ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA–HQ–OPPT–2016–0387; FRL–9950–08]

RIN 2070–AK11

Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing Under TSCA Section 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 vapor degreasing and EPA's proposed determination is 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 (including import), processing, and distribution in commerce of TCE for use in vapor degreasing; to prohibit commercial use of TCE in vapor degreasing; 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 March 20, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0387, 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 Once submitted, comments cannot be edited or withdrawn.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 ID No. EPA–HQ–OPPT–2016–0387 contains supporting information used in developing the proposed rule, comments on the proposed rule, and additional supporting information. In addition to being available online at *http://www.regulations.gov,* 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:* Cindy Wheeler, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 566–0484; email address: *wheeler.cindy@epa.gov*.

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

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this proposed action if you manufacture (defined under TSCA to include import), process, or distribute in commerce TCE or commercially use TCE in vapor degreasers. 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:

- 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 TSCA section 6(a) rule are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

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

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

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines after risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk.

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 authorizes EPA to issue rules under TSCA section 6(a) that are consistent with the scope of the completed risk assessment and consistent with the other applicable requirements of TSCA section 6. 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 vapor degreasing.

C. What action is the Agency taking?

EPA's proposed determination is that the use of TCE in vapor degreasing presents an unreasonable risk of injury to health. Accordingly, EPA is proposing under TSCA section 6 to prohibit the manufacture (including import), processing, and distribution in commerce of TCE for use in vapor degreasing; to prohibit commercial use of TCE in vapor degreasing; and to require manufacturers, processors, and distributors, except for retailers, to provide downstream notification of this prohibition throughout the supply chain (*e.g.,* via a Safety Data Sheet (SDS)), and to keep records. The application of this supply chain approach is necessary so that TCE no longer presents the identified unreasonable risks. EPA is requesting public comment on this proposal.

This proposal is related to the proposed rule on TCE aerosol degreasing and spot cleaning in dry cleaning facilities that published in the **Federal Register** on December 16, 2016 (81 FR 91592) (FRL–9949–86) (Ref. 1). This proposal and the earlier proposal together address risks for workers and consumers associated with exposure to TCE through inhalation that were identified in the 2014 TCE risk assessment and EPA intends to finalize both actions together.

D. Why is the Agency taking this action?

Based on EPA's analysis of worker exposures to TCE, EPA's proposed determination is that the use of TCE in vapor degreasing presents an unreasonable risk to human health. More specifically, this use results in significant non-cancer risks under both acute and chronic exposure scenarios and significant cancer risks from chronic exposures. These adverse health effects include those resulting from 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. 2). TCE may cause fetal cardiac malformations that begin in utero. Cardiac malformations can be irreversible and impact a person's health for a lifetime. In addition, fetal death, possibly resulting from cardiac malformation, can be caused by exposure to TCE. 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. As such, the application of this proposal's supply chain approach tailored to specific uses that present unreasonable risks 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 vapor degreasing; prohibiting the commercial use of TCE in vapor degreasing; 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 (Ref. 3), which is available in the docket, is discussed in Unit VI., and is briefly summarized here.

Alternatives to TCE with similar performance characteristics are readily available. Most of the costs of the rule would be borne by commercial users of TCE in vapor degreasing equipment, because they would have to switch solvents and likely equipment as well. EPA has estimated that the costs to users range from $30M to $45M when annualized over 20 years at a 3% discount rate, and from $32M to $46M over 20 years at a 7% discount rate. These are the total estimated costs of this proposal. The costs of the downstream notification and recordkeeping requirements to manufacturers, processors, and distributors of TCE, estimated to be approximately $3,200 and $4,400 annualized over 20 years using 3% and 7% discount rates respectively. For additional information see Unit 5.1.3 of the Economic Analysis. (Ref. 3) However, because these notification and recordkeeping costs were already accounted for in the economic analysis accompanying the earlier TCE proposal (Ref. 1), they are not included in the total costs for this proposal. EPA accounted for these costs in the prior proposal because it believes the universe of entities distributing TCE for both sets of uses are the same. EPA is taking comment on whether the same firms distribute TCE for these two sets of uses.

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 for non-cancer benefits in the overall benefits at this time. The monetized benefits for the proposed approach range from approximately $65 to $443 million on an annualized basis over 20 years at 3% and $31 million to $225 million at 7% (Ref. 3). The non-monetized benefits resulting from the prevention of the non-cancer adverse effects associated with TCE exposure from use in vapor degreasers include developmental toxicity, toxicity to the kidney, immunotoxicity, reproductive and endocrine effects, neurotoxicity, and toxicity to the liver (Ref. 2). Some of the effects that can be caused by exposure to TCE, such as cardiac malformations and fetal death, occur in utero and can impact a person 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 impacts. Also see Unit VI.D.

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 Integrated Risk Information System (IRIS) TCE assessment concluded that fetal heart malformations are the most sensitive developmental toxicity endpoint associated with TCE inhalation exposure (Ref. 4). 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) 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. 2). 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. 5). For the identified susceptible subpopulations, the proposed regulatory action is protective of the fetal heart malformation endpoint and, for the exposed population as a whole, the proposal is also protective of cancer risk. In addition, 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. 2) also meets the 1995 EPA Policy on Evaluating Health Risks to Children (Ref. 6). Supporting information on TCE exposures and the health effects of TCE exposure on children are also available in the IRIS Toxicological Review of Trichloroethylene (Ref. 4) and the TSCA Chemical Work Plan Risk Assessment on Trichloroethylene (Ref. 2), as well as Unit VI of this preamble.

II. Overview of TCE and the Use Subject to This Proposed Rule

A. What chemical is included in the proposed rule?

This proposed rule applies to TCE (Chemical Abstract Services Registry Number 79–01–6) for use in vapor degreasing.

B. What are the uses of TCE?

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. 2).

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. 2). EPA did not assess this use and is not proposing to regulate this use of TCE under TSCA at this time. However, this does not mean that EPA found that this use or other uses not included in the TCE risk assessment present low risk. Much of the remainder, about 14.7%, is used as a solvent for degreasing of metals. A relatively small percentage, about 1.7%, accounts for all other uses, including TCE use in products, such as aerosol degreasers.

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. 2). 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 TRI data does not represent all of the facilities manufacturing, processing, and/or using TCE because only certain industries and types of facilities are required to report. EPA estimates that there are 2,632 to 6,232 firms using TCE for vapor degreasing in the U.S. (Ref. 3).

The use assessed by EPA that is the subject of this proposal, commercial use of TCE in vapor degreasing, is estimated to represent up to 14.7% of total use of TCE. This use is discussed in detail in Unit VI.

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. 2).

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. 2). EPA's IRIS assessment (Ref. 4) 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. 4).

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: 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 reduced growth, decreased 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. 2).

Immune-related effects following TCE exposures have been observed in adult animal and human studies. In general, these effects were associated with enhanced immune response 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. 2).

Studies in both humans and animals have shown changes in the proximal tubules of the kidney following exposure to TCE (Ref. 2). The IRIS TCE 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. 4). A recent review of TCE by the International Agency for Research on Cancer (IARC) also supported this conclusion (Ref. 7). The 12th report on carcinogens (RoC) by the National Toxicology Program also concluded that TCE is reasonably anticipated to be a human carcinogen 2015 (Ref. 8). These additional recent peer reviews are consistent with EPA's classification that TCE is carcinogenic to humans by all routes of exposures based upon strong epidemiological and animal evidence (Refs. 2, 4).

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. 2). 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. 2).

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. 2).

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. 2).

Animals and humans exposed to TCE consistently experience liver toxicity. Specific effects include the following structural changes: Increased liver weight, increased 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. 2).

TCE is characterized as carcinogenic to humans by all routes of exposure as documented in EPA's IRIS TCE assessment (Ref. 4). 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. 7). The 12th NTP RoC also concluded that TCE exposure is reasonably anticipated to be a human carcinogen (Ref. 8). These additional recent peer reviewed documents are consistent with EPA's classification that TCE is carcinogenic to humans by all routes of exposures based upon strong epidemiological and animal evidence (Refs. 2, 4).

D. What are the environmental impacts of TCE?

Pursuant to TSCA section 6(c), this unit describes the effects of TCE on the environment and the magnitude of the exposure of the environment to TCE. The unreasonable risk determination of this proposal is based solely on risks to human health since those risks are the most serious consequence of use of TCE and are sufficient to support this proposed action. The following is a discussion of the environmental impacts of TCE.

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. 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 vapor degreasing. 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. 2).

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. 2).

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. 9).

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. 2).

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 unit. 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 rules and notices pertaining to TCE under its various authorities.

- *Toxic Substances Control Act:* On December 16, 2016, EPA issued a proposed rule under TSCA section 6 to prohibit the manufacture (including import), processing, distribution in commerce and commercial use of TCE in aerosol degreasers and as a spot removal agent in dry cleaning facilities (Ref. 1). In addition, EPA 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) (Ref. 10).
- *Safe Drinking Water Act:* EPA has 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 milligrams per liter (mg/L) based on classification as a probable human carcinogen. The NPDWR also established an enforceable MCL of 0.005 mg/L. 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 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. The halogenated solvent cleaning NESHAP, controls emissions of several halogenated solvents, including TCE, from halogenated solvent cleaning machines (40 CFR subpart T). The NESHAP includes multiple compliance alternatives to allow maximum compliance flexibility. In 2007, EPA promulgated the Halogenated Solvent Cleaning NESHAP RTR (Risk and Technology Review) Rule (72 FR 25138, May 3, 2007) (FRL–8303–6), in which EPA evaluated the health and environmental risks remaining after promulgation of the original NESHAP and established revised standards that further limit emissions of TCE (and other solvents) in halogenated solvent cleaning. Specifically, EPA promulgated a facility-wide emission limit of 60,000 kilograms per year (kg/year) methylene chloride equivalent, a unit which combines emissions of methylene chloride, trichloroethylene, and perchloroethylene. The facility-wide emission limit applied to all halogenated solvent cleaning machines with the exception of halogenated solvent cleaning machines used by the following industries: Facilities that manufacture narrow tubing, facilities that use continuous web cleaning machines, aerospace manufacturing and maintenance facilities, and military maintenance and depot facilities. EPA also promulgated a facility-wide emission limit of 100,000 kg/year methylene chloride equivalent for halogenated solvent cleaning machines used at military maintenance and depot facilities. TCE is also regulated under the NESHAP rule for synthetic organic chemical manufacturing. This rule consists of four subparts in 40 CFR part 63. In 2003, EPA issued a final NESHAP rule to reduce toxic air pollutant emissions from fabric and other textile coating, printing, and dyeing facilities. The final rule applied to new and existing facilities that emit 10 tons per year or more of a single toxic air pollutant listed in the Clean Air Act or 25 tons per year or more of a combination of those pollutants, including TCE. In addition, EPA has established VOC standards for consumer products under section 183(e) of the Clean Air Act.

- *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) with this proposed rule.

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 exposure 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 (Ref. 11). OSHA acknowledges that many of its PELs are not sufficiently 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. 12 at p. 61386), including the PEL for TCE.

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. 13). The American Conference of Governmental Industrial Hygienists recommended an 8-hour TWA of 10 ppm and an acute, or short term, exposure limit of 25 ppm in 2004 (Ref. 14).

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. 15). 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. 16). Minnesota classifies TCE as a chemical of high concern (Ref. 17). Many other states have considered TCE for similar chemical listings (Ref. 18). 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. 18). Nine states have PELs of 50 ppm (Ref. 18). California's PEL of 25 ppm is the most stringent (Ref. 15). All of these PELs are significantly higher than the exposure levels at which EPA identified unreasonable risks for TCE use for vapor degreasing 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 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. 19). 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. 19). 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. Two of those were for vapor degreasing applications (Refs. 20, 21). In each case, the opinion of the Committee for Risk Assessment was that it was not possible to determine a derived no-effect level (DNEL) for the carcinogenicity properties of the substance in accordance with REACH and that the operational conditions and risk management measures in the applications appeared not to limit the risk. Those measures included use in a specific type of closed vapor degreasing system with personal protective equipment (PPE). Final decisions have not yet been made on the applications.

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. 22). 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. 23). In 2013, Canada added TCE to the Toxic Substances List—Schedule 1 because TCE ''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. 23).

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. 24). 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. 25).

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 vapor degreasing, the use that is the subject of this proposed rule. A more detailed discussion of the risks associated with TCE use in vapor degreasing can be found in Unit VI.

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. 26). 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. 27).

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. 26). 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 TCE risk assessment evaluated commercial and consumer use of TCE as a solvent degreaser (aerosol degreasing and vapor degreasing), commercial use of TCE as a spotting agent at dry cleaning facilities, and consumer use of TCE as a spray-applied protective coating for arts and crafts (Ref. 2).

The uses selected for the TCE risk assessment were chosen because they were expected to involve frequent or routine use of TCE in high concentrations and/or have high potential for human exposure (Ref. 2). However, this does not mean that EPA found that other uses not included in the TCE risk assessment present low risk.

As described in the TCE risk assessment, solvent cleaning or degreasing is widely used to remove grease, oils, waxes, carbon deposits, fluxes, and tars from metal, glass, or plastic surfaces. With respect to vapor degreasing, there are two general types of degreasing machines: Batch and in-line. Batch cleaning machines are the most common type, while in-line cleaners are typically used in large-scale industrial operations. There are a number of variations of each general type of machine. Emissions from degreasing machines typically result from:

- Evaporation of the solvent from the interface between the solvent and the air,
- ''Carry out'' of excess solvent on cleaned parts, and
- Evaporative losses of the solvent during filling and draining of the degreasing machine.

In its assessment of vapor degreasing, the TCE risk assessment concentrated on open top vapor degreasing machines because they are the most prevalent, particularly for smaller operations. The risk assessment identified acute and chronic non-cancer risks for workers who conduct TCE-based solvent vapor degreasing at small degreasing facilities, as well as occupational bystanders to those activities. More specifically, the TCE risk assessment identified risks for non-cancer developmental effects resulting from acute exposure. The risk assessment also identified risks for a range of non-cancer health effects resulting from chronic exposure. Within this range of effects, the greatest risk is for developmental effects (*i.e.,* fetal cardiac defects), although there also are risks for kidney effects and immunotoxicity. In addition, there are risks for adverse reproductive effects, neurotoxicity, and liver toxicity associated with chronic exposures (Ref. 2).

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) 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 no-observed adverse effect level (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. 28). 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 acute inhalation risk assessment used developmental toxicity data to evaluate the acute risks for the TCE use scenarios. As indicated in the TCE risk assessment, EPA's policy supports the use of developmental studies to evaluate the risks of acute exposures. This science-based policy presumes that a single exposure of a chemical at a critical window of fetal development may produce adverse developmental effects (Ref. 5). This is the case with cardiac malformation. EPA reviewed multiple studies for suitability for acute risk estimation including a number of developmental studies of TCE exposure and additional developmental studies of TCE metabolites (Appendix N) (Ref. 2). EPA based its acute risk assessment on the most sensitive health endpoint (*i.e.,* fetal heart malformations) representing the most sensitive human life stage (*i.e.,* the developing fetus) (Ref. 2). 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. 29) developmental toxicity study for each vapor 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 IRIS TCE assessment used the HEC99 for the non-cancer dose-response derivations because the HEC99 was interpreted to be protective for a sensitive individual in the population (Ref. 4). While the HEC99 was used to find the level of risk to be used in making the proposed TSCA section 6(a) determination, the small variation among HEC50, HEC95 and HEC99 would not result in a different risk determination.

For non-cancer effects, EPA estimated exposures that are significantly greater than the point of departure. The baseline cancer risk is estimated to be 3.66×10^{-1} for users of open top vapor degreasing systems.

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

Given these identified risks, EPA conducted an additional analysis consistent with the scope of the TCE risk assessment to better characterize the risk to workers and occupational bystanders from the use of TCE in batch vapor degreasing machines as well as in two different types of in-line systems (conveyor and continuous web cleaning machines) (Ref. 30). This analysis also evaluated the exposure reductions that would result from switching from an open-top vapor degreasing system to a closed-loop vapor degreasing system. More information on the different types of vapor degreasing machines can be found in Unit VI.A.1. In the supplemental analysis, EPA identified short-term and long-term non-cancer and cancer risks for all types of vapor degreasing machines, although the risks for closed-loop machines are estimated to be lower than for any of the other types (Ref. 30).

C. Stakeholder Input on TCE and Vapor Degreasing

On July 29, 2014, EPA held a 2-day public workshop on TCE degreasing (Ref. 31). 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. 31) 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 the 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 as well as EPA's earlier proposal (Ref. 1). The discussions at the public workshop demonstrated that alternatives are available for the vapor degreasing uses that are being addressed in this proposed rulemaking.

On June 1, 2016, EPA convened a Small Business Advocacy Review (SBAR) Panel on TCE in vapor degreasing. The Panel solicited input from eighteen Small Entity Representatives (SERs) and made several recommendations on aspects of this rulemaking. The Panel process, including the final report of the Panel (Ref. 32), is discussed in Unit XII.

V. Regulatory Approach

A. TSCA Section 6 Unreasonable Risk Analysis

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

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

- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances (§ 6(a)(1)).
- Prohibit or otherwise restrict 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 TSCA section 6(a) in order to select the proposed regulatory approach. EPA considered whether a regulatory option (or combination of options) would address the identified unreasonable risks so that the chemical substance no longer presents such risks. To do so, EPA initially analyzed whether the regulatory options could reduce risks (non-cancer and cancer) to levels below those of concern, based on EPA's technical analysis of exposure scenarios. For the non-cancer risks, EPA found 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. For the purposes of this proposal, EPA found that an option addressed the risk so that it was no longer unreasonable if the option could achieve the benchmark MOE or cancer benchmark for the most sensitive endpoint. In evaluating whether a regulatory option would ensure that the chemical substance 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. TSCA Section 6(c)(2) Considerations

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

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

EPA's analysis of the health effects of and magnitude of exposure to TCE can be found in Units IV and VI, which discuss the TCE risk assessment and EPA's regulatory assessment of the use of TCE in vapor degreasing. A discussion of the environmental effects of TCE can be found in Unit II.D.

With respect to the costs and benefits of this proposal and the alternatives EPA considered, as well as the impacts on small businesses, the full analysis is presented in the economic analysis document (Ref. 3) 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.,* risks from chemical substitutions and alternative practices), the relative risk for environmental justice populations and children and other potentially exposed or susceptible subpopulations (as compared to the general population), and the cost of regulatory requirements for the various options. A discussion of the benefits EPA considered can be found in Units VI.C. and VII.

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. EPA took into account reasonably available information about the functionality and performance efficacy of the regulatory options and the ability to implement the use of chemical substitutes or other alternatives (*e.g.,* PPE). Reasonably available information included the existence of other Federal, state, or international regulatory requirements associated with each of the regulatory options as well as the commercial history for the options. A discussion of the costs EPA considered can be found in Units VI.E. and VII, along with a discussion of the cost effectiveness of the proposal and the alternatives that EPA considered. In addition, a discussion of the impacts on small businesses can be found in Unit XII.C.

With respect to the anticipated effects of this proposal on the national economy, EPA considered the number of businesses and workers that would be affected and the costs and benefits to those businesses and workers. In addition, EPA considered the employment impacts of this proposal, as discussed in the economic analysis for this proposal (Ref. 3). EPA found that the direction of change in employment is uncertain, but the expected short term and longer term employment effects are expected to be small.

The benefits of TCE in vapor degreasing are discussed in Unit VI.D., along with the availability of alternatives. The dates that the proposed restrictions would take effect are discussed in Unit X.D., as is the availability of alternatives to TCE vapor degreasing on those dates.

Finally, with respect to this proposal's effect on technological innovation, EPA expects this action to spur innovation, not hinder it. (Ref. 3) An impending ban on the use of TCE in vapor degreasing is likely to increase demand for alternatives, which would be expected to result in the development of new alternatives.

C. Regulatory Options Receiving Limited Evaluation

As discussed previously, EPA analyzed a wide range of regulatory options under TSCA section 6(a). One of the options EPA evaluated involved a TSCA section 6(a)(3) requirement for warning labels or instructions on containers of TCE or on vapor degreasing equipment. However, EPA reasoned that warning labels and instructions alone could not mitigate the identified unreasonable risks presented by TCE to workers operating vapor degreasing equipment. In making this finding, EPA considered several factors including the fact that, in many cases, the workers being exposed are not in a position to influence their employer's decisions about the type of solvent or the type of degreasing equipment that will be used, or ensure that their employer provides appropriate PPE and an adequate respiratory protection program. EPA also considered the analysis of relevant studies that was discussed in the prior proposal on TCE (Ref. 33). This analysis found that even professional users do not consistently pay attention to labels; they often do not understand label information; and they often base a decision to follow label information on previous experience and perceptions of risk (Ref. 33).

EPA found that presenting information about TCE on a label would not adequately address the identified unreasonable risks because the nature of the information the user or owner would need to read, understand, act upon, convey, and ensure adherence to is extremely complex. It would be challenging to most users or owners to follow or convey 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 for the user and bystanders, and time periods during pregnancy with susceptibility of the developing fetus to acute developmental effects, as well as effects to bystanders. It is unlikely that label language changes for this use will result in widespread, consistent, and successful adoption of risk reduction measures by users and owners.

While labeling alone would not address the identified unreasonable risks so that TCE used in vapor degreasing no longer presents such risks, EPA recognizes that the TSCA section 6(a)(3) warnings and instruction requirement can be an important component of an approach that addresses identified unreasonable risks with a specific use prohibition. EPA has included a simple downstream notification requirement as part of this proposed rule to ensure that users would be made aware of the ban on the use of TCE in vapor degreasing.

In addition, early in the process, EPA identified two regulatory options under TSCA section 6(a) that do not pertain to this action and were therefore not evaluated for this proposed rulemaking. First, EPA reasoned that the TSCA section 6(a)(1) regulatory option to prohibit the manufacture (including import), processing or distribution in commerce of TCE or limit the amount of TCE which may be manufactured (including imports), processed or distributed in commerce is not germane because the Agency is not proposing to ban or limit the manufacture (including import), processing or distribution in commerce of TCE for uses other than in vapor degreasing, aerosol degreasing or for spot cleaning in dry cleaning facilities at this time. In addition, EPA reasoned that the TSCA section 6(a)(6) regulatory option to prohibit or otherwise regulate any manner or method of disposal of the chemical is not applicable since EPA did not evaluate the risks associated with ongoing TCE disposal.

VI. Regulatory Assessment of TCE Use in Vapor Degreasing

This Unit describes the current use of TCE in vapor degreasing, the unreasonable risks presented by this use, and how EPA identified which regulatory options address those unreasonable risks so that TCE in vapor degreasing no longer presents such unreasonable risks.

A. Description of the Current Use

Vapor degreasing is a cleaning process that uses a solvent vapor to remove contaminants such as grease, oils, dust, and dirt from fabricated parts. Solvents such as TCE are boiled in a degreasing unit to produce a hot vapor. When parts are placed into the degreaser, the hot vapor within the unit condenses onto the parts, causing beading and dripping. The dripping action carries the contaminants away from the fabricated part, leaving behind a clean surface. After vapor degreasing, the parts are suspended on a rack in order to drain the solvent (Ref. 30). Vapor degreasing is used in a variety of occupational settings such as metal plating, electronics assembly, metal or composite part fabrication, and repair shops.

Vapor degreasing may take place in batches or as part of an in-line (*i.e.,* continuous) system. In batch machines, each load (parts or baskets of parts) is loaded into the machine after the previous load is completed. With in-line systems, parts are continuously loaded into and through the vapor degreasing equipment as well as the subsequent drying steps.

The five basic types of batch vapor degreasers are described in the following paragraphs (Ref. 30):

As the name suggests, open-top vapor degreasers are open at the top to allow introduction of the parts to be cleaned. Heating elements at the bottom of the cleaner heat the liquid solvent to above its boiling point. Solvent vapor rises in the machine to the height of chilled condensing coils on the inside walls of the cleaner. The condensing coils cool the vapor, causing it to condense and return to the bottom of the cleaner. Cleaning occurs in the vapor zone above the liquid solvent and below the condensing coils, as the hot vapor solvent condenses on the cooler work surface. The workload or a parts basket is lowered into the heated vapor zone with a mechanical hoist. While the condensing coils reduce the amount of solvent that escapes the vapor zone, they do not eliminate emissions, and throughout the degreasing process, significant vapor emissions of the solvent can occur. These vapor emissions are hazardous to workers operating the machine, as well as nearby workers. In addition, replacing solvent lost to emissions can be costly. In assessing the use of TCE in vapor degreasers, the TCE risk assessment focused on the use of open top vapor degreasing systems.

Vapor emissions of solvent can be reduced by enclosing the vapor degreasing machine. Open top vapor degreasing systems with enclosures operate in the same manner as standard open top vapor degreasing systems, except that the machine is enclosed on all sides during degreasing. The enclosure is opened and closed when adding or removing parts, and solvent is exposed to the air when the cover is open. Nearly all open top vapor degreasing systems regulated by the NESHAP have a cover because that is a more common compliance strategy than complying with the overall emission limit. A variety of additional controls may be needed to comply with the NESHAP, including two-part covers, extended freeboard (the area above the vapor zone), freeboard refrigeration devices, and holding cleaned parts in the freeboard to allow draining. Enclosed vapor degreasing systems may be vented directly to the atmosphere or first vented to an external carbon filter and then to the atmosphere.

Solvent emissions can be further reduced by using a sealed, closed-loop degreasing system. In airtight closed-loop systems, parts are placed into a basket, which is then placed into an airtight work chamber. The door is closed and solvent vapors are sprayed onto the parts. When cleaning is complete, vapors are exhausted from the work chamber and circulated over a cooling coil to condense and recover the solvent. The parts are dried by forced hot air. Air is circulated through the chamber and residual solvent vapors are captured by carbon adsorption. The door is opened when the residual solvent vapor concentration has reached a specified level.

A refinement of the airtight closed-loop degreasing system is the airless degreasing system. An airless system removes air at some point during the degreasing process. Typically, this takes the form of drawing vacuum, but some machines purge the air with nitrogen. In airless degreasing systems with vacuum drying, a vacuum is generated, typically below 5 torr, which dries the parts. A vapor recovery system recovers the solvent.

The greatest solvent emission reductions are achieved with the airless vacuum-to-vacuum degreasing system. These systems are referred to as airless because the entire cycle is operated under vacuum. Typically, parts are placed into the chamber, the chamber sealed, and then vacuum drawn within the chamber. The parts are then sprayed with hot solvent vapor, which raises the pressure in the chamber. The parts are dried by again drawing vacuum in the chamber. Solvent vapors are recovered through compression and cooling. An air purge then removes residual vapors which can be routed to an optional carbon adsorber and then out a vent. Finally, air is introduced to return the chamber to atmospheric pressure so that the chamber can be opened. These systems have the added benefit of generating vapor at a much lower temperature than open-top degreasing systems because the boiling point of TCE is lower at the lower pressure of these systems.

In contrast to batch degreasers, in-line vapor degreasing systems use an automated parts handling system, often a conveyor, to automatically provide a continuous supply of parts to be cleaned (Ref. 30). Conveyorized vapor degreasing systems are usually fully enclosed except for the conveyor inlet and outlet portals. Conveyorized degreasers are likely used in the same applications as batch vapor degreasers, except that they would be used in larger operations, where the number of parts being cleaned is large enough to warrant the use of a conveyorized system. Conveyorized degreasers use different methods for transporting the parts through the cleaning zone. For example, monorail degreasers use a straight-line conveyor to transport parts into and out of the cleaning zone; these systems are typically used when parts are already being transported through manufacturing areas by a conveyor. Cross-rod degreasers use two parallel chains connected by a rod to support the parts, which are typically loaded manually into perforated baskets or cylinders. Ferris wheel degreasing systems, generally the smallest of the conveyorized degreasers, rotate manually-loaded baskets or cylinders of parts vertically through the cleaning zone and back out. Belt degreasers are used for simple and rapid loading and unloading of parts; the parts are loaded onto a mesh conveyor belt that transports them through the cleaning zone and out the other side.

There are also continuous web cleaning machines (Ref. 30). These in-line degreasers differ from typical conveyorized degreasers in that they are specifically designed for cleaning parts that are coiled or on spools such as films, wires, metal strips, and metal sheets. In continuous web degreasers, parts are uncoiled and loaded onto rollers that transport the parts through the cleaning and drying zones at speeds typically greater than 11 feet per minute. The parts are then recoiled or cut after exiting the machine.

B. Analysis of Regulatory Options

In this unit, EPA explains how it evaluated whether the regulatory options considered would address the unreasonable risks presented by the current use so that TCE in vapor degreasing no longer presents such unreasonable risks. First, EPA characterizes the unreasonable risks associated with the current use of TCE in vapor degreasers. 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 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 cancer and non-cancer risks from acute and chronic exposure for workers operating vapor degreasers and for occupational bystanders, nearby workers who have the potential to be exposed to TCE but are not directly involved with degreasing operations (Ref. 2). Because the TCE risk assessment focused on open top vapor degreasing systems, EPA performed supplemental analysis consistent with the methodology used in the risk assessment for closed-loop, conveyorized, and continuous web degreasers and identified cancer and non-cancer risks from acute and chronic exposure for each of the scenarios (Ref. 30). EPA estimates that there are approximately 2,600 to 6,000 open top vapor degreasing systems currently using TCE, 120 closed-loop systems currently using TCE, and 150 in-line (either conveyorized or continuous web) systems currently using TCE, with an estimated 17 workers and occupational bystanders per machine (Ref. 3). This means that there are an estimated 40,800 to 102,000 persons exposed to TCE from open top vapor degreasing systems, 2,040 persons exposed to TCE from closed-loop systems, and 2,550 persons exposed to TCE from in-line systems.

b. Impacts on minority and low income populations. There is no known disproportionate representation of minority or low income populations in these occupations.

c. Impacts on children. EPA has concerns for effects on the developing fetus from acute and chronic worker and occupational bystander exposures to TCE used in vapor degreasers. The risk estimates are focused on pregnant women because one of the most sensitive health effects associated with TCE exposure from vapor degreasing is adverse effects on the developing fetus. The potential risk due to exposure during pregnancy is significant. 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. 34). More specifically, in this case, a woman who is not planning a pregnancy may not take steps to avoid exposure to TCE in vapor degreasing. EPA estimates that there are over 1,000 pregnant women exposed to TCE as a result of vapor degreasers.

d. Specific vapor degreaser exposure information. In the supplemental analysis (Ref. 30), EPA estimated baseline exposures for all batch vapor degreasing machines, regardless of facility size, and for in-line vapor degreasing machines (both conveyorized and continuous web). Baseline exposures for in-line machines were not specifically calculated in the TCE risk assessment. For the supplemental analysis, estimating the baseline exposures involved 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. 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). Controls required by the 2007 NESHAP were accounted for in the estimations. (Ref. 30) EPA used these estimated airborne concentrations to estimate 8-hour time weighted average (TWA) exposures for workers (*i.e.,* in the near field) and occupational bystanders (*i.e.,* in the far field). Details of the modeling and estimation method for calculating exposure levels during vapor degreasing are available in the supplemental analysis document (Ref. 30). This analysis is based on the methodology used in the peer reviewed TCE risk assessment (Ref. 2). 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 Vapor Degreasing'' (Ref. 30).

The estimated 8-hour TWA exposure levels for open top vapor degreasing systems ranged from 2.74 ppm to 491.36 ppm for workers, with the 50th percentile at 55.16 ppm and the 99th percentile at 190.17 ppm. For occupational bystanders, the exposure levels ranged from 0.33 ppm to 440.61 ppm, with the 50th percentile at 20.45 ppm and the 99th percentile at 144.93 ppm. The estimated 8-hour TWA exposure levels for conveyorized degreasers were even higher, ranging from 5.14 ppm to 32,722 ppm for workers, with the 50th percentile and 99th percentile being 180.74 ppm and 1162.6 ppm, respectively. For bystanders, the levels ranged from 0.63 ppm to 29,410 ppm, with the 50th percentile and 99th percentile being 80.93 ppm and 745.11 ppm, respectively. The estimated 8-hour TWA exposure levels for continuous web degreasers were lower overall than for open top vapor degreasing systems or conveyorized degreasers. These estimates ranged from 4.18 ppm to 50.61 ppm for workers, with the 50th percentile and 99th percentile being 8.18 ppm and 22.42 ppm, respectively. For bystanders, the levels ranged from 0.52 ppm to 45.49 ppm, with the 50th percentile and 99th percentile being 3.70 ppm and 17.49 ppm, respectively.

As part of this supplemental analysis, EPA also evaluated the exposure reductions that would result from switching from an open top vapor degreasing system to a closed-loop vapor degreasing system. The data available on TCE emissions from closed-loop systems was not sufficient to enable EPA to distinguish between the three types of closed-loop systems (airtight, airless, and airless vacuum-to-vacuum) with respect to employee exposures. As a result, for the purpose of assessing exposure, EPA assumed that all of the closed-loop systems achieve a 98% reduction in exposure compared to open top vapor degreasing systems (Ref. 30). This assumption leads to exposure estimates of 0.05 ppm to 9.8 ppm for workers.

However, the assumption of a 98% reduction in exposures compared to open top vapor degreasing systems may be an overestimate for airtight systems, and an underestimate for airless vacuum-to-vacuum systems. EPA requests information and data on TCE emissions from all vapor degreasing systems, particularly information and data that would enable EPA to better distinguish between the different types of closed-loop systems.

The SBAR Panel convened in support of this action heard from several SERs who disagreed with EPA's exposure estimates. These SERs indicated that fewer employees were involved in the degreasing operation, or that the machines were operated for fewer hours per day than EPA estimated. However, another SER stated that his degreasing machines run ten hours a day during the week and six hours on Saturdays, which exceeds EPA's estimate. In addition, most SERs thought that EPA's estimated TWAs were too high, and EPA received some monitoring data indicating lower exposures, but several SERs stated that they complied with the recommended exposure limit of the American Conference of Governmental Industrial Hygienists (ACGIH) of 10 ppm, which is within the exposure ranges estimated by EPA. However, EPA specifically requests exposure data, especially data involving employee exposure monitoring.

e. Specific risks for TCE use in vapor degreasers. Inhalation risks were estimated for all acute exposure scenarios and risks were identified for all types of machines, regardless of the type of exposure (typical vs. reasonable worst case scenario). For acute exposures associated with open top vapor degreasing systems, the MOE is 0.00006 for fetal heart malformations. This equates to exposures that are many times greater than the benchmark MOE of 10. The MOE for fetal heart malformations from acute exposures associated with conveyorized systems is 0.00001, while for continuous web systems, the MOE is 0.0005. Even for acute exposures with closed-loop systems, which we assume reduce TCE emissions as much as 98% from open top vapor degreasing systems, the MOE for fetal heart malformations is 0.003. The MOEs for every vapor degreasing scenario are below the benchmark MOE. Based on this assessment, EPA's proposed determination is that acute TCE exposures from vapor degreasing present unreasonable risks.

Chronic exposures from TCE use in vapor degreasing also present risks. For non-cancer effects, the most sensitive of which are developmental, the benchmark MOE is also 10. For chronic exposures associated with open top vapor degreasing systems, conveyorized systems, continuous web systems, and closed-loop systems, the MOEs are 0.00008, 0.00001, 0.00007, and 0.004, respectively. With respect to cancer, the risk posed to workers ranges from 5.16 $\times 10^{-1}$ for open top vapor degreasing systems to 1×10^{-2} for closed-loop systems, exceeding common cancer benchmarks of 10^{-6} to 10^{-4} (Refs. 2, 30). Therefore, EPA's proposed determination is that chronic TCE exposures due to vapor degreasing also present unreasonable risks.

The SBAR Panel convened in support of this action heard from several SERs who expressed concerns about the underlying TCE risk assessment. Many of the concerns expressed by these SERs were already expressed in the public comments and the peer review comments on the risk assessment. The Summary of External Peer Review and Public Comments and Disposition document explains how EPA responded to the comments received (Ref. 35).

2. Initial analysis of potential regulatory options. Having identified unreasonable risks from the use of TCE in vapor degreasing, EPA evaluated whether regulatory options under TSCA 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 find variations in TCE exposure from vapor degreasing, including: Reducing the amount of TCE in the degreasing formulation, with concentrations varying from 5% to 95% by weight in the product, engineering controls, equipment substitution, and use of PPE. EPA also assessed combinations of these options.

For the engineering controls risk reduction option exposure scenarios, EPA evaluated using local exhaust ventilation to improve ventilation near the vapor degreaser, with an assumed 90% reduction in exposure over baseline levels. The equipment substitution risk reduction option was only evaluated with respect to open top vapor degreasing systems, the evaluation assumed substitution of a closed-loop system for the open top vapor degreasing system. EPA did not identify any equipment substitution options for either conveyorized or continuous web systems; it is likely that a closed-loop system, being a batch-process system, would not meet the specialized production requirements of facilities currently using conveyorized or continuous web systems. EPA requests comment, information, and data on potential equipment substitution options for these systems, including both emissions and cost information. 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 various combinations of these options, including PPE with each of the other three options and reducing the amount of TCE in the solvent solution with each of the other three options. The way that closed-loop systems operate may render local exhaust ventilation redundant, because ventilation is being done as part of the closed system, so EPA did not evaluate local exhaust ventilation and equipment substitution together. EPA requests comment on the accuracy of EPA's assumption that these control options are mutually exclusive.

EPA has estimated that, in order to avoid cancer and non-cancer unreasonable risks, the 8-hour TWA exposure should be approximately 1 ppb (Ref. 36). However, EPA's inhalation exposure level estimates for all types of vapor degreasing machines exceed that figure by several orders of magnitude.

Of the control options evaluated by EPA in its supplemental analysis (Ref. 30), which did not include a ban on the use of TCE in vapor degreasing, the only control options that achieved the necessary exposure reductions for workers operating the degreaser involved PPE in addition to other measures. Even switching from an open top vapor degreasing system to a closed-loop system did not achieve the necessary reductions without the addition of PPE with an APF of 10,000. For that control option, equipment substitution plus PPE, EPA estimated that worker exposure levels would be 0.4 ppb. Other combinations of control options, such as reducing the amount of TCE in the solvent solution and PPE with an APF of 10,000, or reducing the amount of TCE in the solvent solution and engineering controls and PPE, achieved exposure reductions of approximately the same magnitude. However, EPA found that these combinations are unlikely to be practical for users because the exposure reductions needed would only be achieved by a reduction in the concentration of TCE in the degreasing solution to 5%. At 5% TCE, the effectiveness of the solution would be greatly reduced. Additional exposure level estimates for various scenarios are available in the supplemental analysis document, which also documents options that did not meet the risk benchmarks and which do not, for purposes of this proposal, address the identified unreasonable risks (Ref. 30).

3. Assessment of whether regulatory options address the identified unreasonable risks to the extent necessary so that TCE no longer presents such unreasonable risks. After excluding the unrealistic options involving reductions in the amount of TCE in the solvent solution, only two options were left that had the potential to address the identified unreasonable risks. These options were: (a) Prohibiting under TSCA section 6(a)(2) the manufacturing (including import), processing, and distribution in commerce of TCE for use in vapor degreasing, prohibiting the commercial use of TCE in vapor degreasing under TSCA section 6(a)(5), and requiring downstream notification under TSCA section 6(a)(3) when distributing TCE; and (b) prohibiting under TSCA section 6(a)(2) the manufacturing (including import), processing, and distribution in commerce of TCE for use in vapor degreasing except in closed-loop vapor degreasing machines, prohibiting under TSCA section 6(a)(5) the commercial use of TCE in vapor degreasing except in closed-loop vapor degreasing machines, requiring downstream notification under TSCA section 6(a)(3) when distributing TCE, and requiring, under TSCA section 6(a)(5), appropriate PPE (or an exposure limit alternative) for both workers operating closed-loop vapor degreasing machines containing TCE and for occupational bystanders.

a. *Proposed approach to prohibit manufacturing (including import), processing, distribution in commerce, and use of TCE for vapor degreasing and require downstream notification.* As noted previously, the proposed regulatory approach is to prohibit the manufacturing (including import), processing, and distribution in commerce of TCE for vapor degreasing under TSCA section 6(a)(2), prohibit the commercial use of TCE in vapor 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 prohibition under TSCA section 6(a)(3).

As discussed in Unit IV, the baseline risk for exposure to workers and occupational bystanders for vapor degreasing does not achieve the non-cancer MOE benchmarks for all non-cancer effects (*e.g.,* developmental effects, kidney toxicity, and immunotoxicity) or the common cancer benchmarks. Under this proposed approach, exposures to TCE from use in vapor degreasing would be completely eliminated. As a result, both non-cancer and cancer risks from this use of TCE would be eliminated.

The proposed approach would ensure that employees are no longer at risk from TCE exposure associated with vapor degreasing. Prohibiting the manufacturing (including import), processing and distribution in commerce of TCE for use in vapor degreasing would minimize the availability of TCE for vapor degreasing. The downstream notification of these restrictions ensures that processors, distributors, and other purchasers are aware of the manufacturing (including import), processing, distribution in commerce and use restrictions for TCE in vapor degreasing, and helps to ensure that the rule is effectively implemented by discouraging off-label use of TCE manufactured for other uses. Downstream notification is important because EPA is not proposing to prohibit manufacturing, processing and all uses of TCE, just those activities associated with vapor degreasing. This integrated supply chain approach is necessary to address the identified unreasonable risks presented by the use of TCE in vapor degreasing. In addition, the proposed approach would provide staggered compliance dates for implementing the prohibition on manufacturing (including import), processing, distribution in commerce, and commercial use in order to avoid undue impacts on the businesses involved.

b. Variation of the proposed approach that would allow the use of TCE in closed-loop vapor degreasing systems and require under TSCA section 6(a)(5) the use of personal protective equipment in vapor degreasing operations in which TCE is used. Another regulatory option that EPA considered was to allow the use of TCE in closed-loop vapor degreasing systems and require respiratory protection equipment for workers operating the equipment 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 with an alternative to the specified APF respirator of an air exposure limit. EPA's analysis found that use of a SCBA with an APF of 10,000 for workers operating closed-loop vapor degreasing systems that contain TCE could control TCE air concentration to levels that ensure that TCE no longer presents the identified unreasonable risks. Depending on air concentrations and proximity to the vapor degreasing equipment, other employees in the area would also need to wear respiratory protection equipment.

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-facepiece respirator 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 facepiece fit, including those individuals whose beards or sideburns interfere with the facepiece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems and vision problems, increase worker fatigue, and reduce work efficiency (Ref. 37). 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.'' (Ref. 37, at 1189–1190). Nonetheless, it is sometimes necessary to use respiratory protection to control exposure. The OSHA respiratory protection standard requires employers to establish and implement a respiratory protection program to protect their respirator-wearing employees (Ref. 38). This OSHA standard contains a number of implementation 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 adopted a hierarchy of controls established by the industrial hygiene community 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 method of compliance for protecting employees from airborne contaminants and are to be implemented first, before respiratory protection is used. OSHA permits respirators to be used where engineering controls are not feasible or during an interim period while such controls are being implemented.

Under this approach, a company could choose to use a closed-loop system coupled with an air exposure limit. In order to reach the health benchmarks, the air exposure limit would have to be 1 ppb as an 8-hour TWA. Based on EPA's analysis, the only way to achieve an air exposure limit of 1 ppb is with a combination of a closed-loop vapor degreaser and a respirator with an APF of 10,000. However, as previously discussed, EPA acknowledges that available data is limited, particularly with respect to the different types of closed-loop vapor degreasers. It is possible that the more sophisticated airless vacuum-to-vacuum closed-loop systems have lower emissions than EPA estimated, and, therefore, respiratory protection with an APF of 10,000 may not be necessary for operators. As part of this approach, EPA believes it would be necessary to establish employee exposure monitoring requirements to ensure that employee exposures are measured accurately and that employees are not exposed to the identified unreasonable risks associated with TCE use in vapor degreasing. EPA would require upfront monitoring representative of each exposed employee's exposures and would model the requirements on comparable OSHA requirements as well as on the New Chemical Exposure Limit (NCEL) requirements that EPA has long used in addressing employee exposure to chemicals undergoing review under TSCA section 5 (Refs. 38–39). The requirements would specify how and when sampling must be performed and how the samples would have to be analyzed.

EPA is not proposing this option because substitutes for TCE are commercially available and implementation of a respiratory protection program is likely to be difficult for many vapor degreasing facilities. In addition, EPA's economic analysis indicates that this option is more expensive than switching to a different solvent or cleaning system. However, EPA requests comment, information, and data on the utility and feasibility of this option and whether, if it were adopted, it should be implemented by specifying the vapor degreasing technology and either requiring specific PPE or compliance with an air exposure limit. If EPA were to specify both the vapor degreasing technology and the required PPE with the alternative air exposure limit in the final rule, EPA would require the vapor degreasing system to be an airless vacuum-to-vacuum closed-loop system and the PPE to have an APF of 10,000 or otherwise meet the air exposure limit of 1 ppb as an 8-hour TWA. As previously discussed, EPA's assessment of worker exposure from closed-loop systems relies on an assumption that emissions from each closed-loop system are 98% less than the emissions from an open top vapor degreasing system. EPA is requesting information on whether releases from the use of TCE in an airless vacuum-to-vacuum closed-loop system would result in air levels that are at or below the air exposure limit of 1 ppb. To the extent that EPA receives information that indicates that this is the case, EPA would consider finalizing this rule to exclude airless vacuum-to-vacuum closed-loop systems. In contrast, this assumption of a 98% reduction may be overly generous for the most basic of the closed-loop systems, and operators of such systems, even when wearing PPE with an APF of 10,000, would continue to be exposed to the identified unreasonable risks. Under the optional approach, companies choosing to keep using TCE would have to comply with all of OSHA's requirements for respiratory protection programs, including fit-testing and medical monitoring.

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

The proposed option would prevent exposure to TCE from vapor degreasing and thus would prevent the risks of adverse effects and associated impacts. As discussed in Unit IV., TCE exposure is associated with a wide array of adverse health effects. These health effects include those resulting from developmental toxicity (*e.g.,* cardiac malformations, developmental immunotoxicity, developmental neurotoxicity, fetal death), toxicity to the kidney (kidney damage and kidney cancer), immunotoxicity (systemic autoimmune diseases such as 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. 2). These health effects associated with exposure to TCE are serious and can have impacts throughout a lifetime. The following is a discussion of the impacts of significant acute, chronic non-cancer, and cancer effects associated with TCE exposure during vapor degreasing, including the severity of the effect, the manifestation of the effect, and how the effect impacts a person during their lifetime.

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 estimated 454 to 1,066 pregnant women exposed to TCE during the use of vapor degreasers (Ref. 3). 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 are the effect of greatest concern and are 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.,* reduced growth, decreased survival, developmental neurotoxicity, developmental immunotoxicity, and childhood cancers) effects. TCE exposure during development results in qualitatively different immunotoxic effects than when exposure occurs during adulthood. TCE exposure during development can influence the development of the immune system and result in impairment of the immune system's ability to respond to infection, whereas TCE exposures during adulthood result in a more pronounced immune effect related to autoimmune responses.

Cardiac defects, which can result from 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 TCE can cause.

Nearly 1% or about 40,000 births per year in the United States are affected by cardiac defects (Ref. 40). 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. 40). 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. 41). A child with a cardiac defect is 50% more likely to receive special education services compared to a child without birth defects (Ref. 40).

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, making it difficult to predict and 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. 40).

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. 40).

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. 41). 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. 41). 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 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. a. Non-cancer chronic effects. The TCE risk assessment identified kidney toxicity as a significant concern from TCE exposure with the risk from this non-cancer effect being from chronic exposure. There are increased health risks for kidney toxicity to the approximately 2,670 to 6,270 workers and 42,720 to 100,320 occupational bystanders in facilities that use TCE for vapor degreasing, where exposure to TCE is a result of vapor degreasing operations (Ref. 3).

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. 42).

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. 43).

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. 44).

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.

b. Cancer effects. Chronic exposure to TCE can also lead to kidney cancer. The estimated value of the annualized benefit is $12 million to $108 million at 3% and $6 million to $57 million at 7% over 20 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 and treatment impacts of 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 effect that is associated with TCE exposure. There are increased health risks for immunotoxicity to the approximately 2,670 to 6,270 workers and 42,720 to 100,320 bystanders exposed to TCE as a result of vapor degreasing operations (Ref. 3).

Human studies have demonstrated that TCE exposed workers can suffer from systemic autoimmune diseases (*e.g.,* scleroderma) and severe hypersensitivity skin disorders. 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. 45), and the prevalence is four to 253 cases per 1 million persons (Ref. 46). 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. 46).

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. 46).

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 disorders include 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. 45).

The monetary costs for treating these various immunotoxicity disorders will vary depending upon whether the symptoms lead to early diagnosis and this early diagnosis can then influence whether symptoms progress to mild or life-threatening outcomes. For mild symptoms, doctors' visits and outpatient treatment could be sufficient, 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. Cancer effects: 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 IRIS TCE assessment based its cancer findings. There are increased health risks for NHL for the approximately 2,670 to 6,270 workers and 42,720 to 100,320 occupational bystanders exposed to TCE as a result of vapor degreasing operations (Ref. 3).

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. 47). 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. 48).

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 to secondary malignancies (Ref. 49). 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. The estimated value of the monetized benefit is $32 million to $201 million at 3% and $15 million to $98 million at 7% annualized over 20 years.

4. Reproductive and endocrine effects. The TCE risk assessment identified risks of chronic non-cancer reproductive effects for workers and bystanders exposed to TCE. There are increased health risks for reproductive effects for the approximately 2,670 to 6,270 workers and 42,720 to 100,320 occupational bystanders exposed to TCE as a result of vapor degreasing operations (Ref. 3).

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. 50). For females, there can be reduced incidence of fecundability (6.7 million women ages 15 to 44 or 10.9% affected) (Ref. 51), increase in abnormal menstrual cycles, 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. 52). Low T levels are associated with aging; an estimated 39% of men 45 or older have hypogonadism, resulting in low T levels (Ref. 53). 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 a diagnosis. 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 other non-cancer 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 must consider their impact.

5. Neurotoxicity. The TCE risk assessment identified neurotoxicity risks for workers and bystanders from chronic TCE exposures. There are increased health risks of neurotoxicity for the approximately 2,670 to 6,270 workers and 42,720 to 100,320 occupational bystanders exposed to TCE as a result of vapor degreasing operations (Ref. 3).

Studies have also demonstrated neurotoxicity from acute exposures. Neurotoxic effects observed include 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 include delayed newborn reflexes, impaired learning or memory, aggressive behavior, hearing impairment, speech impairment, encephalopathy, impaired executive and motor function and attention deficit (Ref. 4).

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 an adolescent's schooling and ability to make friends, which in turn can impact the type of work or ability to 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. 54). 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 a diagnosis. 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 neurotoxic 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 2,670 to 6,270 workers and 42,720 to 100,320 occupational bystanders exposed to TCE as a result of vapor degreasing operations (Ref. 2).

Specific effects to the liver can include increased liver weight, increase in DNA synthesis (transient), enlarged hepatocytes, enlarged nuclei, and peroxisome proliferation (Ref. 2). In addition, workers exposed to TCE have shown hepatitis accompanying immune-related generalized skin diseases, jaundice, hepatomegaly, hepatosplenomegaly, and liver failure (Ref. 2).

Some form of liver disease impacts at least 30 million people, or 1 in 10 Americans (Ref. 55). Included in this number is at least 20% of those with nonalcoholic fatty liver disease (NAFLD) (Ref. 55). NAFLD tends to impact people who are overweight/obese or have diabetes. However, an estimated 25% do not have any risk factors (Ref. 55). 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. 55). 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. 56). 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. 56). 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. 56). These known environmental risk factors of hepatitis infection may result in increased susceptibility of individuals exposed to organic chemicals. While the incidences in this paragraph 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.

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. 4). 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. 4).

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 estimated to be $21 million to $133 million at 3% and $11 million to $71 million at 7% over 20 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. 57). 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.

D. Availability of Alternatives

TCE is commonly used in vapor degreasing systems for a variety of reasons. It is able to dissolve the greases, fats, oils, waxes, resins, gums and rosin fluxes generally used in metalworking operations and it is compatible with most metal substrates. TCE is non-flammable and it has a relatively low boiling point. It is also available at a relatively low cost. Several SERs providing input to the SBAR Panel convened in support of this rulemaking noted that TCE is particularly well-suited for use in vapor degreasing in the narrow tube, razor blade, and aerospace industries (Ref. 32).

Nevertheless, EPA identified a wide variety of technically and economically feasible alternatives for vapor degreasing with TCE. See Unit 4 of the Economic Analysis for a complete discussion of the technically and economically feasible alternatives to TCE. (Ref. 3). While some substitutes, such as methylene chloride or 1–BP, also present risks to workers, there are numerous other solvents available. These include designer solvents such as hydrofluorocarbon (HFC) and hydrofluoroether (HFE) solvent blends and hydrofluoroolefin (HFO), as well as other alternative solvents and cleaning systems, such as terpene-based cleaners, volatile methyl siloxanes, soy-based cleaners, and water-based cleaners.

Alternatives to TCE fall within several broad categories: Drop-in solvent alternatives, non-drop-in solvent alternatives (designer solvents, such as hydrofluorocarbons, hydrofluoroolefins, and hydrofluoroethers), aqueous cleaning systems, other cleaning solvents (such as glycol ethers, siloxanes, terpenes, soy-based cleaners), and cold cleaning with TCE (Ref. 58).

EPA considered a solvent to be a drop-in alternative if it could be used in an existing vapor degreasing system with only minor modifications. One important consideration for many vapor degreasing machines is the flammability of the solvent. Heating a flammable solvent up to its boiling point increases the likelihood that, if there is a source of ignition or if the vapor concentration exceeds certain limits, the solvent will ignite or explode. Halogens (fluorine, chlorine and bromine) suppress flammability, hence their common use as fire extinguishants. For this reason, halogenated solvents are commonly used in vapor degreasing, although solvent flammability is less of a concern in closed-loop systems operated under vacuum. Depending on the type of vapor degreasing system, the drop-in solvent alternatives identified by EPA include methylene chloride, 1-bromopropane (1–BP or n-propyl bromide), and perchloroethylene. Like TCE, methylene chloride and perchloroethylene are hazardous air pollutants (HAPs) under the Clean Air Act and their use is regulated under the Halogenated Solvent NESHAP (40 CFR part 63, subpart T). Therefore, facilities that switch from TCE to methylene chloride or perchloroethylene will still be regulated by the NESHAP. In addition, although 1–BP is not currently listed as a HAP, EPA is currently considering a petition to list this chemical (Ref. 59).

There are significant hazards associated with all three of these drop-in replacements for TCE in vapor degreasing systems. However, based on EPA's analysis, the adverse effects associated with TCE exposure occur at exposure levels below the levels at which the adverse effects associated with the replacement chemicals occur (Ref. 58). With respect to methylene chloride, in August 2014, EPA issued a risk assessment of its use for paint and coating removal and EPA intends to issue a proposal to regulate this use of methylene chloride. While EPA has not specifically assessed the risks associated with using methylene chloride in vapor degreasing applications for this rulemaking, there are a number of hazard concerns associated with this chemical. The potential effects of methylene chloride exposure include death, liver toxicity, kidney toxicity, reproductive toxicity, specific cognitive impacts, and cancer (Ref. 60). Some of these effects result from a very short, acute exposure; others follow years of occupational exposure. Acute exposures may cause confusion and respiratory suppression in humans and there have been a number of deaths associated with worker exposures in homes and other job sites due to the buildup of carbon monoxide in the blood. Methylene chloride is likely to be carcinogenic in humans, so chronic exposures may increase cancer risk. Chronic exposures to methylene chloride may also lead to liver effects. However, these adverse effects are generally seen at higher exposure levels than those associated with TCE toxicity.

With respect to environmental effects, methylene chloride is volatile and releases of methylene chloride are likely to evaporate to the atmosphere, or if released to soil, migrate to groundwater (Ref. 59). It has a global warming potential (GWP) of 8.7 relative to carbon dioxide and thus can act as a greenhouse gas. Methylene chloride has been shown to biodegrade over a range of rates and conditions and is considered to be moderately persistent in the environment. Measured bioconcentration factors suggest that its bioconcentration potential is low.

EPA also has concerns for 1–BP. In May of 2016, a peer review meeting was held on EPA's draft TSCA Work Plan Chemical Risk Assessment for 1–BP. This draft assessment specifically evaluated the risks associated with the use of 1–BP in vapor degreasing (Ref. 61). According to the peer review draft, most acute exposure scenarios for vapor degreasing identified risks for adverse developmental effects that may occur as a result of a single exposure to 1–BP during a critical window of susceptibility. Likewise, chronic exposure risks for adverse neurological and developmental effects were identified in the draft risk assessment for all uses evaluated without engineering controls. In addition, the draft weight-of-evidence analysis for the cancer endpoint is sufficient to support a probable mutagenic mode of action for 1–BP carcinogenesis. However, these adverse effects are generally seen at higher exposure levels than those associated with TCE toxicity.

1–BP is a volatile liquid with high vapor pressure, moderate water solubility, and high mobility in soil (Ref. 61). It is expected to exhibit low adsorption to soil and thus can migrate rapidly through soil to groundwater. 1–BP is slowly degraded by sunlight and reactants when released to the atmosphere. Based on the estimated half-life of nine to twelve days, long range transport via the atmosphere is possible. Biotic and abiotic degradation studies have not shown this substance to be persistent (overall environmental half-life less than two months). While no measured bioconcentration studies for 1–BP are available, an estimated bioaccumulation factor of 12 suggests that bioconcentration and bioaccumulation in aquatic organisms are low.

EPA is also concerned about the adverse health effects associated with perchloroethylene (tetrachloroethylene) exposure. Based on the available human epidemiologic data and experimental and mechanistic studies, EPA has concluded that it poses a potential human health hazard for noncancer toxicity to the central nervous system, kidney, liver, immune and hematologic system, and on development and reproduction. (Ref. 62) Neurotoxicity has been identified as a sensitive endpoint following either oral or inhalation exposure. In addition, EPA has determined that perchloroethylene (tetrachloroethylene) is likely to be carcinogenic to humans by all routes of exposure (Ref. 62). As with methylene chloride and 1–BP, the adverse health effects associated with perchloroethylene (tetrachloroethylene) are generally seen at higher exposure levels than those associated with TCE toxicity. Perchloroethylene presents low to moderate risk to aquatic organisms (Ref. 62). It is moderately persistent, with a low bioaccumulation potential.

In contrast, aqueous cleaning systems present less risk to workers. Water-based cleaners have been used for many years in applications where users originally used TCE or other chlorinated solvents in vapor degreasing. In these systems, water-based cleaners are used to clean grease or oil from parts, the parts are rinsed, sometimes with deionized water if a spot free part is required for the next process, and dried. The cleaner concentrate, typically made up of boric acid or gluconic acid and other constituents, is generally diluted to between about 5% and 20% in a heated wash bath, depending on the cleaning task and the agitation in the equipment. The rinse is generally heated as well. Often driers composed of air knives that drive the water from the part are used.

Depending on the circumstances, several different types of equipment capable of using water-based cleaners can replace vapor degreasing machines that use TCE. Ultrasonic cleaning systems have transducers for generating the ultrasonic action in a bath. There are some immersion systems where the parts are placed on a platform and moved up and down in the cleaning agent. In certain circumstances parts can be sprayed at pressures of about 60 psi and greater in spray cabinets. Conveyorized spray systems, where the parts go through high pressure spray at between about 80 and 120 psi, are also used in some cases. These systems often have wash, rinse and dry sections.

Water-based cleaners have a few characteristics to consider when evaluating replacements for TCE vapor degreasing (Ref. 63). Since TCE is used primarily to clean metal parts, the water cleaners often contain rust or corrosion inhibitors, which typically are present at very low concentrations, to protect the metals (Ref. 61). In addition, in order to be used in spray equipment, water-based cleaners must be formulated with a non-foaming surfactant. However, there are numerous water-based cleaners available on the market that have been formulated for these purposes (Ref. 64). In addition, the SBAR Panel convened in support of this rulemaking heard from several SERs about the increased water use associated with aqueous cleaning systems (more than 10,000 gallons a day). While this water can be reused in the degreasing system, any effluent is considered industrial wastewater for which a permit may be required under the Clean Water Act (Ref. 32).

SERs providing input to the SBAR Panel noted that, in general the use of TCE in vapor degreasing is declining very rapidly in certain sectors, but is still the method of choice for some, especially for small, intricate parts and substrates (*e.g.,* small tubes). Several SERs contended that none of the currently available chemical alternatives are good substitutes for TCE because of the health hazards associated with the substitutes, potential upcoming regulations and use restrictions on substitutes, compliance with the NESHAP limitations, and cost. In addition, some degreasing applications require highly efficient cleaning, such as electronics and glass to metal seals, which must be absolutely free of soil. A SER stated that no substitutes for critical glass to metal seals have been identified. Several SERs stated that substitutes with lower boiling points are not viable alternatives because they volatilize during processes involving elevated temperatures and because they cannot be shipped in standard drums. Most SERs indicated that replacing their open-top vapor degreasing systems with more sophisticated systems or alternative systems using aqueous cleaners would be very expensive, estimates ranged from $350,000 to $650,000. In contrast, one SER noted that water-based, or aqueous cleaning systems can be developed to replace most TCE-based vapor degreasing systems (Ref. 32). This same SER also stated that potential drawbacks to aqueous cleaning systems are the increased water use and the need for additional facility space. According to this SER, aqueous systems are typically much larger than vapor degreasing systems and aqueous operations often require multiple stages to reach the same cleaning efficiency as vapor degreasers.

Based on this input from the SERs, EPA is specifically requesting additional comments, information, and data to assist EPA in evaluating the availability of alternatives to TCE in vapor degreasing applications, including information on the costs to achieve TCE exposure reductions or to transition to alternative chemicals or processes. In addition, EPA will consider granting a time-limited exemption, under the authority of TSCA section 6(g), for a specific condition of use for which EPA can obtain documentation: That the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; that compliance with the proposed ban would significantly disrupt the national economy, national security, or critical infrastructure; or that TCE vapor degreasing in a specific application, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety. To this end, EPA requests comment on a process for receiving and evaluating petitions and requesting EPA promulgate critical use exemption rules. Under this process, entities who believe that their specific condition of use is a critical or essential use under TSCA section 6(g) would submit a petition for an exemption rulemaking with supporting documentation that they believe demonstrates that the use meets the statutory criteria. EPA would review the petition for completeness and, if the documentation warrants further action, respond to the petition by publishing a proposal in the **Federal Register** inviting comment on a proposed exemption. EPA would consider the comments received, along with any additional information reasonably available, and then take final action on the proposed exemption. EPA requests comment on the specific kinds of documentation that should be required from entities seeking an exemption rulemaking in order to facilitate EPA's and later, the public's review. EPA also requests comment on the appropriate timeframes for EPA action, given that the documentation for any given use could be technical and extensive, and that EPA may also need to develop additional information, such as economic estimates, in order to promulgate an exemption rule under TSCA section 6(g). Finally, members of the potentially regulated community who believe that their operation is a critical or essential use should provide as much detail as possible to EPA about their operation during this comment period, including information on any evaluations of alternatives, the costs to transition to another chemical or process, and any other relevant information. This would assist EPA in reviewing the specific condition of use, as well as in establishing provisions for future exemption petitions.

EPA urges vapor degreasing facilities to think strategically about their choices should TCE be banned for their use or if they are in the market to replace or upgrade vapor degreasing equipment for other reasons. To the extent that a process currently using TCE in a vapor degreasing system can be converted to a significantly less toxic alternative, such as an aqueous cleaning system, it will avoid significant risks to workers and also reduce the likelihood that further actions on toxic solvents by EPA or other regulatory authorities will spur another process change.

E. Impacts of the Proposed and Alternative Regulatory Options

This unit describes the estimated costs of the proposed and alternative regulatory actions that EPA considered.

1. Proposed approach to prohibit manufacturing (including import), processing, distribution in commerce, and use of TCE for vapor degreasing and require downstream notification. The costs of the proposed approach are estimated to include equipment modification costs, product costs, electricity, disposal, and other costs associated with using alternative solvents or systems. Although the proposal imposes costs resulting from downstream notification and recordkeeping requirements, these actions required under this proposed rule are identical in requirement and coverage to those included as part of the earlier proposed rule on TCE use in aerosol degreasing and spot cleaning at dry cleaning facilities (Ref. 1) that is a companion to this proposed rule. These notification and recordkeeping costs were accounted for as part of that proposal and are not included in the costs for this rule. Overall, EPA estimates that 50% of users will switch to drop-in alternatives, 25% will convert to aqueous cleaning systems, and 25% will convert to other alternatives. The total costs for switching from TCE-based vapor degreasing to a substitute are estimated to be approximately $30 million to $45 million per year (annualized at 3% over 20 years) and $32 million to $46 million (annualized at 7% over 20 years).

2. Option that bans manufacturing (including import), processing, distribution in commerce, and use of TCE for vapor degreasing except in airless vacuum-to-vacuum closed-loop systems where proper PPE is used and a requirement for downstream notification. Given equipment costs and the burden of establishing a respiratory protection program which involves training, respirator fit testing and the establishment of a medical monitoring program, EPA anticipates that companies not currently using airless vacuum-to-vacuum systems would choose to switch to substitutes instead of purchasing an airless system and adopting a program for PPE because substitutes are readily available and are more technically and economic feasible. EPA also assumes that this would be the case even if this alternative were expressed as a performance-based air exposure limit for TCE. The estimated annualized costs of switching to a respiratory protection program requiring PPE of APF 10,000 are $30,000 at 3% and $32,000 at 7% per vapor degreasing machine over 20 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. Further, even if cost were not an impediment, 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. For those options that exclude downstream notification, the options are less cost effective and more burdensome to enforce. This is even though EPA assumes monetized enforcement costs to be the same under all options for the purpose of this proposed rulemaking because EPA was unable to monetize the extent to which enforcement costs would vary by regulatory option. The proposed approach to prohibit manufacturing (including import), processing, distribution in commerce, and use of TCE for vapor 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 more difficult since the key requirements are directly placed on the larger 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. Therefore, EPA considers downstream notification to be a critical component of this proposal and EPA also finds that incorporating downstream notification reduces the burden on society by easing implementation, compliance, and enforcement.

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

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.

A. Benefits of the Proposed Rule and the Alternatives That EPA Considered

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 the costs of the effects 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 $65 million to $447 million at 3% and $32 million to $227 million at 7% over 20 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. This information 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 alternative options that EPA considered are unlikely to result in the same health benefits as the proposed rule for the reasons discussed in Unit VI. However, EPA was unable to quantify the differences in benefits that would result from the alternatives.

B. 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 vapor degreasing are discussed in Unit VI.C. Under the proposed option, costs to users of TCE in vapor degreasing applications range from $30 million to $45 million (annualized at 3% over 20 years) and $32 million to $46 million (annualized at 7% over 20 years). Costs of downstream notification and recordkeeping for manufacturers, processors, and distributors on an annualized basis over 20 years are $3,200 and $4,400 using 3% and 7% discount rates respectively. However, the costs of the downstream notification and recordkeeping requirements were already accounted for in the prior proposal on TCE use in aerosol degreasing and as a spotting agent in dry-cleaning facilities, and thus are not included in the total costs for this proposal.

The primary alternative that EPA considered is a requirement that TCE be used for vapor degreasing only in certain closed systems and that workers operating the systems and in the immediate area wear PPE with an APF of 10,000. The estimated annualized costs of this option are $32 million to $46 million annualized over 20 years at 3% and $34 million to $47 million annualized over 20 years at 7%.

C. Comparison of Benefits and Costs

The monetized benefits for preventing the risks resulting from TCE exposure from this use significantly outweigh the estimated costs. Simply comparing the costs and monetized benefits of prohibiting the manufacture (including import), processing, and distribution in commerce of TCE for use in vapor degreasing, prohibiting commercial use of TCE in vapor degreasing, and requiring downstream notification demonstrates that the monetized benefits of this proposed action outweigh the costs. However, 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 in this Unit 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 deciding how best to address the unreasonable risks presented by TCE use in vapor degreasing. 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, and the emotional and psychological costs, the benefits of preventing exposures to TCE emissions from vapor degreasing systems 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 vapor degreasing (the annualized monetized benefits on a 20 year basis range from approximately $65 million to $447 million at 3% and $32 million to $227 million at 7%) far outweigh the costs of the proposal to ban the use of TCE in vapor degreasing (the annualized costs on a 20 year basis range from approximately $30 million to $45 million at 3% and $32 million to $46 million at 7%). Considering the costs and benefits of the proposed and alternative options, while both address the unreasonable risks from TCE exposure, the proposed approach is more cost effective because it achieves the same or greater benefits at lower costs. For more information, see Section 7 in the Economic Analysis.

VIII. Overview of Uncertainties

A discussion of the uncertainties associated with this proposed rule can be found in the TCE risk assessment (Ref. 2) and in the supplemental analysis (Ref. 30) for use of TCE in vapor degreasing. 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 exposure scenarios and to develop the hazard/dose-response and risk characterization. EPA recognizes that the uncertainties may underestimate or overestimate actual risks. These uncertainties include the possibility that releases of and exposures to TCE vary from one vapor degreasing machine 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 vapor degreasing, there are uncertainties in the number of workers exposed to TCE and in the inputs and algorithms of the models used to estimate exposures.

In addition to the uncertainties in the risks, there are uncertainties in the cost and benefits. The uncertainties in the benefits are most pronounced in estimating the benefits from preventing 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 potential risks for adverse health effects that the alternatives may pose and the estimates of the alternatives that users might choose to adopt. 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 assumes no benefits for TCE users that keep the same vapor degreasing machines and switch to methylene chloride, perchloroethylene, 1–BP, or designer solvent alternatives, assumes that TCE users switching to any other alternative suffer no adverse health effects associated with the alternatives (*i.e.,* accrue the full benefits from eliminating TCE exposure), and applies a lowering factor to cancer risk estimates. The higher benefits estimate includes the benefit from entirely eliminating TCE exposure for all alternative compliance strategies, assumes that no risks are introduced by alternatives, and does not apply a lowering factor to cancer risk estimates. 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.

In addition, under certain assumptions EPA's economic analysis estimates that some TCE users will see a cost savings when switching to aqueous systems and certain other solvents. Standard economic theory suggests that financially rational companies would choose technologies that maximize profits so that regulatory outcomes would not typically result in a cost savings for the regulated facilities. There could be several reasons that cost savings might occur in the real world. Potential reasons include lack of complete information or barriers to obtaining information on the cost savings associated with alternatives as well as investment barriers or higher interest rates faced by firms. Additionally, there may be costs associated with these alternatives that are not adequately accounted for in the analysis. To evaluate the effect of this uncertainty, EPA has included a sensitivity analysis that sets the cost savings to zero for these compliance alternatives (Ref. 3 at section 8.2). EPA also recognizes that these firms might experience positive costs of compliance rather than zero costs, so that the actual total costs could be higher than those in the sensitivity analysis. However, EPA has no current basis to estimate these potentially higher costs, since the available data appear to show that there are lower cost substitutes available. EPA requests comment and/or data on any hidden costs that may be missing from the analysis, or any other information that may help explain why some firms appear to be missing current opportunity for cost-savings substitutes.

There are also uncertainties in the estimates of the number of affected vapor degreasing machines, 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 vapor degreasing machines is based upon available industry information and an industry expert (Ref. 3). 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 includes 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. 3).

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

IX. Analysis Under TSCA Section 9 and TSCA Section 26(h) Considerations

A. TSCA Section 9(a) Analysis

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

TSCA section 9(d) instructs the Administrator to consult and coordinate TSCA activities with other Federal agencies for the purpose of achieving the maximum enforcement of TSCA while imposing the least burden of duplicative requirements. For this proposed rule, EPA has consulted with OSHA.

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 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. 12). 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 vapor degreasing or the uses identified in a prior proposal (Ref. 1), aerosol degreasing or for spot cleaning in dry cleaning facilities (Ref. 12).

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

Moreover, recent amendments to TSCA, Public Law 114–182, alter both the manner of identifying unreasonable risk under TSCA and EPA's authority to address unreasonable risk under TSCA, such that risk management under TSCA is increasingly distinct from analogous provisions of the Consumer Product Safety Act (CPSA), the Federal Hazardous Substances Act, 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 TCE from these uses to a sufficient extent 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 (2014). But under TSCA, EPA's substantive burden under TSCA § 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 nonrisk factors.

TSCA is the only regulatory authority able to prevent or reduce risks 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. Furthermore, there are key differences between the newly amended finding requirements of TSCA and those of the OSH Act, CPSA, and the FHSA. For these reasons, in her discretion, the Administrator does not determine that unreasonable risks from the use of TCE in vapor degreasers, aerosol spray degreasers, and as a spot cleaner at dry cleaning facilities may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA.

B. TSCA Section 9(b) Analysis

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

Although several EPA statutes have been used to limit 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 chemical substances.

For these reasons, the Administrator does not determine that unreasonable risks from the use of TCE in vapor degreasers, aerosol spray degreasers, and as a spot cleaner at dry cleaning facilities could be eliminated or reduced to a sufficient extent by actions taken under other Federal laws administered in whole or in part by EPA.

C. Section 26(h) Considerations

EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science. For example, EPA based its proposed determination of unreasonable risk presented by the use of TCE in vapor degreasing systems on the completed risk assessment, which followed a peer review and public comment process, as well as using the best available science and methods (Ref. 2). A supplemental analysis was performed to better characterize the exposed populations and estimate the effects of various control options. This supplemental analysis was performed consistent with the methods and models used in the risk assessment. These analyses were developed for the purpose of determining whether the particular risks are unreasonable. They were also developed to support risk reduction by regulation under section 6 of TSCA, to the extent risks were determined to be unreasonable. It is reasonable and consistent to consider these analysis in this rulemaking for such relevant purposes.

The extent to which the various information, procedures, measures, methods, protocols, methodologies or models, as applicable, used in EPA's decision have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for this rule. Additional information on the peer review and public comment process, such as the peer review plan, the peer review report, and the Agency's response to comments, can be found on EPA's Assessments for TSCA Work Plan Chemicals Web page at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals.*

X. Major Provisions and Enforcement of the Proposed Rule

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

A. Prohibitions on TCE Manufacturing (Including Import), Processing, Distribution in Commerce, and Commercial Use

This proposal would prohibit the manufacture (including import), processing, distribution in commerce, and commercial use of TCE in vapor degreasing.

B. Downstream Notification

EPA has authority under TSCA section 6 to require that a substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate 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 proposal. 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. As discussed in the prior proposal on TCE use in aerosol degreasers and as a spot remover agent in dry cleaning facilities, EPA is proposing a requirement for downstream notification by manufacturers (including importers), processors, and distributors of TCE for any use to ensure compliance with the proposed prohibitions on the manufacture, processing, distribution in commerce, and commercial use of TCE. 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 use, which is likely to decrease unintentional uses of TCE. Downstream notification represents minimal burden and is necessary for effective enforcement of the rule. The specific requirement, that persons who manufacture (including import), process, or distribute in commerce TCE for any use would have to provide written notification of the restrictions to persons to whom TCE is shipped, was included in an earlier proposal on TCE use (Ref. 1). The specific recordkeeping requirements were also contained in the prior proposal (Ref. 1). Those provisions would require manufacturers (including importers), processors, and distributors of TCE for any use to retain documentation of the identity and contact information for persons to whom TCE was shipped as well as the amount of TCE shipped, and a copy of the notification that was provided. This documentation would have to be retained for 3 years from the date of shipment.

As presented in the prior proposal (Ref. 1), the estimated costs of downstream notification and recordkeeping on an annualized basis over 20 years are $3,200 and $4,400 using 3% and 7% discount rates respectively.

C. Enforcement

TSCA section 15 makes it unlawful to fail or refuse to comply with any provision of a rule promulgated under TSCA section 6. Therefore, any failure to comply with this proposed rule when it becomes effective would be a violation of TSCA section 15. In addition, TSCA section 15 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 TSCA section 11.

Violators may be subject to both civil and criminal liability. Under the penalty provision of TSCA section 16, any person who violates TSCA 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 and imprisonment. In addition, other remedies are available to EPA under TSCA sections 7 and 17.

Individuals, as well as corporations, could be subject to enforcement actions. TSCA sections 15 and 16 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.

D. Implementation Dates and Incentives

As proposed in the prior action on TCE use (Ref. 1), the downstream notification requirements and the recordkeeping requirements applicable to manufacturers (including importers) and processors of TCE for any use and persons who distribute TCE in commerce for any use (other than retailers) would take effect 45 days after the final rule is issued. EPA is proposing to make the ban on manufacturing (including importing), processing, or distributing in commerce TCE for vapor degreasing uses, the downstream notification requirements, and the recordkeeping requirements effective 18 months after publication of the final rule. The ban on the use of TCE in vapor degreasing systems would take effect six months after that, or two years after publication of the final rule. EPA heard from the SERs who provided input to the SBAR Panel that converting from a vapor degreasing system that uses TCE to one that does not is often a time-intensive process (Ref. 32). SERs had different ideas on how long it would take for the conversion process. One SER observed that many users do not know exactly how clean their products must be, or how clean their existing system gets them. According to this SER, testing is needed to determine the required cleaning efficiency, and it can take six months for the testing. Changing to a new system could take an additional twelve to eighteen months. Another SER agreed with the estimate of two years for a changeover, while still another SER thought it could take anywhere from six months to four years. In light of this input, EPA believes that it is reasonable to establish the compliance date for the prohibition on TCE in vapor degreasing at two years from the date the final rule is promulgated. EPA believes that, in most cases, the transition can be made within this time, but EPA requests comment on whether there are special situations which may require more time.

EPA would like to encourage as many companies as possible to adopt less hazardous technologies, such as aqueous cleaning systems, instead of switching to an alternative that also presents health risks for workers, albeit of a lower magnitude than TCE. EPA's analysis indicates that the best answer for many vapor degreasing operations may be a switch to water-based cleaners, even though there are higher upfront costs. An effective system that works for a given application and that is acceptable to customers must be researched and designed, new equipment and cleaning solutions must be purchased, new permits may be required, operating and safety procedures must be updated, and affected employees must learn to operate the new equipment. However, once the system is up and running properly, operation of the system on an annual basis is likely to be less expensive and much less hazardous to employees than a vapor degreasing system using TCE.

EPA requests comment on its analysis of the alternatives and the impacts of switching to less hazardous cleaners. EPA is particularly interested in comments and information on water and energy use associated with water-based cleaners and other less-toxic solvents, as well as on the costs of conversion from a system that uses TCE and the length of time such a conversion would take.

EPA is also requesting comment on potential incentives for vapor degreasing facilities to switch to less toxic alternatives. TSCA does not provide the authority for EPA to offer incentives such as tax credits, so there are a limited number of regulatory incentives available to EPA. One potential incentive would be a delayed implementation date for a ban on TCE use in vapor degreasing. This incentive would allow vapor degreasing facilities that intend to convert to aqueous cleaning systems a longer period of time to make the conversion. One way to administer this incentive would be to require vapor degreasing facilities to specifically request an extension for a certain length of time. Of course, in order to limit misuse of this extension opportunity, EPA would have to also require documentation of the facility's clear intention to convert to an aqueous cleaning system. This might include a description of the steps the company has already taken to implement a change to aqueous substitutes, or a description of the specific plan for implementing the change within the extension period requested, with some sort of documentation, such as a contract to purchase equipment. EPA also notes that TSCA section 6(d) generally provides that compliance dates for the start of a ban or phase-out promulgated under section 6(a) must be as soon as practicable, but not later than five years after the rule is promulgated, except for those critical or essential uses exempted under TSCA section 6(g). EPA requests comments on all aspects of this potential incentive, including comments on the length of time that should be allowed for an extension, what documentation should be required, and which technologies or solvents should be eligible for an extension and how to define them. EPA also requests comments on other potential incentives or regulatory flexibilities that EPA could incorporate to encourage the adoption of safer degreasing technologies. Finally, in keeping with the SBAR Panel recommendation regarding flexibility for small businesses, EPA requests comment on whether there are flexibilities other than delayed implementation dates that would be particularly advantageous for small businesses while still ensuring that they address the unreasonable risks to which their workers may be exposed.

XI. 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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14. American Conference of Governmental Industrial Hygienists (ACGIH), Threshold Limit Values & Biological Exposure Indices for 2003, ACGIH, Cincinnati, OH, 2003.
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XII. Statutory and Executive Order Reviews

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

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

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

B. Paperwork Reduction Act (PRA)

The information collection requirements in this proposed rule have been submitted to OMB for review and comment under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by the Agency has been assigned EPA ICR No. 2541.02. You can find a copy of the ICR in the docket for this proposed rule (Ref. 65), 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 three years from the date of shipment. These information collection activities are necessary in order to enhance the prohibitions under the proposed rule by ensuring awareness of the prohibitions throughout the 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 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 EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than February 21, 2017. EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 603 of the RFA, 5 U.S.C. 601 *et seq.,* EPA prepared an initial regulatory flexibility analysis (IRFA) that examines the impact of the proposed rule on small entities along with regulatory alternatives that could minimize that impact. The complete IRFA is available for review in the docket and is summarized here (Ref. 66).

1. Need for the rule. Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines after risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk. Based on EPA's risk assessment of TCE (Ref. 2), EPA's proposed determination is that the use of TCE in vapor degreasing presents an unreasonable risk of injury to health and that the provisions of this proposal are necessary to address the unreasonable risk.

2. *Objectives and legal basis.* The legal basis for this proposal is TSCA section 6(a), which provides authority for the Administrator to apply requirements to the extent necessary so that a chemical substance or mixture no longer presents an unreasonable risk of injury to health or the environment. Additionally, for a chemical substance, such as TCE, which is 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 authorizes EPA to issue rules under TSCA section 6(a) that are consistent with the scope of the completed risk assessment and consistent with the other applicable requirements of TSCA section 6.

3. *Small entities covered by this proposal.* EPA estimates that the proposal would affect approximately 2,500 to 6,000 small entities. The majority of these entities are commercial users of TCE in vapor degreasing machines in a variety of occupational settings such as metal plating, electronics assembly, metal or composite part fabrication, and repair shops.

4. *Compliance requirements and the professional skills needed.* To address the unreasonable risks that EPA has identified, this proposal would prohibit the manufacture (including import), processing, and distribution in commerce of TCE for use in vapor degreasing; prohibit commercial use of TCE in vapor degreasing; and require manufacturers, processors, and distributors, except for retailers, to provide downstream notification of this prohibition throughout the supply chain (*e.g.,* via a Safety Data Sheet (SDS)), and to keep records. Complying with the prohibitions, the downstream notification, and the recordkeeping requirements involve no special skills. However, design and implementation of an alternative to vapor degreasing with TCE may involve special skills, such as engineering experience.

5. *Other Federal regulations.* Other Federal regulations that affect the use of TCE in vapor degreasing are discussed in Unit III.A. of this preamble. Because the NESHAP regulates only emissions from vapor degreasing facilities, not worker exposures, and because the 1971 OSHA PEL is not sufficiently protective, EPA's proposal is not duplicative of other Federal rules nor does it conflict with other Federal rules.

6. *Regulatory alternatives considered.* EPA considered a wide variety of control measures and the Economic Analysis (Ref. 3) examined several alternative analytical options. However, EPA determined that most of the alternatives did not effectively address the unreasonable risk presented by TCE in vapor degreasing. The primary alternative considered by EPA was to allow the use of TCE in closed-loop vapor degreasing systems and require respiratory protection equipment for workers operating the equipment 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 with an alternative to the specified APF respirator of an air exposure limit. Depending on air concentrations and proximity to the vapor degreasing equipment, other employees in the area would also need to wear respiratory protection equipment. While this option would address the unreasonable risks presented by TCE in vapor degreasing, EPA's Economic Analysis indicates that this option is more expensive and, thus less cost effective than switching to a different solvent or cleaning system.

As required by section 609(b) of the RFA, EPA also convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations from small entity representatives that potentially would be subject to the rule's requirements. The SBAR Panel evaluated the assembled materials and small-entity comments on issues related to elements of an IRFA. A copy of the full SBAR Panel Report is available in the rulemaking docket. The Panel recommended that EPA seek additional information on critical uses; availability, effectiveness, and costs of alternatives; implementation timelines; and exposure information to provide flexibility to lessen impacts to small entities, as appropriate. Throughout this preamble, EPA has requested information with respect to these and other topics. The Panel made the following specific recommendations:

a. *Critical uses.* The Panel recommended that EPA provide exemption, in accordance with TSCA section 6(g), for those critical uses for which EPA can obtain adequate documentation that:

- No technically and economically feasible safer alternative is available;
- Compliance with the ban would significantly disrupt the national economy, national security, or critical infrastructure; or
- The specific condition of use, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

To that end, the Panel recommended that EPA include in its proposal specific targeted requests for comment directed towards identifying critical uses (such as the aeronautics industry and national security) and obtaining information to justify exemptions. The Panel also recommended that EPA request public comment on allowing the use of TCE in closed-top vapor degreasing systems with the use of appropriate PPE.

b. *Alternatives.* The Panel recommended that EPA ensure that its analysis of the available alternatives to TCE in vapor degreasing complies with the requirements of section 6(c)(2)(C) and includes consideration, to the extent legally permissible and practicable, of whether technically and economically feasible alternatives that benefit health or the environment, compared to the use being prohibited or restricted, will be reasonably available as a substitute when the proposed requirements would take effect. Specifically, the Panel recommended that EPA:

- Evaluate the feasibility of using alternatives, including the cost, relative safety, and other barriers (such as space constraints, cleaning efficiency, increased energy use, cycle time, boiling points, and water use restrictions); and
- Take into consideration the current and future planned regulation of compounds the Agency has listed as alternatives.

c. *Implementation timelines.* The Panel recommended that EPA provide regulatory flexibility, as applicable, based on additional information, such as delayed compliance or a phase-out option, for small businesses that may be affected by the rule and in its proposal specifically request additional information regarding timelines for transitioning to alternative chemicals or technologies.

d. *Cost information.* The Panel also recommended that EPA specifically evaluate the cost to small business degreasing services without a viable alternative to TCE (*i.e.,* the cost of going out of business). The Panel recommended that EPA request additional information on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies.

e. *Exposure information.* The Panel recommended that EPA include in its proposal specific requests for additional pertinent exposure data that may be available.

f. *Risk assessment.* The Panel recommended that EPA recognize the concerns that the SERs had on the risk assessment by referring readers to the risk assessment and the Agency's Summary of External Peer Review and Public Comments and Disposition document, which addresses those concerns, in the preamble of the proposed rulemaking.

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 persons who commercially use TCE in vapor degreasing equipment. The total estimated annualized cost of the proposed rule is approximately $30 million to $45 million at 3% and $32 million to $46 million at 7% (Ref. 3).

E. Executive Order 13132: Federalism

EPA has concluded that this action has federalism implications, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because regulation under TSCA section 6(a) may preempt state law. EPA provides the following 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. 67). 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. 68). EPA also met with the National Tribal Toxics Council (NTTC) in Washington, DC and via teleconference on April 22, 2015 (Ref. 68). 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 subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is an economically significant regulatory action as defined by Executive Order 12866, and EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children, specifically on the developing fetus. Accordingly, we have evaluated the environmental health or safety effects of TCE used in vapor degreasing on children. The results of this evaluation are discussed in Units I.F., II.C., IV., and VI.C. of this preamble and in the economic analysis (Ref. 3).

Supporting information on the exposures and health effects of TCE exposure on children is also available in the Toxicological Review of Trichloroethylene (Ref. 4) and the TCE risk assessment (Ref. 2).

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

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution in commerce, or use. This rulemaking is intended to protect against risks from 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, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272 note.

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 IV. and VI. 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 certification, Hazardous substances, Import certification, Recordkeeping.

Dated: January 11, 2017.

Gina McCarthy,

Administrator.

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

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

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

Authority: 15 U.S.C. 2605.

■ 2. In § 751.303, add the definition ''Vapor'' in alphabetical order to read as follows:

§ 751.303 Definitions.

* * * * *

Vapor degreasing means a cleaning process involving heating a solvent to produce a hot vapor which is then used to remove contaminants such as grease, oils, dust, and dirt from fabricated parts and other materials.

■ 3. Add § 751.309 to read as follows:

§ 751.309 Vapor degreasing.

(a) After [*date 18 months after the date of publication of the final rule*], all persons are prohibited from manufacturing (including import), processing, and distributing in commerce TCE and mixtures containing TCE for use in vapor degreasing.

(b) After [*date 2 years after the date of publication of the final rule*], all persons are prohibited from commercial use of TCE and mixtures containing TCE in vapor degreasing.

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