemistry Challenge Awards program (through 2017), in partnership with the American Chemical Society, the EPA has received more than 1,700 nominations from American innovators and presented awards to 114 technologies.

HOT ISSUES:

P2: Has been proposed for elimination under the FY 18 President's Budget.

EPP: Based on stakeholder concerns and interagency discussions, the EPA recommendation for the lumber/wood product category was removed in December 2016 and put on hold. Before further action on this product category, EPA would continue coordination with the USDA Forest Service and USDA Natural Resources Conservation Service, Department of Energy, OMB, and CEQ to determine how forestry standards should best be evaluated. The Fiscal Year 2018 President's Budget eliminates all staff and contract funding for this program. Therefore, further action on the lumber/wood category is uncertain.

LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT

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FORMALDEHYDE

SUMMARY:

- The Formaldehyde Standards for Composite Wood Products Act (TSCA Title VI) required that EPA promulgate a rule to set formaldehyde emission standards for composite wood products and implement provisions to ensure compliance with those standards. EPA published a final rule on December 12, 2016. The Agency has since promulgated proposed rule amendments to address issues that have arisen with compliance dates and the labeling of composite wood products since the December 12, 2016 final rule.

BACKGROUND:

Formaldehyde Background

- Formaldehyde is a colorless, flammable gas at room temperature and has a strong odor.
- Formaldehyde can cause respiratory irritation, watery eyes and is classified by EPA as a probable human carcinogen.
- Travel trailers used after Hurricanes' Katrina and Rita in 2005 contained composite wood that emitted high levels of formaldehyde, bringing national attention to the issue.
- The California Air Resources Board (CARB) established a Formaldehyde Air Toxics Control Measure (ATCM) in 2007.
- On March 24, 2008, Sierra Club, et al. submitted a TSCA Section 21 petition requesting EPA adopt the CARB standards through section TSCA 6(a).
- EPA partially denied and accepted the petition to investigate potential regulatory action.
- OPPT held meetings nationwide to take comment on potential EPA action.
- Industry and environmental groups then worked with Congress to craft the Formaldehyde Standards for Composite Wood Products Act, which added Title VI to the Toxic Substances Control Act (TSCA) in 2010.

The Formaldehyde Standards for Composite Wood Products (TSCA Title VI)

- On July 27, 2016, EPA finalized a rule to implement TSCA Title VI.
- The purpose of the law is to reduce formaldehyde emissions from composite wood products, which will reduce overall exposures to formaldehyde and result in benefits from avoided adverse health effects.
- The statute established the same formaldehyde emission standards for composite wood products including hardwood plywood, medium-density fiberboard, and particleboard, as established by the CARB ATCM.
- Although the emission standards are the same under CARB, the statute directed EPA to address areas not included in CARB's standards.
    - Congress deferred to EPA to determine whether laminated products should be considered "hardwood plywood" after considering available information and ensuring compliance with the emission standards.

Final Rule Implementing TSCA Title VI

- Rule issued on December 12, 2016.
- Under the rule, composite wood products need to be tested, certified, labeled and records kept as compliant beginning on December 12, 2017.
- The rule also establishes a third-party certification program and includes procedures for the accreditation bodies (ABs) and third-party certifiers (TPCs).

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HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

TSCA Title VI Rule Amendments Underway

Compliance Dates

- The December 12, 2016, final rule effective date was extended from February 10, 2017 to May 22, 2017, to allow the new Administration time to review the rule provisions.
- EPA addressed this issue by promulgating a direct final rule and parallel proposal on May 24, 2017 to extend the compliance dates; however, negative comment was received so EPA has withdrawn the direct final rule and is now proceeding to issue a subsequent final rule on the compliance dates based on the comments received.

Early Labeling

- EPA has issued a direct final rule and parallel proposal to allow regulated composite wood products and finished goods that meet the formaldehyde emissions standards, and have been certified by an EPA-recognized TPC, to be voluntarily labeled as compliant as soon as compliance can be achieved before the emission standards, labeling, and recordkeeping compliance date.
  - Public comment period closed July 26, 2017.

Voluntary Consensus Standards

- EPA will also soon issue a direct final rule and parallel proposal to allow regulated entities to use most current versions of voluntary consensus standards incorporated by reference in the rule, consistent with CARB.
  - Rule is currently undergoing Office of Federal Register review for Incorporation by Reference of the new standards

HOT ISSUES:

Import Certification

- Some industry stakeholders requested that EPA remove the TSCA import certification requirement.
  - Some industry stakeholders believe the TSCA import certification is unnecessary given that recordkeeping is required for importers to ensure imported composite wood product is TSCA Title VI compliant
  - Other industry stakeholders are supportive of the TSCA import certification requirement because they feel the provision further deters non-compliance of foreign-manufactured products by involving Customs and Border Patrol in monitoring imports.

Laminated Products

- Industry requested EPA exempt all laminated products from testing and certification.
- EPA concluded based on the data provided to the Agency not to exempt all laminated products in the final rule.
  - The public is able through the 12/12/16 final rule to petition EPA to exempt additional laminated products made with other resins/technology from the definition of hardwood plywood based on testing data showing compliance.
  - A stakeholder dialogue/workshop is anticipated to gauge the progression of resin technology.

LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP/OPPT	OGC/OECA/OP/ORD

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LEAD

SUMMARY:

Although lead exposure has declined dramatically in the past 40 years because of actions by EPA, other federal agencies, and states, some populations continue to experience high lead exposures, particularly those in poorer and older neighborhoods. EPA has statutory authorities for addressing lead exposure from air, soil, water, household dust, and old paint and works closely with other federal, state, and local partners to continue reducing lead exposure across the population and internationally.

BACKGROUND:

403 Hazard Standards

- In 2001, EPA established lead hazard standards in dust and soil for residences and child-occupied facilities. EPA's Lead-based Paint (LBP) and Renovation, Repair and Painting (RRP) regulations ensure that all work done by abatement and renovation contractors is done safely and avoids leaving dust that exceeds these standards.
- In 2009, without specifying a timetable for completion, EPA granted a petition which requested that EPA lower the regulatory hazard standard for lead in dust on floors (40 µg/ft2) and window sills (250 µg/ft2).

Public and Commercial Buildings (P&CB)

- § 402(c)(3) of the Toxics Substances Control Act (TSCA) directs EPA to promulgate regulations for renovations in target housing, public buildings built before 1978 and commercial buildings that create lead-based paint hazards.
- For renovations that create lead-based paint hazards, TSCA directs EPA to promulgate work practice, training and certification requirements.
- In 2008, EPA promulgated final regulations applicable to renovations in target housing (pre-1978 residential dwellings) and child-occupied facilities (a subset of P&CBs). Shortly thereafter, a group of litigants challenged the 2008 RRP rule, in part for EPA's failure to evaluate lead-based paint hazards in P&CBs by the statutory deadline (April 1994). The EPA entered into a settlement agreement that, among other things, established a timeline for action on P&CB renovations unless a determination was made that these activities do not create lead-based paint hazards. The settlement has been renegotiated several times since the original agreement.

HIGHLIGHTS:

403 Hazard Standards

- On August 24, 2016, several plaintiffs filed a petition seeking a court order compelling EPA to issue a proposed rule within 90 days of that order, and a final rule within six months. Petitioners contend that EPA has unreasonably delayed its commitment to initiate a rulemaking to lower the hazard standard for lead in dust.
- On January 17, 2017, EPA filed its brief and declaration; petitioner's response brief was filed on January 27, 2017; oral argument occurred June 12, 2017. EPA is waiting on a decision from the court.

Public and Commercial Buildings

- The litigants informed DOJ/OGC in December 2016 that they intend to reactivate the litigation instead of negotiating a new settlement deadline. No further discussions with litigants have occurred and EPA missed the March 31, 2017 deadline.

HOT ISSUES:

- EPA's FY 18 budget virtually eliminates the Lead Hazard Reduction Program except for application processing and database management.

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LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP/OPPT Regional offices	ORD, OGC, OCHP, OP, OECA, OLEM, OAR,

POLYCHLORINATED BIPHENYLS (PCBs)

SUMMARY:

OCSPP manages the continued use of PCBs in buildings and electrical equipment in the U.S. pursuant to TSCA Section 6(e) and 40 CFR part 761.

BACKGROUND:

General PCB Background

- PCBs belong to a broad family of man-made organic chemicals known as chlorinated hydrocarbons. PCBs were widely used due to their non-flammability, chemical stability, high boiling point and electrical insulating properties.
- PCBs can cause a variety of adverse health effects, including cancer and effects on the immune system, reproductive system, nervous system and endocrine system.
- PCBs were used in hundreds of industrial and commercial applications from 1929 until the manufacture, processing, distribution in commerce and use of PCBs was banned under Section 6(e) of TSCA in 1979.
- TSCA Section 6(e) provides that, if it can be demonstrated that there is no unreasonable risk of injury to health or the environment, then EPA may authorize continued uses of PCBs by regulation.
- PCBs are still authorized for use in certain applications including electrical equipment.
- The use of PCB building materials with greater than or equal to 50 ppm PCBs is banned unless specifically authorized by regulation. There is no requirement that building materials be tested for the presence of PCBs.
- OCSPP oversees the continued use of PCBs in buildings and equipment, while the Office of Land and Emergency Management (OLEM) oversees the disposal of PCBs.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

PCBs in School Buildings

Fluorescent Light Ballasts in Schools Proposed Rulemaking

- Schools built or renovated between 1950-1979 have widespread use of polychlorinated biphenyls (PCBs) containing building materials (e.g., non-liquid PCBs in caulk and paint, and liquid PCBs in fluorescent light ballasts (FLB)). EPA is aware of a number of incidents involving releases of PCBs from FLBs in schools that have occurred across the country including hundreds of incidents in New York City, Los Angeles and elsewhere.
- EPA sent a proposed rule to the Office of Management and Budget (OMB) in late 2016 to end the use authorization for PCB-containing fluorescent lights ballasts (FLB) in schools and daycare centers after December 31, 2020.
- EPA's proposal also included, as a condition of use of PCB FLBs until December 31, 2020, that school building and daycare administrators, including owners and operators, will have to notify building occupants, including parents or guardians of minors attending the facility, of the presence of any PCB FLBs. Note that, even in the absence of a new regulation, leaking PCB FLBs are not authorized and must be properly removed and disposed.
- The proposed rule was sent back from OMB to EPA in January 2017.

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PCBs in School Building Materials

- The PCBs Building Materials Workgroup, led by OPPT, issued updated PCBs in Building Materials—Questions & Answers guidance, and associated Fact Sheet in July 2015 to provide guidance on addressing PCBs in school buildings.
- The PCBs Science Workgroup, led by the Office of Research and Development (ORD), developed Exposure Levels for Evaluating PCBs (ELEs) in indoor school air and on surfaces. The air ELEs are public on the EPA website while the surface ELEs are not. Both the air and surface ELEs will tentatively undergo external peer review in Fall 2017.
- EPA's Integrated Risk Information System (IRIS) program is in the early stages of developing a draft assessment for the non-cancer effects of PCBs. The draft assessment is expected to be ready for agency review in the third quarter of FY 2018.
- EPA is currently working to develop more consistency among the EPA regions in handling this issue.

HOT ISSUES:

PCBs in School Buildings

- Some external, non-EPA cost estimates for schools to come into compliance nationwide with TSCA PCB requirements are in the billions of dollars, although the number of schools affected and the amount of material in schools is unknown.
- Advocacy groups alleged TSCA violations against Santa Monica-Malibu Unified School District. EPA was not a party to the lawsuit, but EPA Region 9 approved the school district's plan to address contaminated substrate and worked with the school district as they implemented best management practices and conducted comprehensive air and wipe sampling.

LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP/OPPT/	OLEM/OGC/ORD/Region 9

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PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS)

SUMMARY:

Per- and polyfluoroalkyl substances (PFAS) are a large family of man-made chemicals that include perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), are persistent in the environment, and are distributed globally. PFAS chemicals—primarily PFOA and PFOS, but also others—have been used widely in consumer products, firefighting foams at air fields, and in industrial processes. PFAS chemicals have been detected at sites across the country, often in drinking water. There is substantial concern about the effects of PFAS on public health. EPA is working with federal partners, states, tribes, communities, and industry to address public concerns related to PFAS chemicals, including PFOS and PFOA.

BACKGROUND:

- There is concern about the effects of PFAS on public health, including increased cholesterol levels, low infant birth weights, effects on the immune system, thyroid hormone disruption, and an increased risk for kidney and testicular cancer. There is also concern for the reproductive and life stage health risks of the more sensitive populations, including pregnant mothers and breast-fed infants, from short-term exposures.
- Studies by Centers for Disease Control and Prevention (CDC) have found PFOA and PFOS in the blood of nearly all the people they tested because PFAS chemicals have been used in many consumer products, bioaccumulate, and do not break down in the environment. CDC studies have shown, however, that the levels of PFOA and PFOS in blood have been decreasing since companies stopped producing these chemicals, but information on potential levels of other PFAS chemicals, which are being used as alternatives, is lacking.
- Certain PFAS chemicals, including PFOA and PFOS, are no longer manufactured in the U.S. as a result of voluntary phase-outs under EPA's 2010/2015 PFOA Stewardship Program. EPA remains concerned about the ongoing uses of PFOA and related chemicals that are still available in existing stocks or are being newly introduced by companies not participating in the PFOA Stewardship Program.
- In 2016, EPA established non-regulatory health advisories for PFOA and PFOS in drinking water of 70 parts per trillion (ppt). The health advisories identified the concentration of PFOA and PFOS in drinking water at or below which adverse health effects are not anticipated to occur over a lifetime of exposure.
- EPA Offices and Regions (and other federal agencies) are learning more about the toxicity of PFAS chemicals as well as developing and validating necessary analytical methods to better understand PFAS exposures in communities.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- EPA's New Chemicals program reviews alternatives for PFOA and related chemicals before they enter the marketplace to identify whether the range of toxicity, fate and bioaccumulation issues that have caused past concerns with perfluorinated substances may be present in order to ensure that the new chemicals may not present an unreasonable risk to health or the environment.
- EPA has taken a range of regulatory actions to address PFAS substances in manufacturing and consumer products:

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- On January 21, 2015, EPA proposed a Significant New Use Rule (SNUR) that requires manufacturers (including importers) and processors of PFAS chemicals, including as part of articles, to notify EPA at least 90 days before starting or resuming new uses of the chemicals in any products.
- On September 30, 2013, EPA issued a rule requiring companies to report all new uses of certain PFOA-related chemicals as part of carpets, a category of potentially harmful chemicals once used on carpets to impart soil, water, and stain resistance. Companies must now report to EPA their intent to manufacture (including import) these chemical substances intended for use as part of carpets or to treat carpets, as well as import carpets already containing these chemical substances.

- In 2006, EPA, in cooperation with eight major leading companies in PFAS industry, launched the 2010/2015 PFOA Stewardship Program with the goal of eliminating these chemicals from emissions and products by 2015. All participating companies have met the PFOA Stewardship Program goals EPA remains concerned about the ongoing uses of PFOA and related chemicals that are still available in existing stocks or are being newly introduced by companies not participating in the PFOA Stewardship Program.

HOT ISSUES:

- There are geographical hotspots where exposures are higher than in the general population (e.g. Parkersburg, WV; Decatur, AL; Hoosick Falls, NY), and there are a growing number of investigations nationwide.
- Most recently, the N.C. Department of Environmental Quality (DEQ), in consultation with the N.C. Department of Health and Human Services (DHHS), is leading a state investigation into reports of an unregulated chemical known as GenX (replacing PFOA) in the lower Cape Fear River in N.C.
  - EPA is investigating Chemours' compliance with the requirements of a 2009 Consent Order issued under TSCA section 5 requiring control of releases to the environment associated with production of GenX at the company's Fayetteville, N.C., facility and potential impacts to Wilmington drinking water. EPA is also reviewing the additional toxicity data submitted by the company, as required under the Consent Order, and is updating the risk assessment using more recent production data and the additional GenX toxicity data.
  - Chemours, the company that produces the chemical at its facility in Fayetteville, N.C., maintains that it is currently capturing, removing and disposing of wastewater that contains the byproduct GenX.
  - EPA's health advisory for PFOA and PFOS combined is 70 ppt. There is no EPA health advisory level for GenX
  - NC DEQ and DHHS are continuing to investigate the levels of GenX in the lower Cape Fear region. The state DEQ developed a "health goal" for GenX in drinking water of 140 nanograms per liter (parts per trillion). This updated health goal is expected to be the most conservative and health protective for non-cancer effects in bottle-fed infants, pregnant women, lactating women, children and adults.
  - On July 17, NC Governor Cooper sent a letter to EPA urging EPA to set limits, revisit the consent order, and require Chemours to submit additional studies on GenX.
- PFAS chemicals lack evaluated, quantitative toxicity information and validated analytical methods. The lack of information and methods makes it difficult for EPA Offices and Regions to make evidence-based decisions regarding potential human health risks from ongoing or future exposures.

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LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:

- Lead: OCSPP/OPPT
- Other: Cross-Agency, including OW, OLEM, ORD, OECA, and EPA Regions 1, 2, 3, 4, 5, 6, 8, 9, and 10.

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NEGOTIATED RULEMAKING: CHEMICAL DATA REPORTING REQUIREMENTS FOR INORGANIC BYPRODUCTS

SUMMARY:

EPA is in the process of negotiating a proposed rule to limit chemical data reporting requirements under subsection 8(a) of the Toxic Substances Control Act (TSCA) for manufacturers of any inorganic byproducts when such byproducts are subsequently recycled, reused, or reprocessed. This negotiation process is required by TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The objective of the negotiated rulemaking process is to develop and publish a proposed rule by the statutory deadline of June 22, 2019.

BACKGROUND:

- Under the TSCA Section 8(a) Chemical Data Reporting (CDR) rule, EPA collects data from manufacturers (including importers) on the manufacturing, processing, and use of chemical substances in commerce, for those chemical substances listed on the TSCA Inventory.
- This information supports Agency risk evaluation, risk management, and other programs; it is made publicly available, to the extent possible, while protecting information claimed as confidential business information.
- A byproduct chemical substance is a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture. Because byproduct chemical substances are manufactured for a commercial purpose, this manufacturing is reportable under CDR unless covered by a specific reporting exemption.
- TSCA now includes a requirement that EPA enter into a negotiated rulemaking, which requires forming a negotiating committee (Committee) made up of interested stakeholders, to develop and publish a proposed rule to limit the reporting requirements under TSCA section 8(a) for manufacturers of any inorganic byproduct chemical substances when such byproduct chemical substances, whether by the byproduct chemical substance manufacturer or by any other person, are subsequently recycled, reused, or reprocessed.
- The objective of the negotiated rulemaking process is to develop and publish a proposed rule by June 22, 2019. In the event the Committee reaches a consensus and a proposed rule is developed through the negotiated rulemaking process, a final rule resulting from such negotiated rulemaking must be issued by December 22, 2019.
- In June 2017, EPA established the Committee and invited 25 representatives of industry, States, Non-Governmental Organizations, and Tribes to participate as members (in addition to EPA members).

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- December 2016: EPA published its notice of intent to negotiate and began the process of identifying potential Committee members.
- May 2017: Public meeting held on inorganic byproducts for the purpose of information exchange and to discuss the process of negotiated rulemaking prior to the establishment of the Committee. Notice published announcing first and second Committee meetings.
- June 2017: Committee established, and first Committee meeting held
- August 2017: Second Committee meetings will be held

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- September and October 2017: Third and fourth committee meetings planned

HOT ISSUES:

This negotiated rulemaking has received some trade press, and a small number of public comments on the December 2016 Notice of Intent to Negotiate. Committee members have been active and engaged participants at the public meeting and first Committee meeting, with a few additional members of the public also attending.

Stakeholder interest has largely been supportive of EPA's efforts to move quickly to reach consensus and proceed with the rulemaking. Issues identified by stakeholder and committee members have included:

- Consensus – Requests for increased clarity regarding how consensus must be reached (resolved through Committee subgroup discussions)
- How to balance the burden of reporting with the utility EPA derives from the data submitted

An additional key issue is the significant pressures of short timeframes allotted by the statute and the next CDR reporting period (in June 2020) for finalizing any rule that would result from these negotiations.

LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

OCSPP/OPPT, with a cross-Agency workgroup formed as part of the rulemaking process (including OLEM, ORD, OECA, OGC, and OP).

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ASBESTOS HAZARD EMERGENCY RESPONSE ACT (TSCA TITLE II)

SUMMARY:

The Asbestos Hazard Emergency Response Act (AHERA) and its implementing regulations at 40 CFR part 763, subpart E, require public school districts and non-profit schools to inspect their schools for asbestos-containing building material, prepare asbestos management plans and to take action to prevent or reduce asbestos hazards.

BACKGROUND:

- In addition to requiring schools to inspect for asbestos and maintain asbestos management plans, schools must use asbestos professionals trained pursuant to the EPA asbestos Model Accreditation Plan (MAP).
- EPA developed the asbestos MAP for states to establish training requirements for asbestos professionals who do work in schools and public and commercial buildings.
- The AHERA regulations require school districts and non-profit schools to inspect and then re-inspect for asbestos-containing materials in each school every three years; develop, maintain, and update an asbestos management plan and keep a copy at the school and the school district office; provide yearly notifications to parent, teacher, and employee organizations on the availability of the school's asbestos management plan and any asbestos-related actions taken or planned in the school; designate a contact person to ensure the responsibilities of the public school district or the non-profit school are properly implemented; perform periodic surveillance of known or suspected asbestos-containing building material; ensure that trained and licensed professionals perform inspections and take response actions and provide custodial staff with asbestos-awareness training.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- EPA included asbestos as one of the initial 10 chemical substances subject to the Agency's initial risk evaluations under new TSCA. The scope of the risk evaluation uses the TSCA Title II definition and does not include evaluating legacy uses (including asbestos still in buildings), or uses no longer manufactured or imported into the U.S. Asbestos is defined under AHERA as the "asbestiform varieties of six fiber types – chrysotile (serpentine), crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite or actinolite."

HOT ISSUES:

- Excluding legacy use of asbestos in the risk evaluation has been criticized by some stakeholders.
- The definition being used for the evaluation does not include "Libby Amphibole," which includes primarily winchite and richterite, fiber types not included in the TSCA Title II definition. Libby Amphibole is the asbestos found in the Libby, Montana, vermiculite mine which contaminated vermiculite products. Hundreds of deaths have been attributed to asbestos disease occurring in and around Libby, Montana.
- Vermiculite containing Libby Amphibole is no longer manufactured or processed in the U.S. and is therefore excluded from the risk evaluation.

LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP/OPPT	ORD, OGC, OAR, OECA, OLEM, All Regions

TSCA SECTION 6 RULES: TCE AND METHYLENE CHLORIDE/NMP

SUMMARY:

- Section 6 of the Toxic Substances Control Act (TSCA) provides authority for the EPA to ban or restrict the manufacture (including import), processing, distribution in commerce, and use of chemicals, as well as any manner or method of disposal of chemicals.
- Trichloroethylene (TCE) in aerosol degreasing, spot cleaning in dry cleaning facilities, and in vapor degreasing:
    - EPA has proposed a regulation under section 6 of TSCA to address the risks to human health identified from TCE in commercial and consumer aerosol spray degreasing, as a spot cleaner in dry cleaning, and in vapor degreasing.
- Methylene Chloride/N-Methylpyrrolidone (NMP) in paint removers:
    - EPA has proposed a regulation under section 6 of TSCA to address the risks to human health identified from methylene chloride and NMP in paint and coating removal.
- EPA's proposed rules made determinations that the chemicals present unreasonable risks to human health, EPA proposed regulatory action under section 6(a) to the extent necessary so that the chemicals no longer present such risks.
- TCE, methylene chloride, and NMP are also included in the initial group of ten chemicals to undergo risk evaluation.

BACKGROUND:

- TCE is a volatile organic compound (VOC) and hazardous air pollutant (HAP) classified as a human carcinogen. In the June 2014 TSCA Work Plan Risk Assessment for TCE, EPA identified acute and chronic non-cancer and cancer risks associated with TCE use in commercial degreasing and some consumer uses.
- Methylene chloride is a volatile solvent that is a probable human carcinogen used in consumer and commercial paint and coating removal; at least one worker death annually is attributed to methylene chloride in bathtub refinishing. NMP is a developmental toxicant presenting risks of fetal death and decreased birthweight; it is used in consumer and commercial paint and coating removal and is often a substitute for methylene chloride in consumer uses.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- On December 7, 2016, under section 6(a) of TSCA, EPA proposed to ban uses of TCE as an aerosol degreaser and for spot cleaning in dry cleaning facilities as a result of health risks identified in a 2014 TSCA Chemical Work Plan Chemical Risk Assessment for TCE. The comment period closed on March 16, 2017, and EPA received 28 comments on the proposed rule.
- On January 19, 2017, under section 6(a) of TSCA, EPA proposed to ban the use of TCE in commercial vapor degreasing as a result of health risks identified in a 2014 TSCA Chemical Work Plan Chemical Risk Assessment for TCE. The comment period closed on May 19, 2017, and EPA received 544 comments on the proposed rule. This proposed rule and a proposed rule on TCE in spot cleaners in dry cleaning and consumer and commercial aerosol spray degreasing are planned to be finalized together in one action.
- On January 19, 2017, under section 6(a) of TSCA, EPA proposed to regulate NMP and methylene chloride in paint and coating removal. The comment period closed on May 19, 2017, and EPA received 1,401 comment on the proposed rule.

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HOT ISSUES:

- These actions are the proposed rules taken on existing chemicals under the new statutory standard provided for in the TSCA amendments enacted in June 2016.

LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP/OPPT	OGC, AO

OSCP SCIENCE COORDINATION OVERVIEW

SUMMARY:

The Office of Science Coordination & Policy (OSCP) provides leadership on emerging science policy issues, promoting solutions that utilize cutting-edge science such as the application of computational toxicology to endocrine disruption.

OSCP COORDINATION ACTIVITIES:

- **Systematic Review:** OSCP leads development of the OCSPP systematic review framework to harmonize approaches for the collection, evaluation, and integration of data for human health and ecological risk assessments in OCSPP. OSCP co-leads EPA's Systematic Review Community of Practice (CoP).
- **Computational Toxicology/Tox21/High Throughput Screening & Testing/Alternative Testing Strategies:** OSCP coordinates (for OCSPP and the Agency) the development and regulatory use of computational toxicology tools to increase the pace and quality of chemical safety decisions. [HYPERLINK "https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-edsp-21st-century"], or "CompTox", uses computer models and high throughput cell-based methods in place of traditional animal-based chemical testing methods.
- **Scientific Integrity (SI):** OSCP leads efforts to ensure OCSPP's adherence to professional values and practices when conducting, communicating, and applying the results of science and scholarship. Scientific Integrity ensures objectivity, clarity, reproducibility, and utility. It also provides insulation from bias, fabrication, falsification, plagiarism, outside interference, and censorship.
- **Scientific Peer Reviews Conducted Under the Federal Advisory Act (FACA):** OSCP oversees OCSPP's FACA committees that provide independent advice and expert consultation at the request of the EPA Administrator with respect to the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures or approaches for chemicals. [HYPERLINK "https://www.epa.gov/tsca-peer-review"] reviews chemicals regulated under Toxic Substances Control Act (TSCA). [HYPERLINK "https://www.epa.gov/sap"] reviews issues that are applicable to chemicals regulated under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA).
- **The Endocrine Disruptor Program (EDSP):** OSCP coordinates the development and implementation of the EDSP within OCSPP. [HYPERLINK "https://www.epa.gov/endocrine-disruption"] prioritizes, screens and tests pesticides and other environmental contaminants for potential effects on estrogen, androgen, and thyroid hormone systems in humans and wildlife. The EDSP engages closely with other EPA Offices, other Federal agencies, international organizations and outside stakeholders.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- The Science Advisory Committee on Chemicals (SACC) was established December 2016.

HOT ISSUES:

- Upcoming [HYPERLINK "https://www.gpo.gov/fdsys/pkg/FR-2017-06-06/pdf/2017-11694.pdf"] to consider and review the ''Continuing Development of Alternative High-Throughput Screens to Determine Endocrine Disruption, Focusing on Androgen Receptor, Steroidogenesis, and Thyroid Pathways'' scheduled for November 28 - 30, 2017.
- Release of NAS Report "[HYPERLINK "https://www.nap.edu/catalog/24758/application-of-systematic-review-methods-in-an-overall-strategy-for-evaluating-low-dose-toxicity-from-endocrine-active-chemicals"]." EPA is reaching out to other federal partners to collaborate on the report's recommendations.

LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

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OCSPP/OSCP OPP, OPPT, ORD, OW, OGC, OP, OLEM, FDA, NIH, CDC, CPSC

LAUTENBER CHEMICAL SAFTEY ACT SCIENCE ADVISORY COMMITTEE ON CHEMICALS (SACC)

SUMMARY:

The Science Advisory Committee on Chemicals (SACC) was established in 2016 under the authority of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) and operates in accordance with the Federal Advisory Committee Act (FACA) to provide independent scientific advice and recommendations to the EPA on the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated by TSCA.(see [HYPERLINK "https://www.epa.gov/tsca-peer-review/science-advisory-committee-chemicals-basic-information"])

BACKGROUND:

- SACC is currently comprised of 18 members (see [HYPERLINK "https://www.epa.gov/tsca-peer-review/members-science-advisory-committee-chemicals"]), appointed by the administrator from public nominations. Members have expertise in:
    - Toxicology; environmental risk assessment; exposure assessment; and related sciences, (e.g., synthetic biology, pharmacology, biotechnology, nanotechnology, biochemistry, biostatistics, PBPK modeling, computational toxicology, epidemiology, environmental fate, and environmental engineering and sustainability).
- SACC members also have professional experiences in government, labor, public health, public interest, animal protection, industry, or other groups.
- SACC members serve staggered terms of appointment, generally of two to three years duration. If necessary, subcommittees will be formed to supplement the expertise of the 18 members.

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- SACC establishment charter filed with Congress on December 30, 2016.
- 18 current members were appointed by the Administrator effective January 19, 2017.

HOT ISSUES:

- Potential augmentation of the SACC membership to better address the Committee's objectives and scope of activities.

LEAD OFFICE/REGION: OTHER KEY OFFICES/REGIONS:

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ENDOCRINE DISRUPTOR SCREENING PROGRAM (EDSP)

SUMMARY:

The Endocrine Disruptor Screening Program (EDSP) prioritizes, screens and tests pesticides and other environmental contaminants for potential effects on estrogen, androgen, and thyroid hormone systems in humans and wildlife.

BACKGROUND:

EDSP's objectives include:

- Integrating data from current and emerging technologies, including computational toxicology and high throughput screening
- Advancing understanding of key events in adverse outcome pathways (AOPs)
- Employing a multi-tiered prioritization, screening, and testing approach
- Minimizing the use of animal studies
- Employing 21st Century informatics supporting data interpretation and decisions
- Promoting transparency and partnerships with a diverse range of partners and stakeholders
- Developing systematic review protocals and for outcomes based approaqches

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- Published the policy stating that the Agency will use high-throughput *in vitro* assays and computational models in the EDSP ([HYPERLINK "https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0305-0001"] FRN)
- Validated 18 high-throughput *in vitro* Estrogen Receptor (ER) binding pathway assays and the ER ToxCast™ ER model as alternative to 3 of 11 Tier 1 Screening Assays ([HYPERLINK "https://www.regulations.gov/document?D=EPA-HQ-OPPT-2015-0305-0001"])
- Screened more than 1800 chemicals that have been evaluated using high-throughput assays and a computational model for the estrogen receptor pathway. These data are publically accessible through the Endocrine Disruption Screening Program for the 21st Century Dashboard ([HYPERLINK "https://actor.epa.gov/edsp21/"])
- Developed an initial approach and conducted [HYPERLINK "https://www.epa.gov/sites/production/files/2015-06/documents/120214minutes.pdf"] of Integrated Bioactivity and Exposure Ratio (IBER) for prioritization
- Completed the [HYPERLINK "https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-tier-1-screening-determinations-and"] for 52 List 1 chemicals (50 pesticidal active ingredient and 2 inert ingredients). EPA concluded that additional tests, including certain Tier 2 tests, were needed for 18 List 1 test chemicals
- Published the final [HYPERLINK "https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-890-endocrine-disruptor-screening-program"] for EDSP Tier 2 ecotoxicity testing

HOT ISSUES:

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Upcoming [HYPERLINK "https://www.gpo.gov/fdsys/pkg/FR-2017-06-06/pdf/2017-11694.pdf"] to consider and review the ''Continuing Development of Alternative High-Throughput Screens to Determine Endocrine Disruption, Focusing on Androgen Receptor, Steroidogenesis, and Thyroid Pathways'' scheduled for November 28 - 30, 2017

LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP/OSCP	OPP, OPPT, ORD, OW, OGC, OP, OLEM

FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICDE ACT SCIENTIFIC ADVISORY PANEL (FIFRA SAP)

SUMMARY:

The Scientific Advisory Panel (SAP) was established in 1975 under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and operates in accordance with the Federal Advisory Committee Act (FACA) to provide independent scientific advice and recommendations to the EPA on the scientific and technical aspects of health and safety issues related to pesticides. (see [HYPERLINK "https://www.epa.gov/sap/fifra-scientific-advisory-panel-sap-basic-information"]).

BACKGROUND:

- By statute, the SAP must consist of 7 members (see [HYPERLINK "https://www.epa.gov/sap/fifra-scientific-advisory-panel-members"]), appointed by the EPA Administrator from nominations provided by the National Institutes of Health (NIH) and the National Science Foundation (NSF). Members have expertise in:
  - Toxicology; pathology; environmental Biology; and related sciences (e.g., exposure assessment, biostatistics, computational toxicology, epidemiology, and environmental fate).
- SAP members serve staggered terms of appointment, generally of three to six years duration.
- For each review, the SAP is augmented by additional experts (known as the Food Quality Protection Act Science Review Board, or FQPA SRB).

HIGHLIGHTS / RECENT ACCOMPLISHMENTS:

- SAP renewal charter filed with Congress on October 17, 2016.
- December 13-16, 2016, FIFRA SAP meeting to consider and review EPA's evaluation of the carcinogenic potential of the herbicide glyphosate; meeting minutes and final report issued March 16, 2017
- 2 current FIFRA SAP members were re-appointed by the Administrator for 1 year effective July 15, 2017.

HOT ISSUES:

- Nominations from NIH and NSF received in May 2017.
  - September 2017 Federal Register Notice seeking public comments on candidates under consideration.
  - 4 new member appointments needed in 2018: 2 new member appointments by May 2018 and 2 new member appointments by July 2018.
- Upcoming FIFRA SAP Meetings (announced in the Federal Register on June 6, 2017):

- October 24 to 27, 2017 to consider and review physiologically based pharmacokinetic modeling to address pharmacokinetic differences between and within species.
- November 28 to 30, 2017 to consider and review the "Continuing Development of Alternative High-Throughput Screens to Determine Endocrine Disruption, Focusing on Androgen Receptor, Steroidogenesis, and Thyroid Pathways."

LEAD OFFICE/REGION:	OTHER KEY OFFICES/REGIONS:
OCSPP/OSCP	OCSPP/OPP

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