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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA-HQ-OPPT-2016-0163; FRL-9949-86]

RIN 2070-AK03

Trichloroethylene; Regulation of Certain Uses under TSCA §6(a)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Trichloroethylene (TCE) is a volatile organic compound widely used in industrial and commercial processes and has some limited uses in consumer and commercial products. EPA identified significant health risks associated with TCE use in aerosol degreasing and for spot cleaning in dry cleaning facilities. EPA has preliminarily determined that these risks are unreasonable risks. To address these unreasonable risks, EPA is proposing under section 6 of the Toxic Substances Control Act (TSCA) to prohibit the manufacture, processing, and distribution in commerce of TCE for use in aerosol degreasing and for use in spot cleaning in dry cleaning facilities; to prohibit commercial use of TCE for aerosol degreasing and for spot cleaning in dry cleaning facilities; to require manufacturers, processors, and distributors, except for retailers of TCE for any use, to provide downstream notification of these prohibitions throughout the supply chain; and to require limited recordkeeping.

DATES: Comments must be received on or before [*insert date* 60 *days after date of publication in the* **Federal Register**].

ADDRESSES: Submit your comments, identified by docket identification (ID) number

EPA-HQ-OPPT-2016-0163, 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 Once submitted, comments cannot be edited or withdrawn.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-2016-0163 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*: Toni Krasnic, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC

20460-0001; telephone number: (202) 564-0984; email address: *krasnic.toni@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 TSCA to include import), process, or distribute in commerce TCE or commercially use TCE in aerosol degreasers or for spot cleaning in dry cleaning facilities. 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:

- All Other Miscellaneous Textile Product Mills (NAICS code 314999).
- Petroleum Refineries (NAICS code 324110).
- Petroleum Lubricating Oil and Grease Manufacturing (NAICS code 324191).
- Petrochemical Manufacturing (NAICS code 325110).
- Industrial Gas Manufacturing (NAICS code 325120).
- Other Basic Inorganic Chemical Manufacturing (NAICS code 325180).
- All Other Basic Organic Chemical Manufacturing (NAICS code 325199).
- Plastics Material and Resin Manufacturing (NAICS code 325211).
- Synthetic Rubber Manufacturing (NAICS code 325212).

• Paint and Coating Manufacturing (NAICS code 325510).

• Adhesive Manufacturing (NAICS code 325520).

• Soap and Other Detergent Manufacturing (NAICS code 325611).

• Polish and Other Sanitation Good Manufacturing (NAICS code 325612).

• All Other Miscellaneous Chemical Product and Preparation Manufacturing (NAICS code 325998).

• Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing (NAICS code 326113).

• All Other Plastics Product Manufacturing (NAICS code 326199).

• Rubber and Plastics Hoses and Belting Manufacturing (NAICS code 326220).

• All Other Rubber Product Manufacturing (NAICS code 326299).

• Cement Manufacturing (NAICS code 327310).

• Ground or Treated Mineral and Earth Manufacturing (NAICS code 327992).

• Iron and Steel Pipe and Tube Manufacturing from Purchased Steel (NAICS code 331210).

• Steel Wire Drawing (NAICS code 331222).

• Copper Rolling, Drawing, Extruding, and Alloying (NAICS code 331420)

• Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding (NAICS code 331491).

• Nonferrous Metal Die-Casting Foundries (NAICS code 331523).

• Powder Metallurgy Part Manufacturing (NAICS code 332117).

• Metal Crown, Closure, and Other Metal Stamping (except Automotive) (NAICS code 332119).

• Saw Blade and Hand Tool Manufacturing (NAICS code 332216).

• Metal Window and Door Manufacturing (NAICS code 332321).

• Power Boiler and Heat Exchanger Manufacturing (NAICS code 332410).

• Other Fabricated Wire Product Manufacturing (NAICS code 332618).

• Machine Shops (NAICS code 332710).

• Precision Turned Product Manufacturing (NAICS code 332721).

• Bolt, Nut, Screw, Rivet, and Washer Manufacturing (NAICS code 332722).

• Metal Heat Treating (NAICS code 332811).

• Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers (NAICS code 332812).

• Electroplating, Plating, Polishing, Anodizing, and Coloring (NAICS code 332813).

• Oil and Gas Field Machinery and Equipment Manufacturing (NAICS code 333132).

• Cutting Tool and Machine Tool Accessory Manufacturing (NAICS code 333515).

• Small Arms, Ordnance, and Ordnance Accessories Manufacturing (NAICS code 332994).

• Fluid Power Pump and Motor Manufacturing (NAICS code 333996).

• All Other Miscellaneous Fabricated Metal Product Manufacturing (NAICS code 332999).

• Oil and Gas Field Machinery and Equipment Manufacturing (NAICS code 333132).

• Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing (NAICS code 333413).

• Cutting Tool and Machine Tool Accessory Manufacturing (NAICS code 333515).

• Pump and Pumping Equipment Manufacturing (NAICS code 333911).

• Fluid Power Pump and Motor Manufacturing (NAICS code 333996).

• Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing (NAICS code 334511).

• Automatic Environmental Control Manufacturing for Residential, Commercial, and Appliance Use (NAICS code 334512).

• Motor and Generator Manufacturing (NAICS code 335312).

• Primary Battery Manufacturing (NAICS code 335912).

• Carbon and Graphite Product Manufacturing (NAICS code 335991).

• Motor Vehicle Brake System Manufacturing (NAICS code 336340).

• Aircraft Manufacturing (NAICS code 336411).

• Other Aircraft Parts and Auxiliary Equipment Manufacturing (NAICS code 336413).

• Guided Missile and Space Vehicle Manufacturing (NAICS code 336414).

• Ship Building and Repairing (NAICS code 336611).

• Dental Equipment and Supplies Manufacturing (NAICS code 339114).

• Other Chemical and Allied Products Merchant Wholesalers (NAICS code 424690).

• Petroleum Bulk Stations and Terminals (NAICS code 424710).

• Hazardous Waste Treatment and Disposal (NAICS code 562211).

• Solid Waste Combustors and Incinerators (NAICS code 562213).

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 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 section 6(a) of TSCA (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, 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. Section 6(b)(4) (15 U.S.C. § 2605(b)(4)) specifies that risk evaluations must be conducted 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.

Since the original enactment of TSCA in 1976, EPA has addressed exposure to workers. For example, EPA routinely places restrictions on conditions of manufacturing, processing, distribution and use under the TSCA section 5 (15 U.S.C. 2604) new chemicals program. Further, as defined in TSCA, the term "potentially exposed or susceptible subpopulation" specifically includes workers. (15 U.S.C. 2602(12)). Thus, TSCA unambiguously provides EPA with the authority to address chemical risks to workers.

When issuing a rule under TSCA section 6(a), EPA must consider and publish a statement based on reasonably available information on the:

• Health effects of the chemical substance in question, TCE in this case, and the magnitude of human exposure to TCE;

• Environmental effects of TCE and the magnitude of exposure of the environment to TCE;

• Benefits of TCE for various uses; and the

• 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.

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.

For a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which a completed risk assessment was published prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, TSCA section 26(l)(4) expressly recognizes that EPA may 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. TCE is such a chemical substance. It is listed in the 2014 update to the TSCA Work Plan and the completed risk assessment was published on June 25, 2014. The scope of the completed risk assessment includes aerosol degreasing and spot cleaning. The completed risk assessment also evaluated vapor degreasing, which EPA plans to address in a separate proposed rule.

C. What action is the Agency taking?

EPA has preliminarily determined that the use of TCE in aerosol degreasing and for spot cleaning in dry cleaning facilities presents an unreasonable risk of injury to health. Accordingly, EPA is proposing under section 6 of TSCA to prohibit the manufacture, processing, and distribution in commerce of TCE for use in aerosol degreasing and for use in spot cleaning in dry cleaning facilities; to prohibit commercial use of TCE for aerosol degreasing and for spot cleaning in dry cleaning facilities; and to require manufacturers, processors, and distributors, except for retailers, to provide downstream notification of these prohibitions throughout the supply chain (e.g., via a

Safety Data Sheet (SDS)) and to keep limited records. The application of this supply chain approach is necessary so that the chemical substance no longer presents the identified unreasonable risks. EPA is requesting public comment on this proposal.

EPA's analysis of worker and consumer populations' exposures to TCE also preliminarily indicates that the use of TCE in vapor degreasing presents an unreasonable risk of injury to health. EPA intends to issue a separate proposed rule for TCE use in vapor degreasing, but plans to issue one final rule covering both today's proposal and the vapor degreasing proposal.

D. Why is the Agency taking this action?

Based on EPA's analysis of worker and consumer populations' exposures to TCE, EPA has preliminarily determined that the use of TCE in aerosol degreasing and as a spot cleaner in dry cleaning facilities presents an unreasonable risk to human health. More specifically, these uses result in significant non-cancer risks (acute and chronic exposure scenarios) and cancer risks. These adverse health effects include developmental toxicity (e.g., cardiac malformations, developmental immunotoxicity, developmental neurotoxicity, fetal death), toxicity to the kidney (kidney damage and kidney cancer), immunotoxicity (such as systemic autoimmune diseases, e.g., scleroderma, and severe hypersensitivity skin disorder), non-Hodgkin's lymphoma, reproductive and endocrine effects (e.g., decreased libido and potency), neurotoxicity (e.g., trigeminal neuralgia), and toxicity to the liver (impaired functioning and liver cancer) (Ref. 1). TCE may cause fetal cardiac malformations that begin in utero. In addition, fetal death, possibly resulting from cardiac malformation, can be caused by exposure to TCE. Cardiac malformations can be irreversible and impact a person's health for a lifetime. In utero exposure to TCE may

cause other effects, such as damage to the developing immune system, which manifest later in adult life and can have long-lasting health impacts. Certain effects that follow adult exposures, such as kidney and liver cancer, may develop many years after initial exposure.

As discussed in Unit I.C, EPA is not proposing to prohibit all manufacturing, processing, distribution in commerce, and use of TCE. The application of this supply chain approach tailored to specific uses that present unreasonable risk to human health is necessary so that the chemical substance no longer presents the identified unreasonable risks.

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

EPA has evaluated the potential costs of multiple regulatory options, including the proposed approach of prohibiting the manufacture (including import), processing, and distribution in commerce of TCE for use in aerosol degreasing and for spot cleaning in dry cleaning facilities; prohibiting the commercial use of TCE for aerosol degreasing and for spot cleaning in dry cleaning facilities; and requiring manufacturers, processors, and distributors, except for retailers, to provide downstream notification of these prohibitions throughout the supply chain as well as associated recordkeeping requirements. This analysis, which is available in the docket, is discussed in Units VI and VII, and is briefly summarized here.

Costs of the proposed approach are discussed in Units VI.C.1 and VII.C.1. Alternatives to TCE are readily available at similar cost and performance. Blenders of TCE aerosol degreasers and spot cleaners are expected to reformulate their products. Reformulation costs are expected to be incurred during the first year and total $286,000

for reformulation of dry cleaning spot remover products and total $416,000 for aerosol degreasing products. Annualized costs of reformulation are approximately $32,000 per year (annualized at 3% over 15 years) and $41,000 (annualized at 7% over 15 years) for aerosol degreasing, and $22,000 per year (annualized at 3% over 15 years) and $28,000 (annualized at 7% over 15 years) for dry cleaning spot removers. Costs to users of aerosol degreasers and dry cleaning spotters are negligible as substitute products of similar performance are currently available on the market and are similarly priced (Ref. 2). Costs of downstream notification and recordkeeping are estimated to cost a total of $51,000 in the first year. On an annualized basis over 15 years are estimated to be approximately $3,900 and $5,000 using 3% and 7% discount rates respectively. Agency costs for enforcement are estimated to be approximately $112,000 and $109,000 annualized over 15 years at 3% and 7% respectively. Total costs of the proposed approach to prohibit manufacturing, processing, distribution in commerce for use of TCE in aerosol degreasing and for spot cleaning in dry cleaning facilities; commercial use of TCE in aerosol degreasing and spot cleaning in dry cleaning facilities; and require downstream notification and recordkeeping are estimated to be approximately $170,000 and $183,000 annualized over 15 years at 3% and 7% respectively. Total first-year costs to industry are estimated to be approximately $874,000 (Ref. 2).

Although TCE causes a wide range of non-cancer adverse effects and cancer, monetized benefits included only benefits associated with reducing cancer risks. The Agency does not have sufficient information to include a quantification or valuation estimate in the overall benefits at this time. The monetized benefits for the proposed approach range from approximately $9.3 million to $25.0 million on an annualized basis

over 15 years at 3% and $4.5 million to $12.8 million at 7% (Ref. 2). There are also non-monetized benefits resulting from the prevention of the non-cancer adverse effects associated with TCE exposure from use in aerosol degreasing and spot cleaning for dry cleaning. These include developmental toxicity, toxicity to the kidney, immunotoxicity, reproductive and endocrine effects, neurotoxicity, and toxicity to the liver (Ref. 1). The adverse effects of TCE exposure as identified in the risk assessment include fetal cardiac malformations that begin in utero and fetal death. Cardiac malformations can be irreversible and impact a person's health for a lifetime. Other effects, such as damage to the developing immune system, may first manifest when a person is an adult and can have long-lasting health impacts. Certain effects that follow adult exposures, such as kidney and liver cancer, may develop many years after initial exposure. Also see Unit VIII.

Another alternative regulatory option considered was a respiratory protection program requiring an air-supplied respirator with an APF of 10,000. The costs of implementing a respiratory protection program, including a supplied-air respirator and related equipment, training, fit testing, monitoring, medical surveillance, and related requirements, would far exceed the costs of switching to alternatives, on a per facility basis. The estimated annualized costs of switching to a respiratory protection program requiring personal protective equipment (PPE) of 10,000 are $8,200 at 3% and $9,000 at 7% per dry cleaning facility and $8,300 at 3% and $9,100 at 7% per aerosol degreasing facility over 15 years. In addition, there would be higher EPA administration and enforcement costs with a respiratory protection program than there would be with an enforcement program under the proposed approach. The higher costs of this option render

this option a less cost effective option than the proposed approach at addressing the identified unreasonable risks so TCE no longer presents such risks.

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*). EPA has identified women of childbearing age and the developing fetus as a susceptible subpopulation relevant to its risk assessment for TCE. After evaluating the developmental toxicity literature for TCE, the TCE Integrated Risk Information System (IRIS) assessment concluded that fetal heart malformations are the most sensitive developmental toxicity endpoint associated with TCE inhalation exposure (Ref. 3). In its TSCA Chemical Work Plan Risk Assessment for TCE, EPA identified developmental toxicity as the most sensitive endpoint for TCE inhalation exposure (i.e., fetal heart malformations; Ref. 1) for the most sensitive human life stage (i.e., women of childbearing age between the ages of 16 and 49 years and the developing fetus) (Ref. 1). EPA used developmental toxicity endpoints for both the acute and chronic non-cancer risk assessments based on its developmental toxicity risk assessment policy that a single exposure of a chemical within a critical window of fetal development may produce adverse developmental effects (Ref. 33). While the proposed regulatory action is protective of the fetal heart malformation endpoint and is also protective of cancer risk from chronic exposure, the supporting non-cancer risk analysis of children and women of childbearing age conducted in the TSCA Chemical Work Plan Risk Assessment for TCE (Ref. 1) also meets the 1995 EPA Policy on Evaluating Health Risks to Children. Supporting information on TCE exposures and the health effects of TCE exposure on children are available in the Toxicological Review

of Trichloroethylene (Ref. 3) and the TSCA Chemical Work Plan Risk Assessment on Trichloroethylene (Ref. 1), as well as Units VI.B.1.c and VII.B.1.c of this preamble.

II. Overview of TCE and Uses Subject to This Proposed Rule

A. What chemical is included in the proposed rule?

This proposed rule would apply to TCE (Chemical Abstract Services Registry Number 79-01-6) for use in aerosol degreasing and for spot cleaning in dry cleaning facilities.

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

In 2011, global consumption of TCE was 945 million pounds and consumption in the United States was 255 million pounds. TCE is produced within and imported into the United States. Nine companies, including domestic manufacturers and importers, reported a total production and import of 225 million pounds of TCE in 2011 to EPA pursuant to the Chemical Data Reporting CDR rule (Ref. 1).

Individuals, including workers, consumers and the general population, are exposed to TCE from industrial/commercial, consumer, and environmental sources, in different settings such as homes and workplaces, and through multiple exposure pathways (air, water, soil) and routes (inhalation, ingestion, dermal).

The majority (about 83.6%) of TCE is used as an intermediate chemical for manufacturing refrigerant HFC-134a. This use occurs in a closed system that has low potential for human exposure (Ref. 1). EPA did not assess this use and is not proposing to regulate this use of TCE under TSCA. Much of the remainder, about 14.7 percent, is used as a solvent for degreasing of metals. A relatively small percentage, about 1.7 percent, accounts for all other uses, including TCE use in products, such as aerosol degreasers and

spot cleaners.

Based on the Toxics Release Inventory (TRI) data for 2012, 38 companies used TCE as a formulation component, 33 companies processed TCE by repackaging the chemical, 28 companies used TCE as a manufacturing aid, and 1,113 companies used TCE for ancillary uses, such as degreasing (Ref. 1). Based on the latest TRI data from 2014, the number of users of TCE has significantly decreased since 2012: 24 companies use TCE as a formulation component, 20 companies process TCE by repackaging the chemical, 20 companies use TCE as a manufacturing aid, and 97 companies use TCE for ancillary uses, such as degreasing.

The uses assessed by EPA that are the subject of this proposal, the use of TCE in aerosol degreasing and for spot cleaning in dry cleaning facilities, are estimated to represent up to 1.7 percent of total use of TCE. Aerosol degreasing is the use of TCE in aerosol spray products applied from a pressurized can to remove residual contaminants from fabricated parts. Spot cleaning is the use of TCE in dry cleaning facilities to clean stained areas on textiles or clothing. These uses are discussed in detail in Units VI and VII.

C. What are the potential health effects of TCE?

A broad set of relevant studies including epidemiologic studies, animal bioassays, metabolism studies, and mechanistic studies show that TCE exposure is associated with an array of adverse health effects. TCE has the potential to induce developmental toxicity, immunotoxicity, kidney toxicity, reproductive and endocrine effects, neurotoxicity, liver toxicity, and several forms of cancer (Ref. 1).

TCE is fat soluble (lipophilic) and easily crosses biological membranes. TCE has

been found in human maternal and fetal blood and in the breast milk of lactating women (Ref. 1). EPA's Integrated Risk Information System (IRIS) assessment (Ref. 3) concluded that TCE poses a potential health hazard for non-cancer toxicity including fetal heart malformations and other developmental effects, immunotoxicity, kidney toxicity, reproductive and endocrine effects, neurotoxicity, and liver effects. The IRIS assessment also evaluated TCE and its metabolites. Based on the results of *in vitro* and *in vivo* tests, TCE metabolites have the potential to bind or induce damage to the structure of deoxyribonucleic acid (DNA) or chromosomes (Ref. 3).

An evaluation of the overall weight of the evidence of the human and animal developmental toxicity data suggests an association between pre- and/or post-natal TCE exposures and potential adverse developmental outcomes. TCE-induced heart malformations and immunotoxicity in animals have been identified as the most sensitive developmental toxicity endpoints for TCE. Human studies examined the possible association of TCE with various prenatal effects. These adverse effects of developmental TCE exposure may include: fetal death (spontaneous abortion, perinatal death, pre- or post-implantation loss, resorptions); decreased growth (low birth weight, small for gestational age); congenital malformations, in particular heart defects; and postnatal effects such as growth, survival, developmental neurotoxicity, developmental immunotoxicity, and childhood cancers. Some epidemiological studies reported an increased incidence of birth defects in TCE-exposed populations from exposure to contaminated water. As for human developmental neurotoxicity, studies collectively suggest that the developing brain is susceptible to TCE toxicity. These studies have reported an association with TCE exposure and central nervous system birth defects and

postnatal effects such as delayed newborn reflexes, impaired learning or memory, aggressive behavior, hearing impairment, speech impairment, encephalopathy, impaired executive and motor function and attention deficit disorder (Ref. 1).

Immune-related effects following TCE exposures have been observed in adult animal and human studies. In general, these effects were associated with inducing enhanced immune responses as opposed to immunosuppressive effects. Human studies have reported a relationship between systemic autoimmune diseases, such as scleroderma, with occupational exposure to TCE. There have also been a large number of case reports in TCE-exposed workers developing a severe hypersensitivity skin disorder, often accompanied by systemic effects to the lymph nodes and other organs, such as hepatitis (Ref. 1).

Studies in both humans and animals have shown changes in the proximal tubules of the kidney following exposure to TCE (Ref. 1). The TCE IRIS assessment concluded that TCE is carcinogenic to humans based on convincing evidence of a causal relationship between TCE exposure in humans and kidney cancer (Ref. 3). A recent review of TCE by the International Agency for Research on Cancer (IARC) also supported this conclusion (Ref. 4). The 13th report on carcinogens (RoC) by the National Toxicology Program also concluded that TCE is reasonably anticipated to be a human carcinogen 2015 (Ref. 5). These additional recent peer reviews are consistent with EPA's classification that TCE is carcinogenic to humans by all routes of exposure based upon strong epidemiological and animal evidence (Refs. 1 and 3).

TCE metabolites appear to be the causative agents that induce renal toxicity, including cancer. S-dichlorovinyl-L-cysteine (DCVC), and to a lesser extent other

metabolites, appears to be responsible for kidney damage and kidney cancer following TCE exposure. Toxicokinetic data suggest that the TCE metabolites derived from glutathione conjugation (in particular DCVC) can be systemically delivered or formed in the kidney. Moreover, DCVC-treated animals showed the same type of kidney damage as those treated with TCE (Ref. 1). The toxicokinetic data and the genotoxicity of DCVC further suggest that a mutagenic mode of action is involved in TCE-induced kidney tumors, although cytotoxicity followed by compensatory cellular proliferation cannot be ruled out. As for the mutagenic mode of action, both genetic polymorphisms (Glutathione transferase (GST) pathway) and mutations to tumor suppressor genes have been hypothesized as possible mechanistic key events in the formation of kidney cancers in humans (Ref. 1).

The toxicological literature provides support for male and female reproductive effects following TCE exposure. Both the epidemiological and animal studies provide evidence of adverse effects to female reproductive outcomes. However, more extensive evidence exists in support of an association between TCE exposures and male reproductive toxicity. There is evidence that metabolism of TCE in male reproductive tract tissues is associated with adverse effects on sperm measures in both humans and animals. Furthermore, human studies support an association between TCE exposure and alterations in sperm density and quality, as well as changes in sexual drive or function and altered serum endocrine levels (Ref. 1).

Neurotoxicity has been demonstrated in animal and human studies under both acute and chronic exposure conditions. Evaluation of multiple human studies revealed TCE-induced neurotoxic effects including alterations in trigeminal nerve and vestibular

function, auditory effects, changes in vision, alterations in cognitive function, changes in psychomotor effects, and neurodevelopmental outcomes. These studies in different populations have consistently reported vestibular system-related symptoms such as headaches, dizziness, and nausea following TCE exposure (Ref. 1).

Animals and humans exposed to TCE consistently experience liver toxicity. Specific effects include the following structural changes: increased liver weight, increase in DNA synthesis (transient), enlarged hepatocytes, enlarged nuclei, and peroxisome proliferation. Several human studies reported an association between TCE exposure and significant changes in serum liver function tests used in diagnosing liver disease, or changes in plasma or serum bile acids. There was also human evidence for hepatitis accompanying immune-related generalized skin diseases, jaundice, hepatomegaly, hepatosplenomegaly, and liver failure in TCE-exposed workers (Ref. 1).

TCE is characterized as carcinogenic to humans by all routes of exposure as documented in EPA's TCE IRIS assessment (Ref. 3). This conclusion is based on strong cancer epidemiological data that reported an association between TCE exposure and the onset of various cancers, primarily in the kidney, liver, and the immune system, i.e., non-Hodgkin's lymphoma (NHL). Further support for TCE's characterization as a carcinogen comes from positive results in multiple rodent cancer bioassays in rats and mice of both sexes, similar toxicokinetics between rodents and humans, mechanistic data supporting a mutagenic mode of action for kidney tumors, and the lack of mechanistic data supporting the conclusion that any of the mode(s) of action for TCE-induced rodent tumors are irrelevant to humans. Additional support comes from the 2014 evaluation of TCE's carcinogenic effects by IARC, which classifies TCE as carcinogenic to humans (Ref. 4).

The 13th Report on Carcinogens (RoC) by the National Toxicology Program also concluded that TCE exposure is reasonably anticipated to be a human carcinogen (Ref. 5). These additional recent peer reviewed documents are consistent with EPA's classification that TCE is carcinogenic to humans by all routes of exposure based upon strong epidemiological and animal evidence (Refs. 1 and 3).

D. What are the environmental impacts of TCE?

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

1. *Environmental effects and impacts*. TCE enters the environment as a result of emissions from metal degreasing facilities, and spills or accidental releases, and historic waste disposal activities. Because of its high vapor pressure and low affinity for organic matter in soil, TCE evaporates fairly rapidly when released to soil; however, where it is released onto land surface or directly into the subsurface, TCE can migrate from soil to groundwater (Ref. 1). Based on TCE's moderate persistence, 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 the use of TCE for spot cleaning in dry cleaning facilities and in aerosol degreasers. This should not be misinterpreted to mean that the fate and transport properties of TCE suggest that water and soil contamination is likely low or does not pose an environmental concern. EPA is addressing TCE contamination in groundwater, drinking water, and

contaminated soils at a large number of sites. While the primary concern with this contamination has been human health, there is potential for TCE exposures to ecological receptors in some cases (Ref. 1).

2. *What is the global warming potential of TCE?* 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 high variability in the atmospheric lifetime of greenhouse gases, the 100-year scale (GWP100) is typically used. TCE has relatively low global warming potential at a GWP100 of 140 and thus the impact is low (Ref. 1).

3. *What is the ozone depletion potential of TCE?* TCE is not an ozone-depleting substance and is listed as acceptable under the Significant New Alternatives Policy (SNAP) program for degreasing and aerosols. In 2007, TCE was identified as a substitute for two ozone depleting chemicals, methyl chloroform and CFC–113, for metals, electronics, and precision cleaning (72 FR 30142, May 30, 2007) (FRL-8316-8) (Ref. 6).

4. *Is TCE a volatile organic compound (VOC)?* TCE is 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 TCE persist in the environment and bioaccumulate?* TCE may be persistent, but it is not bioaccumulative. TCE is slowly degraded by sunlight and reactants when released to the atmosphere. Volatilization and microbial biodegradation influence the fate of TCE when released to water, sediment or soil. The biodegradation of TCE in the environment is dependent on a variety of factors and so a wide range of

degradation rates have been reported (ranging from days to years). TCE is not expected to bioconcentrate in aquatic organisms based on measured bioconcentration factors of less than 1000 (Ref. 1).

III. Regulatory Actions Pertaining to TCE

Because of its potential health effects, TCE is subject to state, federal, and international regulations restricting and regulating its use, which are summarized in this section. None of these actions addresses the unreasonable risks under TSCA that EPA is seeking to address in this proposed rule.

A. Federal actions pertaining to TCE

Since 1979, EPA has issued numerous final rules and notices pertaining to TCE under its various authorities.

• *Safe Drinking Water Act*: EPA issued drinking water standards for TCE pursuant to section 1412 of the Safe Drinking Water Act. EPA promulgated the National Primary Drinking Water Regulation (NPDWR) for TCE in 1987 (52 FR 25690, July 8, 1987). The NPDWR established a non-enforceable maximum contaminant level (MCL) goal of zero mg/L based on classification as a probable human carcinogen. The NPDWR also established an enforceable MCL of 0.005 mg/L based on analytical feasibility. EPA is evaluating revising the TCE drinking water standard as part of a group of carcinogenic volatile organic compounds.

• *Clean Water Act*: EPA identified TCE as a toxic pollutant under section 307(a)(1) of the Clean Water Act (33 U.S.C. 1317(a)(1)) in 1979 (44 FR 44502, July 30, 1979) (FRL-1260-5). In addition, EPA developed recommended TCE ambient water quality criteria for the protection of human health pursuant to section 304(a) of the Clean

Water Act.

• *Clean Air Act*: TCE is designated a hazardous air pollutant (HAP) under the Clean Air Act (42 U.S.C. 7412(b)(1)). EPA promulgated National Emission Standards for Hazardous Air Pollutants (NESHAPs) for TCE for several industrial source categories, including halogenated solvent cleaning, fabric printing, coating, and dyeing, and synthetic organic chemical manufacturing.

• *Resource Conservation and Recovery Act (RCRA)*: EPA classifies certain wastes containing TCE as hazardous waste subject to Subtitle C of RCRA pursuant to the toxicity characteristics or as a listed waste. RCRA also provides authority to require cleanup of hazardous wastes containing TCE at RCRA facilities.

• *Comprehensive Environmental Response, Compensation and Liability Act (CERCLA)*: EPA designated TCE as a hazardous substance with a reportable quantity pursuant to section 102(a) of CERCLA and EPA is actively overseeing cleanup of sites contaminated with TCE pursuant to the National Contingency Plan (NCP).

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

The Occupational Safety and Health Administration (OSHA) established a permissible exposure limit (PEL) for TCE in 1971. The PEL is an 8-hour time-weighted average (TWA) TCE concentration of 100 ppm. In addition, the TCE PEL requires that exposures to TCE not exceed 200 ppm (ceiling) at any time during an eight hour work shift with the following exception: exposures may exceed 200 ppm, but not more than

300 ppm (peak), for a single time period up to 5 minutes in any 2 hours (Refs. 7 and 8). OSHA acknowledges that many of its PELs are not protective of worker health. OSHA has noted that "with few exceptions, OSHA's PELs, which specify the amount of a particular chemical substance allowed in workplace air, have not been updated since they were established in 1971 under expedited procedures available in the short period after the OSH Act's adoption… Yet, in many instances, scientific evidence has accumulated suggesting that the current limits are not sufficiently protective." (Ref. 9 at p. 61386), including the PEL for TCE (Ref. 65).

To provide employers, workers, and other interested parties with a list of alternate occupational exposure limits that may serve to better protect workers, OSHA's web page highlights selected occupational exposure limits derived by other organizations. For example, the National Institute for Occupational Safety and Health considers TCE a potential occupational carcinogen and recommended an exposure limit of 25 ppm as a 10-hour TWA in 2003 (Ref. 10). The American Conference of Governmental Industrial Hygienists recommended an 8-hour TWA of 10 ppm and acute, or short-term, exposure limit of 25 ppm in 2004 (Ref. 11).

B. State actions pertaining to TCE

Many states have taken actions to reduce risks from TCE use. TCE is listed 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. In addition, the California Code of Regulations, Title 17, Section 94509(a) lists standards for VOCs for consumer products sold, supplied, offered for sale, or manufactured for use

in California (Ref. 12). As part of that regulation, use of consumer general purpose degreaser products that contain TCE are banned in California and safer substitutes are in use.

In Massachusetts, TCE is a designated high hazard substance, with an annual reporting threshold of 1,000 pounds (Ref. 13). Minnesota classifies TCE as a chemical of high concern. Many other states have considered TCE for similar chemical listings (Ref. 14). Several additional states have various TCE regulations that range from reporting requirements to product contamination limits to use reduction efforts aimed at limiting or prohibiting TCE content in products.

Most states have set PELs identical to the OSHA 100 ppm 8-hour TWA PEL (Ref. 15). Nine states have PELs of 50 ppm (Ref. 15). California's PEL of 25 ppm is the most stringent (Ref. 12). All of these PELs are significantly higher than the exposures at which EPA identified unreasonable risks for TCE use in aerosol degreasers and for spot cleaning in dry cleaning facilities and would not be protective.

C. International actions pertaining to TCE

TCE is also regulated internationally and the international industrial and commercial sectors have moved to alternatives. TCE is prohibited for use in the European Union (EU) as an aerosol degreaser and spotting agent at dry cleaning facilities based on its classification as a carcinogenic substance (Ref. 16). TCE was added to the EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) restriction of substances classified as a carcinogen category 1B under the EU Classification and Labeling regulation in 2009 (Ref. 16). The restriction prohibits the placing on the market or use of TCE as a substance, as a constituent of other substances,

or in mixtures for supply to the general public when the individual concentration of TCE in the substance or mixture is equal to or greater than 0.1% by weight (Ref. 16). In 2010, TCE was added to the Candidate List of substances for inclusion in Annex XIV of REACH, or the Authorisation List. Annex XIV includes Substances of Very High Concern that are subject to use authorization due to their hazardous properties. TCE meets the criteria for classification as a carcinogen. In 2011, TCE was recommended for inclusion in Annex XIV of REACH due to the very high volumes allocated to uses in the scope of authorization and because at least some of the described uses appeared to result in significant exposure of workers and professionals, and could be considered widely dispersive uses. In 2013, the Commission added TCE to Annex XIV of REACH, making it subject to authorization. As such, entities that wanted to use TCE were required to apply for authorization by October 2014, and those entities without an authorization were required to stop using TCE by April 2016. The European Chemicals Agency (ECHA) received 19 applications for authorization from entities interested in using TCE beyond April 2016. None of the applications were for use of TCE in aerosol degreasers or for spot cleaning in dry cleaning facilities (Ref. 16).

Canada conducted a hazard assessment of TCE in 1993 and concluded that "trichloroethylene occurs at concentrations that may be harmful to the environment, and that may constitute a danger in Canada to human life or health. It has been concluded that trichloroethylene occurs at concentrations that do not constitute a danger to the environment on which human life depends" (Ref. 17). In 2003, Canada issued the Solvent Degreasing Regulations (SOR/2003-283) to reduce releases of TCE into the environment from solvent degreasing facilities using more than 1,000 kilograms of TCE per year (Ref.

17). In 2013, Canada added TCE to the Toxic Substances List – Schedule 1 because TCE was found to be toxic under conditions (a) and (c) of Section 64(a) of the Canadian Environmental Protection Act (CEPA) because it "is entering or may enter the environment in a quantity or concentration or under conditions that: (a) have or may have an immediate or chronic harmful effect on the environment or its biological diversity, and (c) constitute or may constitute a danger in Canada to human life or health." (Ref. 18).

In Japan, the Chemical Substances Control Law considers TCE a Class II substance (substances that may pose a risk of long-term toxicity to humans or to flora and fauna in the human living environment, and that have been, or in the near future are reasonably likely to be, found in considerable amounts over a substantially extensive area of the environment) (Ref. 19). Japan also controls air emissions and water discharges containing TCE, as well as aerosol products for household use and household cleaners containing TCE.

TCE is listed in the Australian National Pollutant Inventory, a program run cooperatively by the Australian, State and Territory governments to monitor common pollutants and their levels of release to the environment. Australia classifies TCE as a health, physicochemical and/or ecotoxicological hazard, according to the Australian National Occupational Health and Safety Commission (Ref. 20).

IV. TCE Risk Assessment

In 2013, EPA identified TCE use as a solvent degreaser (aerosol degreasing and vapor degreasing) and spot remover in dry cleaning operations as a priority for risk assessment under the TSCA Work Plan. This Unit describes the development of the TCE 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 each use subject to today's proposed rule can be found in Units VI and VII.

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. 21). 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. 22).

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. 21). Using the TSCA Work Plan chemical prioritization criteria, TCE ranked high for health hazards and exposure potential and was included on the initial list of TSCA Work Plan chemicals for assessment.

B. TCE risk assessment

EPA finalized a TSCA Work Plan Chemical Risk Assessment for TCE (TCE risk assessment) in June 2014, following the July 2013 peer review of the December 2012 draft TCE risk assessment. All documents from the July 2013 peer review of the draft TCE risk assessment are available in EPA Docket Number EPA-HQ-OPPT-2012-0723. TCE appears in the 2014 update of the TSCA Work Plan for Chemical Assessments and the completed risk assessment is noted therein. The draft TCE risk assessment evaluated commercial and consumer use of TCE as a solvent degreaser (aerosol degreasing and vapor degreasing) and consumer use of TCE as a spray-applied protective coating for arts

and crafts (Ref. 1). In response to specific comments and information provided by the peer reviewers, the commercial use of TCE as a spotting agent at dry cleaning facilities was evaluated, using the near-field/far-field mass balance approach, for the final risk assessment. The use of TCE in commercial/industrial vapor degreasing, and in arts and crafts, is not addressed in today's proposal. EPA intends to issue a separate proposed rule on TCE use in vapor degreasers at commercial/industrial facilities soon. EPA also published a final Significant New Use Rule (SNUR) that would require manufacturers (including importers) and processors of TCE to notify the Agency before starting or resuming any significant new uses of TCE in certain consumer products, including in spray fixatives used to finish arts and crafts (81 FR 20535; April 8, 2016).

The TCE risk assessment evaluated health risks to consumers and workers, including occupational bystanders, from inhalation exposures to TCE. A summary of the peer review and public comments, along with EPA's response, is available in the docket for the risk assessment and can be accessed electronically at *https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0723-0039*. While solvent degreasing (both aerosol and vapor) is within the scope of the TCE risk assessment, with respect to aerosol degreasing, the assessment targeted consumer use of specific products. Therefore, using the peer reviewed near-field/far-field mass balance approach that was used in the risk assessment, EPA performed supplemental analyses of worker and bystander inhalation risk from TCE aerosol degreaser use in occupational settings. The TCE risk assessment identified primary uses of TCE and selected uses including aerosol degreasing and spot cleaning in dry cleaning facilities as those that were expected to involve frequent or routine use of TCE in high concentrations and/or

have high potential for human exposure (Refs. 1, 23, 24, and 25) and therefore were included in the scope of the risk assessment. However, this does not mean that EPA determined that other uses not included in the TCE risk assessments present low risk.

The TCE risk assessment identified acute non-cancer risks (i.e., developmental effects) for most occupational and consumer exposure scenarios, including commercial vapor degreasing, spot cleaning, and consumer aerosol degreasing exposure scenarios (Ref. 1). For chronic non-cancer risks there is a range of human health effects in both the occupational vapor degreasing and spot cleaning exposure scenarios with the greatest concern for developmental effects (i.e., fetal cardiac defects), as well as kidney effects and immunotoxicity. In addition, there are chronic non-cancer risks for adverse reproductive effects, neurotoxicity, and liver toxicity (Ref. 1).

Margins of exposure (MOEs) were used in this assessment to estimate non-cancer risks for acute and chronic exposures. The MOE is the health point of departure (an approximation of the no-observed adverse effect level (NOAEL) for a specific endpoint divided by the exposure concentration for the specific scenario of concern. The benchmark MOE accounts for the total uncertainty factor based on the following uncertainty factors: intraspecies, interspecies, subchronic to chronic, and lowest observed adverse effect level (LOAEL) to NOAEL. Uncertainty factors are intended to account for (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 LOAEL rather than from a NOAEL (Ref. 26). 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.

The TCE risk assessment estimated acute non-cancer risks for consumers and residential bystanders from the use of TCE-containing aerosol degreasers and spray-applied protective coatings. Exposure scenarios with MOEs below the benchmark MOE have significant risks of concern and typically, non-cancer adverse effects are more likely to result from exposure scenarios with MOEs below the benchmark MOE. For non-cancer effects EPA estimated exposures that are significantly larger than the point of departure. The TCE risk assessment also estimated acute non-cancer risk for workers and occupational bystanders for uses including spot cleaning in dry cleaning facilities.

The TCE risk assessment also estimated chronic non-cancer risk for workers and occupational bystanders for uses including spot cleaning in dry cleaning facilities. These include developmental toxicity, toxicity to the kidney, immunotoxicity, reproductive and endocrine effects, neurotoxicity, and toxicity to the liver.

There are also cancer risks for persons occupationally exposed to TCE when using TCE-containing spot cleaners in dry cleaning facilities. For users of TCE-containing spot cleaning products, these cancer risks are 1.35×10^{-2} for spot cleaning. In the supplemental analysis following the TCE risk assessment, EPA also identified acute and chronic non-cancer and cancer risks for the commercial aerosol degreasing use scenario for workers and occupational bystanders using aerosol degreasers (Ref. 23).

The levels of acute and chronic exposures estimated to present low risk for non-

cancer effects also result in low risk for cancer.

Given the risks identified in the TCE risk assessment, the agency undertook further analysis to help determine whether the use of TCE for spot cleaning in dry cleaning facilities and in aerosol degreasers poses an unreasonable risk.

C. *Supplemental analysis using the methodology of the TCE risk assessment*

Because the TCE risk assessment concentrated on consumer use of aerosol degreasers and because the aerosol degreaser products available to consumers are also available to commercial users, following release of the TCE risk assessment, EPA analyzed the risk to workers and occupational bystanders from commercial use of TCE-containing aerosol degreasers and identified short-term and long-term non-cancer and cancer risks for the commercial aerosol degreasing use scenario (Ref. 23). This analysis is consistent with the scope of the TCE risk assessment and was based on the peer-reviewed near-field/far-field mass balance approach that was used in the TCE risk assessment (Ref. 1). EPA also conducted supplemental analyses of various parameters of exposure scenarios, consistent with the methodology used in the risk assessment, on the use of TCE-containing aerosol degreasers by consumers and use of TCE for spot cleaning in dry cleaning facilities. Prior to promulgation of the final rule, EPA will peer review the "Supplemental Occupational Exposure and Risk Reduction Technical Report in Support of Risk Management Options for Trichloroethylene (TCE) Use in Aerosol Degreasing" (Ref. 25) and the exposure assessment for TCE use in spot cleaning in dry cleaning facilities in the "TSCA Work Plan Chemical Risk Assessment. Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses" (Ref. 1).

D. *Expert meeting on TCE*

On July 29, 2014, EPA held a 2-day public workshop on TCE degreasing (Ref. 27). The purpose of the workshop was to collect information from users, academics, and other stakeholders on the use of TCE as a degreaser in various applications, e.g., in degreasing metal parts, availability and efficacy of safer alternatives, safer engineering practices and technologies to reduce exposure to TCE, and to discuss possible risk reduction approaches. The workshop included presentations by experts, breakout sessions with case studies, and public comment opportunities (Ref. 27) and informed EPA's assessment of the alternatives to TCE considered in this proposed rule. All documents from the public workshop are available in EPA Docket Number EPA-HQ-OPPT-2014-0327. Informed in part by the workshop and other analysis, including discussion with Toxics Use Reduction Institute at the University of Massachusetts Lowell, EPA has concluded that TCE alternatives are available for all applications subject to this proposed rule (Ref. 2). The discussions of the meeting demonstrated that alternatives are available for aerosol uses that are being addressed in this proposed rulemaking.

V. Regulatory Approach

A. TSCA section 6 unreasonable risk analysis

Under section 6(a) of TSCA, 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.

The 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 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 record keeping 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 determine the proposed regulatory approach (Refs. 28 and 29). For each use, EPA considered whether a regulatory option (or combination of options) would address the identified unreasonable risks so that it no longer presents such risks. To do so, EPA initially analyzed whether the regulatory options could reduce risks (non-cancer and cancer) so that TCE no longer presents unreasonable risks, based on EPA's technical analysis of exposure scenarios. For the non-cancer risks, EPA determined an option could be protective against the risk if it could achieve the benchmark MOE for the most sensitive non-cancer endpoint. EPA's assessments for these uses indicate that when exposures meet the benchmark MOE for the most sensitive endpoint, they also result in

low risk for cancer.

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. In determining whether a regulatory option would impose requirements to the extent necessary so that TCE no longer presents the identified unreasonable risks, 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 impacted by environmental justice or children's health concerns.

B. Section 6(c)(2) considerations. As noted previously, TSCA section 6(c)(2) requires EPA to factor in, to the extent practicable, the following considerations in selecting regulatory requirements:

• Health effects of TCE and the magnitude of human exposure to TCE;

• Environmental effects of TCE and the magnitude of exposure of the environment to TCE;

• Benefits of TCE 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 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 regulatory options and consideration of the TSCA section 6(c)(2) factors are discussed in more detail in Unit VI for aerosol degreasing and in Unit VII for spot cleaning in dry cleaning facilities.

To the extent information was 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 or other susceptible subpopulations (as compared to the general population), and the cost of regulatory requirements for the various options.

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. 30). EPA took into account the 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 (e.g., PPE). 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.

C. Regulatory options receiving limited evaluation

As discussed previously, EPA analyzed a wide range of regulatory options under TSCA section 6(a). Early in the process, EPA identified two regulatory options under section 6(a) that do not pertain to this action and were therefore not evaluated for this proposed rulemaking. First, EPA determined that the TSCA section 6(a)(1) regulatory option to prohibit the manufacture, processing or distribution in commerce of TCE or limit the amount of TCE which may be manufactured, processed or distributed in commerce is not applicable because the Agency is not proposing to ban or limit the manufacture, processing or distribution in commerce of TCE for uses other than in aerosol degreasing or for spot cleaning in dry cleaning facilities at this time. 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 TCE disposal.

Another option EPA evaluated would require warning labels and instructions on TCE-containing aerosol degreasers and for spot cleaning in dry cleaning facilities pursuant to section 6(a)(3) (Refs. 28 and 29). The Agency determined that warning labels and instructions alone could not mitigate the risks to the extent necessary so that TCE no longer presents the identified unreasonable risks to users. The Agency based this determination on an analysis of 48 relevant studies or meta-analyses, which found that consumers and professionals do not consistently pay attention to labels; consumers and professionals 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. 37).

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 not only on attributes of the label and the user, but also on the multiple steps required in the processes of attention, comprehension, judgment, and action (Ref. 37).

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. 37). In addition, while some studies have shown that different components of labels and warnings tend to have some influence, the evidence does not suggest that labels alone would be sufficient to ensure that users take the steps needed to protect themselves.

The Agency further determined that presenting information about TCE on a label would not adequately address the identified unreasonable risks 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 TCE. 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 window periods during pregnancy when the developing fetus is susceptible to adverse effects from acute exposures, as well as effects to bystanders. It is unlikely that label language changes will for this use result in widespread, consistent, and successful adoption of risk reduction measures by users.

Additionally, 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. 38).

While this regulatory option alone does not address the risks, EPA recognizes that the section 6(a)(3) warnings and instruction requirement can be an important component to an approach for addressing unreasonable risks associated with TCE use in aerosol degreasers and for spot cleaning in dry cleaning facilities and has included a very simple

downstream notification requirement as part of the proposed rulemaking.

VI. Regulatory Assessment of TCE Use in Aerosol Degreasing

This Unit describes the current use of TCE in aerosol degreasing, the unreasonable risks presented by this use, and how EPA preliminarily determined which regulatory options are necessary to address those unreasonable risks.

A. Description of the current use

Aerosol degreasing is a process that uses aerosol spray products, typically applied from a pressurized can, to remove residual contaminants from parts. The aerosol droplets bead up on the fabricated part and then drip off, carrying away any contaminants and leaving behind a clean surface. Components of an item can be cleaned in place or removed from the item for more thorough cleaning. Aerosol degreasers can also be sprayed onto a rag that is used to wipe components clean.

Aerosol degreasers are primarily used for niche industrial or manufacturing uses and some commercial service uses, such as degreasing of metals, degreasing of electrical motors, and electronic cleaners. One example of a commercial setting for the aerosol degreaser use is repair shops, where service items are cleaned to remove any contaminants that would otherwise compromise the item's operation. Internal components may be cleaned in place or removed from the item, cleaned, and then re-installed once dry. EPA identified 16 different aerosol spray degreaser products that contain TCE, blended by 6 different firms. EPA estimates that about 2,200 commercial facilities use TCE aerosol spray degreasers (Ref. 2). EPA requests comment on uses of TCE aerosol degreasers and TCE aerosol degreasing products that the agency did not identify.

Consumer use of TCE in aerosol degreasers is similar to commercial use but occurs in consumer settings. The aerosol products used in consumer settings are the same as those used in commercial settings. TCE use is very limited in products intended for consumers due to existing VOC regulations in California and in a number of northeast, mid-Atlantic, and Midwestern states. Consumer Specialty Products Association (CSPA) member companies have consistently stated that they do not formulate TCE to be sold into consumer products, and the products are generally only sold in the commercial supply chains (Ref. 31). However, due to the wide availability of products available on the Internet and through various suppliers that serve commercial and consumer customers, consumers are able to purchase aerosol degreasing products containing TCE. As a result, EPA evaluated consumer exposures to aerosol degreasers containing TCE in its TCE risk assessment, and identified potential risks to consumers from aerosol degreasers.

There are currently TCE alternatives available on the market for all of the existing uses of aerosol degreasing that are similar in efficacy and cost (Refs. 2, 32). The most likely substitute products would be products with hydrocarbon/mineral spirits, products that are acetone or terpene based, and some that contain perchloroethylene or 1-bromopropane. All substitutes are expected to be less hazardous than TCE. Substitutes that are hazardous but at dose levels higher than the dose levels at which TCE causes adverse effects include perchloroethylene and 1-bromopropane. EPA does not advocate that perchloroethylene or 1-bromopropane be used as substitutes. EPA released a draft risk assessment for 1-bromopropane on March 3, 2016. The schedule for finalizing the assessment of 1-bromopropane and other chemicals is still under development. Many

substitutes are expected to be significantly less hazardous than TCE, based on currently available information. These include formulations that may be categorized as acetone-, citrus terpene-, hydrocarbon-, and water-based degreasers. Several formulations are made with chemicals that are expected to have lower relative exposure potential, compared to TCE, based on currently available information. These include citrus terpenes and water-based degreasers. EPA has not developed risk estimates related to the use of substitutes, however, the benefits analysis incorporates the potential for certain alternatives to result in risks to users by assuming no benefits for TCE users that switch to perchloroethylene or 1-bromopropane alternatives in its lower estimate for benefits. EPA estimates that 25% of TCE users will substitute perchloroethylene or 1-bromopropane, 50% will substitute hydrocarbon/mineral spirits, and 25% will substitute acetone/terpene alternatives (Ref. 2). Although some substitutes, including perchloroethylene and 1-bromopropane, are hazardous, effects from these chemicals are generally seen at levels that are higher than the levels that are associated with TCE toxicity. Thus, considering similar exposure potentials for substitutes, the overall risk potential for the substitutes will be less than for TCE (Ref. 32).

B. Analysis of regulatory options

In this section, EPA explains how it determined whether the regulatory options considered would address the unreasonable risks presented by this use. First, EPA characterizes the unreasonable risks associated with the current use of TCE in aerosol degreasing. Then, the Agency describes its initial analysis of which regulatory options have the potential to reach the protective non-cancer and cancer benchmarks. The levels of acute and chronic exposures estimated to present low risk for non-cancer effects also

result in low risk for cancer. Lastly, this section evaluates how well those regulatory options would address the identified unreasonable risks in practice.

1. *Risks associated with the current use. a. General impacts.* The TCE risk assessment identified acute non-cancer risks for consumers and residential bystanders from the use of TCE-containing aerosol degreasers (Ref. 1). EPA performed supplemental analysis consistent with the methodology used for the consumer use scenario included in the TCE risk assessment (Ref. 24), and identified acute and chronic non-cancer risks and cancer risks for the commercial aerosol degreasing use scenario (Ref. 23). EPA estimates that there are approximately 10,800 workers and occupational bystanders at commercial aerosol degreasing operations, and approximately 22,000 consumers and bystanders exposed to TCE during the consumer use of aerosol degreasers (Ref. 2).

b. Impacts on minority populations. There is no known disproportionate representation of minority populations in occupations using aerosol degreasers. All employees and consumers using aerosol degreasers would benefit from risk reduction.

c. Impacts on children. EPA has concerns for effects on the developing fetus from acute and chronic worker and consumer maternal exposures to TCE. The risk estimates are focused on pregnant women because one of the most sensitive health effects associated with TCE exposure from the use of consumer and commercial aerosol degreasers is adverse effects on the developing fetus. The potential for exposure is significant because approximately half of all pregnancies are unintended. If a pregnancy is not planned before conception, a woman may not be in optimal health for childbearing (Ref. 33). The pregnancy estimate includes women who have live births, induced

abortions, and fetal losses (Ref. 2).

EPA also examined acute risks for consumer exposures in residential settings. EPA assumed that affected consumers would be individuals that intermittently use TCE aerosol degreasers in and around their homes, whereas bystanders would be individuals in close proximity to the use activity but not using the product. EPA assumed that consumer users would generally be adults of both sexes (16 years old and older, including women of childbearing age), although exposures to teenagers and even younger individuals may be possible in residential settings as bystanders. However, risk estimates focused on pregnant women. This is because one of the most sensitive health effects associated with TCE exposure is adverse effects on the developing fetus (Ref. 3).

d. Exposures for this use. For consumer exposures, EPA used the Exposure and Fate Assessment Screening Tool Version 2/Consumer Exposure Module to estimate TCE exposures for the consumer use scenarios (Ref. 1). This modeling approach was selected because emissions and monitoring data were not available for the aerosol degreasing TCE uses under consideration. The model used a two-zone representation of a house to calculate potential TCE exposure levels for consumers and bystanders. The modeling approach integrated assumptions and input parameters about exposure duration, the chemical emission rate over time, the volume of the house and the room of use, the air exchange rate and interzonal airflow rate. The model also considered the exposed individual's location as it relates to use, body weight, and inhalation rate during and after the product use (Ref. 1). No respirator scenarios were considered for use by consumers because EPA cannot require use of respirators by consumers under TSCA section 6(a). EPA used both an air exchange rate of 0.45 per hour based on the central tendency

ventilation rate for a home in the United States and a higher ventilation rate (1.26 air exchanges per hour, representing the upper 10% of U.S. homes) to represent use of the TCE aerosol degreaser in a well-ventilated space (Refs. 1, 24). EPA also considered a range of concentrations of TCE in the aerosol degreasers that the consumers used (5% to 90%) (Refs 1, 24). In the modeling, TCE in the aerosol degreaser entered the room air through overspray of the product and evaporation from a thin film. The inhalation acute dose rates were computed iteratively by calculating the peak concentrations for each simulated 1-second interval and then summing the doses over 24 hours to form a 24-hour dose (Ref. 1).

The high-end inhalation exposure estimates for the consumer scenarios were 2 ppm for users of TCE-containing aerosol degreasers and 0.8 ppm for bystanders of TCE-containing solvent degreasers (Ref. 1).

For exposures in commercial settings, EPA determined baseline exposures using a near-field/far-field modeling approach to estimate airborne concentrations of TCE and Monte Carlo simulation to establish the range and likelihood of exposures (Ref. 23). The near-field/far-field model estimates airborne concentrations in a near field (a zone close to the source of exposure) and a far field (a zone farther from the source of exposure but within the occupational building). EPA used these estimated airborne concentrations to estimate 8-hour time weighted average exposures for workers (i.e., in the near field) and occupational bystanders (i.e., in the far field). A worker is defined as the person performing the task in which TCE is used. Occupational bystanders are defined as other people within the building who are not performing the TCE-based task. Details of the modeling and estimation method for calculating exposure levels during aerosol

degreasing are available in the analysis document, *Supplemental Occupational Exposure and Risk Reduction Technical Report in Support of Risk Management Options for Trichloroethylene (TCE) Use in Aerosol Degreasing* (Ref. 23). As discussed in Unit IV.C, this analysis is based on the methodology used in the peer reviewed TCE risk assessment (Ref. 1).

EPA assumed that a worker applies aerosol degreasers 260 days a year, once per hour, and that no applications occur during the first hour of the 8-hour work day. EPA also assumed that aerosol degreasing facilities use 192.2 grams of degreaser per day and for 100% TCE degreaser this would be 27.5 grams of TCE per application. For degreasers with differing concentrations of TCE, the per-application quantity was adjusted accordingly (Refs. 1 and 23).

e. Risks for this use. As discussed in Unit IV.B, TCE is associated with a range of non-cancer adverse health effects in humans and animals and is carcinogenic to humans. MOEs were used in this assessment to estimate non-cancer risks for acute and chronic exposures. Exposure scenarios with MOEs below the benchmark MOE for the individual toxicity endpoints have risks of concern, as explained in detail in the TCE risk assessment (Ref. 1). Cancer risks express the incremental probability of an individual developing cancer over a lifetime as a result of exposure to TCE under specified use scenarios.

The acute inhalation risk assessment used developmental toxicity data to evaluate the acute risks for the TCE use scenarios. As indicated in the TSCA Work Plan Risk Assessment on TCE, EPA's policy supports the use of developmental studies to evaluate the risks of acute exposures. This science-based policy is based on the presumption that a

single exposure of a chemical at a critical window of fetal development, as in the case of cardiac malformation, may produce adverse developmental effects (Ref. 34 and 35). EPA reviewed multiple studies for suitability for acute risk estimation including a number of developmental studies of TCE exposure and additional studies of TCE metabolites administered developmentally (Appendix N) (Ref. 1). EPA based its acute risk assessment on the most sensitive health endpoint (i.e., fetal heart malformations; Ref. 1) representing the most sensitive human life stage (i.e., the developing fetus). The acute risk assessment used the physiologically based pharmacokinetic (PBPK)-derived hazard values (HEC50, HEC95, or HEC99; HECXX is the Human Equivalent Concentration at a particular percentile) from the Johnson et al. (2003) (Ref. 36) developmental toxicity study for each aerosol degreaser use scenario. Note that the differences among these hazard values is small and no greater than 3-fold (i.e., 2- fold for HEC50/HEC95 ratios; 3-fold for HEC50/HEC99 ratios; 1.4-fold for HEC95/HEC99 ratios). The TCE IRIS assessment preferred the HEC99 for the non-cancer dose-response derivations because the HEC99 was interpreted to be protective for a sensitive individual in the population. While the HEC99 was used to determine the level of risk to be used in making the preliminary section 6(a) determination, the small variation among HEC50, HEC95 and HEC99 would not result in a different risk determination.

Acute inhalation risks were estimated for all residential exposure scenarios of aerosol degreasing based on concerns for developmental effects. Risks of concern were identified for consumer users and bystanders, regardless of the type of exposure (typical vs. worst case scenario) and whether room ventilation was used. For acute consumer aerosol degreasing exposures, the high end MOE is 0.002 for fetal heart malformations.

This means that exposures are estimated to be 5,000 times greater than exposures used to calculate the benchmark MOE of 10. All of the residential use scenarios resulted in MOE values significantly below the benchmark MOE of 10 irrespective of the percentile HEC value used to estimate the MOEs (Refs. 1, 24). Given this significant difference between the benchmark MOEs and the MOEs from the residential use scenarios, EPA has preliminarily determined that the risks TCE present for the consumer aerosol degreasing use are unreasonable risks.

For occupational aerosol degreasing exposures the MOE is 0.003 for fetal heart malformation and is also representative of MOEs for kidney toxicity and immunotoxicity. This equates to estimated exposures that are more than 3,000 times greater than those needed to achieve the benchmark MOE. For chronic occupational aerosol degreasing exposures the baseline cancer risk is 1.6×10^{-2} exceeding standard cancer benchmarks of 10^{-6} to 10^{-4} (Refs. 1, 23). EPA has preliminarily determined that TCE presents unreasonable risks for the occupational aerosol degreasing use.

2. Initial analysis of potential regulatory options. Having identified unreasonable risks from the use of TCE in aerosol degreasing, EPA evaluated whether regulatory options under section 6(a) could reach the risk (non-cancer and cancer) benchmarks.

EPA assessed a number of exposure scenarios associated with risk reduction options in order to determine variations in TCE exposure from aerosol degreasing, including: material substitution, engineering controls, and use of PPE. EPA also assessed combinations of these options. The material substitution scenarios involved reducing the concentration of TCE in the degreasing formulation, with concentrations varying from 5 to 95 percent by weight in the product. For the engineering controls risk reduction option

exposure scenarios, EPA evaluated using local exhaust ventilation to improve ventilation near the worker activity, with estimated 90% reduction in exposure levels. The PPE risk reduction option exposure scenarios evaluated workers and occupational bystanders wearing respirators with an assigned protection factor (APF) varying from 10 to 10,000. Additionally, EPA evaluated all combinations of the above three options: material substitution plus PPE, material substitution plus engineering controls such as local exhaust ventilation, PPE plus engineering controls such as local exhaust ventilation, and materials substitution plus PPE plus engineering controls such as local exhaust ventilation.

EPA's inhalation exposure modeling estimated exposures to characterize the range of workplace scenarios. Inhalation exposure level estimate for facilities without local exhaust ventilation ranged from 1.00 ppm to 14.36 ppm as 8-hour TWAs for workers and 0.21 ppm to 13.58 ppm for bystanders. For facilities with local exhaust ventilation which was estimated to have an effectiveness of 90%, EPA's inhalation exposure level estimates were 0.586 ppm for workers and 0.507 ppm for bystanders. This estimate was for the 99th percentile and assumed that the aerosol degreaser was 100% TCE and that no PPE was used. The exposure estimates for wearing PPE combined with facilities having local exhaust ventilation ranged from 0.0000586 ppm to 0.0586 ppm for workers and 0.0000507 ppm to 0.0507 ppm for bystanders. The range represents the 10 to 10,000 range of respirator APFs considered. The exposure estimates for material substitution plus local exhaust ventilation ranged from 0.0293 ppm to 0.556 ppm for workers and 0.0253 ppm to 0.482 ppm for bystanders. The range represents the various TCE concentrations (5% to 95%) considered for material substitution. Additional

exposure level estimates for various scenarios are available in the analysis document *Supplemental Occupational Exposure and Risk Reduction Technical Report in Support of Risk Management Options for Trichloroethylene (TCE) Use in Aerosol Degreasing* (Ref. 23).

Overall, EPA evaluated dozens of distinct exposure scenarios. The results indicate that regulatory options such as reducing the concentration of TCE in aerosol degreasers and using local exhaust ventilation to improve ventilation near worker activity, 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. 23 and 24). The results also demonstrate that all risk reduction options meeting the benchmark MOEs and cancer benchmarks for TCE aerosol degreasers require the use of a respirator, whether used alone or in conjunction with additional levels of protection. Therefore, EPA found options setting a maximum concentration in products under section 6(a)(2) to not be protective because the options failed—by orders of magnitude—to meet the risk benchmarks. Options found not to meet the risk benchmarks and, therefore, found not to address the identified unreasonable risks are documented in EPA's supplemental technical reports on aerosol degreasing (Refs. 23 and 24).

3. Assessment of regulatory options to determine whether they address the identified unreasonable risks to the extent necessary so that TCE no longer presents such risks. As discussed in Unit V, EPA considered a number of regulatory options under section 6(a) which are reflected in EPA's supporting analysis (Refs. 28 and 29). In assessing these options, EPA considered a wide range of exposure scenarios (Refs. 23,

24, 25). These include both baseline and risk reduction scenarios involving varying factors such as exposure concentration percentiles, local exhaust ventilation 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 the aerosol degreasing use as a whole rather than as separate consumer and commercial uses given that the differences in the use itself between workers and consumers differ only in the degree of repetition and duration and, furthermore, that not addressing them jointly would facilitate products intended for one segment being intentionally or unintentionally acquired and misused by the other.

The options that had the potential to address the identified unreasonable risks for consumer use, commercial use, or both uses of TCE in aerosol degreasing included: a) prohibiting the manufacturing, processing, and distribution in commerce of TCE for use in aerosol degreasing under section 6(a)(2) plus prohibiting the use of TCE in commercial aerosol degreasing under section 6(a)(5) and requiring downstream notification when distributing TCE for other uses under section 6(a)(3); b) variations on such a supply-chain approach (such as just prohibiting the manufacturing, processing, and distribution in commerce of TCE for use in aerosol degreasing products under section 6(a)(2) or just prohibiting the commercial use of TCE in aerosol degreasing under section 6(a)(5)); c) prohibiting the manufacturing, processing, and distribution in commerce of TCE for use in consumer aerosol degreasing products under section 6(a)(2) and requiring downstream notification (e.g., via a Safety Data Sheet (SDS)) when distributing TCE for other uses under section 6(a)(3); and d) requiring the use of PPE in commercial aerosol degreasing operations in which TCE is used under section 6(a)(5) or

requiring the use of PPE and engineering controls (local exhaust ventilation) in commercial aerosol degreasing operations in which TCE is used under section 6(a)(5).

The full range of regulatory options considered under section 6(a) is reflected in EPA's supporting analysis (Ref. 29). A discussion of those regulatory options that could reach the risk benchmarks for consumer use, commercial use, or both is provided in this Unit, along with the Agency's evaluation of how well those regulatory options would address the identified unreasonable risks in practice.

a. *Proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for aerosol degreasing and require downstream notification.* As noted previously, the proposed regulatory approach for TCE use in aerosol degreasing would prohibit the manufacturing, processing, and distribution in commerce of TCE for aerosol degreasing under TSCA section 6(a)(2), prohibit the commercial use of TCE for aerosol degreasing under TSCA section 6(a)(5), and require manufacturers, processors, and distributors, except for retailers, to provide downstream notification, e.g., via a Safety Data Sheet (SDS), of the prohibitions under TSCA section 6(a)(3).

As discussed in Unit VI.B.1, the baseline risk for exposure to workers and consumers for aerosol degreasing departs from non-cancer MOE benchmarks for all non-cancer effects (e.g., developmental effects, kidney toxicity, and immunotoxicity) and standard cancer benchmarks. Under this proposed approach, exposures to TCE from use in aerosol degreasing would be completely eliminated. As a result, both non-cancer and cancer risks would be eliminated (Refs. 23 and 24).

The proposed approach would ensure that workers and consumers are no longer at risk from TCE exposure associated with this use. Prohibiting the manufacturing,

processing and distribution in commerce of TCE for use in aerosol degreasing would minimize the availability of TCE for aerosol degreasing. The prohibition of the use of TCE in commercial aerosol degreasing would eliminate commercial demand for TCE aerosol degreasing products and significantly reduce the potential for consumer use of commercial products. These complementary provisions would protect both workers and consumers; workers would not be exposed to TCE and the risk to consumers would be minimized because commercial aerosol degreasing products containing TCE would not be available, so consumers would not be able to divert commercial–use products from the supply chain. The downstream notification of these restrictions ensures that processors, distributors, and other purchasers are aware of the manufacturing, processing, distribution in commerce and use restrictions for TCE in aerosol degreasing, and helps to ensure that the rule is effectively implemented by avoiding off-label use as an aerosol degreaser of TCE manufactured for other uses. Downstream notification also streamlines and aids in compliance and enhances enforcement. Overall, downstream notification facilitates implementation of the rule. This integrated supply chain proposed approach minimizes the risk from TCE in aerosol degreasing. In addition, the proposed approach would provide staggered compliance dates for implementing the prohibition of manufacturing, processing, distribution in commerce, and commercial use in order to avoid undue impacts on the businesses involved.

b. Options that are variations of the proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for aerosol degreasing and require downstream notification. One variation of the proposed approach would be to prohibit manufacture, processing, and distribution in commerce for the

consumer and commercial aerosol degreasing uses alone. This option could reach the risk benchmarks for TCE. However, while this option could address the identified unreasonable risks, in practice given the continued availability of TCE for other uses, it would not do so. Without the accompanying prohibition on commercial use and downstream notification that is included in the proposed approach, this option would leave open the likelihood that commercial users or consumers could obtain off-label TCE for aerosol degreasing. For example, if only manufacturing, processing and distribution in commerce for the aerosol degreasing use were prohibited without also prohibiting the commercial use and providing the downstream notice, commercial users or consumers could more easily acquire TCE for degreasing from sources that make it available for other uses. This would be particularly easy for commercial users given that a company may buy a chemical substance for one use and also use it for another. Without downstream notification, unsophisticated purchasers, in particular, are likely to be unfamiliar with the prohibitions regarding this use and mistakenly use TCE for aerosol degreasing and thereby expose themselves and bystanders to unreasonable risks. Thus, under these variations, EPA anticipates that the risk benchmarks would not actually be realized by many users. Therefore, these variations fail to address the identified unreasonable risks, considering the practical limitations of the options.

Another regulatory option that EPA considered was to prohibit only the commercial use of TCE for aerosol degreasing. This approach would eliminate both non-cancer and cancer risks for commercial settings only, but would not eliminate risks to consumers. By prohibiting commercial use alone, without a prohibition on the manufacture, processing, and distribution in commerce for consumer and commercial

use, this would not address consumer risks as consumers would still be able to purchase aerosol degreasing products containing TCE, including those products labeled and marketed as "professional strength" or "commercial grade" products. Consumers would continue to be exposed far above the health benchmarks and would not be protected from the unreasonable risks posed by TCE.

c. Prohibit the manufacturing, processing, and distribution in commerce of TCE for use in consumer aerosol degreasing products under section 6(a)(2) or prohibit the manufacturing, processing, and distribution in commerce of TCE for use in consumer aerosol degreasing products under section 6(a)(2) and require downstream notification when distributing TCE for other uses section 6(a)(3). EPA considered prohibiting the manufacturing, processing, and distribution in commerce of TCE for use in consumer aerosol degreasing products 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 TCE use in aerosol degreasing. However, EPA has determined 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 commercial aerosol degreasing.

d. Require the use of personal protective equipment in commercial aerosol degreasing operations in which TCE is used under section 6(a)(5) or require the use of

personal protective equipment and engineering controls in commercial aerosol degreasing operations in which TCE is used under section 6(a)(5). Another regulatory option that EPA considered was to require respiratory protection equipment at commercial aerosol degreasing operations in the form of a full face piece self-contained breathing apparatus (SCBA) in pressure demand mode or other positive pressure mode with an APF of 10,000. EPA's analysis determined that use of a SCBA with an APF of 10,000 for commercial aerosol degreasing uses could control TCE air concentration to levels that allow for meeting the benchmarks for non-cancer and cancer risks for the commercial uses addressed in this proposed rule.

Although respirators could reduce exposures to levels that are protective of non-cancer and cancer risks, there are many documented limitations to successful implementation of respirators with an APF of 10,000. Not all workers can 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 a tight fitting full-face piece respirators to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good face piece fit, including those individuals whose beards or sideburns interfere with the face piece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue and reduced work efficiency (63 FR 1156, 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, it is sometimes necessary to use respiratory protection to control exposure. 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 that would be difficult to fully implement in some small business settings where they are not already using respirators.

In addition, OSHA has adopted a hierarchy of industrial hygiene controls established by the industrial hygiene community to be used to protect employees from hazardous airborne contaminants, such as TCE (see, e.g., 29 CFR 1910.134(a)(1); 29 CFR 1910.1000(e), and OSHA's substance-specific standards in 29 CFR 1910, subpart Z). According to the hierarchy, substitution of less toxic substances, engineering controls, administrative controls, and work practice controls are the preferred methods of compliance for protecting employees from airborne contaminants and are to be implemented first, before respiratory protection is used. OSHA permits respirators o be used only where engineering controls and effective work practices are not feasible or during an interim period while such controls are being implemented.

Also for commercial aerosol degreasing uses, EPA considered requiring a

combination of local exhaust ventilation and a supplied-air respirator with an APF of 1,000, with a performance based option using an air exposure limit. This option could also reduce risks to the health benchmarks for workers when used properly (Ref. 23). However, while this option has the benefit of incorporating engineering controls and use of a respirator with a lower APF, there are still the limitations to successful implementation of the use of supplied-air respirators in the workplace as discussed previously. Further, this option would also require the use of prescriptive and expensive engineering controls to reach the risk benchmarks, unless the optional use of an air exposure limit is implemented (Ref. 39). Even if the performance-based option of meeting an air concentration level as an exposure limit for TCE were used, this would depend upon the use of both engineering controls and a respirator to meet the exposure limit for TCE.

Furthermore, neither of these variations of relying upon PPE for commercial aerosol degreasing use would do anything to reduce the risks to consumer users. Therefore, considering the practical limitations of PPE for this scenario as well as the unmitigated risks to consumers, this option would not address the unreasonable risks presented by these uses.

Even if either of these approaches were coupled with a section 6(a)(2) prohibition on the manufacture, processing and distribution in commerce of TCE for use in consumer aerosol degreasing products, this would not protect consumers because they would be able to buy and use commercial aerosol degreasing products, e.g., via the Internet.

EPA could also require that TCE products be distributed with a respirator with an appropriate assigned protection factor to protect for the risks from TCE. EPA determined

that this option would not address the identified unreasonable risks because simply packaging a respirator with a chemical (or any product) does not mean that a worker or consumer would actually use it properly or even understand how to use it (Refs. 28 and 29).

C. Availability of substitutes and impacts of the proposed and alternative regulatory options

This Unit examines the availability of substitutes for TCE in aerosol degreasing and describes the estimated costs of the proposed and alternative regulatory actions that EPA considered. More information on the benefits and costs of this proposal as a whole can be found in Unit VIII.

Overall, EPA notes that the cost of aerosol degreasing product reformulations are low. Total first-year reformulation costs are estimated to be $416,000 and annualized costs are estimated to be approximately $32,000 per year (annualized at 3% over 15 years) and $41,000 (annualized at 7% over 15 years). A wide variety of effective substitutes are available, as previously noted, and the current existence of non-TCE containing aerosol degreasers indicates that there are no specific aerosol degreasing uses for which TCE is critical. TCE use is limited in aerosol degreasing products intended for consumers due to existing VOC regulations in California and in a number of other states. New Hampshire and Virginia prohibit use of TCE in aerosol adhesives. Connecticut, Delaware, the District of Columbia, Illinois, Indiana, Maine, Maryland, Massachusetts, Michigan, New York, and Rhode Island prohibit the use of TCE in aerosol adhesives, contact adhesives, electrical cleaners, footwear/leather care products, adhesive removers, general purpose degreasers, and graffiti removers (Ref. 15). New Jersey prohibits the use

of TCE in all those products and also in brake cleaners, engine degreasers, and carburetor/fuel-injection air intake cleaners. In addition to prohibiting the use of TCE in all those products, California also prohibits the use of TCE in bathroom and tile cleaners, construction and panel/floor covering adhesives; carpet/upholstery cleaner, general purpose cleaners, fabric protectant, multi-purpose lubricant, penetrant, metal polish or cleanser, multi-purpose solvent, oven cleaners, paint thinner, pressurized gas duster, sealant or caulking compound, spot remover, and silicone-based multi-purpose lubricant (Ref. 12). The range of the State-mandated prohibitions demonstrate that other chemicals can be substituted for TCE for a wide range of uses because other chemicals or mixtures of chemicals can impart properties similar to those of TCE. Further, the fact that 10 states and the District of Columbia have specifically prohibited the use of TCE in general purpose degreasers and general purpose degreasers continue to be sold in those jurisdictions, demonstrates that TCE is not critical to the degreasing use and there are efficacious substitutes.

TCE is also prohibited in the European Union in aerosol degreasers (Ref. 16); TCE substitutes are used for aerosol degreasing. These regulations confirm that TCE is not a critical chemical for aerosol degreasing and that substituting alternate chemicals would not be overly difficult. Producers of aerosol degreasing products containing TCE also produce aerosol degreasing products with substitute chemicals. Thus, there is already precedent for producers reformulating products to meet demand in some states and countries. In addition, EPA expects that one effect of a ban on the use of TCE in aerosol degreasing products would be increased technological innovation, resulting in the development of additional alternatives.

1. Proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for aerosol degreasing and require downstream notification. The costs of the proposed approach are estimated to include product reformulation costs, downstream notification costs, recordkeeping costs, and Agency costs. The total first-year costs of aerosol degreasing product reformulations are estimated to be $416,000 and annualized costs are estimated to be approximately $32,000 per year (annualized at 3% over 15 years) and $41,000 (annualized at 7% over 15 years). The cost for reformulation includes a variety of factors such as identifying the substitute for TCE, assessing the efficacy of the new formulation and determining shelf-life. The costs to users of aerosol degreasers are negligible as substitute products are currently available on the market and are similarly priced. The first-year costs of downstream notification and recordkeeping are estimated to be $51,000 and on an annualized basis over 15 years are $3,900 and $5,000 using 3% and 7% discount rates respectively (Ref. 2). Agency costs for enforcement are estimated to be approximately $112,000 and $109,000 annualized over 15 years at 3% and 7%, respectively. Annual recurring costs to the Agency for enforcement are estimated to be $121,000 per year. The total cost of the proposed approach for aerosol degreasing use is estimated to be $37,000-$40,000 and $46,000-$49,000 annualized over 15 years at 3% and 7%, respectively.

2. Options that require personal protective equipment. 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 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 as an exposure limit for TCE. The estimated annualized costs of switching to a respiratory protection program requiring PPE of APF 10,000 are $8,300 at 3% and $9,100 at 7% per aerosol degreasing facility over 15 years. The estimated annualized costs of switching to a respiratory protection program requiring PPE of APF 1,000 are $5,400 at 3% and $5,500 at 7% per facility over 15 years. In addition, there would be higher EPA administration and enforcement costs with a respiratory protection program than there would be with an enforcement program under the proposed approach. Further, even if cost were not an impediment, in addition to cost, there are many limitations to the successful implementation of respirators with an APF of 10,000 in a workplace.

3. Options that exclude downstream notification. EPA was unable to monetize the extent to which enforcement costs would vary by regulatory option so EPA assumed monetized enforcement costs to be the same under all options for the purpose of this proposed rulemaking. The proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for aerosol degreasing and require downstream notification 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 TCE 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 (Ref. 40). Under these other options, enforcement activities must target firms that might perform the activity where a TCE use is restricted or prohibited. Identifying which establishments might use aerosol degreasers is difficult because aerosol

degreasing is not strictly specific to any industry (Ref. 2). Therefore, while EPA considers downstream notification to be a critical component of this proposal, EPA also finds that incorporating downstream notification reduces the burden on society by easing implementation, compliance, and enforcement (Ref. 41).

D. Summary

The proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for aerosol degreasing and require downstream notification is necessary to ensure that TCE no longer presents unreasonable risks for all users. This option does not pose an undue burden on industry because comparably effective and priced substitutes to TCE for aerosol degreasing are readily available. The supply chain approach ensures protection of consumers from the identified unreasonable risks by precluding the off-label purchase of commercial products by consumers. The downstream notification (e.g., via SDS) component of the supply chain approach provides notice of the prohibition throughout the supply chain and, while slightly more costly to upstream entities, helps to ensure that the use no longer presents unreasonable risks because it streamlines and aids in compliance and enhances enforcement.

VII. Regulatory Assessment of TCE use for Spot Cleaning in Dry Cleaning Facilities

This Unit describes the current use of TCE for spot cleaning in dry cleaning facilities, the unreasonable risks presented by this use, and how EPA preliminarily determined which regulatory options are necessary to address the identified unreasonable risks.

A. *Description of the current use*

TCE was first introduced as a dry cleaning solvent in the United States in the

1930s (Ref. 2). It was never widely used as a primary dry cleaning solvent; however, TCE is still used for spot cleaning in dry cleaning facilities to remove oily-type stains, including fats, waxes, grease, cosmetics, and paints. Stained fabrics are typically "pre-spotted" with spot treatment products, which are often solvent-based such as those containing TCE, prior to being placed in dry cleaning machines (Refs. 42, 43). TCE is one of many available spotting agents used in dry cleaning facilities. A range of alternative spotting agents are used in dry cleaning facilities including certain halogenated solvents, such as perchloroethylene, 1-bromopropane, and methylene chloride; water- and soy-based spotting agents; hydrocarbon/mineral spirits; glycol ethers; and others (Ref. 2). TCE is applied by a squirt bottle directly onto the stain on the garment (Ref. 1). Squirt bottles are hand filled from larger volume containers of the spotting agent. After application, the TCE-based spotting agent is patted with a brush to break up the stain without harming fabric and suction vacuumed from the garment, which is then placed in the dry cleaning machine. The TCE spotting agent from the vacuum is collected as hazardous waste. Concentrations of TCE in commercial spotting agents vary from 10% to 100% (Refs. 42, 43).

EPA estimates that there are approximately 61,000 dry cleaning facilities in the United States, with an estimated 210,000 workers. Approximately 32,000 to 52,000 of those dry cleaning facilities are estimated to be using TCE in spot cleaning, with an estimated 105,000 to 168,000 workers and occupational bystanders (Ref. 2). Less than 1% of the total 225 million pounds of TCE used in the United States is for dry cleaning with approximately 50% to 80% of dry cleaners estimated to be using TCE for spot cleaning in dry cleaning facilities (Ref. 2). A typical dry cleaning facility uses 0.84 to 8.4

gallons per year of TCE for spot cleaning operations (Ref. 1).

There are currently a wide variety of comparably effective substitutes on the market and in use in dry cleaning operations that are similarly priced to TCE (Ref. 2), including substitute water-based cleaners (Ref. 44), methyl esters (soy) cleaners, hydrocarbon/mineral spirits, glycol ethers, perchloroethylene, methylene chloride, and 1-bromopropane (Ref. 32). Chemical substitutes that would most likely be used are water-based cleaners, methyl esters (soy) cleaners, hydrocarbon/mineral spirits, glycol ethers, perchloroethylene, 1-bromopropane, methylene chloride, and others. EPA estimates that 5% of users will switch to aqueous cleaners, 25% will switch to perchloroethylene and 1-bromopropane, and 70% will switch to other alternatives (Ref. 2). In general, substitutes are less toxic than TCE (Refs. 32, 44). Thus, considering similar exposure potentials for substitutes, the overall risk potential for the substitutes will be less than for TCE (Ref. 32).

B. Analysis of regulatory options

In this Unit, EPA explains how it determined whether the regulatory options considered would address the unreasonable risks presented by this use. First, EPA characterizes the unreasonable risks associated with the current use of TCE for spot cleaning in dry cleaning facilities. Then, the Agency describes its initial analysis of which regulatory options have the potential to achieve non-cancer and cancer benchmarks. The levels of acute and chronic exposures estimated to present low risk for non-cancer effects also results in low risk for cancer. Lastly, this Unit evaluates how well those regulatory options would address the identified unreasonable risks in practice.

1. *Risks associated with the current use.* a. *General impacts*. The TCE risk

assessment identified non-cancer risks and cancer risks for chronic exposures of workers and occupational bystanders in dry cleaning facilities that use TCE for spot cleaning (Ref. 1). EPA also identified acute non-cancer risks for workers and occupational bystanders (Ref. 1). The size of the potentially exposed population is approximately 105,000-168,000 workers and occupational bystanders in dry cleaning operations (Ref. 2).

b. *Impacts on minority populations*. In dry cleaning facilities, Asian and Hispanic populations are over-represented. 13% of dry cleaning workers are Asian, compared to 5% of the national population. Also, 30% of dry cleaning workers are Hispanic (of any race) compared to 16% of the national population (Ref. 2). Because minority populations are disproportionately over-represented in this industry they are disproportionately exposed; thus, there would be disproportionately positive benefits for these populations from the regulatory approach set forth in this proposal.

c. *Impacts on children*. EPA has concern for effects on the developing fetus from acute and chronic maternal exposures to TCE in dry cleaning facilities. The risk estimates are focused on pregnant women because adverse effects on the developing fetus is one of the most sensitive health effects associated with TCE exposure. Of the up to 168,000 workers and occupational bystanders in dry cleaning operations who make up the exposed population, 3.2% are estimated to be pregnant women. Thus, up to approximately 5,400 pregnant women are estimated to be exposed to TCE in spot cleaning in dry cleaning facilities each year. The pregnancy estimate includes women who have live births, induced abortions, and fetal losses (Ref. 2). The potential for exposure is significant because approximately half of all pregnancies are unintended. If a pregnancy is not planned before conception, a woman may not be in optimal health for

childbearing (Ref. 33).

d. *Exposures for this use*. TCE exposures for this use are through the inhalation route. EPA used readily available information from a 2007 study on spotting chemicals, prepared for the California EPA and EPA, to estimate releases of TCE and associated inhalation exposures to workers from spot cleaning operations in dry cleaning facilities (Ref. 1). The near field/far field mass balance model, which has been extensively peer-reviewed, was used for this estimation of workplace exposure levels during spot cleaning (Ref. 1). The near-field/far-field model estimates airborne concentrations in a near field (a zone close to the source of exposure) and a far field (a zone farther from the source of exposure but within the occupational building). EPA used these estimated airborne concentrations to estimate exposures for the worker applying the spotting agent (i.e., in the near field) and the occupational bystanders (i.e., in the far field). A worker is defined as the person performing the task in which TCE is used. Occupational bystanders are defined as other persons within the dry cleaning facility who are not performing the TCE-based task. EPA assumed that dry cleaning facilities operated 260 days per year for 8 hours a day; that the concentration in the spotting agent ranged from 10 to 100% and that a typical dry cleaning facility used 0.84 to 8.4 gallons of TCE per year for spotting operations. Details of the modeling and estimation method for calculating exposure levels during spot cleaning are available in the TCE risk assessment (Ref. 1).

e. *Risks for this use*. As discussed in Unit IV.B, TCE is associated with a range of non-cancer health effects in humans and animals and is also carcinogenic to humans.

As discussed in Unit IV.B, MOEs were used in this assessment to estimate non-cancer risks for acute and chronic exposures. Exposure scenarios with MOEs below the

benchmark MOE have risks of concern and typically, non-cancer adverse effects are more likely to result from exposure scenarios with MOEs below the benchmark MOE. For the use of TCE as a spot cleaner in dry cleaning facilities, the risk estimates for a range of non-cancer effects were below the benchmark MOE of 10 for developmental effects. The MOE for acute developmental effects is 0.002 for fetal heart malformation (Refs. 1, 25). For chronic occupational spot cleaning exposures, the MOE is 0.003 for fetal heart malformation and is similar to MOEs for kidney toxicity and immunotoxicity. In the baseline exposure scenarios, the MOEs are 3,000 times less than the benchmark MOEs (Refs. 1, 25). EPA has preliminarily determined that TCE presents unreasonable non-cancer risks from spot cleaning in dry cleaning facilities.

Cancer risks determine the incremental probability of an individual developing cancer over a lifetime as a result of exposure to TCE. For chronic occupational spot cleaning exposures the baseline cancer risk is 1×10^{-2} which exceeds the standard cancer benchmarks of 10^{-6} to 10^{-4} (Refs. 1 and 25). Accordingly, EPA has preliminarily determined that TCE presents unreasonable cancer risks from spot cleaning in dry cleaning facilities.

2. Initial analysis of potential regulatory options. Having identified unreasonable risks from the use of TCE in spot cleaning in dry cleaning facilities, EPA evaluated whether regulatory options under section 6(a) could reach the risk (non-cancer and cancer) benchmarks.

EPA assessed a number of exposure scenarios associated with risk reduction options in order to determine variations in TCE exposure when spot cleaning in dry cleaning facilities: material substitution, engineering controls, and use of PPE, as well as

combinations. The materials substitution scenarios involved reducing the concentration of TCE in the spot cleaning formulation, with concentrations varying from 5% to 95% total weight of the formulation. For the engineering control risk reduction option exposure scenarios, EPA evaluated using local exhaust ventilation to improve ventilation near the worker activity, with estimated 90% reduction in exposure levels. The PPE risk reduction option exposure scenarios evaluated workers and occupational bystanders wearing respirators with APF varying from 10 to 10,000. Additionally, EPA evaluated all combinations of the above three options: material substitution plus PPE; material substitution plus local exhaust ventilation; PPE plus local exhaust ventilation; and material substitution plus PPE plus local exhaust ventilation.

EPA's site-specific inhalation exposure level estimate for facilities without local exhaust ventilation ranged from 0.08 to 19 ppm as 8-hour TWAs. Although relevant exposure monitoring data were limited, EPA identified a study specific to spot cleaning with TCE (Ref. 42). In this study, TWA levels for worker exposure to TCE during spot cleaning (with no local exhaust ventilation) ranged from 2.37 to 3.11 ppm. This range of exposure levels falls within EPA's estimated exposure range of 0.08 to 19 ppm and is within a factor of 10 of EPA's high-end estimate of 19 ppm (Ref. 43).

For facilities with local exhaust ventilation, EPA's inhalation exposure level estimates were 5.0×10^{-1} ppm for workers and 4.2×10^{-1} for bystanders. The exposure estimates for wearing PPE combined with facilities having local exhaust ventilation ranged from 5.0×10^{-5} ppm to 5.0×10^{-2} ppm for workers and 4.2×10^{-5} ppm to 4.2×10^{-2} ppm for bystanders. The exposure estimates for material substitution plus local exhaust ventilation ranged from 2.5×10^{-2} ppm to 4.7×10^{-1} ppm for workers and 2.1×10^{-2} ppm

to 4.0 x 10^{-1} ppm for bystanders. All exposure level estimates for the various scenarios considered are available in the TCE risk assessment (Ref. 1) and *Supplemental Occupational Exposure and Risk Reduction Technical Report in Support of Risk Management Options for Trichloroethylene (TCE) Use in Spot Cleaning* (Ref. 25).

The results indicate that alternate regulatory options such as reducing the concentration of TCE in spot cleaners for dry cleaning facilities and using local exhaust ventilation to improve ventilation near worker activity could not achieve the target MOE benchmarks for non-cancer endpoints for acute and chronic exposures and standard cancer risk benchmarks for chronic exposures. The results also demonstrate that all risk reduction options require the use of a respirator, whether used alone or in conjunction with additional levels of protection, in order to meet the non-cancer and cancer risk benchmarks (Ref. 25). Therefore, EPA found that options setting a maximum concentration in products under section 6(a)(2) did not address the identified unreasonable risks because the options failed—by orders of magnitude—to meet the risk benchmarks. Options found not to meet the risk benchmarks and which, therefore, do not address the identified unreasonable risks are documented in EPA's supplemental technical report on spot cleaning (Ref. 25).

3. Assessment of regulatory options to determine whether they address the identified unreasonable risks to the extent necessary so that TCE no longer presents such risks. As discussed in Unit V., EPA considered a number of regulatory options under section 6(a) to address TCE risks from spot cleaning in dry cleaning facilities which are reflected in EPA's supporting analysis (Ref. 29). In assessing these options, EPA considered a wide range of exposure scenarios (Ref. 25). These include both baseline and

risk reduction scenarios involving varying factors such as reduction of TCE content in spot cleaners, exposure concentration percentiles, local exhaust ventilation use, respirator use, working lifetimes, etc. The options that could reduce the risks of TCE use to the benchmark MOE and standard cancer benchmarks for spot cleaning in dry cleaning include a) prohibiting the manufacture, processing, and distribution in commerce of TCE for use as a spot cleaner in dry cleaning facilities (section 6(a)(2)) plus prohibiting the use of TCE as a spot cleaner in dry cleaning facilities (section 6(a)(5)) and requiring downstream notification when distributing TCE for other uses under section 6(a)(3); b) variations on such a supply-chain approach (such as just prohibiting the manufacture, processing, distribution in commerce of TCE for use as a spot cleaner in dry cleaning facilities under section 6(a)(2) or just prohibiting the commercial use of TCE as a spot cleaner in dry cleaning facilities under section 6(a)(5)); c) requiring the use of personal protective equipment in dry cleaning facilities in which TCE is used as a spot cleaner under section 6(a)(5) or requiring the use of personal protective equipment and engineering controls in dry cleaning facilities in which TCE is used as a spotting agent under section 6(a)(5).

The full range of regulatory options considered under section 6(a) is reflected in EPA's supporting analysis (Ref. 29). A discussion of the regulatory options that were determined to have the potential to address the identified unreasonable risks is provided in this Unit, along with the Agency's evaluation of how well those regulatory options would address the unreasonable risks in practice.

a. *Proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for spot cleaning in dry cleaning facilities and require*

downstream notification. As noted previously, the proposed regulatory approach uses several elements of TSCA section 6(a) to address the risk of TCE use for spot cleaning in dry cleaning facilities throughout the supply chain. The proposed regulatory approach would prohibit the manufacturing, processing, and distribution in commerce of TCE for spot cleaning in dry cleaning facilities under TSCA §6(a)(2), prohibit the commercial use of TCE for spot cleaning in dry cleaning facilities under TSCA §6(a)(5), and require manufacturers, processors, and distributors, except for retailers, to provide downstream notification, e.g., via a SDS, of the prohibitions under TSCA §6(a)(3).

As discussed in Unit VII.B.1, the MOEs for occupational exposure for spot cleaning in dry cleaning facilities are below the non-cancer MOE benchmarks for all non-cancer effects (e.g., developmental effects, kidney toxicity, and immunotoxicity) and standard cancer benchmarks. Under this proposed approach, exposures to TCE from this use would be completely eliminated. As a result, both non-cancer and cancer risks from exposure to TCE from this use would be eliminated (Ref. 39). All employees in dry cleaning facilities would benefit; and Asian and Hispanic populations, which are over-represented in dry cleaning facilities, would disproportionally benefit from the proposed approach.

The proposed approach would ensure that workers and occupational bystanders are no longer at risk from TCE exposure associated with this use throughout the supply chain. By proposing to prohibit the manufacture, processing and distribution in commerce of TCE for use as a spot cleaner in dry cleaning facilities, EPA would ensure that manufacturers, processors and distributors would not sell TCE for a use that EPA has determined presents an unreasonable risk of injury to health, and the intentional or

unintentional availability of TCE for spot cleaning in dry cleaning facilities would be minimized. The proposal to prohibit commercial use of TCE as a spot cleaner in dry cleaning facilities would eliminate commercial demand for TCE-based spot cleaning products and would more effectively protect workers and bystanders than a prohibition only on manufacture, processing or distribution for this use under Section 6(a)(2). The prohibition on commercial use ensures that commercial users would not be able to divert TCE manufactured for other allowable uses to this prohibited use without consequence. The downstream notification of these restrictions ensures that processors, distributors, and purchasers are aware of the manufacturing, processing, and distribution in commerce and use restrictions for TCE spot cleaner uses in dry cleaning facilities and helps to ensure that the rule is effectively implemented by avoiding off-label use as a spot cleaner of TCE manufactured for other uses. Downstream notification also streamlines and aids in compliance and enhances enforcement. Overall, downstream notification facilitates implementation of the rule. Collectively the proposed approach completely mitigates the risk from TCE in spot cleaners in dry cleaning facilities. In addition, the proposed approach would provide staggered compliance dates for implementing the prohibition of manufacturing, processing, distribution in commerce, and commercial use in order to avoid undue impacts on the businesses involved.

b. Options that are variations of the proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for spot cleaning in dry cleaning facilities and require downstream notification. Another regulatory option that EPA considered was to prohibit only the commercial use of TCE for spot cleaning in dry cleaning facilities under TSCA §6(a)(5). This option could reach the risk benchmarks

for TCE (Ref. 29). While this approach could eliminate non-cancer and cancer risks, in practice it would not address the identified unreasonable risks because users would easily be able to obtain TCE for use in dry cleaning facilities or would likely unknowingly purchase spot agents which contain TCE. If the Agency were to prohibit use alone, without the prohibition on manufacture, processing, and distribution in commerce for the use of TCE for spot cleaning in dry cleaning facilities, there is a greater likelihood that TCE manufactured for non-prohibited uses could be diverted to prohibited uses. Users would likely unknowingly purchase materials that they do not realize contain TCE because they would not be aware of the prohibition, which would result in unreasonable risks for those users. Taking the supply chain approach to addressing the risk of TCE in spot cleaning at commercial dry cleaning facilities helps to ensure that TCE manufactured for other allowed uses would not be used for this prohibited use.

Due to the large number of dry cleaning facilities in the United States (approximately 61,000), EPA is concerned that without the section 6(a)(3) downstream notification requirement, these entities might not become aware of the prohibition on TCE in spot cleaning because they may be unaware that certain products actually contain TCE. Thus, without downstream notification, EPA anticipates that the risk benchmarks would not actually be realized by many users. Therefore, such an option fails to address the identified unreasonable risks, considering the practical limitations.

Another regulatory option that EPA considered was to prohibit only the manufacturing, processing or distribution in commerce of TCE for spot cleaning in dry cleaning facilities under TSCA section 6(a)(2) or, a variation of this option: a prohibition of manufacturing, processing, or distribution in commerce of TCE for spot cleaning in

dry cleaning facilities and require downstream notification when distributing TCE for other uses under section 6(a)(3). This option could reach the risk benchmarks for TCE (Ref. 29). However, this option introduces weaknesses, such as likelihood for users to obtain TCE for spot cleaning through other means, and thereby fails to address the identified unreasonable risks. For example, if only manufacturing, processing and distribution in commerce for the spot cleaning use in dry cleaners were prohibited without also prohibiting the use, dry cleaning facilities could go to other sources to acquire TCE for non-prohibited uses and divert those uses to the spot cleaning use without consequence. This would be the case even if the prohibition on manufacturing, processing and distribution in commerce were accompanied by the downstream notification requirement. A combined approach would ensure that the section 6(a) requirements address the identified unreasonable risks.

c. Require the use of personal protective equipment in commercial dry cleaning facilities in which TCE is used as a spot cleaner under section 6(a)(5) or require the use of personal protective equipment and engineering controls in commercial dry cleaning facilities in which TCE is used as a spot cleaner under section 6(a)(5). Another regulatory option that EPA considered was to require the use of respirators in the form of a supplied-air respirator with an APF of 10,000 for workers at risk of exposure to TCE with a performance based option using an air exposure limit. See Unit VI.B.3.d for a discussion of issues and drawbacks of requiring the use of a supplied-air respirator. In addition, while this option could mitigate the risk for workers, dry cleaning facilities are generally small shops and many are co-located in commercial shopping centers where the work goes on in plain view of customers or are co-located with residential buildings. It is

highly unlikely that dry cleaning operations would undertake fitting all of their workers with the full face piece SCBA apparatus with accompanying supplied air breathing device necessary to mitigate risk. This approach could have separate economic impacts because consumers may not wish to enter an establishment in which workers are wearing supplied-air respirators. In addition, many dry cleaning establishments are located near residential areas. Local residents may react adversely to an establishment using chemicals which require a supplied-air respirator.

EPA also considered requiring the combination of the use of local exhaust ventilation which achieves 90% reduction in airborne concentrations to improve ventilation near the worker activity and a supplied-air respirator with an APF of 1,000 with a performance based option using an air exposure limit. EPA conducted a risk analysis for both baseline exposures and exposures after implementing risk management options, allowing for a direct comparison of the acute and chronic risks associated with the exposures following application of a risk reduction option. This option would also reduce risks to the health benchmarks for workers when used properly (Ref. 25). While this option has the benefit of incorporating engineering controls and use of a respirator with a lower APF, there are still the limitations to successful implementation of the use of supplied-air respirators in the workplace as discussed previously.

C. Availability of Substitutes and Impacts of the Proposed and Alternative Regulatory Options

This Unit examines the availability of substitutes for TCE as a spot cleaner in dry cleaning facilities and describes the estimated costs of the proposal and the alternatives that EPA considered. More information on the benefits and costs of this proposal as a

whole can be found in Unit VIII.

Overall, EPA notes that the costs of dry cleaning spot cleaning product reformulation are low. Total first-year reformulation costs are estimated to be $286,000 and annualized costs are approximately $22,000 per year (annualized at 3% over 15 years) and $28,000 (annualized at 7% over 15 years). A wide variety of effective substitutes for TCE in spot cleaning applications indicates that producers and users can readily shift from TCE to less hazardous chemical substitutes. Limitations on these or similar uses of TCE are already in place in many states in the United States and internationally. For example, TCE use is prohibited in California for aerosol and non-aerosol consumer spot removers. TCE is also prohibited in the European Union for spot cleaning use in dry cleaning facilities. In addition, according to the Drycleaning and Laundry Institute, a trade association representing more than 4,000 dry cleaning operations in the United States, not all dry cleaning facilities use TCE, and many other alternatives are available and equally effective (Refs. 42, 43). Further, prohibitions in California and the European Union indicate that the transition can be made to substitutes, demonstrating that switching to alternatives would not be overly difficult for users. Producers of spot cleaning products containing TCE also produce spot cleaning products with substitute chemicals. Thus, there is already precedent for producers reformulating products to meet demand in some states and countries. In addition, EPA expects that one effect of a ban on the use of TCE for spot cleaning at dry cleaning facilities would be increased technological innovation, resulting in the development of additional alternatives.

1. Proposed approach to prohibit manufacturing, processing, distribution in

commerce, and use of TCE for spot cleaning in dry cleaning facilities and require downstream notification. The costs of the proposed approach are estimated to include product reformulation costs, downstream notification and recordkeeping costs, and Agency costs. The total first-year costs of dry cleaning spot cleaning product reformulation are approximately $286,000 and annualized are estimated to be $22,000 per year (at 3% over 15 years) and $28,000 (at 7% over 15 years). The costs to users of dry cleaning spot cleaning products are negligible as substitute products are currently available on the market and are similarly priced. The costs of downstream notification and recordkeeping are estimated to be $51,000 and on an annualized basis over 15 years are $3,900 and $5,000 using 3% and 7% discount rates respectively. Agency costs for enforcement are estimated to be approximately $112,000 and $109,000 annualized over 15 years at 3% and 7%, respectively. Annual recurring costs to the Agency for enforcement are estimated to be $121,000 per year. The total cost of the proposed approach for the dry cleaning spot cleaning use is estimated to be $130,000 to $133,000 and $135,000 to $137,000 annualized at 3% and 7%, respectively, over 15 years.

2. Options that require personal protective equipment. The costs of implementing a respiratory protection program, including a supplied-air respirator and related equipment, training, fit testing, monitoring, medical surveillance, and related requirements, would far exceed the costs of switching to alternatives, on a per facility basis. The estimated annualized costs of switching to a respiratory protection program requiring PPE of 10,000 are $8,200 at 3% and $9,000 at 7% per dry cleaning facility over 15 years. The estimated annualized costs of switching to a respiratory protection program requiring PPE of 1,000 are $5,800 at 3% and $5,800 at 7% per dry cleaning facility over

15 years. In addition, there would be higher EPA administration and enforcement costs with respiratory protection program than there would be with an enforcement program under the proposed approach.

3. Options that exclude downstream notification. EPA was unable to monetize the extent to which enforcement costs would vary by regulatory option so EPA assumed monetized enforcement costs to be the same under all options for the purpose of this proposed rulemaking. The proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for spot cleaning in dry cleaning facilities and require downstream notification 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 TCE 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. Under these other options, enforcement activities must target firms that might perform the activity where a TCE use is restricted or prohibited. For the prohibition on TCE in dry cleaning spot removers, this would include all dry cleaning establishments. (Ref. 2). Therefore, while EPA considers downstream notification to be a critical component of this proposal, EPA also finds that incorporating downstream notification reduces the burden on society by easing implementation, compliance, and enforcement.

D. Summary

The proposed approach to prohibit manufacturing, processing, distribution in commerce, and use of TCE for spot cleaning in dry cleaning facilities and require

downstream notification is necessary to ensure that TCE no longer presents unreasonable risks for this use. This option does not pose an undue burden on industry because comparable substitutes to TCE for spot cleaning in dry cleaning facilities are readily available. This approach also protects workers and occupational bystanders from the identified unreasonable risks by providing downstream notification of the prohibition throughout the supply chain and avoiding off-label purchase and use of TCE for the prohibited use. Downstream notification streamlines compliance and aids in compliance and enhances enforcement.

VIII. Other Factors Considered

When issuing a rule under TSCA section 6(a), EPA must consider and publish a statement based on reasonably available information on the:

• Health effects of the chemical substance in question, TCE in this case, and the magnitude of human exposure to TCE;

• Environmental effects of TCE and the magnitude of exposure of the environment to TCE;

• Benefits of TCE for various uses; and the

• 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, benefits, and cost-effectiveness of the rule and of the one or more primary alternatives that EPA considered.

TSCA section 6(c)(2)(B) instructs EPA, when selecting among prohibitions and other restrictions under 6(a) to factor in, to the extent practicable, these considerations. This Unit provides more information on the benefits, costs, and cost-effectiveness of this

proposal and the alternatives that EPA considered.

As discussed in Unit IV.B, TCE exposure is associated with a wide array of adverse health effects. These health effects include developmental toxicity (e.g., cardiac malformations, developmental immunotoxicity, developmental neurotoxicity, fetal death), toxicity to the kidney (kidney damage and kidney cancer), immunotoxicity (such as systemic autoimmune diseases e.g., scleroderma) and severe hypersensitivity skin disorder, non-Hodgkin's lymphoma, endocrine and reproductive effects (e.g., decreased libido and potency), neurotoxicity (e.g., trigeminal neuralgia), and toxicity to the liver (impaired functioning and liver cancer) (Ref. 1). TCE may cause fetal cardiac malformations that begin in utero. In addition, fetal death, possibly resulting from cardiac malformation, can be caused by exposure to TCE. Cardiac malformations can be irreversible and impact a person's health for a lifetime. Other effects, such as damage to the developing immune system, may first manifest when a person is an adult and can have long-lasting health impacts. Certain effects that follow adult exposures, such as kidney and liver cancer, may develop many years after initial exposure. The point during a lifetime when the effect manifests itself and the expected impacts to a person during her/his lifetime are important factors in determining the benefits of mitigating and preventing TCE exposure.

Based on EPA's analysis of worker and consumer populations' exposure to TCE, EPA has determined that there are significant cancer and non-cancer risks (acute and chronic) from TCE exposure, which can result in developmental effects, kidney toxicity, immunotoxicity, reproductive toxicity, neurotoxicity, and liver toxicity. These risks are unreasonable risks because the chemical exposures predicted for the various scenarios

assessed are above what would be necessary to achieve the MOE benchmarks for cardiac defects, kidney toxicity, immunotoxicity, liver toxicity, neurotoxicity and endocrine and reproductive toxicity. For commercial use scenarios of aerosol degreasing and use of TCE for spot cleaning in dry cleaning facilities, as well as for all the residential use scenarios, exposures are far beyond what would be necessary to achieve the MOE benchmark for cardiac defects. For example, the 99th percentile of the upper end exposure use scenario for aerosol degreasing has a MOE of 0.003 for chronic exposures and 0.002 for acute exposures. Thus, for this aerosol degreasing use scenario, people are exposed at a level that is 3,000 times higher than what EPA determines is protective for the non-cancer health effect.

The number of people at risk for the developmental effects is estimated to be up to approximately 5,400 pregnant women in dry cleaning operations and approximately 900 pregnant women exposed to TCE during the use of aerosol degreasers. The potential for exposure is significant because approximately half of all pregnancies are unintended. If a pregnancy is not planned before conception, a woman may not be in optimal health for childbearing (Ref. 33).

Given the large differential between the benchmark MOE and the MOEs resulting from EPA's estimates of exposures, people exposed to TCE in aerosol degreasing and during dry cleaning operations are at significant risk for the multiple adverse non-cancer health effects caused by TCE and the impacts discussed below on many facets of their life that these adverse health effects cause. These risks are significant even when considered alone. However, workers may be also be impacted by the significant risks for several types of cancer. The cancer risks to workers using TCE in aerosol degreasing and

for spot cleaning in dry cleaning facilities are 1.6×10^{-2} or more than one and one-half cases in one hundred for aerosol degreasing and 1.4×10^{-2} or more than one case in one hundred for use of TCE for spot cleaning in dry cleaning facilities.

The risk reduction from preventing TCE exposure cannot be comprehensively quantified or monetized even though the adverse effects are well-documented, the TCE risk assessment estimating these risks has been peer-reviewed, and the benefits of reducing the risk of these health endpoints can be described. It is relatively straightforward to monetize the benefits of reducing the risk of cancer (kidney cancer, liver cancer, non-Hodgkin's lymphoma) due to TCE exposure. The estimated value of the annualized benefit is estimated to be $9.3 million to $25.0 million at 3% and $4.5 million to $12.8 million at 7% over 15 years. It is currently not possible to monetize the benefits of reducing the risks of the costs of non-cancer effects (all developmental toxicity, kidney toxicity, immunotoxicity, reproductive toxicity, neurotoxicity, and liver toxicity) of TCE exposure. There are two reasons for this. First, dose response information and concentration response functions in humans are not available, which would allow EPA to estimate the number of population-level non-cancer cases that would be avoided by reducing exposures to levels corresponding with MOE benchmarks. Second, even it were possible to calculate the number of cases avoided, EPA may not be able to monetize the benefits of these avoided cases due to limitations in data needed to apply established economic methodologies. However, being unable to quantitatively assess individual risk and population-level non-cancer cases avoided from TCE exposure does not negate the impact of these effects. Similarly, the inability to monetize an adverse effect does not reflect the severity of the effect, the lifetime nature of the impact, or the magnitude of the

benefit in preventing the adverse impact from TCE exposure, such as a cardiac malformation, on a person. In considering the benefits of preventing TCE exposure, EPA considered the type of effect, the severity of the effect, the duration of the effect, and costs and other monetary impacts of the health endpoint.

The health endpoints associated with TCE exposure are serious. The following is a discussion of the impacts of the most significant cancer and non-cancer effects associated with TCE exposure, including the severity of the effect, the manifestation of the effect, and how the effect impacts a person during their lifetime. While TCE can cause a variety of adverse health effects, the general population incidences of these adverse health outcomes are not due solely to TCE.

A. Benefits of the proposed rule and the alternatives that EPA considered

1. *Developmental effects*. The TCE risk assessment (and EPA's 2011 IRIS Assessment) identified developmental effects as the critical effect of greatest concern for both acute and chronic non-cancer risks. There are increased health risks for developmental effects to the approximately 900 pregnant women exposed to TCE during the use of aerosol degreasers and approximately 5,400 pregnant women working in dry cleaning operations (Ref. 2). Specifically, these assessments identified fetal cardiac malformations in the offspring of mothers exposed to TCE during gestation as the critical effect. Although fetal cardiac defects is the most sensitive endpoint and is the focus of the discussion in this Unit, TCE exposures can result in other adverse developmental outcomes, including prenatal (e.g., spontaneous abortion and perinatal death, decreased birth weight, and congenital malformations) and postnatal (e.g., growth, survival, developmental neurotoxicity, developmental immunotoxicity, and childhood cancers)

effects. Developmental TCE exposure results in qualitatively different immunotoxicity effects than adult exposure. These effects influence the development of the immune system and result in impairment of the immune system to respond to infection whereas adult exposures result in more pronounced immune response related to autoimmune responses.

Cardiac defects, which can result from very low level exposure to TCE, affect the structural development of a baby's heart and how it works. The defects impact how blood flows through the heart and out to the rest of the body. The impact can be mild (such as a small hole in the heart) or severe (such as missing or poorly formed septal wall and valves of the heart). While diagnosis for some cardiac defects can occur during pregnancy, for other cardiac defects, detection may not occur until after birth or later in life, during childhood or adulthood. These cardiac defects can be occult or life-threatening with the most severe cases causing early mortality and morbidity. While the incidences in the following paragraphs reflect adverse health outcomes beyond just exposure to TCE, the general population numbers provide a context for understanding the impact of the adverse health effects that TCE can cause.

Nearly 1% or about 40,000 births per year in the United States are affected by cardiac defects (Ref. 46). About 25% of those infants with a cardiac defect have a critical defect. Infants with critical cardiac defects generally need surgery or other procedures in their first year of life. Some estimates put the total number of individuals (infants, children, adolescents, and adults) living with cardiac defects at 2 million (Ref. 46). Cardiac defects can be caused by genetics, environmental exposure, or an unknown cause.

Infant deaths resulting from cardiac defects often occur during the neonatal period. One study indicated that cardiac defects accounted for 4.2% of all neonatal deaths. Of infants born with a non-critical cardiac defect, 97% are expected to survive to the age of one, with 95% expected to survive to 18 years of age. Of infants born with a critical cardiac defect, 75% are expected to survive to one year of age, with 69% expected to survive to 18 years of age (Ref. 47). A child with a cardiac defect is 50% more likely to receive special education services compared to a child without birth defects (Ref. 46).

Treatments for cardiac defects vary. Some affected infants and children might need one or more surgeries to repair the heart or blood vessels. In other instances, a heart defect cannot be fully repaired, although treatments have advanced such that infants are living longer and healthier lives. Many children are living into adulthood and lead independent lives with little or no difficulty. Others, however, may develop disability over time which is hard to predict and for which it is difficult to quantify impacts.

Even though a person's heart defect may be repaired, for many people this is not a cure. They can still develop other health problems over time, depending on their specific heart defect, the number of heart defects they have, and the severity of their heart defect. For example, some related health problems that might develop include irregular heart beat (arrhythmias), increased risk of infection in the heart muscle (infective endocarditis), or weakness in the heart (cardiomyopathy). In order to stay healthy, a person needs regular checkups with a cardiologist. They also might need further operations after initial childhood surgeries (Ref. 46).

Depending upon the severity of the defect, the costs for surgeries, hospital stays,

and doctor's appointments to address a baby's cardiac defect can be significant. The costs for the defects may also continue throughout a person's lifetime. In 2004, hospital costs in the United States for individuals with a cardiac defect were approximately $1.4 billion (Ref. 46).

Beyond the monetary cost, the emotional and mental toll on parents who discover that their child has a heart defect while *in utero* or after birth will be high (Ref. 47). They may experience anxiety and worry over whether their child will have a normal life of playing with friends and participating in sports and other physical activities, or whether their child may be more susceptible to illness and be limited in the type of work and experiences they can have. In addition, parents can be expected to experience concerns over potential unknown medical costs that may be looming in the future, lifestyle changes, and being unable to return to work in order to care for their child.

The emotional and mental toll on a person throughout childhood and into adolescence with a heart defect also should be considered (Ref. 47). Cardiac patients who are children may feel excluded from activities and feel limited in making friends if they have to miss school due to additional surgeries, or may not be able to fully participate in sports or other physical exercise. Children may feel self-conscious of the scars left by multiple surgeries. This, in turn, adds emotional and mental stress to the parents as they observe their child's struggles.

As a person with a heart defect enters adulthood, the emotional or mental toll of a cardiac defect may continue or in other instances the problem may only surface as the person becomes an adult. If a cardiac defect impacts a person's ability to enter certain careers, this could take a monetary as well as emotional toll on that person and on their

parents or families who may need to provide some form of financial support. The monetary, emotional, and mental costs of heart defects can be considerable, and even though neither the precise reduction in individual risk of developing a cardiac defect from reducing TCE exposure or the total number of cases avoided can be estimated, their impact should be considered.

2. *Kidney toxicity.* The TCE risk assessment identified kidney toxicity as a significant concern for non-cancer risk from TCE exposure with the risk being from chronic exposure. There are increased health risks for kidney toxicity to the approximately 10,800 workers and occupational bystanders at commercial aerosol degreasing operations and the up to approximately 168,000 workers and occupational bystanders in dry cleaning operations (Ref. 2).

Exposure to TCE can lead to changes in the proximate 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(s) 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(s) is impaired over a long period of time, the kidney(s) could be damaged to the point that it no longer functions. When a kidney(s) no longer functions, a person needs dialysis and ideally a kidney transplant. In some cases, a non-functioning kidney(s)

can result in death. Kidney dialysis and kidney transplantation are expensive and incur long-term health costs if kidney function fails (Ref. 48).

Approximately 31 million people, or 10% of the adult population, in the United States have chronic kidney disease. In the United States, it is the ninth leading cause of death. About 93% of chronic kidney disease is from known causes, including 44% from diabetes and 28.4% from high blood pressure. Unknown or missing causes account for about 6.5% of cases, or about 2 million people (Ref. 49).

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. 50).

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 TCE exposure or the total number of cases avoided can be estimated, these costs must still be considered because they can significantly impact those exposed to TCE.

Chronic exposure to TCE can also lead to kidney cancer. The estimated value of

the annualized benefit is $276,000 to $661,000 for aerosol degreasing and $1.4 million to $5.5 million for spot cleaning in dry cleaning facilities at 3% over 15 years; and $135,000 to $349,000 for aerosol degreasing and $677,000 to $2.9 million for spot cleaning in dry cleaning facilities at 7% over 15 years. Kidney cancer rarely shows signs or symptoms in its early stages. As kidney cancer progresses, the cancer may grow beyond the kidney spreading to lymph nodes or distant sites like the liver, lung or bladder increasing the impacts on a person and the costs to treat it. This metastasis is highly correlated with fatal outcomes. Impacts of kidney cancer that are not monetized include the emotional, psychological impacts and the impacts of treatment for the cancer on the well-being of the person.

3. *Immunotoxicity. a. Non-cancer chronic effects.* The TCE risk assessment identified immunotoxicity as a chronic non-cancer risk from TCE exposure. There are increased health risks for immunotoxicity to the approximately 10,800 workers and occupational bystanders at commercial aerosol degreasing operations and the up to approximately 168,000 workers and occupational bystanders in dry cleaning operations (Ref. 1).

Human studies have demonstrated that TCE exposed workers can suffer from systemic autoimmune diseases (e.g., scleroderma) and severe hypersensitivity skin disorder. Scleroderma is a chronic connective tissue disease with autoimmune origins. The annual incidence is estimated to be 10 to 20 cases per 1 million persons (Ref. 51), and the prevalence is four to 253 cases per 1 million persons (Ref. 52). About 300,000 Americans are estimated to have scleroderma. About one third of those people have the systemic form of scleroderma. Since scleroderma presents with symptoms similar to

other autoimmune diseases, diagnosis is difficult. There may be many misdiagnosed or undiagnosed cases (Ref. 52).

Localized scleroderma is more common in children, whereas systemic scleroderma is more common in adults. Overall, female patients outnumber male patients about 4-to-1. Factors other than a person's gender, such as race and ethnic background, may influence the risk of getting scleroderma, the age of onset, and the pattern or severity of internal organ involvement. The reasons for this susceptibility are not clear. Although scleroderma is not directly inherited, some scientists believe there is a slight predisposition to it in families with a history of rheumatic diseases (Ref. 53).

The symptoms of scleroderma vary greatly from person-to-person with the effects ranging from very mild to life threatening. If not properly treated, a mild case can become much more serious. Relatively mild symptoms are localized scleroderma, which results in hardened waxy patches on the skin of varying sizes, shapes and color. The more life threatening symptoms are from systemic scleroderma, which can involve the skin, esophagus, gastrointestinal tract (stomach and bowels), lungs, kidneys, heart and other internal organs. It can also affect blood vessels, muscles and joints. The tissues of involved organs become hard and fibrous, causing them to function less efficiently.

Severe hypersensitivity skin disorder includes exfoliative dermatitis, mucous membrane erosions, eosinophilia, and hepatitis. Exfoliative dermatitis is a scaly dermatitis involving most, if not all, of the skin. Eosinophilia on the other hand is a chronic disorder resulting from excessive production of a particular type of white blood cells. If diagnosed and treated early a person can lead a relatively normal life (Ref. 51).

The monetary costs for treating these various immunotoxicity disorders will vary

depending upon whether the symptoms lead to early diagnosis and early diagnosis can influence whether symptoms progress to mild or life threatening outcomes. For mild symptoms, doctors' visits and outpatient treatment could be appropriate while more severe immunotoxicity disorders, may require hospital visits. Treatments for these conditions with immune modulating drugs also have countervailing risks.

These disorders also take an emotional and mental toll on the person as well as on their families. Their quality of life may be impacted because they no longer have the ability to do certain activities that may affect or highlight their skin disorder, such as swimming. Concerns over doctor and hospital bills, particularly if a person's ability to work is impacted, may further contribute to a person's emotional and mental stress. While neither the precise reduction in individual risk of developing this disorder from TCE exposure or the total number of cases avoided can be estimated, this should be considered.

b. *Non-Hodgkin's Lymphoma.* EPA's 2011 IRIS assessment for TCE found that TCE is carcinogenic. Chronic exposure to TCE, by all routes of exposure, can result in non-Hodgkin's lymphoma (NHL), one of the three cancers for which the EPA TCE IRIS assessment based its cancer findings. There are increased health risks for NHL for the approximately 10,800 workers and occupational bystanders at commercial aerosol degreasing operations and the up to approximately 168,000 workers and occupational bystanders in dry cleaning operations (Ref. 2).

NHL is a form of cancer that originates in a person's lymphatic system. For NHL, there are approximately 19.7 new cases per 100,000 men and women per year with 6.2 deaths per 100,000 men and women per year. NHL is the seventh most common form of

cancer (Ref. 53). Some studies suggest that exposure to chemicals may be linked to an increased risk of NHL. 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. 54).

Symptoms are painless, 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 is advancing, the approach may be to monitor the condition, while more aggressive NHL could require chemotherapy, radiation, stem cell transplant, medications that enhance a person's immune system's ability to fight cancer, or medications that deliver radiation directly to cancer cells.

Treatment for NHL will result in substantial costs for hospital and doctors' visits in order to treat the cancer. The treatments for NHL can also have countervailing risks and can lead to higher susceptibility of patients for secondary malignancies (Ref. 55). 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. This emotional and mental toll will extend to the person's family and friends as they struggle with the diagnosis and success and failure of a treatment regime. If a person has children, this could affect their mental and emotional well-being and may impact their success in school. A discussion of the monetized benefits associated with reducing risk of NHL is located in Unit VIII.B. The estimated value of the annualized benefit is $759,000 to $1.2 million for aerosol degreasing and $3.9 million to $10.1 million for spot cleaning in dry cleaning facilities at 3% over 15 years; and $355,000 to

$601,000 for aerosol degreasing and $1.8 million to $5.0 million for spot cleaning in dry cleaning facilities at 7% over 15 years.

4. Reproductive and endocrine effects. The TCE risk assessment identified chronic non-cancer risks for reproductive effects for workers and bystanders exposed to TCE. There are increased health risks for reproductive effects for the approximately 10,800 workers and occupational bystanders at commercial aerosol degreasing operations and the up to approximately 168,000 workers and occupational bystanders in dry cleaning operations (Ref. 2).

The reproductive effect for both females and males can be altered libido. The prevalence of infertility is estimated at about 10-15% of couples with a decreased libido among the factors of infertility (Ref. 56). For females, there can be reduced incidence of fecundability (6.7 million women ages 15 to 44 or 10.9% affected) (Ref. 57), increase in abnormal menstrual cycle, and amenorrhea (the absence of menstruation). Reproductive effects on males can be decreased potency, gynaecomastia, impotence, and decreased testosterone levels, or low T levels. Approximately 2.4 million men age 40 to 49 have low T levels, with a new diagnosis of about 481,000 androgen deficiency cases a year. Other estimates propose a hypogonadism prevalence of about 13 million American men (Ref. 58). Low T levels are associated with aging; an estimated 39% of men 45 or older have hypogonadism, resulting in low T levels (Ref. 59). Hormone therapy and endocrine monitoring may be required in the most severe cases. Low T levels are associated with aging; an estimated 39% of men 45 or older have hypogonadism, resulting in low T levels (Ref. 59). Hormone therapy and endocrine monitoring may be required in the most severe cases.

The monetary costs of these potential reproductive effects involve doctor's visits in order to try to determine why there is a change. In some instances, a person or couple may need to visit a fertility doctor.

The impact of a reduced sex drive can take an emotional and mental toll on single people as well as couples. For people trying to get pregnant, decreased fertility can add stress to a relationship as the cause is determined and avenues explored to try to resolve the difficulties in conceiving. A person or couples' quality of life can also be affected as they struggle with a reduced sex drive. Similar to effects discussed previously, while neither the precise reduction in individual risk of developing this disorder from reducing TCE exposure or the total number of cases avoided can be estimated, the Agency still considers their impact.

5. Neurotoxicity. The TCE risk assessment identified chronic risks for neurotoxicity for workers and bystanders. There are increased health risks for neurotoxicity to the approximately 10,800 workers and bystanders at commercial aerosol degreasing operations and the up to approximately 168,000 workers and bystanders in dry cleaning operations (Ref. 2).

Studies have also demonstrated neurotoxicity for acute exposure. Neurotoxic effects observed are alterations in trigeminal nerve and vestibular function, auditory effects, changes in vision, alterations in cognitive function, changes in psychomotor effects, and neurodevelopmental outcomes. Developmental neurotoxicity effects are delayed newborn reflexes, impaired learning or memory, aggressive behavior, hearing impairment, speech impairment, encephalopathy, impaired executive and motor function and attention deficit (Ref. 3).

The impacts of neurotoxic effects due to TCE exposure can last a person's entire lifetime. Changes in vision may impact a person's ability to drive, which can create difficulties for daily life. Impaired learning or memory, aggressive behavior, hearing impairment, speech impairment, encephalopathy, impaired executive and motor function and attention deficit can impact a child's educational progression and adolescent's schooling and ability to make friends, which in turn can impact the type of work or ability get work later in life.

Neurotoxicity in adults can affect the trigeminal nerve, the largest and most complex of the 12 cranial nerves, which supplies sensations to the face, mucous membranes, and other structures of the head. Onset of trigeminal neuralgia generally occurs in mid-life and known causes include multiple sclerosis, sarcoidosis and Lyme disease. There is also a co-morbidity with scleroderma and systemic lupus. Some data show that the prevalence of trigeminal neuralgia could be between 0.01% and 0.3% (Ref. 60). Alterations to this nerve function might cause sporadic and sudden burning or shock-like facial pain to a person. One way to relieve the burning or shock-like facial pain is to undergo a procedure where the nerve fibers are damaged in order to block the pain. This treatment can have lasting impact on sensation which may also be deleterious for normal pain sensation. The potential side effects of this procedure includes facial numbness and some sensory loss.

The monetary health costs can range from doctor's visits and medication to surgeries and hospital stays. Depending upon when the neurotoxic effect occurred, the monetary costs may encompass a person's entire lifetime or just a portion.

The personal costs (emotional, mental, and impacts to a person's quality of life)

cannot be discounted. Parents of a child with impaired learning, memory, or some other developmental neurotoxic effect may suffer emotional and mental stress related to worries about the child's performance in school, ability to make friends, and quality of the child's life because early disabilities can have compounding effects as they grow into adulthood. The parent may need to take off work unexpectedly and have the additional cost of doctor visits and/or medication.

For a person whose trigeminal nerve is affected there is an emotional and mental toll as they wonder what is wrong and visit doctors in order to determine what is wrong. Depending on the severity of the impact to the nerve they may be unable to work. Doctor visits and any inability to work will have a monetary impact to the person. There are varying costs (emotional, monetary, and impacts to a person's quality of life) from the neurotoxicity effects due to TCE exposure. However, while neither the precise reduction in individual risk of developing this disorder from reducing TCE exposure or the total number of cases avoided can be estimated, this is not a reason to disregard their impact.

6. Liver toxicity. The TCE risk assessment identified liver toxicity as an adverse effect of chronic TCE exposure. There are increased health risks for liver toxicity to the approximately 10,800 workers occupational bystanders at commercial aerosol degreasing operations and the up to approximately 168,000 workers and occupational bystanders in dry cleaning operations (Ref. 1).

Specific effects to the liver can include increased liver weight, increase in DNA synthesis (transient), enlarged hepatocytes, enlarged nuclei, and peroxisome proliferation (Ref. 1). In addition, workers exposed to TCE have shown hepatitis accompanying immune-related generalized skin diseases, jaundice, hepatomegaly, hepatosplenomegaly,

and liver failure (Ref. 1).

Some form of liver disease impacts at least 30 million people, or 1 in 10 Americans (Ref. 61). Included in this number is at least 20% of those with nonalcoholic fatty liver disease (NAFLD) (Ref. 61). NAFLD tends to impact people who are overweight/obese or have diabetes. However, an estimated 25% do not have any risk factors (Ref. 61). 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. 61). The most common known causes to this disease burden are attributable to alcoholism and viral infections, such as hepatitis A, B, and C. In 2013, there were 1,781 reported acute cases of viral hepatitis A and the estimated actual cases were 3,500 (Ref. 62). For hepatitis B in 2013 there were 3,050 reported acute cases, while the estimated actual incidence was 19,800, and the estimated chronic cases in the United States is between 700,000 to 1.4 million (Ref. 62). For hepatitis C, in 2013 there were 2,138 reported cases; however, the estimated incidence was 29,700 and the estimated number of chronic cases is between 2.7 to 3.9 million (Ref. 62). These known environmental risk factors of hepatitis infection may result in increased susceptibility of individuals exposed to organic chemicals.

Effects from TCE exposure to the liver can occur quickly. Liver weight increase has occurred in mice after as little as 2 days of inhalation exposure (Ref. 3). Human case reports from eight countries indicated symptoms of hepatitis, hepatomegaly and elevated liver function enzymes, and in rare cases, acute liver failure developed within as little as 2-5 weeks of initial exposure to TCE (Ref. 3).

Chronic exposure to TCE can also lead to liver cancer. There is strong

epidemiological data that reported an association between TCE exposure and the onset of various cancers, including liver cancer. The estimated value of the annualized benefit is $493,000 to $811,000 for aerosol degreasing and $2.5 million to $6.7 million for spot cleaning in dry cleaning facilities at 3% over 15 years; and $252,000 to $436,000 for aerosol degreasing and $1.3 million to $3.6 million for spot cleaning in dry cleaning facilities at 7% over 15 years.

Additional medical and emotional costs are associated with non-cancer liver toxicity from TCE exposure, although they cannot be quantified. These costs include doctor and hospital visits and medication costs. In some cases, the ability to work can be affected, which in turn impacts the ability to get proper ongoing medical care. Liver toxicity can lead to jaundice, weakness, fatigue, weight loss, nausea, vomiting, abdominal pain, impaired metabolism, and liver disease. Symptoms of jaundice include yellow or itchy skin and a yellowing of the whites of the eye, and a pale stool and dark urine. These symptoms can create a heightened emotional state as a person tries to determine what is wrong with them.

Depending upon the severity of the jaundice, treatments can range significantly. Simple treatment may involve avoiding exposure to the TCE; however, this may impact a person's ability to continue to work. In severe cases, the liver toxicity can lead to liver failure, which can result in the need for a liver transplant, 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. 63). The mental and emotional toll on an individual and their family as they try to determine 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.

7. Disproportionate impacts on environmental justice communities. An additional factor that cannot be monetized is the disproportionate impact on environmental justice communities. Asian and Hispanic populations are disproportionately represented in dry cleaning facilities. 13% of dry cleaning workers are Asian, compared to 5% of the national population, and 30% of dry cleaning workers are Hispanic (of any race), compared to 16% of the national population, indicating that these two populations are over-represented. Because they are disproportionately over-represented in the dry cleaning industry, these populations are disproportionately exposed to TCE during spot cleaning in dry cleaning facilities and disproportionately at risk to the range of adverse non-cancer effects and cancer.

B. Monetized benefits of the proposed rule and the alternatives that EPA considered.

The benefits that can be monetized from risk reductions due to the proposed prohibitions on manufacture, processing, and distribution in commerce of TCE for aerosol degreasing, and the prohibition on commercial use of TCE in aerosol degreasing are estimated to be $1.5 million to $2.7 million (annualized at 3% over 15 years) and $700,000 to $1.4 million (annualized at 7% over 15 years). The monetized benefits from similar prohibitions to mitigate the risks from TCE for spot cleaning in dry cleaning facilities are estimated to be $7.8 million to $22.3 million (annualized at 3% over 15 years) and $3.7 million to $11.4 million (annualized at 7% over 15 years). The total monetized benefits for the proposed rule range from approximately $9.2 million to $24.8 million on an annualized basis over 15 years at 3% and $4.4 million to $12.6 million at 7%. The alternatives considered are unlikely to result in the same health benefits as the

proposed rule for the reasons discussed in Units VI and VII. However, EPA was unable to quantify the differences in benefits that would result from the alternatives.

C. Costs of the proposed rule and the alternatives that EPA considered

The details of the costs of the proposed approach for use of TCE in aerosol degreasing are discussed in Unit VI.C.1 and the details of the costs of the proposed approach for spot cleaning in dry cleaning facilities are discussed in Unit VII.C.1. Under the proposed option, costs to users of aerosol degreasers are negligible as substitute products are currently available on the market and are similarly priced. Total costs of aerosol degreasing product reformulations are estimated to be approximately $416,000 in the first year and $32,000 per year (annualized at 3% over 15 years) and $41,000 (annualized at 7% over 15 years). Costs of downstream notification and recordkeeping are estimated to be $51,000 in the first-year and on an annualized basis over 15 years are $3,900 and $5,000 using 3% and 7% discount rates respectively. Agency costs for enforcement are estimated to be approximately $112,000 and $109,000 annualized over 15 years at 3% and 7%, respectively. The total cost of the proposed approach for the aerosol degreasing use is estimated to be $37,000 to $40,000 and $46,000 to $49,000 annualized over 15 years at 3% and 7%, respectively. Annual recurring costs to the Agency for enforcement are estimated to be $121,000 per year.

Under the proposed approach, dry cleaners are expected to switch to alternatives because they are readily available at similar cost and performance. Blenders of TCE spot cleaners are expected to reformulate their products. Total costs of reformulation are estimated to be $286,000 in the first year and annualized costs are approximately $22,000 per year (annualized at 3% over 15 years) and $28,000 (annualized at 7% over 15 years).

Costs of downstream notification and recordkeeping are estimated to be $51,000 in the first-year and on an annualized basis over 15 years are $3,900 and $5,000 using 3 and 7 percent discount rates respectively. Agency costs for enforcement are estimated to be approximately $112,000 to $109,000 annualized over 15 years at 3% and 7%. Annual recurring costs to the Agency for enforcement are estimated to be $121,000 per year. The total cost of the proposed approach for the dry cleaning spotting use is estimated to be $130,000-$133,000 and $135,000-$137,000 annualized over 15 years at 3% and 7%, respectively.

Total costs of the proposed rule for both uses are estimated to be $170,000 annualized over 15 years at 3% and $183,000 annualized over 15 years at 7%.

Alternatives that EPA considered include the use of PPE as well as an option that would prohibit the use of TCE in aerosol degreasing and as a spot cleaner at dry cleaning facilities, without the companion prohibition on manufacture, processing, or distribution in commerce for these uses or the downstream notification requirements. As discussed in Unit VI.,. EPA assumed that no users would adopt PPE because the per-facility costs were prohibitively expensive. The estimated annualized costs of switching to a respiratory protection program requiring PPE of 10,000 are $8,200 at 3% and $9,000 at 7% per dry cleaning facility and $8,300 at 3% and $9,100 at 7% per aerosol degreasing facility over 15 years. EPA also found that a use prohibition alone without downstream notification requirements would not address the identified unreasonable risks. EPA estimated the costs of this option to be $166,000 annualized over 15 years at 3% and $178,000 annualized over 15 years at 7%.

D. Comparison of benefits and costs

The monetized benefits for preventing the risks resulting from TCE exposure from both these uses significantly outweigh the estimated costs. Even though simply comparing the costs and monetized benefits of prohibiting the manufacture, processing, and distribution in commerce of TCE as an aerosol degreaser; prohibiting its use as an aerosol degreaser; and requiring downstream notification demonstrates that the monetized benefits of this proposed action outweigh the 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 TCE exposure can profoundly impact an individual's quality of life. Some of the adverse effects associated with TCE exposure can be immediately experienced and can affect a person from childhood throughout a lifetime (e.g., cardiac malformations, developmental neurotoxicity, and developmental immunotoxicity). Others (e.g., adult immunotoxicity, kidney and liver failure or cancers) 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 TCE exposure cannot be quantitatively estimated, the qualitative discussion highlights how some of these non-cancer effects occurring much earlier in life from TCE exposure may be as severe as cancer's mortality and morbidity 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.

While the impacts of non-cancer effects cannot be monetized, EPA considered the impacts of these effects in making its determination about how best to address the

unreasonable risks presented by TCE use in aerosol degreasing and as a spot cleaner in dry cleaning facilities. Considering only monetized benefits would significantly underestimate the impacts of TCE-induced non-cancer adverse outcomes on a person's quality of life to perform basic skills of daily living, including the ability to earn a living, the ability to participate in sports and other activities, and the impacts on a person's family and relationships.

Thus, considering costs, benefits that can be monetized (risk of cancer), and benefits that cannot be quantified and subsequently monetized (risk of developmental toxicity, kidney toxicity, immunotoxicity, reproductive toxicity, neurotoxicity, and liver toxicity), including benefits related to the severity of the effects and the impacts on a person throughout her/his lifetime in terms of medical costs, effects on earning power and personal costs, emotional and psychological costs, and the disproportionate impacts on Asian and Hispanic communities, the benefits of preventing TCE exposure outweigh the costs. Further, if EPA were to consider only the benefits that can be monetized in comparison to the cost, the monetized benefits from preventing kidney and liver cancer and non-Hodgkin's lymphoma from the use of TCE in aerosol degreasing (the annualized monetized benefits on a 15 year basis range from approximately $1.5 million to $2.7 million at 3% and $700,000 to $1.4 million at 7%) and the use of TCE in spot cleaners in dry cleaning facilities (the annualized monetized benefits on a 15 year basis range from approximately $7.8 million to $22.3 million at 7% and $3.7 million to $11.4 million at 3%) far outweigh the costs of the proposed approaches for use of TCE in aerosol degreasing (the annualized costs on a 15 year basis range from approximately $37,000 to $40,000 at 3% and $46,000 to $49,000 at 7%) and for use of TCE in spot cleaners in dry

cleaning facilities (the annualized costs on a 15 year basis range from approximately $130,000 to $133,000 at 3% and $135,000 to $137,000 at 7%).

IX. Overview of Uncertainties

A discussion of the uncertainties associated with this proposed rule can be found in the TCE risk assessment (Ref. 1) and in the supplemental analysis (Refs. 23, 24, 25) for use of TCE in aerosol degreasing and use of TCE for spot cleaning in dry cleaning facilities. A summary of these uncertainties follows.

EPA used a number of assumptions in the TCE 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: (1) Releases of and exposures to TCE can vary from one aerosol degreasing activity 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 aerosol degreasing, there are uncertainties in the number of workers exposed to TCE and in the inputs to the models used to estimate exposures. (2) Although EPA found information about TCE products intended for consumer use, there is some general uncertainty regarding the nature and extent of the consumer use of aerosol products containing TCE. (3) Releases of and exposures to TCE can vary from one dry cleaning facility to the next. EPA attempted to quantify this uncertainty by evaluating multiple scenarios to establish a range of releases and exposures. There is also uncertainty in the number of workers exposed to TCE for spot cleaning in dry cleaning facilities. There are uncertainties in the model and inputs used to model the exposures to TCE from these uses.

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 non-cancer adverse effects 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 include the reliance on professional judgment to estimate the alternatives that users might choose to adopt and the potential risks for adverse health effects that the alternatives may pose. While there are some products that have comparable risks, there are a number of alternatives that are likely to be of lower risk, although EPA is unable to estimate the incremental change in the risk. To account for this uncertainty, EPA includes a lower and a higher estimate for the benefits from eliminating exposure to TCE. The lower benefits estimate does not include any benefits for firms that switch to anything other than water-based, methyl ester (soy-based) cleaners, or acetone degreasers. The higher benefits estimate includes the benefit from entirely eliminating TCE exposure for all alternative compliance strategies and assumes that no risks are introduced by alternatives. This inability to adequately account for adverse health effects of alternatives in the benefits analysis is expected to contribute most to the uncertainty in the estimates.

There are also uncertainties in the estimates of the number of affected facilities, particularly those for the aerosol degreasing use and for numbers of processors and distributors of TCE-containing products not prohibited by the proposed rule who are required to provide downstream notification and/or maintain records. The estimate for number of facilities using TCE-containing aerosol degreasers is based on EPA

calculations using data derived from the California Air Resources Board Initial Statement of Reasons for the Proposed Airborne Toxic Control Measure for Emissions of Chlorinated Toxic Air Contaminants from Automotive Maintenance and Repair Activities (Ref. 2). To estimate the number of processors, EPA relied on public 2012 CDR data. The number of sites is reported in the CDR data as a range. The midpoint of the reported ranges was used to estimate the total number of sites using the chemical. Furthermore, the CDR data only include processors immediately downstream of those reporting to CDR. Finally, EPA estimated the number of wholesaler firms distributing products containing TCE by taking a ratio of the number of Chemical and Allied Products Merchant Wholesaler firms to Basic Chemical Manufacturing firms and applying it to the estimated number of manufacturers and processors of TCE (Ref. 2).

Another uncertainty concerns the estimate for the cost of reblending products and the time required to reblend those products. EPA used a study on the automotive aftermarket parts products industry that provided a range of costs for product reformulation and used the mean value of $26,000 from that study. EPA contacted both dry cleaners and blenders of aerosol degreasing products for additional information and received a few estimates from the aerosol degreasing product blenders which ranged from $15,000 to $30,000. However, EPA received no information from dry cleaning spot cleaning product blenders, so there is some uncertainty as to how representative the estimate is for that industry.

EPA also assumes that companies are generally able to reblend products within 6 months following publication of the final rule; however, it is not certain whether they may experience additional costs if they are not able have a product available to market at

that time.

EPA will consider additional information received during the public comment period, including comments on implementation timeframes. This includes public comments, scientific publications, and other input submitted to EPA during the comment period.

X. Analysis under Section 9 of TSCA (Other Authorities) for Aerosol Degreasing and Spot Cleaning in Dry Cleaning Facilities and TSCA Section 26(h) Considerations

A. Section 9 Analysis

1. Section 9(a) analysis. Section 9(a) of TSCA provides that, if the Administrator determines in her discretion that unreasonable risks may be prevented or reduced to a sufficient extent by 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 unreasonable risks or if that agency initiates action under its own law to protect against the risk, EPA is precluded from acting against the risk under sections 6 or 7 of TSCA.

Section 9(d) of TSCA 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 today's proposed rule, EPA has consulted with CPSC and OSHA.

CPSC protects the public from unreasonable risks of injury or death associated with the use of consumer products under the agency's jurisdiction. There are no CPSC

regulations on use of TCE in aerosol degreasers and for spot cleaning at dry cleaning facilities (Ref. 64).

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 adopted an eight-hour time weighted average PEL of 100 ppm along with a ceiling limit in 1971 shortly after the agency was formed. It was based on the American Conference of Governmental Industrial Hygienists (ACGIH) recommended occupational exposure limit that was in place at that time. OSHA recognizes that the TCE PEL and many other PELs issued shortly after adoption of the OSHA Act in 1970 are outdated and inadequate for ensuring protection of worker health. OSHA recently published a Request for Information on approaches to updating PELs and other strategies to managing chemicals in the workplace (Ref. 9). OSHA's current regulatory agenda does not include revision to the TCE PEL or other regulations addressing the risks EPA has identified when TCE is used in aerosol degreasing or for spot cleaning in dry cleaning facilities (Ref. 9).

EPA has determined that risks from the use of TCE in aerosol spray degreasers and as a spot cleaner in dry cleaning facilities are best managed by regulation under TSCA rather than by referral to other agencies. Today's proposed rule addresses risk from TCE exposure to populations in both workplaces 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

proposed rulemaking under TSCA. 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 TCE risk, such as consumer products. And neither agency has authority to bar the manufacture, processing or distribution for these uses and require downstream notification of restrictions like EPA proposes to do.

Moreover, recent amendments to TSCA, Pub. L. 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 these uses of TCE 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(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, October 10, 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 risk from these uses of TCE 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. Accordingly, EPA determines that referral to other Federal authorities for risk management would not necessarily address the unreasonable risk. As noted previously, 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 these uses of TCE may be prevented or reduced to a sufficient extent by an action taken under a Federal law not

administered by EPA.

2. Section 9(b) analysis. If EPA determines that actions under other Federal authorities administered in whole or in part by EPA may eliminate or sufficiently reduce unreasonable risks, section 9(b) of TSCA instructs EPA to use these other statutes 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 determination, section 9(b)(2) of TSCA 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 TCE exposure, as discussed in Unit III.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 TCE is used. Under RCRA, TCE that is discarded may be considered a hazardous waste and subject to requirements designed to reduce exposure from the disposal of TCE to air, land and water. RCRA does not address exposures during use of products containing TCE. Only TSCA provides EPA the authority to regulate the manufacture (including import), processing, and distribution in commerce, and use of chemicals substances.

B. Section 26(h) Considerations

In proposing this rule under section 6 of TSCA, the EPA has made a decision based on science. EPA has used scientific information, technical procedures, measures,

methods, protocols, methodologies, and models consistent with the best available science. Specifically, EPA based its preliminary determination of unreasonable risk presented by the use of TCE in aerosol degreasing products and as a spot cleaner in dry cleaning facilities on the completed risk assessment, which followed a peer review and public comment process, as well as using best available science and methods (Ref. 1). 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*.

The scientific information and technical measures and models used in the risk assessment and supplemental analyses are consistent with the intended use for risk reduction by regulation under section 6 of TSCA. The degree of clarity and completeness of the science used in the risk assessment and supplemental analyses are described in the risk assessment (Ref. 1) and Unit IX. Similarly, the variability and uncertainty in the information or models and methods used are described in the risk assessment (Ref. 1) and Unit IX.

XI. Major Provisions of the Proposed Rule

A. Prohibitions on TCE Manufacturing, Processing, Distribution in Commerce, and Commercial Use

The rule would prohibit 1) the manufacture, processing, distribution in commerce, and commercial use of TCE in aerosol degreasers; and 2) the manufacture, processing, distribution in commerce, and use of TCE for spot cleaning in dry cleaning facilities.

B. Downstream Notification

EPA has authority under 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 TCE manufacturers and processors are likely to manufacture or process TCE or TCE containing products for other uses that would not be regulated under this proposed rule. Other companies may be strictly engaged in distribution in commerce of TCE, 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 TCE for any use to ensure compliance with the prohibition on manufacture, processing, distribution in commerce, and commercial use of TCE for spot cleaning in dry cleaning facilities and in aerosol degreasers. 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 TCE for spot cleaning in dry cleaning facilities and in aerosol degreasers, which is likely to decrease unintentional uses of TCE by these entities. Downstream notification represents minimal burden and is necessary for effective enforcement of the rule. The estimated cost of downstream notification is $51,000 in the first year and $3,900 and $5,000 on an annualized basis over 15 years using 3 and 7 percent discount rates respectively.

C. Enforcement

Section 15 of TSCA makes it unlawful to fail or refuse to comply with any provision of a rule promulgated under section 6 of TSCA. 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.

XII. 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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XIII. Statutory and Executive Order Reviews

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

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

This action is a significant regulatory action because it may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866 (58 FR 51735, October 4, 1993). Accordingly, EPA submitted the action to the Office of Management and Budget (OMB) for review under Executive Order 12866 and Executive Order 13563 (76 FR 3821, January 21, 2011), and

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 Unit VIII. (Ref. 2).

B. Paperwork Reduction Act (PRA)

The information collection requirements in this proposed rule have been submitted to OMB for review and comment 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 2541.01. You can find a copy of the ICR in the docket for this proposed rule, and it is briefly summarized here.

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 TCE to notify companies downstream in the supply chain of the prohibitions of TCE 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 TCE to retain certain information at the company headquarters for two 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 TCE supply chain, and to provide EPA with information upon inspection of companies downstream who purchased TCE. EPA believes that these information collection activities would not significantly impact the regulated entities.

Respondents/affected entities: TCE manufacturers, processors, and distributors.

Respondent's obligation to respond: Mandatory.

Estimated number of respondents: 697.

Frequency of response: On occasion.

Total estimated burden: 348.5 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $16,848 (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 [insert date 30 days after publication in the *Federal Register*]. The EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq*. The small entities subject to the requirements of this action are blenders of TCE-containing dry cleaning spot removers and aerosol degreasers, users of dry cleaning spot removers and

aerosol degreasers, and manufacturers, processors, and distributors of non-prohibited TCE-containing products. Users of these products are not expected to experience costs as there are currently a number of alternatives available that are similar in performance and cost. There are no small governmental jurisdictions or non-profits expected to be affected by the proposed rule. Overall, EPA estimates there are approximately 51,000 small entities affected by the proposed rule.

Comparing the total annualized compliance cost for companies to their revenue, the Agency has estimated that all companies are expected to have cost impacts of less than one percent of their revenues, ranging from an estimated high of 0.3 percent of revenues to a low of 0.01 percent of revenues. Details of this analysis are presented in the Economic Analysis for this proposed rule (Ref. 2).

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 TCE. The total estimated annualized cost of the proposed rule is approximately $170,000 at 3% and $183,000 at 7% (Ref. 2).

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 preliminary federalism summary impact statement. The Agency consulted with state and local officials early in the process of developing the proposed action to permit them to have

meaningful and timely input into its development. 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. 65). Although EPA provided these organizations an opportunity to provide follow-up comments in writing, no written follow-up was received by the Agency.

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 TCE is not manufactured, processed, or distributed in commerce by tribes. TCE is not regulated by tribes, 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 TCE under TSCA section 6, and in another teleconference with tribal officials on May 27, 2015 (Ref. 66). EPA also met with the

National Tribal Toxics Council (NTTC) in Washington, D.C. and via teleconference on April 22, 2015 (Ref. 66). In those meetings, EPA provided background information on the proposed rule and a summary of issues being explored by the Agency. These officials expressed concern for TCE contamination on tribal lands and supported additional regulation of TCE.

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

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866. This action's health and risk assessment of TCE exposure on children are contained in Units VI.B.1.c and VII.B.1.c of this preamble. Supporting information on the exposures and health effects of TCE exposure on children is also available in the Toxicological Review of Trichloroethylene (Ref. 3) and the TCE risk assessment (Ref. 1).

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 TCE, 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.

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.B., VII.B, and VIII. of this preamble address public health impacts from TCE. EPA has determined that there would not be a disproportionately high and adverse health or environmental effects on minority, low income, or indigenous populations from this proposed rule.

List of Subjects in 40 CFR Part 751

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

Dated: December 6, 2016,

Gina McCarthy,

Administrator.

Therefore, it is that 40 CFR chapter I, subchapter R, is proposed to be amended by adding a new part 751 to read as follows:

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

Subpart A—General Provisions

Sec.

751.1 Purpose.

751.5 Definitions.

751.7 Exports and imports.

751.9 Enforcement and Inspections.

Subpart B—[RESERVED]

Subpart C—[RESERVED]

Subpart D—Trichloroethylene

751.301 General.

751.303 Definitions.

751.305 Aerosol Degreasing.

751.307 Spot Cleaning in Dry Cleaning Facilities.

751.309 [RESERVED].

751.311 Downstream Notification.

751.313 Recordkeeping.

Authority: 15 U.S.C. 2605

Subpart A—General Provisions

§ 751.1 Purpose.

This part sets forth requirements, such as prohibitions concerning the manufacture (including import), processing, distribution in commerce, uses, and/or disposal of certain chemical substances and mixtures under section 6(a) of the Toxic Substances Control Act, 15 U.S.C. 2605(a).

§ 751.5 Definitions.

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

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

CASRN means Chemical Abstracts Service Registry Number.

EPA means the U.S. Environmental Protection Agency.

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

§ 751.7 Exports and imports.

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

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

127.28.

§ 751.9 Enforcement and Inspections.

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

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

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

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

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

Subpart B—[RESERVED]

Subpart C—[RESERVED]

Subpart D—Trichloroethylene

§ 751.301 General.

This subpart sets certain restrictions on the manufacture (including import), processing, distribution in commerce, and uses of trichloroethylene (TCE) (CASRN 79-01-6) to prevent unreasonable risks to health associated with human exposure to TCE for the specified uses.

§ 751.303 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:

Aerosol degreasing means the use of a chemical in aerosol spray products applied from a pressurized can to remove contaminants.

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 §751.311 and §751.313.

Dry cleaning facility means an establishment with one or more dry cleaning systems.

Dry cleaning system means a dry-to-dry machine and its ancillary equipment or a transfer machine system and its ancillary equipment.

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

Spot cleaning means use of a chemical to clean stained areas on materials such as textiles or clothing.

§ 751.305 Aerosol Degreasing.

(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 TCE in aerosol degreasing products and TCE for use in aerosol degreasing products.

(b) After [*Date 270 calendar days after the date of publication of the final rule*], all persons are prohibited from commercial use of TCE in aerosol degreasing products.

§ 751.307 Spot Cleaning at Dry Cleaning Facilities.

(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 TCE for spot cleaning at dry cleaning facilities.

(b) After [*Date 270 calendar days after the date of publication of the final rule*], all persons are prohibited from commercial use of TCE for spot cleaning at dry cleaning facilities.

§ 751.309 [RESERVED].

§ 751.311 Downstream Notification.

Each person who manufactures, processes, or distributes in commerce TCE 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 TCE is shipped, in writing, of the restrictions described in this subpart.

§ 751.313 Recordkeeping.

(a) Each person who manufactures, processes, or distributes in commerce any TCE 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 of:

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

(2) The amount of TCE shipped.

(3) Downstream notification.

(b) The documentation in (a) must be retained for 2 years from the date of shipment.

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