PRE-PUBLICATION NOTICE

On June 7, 2023, Michal S. Regan, the EPA Administrator, signed the following document:

Action:	**Proposed Rule (NPRM)**
Title:	**Perchloroethylene (PCE); Regulation under the Toxic Substances Control Act (TSCA)**
FRL #:	**FRL-8329-02-OCSPP**
Docket ID #:	**EPA-HQ-OPPT-2020-0720**

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA-HQ-OPPT-2020-0720; FRL-8329-02-OCSPP]

RIN 2070-AK84

Perchloroethylene (PCE); Regulation under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to address the unreasonable risk of injury to human health presented by perchloroethylene (PCE) under its conditions of use as documented in EPA's December 2020 Risk Evaluation for PCE and December 2022 revised risk determination for PCE prepared under the Toxic Substances Control Act (TSCA). PCE is a widely used solvent in a variety of occupational and consumer applications including fluorinated compound production, petroleum manufacturing, dry cleaning, and aerosol degreasing. EPA determined that PCE presents an unreasonable risk of injury to health due to the significant adverse health effects associated with exposure to PCE, including neurotoxicity effects from acute and chronic inhalation exposures and dermal exposures, and cancer from chronic inhalation exposures to PCE. TSCA requires that EPA address by rule any unreasonable risk of injury to health or the environment identified in a TSCA risk evaluation and apply requirements to the extent necessary so the chemical no longer presents unreasonable risk. PCE, also known as perc and tetrachloroethylene, is a neurotoxicant and a likely human carcinogen. Neurotoxicity, in particular impaired visual and cognitive function and diminished color discrimination, are the most sensitive adverse effects driving the unreasonable risk of PCE, and other adverse effects associated with exposure include central nervous system depression,

kidney and liver effects, immune system toxicity, developmental toxicity, and cancer. To address the identified unreasonable risk, EPA is proposing to prohibit most industrial and commercial uses of PCE; the manufacture (including import), processing, and distribution in commerce of PCE for the prohibited industrial and commercial uses; the manufacture (including import), processing, and distribution in commerce of PCE for all consumer use; and, the manufacture (including import), processing, distribution in commerce, and use of PCE in dry cleaning and related spot cleaning through a 10-year phaseout. For certain conditions of use that would not be subject to a prohibition, EPA is also proposing to require a PCE workplace chemical protection program that includes requirements to meet an inhalation exposure concentration limit and prevent direct dermal contact. EPA is also proposing to require prescriptive workplace controls for laboratory use, and to establish recordkeeping and downstream notification requirements. Additionally, EPA proposes to provide certain time-limited exemptions from requirements for certain critical or essential emergency uses of PCE for which no technically and economically feasible safer alternative is available.

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

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0720, through the Federal eRulemaking Portal at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information

whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets/*.

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Kelly Summers, Existing Chemicals Risk Management Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number (202) 564-2201; email address: *PCE.TSCA@epa.gov.*

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

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this Action apply to me?

You may be potentially affected by the proposed action if you manufacture (defined under TSCA to include import), process, distribute in commerce, use, or dispose of PCE or products containing PCE. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities include:

- Crude Petroleum Extraction (NAICS code 211120).
- Support Activities for Oil and Gas Operations (NAICS code 213112).
- Nonwoven Fabric Mills (NAICS code 313230).
- Wood Window and Door Manufacturing (NAICS code 321911).
- Paper Bag and Coated and Treated Paper Manufacturing (NAICS code 322220).
- Commercial Screen Printing (NAICS code 323113).

• 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).

• Rubber Product Manufacturing for Mechanical Use (NAICS code 326291).

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

• Pottery, Ceramics, and Plumbing Fixture Manufacturing (NAICS code 327110).

• Glass Container Manufacturing (NAICS code 327213).

• Cement Manufacturing (NAICS code 327310).

• Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and

Aluminum) (NAICS code 331492).

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

• Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing (NAICS code 332215).

• Saw Blade and Handtool Manufacturing (NAICS code 332216).

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

• 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).

• Industrial Valve Manufacturing (NAICS code 332911).

• Fluid Power Valve and Hose Fitting Manufacturing (NAICS code 332912).

• Plumbing Fixture Fitting and Trim Manufacturing (NAICS code 332913).

• Other Metal Valve and Pipe Fitting Manufacturing (NAICS code 332919).

• Ball and Roller Bearing Manufacturing (NAICS code 332991).

• Small Arms Ammunition Manufacturing (NAICS code 332992).

• Ammunition (except Small Arms) Manufacturing (NAICS code 332993).

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

• Fabricated Pipe and Pipe Fitting Manufacturing (NAICS code 332996).

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

• Other Industrial Machinery Manufacturing (NAICS code 333249).

• Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing (NAICS code 333415).

• Machine Tool Manufacturing (NAICS code 333517).

• Measuring, Dispensing, and Other Pumping Equipment Manufacturing (NAICS code 333914).

• Welding and Soldering Equipment Manufacturing (NAICS code 333992).

• Packaging Machinery Manufacturing (NAICS code 333993).

• Industrial Process Furnace and Oven Manufacturing (NAICS code 333994).

• Fluid Power Cylinder and Actuator Manufacturing (NAICS code 333995).

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

• All Other Miscellaneous General Purpose Machinery Manufacturing (NAICS code 333999).

• Instruments and Related Products Manufacturing for Measuring, Displaying, and Controlling Industrial Process Variables (NAICS code 334513).

• Analytical Laboratory Instrument Manufacturing (NAICS code 334516).

• Motor Vehicle Body Manufacturing (NAICS code 336211).

• Travel Trailer and Camper Manufacturing (NAICS code 336214).

• Other Motor Vehicle Parts Manufacturing (NAICS code 336390).

• Aircraft Manufacturing (NAICS code 336411).

• Aircraft Engine and Engine Parts Manufacturing (NAICS code 336412).

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

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

• Guided Missile and Space Vehicle Propulsion Unit and Propulsion Unit Parts Manufacturing (NAICS code 336415).

• Other Guided Missile and Space Vehicle Parts and Auxiliary Equipment Manufacturing (NAICS code 336419).

• Ship Building and Repairing (NAICS code 336611).

• Surgical and Medical Instrument Manufacturing (NAICS code 339112).

• Jewelry and Silverware Manufacturing (NAICS code 339910).

• Sporting and Athletic Goods Manufacturing (NAICS code 339920).

• Doll, Toy, and Game Manufacturing (NAICS code 339930).

• Office Supplies (except Paper) Manufacturing (NAICS code 339940).

• Gasket, Packing, and Sealing Device Manufacturing (NAICS code 339991).

• Musical Instrument Manufacturing (NAICS code 339992).

• Fastener, Button, Needle, and Pin Manufacturing (NAICS code 339993).

• Broom, Brush, and Mop Manufacturing (NAICS code 339994).

• Burial Casket Manufacturing (NAICS code 339995).

• All Other Miscellaneous Manufacturing (NAICS code 339999).

• Motor Vehicle Supplies and New Parts Merchant Wholesalers (NAICS code 423120).

• Home Furnishing Merchant Wholesalers (NAICS code 423220).

• Industrial Supplies Merchant Wholesalers (NAICS code 423840).

• Service Establishment Equipment and Supplies Merchant Wholesalers (NAICS code 423850).

• Other Miscellaneous Durable Goods Merchant Wholesalers (NAICS code 423990).

• Grain and Field Bean Merchant Wholesalers (NAICS code 424510).

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

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

• Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and

Terminals) (NAICS code 424720).

• New Car Dealers (NAICS code 441110).

• Used Car Dealers (NAICS code 441120).

• Other Gasoline Stations (NAICS code 447190).

• Sporting Goods Stores (NAICS code 451110).

• All Other Miscellaneous Store Retailers (except Tobacco Stores) (NAICS code 453998).

• Scheduled Passenger Air Transportation (NAICS code 481111).

• Scheduled Freight Air Transportation (NAICS code 481112).

• Pipeline Transportation of Natural Gas (NAICS code 486210).

• Teleproduction and Other Postproduction Services (NAICS code 512191).

• Other Motion Picture and Video Industries (NAICS code 512199).

• Miscellaneous Intermediation (NAICS code 523910).

• Other Financial Vehicles (NAICS code 525990).

• Lessors of Other Real Estate Property (NAICS code 531190).

• Offices of Real Estate Agents and Brokers (NAICS code 531210).

• Testing Laboratories (NAICS code 541380).

• Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology) (NAICS code 541715).

• Marketing Research and Public Opinion Polling (NAICS code 541910).

• All Other Professional, Scientific, and Technical Services (NAICS code 541990).

• Offices of Other Holding Companies (NAICS code 551112).

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

• Solid Waste Landfill (NAICS code 562212).

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

• Other Nonhazardous Waste Treatment and Disposal (NAICS code 562219).

• Remediation Services (NAICS code 562910).

• Materials Recovery Facilities (NAICS code 562920).

• All Other Miscellaneous Waste Management Services (NAICS code 562998).

• General Automotive Repair (NAICS code 811111).

• Automotive Exhaust System Repair (NAICS code 811112).

• Automotive Transmission Repair (NAICS code 811113).

• Other Automotive Mechanical and Electrical Repair and Maintenance (NAICS code 811118).

• Automotive Body, Paint, and Interior Repair and Maintenance (NAICS code 811121).

• Automotive Glass Replacement Shops (NAICS code 811122).

• Automotive Oil Change and Lubrication Shops (NAICS code 811191).

• All Other Automotive Repair and Maintenance (NAICS code 811198).

• Consumer Electronics Repair and Maintenance (NAICS code 811211).

• Computer and Office Machine Repair and Maintenance (NAICS code 811212).

• Communication Equipment Repair and Maintenance (NAICS code 811213).

• Other Electronic and Precision Equipment Repair and Maintenance (NAICS code 811219).

• Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance (NAICS code 811310).

• Home and Garden Equipment Repair and Maintenance (NAICS code 811411).

• Other Personal and Household Goods Repair and Maintenance (NAICS code 811490).

• Drycleaning and Laundry Services (except Coin-Operated) (NAICS code 812320).

• Industrial Launderers (NAICS code 812332).

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 the U.S. Environmental Protection Agency hereinafter EPA or "the Agency," determines through a TSCA section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must by rule apply one or more requirements listed in TSCA section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents such risk.

C. What action is the Agency taking?

Pursuant to TSCA section 6(b), EPA determined that PCE presents an unreasonable risk of injury to health, without consideration of costs or other nonrisk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations (PESS) identified as

relevant to the 2020 Risk Evaluation for PCE by EPA, under the conditions of use (Refs. 1 and 2). The term "conditions of use" is defined at TSCA section 3(4) (15 U.S.C. 2602(4)) to mean the circumstances under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. A detailed description of the conditions of use that drive EPA's determination that PCE presents an unreasonable risk is included in Unit III.B.1. EPA notes that all TSCA conditions of use of PCE are subject to this proposal. Accordingly, to address the unreasonable risk, EPA is proposing, under TSCA section 6(a), to:

(i) Prohibit most industrial and commercial uses and the manufacture (including import), processing, and distribution in commerce, of PCE for those uses, outlined in Unit IV.A.1.;

(ii) Prohibit the manufacture (including import), processing, and distribution in commerce of PCE for all consumer use, outlined in Unit IV.A.1.;

(iii) Prohibit the manufacture (including import), processing, distribution in commerce, and commercial use of PCE in dry cleaning and spot cleaning through a 10-year phaseout, outlined in Unit IV.A.1.;

(iv) Require strict workplace controls, including a PCE Workplace Chemical Protection Program (WCPP), which would include requirements to meet an inhalation exposure concentration limit and prevent direct dermal contact with PCE, for the 16 occupational conditions of use not prohibited, outlined in Unit IV.A.2.;

(v) Require prescriptive workplace controls for laboratory use, outlined in Unit IV.A.3.; and

(vi) Establish recordkeeping and downstream notification requirements, outlined in Unit IV.A.4.

(vii) Provide a 10-year time limited exemption under TSCA section 6(g) for certain

emergency uses of PCE in furtherance of National Aeronautics and Space Administration's mission, for specific conditions of use which are critical or essential and for which no technically and economically feasible safer alternative is available, outlined in Unit IV.A.5.

In addition, EPA is proposing to amend the general provision of 40 CFR part 751, Subpart A, to define "authorized person," "direct dermal contact," "ECEL," "exposure group," "owner or operator," "potentially exposed person," "regulated area," and "retailer" so that these definitions may be commonly applied to this and other rules under TSCA section 6 that would be codified under 40 CFR part 751. EPA seeks public comment on all aspects of this proposed rule.

D. Why is the Agency taking this action?

Under TSCA section 6(a), "[i]f the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule… apply one or more of the [section 6(a)] requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk." PCE was the subject of a risk evaluation under TSCA section 6(b)(4)(A) that was issued in December 2020 (2020 Risk Evaluation for PCE) (Ref. 1). In addition, EPA issued a revised unreasonable risk determination in December 2022 (Ref. 2), determining that PCE, as a whole chemical substance, presents an unreasonable risk of injury to health under the conditions of use. As a result, EPA is proposing to take action to the extent necessary so that PCE no longer presents such risk. The unreasonable risk is described in Unit III.B.2. and the conditions of use that drive the unreasonable risk for PCE are described in Unit III.B.1.

PCE's hazards are well established. EPA's 2020 Risk Evaluation for PCE considered the hazards associated with exposure to PCE and determined that PCE presents an unreasonable risk

of injury to health due to the significant adverse health effects associated with exposure to PCE. While some of the risks of adverse effects from PCE exposure are associated with acute single exposures, other risks are associated with long-term repeated exposures. The most sensitive health effect driving the unreasonable risk of PCE and selected as the basis for this proposed rule is neurotoxicity, based on the best available science and weight of scientific evidence and in consideration of the severity of the hazards, magnitude of exposure, population exposed, and uncertainties in the December 2020 Risk Evaluation for PCE and December 2022 revised risk determination for PCE. The most sensitive endpoint is dependent on both the point of departure (POD) and the associated total uncertainty factor. For PCE, impaired visual and cognitive function and diminished color discrimination following chronic exposures represent the most sensitive endpoint indicating neurotoxicity, based on epidemiological data reported in two studies that identified lowest observed adverse effect levels for color confusion and impaired pattern recognition and reaction time in pattern memory. Other significant adverse outcomes include kidney and liver effects, immune system toxicity, reproductive toxicity, developmental toxicity, and cancer. For this proposed rulemaking, EPA has determined that protecting against the most sensitive endpoint would also address the risk for other acute, chronic non-cancer, and cancer endpoints. This proposed rule would eliminate the unreasonable risk to human health from the TSCA conditions of use of PCE, as identified in the 2020 Risk Evaluation for PCE and the revised unreasonable risk determination for PCE in December 2022.

EPA is not proposing a complete ban on PCE. The Agency has considered the benefits of PCE for various uses as required under TSCA section 6(c)(2)(A) and (B) and recognizes that continued use of PCE for some TSCA conditions of use may provide benefits that complement the Agency's efforts to address climate-damaging hydrofluorocarbons (HFCs) under the American Innovation and Manufacturing Act of 2020 (AIM Act) (42 U.S.C. 7675), supporting

human health and environmental protection under these programs, and that for these uses, strict workplace controls to address the unreasonable risk can be implemented. Therefore, this rule proposes to allow PCE's continued use in tandem with strict workplace controls for the generation of HFC-125 and HFC-134a, two of the regulated substances that are subject to a phasedown under the AIM Act. While HFC-125 and HFC-134a are two of the regulated substances subject to the phasedown in production and consumption by 85% over the next 15 years, HFCs-134a and -125 can be mixed with other substances to make lower global warming potential blends that are likely to be used to facilitate the transition from certain other HFCs and HFC blends with higher global warming potentials in certain applications.

Additionally, the Agency recognizes that some conditions of use may be important for national security applications or for other critical needs. For example, PCE is a critical diluent (to modify the consistency or other properties in a formulation) for maskant applied to military and commercial aircraft skin panels that prevents chemical milling or industrial etching of certain areas and is also used in petrochemical manufacturing as a processing aid in catalyst regeneration for reformate and isomerate (these are gasoline blending stocks) that make up an estimated 45% of the U.S. gasoline pool. Therefore, this rule proposes to allow certain continued uses of PCE provided that sufficient worker protections are in place to address the unreasonable risk for certain occupational conditions of use. For the conditions of use for which EPA is proposing strict workplace controls under a WCPP, EPA expects that many workplaces already have stringent controls in place that reduce exposures to PCE; for some workplaces, EPA understands that these existing controls may already reduce exposures enough to meet the inhalation exposure concentration limit proposed in this rulemaking or to prevent direct dermal contact with PCE.

Accordingly, EPA is proposing strict workplace controls to address the unreasonable risk

and allow continued use of PCE for several conditions of use, including for processing as a reactant/intermediate, use in vapor degreasing, use as a maskant for chemical milling, use in adhesives and sealants, use as a processing aid in catalyst regeneration in petrochemical manufacturing, and use as a laboratory chemical, which comprise more than an estimated 80% of the current production volume of PCE. EPA is proposing to ban or phaseout most conditions of use of PCE, including use in dry cleaning and spot cleaning, aerosol degreasing, paints and coatings, aerosol lubricants, and wipe cleaning, comprising less than an estimated 20% of the current production volume of PCE. Of the conditions of use that would not be prohibited, EPA expects the production volume for those conditions of use to decline over time. For example, EPA expects the industrial and commercial use of PCE as a reactant in the generation of HFC-134a and HFC-125 to decline over time, in light of the AIM Act requirements to phase down production and consumption of listed HFCs by 85% over the next 15 years. Unit IV.A. describes EPA's proposed regulatory action and Unit IV.B. describes the alternative regulatory actions as required under TSCA section 6(c)(2)(A). The rationale for the proposed regulatory action and alternative regulatory actions, including the TSCA section 6 requirements considered in developing the regulatory actions, is described in Units III.B.3. and V.

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

EPA has prepared an Economic Analysis of the potential incremental impacts associated with this rulemaking that can be found in the rulemaking docket (Ref. 3). As described in more detail in the Economic Analysis (Ref. 3) and in Units VI.D. and X.D., EPA was unable to quantify all incremental costs of this proposed rule. The quantifiable cost of the proposed rule is estimated to be $14.0 million annualized over 20 years at a 3% discount rate and $14.3 million annualized over 20 years at a 7% discount rate. These costs take compliance with implementation of a WCPP into consideration, which would include an existing chemical

exposure limit (ECEL) of 0.14 ppm (0.98 mg/m^3) for inhalation exposures as an 8-hour time-weighted average (TWA), dermal controls to prevent direct dermal contact, applicable personal protective equipment (PPE) requirements, and reformulation costs of numerous products. The most notable unquantified costs include possible costs from prohibition of use of PCE as a processing aid outside of the petrochemical industry; EPA's analysis was unable to quantify these costs, as described more fully in Section 7.11 in the Economic Analysis (Ref. 3). The economic impact on users of PCE for chemical milling and vapor degreasing is also unclear because there are no clear alternatives to PCE; these users might have to use PPE to meet the requirements of a WCPP for PCE. Chemical milling using PCE is most prominent in the aerospace industry. Vapor degreasing is used in several advanced manufacturing industries, including aerospace, automotive, energy, medical devices, and others (Ref. 3).

In addition, EPA estimates that 6,000 dry cleaners still use PCE, a majority of which are small businesses. Nevertheless, despite information EPA has sought from stakeholders, it is still unclear as to the impact of a prohibition of PCE for dry cleaning through a gradual phaseout; EPA has not been able to estimate the number of dry cleaning facility closures that may be associated with this phaseout. More information on the challenges of estimating these impacts, in part due to the age of relevant machines in use, is in the Economic Analysis (Ref. 3). Overall, EPA expects few closures because EPA estimates that only about 60 PCE machines are expected to be in use at the end of the proposed phaseout period given the age of the machines and the declining trend of use; this is detailed in Section 7.7 of the Economic Analysis. Table 7-10 in that section details the age of the PCE dry cleaning machines in New York State, for which EPA has data. EPA believes that the data is generalizable to other states; industry has informed the Agency that very few PCE machines have been purchased in recent years. Based on the estimated revenues per firm presented in Table 31 of the Economic Analysis and the 6,000

estimated number of dry cleaning firms using PCE as dry cleaning solvent (see Section 6.1.5 (A) of the Economic Analysis), the total revenue for dry cleaning firms using PCE as dry cleaning solvent is approximately $3.1 billion. According to IRS (2013) data, profit in this sector is about 4.8% of sales, implying that total profit of firms using PCE as dry cleaning solvent is about $148 million. However, EPA has proposed a 10-year phaseout of PCE in dry cleaning and estimates that only about 60 PCE dry cleaning machines would remain at the end of the phaseout (see Section 7.7.3. of the Economic Analysis). This suggests that the proposed option would only affect about $31 million of the industry's total revenue and about $1.5 million of the industry's profit. Many of these firms would likely choose to purchase non-PCE machines or become drop shops (do dry cleaning at another site) rather than close. A detailed sensitivity analysis of varying assumptions on ages of PCE dry cleaning machines and PCE dry cleaning machine life is provided in Section 11 of the Economic Analysis.

The actions proposed in this rule are expected to achieve health benefits for the American public, some of which can be monetized and others that, while tangible and significant, cannot be monetized. The monetized benefits of this rule are approximately $10.2 million to $46.3 million annualized over 20 years at a 3% discount rate and $4.72 million to $29.4 million annualized over 20 years at a 7% discount rate. The monetized benefits include potential reductions in risk of liver, kidney, brain, and testicular cancer. Non-monetized benefits include risk reduction of neurotoxicity, kidney toxicity, liver effects, immune/hematological effects, reproductive effects, and developmental effects (Ref. 3). Neurotoxic effects of PCE in human studies include visual deficits, impaired cognition, and decreased math scores. Also, prenatal and early childhood exposure to PCE in drinking water are associated with increases in drug, alcohol, and tobacco use (Ref. 1). Reductions in PCE exposure are therefore likely to be associated with large dollar-valued, but currently unmonetized, benefits.

Additionally, the Agency expects that the proposed dry cleaning phaseout will decrease health risks for affected populations that may own/operate or work at dry cleaning facilities. As described in more detail in the Economic Analysis, the Agency analyzed the demographic characteristics of several populations that would be impacted by this rulemaking, including for dry cleaning (Ref. 3). Based on reasonably available information, the Agency understands that a significant number of members of minority populations may own or work at dry cleaning facilities.

II. Background

A. Overview of Perchloroethylene

This proposed rule applies to PCE (CASRN 127-18-4) and is specifically intended to address the unreasonable risk of injury to health EPA has identified in the 2020 Risk Evaluation for PCE and the 2022 revised unreasonable risk determination, as described in Unit III.B.2. PCE is a colorless volatile liquid with a mildly sweet odor that is produced in and imported into the United States. PCE is manufactured, processed, distributed, used, and disposed of as part of many industrial, commercial, and consumer conditions of use.

As outlined in further detail in Unit III.B.1., PCE is used for the production of fluorinated compounds, as a solvent for dry cleaning and vapor degreasing; in catalyst regeneration in petrochemical manufacturing; and in a variety of commercial and consumer applications such as adhesives, paints and coatings, aerosol degreasers, brake cleaners, aerosol lubricants, sealants, stone polish, stainless steel polish and wipe cleaners. According to data submitted for the EPA's 2016 Chemical Data Reporting rule (CDR), the total aggregate annual production volume of PCE in the U.S. decreased from 388 million pounds to around 324 million pounds between 2012 and 2015 (Ref. 4). The total aggregate annual production volume ranged from 250 to 500 million pounds between 2016 and 2019 according to CDR (Ref. 5).

B. Regulatory Actions Pertaining to PCE

Because of its adverse health effects, PCE is subject to numerous Federal laws and regulations in the United States and is also subject to regulation by some States and other countries. A summary of EPA regulations pertaining to PCE, as well other Federal, State, and international regulations (Ref. 6) is in the docket and in Appendix A of the 2020 Risk Evaluation for PCE (Ref. 1).

C. Consideration of Occupational Safety and Health Administration (OSHA) Occupational Health Standards in TSCA Risk Evaluations and TSCA Risk Management Actions

Although EPA must consider and factor in, to the extent practicable, certain nonrisk factors as part of TSCA section 6(a) rulemaking (see TSCA section 6(c)(2)), EPA must nonetheless still ensure that the selected regulatory requirements apply "to the extent necessary so that the chemical substance or mixture no longer presents [unreasonable] risk." 15 U.S.C. 2605(a). This requirement to eliminate unreasonable risk is distinguishable from approaches mandated by some other laws, including the Occupational Safety and Health Act (OSH Act), which includes both significant risk and feasibility (technical and economic) considerations in the setting of standards.

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

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

Thus, the standards for chemical hazards that OSHA promulgates under the OSH Act share a broadly similar purpose with the standards that EPA promulgates under TSCA section 6(a). The control measures OSHA and EPA require to satisfy the objectives of their respective statutes may also, in many circumstances, overlap or coincide. However, as this section outlines, there are important differences between EPA's and OSHA's regulatory approaches and jurisdiction, and EPA considers these differences when deciding whether and how to account for OSHA requirements (Ref. 6) when evaluating and addressing potential unreasonable risk to workers so that compliance requirements are clearly explained to the regulated community.

1. *OSHA requirements.*

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

a. *General Duty Clause of the OSH Act.*

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

requirements. OSHA, under limited circumstances, has cited the General Duty Clause for regulating exposure to chemicals. To prove a violation of the General Duty Clause, OSHA must prove employer or industry recognition of the hazard, that the hazard was causing or likely to cause death or serious physical harm, and a feasible method to eliminate or materially reduce the hazard was available. In rare situations, OSHA has cited employers for violation of the General Duty Clause where exposures were below a chemical-specific permissible exposure limit (PEL), a TWA based on an employee's average airborne exposure in any 8-hour work shift of a 40-hour work week which shall not be exceeded (Ref. 7). In such situations, OSHA must demonstrate that the employer had actual knowledge that the PEL was inadequate to protect its employees from death or serious physical harm. Because of the heavy evidentiary burden on OSHA to establish violations of the General Duty Clause, it is not frequently used to cite employers for employee exposure to chemical hazards.

b. *OSHA standards.*

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

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

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

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

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

requirements sufficient to ensure that the chemical substance no longer presents a significant risk to workers. As described in that notice, while new advancements or developments in science and technology from the time a PEL is promulgated may improve the scientific basis for making findings of significant risk, technical feasibility or economic feasibility, OSHA has been unable to update most of the PELs established in 1971 and they remain frozen at levels at which they were initially adopted (79 FR 61384, October 10, 2014). One example of how industries have evolved in the intervening 50 years as to what is technologically and economically feasible is the halogenated solvent cleaning industry, which, in response to EPA's National Emission Standards for Hazardous Air Pollutants (NESHAP) promulgated under Section 112 of the 1990 Clean Air Act Amendments (see National Emissions Standards for Halogenated Solvent Cleaning, 40 CFR part 63, subpart T), has made equipment improvements that conserve solvent resources and reduce workplace exposure.

In sum, the great majority of OSHA's chemical standards are outdated or do not sufficiently reduce risk to workers. While it is possible in some cases that the OSHA standards for some chemicals reviewed under TSCA will eliminate unreasonable risk, based on EPA's experience thus far in conducting occupational risk assessments under TSCA EPA believes that OSHA chemical standards would in general be unlikely to address unreasonable risk to workers within the meaning of TSCA, since TSCA section 6(b) unreasonable risk determinations may account for unreasonable risk to more sensitive endpoints and working populations than OSHA's risk evaluations typically contemplate, and EPA is obligated to apply TSCA section 6(a) risk management requirements to the extent necessary so that the unreasonable risk is no longer presented.

Because the requirements and application of TSCA and OSHA regulatory analyses differ, and because many of OSHA's chemical-specific standards are based on outdated information

regarding the technological and economic feasibility of the standards and the risks associated with exposure, it is necessary for EPA to conduct risk evaluations and, where it finds unreasonable risk to workers, develop risk management requirements for chemical substances that OSHA also regulates, and it is expected that EPA's findings and requirements may sometimes diverge from OSHA's. However, it is also appropriate that EPA consider the chemical standards that OSHA has already developed to limit the compliance burden to employers by aligning management approaches required by the agencies, where alignment will adequately address unreasonable risk to workers. The following unit discusses EPA's consideration of OSHA standards in its risk evaluation and management strategies under TSCA.

2. *Consideration of OSHA standards in TSCA risk evaluations.*

When characterizing the risk during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in scenarios where no mitigation measures are assumed to be in place for the purpose of determining unreasonable risk (see Unit II.C.2.a.). (It should be noted that there are some cases where scenarios may reflect certain mitigation measures, such as in instances where exposure estimates are based on monitoring data at facilities that have existing engineering controls in place. For example, the Halogenated Solvent Cleaning NESHAP, first promulgated in 1994 and last updated in 2007, established standards reflecting the maximum achievable control technology for major and certain area sources, standards reflecting generally available control technology for other area sources, and facility-wide emission limits for certain halogenated solvent cleaning machines. Consequently, emissions monitoring from facilities meeting the NESHAP would reflect emissions reduction resulting from existing engineering controls already in place to meet the standards.)

In addition, EPA believes it may be appropriate to also evaluate the levels of risk present in scenarios considering applicable OSHA requirements as well as scenarios considering industry

or sector best practices for industrial hygiene that are clearly articulated to the Agency. EPA may evaluate risk under scenarios that consider industry or sector best practices for industrial hygiene that are clearly articulated to the Agency, when doing so serves to inform its risk management efforts. Characterizing risks using scenarios that reflect different levels of mitigation can help inform potential risk management actions by providing information that could be used during risk management to tailor risk mitigation appropriately to address any unreasonable risk identified (see Unit II.C.2.b. and Unit II.C.3.).

a. *Risk characterization for unreasonable risk determination.*

When making unreasonable risk determinations as part of TSCA risk evaluations, EPA cannot assume as a general matter that all workers are always equipped with and appropriately using sufficient PPE, although it does not question the veracity of public comments received on the 2020 Risk Evaluation for PCE regarding the occupational safety practices often followed by industry respondents. When characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in scenarios where PPE is not assumed to be used by workers. This approach of not assuming PPE use by workers considers the risk to PESS (workers and occupational non-users (ONUs)) who may not be covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan. Mitigation scenarios included in the EPA risk evaluation in order to inform its risk management efforts (e.g., scenarios considering use of PPE) likely represent current practice in many facilities where companies effectively address worker and bystander safety requirements. However, the Agency cannot assume that all facilities across all uses of the chemical substance will have adopted these practices for the purposes of making the TSCA risk determination.

Therefore, EPA makes its determinations of unreasonable risk based on scenarios that do

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

b. *Risk evaluation to inform risk management requirements.*

In addition to the scenarios described previously, EPA risk evaluations may characterize the levels of risk present in scenarios considering applicable OSHA requirements (e.g., chemical-specific PELs and/or chemical-specific health standards with PELs and additional ancillary provisions) as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency to help inform risk management decisions.

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

When undertaking risk management actions, EPA: 1) Develops occupational risk mitigation measures to address any unreasonable risk identified by EPA, striving for consistency with applicable OSHA requirements and industry best practices, including appropriate application of the hierarchy of controls (Ref. 8), when those measures would address an unreasonable risk; and 2) Ensures that EPA requirements apply to all potentially exposed workers in accordance with TSCA requirements. Consistent with TSCA section 9(d), EPA consults and coordinates TSCA activities with OSHA and other relevant Federal agencies for the

purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements.

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

For evaluation scenarios which involve OSHA chemical-specific PELs, EPA's risk evaluation in some cases may illustrate that limiting exposure to OSHA's PEL would result in acceptable levels of risk under TSCA under certain conditions of use. In these cases, TSCA risk management requirements could incorporate and reinforce requirements in OSHA standards and ensure that risks are addressed, including for circumstances where OSHA requirements are not applicable (e.g., public sector workers not covered by an OSHA State plan, and self-employed workers) by asserting TSCA compliance/enforcement as well. EPA's risk evaluation may also find unreasonable risk under TSCA associated with some occupational conditions of use, even when the applicable OSHA requirements are being met. In these cases, EPA would need to develop risk management requirements beyond those included in OSHA's standards.

4. *PCE and OSHA requirements.*

EPA incorporated the considerations described earlier in this unit in the 2020 Risk Evaluation for PCE, the December 2022 revised unreasonable risk determination for PCE, and this rulemaking. Specifically, in the TSCA 2020 Risk Evaluation for PCE, EPA presented risk estimates based on workers' exposures with and without respiratory protection. EPA determined

that even when respirators are used by workers, most of the conditions of use evaluated presented an unreasonable risk. Additional consideration of OSHA standards in the revised unreasonable risk determination is discussed further in the *Federal Register* notice announcing that document (Ref. 9). In Units III.B.3. and Unit V., EPA outlines the importance of considering the hierarchy of controls utilized by the industrial hygiene community (hereafter referred to as "hierarchy of controls") when developing risk management actions in general, and specifically when determining if and how regulated entities may meet a risk-based exposure limit for PCE. The hierarchy of controls is a prioritization of exposure control strategies from most protective and preferred to least protective and preferred techniques. In order of precedence, they are: elimination of the hazard, substitution with a less hazardous substance, engineering controls, administrative controls such as training or exclusion zones with warning signs, and, finally, use of PPE (Ref. 8). Under the hierarchy of controls the use of respirators (and all PPE) should only be considered after all other measures have been taken to reduce exposures. As discussed in Units IV.A. and V.A.1., EPA's risk management approach would not rely solely or primarily on the use of respirators and dermal PPE to address unreasonable risk to workers; instead, EPA is proposing prohibitions for most conditions of use and a WCPP for certain occupational conditions of use. The WCPP would require consideration of the hierarchy of controls before use of respirators and other PPE. The WCPP is discussed in full in Units IV.A.2. and V.A.1.b.

In accordance with the approach described earlier in Unit II.C.3., EPA intends for this regulation to be as consistent as possible with the existing OSHA standards, with additional requirements as necessary to address the unreasonable risk. One notable difference between the WCPP and the OSHA standards are the exposure limits. The WCPP would include an ECEL of 0.14 ppm as an 8-hour TWA to address unreasonable risk for chronic cancer and non-cancer and acute non-cancer inhalation endpoints. EPA recognizes that for PCE, the ECEL would be

significantly lower than the OSHA PEL (100 ppm as an 8-hour TWA). In addition to the distinctions in statutory requirements described in this unit, EPA has identified several factors contributing to the differences in these levels, outlined here.

The TSCA ECEL value for PCE is a lower value than the OSHA PEL (and other existing OELs, discussed in Unit II.C.5.) for many reasons, including the age of the data and studies the values are based on and that the values may not fully capture either the complete database of studies considered in the 2020 Risk Evaluation for PCE or more recent advances in modeling and scientific interpretation of toxicological data applied in the calculation of the PCE ECEL. EPA considers the PCE ECEL to represent the best available science under TSCA section 26(h) because it was derived from information in the 2020 Risk Evaluation for PCE, which was subject to peer review, and which is the result of a systematic review process that investigated the reasonably available information in order to identify relevant adverse health effects. Additionally, by using the information from the 2020 Risk Evaluation for PCE, the ECEL incorporates advanced modeling and peer-reviewed methodologies, and accounts for exposures to potentially exposed and susceptible subpopulations, as required by TSCA.

For PCE, the EPA ECEL is an 8-hour occupational inhalation exposure limit based on chronic non-cancer neurotoxicity effects, and takes into consideration the uncertainties identified in the 2020 Risk Evaluation for PCE (Ref. 10). The ECEL represents the concentration at which an adult human, including a member of a PESS, would be unlikely to suffer adverse effects if exposed for a working lifetime. EPA has determined as a matter of risk management policy that ensuring exposures remain at or below the ECEL will eliminate any unreasonable risk of injury to health from occupational inhalation exposures. In addition to the ECEL, as part of this rulemaking EPA is proposing an ECEL action level, a value half of the ECEL, that would trigger additional monitoring to ensure that workers are not exposed to concentrations above the ECEL.

For PCE, the ECEL of 0.14 ppm is based on the most sensitive point of departure across acute, chronic non-cancer, and cancer endpoints. Neurotoxicity based on visual and cognitive deficits following chronic exposure was the basis of the PCE ECEL based on epidemiological data from Cavalleri et al., 1994 and Echeverria et al., 1995 (Refs. 10, 1, 11, 12). The ECEL incorporates a benchmark margin of exposure of 100 to account for human variability and the absence of a no-effect level in the studies.

The OSHA PEL for PCE of 100 ppm as an 8-hour TWA was established in 1971. OSHA is required to promulgate a standard that reduces significant risk to the extent that it is technologically and economically feasible to do so (81 FR 16285). A 1989 update to 25 ppm based on a quantitative cancer risk assessment and technological feasibility analysis was later vacated by court order, reverting to the original PEL of 100 ppm (Ref. 13); (See also 54 FR 2332, 2686, 2688 (1989)). The basis of the 100 ppm PEL is unclear, however most original PELs were based on acute health effects only observable at higher concentrations as more sensitive chronic studies, including the chronic exposure studies used to inform the PCE ECEL, were not available at the time the PEL was established (see, e.g., 79 FR 61383, 61388). As discussed in Units II.D., III.B., and VII.D., the TSCA ECEL represents the best available science at time of publication of the 2020 Risk Evaluation for PCE. As described earlier, in a 2014 request for information OSHA described how, while new developments in science and technology from the time the PEL for PCE was established in 1971 may improve the scientific basis for making findings of significant risk, technical feasibility, or economic feasibility that is required under section 6(b)(5) of the OSH Act, OSHA has been unable to update the PEL for PCE and it remains frozen at the level that was originally adopted in 1971 (79 FR 61383, October 10, 2014).

5. *PCE and other occupational exposure limits.*

EPA is aware of other OELs for PCE, including the ACGIH TLV, the California Division

of Occupational Safety and Health (Cal/OSHA) PEL, and the National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL).

The 8-hour TWA TLV recommended by the ACGIH is 25 ppm. This TLV is based on "discomfort and subjective complaints" occurring at 100 ppm and above (Ref. 14). Neurological effects such as dizziness, headache, sleepiness, and incoordination were also indicated at 100 ppm and above. The TLV appears to use a four-fold "margin of safety" consistent with other TLV reports but lower than what would be recommended by EPA guidance (Ref. 15), which would support a downward adjustment of 30x-100x. The TLV report acknowledges that the liver effects were observed at as low as 9 ppm in mice after only 30 days of continuous exposure, however ACGIH determined that the exposure pattern was not representative of occupational scenarios. Additionally, quantitative risks from cancer were not considered because PCE was classified as only an animal carcinogen. Notably, the TLV report did not cite either epidemiological study used as the basis of the EPA ECEL, despite them being published 1-2 years prior to the 1996 TLV update.

The Cal/OSHA PEL is 25 ppm, lower than the OSHA PEL and equivalent to the ACGIH TLV. The 25 ppm value is also equivalent to the vacated 1989 OSHA PEL, which was based on a quantitative cancer risk assessment and technological feasibility analysis. Despite the Cal/OSHA PEL being equivalent to the vacated 1989 OSHA PEL based on cancer, Cal/OSHA did not perform a quantitative cancer risk assessment and the PEL is primarily based on non-cancer central nervous systems (CNS) effects (Ref. 16*)*.

In 1976, the NIOSH REL for PCE was 50 ppm as a TWA for up to a 10-hour workday, 40-hour workweek (Ref. 17). This REL was considered protective of neurological effects as well as eye and respiratory tract irritation. The current REL for PCE is "Ca (potential occupational carcinogen) minimize workplace exposure concentrations" (Ref. 18). As described in NIOSH's

Appendix A, this non-quantitative value is based on the lowest feasible concentration (Ref. 19).

D. Summary of EPA's Risk Evaluation Activities on PCE

In December 2016, EPA selected PCE as one of the first 10 chemicals for risk evaluation under TSCA section 6 (15 U.S.C. 2605). EPA published the scope of the PCE risk evaluation in June 2017 (82 FR 31592, July 7, 2017) (FRL-9963-57), and, after receiving public comments, published the problem formulation in June 2018 (83 FR 26998, June 11, 2018) (FRL-9978-40). In May 2020, EPA published a draft risk evaluation (85 FR 26464, May 4, 2020) (FRL-10008-63), and after public comment and peer review by the Science Advisory Committee on Chemicals (SACC), EPA issued the 2020 Risk Evaluation for PCE in December 2020 in accordance with TSCA section 6(b) (85 FR 82474, December 18, 2020) (FRL-10017-44). EPA subsequently issued a draft revised TSCA unreasonable risk determination for PCE (87 FR 39085, June 30, 2022) (FRL-9942-01-OCSPP), and after public notice and receipt of comments, published a revised Unreasonable Risk Determination for PCE (87 FR 76481, December 14, 2022) (FRL-9942-01-OCSPP). The 2020 Risk Evaluation for PCE and supplemental materials are in docket EPA-HQ-OPPT-2019-0502, with the December 2022 revised unreasonable risk determination and additional materials supporting the risk evaluation process in docket EPA-HQ-OPPT-2016-0732, on *https://www.regulations.gov*.

1. *2020 Risk Evaluation.*

In the 2020 Risk Evaluation for PCE, EPA evaluated risks associated with 61 conditions of use within the following categories: manufacture (including import), processing, distribution in commerce, industrial and commercial use, consumer use, and disposal. Descriptions of these conditions of use are in Unit III.B.1. The 2020 Risk Evaluation for PCE identified significant adverse health effects associated with exposure to PCE, including neurotoxicity effects from acute and chronic inhalation exposures and dermal exposures, and cancer from chronic

inhalation exposures to PCE. A further discussion of the hazards of PCE is in Unit III.B.2.

2. *Revised Unreasonable Risk Determination.*

EPA has been revisiting specific aspects of its first ten TSCA existing chemical risk evaluations, including the 2020 Risk Evaluation for PCE, to ensure that the risk evaluations upon which risk management decisions are made better align with TSCA's objective of protecting human health and the environment. For PCE, EPA revised the original unreasonable risk determination based on the 2020 Risk Evaluation for PCE and issued a final revised unreasonable risk determination in December 2022 (Ref. 2). EPA revised the risk determination for the 2020 Risk Evaluation for PCE pursuant to TSCA section 6(b) and consistent with Executive Order 13990 (entitled "Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis") and other Administration priorities (Refs. 20, 21, and 22). The revisions consisted of making the risk determination based on the whole chemical substance instead of by individual conditions of use (which resulted in the revised risk determination superseding the prior "no unreasonable risk" determinations and withdrawing the associated TSCA section 6(i)(1) "no unreasonable risk" order); and clarifying that the risk determination does not reflect an assumption that all workers are always provided and appropriately wear PPE (Ref. 2).

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

EPA determined that PCE presents an unreasonable risk of injury to health. The unreasonable risk determination is driven by risks to workers and ONUs (workers who do not directly handle the chemical but perform work in an area where the chemical is present) due to occupational exposures to PCE (i.e., during manufacture, processing, industrial and commercial uses, or disposal); to children of employees at dry cleaning facilities due to PCE exposures at those facilities; and to consumers and bystanders associated with consumer uses of PCE due to exposures from consumer use of PCE and PCE-containing products. EPA did not identify risks of injury to the environment that drive the unreasonable risk determination for PCE. The PCE conditions of use that drive EPA's determination that the chemical substance poses unreasonable risk to health are listed in the unreasonable risk determination (Ref. 2) and also in Unit III.B.1., with descriptions to aid chemical manufacturers, processors, and users in determining how their particular use or activity would be addressed under the proposed regulatory provisions.

While the 2020 Risk Evaluation for PCE estimated different risks for occupational non-users and workers, the benchmark (and thus the ECEL value) is the same for both populations. That is, while workers and occupational non-users may have different exposure patterns, the level of exposure such that risks are no longer unreasonable is the same for both workers and occupational non-users. Thus, for the purposes of risk management, the distinction between worker and occupational non-user is no longer relevant, and both are encompassed by the definition of a potentially exposed person, as outlined in Unit IV.A.2.a.

3. *Fenceline screening analysis.*

The 2020 Risk Evaluation for PCE excluded the assessment of certain exposure pathways that were or could be regulated under another EPA-administered statute (see section 1.4.2 of the December 2020 Risk Evaluation for PCE) (Refs. 1, 2). This resulted in the surface water, drinking water, and ambient air pathways for PCE exposure not being assessed for human health

risk to the general population. In June 2021, EPA made a policy announcement on the path forward for TSCA chemical risk evaluations, indicating that EPA would, among other things, examine whether the exclusion of certain exposure pathways from the risk evaluations would lead to a failure to identify and protect fenceline communities (Refs. 9, 23). EPA then conducted a screening analysis to identify whether there may be potential risks to people living near the fenceline of facilities releasing PCE.

In order to assess the potential risk to the general population in proximity to a facility releasing PCE, EPA developed the TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0, which was presented to the SACC in March 2022, with a report issued by the SACC on May 18, 2022 (Ref. 24). This analysis is discussed in Unit VI.A.

III. Regulatory Approach

A. Background

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

• Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of the substance or mixture, or limit the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce (TSCA section 6(a)(1)).

• Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of the substance or mixture for a particular use or above a specific concentration for a

particular use (TSCA section 6(a)(2)).

• Limit the amount of the substance or mixture which may be manufactured, processed, or distributed in commerce for a particular use or above a specific concentration for a particular use specified (TSCA section 6(a)(2)).

• Require clear and adequate minimum warning and instructions with respect to the substance or mixture's use, distribution in commerce, or disposal, or any combination of those activities, to be marked on or accompanying the substance or mixture (TSCA section 6(a)(3)).

• Require manufacturers and processors of the substance or mixture to make and retain certain records, or conduct certain monitoring or testing (TSCA section 6(a)(4)).

• Prohibit or otherwise regulate any manner or method of commercial use of the substance or mixture (TSCA section 6(a)(5)).

• Prohibit or otherwise regulate any manner or method of disposal of the substance or mixture, or any article containing such substance or mixture, by its manufacturer or processor or by any person who uses or disposes of it for commercial purposes (TSCA section 6(a)(6)).

• Direct manufacturers or processors of the substance or mixture to give notice of the unreasonable risk determination to distributors, certain other persons, and the public, and to replace or repurchase the substance or mixture (TSCA section 6(a)(7)).

As described in Unit III.B.3., EPA analyzed how the TSCA section 6(a) requirements could be applied to address the unreasonable risk found to be present in the 2020 Risk Evaluation for PCE and the final revised unreasonable risk determination, so that PCE no longer presents such unreasonable risk. EPA's proposed regulatory action and two alternative regulatory actions are described in Unit IV. EPA is requesting public comment on all elements of the proposed regulatory action and the alternative regulatory actions and is providing notice that based on consideration of comments and any new information submitted to EPA during the comment

period on this proposed rule, EPA may in the final rule modify elements of the proposed regulatory action. The public should understand that public comments could result in changes to elements of the proposed and alternative regulatory actions when this rule is finalized. For example, elements such as timelines for phase out could be lengthened or shortened, ECELs could be modified, or the WCPP could have conditions added or eliminated.

Under the authority of TSCA section 6(g), EPA may consider granting a time-limited exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use if EPA finds that: 1) The specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; 2) Compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or 3) The specific condition of use, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety. Based on reasonably available information, EPA has analyzed the need for an exemption and is proposing that a TSCA section 6(g) exemption is warranted for certain conditions of use, as detailed in Unit IV.A.5. EPA is requesting comment on the proposed rule's section 6(g) exemption provisions and rationale. In addition, EPA has found that two TSCA section 6(g) exemptions may be warranted if the second alternative regulatory action considered by EPA is adopted in the final rule. Therefore, the public should assume that if EPA were to promulgate the second alternative to the proposed regulatory action, EPA would at the same time grant an exemption from the rule requirements for two conditions of use under TSCA section 6(g). Unit IV.B.2.b. includes information regarding EPA's second alternative action that includes exemptions under TSCA section 6(g). EPA is requesting public comment regarding the need for exemptions from the rule (and under what specific circumstances), including exemptions from the proposed regulatory

action (e.g., a WCPP) and the primary and second alternative regulatory actions, pursuant to the provisions of TSCA section 6(g).

TSCA section 6(c)(2)(A) requires EPA, in proposing and promulgating TSCA section 6(a) rules, to consider and include a statement addressing certain factors, including the costs and benefits and the cost effectiveness of the regulatory action and of the one or more primary alternative regulatory actions considered by the Administrator. A description of all TSCA section 6 requirements considered in developing this proposed regulatory action is in Unit III.B.3., and Unit V. includes more information regarding EPA's consideration of exemptions and alternatives. TSCA section 6(c)(2)(C) requires that in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use and in setting an appropriate transition period for such action, EPA consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as substitutes when the proposed prohibition or restriction takes effect. Unit V.B. includes more information regarding EPA's consideration of alternatives, and Unit VI. provides more information on EPA's considerations more broadly under TSCA section 6(c)(2).

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

1. *Consultations.*

EPA conducted consultations and outreach in developing this proposed regulatory action. The Agency held a federalism consultation from July 22, 2021, until October 22, 2021, as part of this rulemaking process and pursuant to Executive Order 13132. This included a background presentation on September 9, 2020, and a consultation meeting on July 22, 2021. During the consultation, EPA met with State and local officials early in the process of developing the

proposed action in order to receive meaningful and timely input into its development (Ref. 25). During the consultation, participants and EPA discussed additional reporting requirements as a risk management tool to address the unreasonable risk, EPA's consideration of safer alternatives, and potential impacts to drinking water utilities (Ref. 25).

PCE is not manufactured (including imported), processed, distributed in commerce, or regulated by Tribal governments. However, EPA consulted with Tribal officials during the development of this proposed action (Ref. 26). The Agency held a Tribal consultation from May 17, 2021, to August 20, 2021, with meetings on June 15 and July 8, 2021. Tribal officials were given the opportunity to meaningfully interact with EPA risk managers concerning the current status of risk management. During the consultation, EPA discussed risk management under TSCA section 6(a), findings from the 2020 Risk Evaluation for PCE, types of information that would be helpful to inform risk management, principles for transparency during the risk management process, and types of information EPA is seeking from Tribes (Ref. 26). EPA received no written comments as part of this consultation.

In addition to the formal consultations, EPA also conducted outreach to advocates of communities that might be subject to disproportionate risk from the exposures to PCE, such as minority populations, low-income populations, and indigenous peoples. EPA's Environmental Justice (EJ) consultation occurred from June 3, 2021, through August 20, 2021. On June 16, 2021, and July 6, 2021, EPA held public meetings as part of this consultation. These meetings were held pursuant to and in compliance with Executive Orders 12898 and 14008. EPA received five written comments following the EJ meetings, in addition to oral comments provided during the consultation (Refs. 27, 28, 29, 30, 31). In general, commenters supported strong outreach to affected communities, encouraged EPA to follow the hierarchy of controls utilized by the industrial hygiene community, favored prohibitions, and noted the uncertainty, and in some cases

inadequacy, of PPE. Commenters also urged EPA to address in this rulemaking ongoing releases from hazardous waste and disposal sites, in particular vapor intrusion of PCE from contaminated groundwater, soil, and indoor air. Additionally, commenters expressed concern that the adverse health impacts of PCE dry cleaning fall disproportionately to owners and employees of minority owned small businesses, noted the viability of professional wet cleaning as an alternative to PCE dry cleaning, and urged EPA to consider adverse economic impacts of the regulation and establishing a financial program to offset transition costs to local communities (Ref. 32).

As required by section 609(b) of the Regulatory Flexibility Act (RFA), EPA convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations from small entity representatives (SERs) that potentially would be subject to this proposed rule's requirements (Ref. 33). EPA met with SERs before and during Panel proceedings, on September 26, 2022, and November 10, 2022. Panel recommendations are in Unit X.C. and in the Initial Regulatory Flexibility Analysis (IRFA) (Ref. 34), the Panel report is in the docket (Ref. 33). EPA requests comment on all elements of the IRFA, and, in particular, the flexibilities that EPA has identified following input from the SERs during the SBAR process. Additional requests for comment based on Panel recommendations are in Unit VIII.

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

2. *Other stakeholder engagement.*

In addition to the formal consultations described in Unit X., EPA held a webinar on January 14, 2021, providing an overview of the TSCA risk management process and the risk evaluation findings for PCE. EPA also presented on the risk evaluation and risk management under TSCA for PCE at a Small Business Administration (SBA) Office of Advocacy Environmental roundtable on January 15, 2021. At both events, EPA staff provided an overview of the TSCA risk management process and the findings in the 2020 Risk Evaluation for PCE

(Ref. 35). Attendees of these meetings were given an opportunity to voice their concerns regarding the risk evaluation and risk management.

Furthermore, EPA engaged in discussions with representatives from different industries, non-governmental organizations, technical experts and users of PCE. A list of external meetings held during the development of this proposed rule is in the docket (Ref. 36); meeting materials and summaries are also in the docket. The purpose of these discussions was to create awareness and educate stakeholders and regulated entities on the provisions for risk management required under TSCA section 6(a); explain the risk evaluation findings; obtain input from manufacturers, processors, distributors, users, academics, advisory councils, and members of the public health community about uses of PCE; identify workplace practices, engineering controls, administrative controls, PPE, and industrial hygiene plans currently in use or feasibly adoptable to reduce exposure to PCE under the conditions of use; understand the importance of PCE in the various uses subject to this proposed rule; compile knowledge about critical uses, substitute chemicals or alternative methods; identify various standards and performance specifications; and generate potential risk reduction strategies. EPA has met with, or otherwise communicated with, a variety of companies, trade associations and non-governmental organizations to discuss the topics outlined in this paragraph; a list of external meetings held during the development of this proposed rule is in the docket (Ref. 36).

3. *Children's environmental health.*

The EPA 2021 Policy on Children's Health (Ref. 37) requires EPA to protect children from environmental exposures by consistently and explicitly considering early life exposures (from conception, infancy, early childhood and through adolescence until 21 years of age) and lifelong health in all human health decisions through identifying and integrating children's health data and information when conducting risk assessments. TSCA section 6(b)(4)(A) also requires

EPA to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." Infants, children, and pregnant women are listed as examples of subpopulations that may be considered relevant "potentially exposed or susceptible subpopulations" in the TSCA section 3(12) definition of that term. In addition, TSCA section 6(a) requires EPA to apply one or more risk management requirements under TSCA section 6(a) so that PCE no longer presents an unreasonable risk (including unreasonable risk to PESS).

The 2020 Risk Evaluation for PCE evaluated the hazards of PCE to toddlers and older children (11-15 years and 16-20 years) and did not find disproportionate adverse health impacts to these groups (Ref. 1). Evidence of hazards to infants and males and females of reproductive age was found for reproductive and developmental toxicity. The reproductive and developmental health effects of concern related to exposures to PCE are reduced sperm quality, spontaneous abortion, and decreased fetal/placental weight. The most sensitive non-cancer hazard driving the unreasonable risk for PCE is neurotoxicity (CNS effects). Early lifestage development of the nervous system can be a sensitive period, however the studies on PCE do not provide sufficient evidence of greater sensitivity to neurotoxicity in early lifestages than later lifestages, such as during adulthood. While the literature contains methodological limitations in human studies, animal studies were considered adequate to represent reproductive and development effects in the 2020 Risk Evaluation for PCE.

The 2020 Risk Evaluation for PCE released in December 2020 considered impacts on both children and adults from occupational and consumer use from inhalation and dermal exposures, as applicable. For occupational use, the risk evaluation considered males (>16 years

of age) and females of reproductive age (>16 years of age to less than 50 years of age) for both dermal and inhalation exposures. Additionally, because many dry cleaners are family owned and operated, the risk evaluation assumed children of employees may spend the full workday at dry cleaning facilities, in particular those too young to be in school, during which time they may be exposed to similar air concentration levels as ONUs. The risk evaluation considered inhalation exposures to children of employees present at dry cleaners by evaluating central nervous system effects for the most sensitive lifestage: infants less than one year old. Children of employees present at dry cleaners would be exposed to higher PCE concentrations than children who live or attend daycare or school above or adjacent to dry cleaners, and EPA therefore expects that risks to those populations are covered by evaluation of children within dry cleaning facilities. For consumer use, EPA evaluated dermal exposures for children ages 11 to 15 and 16 to 20 years of age and adults >20 years of age, and the evaluation of bystander exposure from inhalation exposures includes infants, toddlers and older children. While risks to children are not disproportionate, effects observed in studies include central nervous system effects from acute inhalation exposure.

B. Regulatory Assessment of PCE.

1. *Description of conditions of use.*

This unit describes the TSCA conditions of use that drive EPA's unreasonable risk determination for the chemical substance PCE. Condition of use descriptions were obtained from EPA sources such as CDR use codes, the 2020 Risk Evaluation for PCE and related documents, as well as the Organisation for Economic Co-operation and Development harmonized use codes and stakeholder engagements. For additional description of the conditions of use, including process descriptions and worker activities considered in the risk evaluation, see the Problem Formulation of the 2020 Risk Evaluation for PCE, the 2020 Risk Evaluation for PCE, and

supplemental files (Refs. 38, 1, 39). EPA acknowledges that some of the terms in this unit may be defined under other statutes, however the descriptions here are intended to provide clarity to the regulated entities who will implement the provisions of this rulemaking under TSCA section 6(a).

a. *Manufacturing (including import).*

i. *Domestic manufacture.* This condition of use refers to the making or producing of a chemical substance within the United States (including manufacturing for export), or the extraction of a component chemical substance from a previously existing chemical substance or a complex combination of substances. This description does not apply to PCE production as a byproduct, including during the manufacture of 1,2-dichloroethane which EPA intends to consider in the risk evaluation for 1,2-dichloroethane (Ref. 40).

ii. *Import.* This condition of use refers to the act of causing a chemical substance or mixture to arrive within the customs territory of the United States.

b. *Processing.*

i. *Processing as a reactant/intermediate.* This condition of use refers to processing PCE in chemical reactions for the manufacturing of another chemical substance or product. Through processing as a reactant or intermediate, PCE serves as a feedstock in the production of another chemical product via a chemical reaction in which PCE is completely consumed. For example, PCE is used as a reactant in the production of HFCs, hydrochlorofluorocarbons (HCFCs), and chlorofluorocarbons (CFCs). This condition of use includes reuse of PCE, including PCE originally generated as a byproduct or residual PCE as a reactant.

ii. *Processing into formulation, mixture or reaction product in cleaning and degreasing products.* This condition of use refers to when PCE is added to a cleaning or degreasing product (or product mixture) prior to further distribution of the product. For example, formulators may

mix PCE at varying concentrations with other additives to formulate cleaning or degreasing products that are used to remove dirt and dissolve oils, greases, and similar materials from textiles, glassware, metal surfaces, furniture, furnishings, and other articles, or to cleanse, sanitize, bleach, scour, polish, protect, or improve the appearance of surfaces.

iii. *Processing into formulation, mixture or reaction product in adhesive and sealant products.* This condition of use refers to when PCE is added to an adhesive or sealant product (or product mixture) prior to further distribution of the product. For example, formulators may mix PCE at varying concentrations with other additives to formulate products that promote bonding between other substances, promote adhesion of surfaces, or prevent seepage of moisture or air.

iv. *Processing into formulation, mixture or reaction product in paint and coating products.* This condition of use refers to when PCE is added to a paint or coating product (or product mixture) prior to further distribution of the product. For example, formulators may mix PCE at varying concentrations with other additives to formulate paint and coating products that are applied to surfaces to enhance properties such as water repellency, gloss, fade resistance, ease of application, or foam prevention. Additionally, PCE is incorporated into coating products, such as maskant, that protect a substrate during exposure to a chemical process such as chemical milling, plating, and anodizing.

v. *Processing into formulation, mixture or reaction product in other chemical products and preparations.* This condition of use refers to when PCE is added to other chemical products (or product mixtures) or preparations prior to further distribution of the product. For example, formulators may mix PCE at varying concentrations with other additives to formulate inks, toners, colorants, photographic supplies, lubricants, greases, mold releases, and other products.

vi. *Processing by repackaging.* This condition of use refers to the preparation of a chemical substance or mixture for distribution in commerce in a different form, state, or quantity.

This includes transferring of PCE from a bulk container into smaller containers.

vii. *Recycling.* This condition of use refers to processing waste streams of PCE at a third-party site for the purpose of recovering materials or otherwise preparing the waste for reuse instead of disposal. Waste solvents can be restored via solvent reclamation/recycling. The recovery process may involve an initial vapor recovery or mechanical separation step followed by distillation, purification, and final packaging.

c. *Industrial and commercial use.*

i. *Industrial and commercial use as solvent for open-top batch vapor degreasing.* This condition of use refers to the industrial and commercial use of PCE as a solvent for cleaning and degreasing through the process of heating PCE to its volatilization point and using its vapors to remove dirt, oils, greases, and other surface contaminants from metal and other parts using batch open-top vapor degreaser machines.

ii. *Industrial and commercial use as solvent for closed-loop batch vapor degreasing.* This condition of use refers to the industrial and commercial use of PCE as a solvent for cleaning and degreasing through the process of heating PCE to its volatilization point and using its vapors to remove dirt, oils, greases, and other surface contaminants from metal and other parts using batch closed-loop degreaser machines.

iii. *Industrial and commercial use as solvent for in-line conveyorized vapor degreasing.* This condition of use refers to the industrial and commercial use of PCE as a solvent for cleaning and degreasing through the process of heating PCE to its volatilization point and using its vapors to remove dirt, oils, greases, and other surface contaminants from metal and other parts using in-line conveyorized vapor degreaser machines.

iv. *Industrial and commercial use as solvent for in-line web cleaner vapor degreasing.* This condition of use refers to the industrial and commercial use of PCE as a solvent for cleaning

and degreasing through a process of heating PCE to its volatilization point and using its vapors to remove dirt, oils, greases, and other surface contaminants from metal and other parts using web vapor degreaser machines.

v. *Industrial and commercial use as solvent for cold cleaning.* This condition of use refers to the industrial and commercial use of PCE as a non-boiling solvent in cold cleaning machines, including simple spray sinks and dip tanks, to remove dirt, oils, greases, and other surface contaminants from metal and other parts.

vi. *Industrial and commercial use as solvent for aerosol spray degreaser/cleaner.* This condition of use refers to the industrial and commercial use of PCE as a solvent in degreasing and cleaning products to remove dirt, grease, stains, spots, and foreign matter through a process that uses an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from electronics, metals, and other fabricated materials. This description includes use of PCE in products for energized electrical cleaning for equipment with an electrical current running through it, such as electric motors, armatures, relays, electric panel, generators, and other equipment. This description does not apply to use of PCE in products intended for automotive care, welding, or mold cleaning, which are described in different conditions of use.

vii. *Industrial and commercial use as a solvent for aerosol lubricants.* This condition of use refers to the industrial and commercial use of PCE in aerosolized products to reduce friction, heat generation and wear between solid surfaces.

viii. *Industrial and commercial use as a solvent for penetrating lubricants and cutting tool coolants.* This condition of use refers to the industrial and commercial use of PCE in liquid products such as metalworking, cutting, and tapping fluids, including penetrating lubricants and cutting tool coolants, to reduce friction, heat generation and wear between solid surfaces.

ix. *Industrial and commercial use in solvent-based adhesives and sealants.* This

condition of use refers to the industrial and commercial use of PCE as a solvent in adhesive and sealant products to promote bonding between other substances, promote adhesion of surfaces, or prevent seepage of moisture or air.

x. *Industrial and commercial use in solvent-based paints and coatings.* This condition of use refers to the industrial and commercial use of PCE as a solvent in paint and coating, including maskant, that is applied to surfaces to enhance properties such as water repellence, increased gloss, improved fade resistance, ease of application, and foam prevention. This description does not apply to the use of PCE in maskant for chemical milling, which is described in a different condition of use

xi. *Industrial and commercial use in maskant for chemical milling.* This condition of use refers to the industrial and commercial use of PCE as a solvent in maskants or elastomer-based coatings that are used to protect a substrate during exposure to a chemical process, such as chemical milling, plating and anodizing.

xii. *Industrial and commercial use as a processing aid in pesticide, fertilizer and other agricultural chemical manufacturing.* This condition of use refers to the industrial and commercial use of PCE to improve the processing characteristics or the operation of process equipment or to alter or buffer the pH of the substance of mixture during the production of non-pesticidal products used to increase the productivity and quality of plant, animal and forestry crops produced on a commercial scale. Processing aids are added to a reaction mixture to aid in the manufacture or synthesis or another chemical substance but are not intended to remain in or become part of the product or product mixture or affect the function of a substance or article created.

xiii. *Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing.* This condition of use refers to the industrial and commercial use

of PCE to improve processing characteristics or the operation of process equipment during the production of oil, gas, and other similar products. For example, PCE is used in both reforming and isomerization processes at refineries. In the reforming process, PCE is added directly to a regenerator in a Continuous Catalytic Regeneration reforming unit, and in the isomerization process, PCE is added to the hydrocarbon feed. In both processes, PCE provides chlorine ions to regenerate the catalysts and is consumed in the process.

xiv. *Industrial and commercial use in wipe cleaning.* This condition of use refers to the industrial and commercial use of PCE in non-aerosol degreasing and cleaning products to remove dirt, grease, stains, spots, and foreign matter from furniture and furnishings or to cleanse, sanitize, bleach, scour, polish, protect, or improve the appearance of surfaces through wipe cleaning.

xv. *Industrial and commercial use in other spot cleaning and spot removers, including carpet cleaning.* This condition of use refers to the industrial and commercial use of PCE in products to remove dirt, grease, stains, spots, and foreign matter from furniture and furnishes, including carpets and rugs. This description does not apply to the use of PCE as a spot cleaner at dry cleaning facilities, which is described under other conditions of use.

xvi. *Industrial and commercial use in mold release.* This condition of use refers to the industrial and commercial use of PCE in products to remove dirt, grease, stains, spots, and foreign matter, including release agent residues, from molds and casting surfaces.

xvii. *Industrial and commercial use in dry cleaning and spot cleaning post-2006 dry cleaning.* This condition of use refers to industrial and commercial use of PCE in products for spot cleaning and as a solvent in degreasing and cleaning applications to remove dirt, grease, stains, spots, and foreign matter from garments at dry cleaning facilities that use PCE dry cleaning machines after the promulgation of the 2006 PCE NESHAP for Dry Cleaning Facilities

(40 CFR part 63, subpart M). This includes dry cleaning facilities using third generation (dry-to-dry, non-vented machines with refrigerated condensers), fourth generation (dry-to-dry, non-vented machines with both refrigerated condensers and carbon adsorbers as secondary vapor controls), or fifth generation (dry-to-dry, non-vented machines with secondary vapor controls, a monitor inside the machine drum, and an interlocking system to ensure the concentration is below approximately 300 ppm before the loading door can be opened) PCE dry cleaning machines.

xviii. *Industrial and commercial use in dry cleaning and spot cleaning 4th/5th gen only dry cleaning.* This condition of use refers to industrial and commercial use of PCE in products for spot cleaning and as a solvent in degreasing and cleaning applications to remove dirt, grease, stains, spots, and foreign matter from garments at dry cleaning facilities that use fourth generation or fifth generation PCE machines. In addition to use as a solvent in dry cleaning equipment, PCE is found in products to spot clean garments to remove stains or spots before and after dry cleaning treatment.

xix. *Industrial and commercial use in automotive care products (e.g., engine degreaser and brake cleaner).* This condition of use refers to the industrial and commercial use of PCE in aerosolized products to remove dirt, grease, stains, and foreign matter from interior and exterior vehicle surfaces. This description includes use of products for motorized vehicle maintenance and their parts, but does not include energized electrical cleaners, which is covered by the industrial and commercial use as a solvent for aerosol spray degreaser/cleaner. Additionally, this description does not include use of non-aerosolized products intended for automotive care, which are covered by different conditions of use.

xx. *Industrial and commercial use in non-aerosol cleaner.* This condition of use refers to the industrial and commercial use of PCE in non-aerosol products to remove dirt, grease, stains,

and foreign matter from furniture, furnishings, interior or exterior vehicles, and other materials, or to clean, sanitize, bleach scour, polish, or improve the appearance of surfaces in all other applications not specified elsewhere in this section.

xxi. *Industrial and commercial use in metal (e.g., stainless steel) and stone polishes.* This condition of use refers to the industrial and commercial use of PCE in non-aerosolized products for metal (e.g., stainless steel) and stone polishing applications, including stone and marble cleaner and wax.

xxii. *Industrial and commercial use in laboratory chemicals.* This condition of use refers to the industrial and commercial use of PCE, often in small quantities, in a laboratory process or in specialized laboratory equipment for instrument calibration/maintenance chemical analysis, chemical synthesis, extracting and purifying other chemicals, dissolving other substances, executing research, development, test and evaluation methods, and similar activities.

xxiii. *Industrial and commercial use in welding.* This condition of use refers to the industrial and commercial use of PCE in welding applications. For example, PCE can be found in aerosolized products that cast or join materials, promote the fusing of minerals, and prevent oxide formation, including products that reduce welding spatter or prevent the spatter from sticking to surfaces.

xxiv. *Industrial and commercial use in other textile processing.* This condition of use refers to the industrial and commercial use of PCE in processing textile products not described elsewhere. For example, PCE is used as a scourer and for sizing and finishing of cloth.

xxv. *Industrial and commercial use in wood furniture manufacturing.* This condition of use refers to the industrial and commercial use of PCE in the manufacture of wood furniture or wood furniture components (including household furniture, wood office furniture, wood containers and pallets, and all other wood products) not described elsewhere.

xxvi. *Industrial and commercial use in foundry applications.* This condition of use refers to the industrial and commercial use of PCE in metal foundry, smelting, and metallurgical applications not described elsewhere, such as soldering/desoldering, at nonferrous metal foundries (except die-casting), nonferrous metal diecasting foundries, aluminum foundries, and iron foundries.

xxvii. *Industrial and commercial use in specialty Department of Defense uses (oil analysis and water pipe repair).* During the risk evaluation, the Department of Defense (DOD) provided monitoring data for PCE in various uses, including for oil analysis and water pipe repair. This condition of use refers to the industrial and commercial use of PCE in specialty DOD uses in oil analysis and water pipe repair. After the risk evaluation was published, DOD determined there is no current data to indicate that PCE is required for these specialty uses.

xxviii. *Commercial use in inks and ink removal products (based on printing).* This condition of use refers to the commercial use of PCE in ink and ink removal products used in printing for writing, printing, or creating an image on paper and other substrates, applied to substrates to change their color or hide images, or to remove dirt and other contaminants from substrates such as cleaning machines or printing plates, at print shops.

xxix. *Commercial use in inks and ink removal products (based on photocopying).* This condition of use refers to the commercial use of PCE in ink and ink removal products used in photocopying for writing, printing, creating an image on paper and other substrates, applied to substrates to change their color or hide images, or to remove dirt and other contaminants from substrates such as cleaning machines or printing plates.

xxx. *Commercial use in photographic film.* This condition of use refers to the commercial use of PCE in photographic supplies, film, photoprocessing chemicals, and photographic paper. For example, PCE is used as a liquid-gate fluid to help protect scratching of optical negatives

during filming.

xxxi. *Commercial use in metal mold cleaning, release and protectant products.* This condition of use refers to the commercial use of PCE in mold release products to create barriers to prevent certain materials from adhering to each other. This description does not apply to the use of PCE in mold cleaning products that remove residual coatings from mold release, which is described under a different condition of use.

d. *Consumer use.*

i. *Consumer use in cleaners and degreasers (other).* This condition of use refers to the consumer use of PCE as a solvent in degreasing and cleaning products use to remove dirt, grease, stains, spots, and foreign matter through a process that uses an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from electronics, metals, and other fabricated materials not described elsewhere in this section.

ii. *Consumer use in dry cleaning solvent.* This condition of use refers to consumer exposure to PCE used to remove dirt, grease, stains, spots, and foreign matter from garments via dry cleaning, in particular the transportation, storage, and wear of articles that were dry cleaned with PCE. For example, garments that are dry cleaned at facilities that use PCE as a dry cleaning solvent have residual concentrations of PCE remaining in the article after a dry cleaning event.

iii. *Consumer use in automotive care products (brake cleaner).* This condition of use refers to the consumer use of PCE in aerosolized products to remove dirt, grease, stains, and foreign matter from interior and exterior vehicle surfaces, including brake cleaner.

iv. *Consumer use in automotive care products (parts cleaner).* This condition of use refers to the consumer use of PCE in non-aerosolized products that are to remove dirt, grease, stains, and foreign matter from interior and exterior vehicle surfaces, including parts cleaner.

v. *Consumer use in aerosol cleaner (vandalism mark and stain remover)*. This condition

of use refers to the consumer use of PCE in aerosolized products for cleaning and furniture care, including vandalism mark and stain remover.

vi. *Consumer use in non-aerosol cleaner (e.g., marble and stone polish)*. This condition of use refers to the consumer use of PCE in non-aerosolized products for cleaning and furniture care, typically in the form of a solid or liquid cleaner not described elsewhere in this section, including liquid marble and stone polish.

vii. *Consumer use in lubricants and greases (cutting fluid)*. This condition of use refers to the consumer use of PCE in non-aerosolized products to reduce friction, heat generation and wear between solid surfaces, including cutting fluid.

viii. *Consumer use in lubricants and greases (lubricants and penetrating oils)*. This condition of use refers to the consumer use of PCE in aerosolized products to reduce friction, heat generation and wear between solid surfaces, including lubricant and penetrating oils.

ix. *Consumer use in adhesives for arts and crafts (including industrial adhesive, arts and crafts adhesive, gun ammunition sealant).* This condition of use refers to the consumer use of PCE as an adhesive in arts, crafts, and hobby products to promote bonding between other substances, promote adhesion of surfaces, or prevent seepage of moisture or air, in particular industrial adhesive, adhesive for arts and crafts, and gun ammunition sealant. For example, PCE may be used in gun ammunition sealant products to ensure no moisture gets into ammunition casings.

x. *Consumer use in adhesives for arts and crafts (livestock grooming adhesive).* This condition of use refers to the consumer use of PCE in livestock grooming adhesive spray.

xi. *Consumer use in adhesives for arts and crafts (column adhesive, caulk and sealant).* This condition of use refers to the consumer use of PCE for column adhesive, caulk and sealant.

xii. *Consumer use in solvent-based paints and coatings (outdoor water shield (liquid)).*

This condition of use refers to the consumer use of PCE in solvent-based non-aerosol paint and coating products to enhance properties such as water repellence, increased gloss, improved fade resistance, ease of application, or foam prevention, in particular the use in outdoor water shield sealants and coatings.

xiii. *Consumer use in solvent-based paints and coatings (coating and primers (aerosol)).* This condition of use refers to the consumer use of PCE in solvent-based paint and coating aerosol products to enhance properties such as water repellence, increased gloss, improved fade resistance, ease of application, or foam prevention, in particular the use in aerosolized coating and primers.

xiv. *Consumer use in solvent-based paints and coatings (rust primer and sealant (liquid)).* This condition of use refers to the consumer use of PCE in solvent-based paint and coating liquid products to enhance properties such as water repellence, increased gloss, improved fade resistance, ease of application, or foam prevention, in particular the use in liquid rust primer and sealant.

xv. *Consumer use in solvent-based paints and coatings (metallic overglaze).* This condition of use refers to the consumer use of PCE in solvent-based paint and coating products to enhance properties such as water repellence, increased gloss, improved fade resistance, ease of application, or foam prevention, in particular the use in solvent based metallic overglaze for ceramics.

xvi. *Consumer use in metal (e.g., stainless steel) and stone polishes.* This condition of use refers to the consumer use of PCE in liquid wax-based products for metal (e.g., stainless steel) and stone polishing.

xvii. *Consumer use in inks and ink removal products.* This condition of use refers to the consumer use of PCE in ink and ink removal products for writing, printing, creating an image on

paper and other substrates, applied to substrates to change their color or hide images, or to remove dirt and other contaminants from substrates.

xviii. *Consumer use in welding.* This condition of use refers to the consumer use of PCE in products that cast or join materials, promote the fusing of minerals, or prevent oxide formation, including products that reduce welding spatter or prevent the spatter from sticking to surfaces.

xix. *Consumer use in metal mold cleaning, release and protectant products.* This condition of use refers to the consumer use of PCE in products to create barriers to prevent certain materials from adhering to each other and assist in the removal of dirt, grease, oils, and other contaminants from metal molds, machinery, electrical and electronic equipment, pins, and mechanical equipment.

e. *Disposal.*

This condition of use refers to the process of disposing generated waste streams of PCE that are collected and transported to a third-party site for their final disposition, such as waste incineration or landfilling.

f. Terminology in this proposed rule.

For purposes of this proposed rulemaking "occupational conditions of use" refers to the TSCA conditions of use described in Units III.B.1.a., b., c., and e. Although EPA identified both industrial and commercial uses in the 2020 Risk Evaluation for PCE for purposes of distinguishing scenarios, the Agency clarified then and clarifies now that EPA interprets the authority Congress gave to the Agency to "regulat[e] any manner or method of commercial use" under TSCA section 6(a)(5) to reach both industrial and commercial uses.

Additionally, in the 2020 Risk Evaluation for the chemical substance PCE, EPA identified and assessed all known, intended, and reasonably foreseen industrial, commercial, and

consumer uses of PCE in order to determine whether PCE as a whole chemical substance presents unreasonable risks to health and the environment. EPA determined that all industrial, commercial, and consumer uses of PCE evaluated in the 2020 Risk Evaluation for PCE drive the EPA determination that PCE presents unreasonable risk of injury to health. As such, for purposes of this risk management rulemaking, "consumer use" refers to all consumer uses including known, intended, and reasonably foreseen consumer uses of PCE. Likewise, for the purpose of this risk management rulemaking, "industrial and commercial use" refers to all industrial and commercial uses, including known, intended, or reasonably foreseen PCE industrial and commercial use.

EPA is not proposing to incorporate the descriptions of known, intended or reasonably foreseen conditions of use in Unit III.B.1.a through e into the regulatory text as definitions because these conditions of use represent those evaluated in the 2020 Risk Evaluation for PCE whereas the regulatory text applies to all TSCA consumer and industrial/commercial uses. EPA requests comment on whether EPA should promulgate definitions for those conditions of use evaluated in the 2020 Risk Evaluation for PCE that would not be prohibited, and, if so, whether the descriptions in this unit are consistent with the conditions of use evaluated in the 2020 Risk Evaluation for PCE and whether they provide a sufficient level of detail to improve the clarity and readability of the regulation if EPA were to promulgate a regulation that contains a list of the industrial and commercial conditions of use evaluated in the 2020 Risk Evaluation for PCE.

EPA further notes that this proposed rule does not apply to any substance excluded from the definition of "chemical substance" under TSCA section 3(2)(B)(ii) through (vi). Those exclusions include, but are not limited to, any pesticide (as defined by the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; and any food, food additive, drug, cosmetic, or device, as defined in section

201 of the Federal Food, Drug, and Cosmetic Act (FFDCA), when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device.

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

EPA has determined that PCE presents an unreasonable risk of injury to human health under the conditions of use based on acute and chronic non-cancer risks and chronic cancer risks (Ref. 2). As described in the TSCA section 6(b) 2020 Risk Evaluation for PCE, EPA identified non-cancer adverse effects from acute and chronic inhalation and dermal exposures to PCE, and cancer from chronic inhalation and dermal exposures to PCE (Ref. 1). EPA identified neurotoxicity as the most robust and sensitive endpoint for non-cancer adverse effects from acute inhalation and dermal exposures and as the most robust and sensitive endpoint for non-cancer adverse effects from chronic inhalation and dermal exposures for all conditions of use (Ref. 1). Additional risks associated with other adverse effects (e.g., kidney, liver, immune system, and developmental toxicity) were identified for acute and chronic exposures. EPA also concluded, based on EPA's Guidelines for Carcinogen Risk Assessment (Ref. 41), that PCE is likely to be carcinogenic to humans by all routes of exposure and calculated cancer risks from chronic inhalation and dermal exposures. Unit VI.A. summarizes the health effects and the magnitude of exposures (Ref. 1).

To make the unreasonable risk determination for PCE, EPA evaluated exposures to workers, ONUs, children of workers at dry cleaners, consumer users, and bystanders to consumer use using reasonably available monitoring and modeling data for inhalation and dermal exposures (Ref. 2). EPA conducted a screening level analysis to assess potential risks from the air and water pathways to fenceline communities. A discussion of EPA's analysis and the expected effects of this rulemaking on fenceline communities is in Unit VI.A.

For the 2020 Risk Evaluation for PCE, EPA considered PESS. EPA identified the

following groups as PESS: workers, ONUs, children of workers at dry cleaners, consumers, bystanders, developing fetuses (and by extension, women of childbearing age), and those with certain pre-existing health conditions, higher body fat content, or particular genetic polymorphisms (Ref. 1). All PESS are included in the quantitative and qualitative analyses described in the risk evaluation, and were considered in the determination of unreasonable risk for PCE. As discussed in Unit II.D. and Unit VI.A., the 2020 Risk Evaluation for PCE excluded the air and water exposure pathways to the general population from the published risk evaluations and may have caused some risks to be unaccounted for in the risk evaluation. EPA considers these receptors a subset of the general population and categorizes them as fenceline communities; they may also be considered PESS. See Unit VI.A. for further discussion on assessing and protecting against risk to fenceline communities.

3. *Description of TSCA Section 6 requirements for risk management.*

EPA examined the TSCA section 6(a) requirements (listed in Unit III.A.) to identify which ones have the potential to eliminate the unreasonable risk for PCE. This Unit summarizes the TSCA section 6 considerations for issuing regulations under TSCA section 6(a). Unit V. outlines how EPA applied these considerations specifically to managing the unreasonable risk from PCE.

As required, EPA developed a proposed regulatory action and one or more primary alternative regulatory actions, which are described in Units IV.A. and IV.B., respectively. To identify and select a regulatory action, EPA considered the two routes of exposure driving the unreasonable risk, inhalation and dermal, and the exposed populations. For occupational conditions of use (see Unit III.B.1.f.), EPA considered how it could directly regulate manufacturing (including import), processing, distribution in commerce, industrial and commercial use, or disposal to address the unreasonable risk. EPA does not have direct authority

to regulate consumer use. Therefore, EPA considered how it could exercise its authority under TSCA to regulate the manufacturing (including import), processing, and/or distribution in commerce of PCE at different points in the supply chain to eliminate exposures or restrict the availability of PCE and PCE -containing products for consumer use in order to address the unreasonable risk.

As required by TSCA section 6(c)(2), EPA considered several factors, in addition to identified unreasonable risk, when selecting among possible TSCA section 6(a) requirements. To the extent practicable, EPA factored into its decisions: (i) The effects of PCE on health and the environment; (ii) The magnitude of exposure to PCE of human beings and the environment; (iii) The benefits of PCE for various uses; and (iv) The reasonably ascertainable economic consequences of the rule. In evaluating the reasonably ascertainable economic consequences of the rule, EPA considered: (i) The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; (ii) The costs and benefits of the proposed regulatory action and one or more primary alternative regulatory actions considered; and (iii) The cost effectiveness of the proposed regulatory action and of the one or more primary alternative regulatory actions considered. See Unit VI. for further discussion related to TSCA section 6(c)(2)(A) considerations, including the statement of effects of the proposed rule with respect to these considerations.

EPA also considered the regulatory authority under TSCA and other statutes such as the OSH Act, Consumer Product Safety Act (CPSA), and other EPA-administered statutes to examine: (1) Whether there are opportunities for all or part of risk management action on PCE to be addressed under other statutes, such that a referral may be warranted under TSCA sections 9(a) or 9(b); or (2) Whether TSCA section 6(a) regulation could include alignment of requirements and definitions in and under existing statutes to minimize confusion to the

regulated entities and the general public.

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

To the extent information was reasonably available, when selecting regulatory actions, EPA considered pollution prevention and the hierarchy of controls adopted by OSHA and NIOSH, with the goal of identifying risk management control methods that are permanent, feasible, and effective. EPA also considered how to address the unreasonable risk while providing flexibility to the regulated entities where appropriate. EPA considered the information presented in the 2020 Risk Evaluation for PCE, as well as additional input from stakeholders (as described in Unit III.A.), and anticipated compliance strategies from regulated entities.

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

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

IV. Proposed and Alternative Regulatory Actions

This unit describes the proposed regulatory action by EPA so that PCE will no longer present an unreasonable risk of injury to health. In addition, as indicated by TSCA section

6(c)(2)(A), EPA must consider the costs and benefits and the cost-effectiveness of the proposed regulatory action and one or more primary alternative regulatory actions. In the case of PCE, the proposed regulatory action is described in Unit IV.A. and the two alternative regulatory actions considered are described in Unit IV.B. An overview of the proposed regulatory action and two alternative regulatory actions for each condition of use is in Unit IV.C. The rationale for the proposed and alternative regulatory actions and associated compliance timeframes are discussed in this unit and in more detail in Unit V.A.

A. Proposed regulatory action.

EPA is proposing under TSCA section 6(a) to: Prohibit most industrial and commercial uses and the manufacture (including import), processing, and distribution in commerce of PCE for those uses, outlined in Unit IV.A.1.a.; Prohibit the manufacture (including import), processing, and distribution in commerce of PCE for all consumer use, outlined in Unit IV.A.1.b.; Prohibit the manufacture (including import), processing, distribution in commerce, and commercial use of PCE in dry cleaning and spot cleaning through a 10-year phaseout, outlined in Unit IV.A.1.c.; Require strict workplace controls, including a PCE WCPP, which would include requirements to meet an inhalation exposure concentration limit and prevent direct dermal contact with PCE, for 16 occupational conditions of use not prohibited, outlined in Unit IV.A.2.; Require prescriptive workplace controls for laboratory use, outlined in Unit IV.A.3.; Establish recordkeeping and downstream notification requirements, outlined in Unit IV.A.4; and Provide a 10-year time limited exemption under TSCA section 6(g) for certain critical or essential emergency uses of PCE for which no technically and economically feasible safer alternative is available, outlined in Unit IV.A.5. As the manufacture and processing of PCE presents an unreasonable risk to health in the United States, the manufacture and processing of PCE for export would also be prohibited or restricted in accordance with TSCA section 12(a)(2).

1. *Prohibitions of manufacturing, processing, distribution in commerce, and use.*

a. *Prohibition of certain industrial and commercial uses and manufacturing, processing, and distribution in commerce of PCE for those uses.*

EPA is proposing to prohibit the manufacturing, processing, distribution in commerce, and use of PCE for industrial and commercial uses, except for those uses which would continue under the WCPP (as described in Unit IV.A.2.), and laboratory use (as described in Unit IV.A.3.). The proposed prohibitions under TSCA would not apply to any use of PCE that is excluded from TSCA's definition of "chemical substance" under TSCA section 3(2)(B)(ii) through (vi). This proposed prohibition would include a prohibition on the manufacturing, processing, distribution in commerce, and use of PCE for the following industrial and commercial uses:

- As a processing aid in pesticide, fertilizer and other agricultural chemical manufacturing;
- In specialty DOD uses (oil analysis and water pipe repair);
- In solvent-based paints and coatings;
- As solvent for aerosol spray degreaser/cleaner;
- As solvent for cold cleaning;
- In other textile processing;
- In wood furniture manufacturing;
- As a solvent for aerosol lubricants;
- In wipe cleaning;
- In other spot cleaning and spot removers, including carpet cleaning;
- In automotive care products (e.g., engine degreaser and brake cleaner);
- In non-aerosol cleaner;

- In metal (e.g., stainless steel) and stone polishes;
- In foundry applications;
- In welding;
- For mold release;
- As a solvent for penetrating lubricants and cutting tool coolants;
- For photographic film;
- In inks and ink removal products (based on printing);
- In inks and ink removal products (based on photocopying); and
- In metal mold cleaning, release and protectant products.

EPA is also proposing to prohibit the following condition of use, which is the upstream processing condition of use for some of the prohibited industrial and commercial uses: processing into formulation, mixture or reaction product in other chemical products and preparations. EPA is also proposing to phase out the use of PCE at industrial and commercial dry cleaning facilities as described in Unit IV.A.1.c.

EPA has considered the sensitive nature of the DOD applications for which EPA received monitoring data for the 2020 Risk Evaluation for PCE, including for the industrial and commercial use in specialty DOD uses (oil analysis and water pipe repair). The Agency understands that DOD has no current data that indicate PCE is required for these specialty uses and EPA has not identified any other entities using PCE in this way. Because there are no known entities engaged in this condition of use, EPA believes a prohibition is reasonable and would prevent any future entities from engaging in this use. EPA is therefore proposing to prohibit the manufacturing, processing, distribution in commerce, and use of PCE for the industrial and commercial use in specialty DOD uses (oil analysis and water pipe repair).

As discussed in Units III.B.3. and V.A., based on consideration of alternatives under

TSCA section 6(c)(2)(C), uncertainty relative to the feasibility of exposure reduction to sufficiently address the unreasonable risk across the broad range of work environments and activities, and the irreversible health effects associated with PCE exposures, EPA has determined that prohibition is the best way to address the unreasonable risk from PCE driven in part by the conditions of use identified in this unit. As noted in Unit III.B.1.f., this proposal does not apply to any substance excluded from the definition of "chemical substance" under TSCA section 3(2)(B)(ii) through (vi). EPA requests comment on the impacts, if any, a prohibition on the processing of PCE into a formulation, mixture or reaction product in other chemical products and preparations, or other aspects of this proposal, may have on the production and availability of any pesticide or other substance excluded from the TSCA definition of "chemical substance."

EPA is proposing to stagger the compliance dates for the proposed prohibitions described in this unit, such that the requirements would come into effect in 12 months for manufacturers, 15 months for processers, 18 months for distributing to retailers, 21 months for all other distributors (including retailers), and 24 months for industrial and commercial users after the publication date of the final rule. When proposing these compliance dates as required under TSCA section 6(d), EPA considered irreversible health effects and risks associated with PCE exposure. EPA has no reasonably available information indicating that the proposed compliance dates are not practicable for the activities that would be prohibited, or that additional time is needed for products to clear the channels of trade. However, EPA requests comment on whether additional time is needed, for example, for products to clear the channels of trade, or for implementing the use of substitutes; comments should include documentation such as the specific use of the chemical throughout the supply chain; concrete steps taken to identify, test, and qualify substitutes for those uses (including details on the substitutes tested and the specific certifications that would require updating); and estimates of the time required to identify, test,

and qualify substitutes with supporting documentation. EPA also requests comment on whether these are the appropriate types of information for use in evaluating compliance requirements, and whether there are other considerations that should apply. EPA may finalize significantly shorter or longer compliance timeframes based on consideration of public comments.

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

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

b. *Prohibition of manufacturing, processing and distribution in commerce of PCE for consumer use.*

In the 2020 Risk Evaluation for PCE, EPA evaluated consumer use of PCE:

• In cleaners and degreasers (other);

• In automotive care products (brake cleaner);

• In automotive care products (parts cleaner);

• In aerosol cleaner (vandalism mark and stain remover);

• In non-aerosol cleaner (e.g., marble and stone polish);

• In lubricants and greases (cutting fluid);

• In lubricants and greases (lubricants and penetrating oils);

• In adhesives for arts and crafts (including industrial adhesive, arts and crafts adhesive,

gun ammunition sealant);

- In adhesives for arts and crafts (livestock grooming adhesive);
- In adhesives for arts and crafts (column adhesive, caulk and sealant);
- In solvent-based paints and coatings (outdoor water shield (liquid));
- In solvent-based paints and coatings (coatings and primers (aerosol));
- In solvent-based paints and coatings (rust primer and sealant (liquid));
- In solvent-based paints and coatings (metallic overglaze);
- In metal (e.g., stainless steel) and stone polishes;
- In inks and ink removal products;
- In welding; and
- In metal mold cleaning, release and protectant products.

The consumer uses evaluated in the 2020 Risk Evaluation for PCE constitute all known, intended, and reasonably foreseen consumer uses of PCE. EPA determined that all of these consumer uses drive unreasonable risk of injury to health. As such, for purposes of this risk management rulemaking, "consumer use" refers to all consumer uses, including all known, intended, and reasonably foreseen consumer uses of PCE. EPA is proposing to prohibit the manufacturing, processing, and distribution in commerce of PCE for all consumer use. EPA is proposing to phase out consumer use in dry cleaning solvent (i.e., exposure to clothing or articles recently dry cleaned with PCE as described in Unit III.B.1.d.ii.) by phasing out the use of PCE at industrial and commercial dry cleaning facilities as described in Unit IV.A.1.c.; thus, consumer use of clothing and articles that have been commercially dry cleaned with PCE would not be subject to the prohibitions and compliance timeframes described in this unit.

As discussed in Units III.B.3. and V.A., based on consideration of the severity of the hazards of PCE in conjunction with the limited options available to adequately address the

identified unreasonable risk to consumers and bystanders under TSCA section 6(a), EPA is proposing to address the unreasonable risk from consumer use by prohibiting the manufacturing (including import), processing, and distribution in commerce of PCE for consumer use in order to remove PCE and products containing PCE from the market, thereby effectively eliminating instances of consumer use.

Additionally, EPA is proposing to prohibit retailers from distributing in commerce PCE, including any PCE-containing products, in order to prevent products intended for industrial and commercial use under the WCPP outlined in Unit IV.A.2. from being purchased by consumers. A retailer is any person or business entity that distributes or makes available products to consumers, including through e-commerce internet sales or distribution. If a person or business entity distributes or makes available any product to at least one consumer, then it is considered a retailer (as EPA proposes to define that term in 40 CFR 751.5). For a distributor not to be considered a retailer, the distributor must distribute or make available chemical substances solely to commercial or industrial end-users or businesses. Prohibiting manufacturers (including importers), processors, and distributors from distributing PCE, or any products containing PCE, to retailers would prevent retailers from making these products available to consumers, which would help address that part of the unreasonable risk driven by consumer use of PCE.

EPA is proposing that the prohibition described in this unit would take effect in 12 months for manufacturers, 15 months for processers, 18 months for distributing to retailers, and 21 months for all other distributors (including retailers) after the publication date of the final rule in the *Federal Register*. EPA considered irreversible health effects and risks associated with PCE exposure when proposing compliance dates. EPA has no reasonably available information indicating these proposed compliance dates are not practicable for the activities that would be prohibited, or that additional time is needed for products to clear the channels of trade. However,

EPA requests comment on whether additional time is needed, for example, for products to clear the channels of trade. EPA may finalize significantly shorter or longer compliance timeframes based on consideration of public comments.

c. Prohibition and phaseout of PCE in dry cleaning.

EPA is proposing to prohibit the manufacturing, processing, distribution in commerce, and industrial and commercial use of PCE for dry cleaning and spot cleaning, including in 3rd generation (dry-to-dry machines with refrigerated condenser) and 4th/5th generation (dry-to-dry machines with refrigerated condenser and carbon adsorber process controls) machines.

As discussed in Units III.B.3. and V.A., based on a consideration of alternatives under TSCA section 6(c)(2)(C), uncertainty relative to the feasibility of exposure reduction to sufficiently address the unreasonable risk across the broad range of work environments and activities, and the irreversible health effects associated with PCE exposures, EPA has determined that prohibition is the best way to address the unreasonable risk. A prohibition on the manufacturing, processing, distribution in commerce, and industrial and commercial use of PCE in dry cleaning and spot cleaning would address the unreasonable risk for the following conditions of use evaluated in the 2020 Risk Evaluation and described further in Unit III.B.1:

• Industrial and commercial use in dry cleaning and spot cleaning post-2006 dry cleaning;

• Industrial and commercial use in dry cleaning and spot cleaning 4th/5th generation only dry cleaning; and

• Consumer use in dry cleaning solvent (i.e., exposure to clothing or articles recently dry cleaned with PCE).

EPA recognizes that the transition to an alternative dry cleaning process or solvent could require significant time and investment from dry cleaning facilities; therefore, EPA is proposing a phaseout period to take place following the publication date of the final rule. The phaseout

would start with a prohibition on the use of PCE in any dry cleaning machine acquired 6 months or later after the publication date of the rule, followed by a prohibition on the use of PCE in 3rd generation machines 3 years after the publication date of the rule. Full implementation of the phaseout would be achieved with a prohibition on the use of PCE in all dry cleaning and spot cleaning, including in 4th and 5th generation machines, 10 years after the publication date of the final rule and a prohibition on the manufacturing, processing, and distribution in commerce of PCE for use in dry cleaning solvent 10 years after the publication date of the final rule. When proposing these compliance dates, EPA considered reasonably available information, including market research, existing State actions restricting the use of PCE in dry cleaning (Title 17, California Code of Regulations 39109 and 93110; Minnesota HF 91; 6 NYCRR Part 232), and engagement with industry, trade associations, and State and local agencies. Based on this reasonably available information, EPA understands that the use of PCE in dry cleaning is currently declining and that very few PCE machines are being produced or sold in the U.S. market (Ref. 33). As described more fully in the Economic Analysis (Ref. 3), EPA assumes dry cleaning machines are retired 15 to 25 years after the manufactured date. Therefore, EPA assumes most dry cleaning machines manufactured and installed before 2005, such as for 3rd generation machines, would be beyond their projected useful life by the proposed phaseout dates outlined in this Unit. A 3-year phaseout of the use of PCE in 3rd generation dry cleaning machines takes into consideration the age of existing 3rd generation dry cleaning machines as well as public comments submitted on the proposed amendments to the PCE Dry Cleaning NESHAP (December 27, 2021, 86 FR 73207) recommending a 3- to 5-year compliance timeframe at minimum to account for supply issues related to those machines. A 10-year phaseout of the use of PCE in dry cleaning and spot cleaning takes into account that, while the average projected useful lifespan of dry cleaning machines is 15 to 25 years, the purchase of new

PCE dry cleaning machines has been in decline. As described more fully in the Economic Analysis, EPA estimates that 6,000 dry cleaners still use PCE and estimates that about 60 machines are expected to still be in use at the end of the 10-year phaseout period given the declining trend of use and age of machines. EPA believes that the proposed 6-month and 3-year compliance dates for the start of the phaseout, and the proposed 10-year compliance date for full implementation of the phaseout, are consistent with requirements in TSCA section 6(d)(1)(C) and (D), respectively, to specify mandatory compliance dates for the start of phaseout requirements that are as soon as practicable but not later than 5 years after the date of promulgation of the rule, and to specify mandatory compliance dates for full implementation of phaseout requirements that are as soon as practicable. EPA also believes that these compliance dates provide for a reasonable transition period, consistent with TSCA section 6(d)(1)(E). EPA has no reasonably available information indicating that the proposed compliance dates are not practicable for the activities that would be prohibited. However, EPA requests comment on the amount of time needed, for example, for dry cleaners to transition to an alternative process or solvent. EPA also requests comment regarding the number of entities that could potentially close as well as associated costs with a 10-year phaseout of PCE for use in dry cleaning as identified in this unit. EPA may finalize significantly shorter or longer compliance timeframes based on consideration of public comments.

d. *De minimis level.*

To aid the regulated community with implementing the prohibitions, and to account for de minimis levels of PCE as an impurity in products, EPA is proposing that products containing PCE at concentrations less than 0.1% by weight are not subject to the prohibitions described in this unit. EPA has determined that the prohibitions are only necessary for products containing PCE at levels equal to or greater than 0.1% by weight in order to eliminate the unreasonable risk

of injury resulting from inhalation and dermal exposures from PCE-containing products during occupational and consumer conditions of use. EPA's description for how allowing for a concentration of PCE up to 0.1% would address the unreasonable risk associated with PCE-containing products and rationale for this regulatory approach are in Unit V.A. EPA requests comment on allowing this de minimis level of PCE in products to account for impurities.

2. *Workplace Chemical Protection Program (WCPP).*

a. *Overview.*

As described in Unit III.B.3., under TSCA section 6(a), EPA is required to issue a regulation applying one or more of the TSCA section 6(a) requirements to the extent necessary so that the unreasonable risk of injury to health or the environment from a chemical substance is no longer presented. The TSCA section 6(a) requirements provide EPA the authority to limit or restrict a number of activities, alone or in combination, including the manufacture, processing, distribution in commerce, commercial use, and disposal of the chemical substance. Given this authority, EPA may find it appropriate in certain circumstances to propose requirements under a WCPP for certain occupational (i.e., manufacturing, processing, industrial and commercial use, and disposal) conditions of use. A WCPP for PCE would encompass the inhalation exposure limit and action level, Direct Dermal Contact Control (DDCC) requirements, and the associated implementation requirements described in this unit to ensure that the chemical substance no longer presents unreasonable risk. Under a WCPP, owners or operators would have some flexibility, within the parameters outlined in this unit, regarding how they prevent exceedances of the identified EPA exposure limit thresholds or prevent direct dermal contact. In the case of PCE, meeting the EPA exposure limits and implementing the DDCC requirements for certain occupational conditions of use would address unreasonable risk to potentially exposed persons from inhalation and dermal exposure.

EPA uses the term "potentially exposed person" in this unit and in the regulatory text to include workers, ONUs, employees, independent contractors, employers and all other persons in the work area where PCE is present and who may be exposed to PCE under the conditions of use for which a WCPP would apply. EPA's intention is to require a comprehensive WCPP that would address the unreasonable risk from PCE to potentially exposed persons directly handling the chemical or in the area where the chemical is being used.

Similarly, the 2020 risk evaluation for PCE did not distinguish between employers, contractors, or other legal entities or businesses that manufacture, process, distribute in commerce, use, or dispose of PCE. EPA uses the term "owner or operator" to describe the entity responsible for implementing the WCPP for workplaces where an applicable condition of use is occurring and PCE is present. The term includes any person who owns, leases, operates, controls, or supervises such a workplace.

An ECEL is a risk-based inhalation exposure threshold. The ECEL would be accompanied by monitoring, training, recordkeeping and other requirements to help ensure that the threshold is not exceeded. With an ECEL, regulated entities have some flexibility, within certain parameters outlined in this unit, for preventing exceedances of the identified exposure threshold. Therefore, EPA generally refers to the ECEL and ancillary requirements as a non-prescriptive approach. In the case of PCE, the exposure threshold identified by EPA for certain occupational conditions of use would mitigate unreasonable risk from inhalation exposure driven by those conditions of use for potentially exposed persons.

DDCC requirements are process-based approaches to prevent direct dermal contact with PCE and associated implementation requirements described in this unit to ensure that the chemical substance no longer presents unreasonable risk from dermal exposure. As with the ECEL, DDCC requirements allow regulated entities some flexibility within certain parameters

outlined in this unit for preventing direct dermal contact with PCE. In the case of PCE, EPA has preliminarily determined that preventing direct dermal contact through DDCC requirements for certain conditions of use would mitigate unreasonable risk from dermal exposure driven by those conditions of use for potentially exposed persons.

This unit includes a summary of the proposed PCE WCPP, including a description of the ECEL; proposed implementation requirements and an EPA ECEL action level; proposed monitoring requirements; a description of potential exposure controls, which consider the hierarchy of controls; information that may be used to inform respirator selection; and additional requirements proposed for recordkeeping, and worker training, participation, and notification. This unit also describes proposed DDCC requirements for PCE, including potential exposure controls, which consider the hierarchy of controls; proposed PPE as it relates to dermal protection; and additional requirements proposed for recordkeeping. This unit also describes compliance timeframes for these proposed requirements.

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

i. *ECEL and ECEL action level.* To reduce exposures in the workplace and address the unreasonable risk of injury to health resulting from inhalation exposures to PCE identified under the occupational conditions of use in the TSCA 2020 Risk Evaluation for PCE, EPA is proposing an ECEL of 0.14 parts per million (ppm) (0.98 mg/m3) for inhalation exposures to PCE as an 8-hour TWA. This ECEL is based on the occupational chronic, non-cancer human equivalent concentration (HEC) for neurotoxicity (Ref. 10). EPA has determined, as a matter of risk management policy, that ensuring exposures remain at or below the ECEL would eliminate the contribution to the unreasonable risk of injury to health for PCE resulting from inhalation exposures in an occupational setting. EPA is proposing to establish requirements to meet an ECEL as part of the WCPP for:

• Manufacturing (domestic manufacturing);

• Manufacturing (import);

• Processing as a reactant/intermediate;

• Processing into formulation, mixture, or reaction product in cleaning and degreasing products;

• Processing into formulation, mixture, or reaction products in paint and coating products;

• Processing into formulation, mixture, or reaction products in adhesive and sealant products;

• Processing by repackaging;

• Industrial and commercial use as solvent for open-top batch vapor degreasing;

• Industrial and commercial use as solvent for closed-loop batch vapor degreasing;

• Industrial and commercial use as solvent for in-line conveyorized vapor degreasing;

• Industrial and commercial use as solvent for in-line web cleaner vapor degreasing;

• Industrial and commercial use in maskant for chemical milling;

• Industrial and commercial use in solvent-based adhesives and sealants; and

• Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing.

Each owner or operator of a workplace where these conditions of use occur would be responsible for compliance with the ECEL and the associated requirements. EPA's description for how the requirements related to an ECEL would address the unreasonable risk resulting from inhalation exposures and the rationale for this regulatory approach are outlined in Units III.B.3. and V.A.

If ambient exposures are kept at or below the 8-hour ECEL of 0.14 ppm, EPA expects that a potentially exposed person in the workplace would be protected against non-cancer effects

resulting from occupational exposures, as well as excess risk of cancer (Ref. 10).

EPA is also proposing to establish an ECEL action level of 0.07 ppm as an 8-hour TWA for PCE. Air concentrations at or above the action level would trigger more frequent periodic monitoring of exposures to PCE, as described in this unit. EPA is proposing to adopt the action level approach in implementing the TSCA ECEL, consistent with the action level approach utilized by OSHA in the implementation of OSHA standards, although the values differ due to differing statutory authorities. As explained by OSHA, due to the variable nature of employee exposures, compliance with an action level provides employers with greater assurance that their employees will not be exposed to concentrations above the PELs (Ref. 42). EPA agrees with this reasoning and, like OSHA, expects the inclusion of an ECEL action level will stimulate innovation within industry to reduce exposures to levels below the action level. Therefore, EPA has identified a need for an action level for PCE and is proposing a level that would be half the 8-hour ECEL, which is in alignment with the precedented approach established under most OSHA standards. EPA is soliciting comment regarding an ECEL action level that is half the ECEL and any associated provisions related to the ECEL action level when the ECEL is significantly lower than the OSHA PEL.

In summary, EPA is proposing that each owner or operator of a workplace subject to the ECEL must ensure that no person is exposed to airborne concentration of PCE in excess of 0.14 ppm (0.98 mg/m3) as an 8-hour TWA (ECEL), with an action level identified as 0.07 ppm (0.47 mg/m3) (ECEL action level). For conditions of use for which the requirements to meet an ECEL are being proposed, EPA expects that the regulated community can detect the ECEL and ECEL action level as they are above the threshold of PCE air sampling analytical methods that are widely available in commerce, currently in use, and approved by OSHA and NIOSH, which can range from ≤0.5 parts per billion (ppb) to 9 ppm (Ref. 10). The Agency has also identified

personal breathing zone air sampling devices with a minimum limit of quantitation and level of detection below the ECEL action level (Ref. 43). EPA is requesting comment on issues around the viability of current analytical methods and detection limits for occupational perchloroethylene sampling and/or monitoring methods. EPA's methodology and inputs for the ECEL value are directly derived from the peer reviewed analysis in the December 2020 Risk Evaluation, which was also subject to public comment. As with all aspects of this rulemaking, the public is welcome to comment on the methodology for the ECEL value.

EPA expects that many workplaces already have stringent controls in place that reduce exposures to PCE; for some workplaces, EPA understands that these existing controls may already reduce PCE air concentration levels to near or below the ECEL. As discussed further in Unit V.A.1., for some conditions of use for which EPA is proposing the ECEL, data were submitted during the risk evaluation that indicate inhalation exposures may already be near or below the ECEL for some facilities, indicating that such facilities may already be in compliance with the proposed ECEL. As noted previously in this unit, EPA expects that, if inhalation exposures for affected occupational conditions of use are kept at or below the ECEL, potentially exposed persons reasonably likely to be exposed in the workplace would be protected from the unreasonable risk. EPA is also proposing to require owners or operators to comply with additional requirements under the WCPP that would be needed to ensure successful implementation of the ECEL.

ii. *Monitoring requirements. Overview.* Monitoring requirements are a key component of implementing EPA's proposed WCPP. Initial monitoring for PCE is critical for establishing a baseline of exposure for potentially exposed persons; similarly, periodic exposure monitoring assures continued compliance so that potentially exposed persons in the workplace are not exposed to levels that would result in an unreasonable risk of injury. Periodic exposure

monitoring frequency could change if certain conditions are met, which are described in this unit. Additionally, in some cases, a change in workplace conditions with the potential to impact exposure levels would warrant additional monitoring, which is also described. To ensure compliance with monitoring activities, EPA proposes exposure monitoring recordkeeping requirements outlined in this unit.

Initial exposure monitoring. Under the proposed regulation, each owner or operator of a workplace where any condition of use listed earlier in this unit is occurring would be required to perform initial exposure monitoring to determine the extent of exposure of potentially exposed persons to PCE. Initial monitoring would notify owner or operators of the magnitude of possible exposures to their potentially exposed persons with respect to their unique work conditions and environments. The results of the initial exposure monitoring would determine the frequency of future periodic monitoring, whether additional exposure controls are necessary (such as engineering controls, administrative controls, and/or respiratory protection), and whether the owner or operator would need to demarcate a regulated area as described in this unit.

EPA is proposing to require each owner or operator to establish an initial baseline monitoring sample to determine the magnitude of exposure for all persons who may be exposed to PCE within 6 months after the date of publication of the final rule in the *Federal Register* or within 30 days of introduction of PCE into the workplace, whichever is later. Where PCE is present in the workplace, each owner or operator would be required to determine each potentially exposed person's exposure by either taking a personal breathing zone air sample of each potentially exposed person or taking personal breathing zone air samples that are representative of each potentially exposed person's exposure performing the same or substantially similar operations in each work shift, in each job classification, and in each work area (hereinafter identified as an "exposure group"). Representative 8-hour TWA exposures must be determined

based on one or more samples representing full-shift exposures for each shift for each person in each job classification in each work area. Monitoring samples must be taken when and where the operating conditions are best representative of each potentially exposed person's full-shift exposures. EPA expects that owners and operators would attempt to monitor a baseline for all of the tasks during the same timeframe; however, EPA understands that certain tasks occur less frequently, and EPA is soliciting comments regarding the timing of the initial exposure monitoring so that it would be representative of all tasks involving PCE where exposures may approach the ECEL. If the owner or operator chooses a representative sample, such sampling must include persons that are the closest to the source of PCE, so that the monitoring results are representative of the most highly exposed persons in the workplace. EPA is also soliciting comments regarding use of area sampling instead of personal breathing zone as a representative sample of exposures.

EPA also recognizes that some entities may already have exposure monitoring data. If the owner or operator has monitoring data conducted within five years prior to the effective date of the final rule and the monitoring satisfies all other requirements of this section, including the requirement that the data represents the highest PCE exposures likely to occur under reasonably foreseeable conditions of use, the owner or operator may rely on such earlier monitoring results for the initial baseline monitoring sample.

Periodic exposure monitoring. EPA is proposing to require each owner or operator to conduct, for those exposure groups that exceed the following airborne concentration levels, the following periodic monitoring:

• If all samples taken during the initial exposure monitoring reveal a concentration below the ECEL action level (<0.07 ppm 8-hour TWA), the owner or operator must repeat the periodic exposure monitoring at least once every five years.

• If the most recent exposure monitoring indicates that airborne exposure is above the ECEL (>0.14 ppm 8-hour TWA), the owner or operator must repeat the periodic exposure monitoring within 3 months of the most recent exposure monitoring.

• If the most recent exposure monitoring indicates that airborne exposure is at or above the ECEL action level (≥ 0.07 ppm 8-hour TWA) but at or below the ECEL (≤ 0.14 ppm 8-hour TWA), the owner or operator must repeat the periodic exposure monitoring within 6 months of the most recent exposure monitoring.

• If the most recent (non-initial) exposure monitoring indicates that airborne exposure is below the ECEL action level, the owners or operators must repeat such monitoring within 6 months of the most recent monitoring until two consecutive monitoring measurements, taken at least seven days apart, are below the ECEL action level (<0.07 ppm 8-hour TWA), at which time the owner or operator must repeat the periodic exposure monitoring at least once every 5 years.

Additionally, in instances where an owner or operator does not manufacture, process, use, or dispose of PCE for a condition of use for which the WCPP is proposed over the entirety of time since the last required periodic monitoring event, EPA is proposing that the owner or operator would be permitted to forgo the next periodic monitoring event. However, documentation of cessation of use of PCE would be required and periodic monitoring would be required to resume should the owner or operator restart any of the conditions of use listed in unit IV.A.2. for which the WCPP is proposed.

The proposed periodic monitoring requirements are also outlined in Table 1. EPA requests comment on the timeframes for periodic monitoring outlined in this unit. EPA may finalize significantly shorter or longer compliance timeframes based on consideration of public comments.

Table 1 – Periodic Monitoring Requirements

Air Concentration Condition	Periodic Monitoring Requirement
If all initial exposure monitoring is below the ECEL action level (< 0.07 ppm 8-hour TWA)	Periodic exposure monitoring is required at least once every five years.
If the most recent exposure monitoring indicates that airborne exposure is above the ECEL (> 0.14 ppm 8-hour TWA)	Periodic exposure monitoring is required within 3 months of the most recent exposure monitoring.
If the most recent exposure monitoring indicates that airborne exposure is at or above the ECEL action level but at or below the ECEL (≥ 0.07 ppm 8-hour TWA, ≤ 0.14 ppm 8-hour TWA)	Periodic exposure monitoring is required within 6 months of the most recent exposure monitoring.
If the two most recent (non-initial) exposure monitoring measurements, taken at least seven days apart within a 6 month period, indicate exposure is below the ECEL action level (< 0.07 ppm 8-hour TWA)	Periodic exposure monitoring is required within 5 years of the most recent exposure monitoring.
If the owner or operator engages in a condition of use for which WCPP ECEL would be required but does not manufacture, process, use, or dispose of PCE in that condition of use over the entirety of time since the last required monitoring event	The owner or operator may forgo the next periodic monitoring event. However, documentation of cessation of use of PCE is required and periodic monitoring would be required when the owner or operator resumes the condition of use.

Additional exposure monitoring. In addition to the initial and periodic exposure monitoring, EPA is proposing that each owner or operator conduct additional exposure monitoring whenever a change in the production, process, control equipment, personnel, or work practices may reasonably be expected to result in new or additional exposures at or above the ECEL action level, or when the owner or operator has any reason to believe that new or additional exposures at or above the ECEL action level have occurred. In the event of start-up, shutdown, spills, leaks, ruptures or other breakdowns that may lead to employee exposure, EPA is proposing that each owner or operator must conduct additional initial exposure monitoring to potentially exposed persons (using personal breathing zone sampling) after the cleanup of the spill or repair of the leak, rupture or other breakdown. An additional exposure monitoring event may result in an increased frequency of periodic monitoring. For example, if the initial monitoring results from a workplace are above the ECEL action level, but below the ECEL,

periodic monitoring is required every 6 months. If additional monitoring is performed because increased exposures are suspected, and the results are above the ECEL, subsequent periodic monitoring would have to be performed every 3 months. The required additional exposure monitoring should not delay implementation of any necessary cleanup or other remedial action to reduce the exposures to persons in the workplace.

Other monitoring requirements. For each monitoring event, EPA is proposing to require owners or operators ensure that their methods be accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of PCE. Also, EPA is proposing to require use of appropriate sampling and analytical methods used to determine PCE exposure, including as relevant: (A) Use of an analytical method already approved by EPA, OSHA or NIOSH, or another analytical method that has been demonstrated to meet the proposed accuracy requirement at an appropriate level of detection for the ECEL and ECEL action level; (B) Compliance with the Good Laboratory Practice Standards at 40 CFR part 792. Additionally, EPA is proposing to require owners and operators to re-monitor within 15 working days after receipt of the results of any exposure monitoring when results indicate non-detect or air monitoring equipment malfunction, unless an Environmental Professional as defined at 40 CFR 312.10 or a Certified Industrial Hygienist reviews the monitoring results and determines re-monitoring is not necessary.

EPA is also proposing to require that each owner or operator maintain exposure monitoring records that include the following information for each monitoring event:

(A) Dates, duration, and results of each sample taken;

(B) All measurements that may be necessary to determine the conditions (e.g., work site temperatures, humidity, ventilation rates, monitoring equipment type and calibration dates) that may affect the monitoring results.

(C) Name, workplace address, work shift, job classification, and work area of the person monitored; documentation of all potentially exposed persons whose exposures the monitoring is intended to represent if using a representative sample; and type of respiratory protective device worn by the monitored person, if any.

(D) Use of appropriate sampling and analytical methods, such as analytical methods already approved by EPA, OSHA or NIOSH, or compliance with an analytical method verification procedure.

(E) Compliance with the Good Laboratory Practice Standards at 40 CFR part 792.

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

iii. *Incorporation of the hierarchy of controls.* EPA is proposing to require owners or operators to implement the WCPP in accordance with the hierarchy of controls and encourages the use of pollution prevention to control exposures whenever practicable. Pollution prevention, also known as source reduction, is any practice that reduces, eliminates, or prevents pollution at its source (e.g., elimination and substitution). Similarly, the hierarchy of controls includes, in order of preference, elimination, substitution, engineering controls, and administrative controls, prior to relying on PPE as a means of controlling exposures (Ref. 8). EPA is proposing to require owners or operators to reduce inhalation exposures below the ECEL in accordance with the hierarchy of controls. EPA expects that, for conditions of use for which EPA is proposing a WCPP, compliance at most workplaces would be part of an existing industrial hygiene program. Workplaces that cannot feasibly eliminate the source of PCE emissions or replace PCE with a substitute would have to use engineering and/or administrative controls to implement process changes to reduce exposures to the extent feasible, following the hierarchy of controls (Ref. 8). If an owner or operator chooses to replace PCE with a substitute, EPA recommends that they

carefully review the available hazard and exposure information on the potential substitutes to avoid a substitute chemical that might later be found to present unreasonable risks or be subject to regulation (sometimes referred to as a "regrettable substitution").

If an effort to identify and implement feasible exposure controls such as elimination, substitution, engineering controls, and administrative controls are not sufficient to reduce exposures to or below the ECEL for all persons in the workplace, EPA proposes to require each owner or operator to use such controls to reduce PCE concentrations in the workplace to the lowest levels achievable and, only after levels cannot be further reduced, supplement these controls using respiratory protection before persons are permitted to enter a regulated area, as described in this unit. In such cases, EPA would require that the owner or operator provide those persons exposed or who may be exposed to PCE by inhalation above the ECEL with respirators sufficient to ensure that their exposures do not exceed the ECEL, as described in this unit. EPA also proposes to require that each owner or operator document their evaluation of elimination, substitution, engineering and administrative exposure control strategies, and if applicable the reasons why they found these strategies infeasible to control exposures below the ECEL, in an exposure control plan as described in this unit. In addition, a regulated entity would be prohibited from rotating work schedules of potentially exposed persons to comply with the ECEL 8-hour TWA. EPA may require more, less, or different documentation regarding exposure control strategies in the final rule based on consideration of public comments.

iv. *Regulated area.* Based on the exposure monitoring, EPA is proposing to require that owners or operators of workplaces subject to a WCPP demarcate any area where airborne concentrations of PCE exceed or are reasonably expected to exceed the ECEL. Regulated areas would be demarcated using administrative controls, such as warning signs or highly visible signifiers, in multiple languages as appropriate (e.g., based on languages spoken by potentially

exposed persons), placed in conspicuous areas, and documented through training and recordkeeping. The owner or operator would be required to restrict access to the regulated area from any potentially exposed person that lacks proper training, is not wearing required PPE as described in this unit or is otherwise unauthorized to enter. EPA is proposing to require owners and operators demarcate a regulated area beginning 9 months after the date of publication of the final rule, or within 3 months after receipt of any exposure monitoring that indicates exposures exceeding the ECEL. EPA is soliciting comment on requiring warning signs to demarcate regulated areas, such as the requirements found in OSHA's General Industry Standard for Beryllium (29 CFR 1910.1024(m)(2)).

v. *Notification of monitoring results.* EPA proposes that the owner or operator must, within 15 working days after receipt of the results of any exposure monitoring, notify each person whose exposure is represented by that monitoring in writing, either individually to each potentially exposed person or by posting the information in an appropriate and accessible location accessible to all persons whose exposure is represented by the monitoring, such as public spaces or common areas, outside the regulated area. This notice must include the exposure monitoring results, identification and explanation of the ECEL and ECEL action level in plain language, any corresponding required respiratory protection, if applicable, the quantity, location, manner of PCE use and identified releases of PCE that could result in exposure to PCE, and whether the airborne concentration of PCE exceeds the ECEL limit. The notice must also include a description of actions taken by the owner or operator to reduce inhalation exposures to or below the ECEL, if applicable, or refer to a document available to the potentially exposed persons which states the actions to be taken to reduce exposures, and be posted in multiple languages if necessary (e.g., notice must be in a language that the potentially exposed person understands, including a non-English language version representing the language of the largest

group of workers who cannot readily comprehend or read English).

c. Direct dermal contact control requirements.

i. *Direct dermal contact.* DDCC requirements are a process-based set of provisions to address unreasonable risk driven by dermal exposure by preventing direct dermal contact in the workplace. In order to address the unreasonable risk driven by dermal exposure to PCE, DDCC requirements would include controls to separate, distance, physically remove, or isolate all person(s) from direct handling of PCE or from skin contact with surfaces that may be contaminated with PCE (i.e., equipment or materials on which PCE may be present) under routine conditions in the workplace (hereafter referred to as direct dermal contact). For purposes of DDCC requirements, direct dermal contact with PCE does not include vapor exposures through the skin, although EPA recommends and encourages owners and operators to implement control measures to prevent or reduce dermal exposures to airborne PCE vapors. The 2020 Risk Evaluation for PCE identified that unreasonable risk to workers is also driven by the dermal exposure, specifically from direct skin contact with PCE; risk exceeding the benchmark was identified even when considering use of chemically resistant gloves in most commercial and industrial conditions of use. EPA's description for how the requirements related to DDCC would address the unreasonable risk resulting from dermal exposures and the rationale for this regulatory approach is outlined in Units III.B.3. and V.A.

Similar to the ECEL, under DDCC requirements, EPA is proposing to require owners and operators implement dermal exposure controls in accordance with the hierarchy of controls. EPA also recommends and encourages the use of pollution prevention as a means of controlling exposures whenever practicable. In addition to the conditions of use for which EPA is proposing to require a WCPP ECEL, EPA is also proposing WCPP DDCC requirements for the following conditions of use: recycling and disposal.

Within certain parameters outlined in this unit, DDCC requirements are non-prescriptive to allow more flexibility to owners and operators to choose their controls to prevent direct dermal contact when compared with prescriptive requirements for specific controls. Each owner or operator of a workplace engaging in a condition of use for which DDCC requirements are proposed would be responsible for compliance with the DDCC requirements and recordkeeping.

As discussed briefly in Unit IV.A.1. and further in Unit V.A.1., EPA expects that many workplaces already have stringent controls in place that reduce dermal exposures to PCE; for some workplaces, EPA understands that these existing controls may already prevent or reduce direct dermal contact with PCE.

ii. *Incorporation of the hierarchy of controls.* As with the requirements to meet an ECEL, EPA is proposing to require owners or operators to implement DDCC requirements in accordance with the hierarchy of controls and encourages the use of pollution prevention to control exposures whenever practicable. EPA recognizes that some owners or operators may have industrial hygiene practices already preventing direct dermal contact with PCE in the workplace. For workplaces that cannot feasibly eliminate the source of PCE dermal exposure or replace PCE with a substitute, workplaces would have to use engineering and/or administrative controls to implement process changes to prevent direct dermal contact with PCE to the extent feasible. If an owner or operator chooses to replace PCE with a substitute, EPA recommends that they carefully review the available hazard and exposure information on the potential substitutes to avoid a regrettable substitution. If an effort to identify and implement feasible exposure controls such as elimination, substitution, engineering controls and administrative controls is not sufficient to prevent direct dermal contact with PCE for potentially exposed persons in the workplace, EPA proposes to require each owner and operator to reduce potential for direct dermal contact with PCE in the workplace by these controls and to supplement these controls

using PPE.

Examples of engineering controls that may prevent or reduce the potential for direct dermal contact include automation, physical barriers between contaminated and clean work areas, enclosed transfer liquid lines (with purging mechanisms in place (e.g., nitrogen, aqueous) for operations such as product changes or cleaning), and design of tools (e.g., a closed-loop container system providing contact-free connection for unloading fresh and collecting spent solvents, pneumatic tools, tongs, funnels, glove bags, etc.). Examples of administrative controls that may prevent or reduce the potential for direct dermal contact include adjusting work practices (i.e., implementing policies and procedures) such as providing safe working distances from areas where direct handling of PCE may occur.

EPA requests comment on available methods to measure the effectiveness of engineering and administrative controls in preventing or reducing the potential for direct dermal contact to PCE. EPA is also requesting comment on available monitoring methods, such as charcoal patch testing, as feasible or effective methods to measure potential direct dermal contact with PCE.

EPA proposes to require that owners and operators document their implementation efforts and compliance with DDCC requirements in an exposure control plan or through any existing documentation of the facility's "Safety and Health Program" that may already be developed as part of meeting OSHA requirements or other safety and health standards (Ref. 44), as described in Unit IV.A.2.e.

d. *Personal Protective Equipment (PPE) program.*

Where elimination, substitution, engineering controls, and administrative controls are not feasible to reduce the air concentration to or below the ECEL and/or prevent direct dermal contact with PCE for all potentially exposed persons, EPA is proposing to require implementation of a PPE program in alignment with OSHA's General Requirements for Personal

Protective Equipment at 29 CFR 1910.132. Consistent with 29 CFR 1910.132, owners and operators would be required to provide PPE, including respiratory protection and dermal protection selected in accordance with the guidelines described in this unit, that is of safe design and construction for the work to be performed. EPA is proposing to require owners and operators ensure each potentially exposed person who is required by this unit to wear PPE to use and maintain PPE in a sanitary, reliable, and undamaged condition. Owners and operators would be required to select and provide PPE that properly fits each potentially exposed person who is required by this unit to use PPE and communicate PPE selections to each affected person.

As part of the PPE program, EPA is also proposing that owners and operators must comply with OSHA's general PPE training requirements at 29 CFR 1910.132(f) for application of a PPE training program, including providing training on proper use of PPE (e.g., when and where PPE is necessary, proper application, wear, and removal of PPE, maintenance, useful life and disposal of PPE). EPA is proposing that owners and operators would provide PPE training to each potentially exposed person who is required by this unit to wear PPE prior to or at the time of initial assignment to a job involving potential exposure to PCE. Owners and operators would also have to re-train each affected person at least once annually or whenever the owner or operator has reason to believe that a previously trained person does not have the required understanding and skill to properly use PPE, or when changes in the workplace or in the PPE to be used render the previous training obsolete.

This unit includes a description of the PPE Program, including proposed PPE as it relates to respiratory protection, proposed PPE as it relates to dermal protection, and other proposed requirements such as additional training for respirators and recordkeeping to support implementation of a PPE program.

i. Respiratory protection. Where elimination, substitution, engineering, and

administrative controls are not feasible to reduce the air concentration to or below the ECEL, EPA proposes to set minimum respiratory PPE requirements based on an entity's most recent measured air concentration and the level of PPE that EPA determined would be needed to reduce exposure to the ECEL. In those circumstances, EPA is proposing to require a respiratory protection PPE program with worksite-specific procedures and elements for required respirator use. The respiratory protection PPE program proposed by EPA would be based on the most recent exposure monitoring concentration measured as an 8-hour TWA and would be administered by a suitably trained program administrator. EPA is also proposing to require each owner or operator select respiratory protection in accordance with the guidelines described in this unit and 29 CFR 1910.134(a) through (l), except (d)(1)(iii), for proper respirator use, maintenance, fit-testing, medical evaluation, and training. EPA is not proposing to cross reference 29 CFR 1910.134(d)(1)(iii) because the WCPP contains requirements for identifying PCE respiratory hazards in the workplace.

Required Respiratory Protection. EPA is proposing to require each owner or operator supply a respirator, selected in accordance with this unit, to each person who enters a regulated area within 3 months after the receipt of any exposure monitoring that indicates exposures exceeding the ECEL and thereafter must ensure that all persons within the regulated area are using the provided respirators whenever PCE exposures exceed or can reasonably be expected to exceed the ECEL. Given the risks associated with PCE exposure above the ECEL, prompt compliance with the respiratory protection requirements is important, but EPA expects that most owners or operators will need some time after the exposure monitoring results are received to acquire the correct respirators and establish a respiratory protection program, including training, fit-testing, and medical evaluations. EPA believes that 3 months should be sufficient for this purpose. EPA is also proposing that owners or operators who would be required to administer a

respiratory protection program must supply a respirator selected in accordance with 29 CFR 1910.134(d)(1) (except (d)(1)(iii)). Additionally, EPA is proposing that the owner or operator must ensure that all filters, cartridges and canisters used in the workplace are labeled and color coded with the NIOSH approval label and that the label is not removed and remains legible. 29 CFR 1910.134(d)(3)(iii), which EPA is proposing to cross-reference, requires either the use of respirators with an end-of-life service indicator certified by NIOSH for the contaminant, in this case PCE, or implementation of a change schedule for canisters and cartridges that ensures that they are changed before the end of their service life. EPA is requesting comment on whether there should be a requirement to replace cartridges or canisters after a certain number of hours, such as the requirements found in OSHA's General Industry Standard for 1,3-Butadiene (29 CFR 1910.1051(h)), or a requirement for a minimum service life of non-powered air-purifying respirators such as the requirements found in OSHA's General Industry Standard for Benzene (29 CFR 1910.1028(g)(3)(D)).

EPA is proposing the following requirements for respiratory protection, based on the exposure monitoring concentrations measured as an 8-hour TWA that exceed the ECEL (0.14 ppm). EPA is proposing to establish minimum respiratory protection requirements, such that any respirator affording a higher degree of protection than the following proposed requirements may be used. While this unit includes respirator selection requirements for respirators of assigned protection factors (APFs) of 1,000 or greater, EPA does not anticipate that respirators beyond APF 25 will be widely or regularly used to address unreasonable risk, particularly when other controls are put in place.

• If the measured exposure concentration is at or below 0.14 ppm: no respiratory protection is required.

• If the measured exposure concentration is above 0.14 ppm and less than or equal to 0.7

ppm (5 times ECEL): Any NIOSH-certified air-purifying quarter mask respirator (APF 5).

• If the measured exposure concentration is above 0.7 ppm and less than or equal to 1.4 ppm (10 times ECEL): Any NIOSH-certified air-purifying half mask or full facepiece respirator equipped with NIOSH-approved organic vapor cartridges or canisters (APF 10).

• If the measured exposure concentration is above 1.4 ppm and less than or equal to 3.5 ppm (25 times ECEL): Any NIOSH-certified air-purifying full facepiece respirator equipped with NIOSH-approved organic vapor cartridges or canisters; any NIOSH-certified powered air-purifying respirator equipped with NIOSH-approved organic vapor cartridges; or any NIOSH-certified continuous flow supplied air respirator equipped with a hood or helmet (APF 25).

• If the measured exposure concentration is above 3.5 ppm and less than or equal to 7.0 ppm (50 times ECEL): Any NIOSH-certified air-purifying full facepiece respirator equipped with NIOSH-approved organic vapor cartridges or canisters; or any NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece and a NIOSH-approved organic vapor cartridge (APF 50).

• If the measured exposure concentration is above 7.0 ppm and less than or equal to 140 ppm (1,000 times ECEL): Any NIOSH-certified supplied air respirator equipped with a half mask or full facepiece and operated in a pressure demand or other positive pressure mode (APF 1,000).

• If the measured exposure concentration is greater than 140 ppm (1,000 times ECEL) or the concentration is unknown: Any NIOSH-certified self-contained breathing apparatus (SCBA) equipped with a full facepiece and operated in a pressure demand or other positive pressure mode; or any NIOSH-certified supplied air respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode in combination with an auxiliary SCBA operated in a pressure demand or other positive pressure mode (APF 10,000).

EPA proposes to require that owners and operators document respiratory protection used and PPE program implementation. EPA proposes to require that owners and operators document in the exposure control plan or other documentation of the facility's safety and health program information relevant to respiratory program, including records on the name, workplace address, work shift, job classification, work area, and type of respirator worn (if any) by each potentially exposed person, maintenance, and fit-testing, as described in 29 CFR 1910.134(f), and training in accordance with 29 CFR 1910.132(f) and 29 CFR 1910.134(k).

ii. *Dermal protection.* Where elimination, substitution, engineering controls, and administrative controls are not feasible or sufficient to fully prevent direct dermal contact with PCE, EPA is proposing to require that appropriate dermal PPE be provided by owners and operators to, and be worn by, persons potentially exposed to direct dermal contact with PCE. To accomplish this, EPA is proposing owners and operators follow the dermal PPE requirements for PPE selection laid out in this unit.

Required Dermal Protection. In choosing appropriate dermal PPE, owners and operators would be required to select gloves, clothing, and protective gear (which covers any exposed dermal area of arms, legs, torso, and face) based on specifications from the manufacturer or supplier that demonstrate an impervious barrier to PCE during expected durations of use and normal conditions of exposure within the workplace, accounting for potential chemical permeation or breakthrough times. In alignment with the OSHA Hand Protection PPE Standard (29 CFR 1910.138), owners and operators would be required to select dermal PPE based on an evaluation of the performance characteristics of the PPE relative to the task(s) to be performed, conditions present, and the duration of use. Further information related to choosing appropriate PPE can be found in the summary of suitable gloves for PCE memo (Ref. 45).

For example, owners and operators can select gloves that have been tested in accordance

with the American Society for Testing and Materials (ASTM) F739 "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact." EPA is proposing that PPE be provided for use for a time period only to the extent and no longer than the time period for which testing has demonstrated that the PPE will be impermeable during expected durations of use and conditions of exposure. EPA is proposing to require that owners and operators also consider other factors when selecting appropriate PPE, including effectiveness of glove type when preventing exposures from PCE alone and in likely combination with other chemical substances used in the work area or when used with glove liners, permeation, degree of dexterity required to perform task, and temperature, as identified in the Hand Protection section of OSHA's Personal Protective Equipment Guidance (Ref. 46).

EPA is proposing that owners and operators would be required to establish, either through manufacturer or supplier-provided documentation or individually prepared 3rd party testing that the selected PPE will be impervious for the expected duration and conditions of exposure, such as using the format specified in ASTM F1194-99(2010) "Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing Materials," reporting cumulative permeation rate as a function of time, or equivalent manufacturer- or supplier- provided testing. Owners and operators would also be required to consider likely combinations of chemical substances to which the clothing may be exposed in the work area when selecting the appropriate PPE such that the PPE will prevent direct dermal contact to PCE. EPA is proposing that PPE must be immediately provided and replaced if any person is dermally exposed to PCE longer than the breakthrough time period for which testing has demonstrated that the PPE will be impermeable or if there is a chemical permeation or breakage of the PPE.

Additionally, EPA is proposing to require that owners and operators subject to this rule comply with provisions of 29 CFR 1910.133(b) for requirements on selection and use of eye and face protection. EPA is soliciting comments on the requirements proposed for appropriate PPE selection, the effectiveness of PPE in preventing direct dermal contact with PCE in the workplace, and general absorption and permeation effects to PPE from direct dermal exposure. In addition, EPA understands that some workplaces rinse and reuse PPE after minimal use and is therefore soliciting comments on the impact on effectiveness of rinsing and reusing certain types of PPE, either gloves or protective clothing and gear. EPA also requests comment on the degree to which additional guidance related to use of PPE might be appropriate.

EPA is also proposing that owners and operators retain records of dermal PPE used and program implementation. EPA proposes to require that owners and operators document in the exposure control plan or other documentation of the facility's safety and health program, information relevant to any dermal PPE program, as applicable, including: (A) The name, workplace address, work shift, job classification, and work area of each person reasonably likely to directly handle PCE or handle equipment or materials on which PCE may present and the type of PPE selected to be worn by each of these persons; (B) The basis for specific PPE selection (e.g., demonstration based on permeation testing or manufacturer specifications that each item of PPE selected provides an impervious barrier to prevent exposure during expected duration and conditions of exposure, including the likely combinations of chemical substances to which the PPE may be exposed in the work area); (C) Appropriately sized PPE and training on proper application, wear, and removal of PPE, and proper care/disposal of PPE; (D) Occurrence and duration of any direct dermal contact with PCE that occurs during any activity or malfunction at the workplace that causes direct dermal exposures to occur and/or glove breakthrough, and corrective actions to be taken during and immediately following that activity or malfunction to

prevent direct dermal contact to PCE; and (E) Training in accordance with 29 CFR 1910.132(f), including any re-training. EPA may require more, less, or different documentation in the final rule based on consideration of public comments.

e. *General WCPP requirements.*

i. *Exposure Control Plan.* EPA proposes to require that owners and operators document their exposure control strategy and implementation in an exposure control plan or through adding EPA-required information to any existing documentation of the facility's safety and health program developed as part of meeting OSHA requirements or other safety and health standards. EPA proposes to require that each owner or operator document in the exposure control plan the following:

(A) Identification and rationale of exposure controls used or not used in the following sequence: elimination of PCE, substitution of PCE, engineering controls, and administrative controls to reduce exposures in the workplace to either at or below the ECEL or to the lowest level achievable and to prevent or reduce direct dermal contact with PCE in the workplace;

(B) The exposure controls selected based on feasibility, effectiveness, and other relevant considerations;

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

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

(E) Description of any regulated area and how it is demarcated, and identification of authorized persons; and description of when the owner or operator expects exposures may be likely to exceed the ECEL;

(F) Regular inspections, evaluations, and updating of the exposure controls to ensure

effectiveness and confirmation that all persons are implementing them as required;

(G) Occurrence and duration of any start-up, shutdown, or malfunction of the facility that causes air concentrations to be above the ECEL or any direct dermal contact with PCE and subsequent corrective actions taken during start-up, shutdown, or malfunctions to mitigate exposures to PCE; and

(H) Availability of the exposure control plan and associated records for potentially exposed persons.

ii. *Workplace Information and Training.* EPA is also proposing to require implementation of a training program in alignment with the OSHA Hazard Communication Standard (29 CFR 1910.1200) and the OSHA General Industry Standard for Methylene Chloride (29 CFR 1910.1052). To ensure that potentially exposed persons in the workplace are informed of the hazards associated with PCE exposure, EPA is proposing to require that owners or operators of workplaces subject to the WCPP institute a training and information program for potentially exposed persons and assure their participation in the training and information program.

As part of the training and information program, the owner or operator would be required to provide information and comprehensive training in an understandable manner (i.e., plain language) and in multiple language as appropriate (e.g., based on languages spoken by potentially exposed persons) to potentially exposed persons prior to or at the time of initial assignment to a job involving potential exposure to PCE. In alignment with the OSHA Hazard Communication Standard, owners and operators would be required to provide information and training to all potentially exposed persons that includes (A) the requirements of the PCE WCPP and how to access or obtain a copy of the requirements of the WCPP; (B) the quantity, location, manner of use, release, and storage of PCE and the specific operations in the workplace that could result in PCE exposure; (C) principles of safe use and handling of PCE in the workplace,

including specific measures the owner or operator has implemented to reduce inhalation exposures to at or below the ECEL or prevent direct dermal contact with PCE, such as work practices and PPE used; (D) the methods and observations that may be used to detect the presence or release of PCE in the workplace (such as monitoring conducted by the owner or operator, continuous monitoring devices, visual appearance or odor of PCE when being released, etc.); and (E) the health hazards associated with exposure with PCE.

In addition to providing training at the time of initial assignment to a job involving potential exposure to PCE, and in alignment with the OSHA General Industry Standard for Beryllium (20 CFR 1910.1024), owners and operators subject to the PCE WCPP would be required to re-train each potentially exposed person annually to ensure they understand the principles of safe use and handling of PCE in the workplace. Owners and operators would also need to update the training as necessary whenever there are changes in the workplace, such as new tasks or modifications of tasks; in particular, whenever there are changes in the workplace that increase exposure to PCE or where potentially exposed persons' exposure to PCE can reasonably be expected to exceed the action level or increase the potential for direct dermal contact with PCE. To support compliance, EPA is proposing that each owner or operator of a workplace subject to the WCPP would be required to provide to the EPA, upon request, all available materials related to workplace information and training.

iii. *Workplace Participation.* EPA encourages owners or operators to consult with persons that have potential for exposure on the development and implementation of exposure control plans and PPE/respirator programs. EPA is proposing to require owners or operators to provide potentially exposed persons or their designated representatives regular access to the exposure control plans, exposure monitoring records, and PPE program implementation and documentation. To ensure compliance in workplace participation, EPA is proposing that the

owner or operator document the notice to and ability of any potentially exposed person that may reasonably be affected by PCE inhalation exposure or direct dermal contact with PCE to readily access the exposure control plans, facility exposure monitoring records, PPE program implementation, or any other information relevant to PCE exposure in the workplace. EPA is requesting comment on how owners and operators can engage with potentially exposed persons on the development and implementation of an exposure control plan and PPE program.

iv. *Recordkeeping.* To support and demonstrate compliance, EPA is proposing that each owner or operator of a workplace subject to WCPP retain compliance records for five years. EPA is proposing to require records to include:

(A) the exposure control plan;

(B) PPE program implementation and documentation, including as necessary, respiratory protection and dermal protection used and related PPE training; and

(C) information and training provided to each person prior to or at the time of initial assignment and any re-training.

In addition, EPA is proposing that owners and operators subject to the WCPP ECEL requirements maintain records to include:

(D) The exposure monitoring records;

(E) Notification of exposure monitoring results; and

(F) To the extent that the owner or operator relies on prior exposure monitoring data, records that demonstrates that it meets all of the requirements of this section.

The owners and operators, upon request by EPA, would be required to make all records that are maintained as described in this unit available to EPA for examination and copying in accordance with EPA requirements. All records required to be maintained by this unit could be kept in the most administratively convenient form (electronic or paper).

v. *Compliance timeframes.* EPA is proposing to require each owner or operator of a workplace subject to an ECEL conduct initial baseline monitoring according to the process outlined in this unit by 6 months after date of publication of the final rule in the *Federal Register* or within 30 days of introduction of PCE into the workplace if PCE use commences at least 6 months after the date of publication. EPA is proposing to require each owner or operator ensure that the airborne concentration of PCE does not exceed the ECEL for all potentially exposed persons within 9 months after the date of publication of the final rule in the *Federal Register*, or beginning 4 months after introduction of PCE into the workplace if PCE use commences at least 6 months after the date of publication.EPA is also proposing to require owners and operators demarcate and maintain a regulated area wherever exposures exceed or can reasonably be expected to exceed the ECEL beginning 9 months after the date of publication of the final rule in the *Federal Register*, or beginning 4 months after introduction of PCE into the workplace if PCE use commences at least 6 months after the date of publication. If applicable, EPA is also proposing that each owner or operator must provide respiratory protection sufficient to reduce inhalation exposures to below the ECEL to all potentially exposed persons in the regulated area within 3 months after receipt of the results of any exposure monitoring that indicates exposures exceeding the ECEL or, if using monitoring data conducted within five years prior to the effective date of this rule that satisfies all other requirements of this section, within 9 months after the date of publication of the final rule in the *Federal Register*. Regulated entities should then proceed accordingly to implement an exposure control plan within 12 months after date of publication of the final rule in the *Federal Register*. EPA requests comment relative to the ability of owners or operators to conduct initial monitoring within 6 months after date of publication of the final rule in the *Federal Register*, and anticipated timelines for any procedural adjustments needed to comply with the requirements outlined in this unit, including establishment of a

respiratory protection program and development of an exposure control plan.

With regard to the compliance timeframe for those occupational conditions of use which are subject to DDCC requirements, EPA is proposing to require each owner and operator of a workplace subject to DDCC establish the process outlined in this unit by 12 months after publication of the final rule in the *Federal Register*. EPA requests comment relative to the ability of owners or operators to implement such processes within 12 months of publication of the final rule in the *Federal Register*, and anticipated timelines for any procedural adjustments needed to comply with the requirements outlined in this unit. EPA may finalize significantly shorter or longer compliance timeframes based on consideration of public comments.

3. *Prescriptive controls.*

a. *Overview.*

In contrast to the proposed non-prescriptive requirements of the ECEL and DDCC where regulated entities would have flexibility to select controls in accordance with the hierarchy of controls to comply with the parameters outlined in this unit, EPA may also find it appropriate in certain circumstances to require specific prescriptive controls for certain occupational conditions of use. In the 2020 Risk Evaluation for PCE, EPA identified certain workplace controls that reduce exposures from PCE adequate to address the unreasonable risk driven by inhalation exposures from the industrial and commercial use of PCE in laboratory chemicals. Therefore, EPA is proposing to require specific prescriptive controls for the industrial and commercial use of PCE in laboratory chemicals, as described in this unit. This unit describes proposed requirements for a fume hood and dermal PPE for the industrial and commercial use of PCE in laboratory chemicals, including additional requirements proposed for recordkeeping. This unit also describes compliance timeframes for these proposed requirements.

b. *Workplace requirements for laboratory use.*

To reduce exposures in the workplace and address the unreasonable risk of injury to health resulting from dermal exposures to PCE identified for the industrial and commercial use as a laboratory chemical, EPA is proposing to require dermal PPE in combination with comprehensive training for tasks particularly related to the use of PCE in a laboratory setting as specified in this unit for each potentially exposed person to direct dermal contact with PCE. Additionally, EPA is proposing to require the use of fume hoods in workplaces engaged in the laboratory chemical condition of use to codify the assumption of existing good laboratory practices that EPA relied upon as a key basis for its evaluation of risk from this condition of use (Ref. 1). Each owner or operator of a workplace where the industrial and commercial use of PCE as a laboratory chemical occurs would be responsible for compliance with the requirements outlined in this unit. EPA's description for how these requirements would address the unreasonable risk and the rationale for this regulatory approach is outlined in Unit III.B.3. and Unit V.A.

EPA is proposing to require dermal PPE, including impermeable gloves and protective clothing, in combination with comprehensive training for tasks where there is potential for direct dermal contact with PCE (see Unit IV.A.2.d.). In selecting and providing appropriate dermal PPE and providing PPE training, owners and operators would be required to follow the PPE program and dermal protection requirements laid out in Unit IV.A.2.d.ii. Unlike DDCC, this proposed provision would not require owners and operators to use elimination, substitution, engineering controls, and administrative controls, prior to relying on PPE, as a means of controlling exposures in accordance with the hierarchy of controls.

For laboratory fume hoods, EPA is proposing to require each owner or operator of a workplace engaged in the laboratory chemical condition of use to ensure fume hoods are in use and functioning properly to minimize exposures to potentially exposed persons in the area where

PCE is used as a laboratory chemical. EPA suggests owners or operators refer to OSHA's 29 CFR 1910.1450, Appendix A National Research Council Recommendations Concerning Chemical Hygiene in Laboratory, for ventilation system characteristics and practices to minimize exposures to workers in the area. As noted in these non-mandatory recommendations, which are based on the National Research Council's 2011 edition of "Prudent Practices in the Laboratory: Handling and Management of Chemical Hazards," recommended practices for laboratory chemical hoods include, but are not limited to, regularly inspecting and maintaining the ventilation system, ensuring a negative pressure differential between the amount of air exhausted from the laboratory and the amount supplied to the laboratory to prevent uncontrolled chemical vapors from leaving the laboratory, and preventing laboratory air from recirculating back into the laboratory (Ref. 47). EPA requests comment on whether it should incorporate in the rule best practices to ensure proper and adequate performance of laboratory fume hoods, such as those identified in OSHA's 29 CFR 1910.1450, Appendix A National Research Council Recommendations Concerning Chemical Hygiene in Laboratory.

To support and demonstrate compliance, EPA is proposing that each owner or operator of a laboratory workplace subject to the requirements of this unit retain compliance records for five years. EPA is proposing to require records to include: (A) PPE program implementation and documentation as outlined in this unit; and (B) Implementation of a properly functioning fume hood using manufacturer's instructions for installation, use, and maintenance of the fume hood, including inspections, tests, development of maintenance procedures, the establishment of criteria for acceptable test results, and documentation of test and inspection results. Every five years, the owner or operator would be required to update these records.

EPA is proposing to require that each owner or operator of a workplace engaged in the industrial and commercial use of PCE as a laboratory chemical ensure fume hoods are in use and

functioning properly and dermal PPE is provided to all potentially exposed persons to direct dermal contact with PCE according to the process outlined in this unit within 12 months after publication of the final rule. EPA requests comment relative to the ability of owners or operators to implement laboratory chemical fume hood and dermal PPE related requirements within 12 months of publication of the final rule, and anticipated timelines for any procedural adjustments needed to comply with the requirements outlined in this unit. EPA may finalize significantly shorter or longer compliance timeframes based on consideration of public comments.

4. *Other requirements.*

a. *Recordkeeping.*

In addition to the recordkeeping requirements for the WCPP and prescriptive controls outlined in this unit, for conditions of use that are not otherwise prohibited under this proposed regulation, EPA is also proposing that manufacturers, processors, distributors, and commercial users maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with the prohibitions, restrictions, and other provisions of this proposed regulation; and to maintain such records for a period of 5 years from the date the record is generated. EPA is proposing that this requirement begin at the effective date of the rule (60 days following publication of the final rule in the *Federal Register*). Recordkeeping requirements would ensure that owners or operators can demonstrate compliance with the regulations if necessary. EPA may require more, less, or different documentation in the final rule based on consideration of public comments.

b. *Downstream notification.*

For conditions of use that are not otherwise prohibited under this proposed regulation, EPA is proposing that manufacturers (including importers), processors, and distributors, excluding retailers, of PCE and PCE-containing products provide downstream notification of the

prohibitions through the Safety Data Sheets (SDS) required by OSHA under 29 CFR 1910.1200(g) by adding to sections 1(c) and 15 of the SDS the following language:

> After [DATE 18 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] this chemical/product cannot be distributed in commerce to retailers for any use. After [DATE 21 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], this chemical/product is and can only be distributed in commerce or processed for the following purposes: Processing as a reactant/intermediate; Processing into formulation, mixture or reaction product in cleaning and vapor degreasing products; Processing into formulation, mixture or reaction product in paint and coating products; Processing into formulation, mixture or reaction product in adhesive and sealant products; Processing by repackaging; Recycling; Industrial and commercial use as solvent in vapor degreasing; Industrial and commercial use in maskant for chemical milling; Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing; Industrial and commercial use in laboratory chemicals; Industrial and commercial use in solvent-based adhesives and sealants; Industrial and commercial use in dry cleaning in 3rd generation machines until [DATE 3 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*]; Industrial and commercial use in dry cleaning and related spot cleaning until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*]; and Disposal.

The intention of downstream notification is to spread awareness throughout the supply chain of the restrictions on PCE under TSCA as well as provide information to commercial end users about allowable uses of PCE.

To provide adequate time to update the SDS and ensure that all products in the supply chain include the revised SDS, EPA is proposing a 2-month period for manufacturers and a 6-month period for processors and distributers to implement the proposed SDS changes following publication of the final rule.

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

5. TSCA section 6(g) exemptions.

Under TSCA section 6(g)(1), EPA may grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture if EPA

makes one of three findings required by the statute. TSCA section 6(g)(1)(A) permits such an exemption if EPA finds that the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure. TSCA section 6(g)(1)(B) permits such an exemption if EPA finds that compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure. Finally, TSCA section 6(g)(1)(C) allows for an exemption if EPA finds that the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

TSCA section 6(g)(2) requires EPA to analyze the need for the exemption, and to make public the analysis and a statement on how the analysis was taken into account when proposing an exemption under TSCA section 6(g). Based on discussions with and information provided by the National Aeronautics and Space Administration (NASA), EPA has analyzed the need for an exemption for certain uses of PCE in an emergency in the furtherance of NASA's mission and is proposing to grant it. This unit presents the results of that analysis.

Pursuant to TSCA section 6(g)(3), if an exemption is finalized, EPA may by rule later extend, modify, or eliminate the exemption, on the basis of reasonably available information and after adequate public justification, if EPA determines the exemption warrants a change. EPA will initiate this rulemaking process at the request of any regulated entity benefiting from such an exemption. The Agency is open to engagement throughout the duration of any 6(g) exemption, and emphasizes that to ensure continuity in the event of an extension or modification, such a request should come at least 2 years prior to the expiration of an exemption.

a. *Analysis of the need for TSCA section 6(g)(1)(A) exemption for certain NASA uses in an emergency for which no technically or economically feasible safer alternative is available.*

EPA considered a TSCA section 6(g) exemption for emergency use of PCE in the furtherance of NASA's mission. For certain specific conditions of use, EPA proposes that use of PCE by NASA and its contractors in an emergency be exempt from the requirements of this rule because it is a critical or essential use provided that (1) there is an emergency; and (2) NASA selected PCE because there are no technically and economically feasible safer alternatives available during the emergency.

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

An emergency is a serious and sudden situation requiring immediate action to remedy harm or avert danger to human health, the environment, or to avoid imperiling NASA space missions. In NASA's case, there may be instances where the emergency use of PCE for specific conditions of use is critical or essential to remedying harm or averting danger to human health, the environment, or avoiding imperiling NASA space missions. Because of the immediate and unpredictable nature of emergencies described in this unit and of the less forgiving environments NASA operates in that offer little to no margin for error, it is likely that, at the time of finalization of this proposal, alternatives to emergency PCE use may not be available in a timely

manner to avoid or reduce harm or immediate danger (Ref. 48). In this way, these emergencies for particular conditions of use meet the criteria for an exemption under TSCA section 6(g)(1)(A), because the emergency use of PCE for listed conditions of use is critical or essential and no technically and economically feasible safer alternative will be available in a timely manner, taking into consideration hazard and exposure.

In support of the TSCA section 6(g)(1)(A) emergency use exemption, NASA submitted detailed criteria which they must use to screen, qualify, and implement materials to be used in spacecraft equipment, as well as historical case studies that outline the loss of life and loss of assets in the discharge of previous missions. In one of several examples detailed, the Apollo I command module fire that claimed the lives of three American astronauts demonstrated the need for careful testing and continuity of materials (Ref. 48). Moreover, due to NASA's rigorous safety testing requirements under various environmental conditions, technically and economically feasible safer alternatives may not be readily available during emergencies and may require certain conditions of use of PCE to alleviate the emergency.

In another example, NASA identified a scenario concerning a mission to the International Space Station (ISS) whereby, during a launch evolution, the countdown was paused immediately prior to launch (T-2 minutes). NASA engineers identified a clogged filter and supply line as the primary issue, which required immediate attention (i.e., line flushing and filter cleaning). In this type of emergency scenario, an already approved chemical substance rated for space system applications is necessary to immediately remedy the situation. Although PCE was not used in this particular incident, if it were needed, in the future to address such an emergency, then the proposed exemption would allow for its lawful use—the countdown would resume and the launch would occur. Conversely, without an exemption under the specific condition of use (e.g., industrial and commercial use in wipe cleaning), NASA's use of PCE would be otherwise

prohibited, which would put NASA in an untenable position of having to choose to either violate the law or place the mission (and potentially the health and safety of its employees involved in the mission) at risk.

The identification and qualification of compatible materials in the context of aviation is iterative and involves expansive collaboration between original equipment manufacturers, federal agencies, and qualifying institutions. This is equally, if not more so, the case in the context of human space flight operations undertaken by NASA (Ref. 48). NASA's mission architecture requirements often are developed many years in advance of an actual launch occurring. As part of mission planning, space systems are designed, full scale mock-ups are built, and mission critical hardware is constructed using materials qualified for spaceflight. Once NASA's mission architecture requirements are developed, NASA may need to retain emergency access to PCE because its alternatives may not have yet gone through NASA's rigorous certification process before their use. Allowing NASA to retain emergency use of PCE would reduce the chances that this rule will hinder future space missions for which mission architecture infrastructure is being developed or is already built. While NASA considers alternatives to the chemical substances it currently uses in its space system designs, NASA has not yet identified technically and economically feasible alternatives to proven chemistries in many current applications. While EPA acknowledges that the use of PCE in emergency situations may be necessary in the near term, it is also EPA's understanding that NASA will continue its work to identify and qualify alternatives to PCE. Thus, EPA is proposing an exemption duration of 10 years.

b. *Proposed exemption for certain emergency uses of PCE in the context of human space flight.*

For the reasons discussed in this Unit, EPA is proposing a 10-year exemption for

emergency use of PCE in furtherance of NASA's mission for the following specific conditions of use: Industrial and commercial use as solvent for cold cleaning; Industrial and commercial use in wipe cleaning. EPA is also proposing to include additional requirements as part of the exemption, pursuant to TSCA section 6(g)(4), including required notification and controls for exposure, to the extent feasible: 1) NASA and its contractors must provide notice to the EPA Administrator of each instance of emergency use within 15 days and; 2) NASA and its contractors would have to comply with the WCPP described in Unit IV.A.2 to the extent feasible.

EPA is proposing to require that NASA notify EPA within 15 days of the emergency use. The notification would include a description of the specific use of PCE in the context of one of the conditions of use for which this exemption is being proposed, an explanation of why the use described qualifies as an emergency, and an explanation with regard to the lack of availability of technically and economically feasible alternatives.

EPA expects NASA and its contractors have the ability to implement a WCPP as described in Unit IV.A.2. for the identified uses in the context of an emergency, to some extent even if not to the full extent of WCPP implementation. Therefore, EPA is proposing to require that during emergency use, NASA must comply with the WCPP to the extent technically feasible in light of the particular emergency. Under the proposed exemption, NASA and its contractors would still be subject to the proposed general recordkeeping requirements discussed in Unit IV.A.4.

EPA requests comment on this TSCA section 6(g) exemption for continued emergency use of PCE in the furtherance of NASA's mission as described in this unit, and whether any additional conditions of use should be included, in particular for any uses qualified for space flight for which no technically and economically feasible safer alternative is available.

Additionally, EPA requests comment on what would constitute sufficient justification of an emergency.

B. Alternative regulatory actions.

As indicated by TSCA section 6(c)(2)(A)(iv)(II) through (III), EPA must consider and publish a statement based on reasonably available information with respect to the reasonably ascertainable economic consequences of the rule, including consideration of the costs and benefits and the cost effectiveness of the proposed regulatory action and one or more primary alternative regulatory actions considered by the Agency. This unit includes a description of the primary alternative regulatory action and the second alternative regulatory action considered by the Agency. An overview of the proposed regulatory action and two alternative regulatory actions for each condition of use is in Unit IV.C.

1. *Primary alternative regulatory action considered.*

The primary alternative regulatory action described in this notice and considered by EPA combines prohibitions, requirements for a WCPP, and prescriptive controls to address the unreasonable risk from PCE driven by the various conditions of use. While in some ways it is similar to the proposed regulatory action, the primary alternative regulatory action described in this notice differs from the proposed regulatory action by providing for a WCPP, including requirements to meet an ECEL or DDCC, for some conditions of use that would be prohibited under the proposed regulatory action. The primary alternative regulatory action also considers prescriptive workplace controls where existing engineering controls, administrative controls, and PPE may already address the unreasonable risk for some conditions of use that would be subject to a WCPP under the proposed regulatory action. The primary alternative regulatory action additionally includes longer compliance timeframes for prohibitions and implementation of WCPP and prescriptive controls, as described in this unit. EPA requests comment on this

primary alternative regulatory action and whether any elements of this primary alternative regulatory action described in this unit should be considered as EPA develops the final regulatory action. EPA is requesting comment on whether to consider a regulatory alternative that would subject more conditions of use to a WCPP, instead of prohibition, than those currently contemplated in the primary alternative regulatory action. EPA also requests monitoring data and detailed descriptions of PCE involving activities for these conditions of use to determine whether these additional conditions of use could comply with the WCPP such that risks are no longer unreasonable. EPA also requests comment on any advantages or drawbacks for the timelines outlined in this unit compared to the timelines identified for the proposed regulatory action in Unit IV.A.

a. *Prohibitions.*

The primary alternative regulatory action considered by EPA would prohibit the manufacturing, processing, distribution in commerce, and use for the following industrial and commercial uses, which EPA is also proposing to prohibit as part of the proposed regulatory action: industrial and commercial use as solvent for cold cleaning; industrial and commercial use in other textile processing; industrial and commercial use in wood furniture manufacturing; industrial and commercial use as a solvent for aerosol lubricants; industrial and commercial use in wipe cleaning; industrial and commercial use in other spot cleaning and spot removers, including carpet cleaning; industrial and commercial use in automotive care products (e.g., engine degreaser and brake cleaner); industrial and commercial use in non-aerosol cleaner; industrial and commercial use in metal (e.g., stainless steel) and stone polishes; industrial and commercial use in foundry applications; industrial and commercial use as a solvent for penetrating lubricants and cutting tool coolants; industrial and commercial use in welding; industrial and commercial use for mold release; commercial use for photographic film;

commercial use in inks and ink removal products (based on printing); commercial use in inks and ink removal products (based on photocopying); and commercial use in metal mold cleaning, release and protectant products. Additionally, the primary alternative regulatory action would prohibit the manufacture, processing, and distribution of PCE for consumer use. As shown in Unit IV.C., which presents an overview of the proposed regulatory action and two alternative regulatory actions for each condition of use, the primary alternative action described in this notice would prohibit fewer occupational conditions of use than the proposed regulatory action.

Regarding compliance timeframes, the primary alternative regulatory action would include longer timeframes for implementation of the prohibitions than the proposed regulatory action. Under the primary alternative action, the prohibitions would generally take effect 6 months later than in the proposed regulatory action. Under a compliance timeframe that is 6 months longer than the proposed regulatory action, the prohibitions for the manufacturing, processing, distribution in commerce, and use of PCE for certain occupational conditions of use described in this unit would take effect 18 months for manufacturers, 21 months for processers, 24 months for distributing to retailers, 27 months for all other distributors (including retailers), and 30 months for industrial and commercial uses after the publication date of the final rule. With regard to the compliance timeframe for the manufacturing, processing, and distribution in commerce for consumer use (other than consumer use of clothing and articles that have been commercially dry cleaned with PCE), under the primary alternative regulatory action, prohibitions described in this unit would take effect in 18 months for manufacturers, 21 months for processors, 24 months for distributing to retailers, and 27 months for all other distributors (including retailers) after the publication date of the final rule.

Like the proposed action, the primary alternative regulatory action would also phaseout the manufacturing, processing, distribution in commerce, and commercial use of PCE for dry

cleaning and spot cleaning, including in 3rd generation (dry-to-dry machines with refrigerated condenser) and 4th/5th generation (dry-to-dry machines with refrigerated condenser and carbon adsorber process controls) machines. However, the timeframes for the phaseout differ between the proposed action and the primary alternative action, described later in this unit. As described in Unit IV.A.3., a prohibition on these conditions of use would address the unreasonable risk driven by the following uses: industrial and commercial use in dry cleaning and spot cleaning post-2006 dry cleaning; industrial and commercial use in dry cleaning and spot cleaning 4th/5th generation only dry cleaning; and consumer use in dry cleaning solvent.

With regards to the prohibition of dry cleaning conditions of use, under the primary alternative regulatory action, the following phaseout timeline would take effect after the publication date of the final rule: prohibition on the use of PCE in dry cleaning machines acquired 12 months after the publication date of the final rule; a prohibition on the use of PCE in 3rd generation machines 5 years after the publication date of the final rule; a prohibition on the use of PCE in dry cleaning and spot cleaning 15 years after the publication date of the final rule; and a prohibition on the manufacturing, processing, and distribution in commerce of PCE for use in dry cleaning solvent 15 years after the publication date of the final rule.

b. *Workplace Chemical Protection Program (WCPP).*

The primary alternative regulatory action described in this notice would require a WCPP, including requirements to meet an ECEL and DDCC, for the following conditions of use: industrial and commercial use in laboratory chemicals; processing into formulation, mixture, or reaction product in other chemical products and preparations; industrial and commercial use as a processing aid in pesticide, fertilizer and other agricultural chemical manufacturing; industrial and commercial use in specialty DOD uses (oil analysis and water pipe repair); industrial and commercial use in solvent-based paints and coatings; and industrial and commercial use as

solvent for aerosol spray degreaser/cleaner. As described in Unit V.A., uncertainties regarding (i) the feasibility of implementing workplace safety control measures in open-systems or when worker activities require manual application or removal of PCE or PCE-containing products, (ii) availability of alternatives, or (iii) whether the use is ongoing or phased out led EPA to propose that most of these conditions of use be prohibited. EPA does not have sufficient information to confidently conclude that these conditions of use can meet requirements of a WCPP for PCE. Therefore, EPA requests comment on the ways in which PCE may be used in these conditions of use, including whether activities may take place in a closed system and the degree to which users of PCE in these sectors could successfully implement an ECEL, DDCC, and ancillary requirements described in Unit IV.A. For the industrial and commercial use in laboratory chemicals, EPA is soliciting comment on non-prescriptive requirements of an ECEL and DDCC as compared to the prescriptive workplace controls of fume hood and dermal PPE EPA is proposing in Unit IV.A.3.

As with the compliance timeframes considered as part of the primary alternative action for prohibition, the primary alternative regulatory action also includes longer compliance timeframes for implementation of a PCE WCPP. Under the primary alternative action, the requirements for the WCPP would take effect 6 months later than in the proposed regulatory action. Under a compliance timeframe that is 6 months longer than the proposed regulatory action, the requirements for owners and operators to conduct initial baseline monitoring would take effect 12 months after the date of publication of the final rule in the *Federal Register*. The requirements for each owner or operator to provide respiratory protection to all potentially exposed persons in the regulated area would be within 3 months after receipt of the results of any exposure monitoring or within 15 months after date of publication of the final rule in the *Federal Register*. Regulated entities would be required to implement an exposure control plan within 18

months after date of publication of the final rule in the *Federal Register*. EPA requests comment on any advantages or drawbacks for the timelines outlined in this unit compared to the timelines identified for the proposed regulatory action in Unit IV.A.

c. *Prescriptive controls.*

The primary alternative regulatory action described in this notice would require prescriptive workplace PPE controls for the following conditions of use (which are all conditions of use for which EPA is proposing WCPP as part of the proposed regulatory action): manufacturing (domestic manufacturing); manufacturing (import); processing as a reactant/intermediate; processing into formulation, mixture or reaction product in cleaning and degreasing products; processing into formulation, mixture or reaction products in paint and coating products; processing into formulation, mixture, or reaction product in adhesive and sealant products; processing by repackaging; recycling; industrial and commercial use as a solvent for open-top batch vapor degreaser; industrial and commercial use as solvent for closed-loop batch vapor degreasing; industrial and commercial use as solvent for in-line conveyorized vapor degreasing; industrial and commercial use as solvent for in-line web cleaner vapor degreaser; industrial and commercial use in maskant for chemical milling; and industrial and commercial use as processing aid in catalyst regeneration in petrochemical manufacturing; and disposal. Additionally, the primary alternative regulatory action described in this notice would require a concentration limit for the industrial and commercial use in solvent-based adhesives and sealants.

i. *Prescriptive controls – PPE.* In the 2020 Risk Evaluation for PCE, EPA identified gloves that would reduce dermal exposures to PCE. Under the primary alternative regulatory action, EPA considered requiring dermal PPE as described in Unit IV.A.2.c. This approach differs from the proposed regulatory action because it does not require the use of elimination,

substitution, engineering controls and administrative controls or work practices, in accordance with the hierarchy of controls, to the extent feasible as a means of controlling dermal exposures to comply with the DDCC. Rather, this approach would require dermal PPE and training to prevent direct dermal contact with PCE as described in Unit IV.A.2.c.iv. EPA is soliciting comment on prescribing specific dermal PPE, such as gloves, for each condition of use that should be considered as EPA develops the final regulatory action.

For inhalation exposures in the 2020 Risk Evaluation for PCE, EPA identified APFs for respirators that would mitigate the unreasonable risk for the conditions of use. However, as described in Unit V.A., EPA has uncertainty that the respirator APF identified in the 2020 Risk Evaluation for PCE for each condition of use is appropriate for the wide variety of workplaces that may be engaged in each condition of use, as each workplace has unique characteristics that impact PCE air concentration levels. For example, EPA expects that some users may already have existing controls in place that reduce PCE air concentration levels below the ECEL (Refs. 49, 50), whereas other users of the same condition of use have different workplace controls that result in air concentration levels above the ECEL. Under the primary alternative regulatory action, EPA considered setting minimum respiratory PPE requirements based on an entity's measured air concentration and the level of PPE needed to reduce exposures to the ECEL, as described in Units IV.A.2.d.i. This approach differs from the proposed regulatory action because it does not require the use of elimination, substitution, engineering controls and administrative controls or work practices, in accordance with the hierarchy of controls, to the extent feasible as a means of controlling inhalation exposures to comply with the ECEL. Rather, this approach would require respirators where inhalation exposures exceed the ECEL based on exposure monitoring. In addition to minimum respiratory PPE requirements, the primary alternative regulatory action would require initial monitoring within 12 months after publication of the final

rule and periodic monitoring once every five years to determine the respiratory protection needed as described in Unit IV.A.2. as well as establishment of a regulated area as described in Unit IV.A.2., establishment of PPE program as described in Unit IV.A.2. and notification of monitoring results as described in Unit IV.A.2., with modifications to not require implementation of all feasible exposure controls according to the hierarchy of controls. EPA is soliciting comment on prescribing specific respirators or APFs for respirators for each condition of use that should be considered as EPA develops the final regulatory action.

EPA understands that many workplaces already have engineering controls or administrative controls in place that reduce exposures to PCE, in particular highly standardized and industrialized workplaces or where PCE is used in a closed system. However, EPA does not have reasonably available information on engineering controls and administrative controls that would mitigate unreasonable risk across a wide variety of workplaces for most occupational conditions of use. EPA is requesting comment on specific controls that mitigate the unreasonable risk from PCE and that could be included as part of a prescriptive workplace controls requirement, which could be considered as EPA develops the final regulatory action. Specifically, EPA is soliciting comment on combinations of specific engineering controls, administrative controls, and PPE that would reduce inhalation exposures to at or below the ECEL of 0.14 ppm as an 8-hour TWA or prevent direct dermal contact with PCE for all workplaces where such controls would be required. Examples of controls and workplace practices include a vapor recovery system (e.g., carbon adsorption system or condenser), enclosed transfer liquid lines (with purging mechanisms in place (e.g., nitrogen, aqueous), equipment such as portable scrubber units to minimize vapor, ventilation units that mitigate vapor escape, and limiting frequency and duration of exposure to PCE. For vapor degreasing, EPA understands that the European Union and Germany have established requirements for

reducing emissions of volatile organic compounds, such as the Solvent Emissions Directive and the German 2 BlmSchV standard for use of chlorinated hydrocarbons in surface cleaning. EPA is soliciting comment on the extent to which such requirements could reduce inhalation exposures to at or below the ECEL of 0.14 ppm as an 8-hour TWA.

As with the compliance timeframes considered as part of the primary alternative action for prohibition and WCPP, the primary alternative regulatory action includes longer compliance timeframes for implementation of prescriptive PPE controls. Under the primary alternative action, the requirements for prescriptive controls would take effect 6 months later than in the proposed regulatory action. Under a compliance timeframe that is 6 months longer than the proposed regulatory action, the requirements for owners and operators to provide dermal PPE and training would take effect 18 months after the publication date of the final rule. For respirator selection and demarcating a regulated area, the requirements for owners and operators to conduct initial baseline monitoring would take effect 12 months after the date of publication of the final rule and requirements to provide a respirator and demarcate a regulated area would take effect 18 months after the publication date of the final rule. EPA is requesting comment on the compliance timeframe needed to implement engineering controls, administrative controls, and PPE that reduce inhalation exposures to at or below the ECEL of 0.14 ppm as an 8-hour TWA or prevent direct dermal contact with PCE for all regulated entities.

ii. *Prescriptive controls – concentration limit.* To reduce exposures in the workplace and address the unreasonable risk of injury to health from PCE for the industrial and commercial use in solvent-based adhesives and sealants, EPA considered setting a concentration limit of PCE in adhesive and sealant products. The primary alternative regulatory action described in this notice would limit the concentration of PCE in adhesive and sealant products to 1% by weight. Any percentage of PCE greater than 1% by weight would be prohibited for the industrial and

commercial use of solvent-based adhesive and sealants products. Additionally, the primary alternative regulatory action would prohibit the import, processing, and distribution in commerce of adhesive and sealant products containing PCE at concentrations greater than 1% by weight. EPA has uncertainty that a concentration limit would reduce inhalation exposures such that PCE no longer presents an unreasonable risk, and therefore did not propose a concentration limit as the preferred option, as described in this Unit.

In the 2020 Risk Evaluation for PCE, EPA identified adhesive and sealant products containing PCE at concentrations ranging from as low as 0.1% PCE by weight to as high as 100% PCE by weight, including several industrial adhesive products with concentrations of PCE below 1% by weight. In considering a concentration limit as a regulatory action to address the unreasonable risk from inhalation and dermal exposures for the industrial and commercial use of solvent-based adhesives and sealants, EPA reviewed the dermal exposure modeling in the 2020 Risk Evaluation for PCE and conducted additional analysis of inhalation exposure data for adhesive products containing PCE below 1% PCE by weight (Ref. 51). Based on the dermal exposure modeling in the 2020 Risk Evaluation for PCE, EPA determined that limiting the concentration of PCE in adhesive and sealant products to 1% would address the unreasonable risk resulting from dermal exposures (Ref. 52). In additional analysis of inhalation exposure data for adhesives in support of risk management, EPA estimated inhalation exposures to PCE from adhesives containing PCE at concentrations ranging from 0.1% to 0.9% using four different approaches. In the analysis, inhalation exposure estimates for central tendency in all four approaches resulted in exposures below the ECEL. However, high-end exposure estimates varied across the four approaches, with two approaches resulting in high-end exposure estimates below the ECEL and two approaches resulting in high-end exposure estimates above the ECEL.

The inhalation exposure estimates provided in the additional inhalation analysis are a

result of several key assumptions and uncertainties, as described in the memo (Ref. 51). EPA therefore has uncertainties regarding whether a concentration limit of 1% PCE in adhesives and sealants would address the unreasonable risk resulting from inhalation exposures in occupational settings. Therefore, EPA is requesting comment on a combination of the 1% concentration limit for adhesives and sealants with specific engineering controls, administrative controls, or respiratory protection that would reduce inhalation exposures to PCE at or below the ECEL of 0.14 ppm as an 8-hour TWA. Additionally, EPA is requesting comment on a combination of a concentration limit with WCPP requirements as described in Unit IV.A.2. EPA also requests monitoring data, formulations used, and detailed descriptions of PCE involving activities for the industrial and commercial use in solvent-based adhesives and sealants to determine whether a concentration limit would reduce inhalation exposures such that risks are no longer unreasonable.

As part of the primary alternative regulatory action, the concentration limit of 1% by weight of PCE for adhesive and sealant products would only be for products intended for industrial and commercial use. As described in Unit IV.B.1.a., the primary alternative regulatory action would prohibit the manufacture, processing, and distribution of PCE for consumer use, including consumer use in adhesives for arts and crafts (including industrial adhesive, arts and crafts adhesive, gun ammunition sealant, livestock grooming adhesive, column adhesive, caulk and sealant). EPA examined the Consumer Exposure Model for the 2020 Risk Evaluation for PCE and found that, when adjusting parameters for product mass and duration of use to the highest values based on consumer product data in the 2020 Risk Evaluation for PCE for consumer adhesive conditions of use, limiting the concentration of PCE to 1% by weight in consumer use of products would not eliminate the unreasonable risk from PCE resulting from inhalation and dermal exposures (Ref. 53).

Regarding compliance timeframes under the primary alternative action, the prohibitions for the import, processing, distribution in commerce, and use of adhesive and sealant products containing PCE at concentrations greater than 1% by weight described in this unit would take effect 18 months for importers, 21 months for processers, 24 months for distributing to retailers, 27 months for all other distributors (including retailers), and 30 months for industrial and commercial uses after the publication date of the final rule.

2. *Second alternative regulatory action considered.*

The second alternative regulatory action, as with the proposed regulatory action and the primary alternative regulatory action, is a combination of prohibition and a WCPP to address the unreasonable risk from PCE driven by the various conditions of use. While in most ways it is similar to the proposed regulatory action, the second alternative regulatory action differs from the proposed regulatory action by prohibiting some conditions of use that would have requirements for a WCPP under the proposed regulatory action. Additionally, the second alternative regulatory action proposes a TSCA section 6(g) time-limited exemption from prohibition for the industrial and commercial use of PCE as maskant for chemical milling and the industrial and commercial use of PCE for vapor degreasing. The second alternative regulatory action also includes shorter compliance timeframes for prohibitions and a WCPP, as described in this unit. EPA requests comment on this second alternative regulatory action and whether any elements of this second alternative regulatory action described in this unit should be considered as EPA develops the final regulatory action. EPA also requests comment on any advantages or drawbacks for the timelines outlined in this unit compared to the timelines identified for the proposed regulatory action in Unit IV.A.

a. *Prohibitions.*

The second alternative action would prohibit more occupational conditions of use than

the proposed regulatory action. In addition to the conditions of use that EPA is proposing to prohibit in the proposed regulatory action, the second alternative regulatory action described in this action would also prohibit the following conditions of use: processing into formulation, mixture or reaction product in paint and coating products; processing into formulation, mixture, or reaction product in cleaning and degreasing products; processing into formulation, mixture or reaction product in adhesive and sealant products; industrial and commercial use as solvent for open-top batch vapor degreasing; industrial and commercial use as solvent for closed-loop batch vapor degreasing; industrial and commercial use as solvent for in-line conveyorized vapor degreasing; industrial and commercial use as solvent for in-line web cleaner vapor degreasing; industrial and commercial use in solvent-based adhesives and sealants; and industrial and commercial use in maskants for chemical milling. Additionally, the second alternative regulatory action would prohibit the manufacture, processing, and distribution of PCE for consumer use.

Like the proposed action, the second alternative regulatory action would also prohibit the manufacturing, processing, distribution in commerce, and commercial use of PCE for dry cleaning and spot cleaning, including in 3rd generation (dry-to-dry machines with refrigerated condenser) and 4th/5th generation (dry-to-dry machines with refrigerated condenser and carbon adsorber process controls) machines. However, the timeframes for the phaseout differ between the proposed action and the second alternative action, described later in this unit. As described in Unit IV.A.3., a prohibition on these conditions of use would address the unreasonable risk driven by the following uses: industrial and commercial use in dry cleaning and spot cleaning post-2006 dry cleaning; industrial and commercial use in dry cleaning and spot cleaning 4th/5th generation only dry cleaning; and consumer use in dry cleaning solvent.

Regarding compliance timeframes, the second alternative regulatory action would include more stringent timeframes for implementation of prohibition than the proposed regulatory action.

Additionally, EPA would not stagger the compliance dates for manufacturers, processors, and distributors. The prohibitions for the manufacturing, processing, distribution in commerce, and use for certain industrial and commercial uses described in this unit would take effect 12 months after the publication date of the final rule. With regard to the compliance timeframe for the manufacturing, processing, and distribution in commerce for consumer use, under the second alternative regulatory action, prohibitions described in this unit would take effect 12 months after the publication date of the final rule. With regard to prohibition of dry cleaning conditions of use, under the second alternative regulatory action, the following would occur: prohibition on the use of PCE in dry cleaning machines acquired after the effective date of the final rule; a prohibition on the use of PCE in 3rd generation machines 6 months after the publication date of the final rule; a prohibition on the use of PCE in dry cleaning and spot cleaning 5 years after the publication date of the final rule; and a prohibition on the manufacturing, processing, and distribution in commerce of PCE for use in dry cleaning solvent 5 years after the publication date of the final rule.

b. *TSCA section 6(g) exemptions.*

Under TSCA section 6(g)(1), EPA may grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture if EPA makes one of three findings required by the statute, as outlined in Unit IV.A.5. TSCA section 6(g)(2) requires EPA to analyze the need for the exemption, and to make public the analysis and a statement on how the analysis was taken into account when proposing an exemption under TSCA section 6(g). Based on discussions with and information provided by industry stakeholders, consultation with the DOD and NASA, and Panel recommendations in the SBAR Panel Report (Ref. 33), EPA has analyzed the need for three different exemptions and would grant two if the second alternative regulatory action described in this notice is adopted in the

final rule. This unit presents the results of that analysis.

i. *Analysis of the need for a TSCA section 6(g)(1)(B) exemption for industrial and commercial use of PCE in maskant for chemical milling essential for national security and critical infrastructure.* EPA has conducted an analysis of the application of this rulemaking to the industrial and commercial use of PCE in maskant for chemical milling and found that a TSCA section 6(g) exemption may be warranted if the second alternative regulatory action considered by EPA is adopted, in its entirety or in relevant part, in the final rule. Based on discussions with and information provided by industry stakeholders, EPA understands that PCE-based maskant is used in commercial and defense aerospace programs that are essential for national security and critical infrastructure (Refs. 54, 55). For example, one facility that comprises 85% of the U.S. market for PCE-based maskant chemical milling uses PCE in the Boeing fuselage manufacturing program for the 737, 747, 767, and 777 and also in defense products for the Bell V-280 Valor, Boeing P-8, Sikorsky CH-53K, Boeing KC-46, and Northrop Grumman B-21. Based on information submitted by industry, the purpose of maskant in chemical milling is to remove excess weight of aluminum not required for structural integrity in commercial and defense products. This process is performed on aluminum aircraft "skins," which are large metal sheets or panels. PCE is used at the beginning of the chemical milling process as a temporary diluent for maskant applied to aircraft skins to prevent chemical milling of certain areas. After application, the maskant cover is scribed in specific locations and dry maskant is pulled or removed, exposing aluminum metal, while the PCE evaporates and is captured into a recovery system. Information submitted by stakeholders notes that PCE does not remain on the airplane skins when the skins are etched nor at any other point after the chemical milling stage of fabrication.

According to information submitted by industry, PCE-based maskant is required to meet

certain performance requirements that other alternatives are unable to meet. For example, PCE-based maskant meets several Boeing Aircraft process specifications such as "Chemical Milling Aluminum Alloys" (BAC 5772), "Maskant Trimming of Fatigue Critical Hardware" (BAC 5986), "Phosphoric Acid Anodizing of Aluminum for Structural Bonding" (BAC 5555), and "Appearance Control of Clad Aluminum Exterior Skins" (Boeing D6-9002). These process specifications are mandatory for suppliers as part of the quality system that aircraft production certificate holders are required to establish under 14 CFR 21.137. Additionally, PCE-based maskant also meets other industry performance requirements such as Stretch Forming, Laser Scribe Compatible, and General Parts Protection.

Representatives from the facility that comprises 85% of the U.S. market for PCE-based maskant chemical milling have described to EPA how efforts to develop new maskant have been ongoing for over 30 years but have not yet found a substitute that meets all of the necessary performance requirements (Ref. 54). PCE-based maskant also allows for solvent capture and recycling. The same company has recaptured and recycled more than 95% of the PCE used for more than 29 years, the remaining PCE being captured using special filters, mats, and non-recoverable mediums that are disposed of by a company that specializes in providing environmental services for controlled chemicals (Ref. 55).

As discussed in this unit and in the Alternatives Assessment (Ref. 56), substitute chemicals for maskant for chemical milling may not meet the performance requirements of maskant needed for chemical milling of aluminum aircraft skins for commercial and defense purposes and thus may not be technically feasible as alternatives. Therefore, EPA has preliminarily determined that if PCE-based maskant were not available, or if industry cannot meet the requirements of the WCPP in the proposed regulatory action or of the prescriptive controls considered as the primary alternative regulatory action, there would be a significant

disruption to national security and critical infrastructure. In addition, due to availability concerns, EPA has preliminarily determined that a ban on the manufacture, processing, and distribution in commerce of PCE-based maskant could also significantly disrupt national security and critical infrastructure. A prohibition on the use of PCE for chemical milling of aluminum aircraft skins could affect the ability to make available new military aircraft on schedule, and consequently, potentially affect DOD's capability and readiness. Such a prohibition would also affect the availability of new civilian aircraft and thus have negative impacts on civilian aviation. Aviation has been designated by the Department of Homeland Security as a key subsector in the Transportation Systems Sector, one of 16 designated critical infrastructure sectors.

Based on the expected significant disruption to national security and critical infrastructure, a TSCA section 6(g) exemption may be warranted if the proposed and primary alternative regulatory actions are not suitable to address the unreasonable risk driven by this condition of use. Therefore, as part of the second alternative regulatory action, EPA would grant a 10-year exemption from prohibition for the industrial and commercial use of PCE as maskant for chemical milling. EPA believes that the information provided by industry on the time needed to identify and qualify substitutes supports a 10-year exemption period. Further, the industry submitter has provided information demonstrating that engineering controls are already in place to lower, to the extent possible, exposure concentrations to PCE and to limit occupational exposures, including supplementing with PPE during tasks that may result in greater exposure. Based on the information submitted, EPA understands that existing controls ensure airborne concentrations of PCE are generally kept below 1 ppm as an 8-hour TWA (below the existing regulatory and voluntary occupational exposure limits described in Units II.C.4. and 5.). While EPA acknowledges that the airborne concentration may exceed the ECEL, the exemption as part of the second alternative regulatory action would include the following provisions to ensure that

exposures are reduced to the lowest levels achievable:: the proposed general recordkeeping requirements discussed in Unit IV.A.4.i., documentation of the engineering controls and PPE used to reduce potentially exposed persons' exposure to the extent possible, and records that demonstrate compliance with the exemption conditions, including the condition that PCE only be used for chemical milling of aluminum aircraft skins.

EPA requests comments on all aspects of the section 6(g) exemption from the prohibition on industrial and commercial use of PCE in maskant for chemical milling as part of the second alternative regulatory option, including information on the extent to which this industry could meet the requirements of the proposed WCPP or prescriptive controls, whether compliance with specific elements of the proposed WCPP should also be required during the period of the exemption, and the time period of the exemption pursuant to TSCA section 6(g)(3).

ii. *Analysis of the need for a TSCA section 6(g)(1)(B) exemption for industrial and commercial use of PCE in vapor degreasing essential for national security and critical infrastructure.* EPA has conducted an analysis of the application of this rulemaking to the industrial and commercial use of PCE in vapor degreasing and found that a TSCA section 6(g) exemption may be warranted if the second alternative regulatory action considered by EPA is adopted, in its entirety or in relevant part, in the final rule. EPA received a request for a section 6(g) exemption from prohibition for the use of PCE in vapor degreasing of aerospace parts from a manufacturer of commercial jetliners and defense, space, and security systems (Refs. 57, 58). The aerospace parts have commercial, DOD, and NASA uses (Ref. 59); as the requester describes, they manufacture and procure these parts and have identified that PCE vapor degreasing is necessary due to technical challenges with other alternative substitute chemicals or methods.

The requester has spent many years developing, qualifying, and implementing alternative

materials and processes to replace PCE vapor degreasing with aqueous cleaning where technically viable. According to the requester, while the transition to aqueous cleaning has been successful for many detail parts, there are technical challenges with alternative substitute chemicals and processes for the vast majority of complex aerospace machining parts and actuation systems, such as structural components, gears, and other parts that make up drive units and control mechanisms. The requester states that PCE vapor degreasing is the best cleaning method to pre-clean most complex machining parts and actuation systems because it does not allow the transfer of contaminates from one part to another. The requester notes that, for those parts approved for aqueous cleaning, the parts so cleaned must be carefully segregated to avoid cross-contamination, which substantially increases the required processing time.

The requester notes that an adequate transition period for this technically challenging aerospace use requires substantial investment and time to develop viable alternatives. The requester is currently in the process of identifying a replacement solvent that can adequately clean, cause no harm to parts, and is not an equally toxic material to PCE. Based on the submitted request, conversion from vapor degreasing to aqueous cleaning is a capital-intensive investment that the requester expects would require several years to plan, permit, construct, and install. Additionally, the requester notes that the aerospace industry needs to ensure that aerospace parts meet DOD and other Federal Aviation Administration (FAA) specifications to ensure safety of flight. For example, in order to replace the chemical with an alternative, the requester notes that they must identify, test, and select an alternative that meets technical requirements derived from FAA mandated standards for a typical part used in a commercial aircraft, such as specifications for specific gravity (ASTM D 792), Water Absorption (ASTM D 750), and other test requirements, which may be a lengthy process (Ref. 60). According to the information submitted, certification with FAA could take at least nine months for individual

parts of components or up to several years for major subsystems or complete aircraft (Ref. 60). The requester also notes that while they do not know the extent that their supply chain has transitioned away from use of PCE in vapor degreasing, PCE has been used in vapor degreasing to meet required levels of cleanliness of certain supplied parts by long-standing design specifications that are incorporated into contracts of a complex supply chain. The requester also told EPA the suppliers are not required to inform the requester of the process they use to clean parts that the supplier provides to the requester, and the requester therefore may not know which solvent a supplier has selected for vapor degreasing or what factors were considered when selecting cleaning systems. According to the requester, material declarations and auditing processes to validate usage may be burdensome, considering that a large portion of the requester's supply chain includes small suppliers. Due to the concerns raised with transitioning to aqueous cleaning or another new cleaning method, the requester has requested that EPA exempt use of PCE in vapor degreasing of aerospace parts for 10 years.

As discussed in this unit, information submitted by the requester indicates that substitute chemicals for vapor degreasing of aerospace parts may not be technically feasible at this time for meeting the cleanliness standards of certain parts as required by DOD and FAA specifications or other specifications included in existing contracts within the supply chain. According to the requester, more time is needed for companies to make the capital-intensive transition from PCE vapor degreasing to aqueous cleaning for those parts that can be cleaned using the aqueous method. In addition, the requester states that they are continuing to work towards identifying a replacement solvent that is able to adequately clean complex machining parts and actuation systems parts without harming them, and that is not a regrettable substitution. Therefore, EPA has preliminarily determined that if the use of PCE for vapor degreasing were not available in the near term for aerospace parts, or if industry could not meet the requirements of the WCPP as

proposed or of the prescriptive controls considered as the primary alternative regulatory action, compliance with such requirements would significantly disrupt national security and critical infrastructure. In addition, due to availability concerns, EPA has preliminarily determined that a ban on the manufacture, processing, and distribution in commerce of PCE for vapor degreasing of aerospace parts could also significantly disrupt national security and critical infrastructure. A prohibition on the use of PCE for vapor degreasing of aerospace parts in the near term could negatively affect DOD's capability and readiness, which includes the ability to adequately maintain aircraft. Such a prohibition could also negatively affect the maintenance of civilian aircraft and potentially have impacts on the safety of civilian flight.

For the reasons discussed in this unit, EPA would grant a 10-year exemption from prohibition as part of the second alternative regulatory action for the industrial and commercial use of PCE in vapor degreasing for aerospace parts. EPA believes that the information provided by the requester on the time needed to identify and qualify substitutes supports a 10-year exemption period. Further, the requester has provided information demonstrating that engineering controls are in place to lower, to the extent possible, exposure concentrations and limit occupational exposures to PCE. The exemption would also include the following conditions: the proposed general recordkeeping requirements discussed in Unit IV.A.4.i., documentation of the engineering controls used to reduce potentially exposed persons' exposure, and records to demonstrate compliance with the exemption conditions, including the condition that PCE only be used in vapor degreasing for aerospace parts where other alternatives present technical feasibility or cleaning performance challenges to meet DOD and FAA specifications or other long-standing design specifications that are included in existing contracts.

EPA requests comments on all aspects of the exemption request and proposed exemption from the prohibition on use of PCE in vapor degreasing as part of the second alternative

regulatory action, including information on the extent to which this industry could meet the requirements of the proposed WCPP or prescriptive controls and whether compliance with specific elements of the proposed WCPP should also be required during the period of the exemption. EPA is requesting comment on whether vapor degreasing of parts and components for non-aerospace applications should also be exempt from prohibition as part of the second alternative regulatory action for the industrial and commercial use of PCE in vapor degreasing. To facilitate EPA's consideration of exemptions for other sectors, comments in support of additional exemptions should include detailed explanations of why and how long exemptions would be needed. Additionally, EPA is soliciting comment on whether it should specify the type of vapor degreasing operation, such as closed-loop batch vapor degreasing, that would be exempt from prohibition as part of the second alternative regulatory action for the industrial and commercial use of PCE in vapor degreasing for aerospace parts and whether it should consider different exemption timeframes for different types of vapor degreasing operations.

iii. *Analysis of the need for a TSCA section 6(g) exemption for industrial and commercial use of PCE in dry cleaning.* Following Panel recommendations in the SBAR Panel Report (Ref. 33), EPA has considered a TSCA section 6(g) exemption for the use of PCE in dry cleaning and has not found that a TSCA section 6(g) exemption is warranted. As discussed in Units IV.A.1.c. and V.A.1., based on consideration of the irreversible health effects associated with PCE exposures, the uncertainty that this sector can comply with a WCPP and reduce exposures sufficiently to address the unreasonable risk, and reasonably available information that indicates that alternatives, such as high flash point hydrocarbons and wet cleaning, are available, EPA determined that a prohibition would be the most appropriate way to eliminate the identified risks that drive the unreasonable risk to health resulting from the following conditions of use: industrial and commercial use in dry cleaning and spot cleaning post-2006 dry cleaning;

industrial and commercial use in dry cleaning and spot cleaning $4^{th}/5^{th}$ generation only dry cleaning; and consumer use in dry cleaning solvent (i.e., exposure to clothing or articles recently dry cleaned with PCE). EPA has uncertainty regarding whether industrial and commercial dry cleaning and spot cleaning users can comply with the provisions of the WCPP, including reducing air concentration to below the ECEL and complying with the WCPP implementation measures such as periodic monitoring, a PPE program, and developing an exposure control plan that reduces exposures in a manner aligns with the hierarchy of controls where PPE is the least preferred option. This uncertainty includes considerations of worker tasks that may occur in open-systems or may require manual application or exposure to PCE or PCE-containing products (e.g., manual stain removal, garment unloading, or transferring solvent from storage container to machine that EPA understands are common tasks at dry cleaning facilities) and difficulties related to respiratory protection, as described in Unit V.A. Based on reasonably available information, including market research, existing State actions restricting the use of PCE in dry cleaning, and engagement with industry, trade associations, and State and local agencies, EPA has determined that a phaseout period of five to fifteen years, as is included in the proposed regulatory action and alternative regulatory actions, are reasonable compliance timeframes to allow dry cleaners time to transition away from PCE. EPA requests comments on all aspects of this analysis of a need for an exemption under TSCA section 6(g), including information on the whether the specific use may be critical or essential, the availability of technically and economically feasible safer alternatives, and the time needed to implement alternatives.

c. *Workplace Chemical Protection Program (WCPP).*

The second alternative regulatory action considered by EPA would require a WCPP as described in Unit IV.A. for the following conditions of use: manufacturing (domestic manufacturing); manufacturing (import); processing as a reactant/intermediate; processing by

repackaging; recycling; industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing; and disposal. As with the proposed regulatory action, under the second alternative regulatory action, recycling and disposal would not be subject to the WCPP ECEL requirements. As with the compliance timeframes considered as part of the second alternative regulatory action for prohibition, the second alternative regulatory action also includes shorter compliance timeframes for implementation of the PCE WCPP than the proposed regulatory action. Under the second alternative action, the requirements for WCPP would take effect 3 months sooner than in the proposed regulatory action. Under a compliance timeframe that is 3 months shorter than the proposed regulatory action, the requirements for owners and operators to conduct initial baseline monitoring would take effect 3 months after the date of publication of the final rule in the *Federal Register*. Each owner or operator would be required to provide respiratory protection to all potentially exposed persons in the regulated area within 3 months after receipt of the results of any exposure monitoring or within 6 months after date of publication of the final rule in the *Federal Register*. Regulated entities would be required to implement an exposure control plan within 9 months after date of publication of the final rule in the *Federal Register*. EPA requests comment on any advantages or drawbacks for the timelines outlined in this unit compared to the timelines identified for the proposed regulatory action in Unit IV.A.

d. *Prescriptive controls.*

The second alternative regulatory action considered by EPA would require fume hood and dermal PPE for the industrial and commercial use as a laboratory chemical, as described in Unit IV.A.3. As with the compliance timeframes considered as part of the second alternative action for prohibition and WCPP, the second alternative regulatory action also includes shorter compliance timeframes for implementation of prescriptive controls. Under the second alternative

action, the requirements for prescriptive controls would take effect 3 months sooner than in the proposed regulatory action. Under a compliance timeframe that is 3 months shorter than the proposed regulatory action, requirements that owners and operators provide dermal PPE and a fume hood would take effect 9 months after the publication date of the final rule.

C. Overview of conditions of use and proposed regulatory action and alternative regulatory actions.

Table 2 is a side-by-side depiction of the proposed regulatory action with the primary and second alternative actions for each condition of use identified as driving the unreasonable risk (Ref. 2). The purpose of this table is to succinctly convey to the public the major differences between the proposed regulatory action and the alternative regulatory actions; as such the actions in each column are truncated and do not reflect all the details of the proposed and alternative regulatory actions, including differences in timeframes. The proposed and alternative regulatory actions are described more fully in Units IV.A. and B.

Table 2 – Overview of Conditions of Use Driving Unreasonable Risk and Proposed Regulatory Action and Alternative Regulatory Actions

	Action		
Condition of Use Driving Unreasonable Risk Determination	**Proposed Regulatory Action**	**Primary Alternative Action**	**Second Alternative Action**
Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing	PCE WCPP	Prescriptive Controls (PPE)	PCE WCPP
Industrial and commercial use in laboratory chemicals	Prescriptive Controls (fume hood, dermal PPE)	PCE WCPP	Prescriptive Controls (fume hood, dermal PPE)
Industrial and commercial use in paints and coatings in maskants for chemical milling	PCE WCPP	Prescriptive Controls (PPE)	Prohibit[1]

	Action		
Condition of Use Driving Unreasonable Risk Determination	**Proposed Regulatory Action**	**Primary Alternative Action**	**Second Alternative Action**
Industrial and commercial use as solvent for open-top batch vapor degreaser	PCE WCPP	Prescriptive Controls (PPE)	Prohibit[1]
Industrial and commercial use as solvent for closed-loop batch vapor degreaser	PCE WCPP	Prescriptive Controls (PPE)	Prohibit[1]
Industrial and commercial use as solvent for in-line conveyorized vapor degreaser	PCE WCPP	Prescriptive Controls (PPE)	Prohibit[1]
Industrial and commercial use as solvent for in-line web cleaner vapor degreaser	PCE WCPP	Prescriptive Controls (PPE)	Prohibit[1]
Industrial and commercial use as a processing aid in pesticide, fertilizer and other agricultural chemical manufacturing	Prohibit	PCE WCPP	Prohibit
Industrial and commercial use in specialty DOD uses (oil analysis and water pipe repair)	Prohibit	PCE WCPP	Prohibit
Industrial and commercial use in solvent-based adhesives and sealants	PCE WCPP	Prescriptive Controls (Concentration limit)	Prohibit
Industrial and commercial use in solvent-based paints and coatings	Prohibit	PCE WCPP	Prohibit
Industrial and commercial use as solvent for aerosol spray degreaser/cleaner	Prohibit	PCE WCPP	Prohibit

	Action		
Condition of Use Driving Unreasonable Risk Determination	**Proposed Regulatory Action**	**Primary Alternative Action**	**Second Alternative Action**
Industrial and commercial use in dry cleaning and spot cleaning post-2006 dry cleaning	Prohibit	Prohibit	Prohibit
Industrial and commercial use in dry cleaning and spot cleaning 4th/5th gen only dry cleaning	Prohibit	Prohibit	Prohibit
Industrial and commercial use as solvent for cold cleaning	Prohibit	Prohibit	Prohibit
Industrial and commercial use in other textile processing	Prohibit	Prohibit	Prohibit
Industrial and commercial use in wood furniture manufacturing	Prohibit	Prohibit	Prohibit
Commercial use for photographic film	Prohibit	Prohibit	Prohibit
Industrial and commercial use as a solvent for aerosol lubricants	Prohibit	Prohibit	Prohibit
Industrial and commercial use in wipe cleaning	Prohibit	Prohibit	Prohibit
Industrial and commercial use in other spot cleaning and spot removers, including carpet cleaning	Prohibit	Prohibit	Prohibit
Industrial and commercial use in automotive care products (e.g., engine degreaser and brake cleaner)	Prohibit	Prohibit	Prohibit

	Action		
Condition of Use Driving Unreasonable Risk Determination	**Proposed Regulatory Action**	**Primary Alternative Action**	**Second Alternative Action**
Industrial and commercial use in non-aerosol cleaner	Prohibit	Prohibit	Prohibit
Industrial and commercial use in metal (e.g., stainless steel) and stone polishes	Prohibit	Prohibit	Prohibit
Industrial and commercial use in foundry applications	Prohibit	Prohibit	Prohibit
Commercial use in inks and ink removal products (based on printing)	Prohibit	Prohibit	Prohibit
Industrial and commercial use in welding	Prohibit	Prohibit	Prohibit
Industrial and commercial use for mold release	Prohibit	Prohibit	Prohibit
Commercial use in inks and ink removal products (based on photocopying)	Prohibit	Prohibit	Prohibit
Commercial use in metal mold cleaning, release and protectant products	Prohibit	Prohibit	Prohibit
Industrial and commercial use as a solvent for penetrating lubricants and cutting tool coolants	Prohibit	Prohibit	Prohibit
Consumer use in dry cleaning solvent	Prohibit[2]	Prohibit[2]	Prohibit[2]
Consumer use in automotive care products (parts cleaner)	Prohibit[2]	Prohibit[2]	Prohibit[2]

	Action		
Condition of Use Driving Unreasonable Risk Determination	**Proposed Regulatory Action**	**Primary Alternative Action**	**Second Alternative Action**
Consumer use in lubricants and greases (lubricants and penetrating oils)	Prohibit[2]	Prohibit[2]	Prohibit[2]
Consumer use in adhesives for arts and crafts (including industrial adhesive, arts and crafts adhesive, gun ammunition sealant)	Prohibit[2]	Prohibit[2]	Prohibit[2]
Consumer use in adhesives for arts and crafts (livestock grooming adhesive)	Prohibit[2]	Prohibit[2]	Prohibit[2]
Consumer use in adhesives for arts and crafts (column adhesive, caulk and sealant)	Prohibit[2]	Prohibit[2]	Prohibit[2]
Consumer use in solvent-based paints and coatings (coatings and primers (aerosol))	Prohibit[2]	Prohibit[2]	Prohibit[2]
Consumer use in solvent-based paints and coatings (metallic overglaze)	Prohibit[2]	Prohibit[2]	Prohibit[2]
Consumer use in welding	Prohibit[2]	Prohibit[2]	Prohibit[2]
Consumer use in metal mold cleaning, release and protectant products	Prohibit[2]	Prohibit[2]	Prohibit[2]
Consumer use in cleaners and degreasers (other)	Prohibit[2]	Prohibit[2]	Prohibit[2]
Consumer use in automotive care products (brake cleaner)	Prohibit[2]	Prohibit[2]	Prohibit[2]

	Action		
Condition of Use Driving Unreasonable Risk Determination	**Proposed Regulatory Action**	**Primary Alternative Action**	**Second Alternative Action**
Consumer use in aerosol cleaner (vandalism mark and stain remover)	Prohibit[2]	Prohibit[2]	Prohibit[2]
Consumer use in non-aerosol cleaner (e.g., marble and stone polish)	Prohibit[2]	Prohibit[2]	Prohibit[2]
Consumer use in lubricants and greases (cutting fluid)	Prohibit[2]	Prohibit[2]	Prohibit[2]
Consumer use in solvent-based paints and coatings (outdoor water shield (liquid))	Prohibit[2]	Prohibit[2]	Prohibit[2]
Consumer use in solvent-based paints and coatings (rust primer and sealant (liquid))	Prohibit[2]	Prohibit[2]	Prohibit[2]
Consumer use in metal (e.g., stainless steel) and stone polishes	Prohibit[2]	Prohibit[2]	Prohibit[2]
Consumer use in inks and ink removal products	Prohibit[2]	Prohibit[2]	Prohibit[2]
Manufacturing (domestic manufacturing)	PCE WCPP	Prescriptive Controls (PPE)	PCE WCPP
Manufacturing (import)	PCE WCPP	Prescriptive Controls (PPE)	PCE WCPP
Processing as a reactant/intermediate	PCE WCPP	Prescriptive Controls (PPE)	PCE WCPP
Processing into formulation, mixture or reaction product in paint and coating products	PCE WCPP	Prescriptive Controls (PPE)	Prohibit

	Action		
Condition of Use Driving Unreasonable Risk Determination	**Proposed Regulatory Action**	**Primary Alternative Action**	**Second Alternative Action**
Processing into formulation, mixture or reaction product in cleaning and degreasing products	PCE WCPP	Prescriptive Controls (PPE)	Prohibit
Processing into formulation, mixture or reaction product in other chemical products and preparations	Prohibit	PCE WCPP	Prohibit
Processing into formulation, mixture or reaction product in adhesive and sealant products	PCE WCPP	Prescriptive Controls (PPE)	Prohibit
Repackaging	PCE WCPP	Prescriptive Controls (PPE)	PCE WCPP
Recycling	PCE WCPP	Prescriptive Controls (dermal PPE)	PCE WCPP
Disposal	PCE WCPP	Prescriptive Controls (dermal PPE)	PCE WCPP

[1] TSCA section 6(g) exemption, including the manufacture (including import), processing, and distribution for this condition of use.
[2] Prohibit manufacture (including import), processing, and distribution in commerce for the consumer use.

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

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

A. Consideration of risk management requirements available under TSCA section 6(a).

1. *Proposed regulatory action.*

a. *Prohibition.*

EPA considered a prohibition as a regulatory option and is proposing it for certain occupational conditions of use (Unit IV.A.). Prohibition is the preferred option for occupational

conditions of use where greater uncertainty exists relative to a sector's ability to comply with provisions of the proposed PCE WCPP, such as an ECEL or DDCC. EPA's 8-hour TWA ECEL for PCE is significantly lower than the OSHA PEL and there is a degree of uncertainty as to whether chemical users under the conditions of use in some sectors will be able to comply with such a level and thus whether the unreasonable risk would be addressed. This uncertainty includes consideration of the difficulties related to respiratory protection, which are discussed in more detail in Unit V.A.1.b., and which include how respirators may present communication problems, vision problems, worker fatigue, and reduced work efficiency (63 FR 1152, January 8, 1998) as well as consideration for that fact that not all workers may be able to wear respirators. Similarly, there is also uncertainty regarding certain chemical users' ability to prevent direct dermal contact with PCE, in particular during use in open-systems or when worker activities require manual application or removal of PCE or a PCE-containing product through rags, aerosols, spray guns, roll applicators, fingers, hands, or other materials. Additionally, prohibition is the preferred option for occupational conditions of use where reasonably available information suggests minimal ongoing use or when feasible safer alternatives are reasonably available. The uncertainties related to whether users under certain conditions of use could comply with the requirements of a PCE WCPP, combined with the severity of the risks of PCE, the prevalence of alternative processes and products (Unit V.B), and in some cases reasonably available information indicating a use is no longer ongoing (Refs. 56, 3), has led EPA to propose prohibitions for most industrial and commercial uses of PCE, as well as for the upstream manufacturing, processing, and distribution in commerce for those uses. EPA requests comment regarding the number of businesses and other entities that could potentially close as well as associated costs with a prohibition of PCE for the industrial and commercial conditions of use identified in Unit IV.A.1.

As outlined in Unit IV.A.1., EPA is proposing to phase out the use of PCE in dry cleaning and associated spot cleaning at dry cleaning facilities. While EPA recognizes the exposure reductions and significant investments in equipment improvements made by dry cleaners, as described by SERs and summarized in the SBAR Panel Report (Ref. 33), EPA has determined that the industrial and commercial uses of PCE in dry cleaning and the consumer use of PCE in dry cleaning drive the unreasonable risk for PCE, and is proposing that prohibition is the most appropriate approach to eliminate the unreasonable risk. Following the Panel recommendations in the SBAR report (Ref. 33), EPA is providing an assessment on the impact of the rule on the dry cleaning industry in the Economic Analysis (Ref. 3), summarized here. Based on consultation with stakeholders, EPA understands that the use of PCE in dry cleaning is currently declining. Stakeholders, including State and Local Agencies and trade associations, have noted an overall year-to-year decline in the use of PCE in dry cleaning and many expect PCE to phase out naturally or decrease to extremely low numbers as older machines are retired and alternative solvents are adopted (Ref. 61). As described more fully in the Economic Analysis, EPA assumes dry cleaning machines are retired 15 to 25 years after the manufactured date. Therefore, EPA assumes most dry cleaning machines manufactured and installed before 2005, such as for 3rd generation machines, would be beyond their projected useful life by the proposed phaseout dates outlined in Unit IV.A.1. Additionally, reasonably available information on the current use of alternatives to PCE in dry cleaning, including cost, effectiveness, and safety, indicate suitable alternatives are available (Refs. 61, 62). As described more fully in the Economic Analysis, EPA expects that multi-solvent or hydrocarbon dry cleaning machines are likely to be the most common alternatives to PCE dry cleaning. However, other alternatives, such as wet cleaning, are available (Refs. 27, 28, 29, 30, 31).

EPA determined prohibition would not be suitable for the remaining occupational

conditions of use, such as processing as a reactant/intermediate and several types of processing into a formulation, mixture, or reaction product; and industrial and commercial uses as a solvent for cleaning and degreasing in vapor degreasers, particularly for aerospace and defense applications, in maskant for chemical milling, in solvent-based adhesives and sealants, as a processing aid in catalyst regeneration in petrochemical manufacturing, and as a laboratory chemical. EPA made this determination based on compelling reasons to not prohibit the activity and identification of a different regulatory action that would address the unreasonable risk. For example, prohibition may not be suitable for conditions of use that may complement the Agency's efforts to address climate-damaging HFCs under the AIM Act, or have national security or other significance for critical sectors, where EPA identified strict workplace controls could be implemented for these uses to address the unreasonable risk as described in Unit V.A.1.b. Additionally, prohibition may not be suitable for conditions of use where alternative substances to PCE are more or equally hazardous, in particular for other solvents undergoing risk evaluation and risk management under TSCA section 6. For example, for processing as a reactant/intermediate, PCE and trichloroethylene (TCE) are both used as feedstock in the manufacture of HFC-134a although they are not drop in substitutes. As another example, PCE, TCE, 1-bromopropane, methylene chloride, and trans-1,2-dichloroethylene are solvents used in vapor degreasing and have or are currently undergoing risk evaluation or risk management under TSCA. In selecting among the TSCA section 6(a) requirements for the proposed approach for conditions of use where alternative substances to PCE may include other solvents undergoing risk evaluation and risk management under TSCA section 6, EPA considered whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute.

For these conditions of use, EPA determined restrictions under a PCE WCPP were more

suitable for addressing the unreasonable risk to the extent necessary so that PCE no longer presents such risk, while also allowing flexibility for regulated entities to continue operations, as described in this unit and in Unit IV.A.

Regarding industrial, commercial, and consumer uses of PCE, TSCA section 6(a)(2) provides EPA with the authority to prohibit or otherwise restrict the manufacture (including import), processing, or distribution in commerce of a substance or mixture "for a particular use" to ensure that a chemical substance no longer presents unreasonable risk. For this rule, EPA proposes that "for a particular use" includes consumer use more broadly, as well as industrial and commercial use, which encompasses all known, intended, and reasonably foreseen uses of PCE. Given the severity and ubiquitous nature of the risks identified in the 2020 Risk Evaluation for PCE for all industrial, commercial, and consumer uses evaluated, and noting that those conditions of use evaluated in the Risk Evaluation encompass all known, intended, and reasonably foreseen uses of PCE, EPA proposes that prohibiting manufacture (including import), processing, and distribution in commerce of PCE for most industrial and commercial use and all consumer use is reasonable and necessary to eliminate the unreasonable risk of PCE, including by precluding retailers from selling PCE and PCE-containing products to consumers. EPA believes that any retailer selling PCE-containing products to consumers would be selling products for one of the consumer uses EPA evaluated in the 2020 Risk Evaluation for PCE and found to drive the unreasonable risk for PCE. Other regulatory options that would restrict the manufacture (including import), processing, and distribution in commerce of PCE for consumer use, such as setting a concentration limit, would not adequately address the identified unreasonable risk driven by consumer use. EPA's proposed requirements to address unreasonable risk to consumers and bystanders to consumer use are described in Unit IV.A.

A key consideration regarding consumer use is the role of retailers and other distributors.

A retailer, as EPA has defined in 40 CFR 751.103 (and proposes to define in 40 CFR 751.5), is any entity that makes available a chemical substance or mixture to consumer end users, including e-commerce internet sales or distribution. Previously, in the 2019 methylene chloride TSCA section 6(a) risk management rule addressing consumer use of methylene chloride in paint and coating removal (40 CFR Part 751, subpart B), EPA prohibited retailers from distributing in commerce paint and coating removers containing methylene chloride (see 40 CFR 751.105(b) and (c)). To meet the same goal of protecting consumers from accessing PCE-containing products that could pose unreasonable risk, for a broader range of consumer conditions of use, EPA considered and is proposing a similar provision to ensure that retailers will not be able to purchase PCE for sale or distribution to consumers and will not be able to sell or distribute PCE to consumers, including making available to consumers products containing PCE. For these reasons, as described in Unit IV.A., EPA's proposal to address unreasonable risk from PCE includes prohibition on the distribution in commerce of PCE to and by retailers.

To support implementation of the proposed prohibitions EPA also considered, and is proposing, a de minimis level for products containing PCE to account for impurities that do not drive the unreasonable risk. EPA conducted an analysis using the methodology in the 2020 Risk Evaluation for PCE to estimate whether there is a weight fraction of PCE in industrial/commercial and consumer products below which the industrial/commercial and consumer uses of those products, respectively, would not drive the unreasonable risk from PCE. EPA examined the Consumer Exposure Model for the 2020 Risk Evaluation for PCE and found that, when adjusting parameters for product mass and duration of use to the highest values based on consumer product data in the 2020 Risk Evaluation for PCE, consumer use of products that are 0.124% PCE or less by weight would not drive the unreasonable risk from PCE (Ref. 53). To identify a concentration limit of PCE in industrial/commercial products that would not drive the

unreasonable risk from PCE, EPA also conducted an analysis using the Brake Servicing Near-Field/Far-Field exposure model in the 2020 Risk Evaluation for PCE and calculated that a PCE concentration of 0.7% in aerosol brake degreasing products would achieve exposure concentrations at or below the ECEL based on a near-field 8-hour TWA of 0.145 ppm at the 95th percentile (Ref. 45). Based on these analyses, EPA is proposing to exclude from prohibition products containing PCE at less than 0.1% by weight, as described in Unit IV.A. EPA has identified uncertainties with a concentration limit of 0.1% addressing the unreasonable risk. For example, the Brake Services Near-Field/Far-Field exposure model is based on a scenario for occupational brake cleaning and may less accurately estimate exposures from other applications where exposures may be different than those predicted by the model, for example due to higher PCE application rates or lower ventilation rates. However, a concentration limit of 0.1% provides a margin of error to account for the uncertainties associated with the 0.7% concentration limit identified in the analysis using the Brake Servicing Near-Field/Far-Field exposure model. EPA is requesting comment on the de minimus concentration limit of PCE in products or formulations, and provides more information on consideration of a concentration limit in Unit V.A.3. Details of the proposed prohibitions are described in more detail in Unit IV.A.

b. *Workplace Chemical Protection Program (WCPP).*

One option EPA considered for occupational conditions of use was establishing requirements for a PCE WCPP, which would include a combination of requirements to the extent necessary to address unreasonable risk driven by inhalation and dermal exposures in the workplace. A PCE WCPP would encompass restrictions on certain occupational conditions of use and could include provisions for an ECEL, DDCC, and ancillary requirements to support implementation of these exposure limits. Due to the low exposure level and stringent requirements in the PCE WCPP that would be necessary to address the unreasonable risk from

PCE, EPA identified only a relatively small number of conditions of use where the Agency expected a PCE WCPP could be successfully implemented.

Existing Chemical Exposure Limit. One requirement considered by EPA to include in a PCE WCPP to address unreasonable risk driven by inhalation exposures to PCE for occupational conditions of use was establishing an ECEL and related implementation measures, such as exposure monitoring. As described in Unit IV.A., the PCE WCPP would be non-prescriptive, in the sense that regulated entities would not be required to use specific controls prescribed by EPA to achieve the exposure concentration limit. Rather, it would be a performance-based exposure limit that would enable owners or operators to determine how to most effectively meet the exposure limit based on conditions at their workplace, consistent with the hierarchy of controls.

A central component of the PCE WCPP is the exposure limit. Exposures remaining at or below the ECEL would address any unreasonable risk of injury to health driven by inhalation exposures for occupational conditions of use.

In the case of PCE, EPA has calculated the ECEL to be 0.14 parts per million (ppm) (0.98 mg/m^3) for inhalation exposures as an 8-hour TWA in workplace settings, based on the chronic, non-cancer HEC for neurotoxicity (CNS) (Ref. 10). This is the concentration at which an adult human, including a member of a susceptible subpopulation, would be unlikely to suffer adverse effects if exposed for a working lifetime. The differences between the ECEL and the OSHA PEL are discussed in more detail in Unit II.C.1.b. EPA chose the chronic non-cancer neurotoxicity endpoint for PCE as the basis for this exposure limit because it is the most sensitive of the endpoints identified, and therefore will be protective of both acute and chronic non-cancer and chronic cancer inhalation endpoints over the course of a working day and lifetime.

In deciding whether an ECEL and related required implementation measures would

appropriately address the unreasonable risk driven by occupational inhalation exposures for specific conditions of use, EPA considered factors related to work activities that may make it difficult to comply with an ECEL, particularly at the low air concentration level EPA has identified. Once EPA identified the appropriate risk-based inhalation limit to address identified unreasonable risk, EPA carefully considered the appropriateness of such an exposure control program for each occupational condition of use of PCE, in the context of the unreasonable risk. Examples include conditions of use with work activities that may take place in the field, making it challenging to establish a regulated area and conduct monitoring; work activities that may take place in open systems that require manual contact with the chemical substance; work activities that may take place in small, enclosed spaces, creating challenges for implementing engineering controls or using respiratory PPE; work activities that require a high range of motion or for some other reason create challenges for the implementation of respiratory PPE; and the type of PPE that would be needed under the PCE WCPP to meet the ECEL in the absence of, or in addition to, other feasible exposure controls, based on analysis in the 2020 Risk Evaluation for PCE describing expected exposures with and without use of PPE.

EPA also considered the feasibility of exposure reduction sufficient to address the unreasonable risk, including in facilities currently complying with the OSHA PEL for PCE or implementing other recommended OELs such as the ACGIH TLV. While EPA acknowledges the regulated community's expected familiarity with OSHA PELs generally, as well as facilities' past and ongoing actions to implement the PCE PEL, the value of EPA's exposure limit is almost three orders of magnitude lower than the OSHA PEL (The differences between the ECEL and the OSHA PEL are discussed in more detail in Unit II.C.4; more information on other OELs is in Unit II.C.5.). This creates a degree of uncertainty as to whether facilities engaging in most conditions of use could meet the ECEL (and associated action level) and whether they could do

so without relying primarily on the use of PPE (which is the least preferred option in the hierarchy of controls), and, therefore, whether exposures could be reduced in a manner aligned with the hierarchy of controls.

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

Direct dermal contact control requirements. Another requirement considered by EPA to include in a PCE WCPP to address unreasonable risk driven by dermal exposures to PCE for occupational conditions of use was requiring DDCC. DDCC under the PCE WCPP would be a process-based requirement to prevent direct dermal contact in the workplace by separating, distancing, physically removing, or isolating potentially exposed persons from direct handling of PCE or from contact with equipment or materials on which PCE may exist under routine

conditions. Similar to the ECEL, DDCC is non-prescriptive, in the sense that it would not require a specific control to prevent direct dermal contact; rather, it would enable regulated entities to determine how to most effectively separate, distance, physically remove, or isolate potentially exposed persons from direct dermal contact with PCE based on what works best for their workplace, in accordance with the hierarchy of controls.

In deciding whether DDCC would appropriately address the unreasonable risk driven by dermal exposures, EPA considered factors related to work activities that may make it difficult to eliminate direct dermal contact. Examples include work activities that may take place in open systems that require manual handling of PCE, such as application or removal of PCE or a PCE-containing product through rags, aerosols, spray guns, roll applicators, fingers, hands, or other materials; or work activities that require a high range of motion or for some other reason create challenges for the implementation of dermal PPE.

EPA also considered whether exposures could be reduced in a manner aligned with the hierarchy of controls and considered the type of PPE that would be needed under the PCE WCPP DDCC to prevent direct dermal contact if elimination, substitution, engineering controls, and administrative controls are not sufficient to prevent direct dermal contact. The 2020 Risk Evaluation for PCE describes expected exposures with and without use of PPE; even if chemically resistant gloves are used in combination with basic workplace training and specific activity training for tasks where dermal exposure can be expected to occur, EPA found that dermal exposures would continue to pose risk concerns for most conditions of use. However, the 2020 Risk Evaluation for PCE identifies several uncertainties regarding the dermal exposures modeled. For example, the 2020 Risk Evaluation for PCE does not consider the frequency, type, and effectiveness of gloves or other types of PPE used or specific workplaces. In addition, the 2020 Risk Evaluation for PCE does not specify the specific activity training beyond procedure

for glove removal and disposal.

In consideration of the whole of the 2020 Risk Evaluation for PCE, including the uncertainties, EPA has preliminarily determined that preventing direct dermal contact to PCE through DDCC requirements, including requirements to reduce exposures in a manner aligned with the hierarchy of controls, workplace specific training, and, if necessary, dermal PPE which covers any exposed skin (including hands, legs, torso, and face), and PPE training, as described in Unit IV.A.2., for certain occupational conditions of use would address the unreasonable risk from dermal exposure driven by these conditions of use for potentially exposed persons.

PCE WCPP. Taking into account these considerations, EPA is proposing that certain conditions of use would be allowed to continue if regulated entities could ensure exposures remain at or below the ECEL, direct dermal contact is prevented, and other requirements are met in the PCE WCPP. In contrast to considerations that would weigh against the likelihood of a facility within a condition of use to successfully implement WCPP, there are certain considerations that indicate a condition of use would likely be able to achieve effective risk management via WCPP. Based on reasonably available information, including monitoring data (Refs. 50, 49), process descriptions, and information related to considerations described previously in this unit, EPA's confidence that requirements to meet an ECEL and prevent direct dermal contact can be implemented is highest in highly standardized and industrialized settings, such as where PCE is used in a closed system.

For example, one of the conditions of use for which EPA is proposing a WCPP is processing of PCE as a reactant. A large volume of PCE is processed for this condition of use, which primarily goes towards the manufacture of HFC-134a and HFC-125 (Refs. 3, 36). Inhalation monitoring data submitted by industry suggests that PCE exposures in some facilities may already be below levels that would be consistent with the proposed ECEL (Ref. 36).

Additionally, the 2020 Risk Evaluation for PCE supports EPA's conclusion that only small reductions in exposure are needed for WCPP ECEL compliance for processing of PCE as a reactant. Based on analysis in the 2020 Risk Evaluation for PCE describing expected exposures with and without use of PPE, EPA identified respirators of APF 25 as the minimum respiratory PPE that is sufficient to mitigate the unreasonable risk driven by inhalation exposures from this condition of use. Also, for dermal exposures, reasonably available information indicates that controls may already be in place at some workplaces to prevent or reduce direct dermal contact with PCE, including enclosed transfer liquid lines with a nitrogen purging mechanism, closed loop samplers, and impervious glove liners in addition to chemically resistant gloves (Ref. 63).

Another condition of use for which EPA is proposing the WCPP is the industrial and commercial use of PCE as a processing aid in catalyst regeneration in petrochemical manufacturing. EPA understands that most workplaces using PCE in isomerization and catalytic reforming (the two uses of PCE in catalyst regeneration in petrochemical manufacturing) already have stringent controls in place that reduce workplace exposures. As described in public comments and through engagement with the American Fuel and Petrochemical Manufacturers (AFPM), other industry trade associations, and individual firms, petroleum refineries use PCE in continuous, closed processes, where it is completely consumed (Refs. 64, 66, 63). Stakeholders have described how, upon delivery by tote or tank truck at refineries, PCE is directly injected from a tote into a closed processing unit or transferred from a truck into a storage tank that is directly hooked up for direct injection in a closed system. Transfer procedures of PCE are performed pursuant to comprehensive written procedures under strict PPE guidelines including, when appropriate, respirators. Information submitted by AFPM indicates that worker exposure is limited to chemical unloading and transfer procedures, which, for AFPM members, may range from 10 to 35 times per year per site for a 15-minute tote changeout or two to 12 times per year

per site for a 30- to 60-minute tank truck transfer (Ref. 64).

While EPA understands that the PCE exposure frequency and duration at petroleum refineries may be less than what was assumed in the risk evaluation, as described in this unit, EPA does not have any recent air monitoring data to confirm that PCE exposures are below the proposed ECEL at petroleum refineries. Based on analysis in the 2020 Risk Evaluation for PCE describing expected exposures with and without use of PPE, EPA identified respirators of APF 10 as the minimum respiratory PPE that would be sufficient to mitigate the unreasonable risk driven by inhalation exposures from this condition of use. Also, for dermal exposures, reasonably available information indicates that controls may already be in place to prevent or reduce direct dermal contact with PCE, such as using PCE in a closed system to limit exposures and implementing comprehensive written procedures with added PPE during transfer procedures.

For both of these conditions of use (processing as a reactant/intermediate and industrial and commercial use in catalyst regeneration in petrochemical manufacturing) the 2020 Risk Evaluation for PCE indicates that only small reductions in exposure would be needed for WCPP compliance. This suggests that, for these conditions of use, the reductions in exposure required to achieve a level that would not result in unreasonable risk may be less than for other conditions of use. This information together with other considerations previously described, including monitoring data indicating exposures near or below the ECEL and other reasonably available information indicating stringent controls may already be in place, adds to EPA's confidence that facilities engaging in these two conditions of use could meet the WCPP requirements.

In addition to EPA's confidence that facilities engaging in these conditions of use could meet the WCPP requirements and thus address the unreasonable risk, EPA found compelling reasons to allow continued use of PCE for these conditions of use because they may complement the Agency's efforts to address climate-damaging HFCs under the AIM Act or have national

security or other significance for critical sectors. For processing of PCE as a reactant/intermediate, HFC-134a and HFC-125 are two of the regulated substances identified in the AIM Act. The AIM Act authorizes EPA to address listed HFCs in three main ways: phasing down HFC production and consumption through an allowance allocation program; facilitating sector-based transitions to next-generation technologies; and issuing certain regulations for purposes of maximizing reclamation and minimizing releases of HFCs from equipment and ensuring the safety of technicians and consumers. EPA anticipates that many entities currently using HFCs with higher global warming potential will transition to alternatives with lower global warming potential as requirements under the AIM Act take effect. HFC-134a and HFC-125, while being regulated substances subject to the overall phasedown in production and consumption of regulated substances under the AIM Act, are likely to be used in blends to facilitate the transition from other HFCs and HFC blends with higher global warming potential in certain applications. By allowing for the continued, controlled use of PCE in the manufacture of HFC-134a and HFC-125, efforts to shift to chemicals or blends with lower global warming potential would not be impeded by this rulemaking. Allowing this use to continue, subject to compliance with the WCPP, would complement industry's ongoing effort to abate the use of HFCs with higher global warming potential.

For the industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing, information submitted to the Agency indicates that isomerization and catalytic reforming processes, which may rely on PCE for catalyst regeneration, are essential to make gasoline that is compliant with environmental regulations, such as the EPA Mobile Source Air Toxics regulations (Ref. 64, 65). Isomerization is a process that reduces the amount of benzene in fuels and catalytic reforming generates hydrogen that is used to remove sulfur compounds (Ref. 64). The resulting products from isomerization and catalytic reforming

processes at petroleum refineries are isomerate and reformate, which go into gasoline blends that make up an estimated 45% of the gasoline pool in the United States (Ref. 64). Based on information submitted to the Agency, EPA believes that petroleum refineries can meet the ECEL, and so does not anticipate that there would be a meaningful impact on the price of gasoline. However, if petroleum refineries are unable to meet or are not already meeting WCPP requirements as part of the proposed regulatory action and second alternative regulatory action or the prescriptive controls as part of the primary alternative action, EPA understands that this rulemaking could result in larger impacts to the petroleum refining sector, with potential impacts that could include an increase in the price of gasoline. Therefore, EPA is requesting comment on the extent to which facilities engaged in the industrial and commercial use of PCE as a processing aid in catalyst regeneration in petrochemical manufacturing may already meet the requirements in the proposed and alternative regulatory actions described in Unit IV. to address the unreasonable risk and is soliciting comment on the impact of such requirements on petroleum refining, with special attention to the price of gasoline.

For PCE to be available for the downstream industrial and commercial uses that would continue under a PCE WCPP, it would need to be manufactured (including imported), processed, and distributed in commerce. Likewise, as long as PCE remains in use, it must also be disposed of. Therefore, EPA is proposing requirements to meet a PCE WCPP for manufacture (including import), certain processing conditions of use, and disposal, to allow for a continued supply chain for specified conditions of use while ensuring that workers are not subject to unreasonable risk from PCE as it moves throughout the supply chain. For recycling and disposal, EPA did not identify human health risk from inhalation exposure as a driver of unreasonable risk and is therefore not proposing to require an ECEL under the PCE WCPP for recycling and disposal activities.

Details of the proposed PCE WCPP, including provisions for the ECEL, DDCC, and prescriptive controls, ancillary required implementation measures, requirements for demonstrating compliance and requirements for distributors, are described in more detail in Unit IV.A.

c. *Prescriptive controls.*

Another requirement EPA considered to address unreasonable risk for occupational conditions of use was requiring specific controls prescribed by EPA, including engineering controls, administrative controls, and/or PPE. In the 2020 Risk Evaluation for PCE, EPA identified that certain workplace controls could reduce exposures. The prescriptive controls EPA considered (such as respirators and gloves) are based on information in the 2020 Risk Evaluation for PCE. In general, prescriptive controls are not preferred as the primary method of risk management because of uncertainties related to feasibility to reduce exposures to address the unreasonable risk across all workplaces engaged in a condition of use and whether the prescriptive controls will be consistently or properly used. EPA understands that workplaces have unique processes and equipment in place and that varying levels of respiratory protection or dermal PPE may be needed for different workplaces. Additionally, as described in Unit III.A.1. and 2., EPA received input during required consultations and additional engagement that options that align with the hierarchy of controls (i.e., elimination and substitution of hazards in the workplace) should be preferred over prescriptive controls.

EPA determined that specific prescriptive controls (i.e., specific engineering or administrative controls, or PPE) may not be able to eliminate unreasonable risk for some conditions of use when used in isolation. In the 2020 Risk Evaluation for PCE, analysis of occupational exposure scenarios (OES) indicated that many conditions of use still posed risk concerns even with the application of respirators with APF 25 or 50 (Ref. 1). Because of the

uncertainty regarding the feasibility of exposure reductions through engineering controls alone, EPA determined that a PCE WCPP ECEL, which would be accompanied by monitoring requirements in tandem with the implementation of engineering controls, administrative controls, and/or PPE as elements of the program, as appropriate, would more successfully reduce exposure so that the unreasonable risk is addressed. Additionally, relying primarily on respirators and gloves to reduce exposures does not consider other more protective controls in the hierarchy, including elimination, substitution, engineering controls, and administrative controls. For occupational conditions of use where compliance with the PCE WCPP ECEL and DDCC is unlikely to be successful, in most cases prohibitions (rather than prescribed controls) would be more appropriate to ensure that PCE does not present unreasonable risk under the conditions of use.

However, based on the 2020 Risk Evaluation for PCE, EPA considered the industrial and commercial use in laboratory chemicals as a strong candidate for prescriptive controls. While inhalation exposures from the industrial and commercial use of PCE as a laboratory chemical did not drive the unreasonable risk determination for PCE, EPA's risk estimates were predicated on its finding that expected safety practices of using PCE in small amounts under a fume hood reduce the potential for inhalation exposures in laboratory settings. To codify assumptions made in the 2020 Risk Evaluation for PCE regarding the use of fume hoods in laboratory settings, EPA is proposing to require fume hoods in laboratory settings that use PCE. This proposed requirement would protect potentially exposed persons in laboratory settings by ensuring that good laboratory practices that reduce the potential for inhalation exposures are consistently applied. Additionally, the 2020 Risk Evaluation for PCE determined that dermal exposures from the industrial and commercial use of PCE as a laboratory chemical drive the unreasonable risk determination for PCE, and analysis in the 2020 Risk Evaluation for PCE indicated that there

would still be risk concerns even if chemically resistant gloves are used in combination with specific activity training for tasks where dermal exposure can be expected to occur. However, as described earlier, the 2020 Risk Evaluation for PCE identifies several uncertainties regarding the use of the dermal exposures modeled. For example, the 2020 Risk Evaluation for PCE does not consider the frequency, type, and effectiveness of gloves or other types of PPE used in laboratory settings. In consideration of the whole of the 2020 Risk Evaluation for PCE, including these uncertainties, EPA has preliminarily determined that preventing direct dermal contact with PCE through dermal PPE which covers any exposed skin and PPE training for the industrial and commercial use in laboratory chemicals would address the unreasonable risk from dermal exposure driven by this condition of use for potentially exposed persons. EPA is requesting comment on whether preventing dermal contact with PCE through dermal PPE and training would adequately address the unreasonable risk from dermal exposures for the industrial and commercial use in laboratory chemicals. Additionally, most laboratories are regulated by OSHA under 29 CFR 1910.1450 requirements for occupational exposure to hazardous chemicals in laboratories, and therefore may be more conducive to the implementation of engineering controls such as fume hoods to evacuate vapors and to the proper use and implementation of a dermal PPE program to adequately reduce overall exposure to PCE. The industrial and commercial use of PCE as a laboratory chemical would be necessary to provide for the analysis of monitoring samples required under the ECEL under this proposed regulation.

For certain occupational conditions of use, prescribed engineering controls, administrative controls, and PPE were considered as part of the alternative regulatory action and are described in more detail later in this unit and in Unit IV.B.

2. *Alternative regulatory actions.*

EPA acknowledges that, for some of the occupational conditions of use that it is

proposing to prohibit, there may be some activities or facilities that could conceivably implement requirements under a PCE WCPP to ensure that exposure remain below an ECEL and prevent direct dermal contact with PCE. In some cases, they may be able to undertake more extensive risk reduction measures than EPA currently anticipates. Therefore, as a primary alternative regulatory action, described in Unit IV.B., EPA is considering and requesting comment on a PCE WCPP – including requirements to ensure exposures remain below an ECEL and prevent direct dermal contact – for some conditions of use of PCE that would be prohibited under the proposed regulatory action. For those conditions of use that would be subject to the PCE WCPP under the primary alternative regulatory action, but not the proposed regulatory action, EPA was not able to identify reasonably available information such as monitoring data or detailed activity descriptions to indicate with certainty that relevant regulated entities for these conditions of use could mitigate identified unreasonable risk through a PCE WCPP. Due to this uncertainty, EPA is requesting comment on the primary alternative regulatory action and in particular the likelihood of successful compliance with a PCE WCPP, as described in Unit IV.A., for the conditions of use listed for the primary alternative regulatory action of PCE WCPP in Unit IV.B.

EPA understands that some of the workplaces engaged in a condition of use may already have stringent engineering controls, administrative controls, and PPE in place to reduce inhalation and dermal exposures to PCE. As part of the alternative regulatory action, EPA considered prescribed engineering controls, administrative controls, and PPE for some occupational conditions of use. In contrast to the proposed non-prescriptive requirements of the WCPP where regulated entities would have flexibility to select controls in accordance with the hierarchy of controls to comply, EPA understands that requiring specific prescriptive controls for certain occupational conditions of use may provide greater certainty to some facilities that they are addressing the unreasonable risk. However, as summarized in this unit, EPA has uncertainty

regarding the feasibility of exposure reductions through specified engineering controls, administrative controls, and/or PPE to address unreasonable risk across all workplaces engaged in certain conditions of use. Prescribing specific engineering controls, administrative controls, or PPE does not consider distinctions in processes, equipment, or workplace layout in all facilities, which may result in varying levels and types of controls needed to reduce inhalation exposures to below the ECEL or to eliminate direct dermal contact. Additionally, as described in Unit V.A.1.b., there is a degree of uncertainty regarding applicability of respirators, including their feasibility and consistency of proper use, especially when exposure monitoring is not regularly conducted. However, as part of the primary alternative regulatory action, EPA is considering PPE and soliciting comment on prescribing specific engineering and administrative controls for some occupational conditions of use. In the 2020 Risk Evaluation for PCE, EPA identified PPE that could reduce exposures and is therefore considering requiring PPE, including respiratory protection and dermal protection, as part of the primary alternative regulatory action for those conditions of use where the proposed regulatory action is a PCE WCPP. Turning to the use of PPE, however, does not consider other more preferable controls in the hierarchy of controls, including elimination, substitution, engineering, and administrative controls. As part of the primary alternative regulatory action, EPA is soliciting comment on prescribing specific engineering or administrative controls that would reduce inhalation and dermal exposures enough to address the unreasonable risk across all workplaces engaged in a condition of use.

While the use of dermal PPE is typical for the use of PCE as a laboratory chemical, EPA recognizes the potential for there to be other exposure controls that could prevent direct dermal contact in a laboratory setting. Therefore, as part of the primary alternative regulatory action, EPA is considering implementation of DDCC as part of a PCE WCPP for the industrial and commercial use of PCE as a laboratory chemical. Similarly, EPA understands there may be

exposure controls other than a fume hood that could reduce inhalation exposures in a laboratory setting and is therefore considering an ECEL as part of a PCE WCPP for the industrial and commercial use of PCE as a laboratory chemical.

EPA also considered proposing a TSCA section 6(g) time-limited exemption for conditions of use that are critical to national security and infrastructure. Based on reasonably available information, and as described earlier in Unit IV.B.2.b, EPA has analyzed the need for an exemption and has found that a TSCA section 6(g) exemption may be warranted under the second alternative regulatory action for the industrial and commercial use in maskant for chemical milling and for the industrial and commercial use in vapor degreasing if the workplaces engaged in that condition of use cannot meet the requirements of the proposed regulatory action (PCE WCPP) or primary alternative regulatory action (prescriptive controls) such that those conditions of use would no longer drive the unreasonable risk. A section 6(g) exemption may mean that the unreasonable risk will not be fully addressed. Note that EPA's second alternative regulatory action endeavors to ensure that worker protections are in place to the extent practicable and that EPA is required to have a time limited requirement for any exemptions granted under TSCA section 6(g), necessitating revisiting the need and justification for any exemption beyond the initial timeframe.

Details of the primary alternative regulatory action and second alternative regulatory action are described in more detail in Unit IV.B.

3. *Risk management requirements considered but not proposed.*

Since it is unlikely that all industrial or commercial facilities with occupational exposures to PCE would be able to implement a WCPP or prescriptive controls, EPA also examined the extent to which a point-of-sale self-certification requirement in order to purchase and subsequently use PCE would further ensure that only facilities able to implement and comply

with a WCPP or prescriptive controls are able to purchase and use PCE, and self-certify to that. Under a self-certification requirement, entities would submit a self-certification to the distributor or retailer each time PCE is purchased. The self-certification would consist of a statement indicating that the facility is implementing a WCPP or required prescriptive controls to control exposures to PCE; the self-certification would be signed and presented by a person authorized to do so by the facility owner or operator. Copies of the self-certification would be maintained as records by both the owner or operator and the distributor or retailer where PCE was purchased. However, because of the number and types of entities where users can obtain PCE or PCE-containing products, EPA does not believe the added requirement and subsequent burden of a point-of-sale self-certification requirement for the use of PCE would be an effective tool for preventing facilities that may be unable to comply with the WCPP or prescriptive controls of this proposed rulemaking from accessing PCE or PCE-containing products. As such, EPA is not proposing a self-certification requirement as an additional component of the requirements for addressing the unreasonable risk of occupational exposures to PCE. However, EPA is requesting comment on whether to include a self-certification requirement for purchasing PCE or PCE-containing products. For example, EPA is interested in learning if, for distributors and retailers, such a self-certification requirement would provide greater certainty that any sale of PCE or PCE-containing products would be for uses that are not prohibited and are to a facility implementing the WCPP or required prescriptive controls.

Also, although NIOSH recognizes PCE as an eye irritant (Ref. 67), EPA is not proposing requirements for eye protection from PCE, because eye irritation or injury is not a component of the unreasonable risk EPA has determined is presented by PCE.

In considering prescriptive controls as a regulatory action described in this unit to address the unreasonable risk driven by dry cleaning conditions of use, EPA examined monitoring data

from New York State Department of Environmental Conservation (NYSDEC) inspections reports for the years 2013-2015 submitted in July 2020 during the public comment period for the draft 2020 Risk Evaluation for PCE. Previously, EPA rated this information as unacceptable for use in the final 2020 Risk Evaluation for PCE due to lack of critical metadata on sample type and sample duration (Refs. 68, 69). However, during risk management, stakeholders confirmed the missing metadata is short-term duration area monitoring (Refs. 70, 71). EPA analyzed the data to help identify how certain controls may show reductions of PCE concentration in ambient air in air monitoring data and reduce risk from inhalation exposures for PCE dry cleaning (Ref. 45). The analysis of the data show that while certain engineering controls such as 4th generation machines and a vapor barrier room result in lower air concentration of PCE based on area monitoring results, the overall statistics of the data show that PCE air concentrations are generally in exceedance of the ECEL of 0.14 ppm as an 8-hour TWA. It should be noted that there are limitations and uncertainties in using area monitoring data to estimate worker exposure. Based on the results of this analysis and the uncertainties of the data, EPA reasoned that prescriptive engineering controls of requiring 4th generation machines or requiring a vapor barrier room do not adequately address the unreasonable risk driven by inhalation exposures to workers from the industrial and commercial uses of PCE in dry cleaning. An industry stakeholder submitted additional NYSDEC inspection reports for the years 2018-2019 in November 2021. EPA considered the NYSDEC 2018-2019 inspection reports in the Economic Analysis to estimate the age of dry cleaning machines and how much PCE each machine typically uses in a year (Ref. 3).

In place of other regulatory actions, EPA considered limiting the weight fraction of PCE in products and formulations to address the unreasonable risk. As described in Unit V.A.1.a., EPA determined that the unreasonable risk from PCE would not be driven by use of products

containing PCE at less than 0.1% by weight. Therefore, EPA is proposing a de minimis level for products containing PCE at levels of less than 0.1% to account for impurities that do not drive the unreasonable risk., as described in Unit IV.A.1.d. However, for most industrial/commercial and consumer conditions of use, the concentration limit of less than 0.1% is so low that it is highly unlikely that PCE would still serve its functional purpose in the product or formulation. EPA thus concluded that a weight fraction would essentially function as a prohibition for most industrial/commercial and consumer conditions of use. EPA therefore did not propose a weight fraction for industrial/commercial and consumer conditions of use. For the industrial and commercial use in solvent-based adhesives and sealants, EPA identified several products available on the market at concentrations of PCE between 0.1% and 1% by weight (Ref. 1). As part of the primary alternative regulatory action, EPA would set a concentration limit of PCE in adhesive and sealant products for industrial and commercial use to 1%, as described in Unit IV.B.1.c.

4. *Additional considerations.*

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

As required under TSCA section 6(d), any rule under TSCA section 6(a) must specify

mandatory compliance dates, which shall be as soon as practicable with a reasonable transition period, but no later than 5 years after the date of promulgation of the rule (except in the case of a use exempted under TSCA section 6(g) or for full implementation of ban or phaseout requirements). These compliance dates are detailed in Unit IV.A. and IV.B. EPA may finalize significantly shorter or longer compliance timeframes based on consideration of public comments. Following Panel recommendations in the SBAR report, and described in Unit IV., EPA considered reasonable compliance timeframes in response to SER input and other appropriate factors, such as the average projected useful lifespan of dry cleaning machines, capital costs for new equipment, and ongoing regulations and rulemakings, including the proposed amendments to the PCE dry cleaning NESHAP (January 5, 2022; 87 FR 421) (Ref. 33). Additionally, following Panel recommendations in the SBAR report, EPA considered compliance timelines based on the availability of technically and economically feasible alternatives, as well as any information provided by other agencies that set requirements for certification or standards relevant to degreasing, parts cleaning, or other uses of PCE. Following Panel recommendations in the SBAR report, EPA is requesting comment on any additional appropriate factors for identifying reasonable compliance timeframes and how to weigh the factors for dry cleaning and other industries, as well as differing compliance or reporting requirements or timetables that account for the resources available to small entities.

B. Consideration of alternatives in deciding whether to prohibit or substantially restrict PCE.

Under TSCA section 6(c)(2)(C), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, EPA must consider, to the extent practicable, whether technically and economically feasible alternatives that benefit human health or the environment, compared to the use so proposed to be prohibited or restricted, will be

reasonably available as a substitute when the proposed prohibition or other restriction takes effect. To that end, in addition to an Economic Analysis (Ref. 3), EPA conducted an Alternatives Assessment, using reasonably available information (Ref. 56).

For this assessment, EPA identified and analyzed alternatives to PCE in products relevant to industrial, commercial, and consumer conditions of use proposed to be prohibited or restricted, even if such restrictions are not anticipated to substantially prevent the condition of use. Based on reasonably available information, including information submitted by industry, EPA understands viable alternatives to PCE may not be available for several conditions of use—for example, the industrial and commercial use in maskant for chemical milling and for the industrial and commercial use in vapor degreasing for certain applications (Refs. 54, 57, 58) — and considered that information to the extent practicable in the development of the regulatory options as described in Unit III.B.3. For some conditions of use, EPA was unable to identify products currently available for sale that contain PCE. EPA is soliciting comments on whether there are products in use or available for sale relevant to these conditions of use that contain PCE at this time, so that EPA can ascertain whether there are alternatives that benefit human health or the environment as compared to such use of PCE. These conditions of use are detailed in the Alternatives Assessment (Ref. 56).

For conditions of use for which products currently containing PCE were identified, EPA identified several hundred commercially available alternative products that do not contain PCE, and listed in the Alternatives Assessment, to the extent practicable, their unique chemical components, or ingredients. For each of these chemical components or ingredients, EPA identified whether it functionally replaced PCE for the product use and screened product ingredients for human health and environmental hazard, as well as identified flammability and global warming potential where information was reasonably available (Ref. 56). EPA then

assigned a rating to the human health and environmental hazards, using a methodology described in the Alternatives Assessment document. In general, EPA identified products containing ingredients with a lower hazard screening rating than PCE for certain endpoints, while some ingredients presented higher hazard screening ratings than PCE (Ref. 56). These alternative hazard screening ratings are described in detail in the Alternatives Analysis grouped under common product use categories (Ref. 56). Additionally, based on input provided by SERs during the SBAR Panel, EPA understands that some available alternatives may present problems for certain users. For example, SERs identified concerns with water-based alternatives such as potential termite and mold damage to wood in buildings or water supply limitations due to a drought. SERs also identified concerns with alcohol-based alternatives that present a fire risk, and which may require users to acquire certain permits or comply with restrictions set by State and local agencies, including fire departments. Information regarding potential problems with available alternatives as indicated by SERs during the SBAR Panel is outlined in the SBAR Panel Report (Ref. 33). Following Panel recommendations in the SBAR report, EPA requests public comment about the feasibility of use of alternatives to PCE and their availability for conditions of use that drive the unreasonable risk.

In deciding whether to propose prohibition or other significant restrictions on a condition of use of PCE and in proposing an appropriate transition period for any such action, EPA has therefore, pursuant to TSCA section 6(c)(2)(C), considered, to the extent practicable, whether technically and economically feasible alternatives that benefit human health or the environment, compared to the use proposed to be prohibited or restricted, would be reasonably available as a substitute when a proposed prohibition or other significant restriction would become effective. EPA is additionally requesting comment on the Alternatives Assessment as a whole.

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

A. Health effects of PCE and the magnitude of human exposure to PCE.

EPA's analysis of the health effects of PCE and the magnitude of human exposure to PCE are in the 2020 Risk Evaluation for PCE (Ref. 1). A summary is presented here.

The 2020 Risk Evaluation for PCE identified potential health effects of PCE including non-cancer adverse health effects such as neurotoxicity and central nervous system effects, kidney and liver effects, immune system toxicity, reproductive toxicity, and developmental toxicity and cancer hazards from carcinogenicity as well as genotoxicity.

Among the non-cancer adverse health effects, EPA identified visual deficits indicative of neurotoxicity as a primary effect of PCE in humans following acute and chronic inhalation and dermal exposures. Identified symptoms of neurotoxicity include color confusion, changes in visual contrast detection, and alteration of visual-spatial function. Impaired visual and cognitive function and diminished color discrimination are the most sensitive adverse effects driving the unreasonable risk of PCE exposure. Additionally, the 2020 Risk Evaluation for PCE identified that PCE exposure is associated with several types of cancer, including liver tumors, brain gliomas, kidney cancer, and testicular cancer. By the criteria presented in EPA's Guidelines for Carcinogen Risk Assessment (Ref. 41), PCE is characterized as "likely to be carcinogenic to humans by all routes of exposure" based on conclusive evidence in mice and rats and suggestive evidence in humans.

Other adverse health effects identified in the 2020 Risk Evaluation for PCE identified include central nervous system depression, kidney nephrotoxicity and proximal tubule nuclear enlargement, liver necrosis and extreme dilation of blood or lymph vessels, reduced sperm quality, reduced red blood cells and hemoglobin, increased immune cells, decreased fetal/placental weight, developmental neurotoxicity, and skeletal effects from chronic exposures (Ref. 1).

Regarding the magnitude of human exposure, one factor EPA considers for the conditions of use that drive unreasonable risk is the size of the exposed population which, for PCE, EPA estimates is 67,675 workers and 22,090 ONUs (Ref. 3). The number of consumers that use the approximately 115 types of products containing PCE each year is unknown.

For the conditions of use that drive the unreasonable risk for PCE, PESS include workers, ONUs, consumer users, and bystanders to consumers using products containing PCE. Children of workers present at dry cleaners are also a PESS group exposed to PCE during industrial and commercial use of PCE in dry cleaning and spot cleaning.

In addition to workers, ONUs, consumers, and bystanders to consumer use directly exposed to PCE, EPA recognizes there is exposure to the general population from air and water pathways for PCE. As mentioned in Unit II.D., EPA has separately conducted a screening approach to assess whether there may be potential risks to the general population from these exposure pathways. While the use of this screening approach indicates that EPA is not able to find that there are no potential risks to fenceline communities, the screening approach was not designed to facilitate the making of an unreasonable risk determination for these communities. This unit summarizes the results of that fenceline analysis. Although EPA is not making a determination of unreasonable risk based on the fenceline screening analysis, the proposed regulatory action described in Unit IV. is expected to reduce the risks identified in the screening approach.

As described in Unit II.D., EPA's analysis methodology was presented to the SACC peer review panel in March 2022, and EPA plans to consider SACC feedback (including the SACC recommendation to EPA to consider multiple years of release data to estimate exposures and associated risks) and make decisions regarding how to assess general population exposures in upcoming risk evaluations, such as for the 1,4-dioxane supplement, the forthcoming 20 High

Priority Substances, and manufacturer-requested risk evaluations. For PCE, EPA recognizes that a key input into the fenceline analysis for the ambient air pathway was data on releases from the most recent Toxics Release Inventory (TRI) reporting year and that the use of more than one year of data could result in different conclusions. Accordingly, in this unit EPA presents the results of its water pathway fenceline analysis based on PCE releases to water and its ambient air pathway fenceline analysis based on PCE releases reported to TRI over a single reporting year as well as over multiple years (Refs. 72, 73).

EPA's fenceline analysis for the air pathway for PCE indicates that EPA is not able to conclude that there are no potential risks to fenceline communities, described further in this unit. Additionally, based on the fenceline analysis for the ambient air pathway for PCE, including the strengths, limitations, and uncertainties associated with the information used to inform the analysis, EPA is unable to determine with this analysis whether those risks drive the unreasonable risk of injury to health presented by PCE. Standard cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk above benchmarks ranging from 1 in 1,000,000 to 1 in 10,000 (i.e., $1x10^{-6}$ to $1x10^{-4}$) depending on the subpopulation exposed (see, e.g., EPA's interpretation set forth in 54 FR 38044 (Sept. 14, 1989) which discusses the use of benchmarks for purposes of Section 112 of the Clean Air Act (CAA); see also EPA's interpretation of the upper bound of acceptable risk and the preferred benchmark described in the Letter of Concern regarding EPA Complaint Nos. 01R-22-R6, 02R-22-R6, and 04R-22-R6 see page 3 footnotes 5 and 6 and page 6 (Ref. 74)). In this fenceline analysis for the ambient air pathway for PCE, estimates of risk to fenceline communities were calculated using 1×10^{-6} as the benchmark for cancer risk in fenceline communities. While EPA is unable to determine, based on the screening level fenceline analysis, whether risks to the general population drive the unreasonable risk, as a matter of risk management policy EPA considers the range of $1x10^{-6}$ to

$1x10^{-4}$ as the appropriate benchmark for increased cancer risk for the general population, including fenceline communities. It is preferable to have the air concentration of PCE result in an increased cancer risk closer to the $1x10^{-6}$ benchmark, with the $1x10^{-4}$ benchmark generally representing the upper bound of acceptability for estimated excess cancer risk. The benchmark value is not a bright line, and the Agency considers a number of factors when determining unreasonable risk, such as the endpoint under consideration, the reversibility of effect, and exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed).

In this unit, EPA presents the results of its ambient air pathway fenceline analysis and the uncertainties associated with the analysis. EPA also describes how the proposal to prohibit the manufacturing (include importing), processing, and distribution in commerce of PCE for most industrial and commercial use and all consumer use, and to prohibit most industrial and commercial use of PCE, is expected to reduce the potential risks identified in the screening analysis to any general population or fenceline communities close to facilities engaging in PCE use. This unit also describes how EPA believes the proposed WCPP requirements may reduce exposures to the general population for facilities identified in the fenceline analysis with expected exposures to fenceline communities that are associated with conditions of use EPA is not proposing to prohibit. EPA therefore does not intend to revisit the air pathway for PCE as part of a supplemental risk evaluation.

There are some uncertainties associated with the fenceline analysis for the air pathway for PCE. The TRI dataset used for the single- and the multi-year fenceline analysis and land use analysis does not include actual release point locations which can affect the estimated concentrations at varying distances modeled. To identify the release location for each facility, EPA used a local-coordinate system based on latitude/longitude coordinates reported in TRI. The

latitude/longitude coordinates may represent the mailing address location of the office building associated with a very large facility or some other area of the facility rather than the actual release location (e.g., a specific process stack). This discrepancy between the coordinates reported in TRI and the actual release point could result in an exposure concentration that does not represent the actual distance where fenceline communities may be exposed. The fenceline analysis also evaluated the most "conservative exposure scenario" that consists of a facility that operates year-round (365 days per year, 24 hours per day, 7 days per week) in a South Coastal meteorologic region and a rural topography setting (Ref. 73). Therefore, the modeled exposures to receptors may be overestimated if there are fewer exposure days per year or hours per day. Additionally, the ambient air fenceline analysis organizes facilities and associated risks by OES and generally crosswalks each OES with the associated condition of use of PCE (Ref. 73). For some OES, EPA identified the associated conditions of use to the category level in the December 2020 Risk Evaluation for PCE but was unable identify to the conditions of use to the subcategory level due to limited information on activities and use of PCE reported under TRI. Therefore, some OES indicating increased cancer risk from ambient air exposures to PCE in the air fenceline analysis may be associated with one or more conditions of use of PCE.

EPA's single year fenceline analysis for the ambient air pathway, based on methods presented to the SACC, evaluated PCE releases reported to TRI over the 2019 reporting year. This single year fenceline analysis identified 65 facilities with some indication of releases and potential exposure with associated cancer risk to receptors within select distances evaluated from 5 to 1,000 meters from the respective releasing facility. Separately, following SACC feedback, EPA applied a slightly modified pre-screening methodology to evaluate 6 years of PCE release data (2015 through 2020 TRI data as well as the 6-year average of that data) rather than a single year of data for facilities with reported releases in TRI. The multi-year fenceline analysis

identified 30 facilities with some indication of releases and potential exposures and associated cancer risk at a distance of 100 meters from the releasing facility. Based on the multi-year fenceline analysis, 12 of these 30 facilities either had risks above the benchmark for cancer at distances farther out to 100 meters when compared to the single year analysis or are facilities that were not captured in the single-year analysis (e.g., did not report in 2019 TRI). Although the multi-year analysis identified several additional facilities with risk estimates above the benchmark for cancer farther out when compared to the single year analysis or that were not captured in the single-year analysis, the results of overall risk profiles (i.e., OES and corresponding conditions of use with risk estimates above the benchmark for cancer at the distances evaluated) for the single year and multi-year fenceline analyses are the same. While the fenceline analysis identified facilities with some indication of releases and potential exposure with associated increased cancer risk that exceeds the $1x10^{-6}$ benchmark at a distance of 100 meters from the releasing facility, the analysis did not identify any facilities exceeding the $1x10^{-4}$ benchmark; the highest risk estimate is in the $1x10^{-5}$ range (Ref. 73).

EPA conducted a land use analysis to determine if EPA can reasonably expect an exposure to fenceline communities to occur within the modeled distances for facilities where there was an indication of risk in the single year or multi-year fenceline analysis. This review consisted of a visual analysis using aerial imagery and interpreting land/use zoning practices around the facility to identify where residential, industrial/commercial businesses, or other public spaces are present within those radial distances indicating risk (as opposed to uninhabited areas), as well as whether the radial distances lie outside the boundaries of the facility. The land use analysis of the 65 facilities indicating risk in the single-year fenceline analysis identified 24 facilities with expected exposure to fenceline communities. The land use analysis of the 12 additional facilities indicating risk in the multi-year fenceline analysis (i.e., facilities where risk

estimates were above the benchmark for cancer at distances farther out when compared to the single-year analysis or facilities that were not captured in the single year analysis) identified 5 additional facilities with expected exposure to fenceline communities. Overall, the land use analysis identified a total of 29 facilities, representing eight OES, with expected exposure to fenceline communities. Those eight OES include: maskant for chemical milling; incorporation into formulation, mixture, or reaction product; industrial processing aid; metalworking fluids; other industrial uses – textile processing; degreasing (batch open-top degreasing; batch closed-loop degreasing; conveyorized vapor degreasing; web vapor degreasing; cold cleaning); manufacturing; and processing as a reactant (Ref. 73).

Under the proposed regulatory action described in Unit IV.A., all of the conditions of use associated with the metalworking fluids and other industrial uses – textile processing OES would be prohibited. EPA is also proposing to prohibit the processing into formulation, mixture or reaction product for other chemical products and preparations that may be associated with the facilities for the incorporation into formulation, mixture or reaction product OES; the industrial and commercial use as a processing aid in pesticide, fertilizer and other agricultural chemical manufacturing that may be associated with the facilities for the processing aid OES; and the industrial and commercial use as solvent for cold cleaning that may be associated with the degreasing OES (batch open-top degreasing; batch closed-loop degreasing; conveyorized vapor degreasing; web vapor degreasing; cold cleaning). As a result, exposures to any fenceline communities from these facilities would be addressed under the prohibitions in the proposed rulemaking.

The remaining facilities with expected exposure to fenceline communities may be associated with the following conditions of use that EPA is not proposing to prohibit: manufacturing; processing as a reactant/intermediate; processing into formulation, mixture or

reaction product for cleaning and degreasing products; processing into formulation, mixture, or reaction product for paint and coating products; processing into formulation, mixture, or reaction product for adhesives and sealants; industrial and commercial use as solvent for open-top batch vapor degreasing; industrial and commercial use as solvent for closed-loop batch vapor degreasing; industrial and commercial use as solvent for in-line conveyorized vapor degreasing; industrial and commercial use as solvent for in-line web cleaner vapor degreasing; industrial and commercial use in maskants for chemical milling; and industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing. For these conditions of use that may be associated with facilities that indicate expected exposure to fenceline communities, the proposed rule would require strict workplace exposure controls via implementation of a WCPP as described in Unit IV.A.2. Under the proposed WCPP requirements, facilities would need to monitor PCE air concentrations by taking personal breathing zone air samples of potentially exposed persons, which would allow facilities to better understand and manage the total releases of PCE within the facility and potentially stack and fugitive emissions. Furthermore, under the WCPP requirements, facilities would need to evaluate controls to determine how to reduce releases and exposures to potentially exposed persons in the workplace. EPA anticipates that this analysis would help facilities to determine the most effective ways to reduce exposures (including possible engineering controls or elimination/substitution of PCE) and whether those methods for exposure reduction impact releases, and therefore may reduce the overall risk to fenceline communities. EPA requests comment on whether owners and operators should be required to attest to whether and why the exposure controls they have selected would not result in increased air releases of PCE from the workplace, and keep records of that statement as part of the WCPP exposure control plan.

Under the proposed rule, only 17 conditions of use would continue (see Unit IV.C. for a

summary). For many of these conditions of use, EPA expects use to decline over time. For example, the manufacturing and processing into formulation, mixture, or reaction product conditions of use can reasonably be expected to decline because, while manufacturing and processing into a formulation, mixture, or reaction product could continue under a WCPP, downstream distribution and use of formulations, mixtures, or reaction products other than for vapor degreasing, chemical milling, adhesives and sealants, petrochemical manufacturing, and laboratory use would be prohibited. Additionally, EPA expects the industrial and commercial use of PCE as a reactant in the generation of HFC-134a and HFC-125 to also decline over time, in light of the AIM Act requirements to phase down production and consumption of listed HFCs by 85% over the next 15 years. HFC-125 and HFC-134a are two of the regulated substances that are subject to the AIM Act phasedown.

For all 17 conditions of use that would remain ongoing, the proposed rule would require strict workplace exposure controls via implementation of a WCPP or prescriptive workplace controls for laboratory use, as described in Unit IV.A.1. In the instances where efforts to reduce exposures in the workplace to levels below the ECEL could lead to adoption of engineering controls that ventilate more PCE outside, EPA believes this potential exposure would be limited as a result of the existing NESHAP for PCE for these conditions of use under the CAA. Applicable NESHAP include: 40 CFR part 63 subpart F, Synthetic Organic Chemical Manufacturing Industry; 40 CFR part 63 subpart DD, Off-Site Waste and Recovery Operations; 40 CFR part 63, Subpart VVV, Publicly Owned Treatment Works; 40 CFR part 63, Subpart VVVVVV, Chemical Manufacturing Area Sources; 40 CFR part 63, Subpart GG, Aerospace Manufacturing and Rework Facilities; 40 CFR part 63, Subpart T, Halogenated Solvent Cleaning, which impose emission standards and work practice requirements reflecting maximum achievable control technologies and generally available control technologies. The CAA required

residual risk reviews for standards reflecting maximum achievable control technologies, and technology reviews are required every 8 years for all NESHAP.

EPA's fenceline analysis for the water pathway for PCE, based on methods presented to the SACC, did not find risks from drinking water, incidental oral ingestion of surface water, or incidental dermal exposure to surface water (Ref. 72). EPA therefore does not intend to revisit the water pathway for PCE as part of a supplemental risk evaluation.

B. Environmental effects of PCE and the magnitude of exposure of the environment to PCE.

EPA's analysis of the environmental effects of PCE and the magnitude of exposure of the environment to PCE are in the 2020 Risk Evaluation for PCE (Ref. 1). The unreasonable risk determination for PCE is based solely on risks to human health; based on the TSCA 2020 Risk Evaluation for PCE, EPA determined that exposures to the environment did not drive the unreasonable risk. A summary is presented here.

The manufacturing, processing, use, and disposal of PCE can result in releases to the environment, including aquatic releases of PCE from facilities that manufacture, use, or process PCE. Fate, exposure, and environmental hazard were evaluated in the 2020 Risk Evaluation for PCE in order to characterize environmental risk of PCE. PCE has low bioaccumulation potential and moderate potential to accumulate in wastewater biosolids, soil, or sediment. Releases of PCE to the environment are likely to volatilize to the atmosphere, where it will slowly photooxidize. It may migrate to groundwater, where it will slowly hydrolyze. Additionally, the bioconcentration potential of PCE is low.

Potential effects of PCE exposure described in the literature for aquatic life include mortality, developmental deformities, immobilization, reproductive effects, growth effects, and biomass effects. EPA concluded that PCE poses a hazard to environmental aquatic organisms, including aquatic invertebrates, fish, amphibians, and aquatic plants (algae). For acute exposures,

PCE is a hazard to aquatic invertebrates based on immobilization, to fish based on immobilization of midge larvae at 7.0 mg/L, to fish based on mortality of rainbow trout as the most sensitive species with acute toxicity values as low as 4.8 mg/L, and amphibians based on developmental effects to the wood frog as the most sensitive species with acute toxicity values as low as 7.8 mg/L. For chronic exposures, PCE is a hazard to aquatic invertebrates, with a toxicity value of 0.5 mg/L; and a chronic toxicity value of 0.84 mg/L for fish. PCE is also a hazard for green algae with a toxicity value of 3.6 mg/L. EPA incorporated modeled exposure data from the Exposure and Fate Assessment Screening Tool or E-FAST (Ref. 75), as well as monitored data from the Water Quality Portal (Ref. 76), to characterize the exposure of PCE to aquatic species.

In the 2020 Risk Evaluation for PCE, the indicators evaluated for risk of injury to the environment include immobilization from acute exposure, growth effects from chronic exposure, and mortality to algae (Ref. 1). Based on the 2020 Risk Evaluation for PCE, EPA did not identify risk of injury to the environment that drive the unreasonable risk determination for PCE.

C. Benefits of PCE for various uses.

PCE is a solvent used in a variety of industrial, commercial, and consumer use applications, including as a feedstock in the production of fluorinated compounds, cleaning and degreasing, adhesives and sealants, paints and coatings, lubricants and greases, processing aid, and other uses. The physical and chemical properties of PCE, such as non-flammability, high volatility, low global warming potential, low vapor pressure, high chloride density, high boiling point, and high solvency of oils, waxes, and greases, as well as relatively low cost, make it a popular and effective solvent for many applications (Refs. 1, 77, 78).

The largest uses of PCE, by production volume, are processing as a reactant and as a solvent in dry cleaning and vapor degreasing (Ref. 1). Based on the 2020 Risk Evaluation for PCE, nearly 65% of the production volume of PCE is used as an intermediate in industrial gas

manufacturing and producing fluorinated compounds. The leading fluorocarbons being produced from PCE are HFC-134a and HFC-125, although a small amount of PCE may be used in the production of CFC-113 for applications vital to U.S. security exempted under Title VI of the Clean Air Act Amendments of 1990 (40 CFR part 82), HCFC-123, and HCFC-124. The second largest use of PCE is as a solvent in dry cleaning facilities. PCE effectively dissolves fats, greases, waxes and oils, without harming natural or human-made fibers. However, there appears to be a trend towards alternatives to PCE in dry cleaning and the demand for PCE dry cleaning solvents has steadily declined as a result of the improved efficiency of dry cleaning equipment, increased chemical recycling and the popularity of wash-and-wear fabrics that eliminate the need for dry cleaning (Refs. 79, 1). According to the 2020 Risk Evaluation for PCE, the third largest use of PCE is as a vapor degreasing solvent. PCE can be used to dissolve many organic compounds, select inorganic compounds and high-boiling waxes and resins, making it useful for cleaning contaminated metal parts and other fabricated materials (Ref. 79). Based on market research, EPA understands that use of PCE as a vapor degreasing solvent has declined and estimates there are 88 facilities that use PCE for vapor degreasing nationwide (Ref. 3).

PCE has many other uses, which, based on the 2020 Risk Evaluation for PCE, collectively constitute about 10% of the production volume (Ref. 1). In petrochemical manufacturing, PCE is used as a chloriding agent for reforming and isomerization catalyst process units, which account for approximately 45% of the gasoline pool in the United States (Refs. 66, 63). The high chloride density of PCE minimizes the amount of chemical needed for catalyst regeneration compared to other chloriding agents and the non-flammability is important for process considerations. PCE is also used in maskant for chemical milling, plating, and anodizing processes in the aerospace (military, commercial, and space) and non-aerospace military industries (Ref. 1), as well as in a mission-critical elastomer adhesive used in human-

rated rocket motor assembly (including rocket motor subsystem components such as the rocket motor nozzle assembly) (Ref. 59).

D. Reasonably ascertainable economic consequences of the proposed rule.

1. *Likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health.*

The reasonably ascertainable economic consequences of this proposed rule include several components, all of which are described in the Economic Analysis for this proposed rule (Ref. 3). With respect to the anticipated effects of this proposed rule on the national economy, EPA considered the number of businesses and workers that would be affected and the costs and benefits to those businesses and workers and did not find that there would be an impact on the national economy (Ref. 3). The economic impact of a regulation on the national economy becomes measurable only if the economic impact of the regulation reaches 0.25% to 0.5% of Gross Domestic Product (GDP). Given the current GDP, this is equivalent to a cost of $40 billion to $80 billion. Therefore, because EPA has estimated that the monetized cost of the proposed rule would range from $14.0 million annualized over 20 years at a 3% discount rate and $14.3 million annualized over 20 years at a 7% discount rate, EPA has concluded that this rule is highly unlikely to have any measurable effect on the national economy (Ref. 3). In addition, EPA considered the employment impacts of this proposed rule, and found that the direction of change in employment is uncertain, but EPA expects the short-term and longer-term employment effects to be small.

There are an estimated 12,202 small entities affected by the proposed option with a per firm and total estimated cost impact of $850 and $10.4 million, respectively. Of the small businesses potentially impacted by this proposed rule, over 99% are expected to have impacts of less than 1% to their firm revenues, 0.1% are expected to have impacts between 1 and 3% to

their firm revenues, and 0.2% are expected to have impacts greater than 3% to their firm revenues. EPA estimates that there are currently 6,000 firms currently using PCE dry cleaning machines, but estimates that only 62 would still be using PCE for dry cleaning by the end of the proposed 10-year phaseout. As described further in the Economic Analysis, EPA believes that almost no new PCE machines have been brought into service in recent years and therefore most existing dry cleaning machines using PCE are old and will no longer be in service by the proposed phaseout date. Based on the estimated revenues per firm presented in Table 3-1 of the Economic Analysis and the 6,000 estimated number of dry cleaning firms using PCE as dry cleaning solvent (see Section 6.1.5 (A) of the Economic Analysis), the total revenue for dry cleaning firms using PCE as dry cleaning solvent is approximately $3.1 billion. According to IRS (2013) data, profit in this sector is about 4.8% of sales, implying that total profit of firms using PCE as dry cleaning solvent is about $148 million. However, EPA has proposed a 10-year phaseout of PCE in dry cleaning and estimates that only about 60 PCE dry cleaning machines would remain at the end of the phaseout (see Section 7.7.3. of the Economic Analysis). This suggests that the proposed option would only affect about $31 million of the industry's total revenue and about $1.5 million of the industry's profit. Many of these firms would likely choose to purchase non-PCE machines or become drop shops (do dry cleaning at another site) rather than close. A detailed sensitivity analysis of varying assumptions on ages of PCE dry cleaning machines and PCE dry cleaning machine life is provided in Section 11 of the Economic Analysis. EPA requests comment on these estimated impacts to the dry cleaning industry, including regarding expected closures. In addition to dry cleaners, additional users of PCE (such as in vapor degreasing) could be strongly impacted because they may have no economical alternative to the use of PCE.

With respect to this proposed rule's effect on technological innovation, EPA expects this

rule to spur more innovation than it will hinder. A prohibition or significant restriction on the manufacture, processing, and distribution in commerce of PCE for uses covered in this proposed rule may increase demand for safer chemical substitutes. This proposed rule is not likely to have significant effects on the environment because PCE does not present an unreasonable risk to the environment, though this proposed rule does present the potential for small reductions in air emissions and soil contamination associated with improper disposal of products containing PCE. The effects of this proposed rule on public health are estimated to be positive, due to the reduced risk of cancer and other non-cancer endpoints from exposure to PCE.

2. *Costs and benefits of the proposed regulatory action and of the one or more primary alternative regulatory actions considered by the Administrator.*

The costs and benefits that can be monetized for this proposed rule are described at length in in the Economic Analysis (Ref. 3). The monetized costs for this proposed rule are estimated to range from $14.0 million annualized over 20 years at a 3% discount rate and $14.3 million annualized over 20 years at a 7% discount rate. The monetized benefits are estimated to be $10.2 to $46.3 million annualized over 20 years at a 3% discount rate and $4.72 million to $29.4 million annualized over 20 years at a 7% discount rate. Costs do not include possible additional costs from prohibition of all uses of PCE (except for petrochemical processing) due to need to switch processes or chemicals. EPA requests comment on costs that may be incurred by firms using PCE products to identify suitable alternatives, test them for their desired applications, learn how to use them safely and effectively, and implement new processes for using the alternative products.

EPA considered the estimated costs to regulated entities as well as the cost to administer and enforce alternative regulatory actions. The primary and second alternative regulatory actions are described in detail in Unit IV.B. The estimated annualized costs of the primary alternative

regulatory action are $14.5 million at a 3% discount rate and $14.7 million at a 7% discount rate over 20 years (Ref. 3). The estimated annualized costs of the second alternative regulatory action are $17.8 million at a 3% discount rate and $19.5 million at a 7% discount rate over 20 years. The monetized benefits of the primary alternative action are estimated to be $10.2 to $46.2 million annualized over 20 years at a 3% discount rate and $4.71 million to $29.3 million annualized over 20 years at a 7% discount rate (Ref. 3). The monetized benefits of the second alternative action are estimated to be $10.2 to $46.4 million annualized over 20 years at a 3% discount rate and $4.73 million to $29.4 million annualized over 20 years at a 7% discount rate. Costs of the second alternative action do not include possible additional costs from prohibition of non-petrochemical processing and chemical milling uses of PCE. These costs for chemical milling could be significant as there is no alternative to the use of PCE in chemical milling for many users. For vapor degreasing, as described in the Economic Analysis, EPA assumes that there are alternatives to PCE for all users, although switching to some of these alternatives may be very expensive due to required revalidation and possible equipment changes. At least one user has told EPA that they have no alternative to the use of PCE in closed-loop vapor degreasing and at least one other user has requested a 10-year phaseout for the use of PCE in vapor degreasing due to the needs for revalidation and possible equipment changes throughout the supply chain (Ref. 3).

This proposal is expected to achieve health benefits for the American public, some of which can be monetized and others that, while tangible and significant, cannot be monetized. EPA believes that the balance of costs and benefits of this proposal cannot be fairly described without considering the additional, non-monetized benefits of mitigating the non-cancer adverse effects. These effects may include neurotoxicity, kidney toxicity, liver toxicity, immunological and hematological effects, reproductive effects, and developmental effects. The multitude of

adverse effects from PCE exposure can profoundly impact an individual's quality of life, as discussed in Unit II.A. (overview), III.B.2. (description of the unreasonable risk), VI.A. (discussion of the health effects), and the 2020 Risk Evaluation for PCE. Chronic adverse effects of PCE exposure include both cancer and the non-cancer effects listed above. Acute effects of PCE exposure could be experienced for a shorter portion of life but are nevertheless significant in nature. The incremental improvements in health outcomes achieved by given reductions in exposure cannot be quantified for non-cancer health effects associated with PCE exposure, and therefore cannot be converted into monetized benefits. The qualitative discussion throughout this rulemaking and in the Economic Analysis highlights the importance of these non-cancer effects. These effects include willingness-to-pay to avoid illness, which includes cost of illness and other personal costs such as pain and suffering. Considering only monetized benefits underestimates the impacts of PCE adverse outcomes and therefore underestimates the benefits of this proposed rule.

3. *Cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.*

Cost effectiveness is a method of comparing certain actions in terms of the expense per item of interest or goal. A goal of this proposed regulatory action is to prevent unreasonable risk resulting from exposure to PCE. The proposed regulatory action would cost $3.0 million per potential prevented cancer case while the primary alternative regulatory action would cost $3.1 million (using the 3% discount rate) and the second alternative regulatory action would cost $3.8 million to achieve the same goals. At a 7% discount rate, the proposed regulatory action would cost $3.0 million per potential prevented cancer case while the primary alternative regulatory action would cost $3.1 million, and the second alternative regulatory action would cost $4.2 million to achieve the same goals. While the proposed regulatory action is lower in cost

compared to the other alternative actions, the difference is small (Ref. 3).

VII. TSCA Section 9 Analysis, Section 14, and Section 26 Considerations

A. TSCA section 9(a) analysis.

TSCA section 9(a) provides that, if the Administrator determines, in the Administrator's discretion, that an unreasonable risk may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA, the Administrator must submit a report to the agency administering that other law that describes the risk and the activities that present such risk. Section 9(a) describes additional procedures and requirements to be followed by EPA and the other Federal agency following submission of any such report. As discussed in this unit, for this proposed rule, the Administrator proposes to exercise his discretion not to determine that the unreasonable risk from PCE under the conditions of use may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA.

In addition, 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 burdens of duplicative requirements. For this proposed rule, EPA has and continues to coordinate with appropriate Federal executive departments and agencies, including OSHA and the Consumer Product Safety Commission (CPSC), to, among other things, identify their respective authorities, jurisdictions, and existing laws with regard to PCE, which are summarized in this unit.

OSHA requires that employers provide safe and healthful working conditions by setting and enforcing standards and by providing training, outreach, education and assistance. As described in Unit II.C., OSHA, in 1971, established a PEL for PCE of 100 ppm of air as an 8-hour TWA with an acceptable ceiling concentration of 200 ppm and an acceptable maximum peak above the acceptable ceiling concentration for an eight-hour shift of 300 ppm, maximum

duration of 5 minutes in any 3 hours. However, the exposure limits established by OSHA are higher than the exposure limit that EPA determined would be sufficient to address the unreasonable risk identified under TSCA from occupational inhalation exposures associated with certain conditions of use. Gaps exist between OSHA's authority to set workplace standards under the OSH Act and EPA's obligations under TSCA section 6 to eliminate unreasonable risk presented by chemical substances under the conditions of use. Health standards issued under section 6(b)(5) of the OSH Act must reduce significant risk only "to the extent feasible." 29 U.S.C. 655(b)(5). To set PELs for chemical exposure, OSHA must first establish that the new standards are economically and technologically feasible (79 FR 61384, 61387, Oct. 10, 2014). But under TSCA section 6(a), EPA's substantive burden is to demonstrate that, as regulated, the chemical substance no longer presents an unreasonable risk, with unreasonable risk being determined without consideration of costs or other nonrisk factors. Thus, if OSHA were to initiate a new action to lower its PEL, the difference in standards between the OSH Act and TSCA may well result in the OSHA PEL being set at a higher level than the exposure limit that EPA determined would be sufficient to address the unreasonable risk under TSCA.

In addition, OSHA may set exposure limits for workers, but its authority is limited to the workplace and does not extend to consumer uses of hazardous chemicals, and thus OSHA cannot address the unreasonable risk from PCE under all of its conditions of use, which include consumer uses. OSHA also does not have direct authority over State and local employees, and it has no authority over the working conditions of State and local employees in States that have no OSHA-approved State Plan under 29 U.S.C. 667.

CPSC, under authority provided to it by Congress in the CPSA, protects the public from unreasonable risk of injury or death associated with the use of consumer products. Under the CSPA, CPSC has the authority to regulate PCE in consumer products, but not in other sectors

such as automobiles, industrial and commercial products, or aircraft, for example. Further, 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), whereas EPA must apply TSCA risk management requirements to the extent necessary so that the chemical no longer presents unreasonable risk and only consider costs and benefits of the regulatory action to the extent practicable, 15 U.S.C. 2605(a), (c)(2). Additionally, the 2016 amendments to TSCA reflect Congressional intent to "delete the paralyzing 'least burdensome' requirement," 162 Cong. Rec. S3517 (June 7, 2016), a reference to TSCA section 6(a) as originally enacted, which required EPA to use "the least burdensome requirements" that protect "adequately" against unreasonable risk, 15 U.S.C. 2605(a) (1976). However, a consumer product safety rule under the CPSA must impose "the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated." 15 U.S.C. 2058(f)(3)(F). Analogous requirements, also at variance with recent revisions to TSCA, affect the availability of action CPSC may take under the Federal Hazardous Substances Act (FHSA) relative to action EPA may take under TSCA. 15 U.S.C. 1262.

EPA therefore concludes that TSCA is the only regulatory authority able to prevent or reduce unreasonable risk of PCE to a sufficient extent across the range of conditions of use, exposures and populations of concern. This unreasonable risk can be addressed in a more coordinated, efficient and effective manner under TSCA than under different laws implemented by different agencies. Moreover, the timeframe and any exposure reduction as a result of updating OSHA or CPSC regulations cannot be estimated, while TSCA requires a much more accelerated 2-year statutory timeframe for proposing and finalizing regulatory requirements to address unreasonable risk. Further, there are key differences between the finding requirements of TSCA and those of the OSH Act, CPSA, and FHSA. For these reasons, in the Administrator's

discretion, the Administrator has analyzed this issue and does not determine that unreasonable risk from PCE may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA. However, EPA is requesting public comment on this issue (*i.e.,* the sufficiency of an action taken under a Federal law not administered by EPA).

B. TSCA section 9(b) analysis.

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

Although several EPA statutes have been used to limit PCE exposure (Ref. 6), regulations under those EPA statutes have limitations because they largely regulate releases to the environment, rather than occupational or consumer exposures. While these limits on releases to the environment are protective in the context of their respective statutory authorities, regulation under TSCA is also appropriate for occupational and consumer exposures and in some cases can provide upstream protections that would prevent the need for release restrictions required by other EPA statutes (e.g., Resource Conservation and Recovery Act (RCRA), CAA, Clean Water Act (CWA)).

The primary exposures and unreasonable risk to consumers, bystanders, workers, and ONUs would be addressed by EPA's proposed prohibitions and restrictions under TSCA section

6(a). In contrast, the timeframe and any exposure reduction as a result of updating regulations for PCE under the CAA, CWA, or RCRA cannot be estimated, nor would they address the direct human exposure to consumers, bystanders, workers, and ONUs from the conditions of use evaluated in the 2020 Risk Evaluation for PCE. More specifically, none of EPA's other statutes (e.g., RCRA, CAA, CWA) can address exposures to workers and ONUs related to the specific activities that result in occupational exposures, for example those associated with RCRA covered disposal requirements. EPA therefore concludes that TSCA is the most appropriate regulatory authority able to prevent or reduce risks of PCE to a sufficient extent across the range of conditions of use, exposures, and populations of concern.

For these reasons, the Administrator does not determine that unreasonable risk from PCE under the conditions of use evaluated in the 2020 TSCA Risk Evaluation for PCE could be eliminated or reduced to a sufficient extent by actions taken under other Federal laws administered in whole or in part by EPA.

C. TSCA section 14 requirements.

EPA is also providing notice to manufacturers, processors, and other interested parties about potential impacts to CBI that may occur if this rule is finalized as proposed. Under TSCA section 14(b)(4), if EPA promulgates a rule pursuant to TSCA section 6(a) that establishes a ban or phase-out of a chemical substance, the protection from disclosure of any CBI regarding that chemical substance and submitted pursuant to TSCA will be "presumed to no longer apply," subject to the limitations identified in TSCA section 14(b)(4)(B)(i) through (iii). If this rule is finalized as proposed, then pursuant to TSCA section 14(b)(4)(B)(iii), the presumption against protection from disclosure would apply only to information about the specific conditions of use that this rule would prohibit or phase out. Manufacturers or processors seeking to protect such information would be able to submit a request for nondisclosure as provided by TSCA sections

14(b)(4)(C) and 14(g)(1)(E). Any request for nondisclosure would need to be submitted within 30 days after receipt of notice from EPA under TSCA section 14(g)(2)(A). EPA anticipates providing such notice via the Central Data Exchange or CDX.

D. TSCA section 26 considerations.

In accordance with TSCA section 26(h), EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science. As in the case of the unreasonable risk determination, risk management decisions for this proposed rule, as discussed in Unit III.B.3. and Unit V., were based on a risk evaluation that was subject to public comment and independent, expert peer review, and was developed in a manner consistent with the best available science and based on the weight of the scientific evidence as required by TSCA sections 26(h) and (i) and 40 CFR 702.43 and 702.45.

In particular, the ECEL value incorporated into the WCPP and de minimis concentration limit are derived from the analysis in the 2020 Risk Evaluation for PCE; they likewise represent decisions based on the best available science and the weight of the scientific evidence (Refs. 10, 45, 53). The ECEL value of 0.14 ppm as an 8-hour TWA is based on the chronic non-cancer HEC for neurotoxicity identified in the 2020 Risk Evaluation for PCE, which is the concentration at which an adult human would be unlikely to suffer adverse effects if exposed for a working lifetime, including susceptible subpopulations. As discussed in Unit V.A.1., EPA used models from the 2020 Risk Evaluation for PCE to derive the proposed de minimis concentration limit, which represents a level below which EPA would not expect product use to drive unreasonable risk.

The extent to which the various information, procedures, measures, methods, protocols, methodologies or models, as applicable, used in EPA's decisions have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record

for this rule. Additional information on the peer review and public comment process, such as the peer review plan, the peer review report, and the Agency's response to comments, can be found in EPA's risk evaluation docket (Docket ID No.: EPA-HQ-OPPT-2016-0732).

VIII. Requests for Comment

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

1. EPA is requesting public comment on all elements of the proposed regulatory action and the alternative regulatory actions.

2. EPA is requesting public comment regarding the need for exemptions from the rule (and under what specific circumstances), including exemptions from the proposed regulatory action (e.g., a WCPP) and the primary and second alternative regulatory actions, pursuant to the provisions of TSCA section 6(g).

3. EPA requests comment on all elements of the IRFA, and, in particular, the flexibilities that EPA has identified following input from the SERs during the SBAR process.

4 EPA requests comment on whether EPA should promulgate definitions for the conditions of use covered by the 2020 Risk Evaluation for PCE that would not be prohibited, and, if so, whether the descriptions in this unit are consistent with the conditions of use evaluated in the 2020 Risk Evaluation for PCE and whether they provide a sufficient level of detail to improve the clarity and readability of the regulation.

5. EPA requests comment on the impacts, if any, a prohibition on the processing of PCE into a formulation, mixture or reaction product in other chemical products and preparations, or

other aspects of this proposal, may have on the production and availability of any pesticide or other substance excluded from the TSCA definition of "chemical substance."

6. EPA requests comment regarding the number of businesses or other entities that could potentially close as well as associated costs with a prohibition of PCE for certain industrial and commercial conditions of use identified in this unit.

7. EPA requests comment on the proposed compliance dates for prohibitions of PCE manufacturing, processing, distribution in commerce, and use and whether additional time is needed, for example, for products to clear the channels of trade, or for implementing the use of substitutes; comments should include documentation such as the specific use of the chemical throughout the supply chain; concrete steps taken to identify, test, and qualify substitutes for those uses (including details on the substitutes tested and the specific certifications that would require updating); and estimates of the time required to identify, test, and qualify substitutes with supporting documentation. EPA also requests comment on whether these are the appropriate types of information for use in evaluating compliance requirements, and whether there are other considerations that should apply.

8. EPA requests comment on the amount of time needed, for example, for dry cleaners to transition to an alternative process or solvent. EPA also requests comment regarding the number of entities that could potentially close as well as associated costs with a 10-year phaseout of PCE for use in dry cleaning as identified in this unit.

9. EPA requests comment on allowing a de minimis level of PCE in products (i.e., concentrations less than 0.1% by weight) to account for impurities.

10. EPA is soliciting comment regarding an ECEL action level that is half the ECEL and any associated provisions related to the ECEL action level when the ECEL is significantly lower than the OSHA PEL.

11. EPA is requesting comment on issues around the viability of current analytical methods and detection limits for occupational perchloroethylene sampling and/or monitoring methods.

12. EPA is soliciting comments regarding the timing of the initial exposure monitoring so that it would be representative of all tasks involving PCE where exposures may approach the ECEL. EPA is also soliciting comments regarding use of area sampling instead of personal breathing zone as a representative sample of exposures.

13. EPA requests comment on the timeframes for periodic monitoring outlined in Table 1 of this unit.

14. EPA is soliciting comment on requiring warning signs to demarcate regulated areas, such as the requirements found in OSHA's General Industry Standard for Beryllium.

15. EPA requests comment on available methods to measure the effectiveness of engineering and administrative controls in preventing or reducing the potential for direct dermal contact to PCE. EPA is also requesting comment on available monitoring methods, such as charcoal patch testing, as feasible or effective methods to measure potential direct dermal contact with PCE.

16. EPA is requesting comment on whether there should be a requirement to replace cartridges or canisters after a certain number of hours, such as the requirements found in OSHA's General Industry Standard for 1,3-Butadiene, or a requirement for a minimum service life of non-powered air-purifying respirators such as the requirements found in OSHA's General Industry Standard for Benzene.

17. EPA is soliciting comments on the requirements proposed for appropriate PPE selection, the effectiveness of PPE in preventing direct dermal contact with PCE in the workplace, and general absorption and permeation effects to PPE from direct dermal exposure.

In addition, EPA understands that some workplaces rinse and reuse PPE after minimal use and is therefore soliciting comments on the impact on effectiveness of rinsing and reusing certain types of PPE, either gloves or protective clothing and gear. EPA also requests comment on the degree to which additional guidance related to use of PPE might be appropriate.

18. EPA is requesting comment on how owners and operators can engage with potentially exposed persons on the development and implementation of an exposure control plan and PPE program.

19. EPA requests comment relative to the ability of owners or operators to conduct initial monitoring within 6 months after date of publication of the final rule in the *Federal Register*, and anticipated timelines for any procedural adjustments needed to comply with the requirements outlined in this unit, including establishment of a respiratory protection program and development of an exposure control plan. EPA also requests comment relative to the ability of owners or operators to implement processes for occupational conditions of use which are subject to DDCC requirements within 12 months of publication of the final rule in the *Federal Register*, and anticipated timelines for any procedural adjustments needed to comply with the requirements outlined in this unit.

20. EPA requests comment on whether it should incorporate in the rule best practices to ensure proper and adequate performance of laboratory fume hoods, such as those identified in OSHA's 29 CFR 1910.1450, Appendix A National Research Council Recommendations Concerning Chemical Hygiene in Laboratory. Additionally, EPA requests comment relative to the ability of owners or operators to implement laboratory chemical fume hood and dermal PPE related requirements within 12 months of publication of the final rule, and anticipated timelines for any procedural adjustments needed to comply with the requirements outlined in this unit.

21. EPA requests comments on the appropriateness of identified compliance timeframes

for recordkeeping and downstream notification requirements described in this unit.

22. EPA requests comment on the primary alternative regulatory action (a combination of prohibitions, requirements for a WCPP, and prescriptive controls) and whether any elements of this primary alternative regulatory action described in this unit should be considered as EPA develops the final regulatory action. In particular, EPA is requesting comment on the likelihood of successful compliance with a PCE WCPP, as described in Unit IV.A., for the conditions of use listed for the primary alternative regulatory action of PCE WCPP in Unit IV.B. Further, EPA is soliciting comment on prescribing specific engineering or administrative controls that would reduce inhalation and dermal exposures enough to address the unreasonable risk across all workplaces engaged in a condition of use. EPA also requests comment on any advantages or drawbacks for the timelines outlined in this unit compared to the timelines identified for the proposed regulatory action in Unit IV.A.

23. EPA requests comment on the ways in which PCE may be used in the conditions of use for which the primary alternative regulatory action would require a WCPP, including whether activities may take place in a closed system and the degree to which users of PCE in these sectors could successfully implement an ECEL, DDCC, and ancillary requirements described in Unit IV.A. For the industrial and commercial use in laboratory chemicals, EPA is soliciting comment on non-prescriptive requirements of an ECEL and DDCC as compared to the prescriptive workplace controls of fume hood and dermal PPE EPA is proposing in Unit IV.A.3.

24. Regulated entities would be required to implement an exposure control plan within 18 months after date of publication of the final rule in the *Federal Register*. EPA requests comment on any advantages or drawbacks for the timelines outlined in this unit compared to the timelines identified for the proposed regulatory action in Unit IV.A.

25. EPA is soliciting comment on prescribing specific dermal PPE, such as gloves, for

each condition of use that should be considered as EPA develops the final regulatory action. Additionally, EPA is soliciting comment on prescribing specific respirators or APFs for respirators for each condition of use that should be considered as EPA develops the final regulatory action.

26. EPA is requesting comment on specific controls that mitigate the unreasonable risk from PCE and that could be included as part of a prescriptive workplace controls requirement, which could be considered as EPA develops the final regulatory action. Specifically, EPA is soliciting comment on combinations of specific engineering controls, administrative controls, and PPE that would reduce inhalation exposures to at or below the ECEL of 0.14 ppm as an 8-hour TWA or prevent direct dermal contact with PCE for all workplaces where such controls would be required. EPA also is soliciting comment on the extent to which such requirements could reduce inhalation exposures to at or below the ECEL of 0.014 ppm as an 8-hour TWA. Additionally, EPA is requesting comment on the compliance timeframe needed to implement engineering controls, administrative controls, and PPE that reduce inhalation exposures to at or below the ECEL of 0.14 ppm as an 8-hour TWA or prevent direct dermal contact with PCE for all regulated entities.

27. EPA requests comment on a combination of the 1% concentration limit for adhesives and sealants with specific engineering controls, administrative controls, or respiratory protection that would reduce inhalation exposures to PCE at or below the ECEL of 0.14 ppm as an 8-hour TWA. Additionally, EPA is requesting comment on a combination of a concentration limit with WCPP requirements. EPA also requests monitoring data, formulations used, and detailed descriptions of PCE involving activities for the industrial and commercial use in solvent-based adhesives and sealants to determine whether a concentration limit would reduce inhalation exposures such that risks are no longer unreasonable.

28. EPA requests comment on the second alternative regulatory action (a combination of prohibition and a WCPP) and whether any elements of this second alternative regulatory action described in this unit should be considered as EPA develops the final regulatory action. EPA also requests comment on any advantages or drawbacks for the timelines outlined in this unit compared to the timelines identified for the proposed regulatory action in Unit IV.A.

29. EPA requests comments on all aspects of the section 6(g) exemption from the prohibition on industrial and commercial use of PCE in maskant for chemical milling as part of the second alternative regulatory option, including information on the extent to which the industry could meet the requirements of the proposed WCPP or prescriptive controls and whether compliance with specific elements of the proposed WCPP should also be required during the period of the exemption.

30. EPA requests comments on all aspects of the exemption request and proposed exemption from the prohibition on use of PCE in vapor degreasing as part of the second alternative regulatory action, including information on the extent to which this industry could meet the requirements of the proposed WCPP or prescriptive controls and whether compliance with specific elements of the proposed WCPP should also be required during the period of the exemption.

31. EPA is requesting comment on whether to consider a regulatory alternative that would subject more conditions of use to a WCPP, instead of prohibition, than those currently contemplated in the primary alternative regulatory action. EPA also requests monitoring data and detailed descriptions of PCE involving activities for these conditions of use to determine whether these additional conditions of use could comply with the WCPP such that risks are no longer unreasonable.

32. EPA is requesting comment on whether vapor degreasing of parts and components for

non-aerospace applications should also be exempt from prohibition as part of the second alternative regulatory action for the industrial and commercial use of PCE in vapor degreasing. To facilitate EPA's consideration of exemptions for other sectors, comments in support of additional exemptions should include detailed explanations of why and how long exemptions would be needed.

33. EPA is soliciting comment on whether it should specify the type of vapor degreasing operation, such as closed loop batch vapor degreasing, that would be exempt from prohibition as part of the second alternative regulatory action for the industrial and commercial use of PCE in vapor degreasing for aerospace parts and whether it should consider different exemption timeframes for different types of vapor degreasing operations.

34. Each owner or operator would be required to provide respiratory protection to all potentially exposed persons in the regulated area within 3 months after receipt of the results of any exposure monitoring or within 6 months after date of publication of the final rule in the *Federal Register*. Regulated entities would be required to implement an exposure control plan within 9 months after date of publication of the final rule in the *Federal Register*. EPA requests comment on any advantages or drawbacks for the timelines outlined in this unit compared to the timelines identified for the proposed regulatory action in Unit IV.A.

35. EPA is requesting comment on the de minimis concentration limit of PCE in products or formulations.

36. EPA is requesting comment on the extent to which facilities engaged in the industrial and commercial use of PCE as a processing aid in catalyst regeneration in petrochemical manufacturing may already meet the requirements in the proposed and alternative regulatory actions described in Unit IV. to address the unreasonable risk and is soliciting comment on the impact of such requirements on petroleum refining, with special attention to the price of

gasoline.

37. EPA is requesting comment on whether preventing dermal contact with PCE through dermal PPE and training would adequately address the unreasonable risk from dermal exposures for the industrial and commercial use in laboratory chemicals.

38. EPA is requesting comment on whether to include a self-certification requirement for purchasing PCE or PCE-containing products.

39. As part of the primary alternative regulatory action, EPA is soliciting comment on prescribing specific engineering or administrative controls that would reduce inhalation and dermal exposures enough to address the unreasonable risk across all workplaces engaged in a condition of use.

40. EPA is soliciting comments on whether, for those product types relevant to industrial, commercial, and consumer conditions of use proposed to be prohibited or significantly restricted where EPA was unable to identify products currently available for sale that contain PCE, there are products in use or available for sale relevant to these conditions of use that contain PCE at this time, so that EPA can ascertain whether there are alternatives that benefit human health or the environment as compared to such use of PCE.

41. EPA is requesting comment on the Alternatives Assessment as a whole.

42. EPA requests comment on whether owners and operators should be required to attest to whether and why the exposure controls they have selected would not result in increased air releases of PCE from the workplace, and keep records of that statement as part of the WCPP exposure control plan.

43. EPA is requesting comment on the estimated economic impacts to the dry cleanining industry, including regarding expected closures.

44. EPA is requesting public comment on an issue raised in its TSCA Section 9(a)

Analysis (*i.e.,* the sufficiency of an action taken under a Federal law not administered by EPA).

45. EPA requests comments on whether it should incorporate in the rule voluntary consensus standards that meet specified performance criteria for environmental monitoring or measurement and seeks information in support of such comments regarding the availability and applicability of voluntary consensus standards that may achieve the sampling and analytical requirements of the rule in lieu of the proposed approach.

46. Following Panel report recommendations (Ref. 33) and in response to input provided by SERs, EPA is requesting comment on the following topics as outlined in the SBAR Panel Report:

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

• EPA requests comment on the methodology and inputs for the ECEL value that are directly derived from the peer reviewed analysis in the December 2020 Risk Evaluation.

• EPA requests comment on reasonable compliance timeframes for small businesses.

• EPA requests comment on differing compliance or reporting requirements or timetables that account for the resources available to small entities.

• EPA requests public comment on specific compliance timeframes for the laundry industry.

• EPA requests comment on any additional appropriate factors for identifying reasonable compliance timeframes and how to weigh the factors for dry cleaning and other industries.

• EPA requests public comment about the feasibility of entities complying with and monitoring for a potential ECEL of 0.14 ppm. Specifically, EPA aims to obtain more

information on potential costs that could be incurred using strategies to meet the requirements of such a standard, such as engineering, administrative, or prescriptive controls and how feasible it would be for entities to implement these strategies in their operations.

• EPA requests public comment about the feasibility of the use of alternatives to PCE and their availability for conditions of use that drive the unreasonable risk.

• EPA requests public comment on the consideration for a TSCA section 6(g) exemption and alternative compliance timeframes for dry cleaning, including information on whether the specific use may be critical or essential, why alternatives may not be feasible for this condition of use, and the ideal time limit for an exemption.

IX. References

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

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X. Statutory and Executive Order Reviews

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

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is a "significant regulatory action", as defined under section 3(f)(1) of Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023). Accordingly, EPA submitted this action to OMB for Executive

Order 12866 review. Documentation of any changes made in response to the Executive Order 12866 review is available in the docket. EPA prepared an economic analysis (Ref. 3) of the potential costs and benefits associated with this action, which is also available in the docket and summarized in Unit VI.D.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted to OMB for review and comment under the PRA, 44 U.S.C. 3501 *et seq*. The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR No. 2740.01 (Ref. 80). You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

There are two primary provisions of the proposed rule that may increase burden under the PRA. The first is downstream notification, which would be carried out by updates to the relevant SDS and which would be required for manufacturers, processors, and distributors in commerce of PCE, who would provide notice to companies downstream upon shipment of PCE about the prohibitions. The information submitted to downstream companies through the SDS would provide knowledge and awareness of the restrictions to these companies. The second primary provision of the proposed rule that may increase burden under the PRA is WCPP-related information generation, recordkeeping, and notification requirements (including development of exposure control plans; exposure level monitoring and related recordkeeping; development of documentation for a PPE program and related recordkeeping; development of documentation for a respiratory protection program and related recordkeeping; development and notification to potentially exposed persons (employees and others in the workplace) about how they can access the exposure control plans, exposure monitoring records, PPE program implementation documentation, and respirator program documentation; and development of documentation demonstrating eligibility for an exemption from the proposed prohibitions, and related

recordkeeping).

Respondents/affected entities: Persons that manufacture, process, use, distribute in commerce, or dispose of PCE or products containing PCE. See also Unit I.A.

Respondent's obligation to respond: Mandatory (TSCA section 6(a) and 40 CFR part 751).

Estimated number of respondents: 12,091.

Frequency of response: On occasion.

Total estimated burden: 64,622 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $7,625,325 (per year), includes $2,753,517 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. After display in the ***Federal Register*** when approved, the OMB control numbers for certain EPA regulations in title 40 of the CFR are listed in 40 CFR part 9 and displayed on the form and instructions or collection portal, as applicable.

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

C. Regulatory Flexibility Act (RFA)

As required by section 609(b) of the RFA, EPA convened a SBAR Panel to obtain advice and recommendations from SERs 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 initial regulatory flexibility analysis (IRFA). A copy of the full SBAR Panel Report (Ref. 33) is available in the rulemaking docket.

Pursuant to section 603 of the RFA, 5 U.S.C. 601 *et seq*., EPA prepared an IRFA (Ref. 34) that examines the impact of the proposed rule on small entities along with regulatory alternatives that could minimize that impact. The complete IRFA is available for review in the docket and is summarized here.

1. *Need for the rule.*

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines after a TSCA section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a PESS identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements listed in TSCA section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents such risk. PCE was the subject of a risk evaluation under TSCA section 6(b)(4)(A) that was issued in December 2020. In addition, in December 2022, EPA issued a revised unreasonable risk determination that PCE as a whole chemical substance presents an unreasonable risk of injury to health under the conditions of use. As a result, EPA is proposing to take action to the extent necessary so that PCE no longer presents such risk.

2. *Objectives and legal basis.*

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines through a TSCA

section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must by rule apply one or more requirements listed in section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents such risk. EPA has determined through a TSCA section 6(b) risk evaluation that PCE presents an unreasonable risk under the conditions of use.

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

The proposed rule potentially affects small manufacturers (including importers), processors, distributors, retailers, users of PCE or of products containing PCE, and entities engaging in disposal. EPA estimates that the proposal would affect approximately 12,202 small entities. Almost half (5,949) of these entities are commercial users of PCE in dry cleaning applications. Users of products containing PCE, including adhesives and sealants, aerosol cleaners/degreasers, liquid cleaners/degreasers, mold cleaners, and other products also account for about half of the affected small entities. EPA also estimates that 69 small entities use PCE in chemical milling, 88 use PCE in recycling and disposal, and 30 incorporate PCE into other formulations, mixtures, and reaction products.

4. *Projected compliance requirements.*

To address the unreasonable risk EPA has identified, EPA is proposing to: prohibit most industrial and commercial uses and the manufacture (including import), processing and distribution in commerce, of PCE for those uses; prohibit the manufacture (including import), processing, and distribution in commerce of PCE for all consumer use; prohibit the manufacture (including import), processing, distribution in commerce, and use of PCE in dry cleaning and related spot cleaning through a 10-year phaseout; require a PCE WCPP, which would include requirements to meet an inhalation exposure concentration limit and prevent direct dermal contact, for certain conditions of use not prohibited; require prescriptive workplace controls for

laboratory use; and establish recordkeeping and downstream notification requirements. There are an estimated 12,189 small entities affected by the proposed option with a per firm cost of $715 with a total estimated cost impact of $8.7 million. This includes $6.7 million for WCPP uses, $1.9 million for uses that are prohibited, and $0.1 million for lab uses.

EPA is proposing to prohibit most conditions of use. For most other conditions of use that drive the unreasonable risk determination for PCE, EPA proposes to address the unreasonable risk with a PCE WCPP, which would include a combination of requirements to address unreasonable risk driven by inhalation and dermal exposures in the workplace. A PCE WCPP would encompass restrictions on certain occupational conditions of use and could include provisions for an ECEL, DDCC, and ancillary requirements to support implementation of these restrictions. Due to the low exposure level and stringent requirements in the PCE WCPP that would be necessary to address the unreasonable risk from PCE, EPA identified only a relatively small number of conditions of use where the Agency expected a PCE WCPP could be successfully implemented.

As described in Unit IV.A., the PCE WCPP would be non-prescriptive, in the sense that regulated entities would not be required to use specific controls prescribed by EPA to achieve the exposure concentration limit. Rather, it would be a performance-based exposure limit that would enable owners or operators to determine how to most effectively meet the exposure limit based on conditions at their workplace.

A central component of the PCE WCPP is the exposure limit. Exposures remaining at or below the ECEL would address any unreasonable risk of injury to health driven by inhalation exposures for occupational conditions of use. EPA's proposed requirements include the specific exposure limits that would be required to meet the TSCA section 6(a) standard to apply one or more requirements to the substance so that it no longer presents unreasonable risk, and also

include ancillary requirements necessary for the ECEL's successful implementation as part of a WCPP.

EPA is not proposing reporting requirements beyond downstream notification (third-party notifications). Regarding recordkeeping requirements, three primary provisions of the proposed rule relate to recordkeeping. The first is recordkeeping of general records: all persons who manufacture, process, distribute in commerce, or engage in industrial or commercial use of PCE or PCE-containing products must maintain ordinary business records, such as invoices and bills-of-lading related to compliance with the prohibitions, restrictions, and other provisions of the regulation.

The second is recordkeeping related to WCPP compliance: under the proposed regulatory action, facilities complying with the rule through WCPP would be required to develop and maintain records associated with ECEL exposure monitoring (including measurements, compliance with Good Laboratory Practice Standards, and information regarding monitoring equipment); ECEL compliance (including the exposure control plan, PPE program implementation, and workplace information and training); DDCC compliance (including the exposure control plan, PPE program implementation, basis for specific PPE selection, occurrence and duration of direct dermal contact with PCE, and workplace information and training); and workplace participation. To support and demonstrate compliance, EPA is proposing that each owner or operator of a workplace subject to the WCPP retain compliance records for five years.

EPA is also proposing to require specific prescriptive controls for the industrial and commercial use of PCE in laboratory chemicals. To reduce exposures in the workplace and address the unreasonable risk of injury to health resulting from dermal exposures to PCE identified for the industrial and commercial use as a laboratory chemical, EPA is proposing to require dermal PPE in combination with comprehensive training for tasks particularly related to the use of PCE in a laboratory setting for each potentially exposed person to direct dermal

contact with PCE. Additionally, EPA is proposing to require the use of fume hoods in workplaces engaged in the laboratory chemical condition of use. To support and demonstrate compliance, EPA is proposing that each owner or operator of a laboratory workplace subject to the workplace controls for laboratory use requirements retain compliance records for five years.

a. *Classes of small entities subject to the compliance requirements.*

The small entities that would be potentially directly regulated by this rule are small entities that manufacture (including import), process, distribute in commerce, use, or dispose of PCE, including retailers of PCE for end-consumer uses.

b. *Professional skills needed to comply.*

Entities that would be subject to this proposal that manufacture (including import), process, or distribute PCE in commerce for consumer use would be required to cease under the proposed rule. The entity would be required to modify their SDS or develop another way to inform their customers of the prohibition on manufacture, processing, and distribution of PCE for consumer use. They would also be required to maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with the prohibitions, restrictions, and other provisions of this proposed regulation. These are all routine business tasks that do not require specialized skills or training.

Entities that use PCE in any industrial and commercial capacity that is prohibited would be required to cease under the proposed rule. Restriction or prohibition of these uses will likely require the implementation of an alternative chemical or the cessation of use of PCE in a process or equipment that may require persons with specialized skills, such as engineers or other technical experts. Instead of developing an alternative method themselves, commercial users of PCE may choose to contract with another entity to do so.

Entities that would be permitted to continue to manufacture, process, distribute, use (with

the exception for use as a laboratory chemical), or dispose of PCE would be required to implement a WCPP and would have to meet the provisions of the program for continued use of PCE. Entities that would be permitted to continue use of PCE as a laboratory chemical would be required to implement prescriptive workplace controls for laboratory use and would have to meet the provisions of the workplace restrictions for continued use of PCE. A transition to a WCPP or prescriptive workplace controls for laboratory use may require persons with specialized skills such as an engineer or health and safety professional. Instead of implementing the WCPP or workplace controls for laboratory use themselves, entities that use PCE may choose to contract with another entity to do so. Records would have to be maintained for compliance with a WCPP or workplace controls for laboratory use, as applicable. While this recording activity itself may not require a special skill, the information to be measured and recorded may require persons with specialized skills such as an industrial hygienist.

5. Relevant federal rules.

Because of its health effects, PCE is subject to numerous state, federal, and international regulations restricting and regulating its use. The following is a summary of the regulatory actions pertaining to PCE; for a full description see appendix A of the 2020 Risk Evaluation for PCE and the summary in the docket (Ref. 6).

EPA has issued numerous rules and notices pertaining to PCE under its various authorities. PCE is a hazardous air pollutant under the CAA (42 U.S.C. 7412(b)(1)). EPA promulgated NESHAP for a number of source-specific categories that emit PCE, including dry cleaning (40 CFR part 63, subpart M) and halogenated solvent cleaning (40 CFR part 63, subpart T).

With this proposed rule under TSCA section 6, certain uses and emissions already regulated under these NESHAP would be prohibited while other uses would be subject to a

WCPP.

Programs within EPA implementing other environmental statutes, including, but not limited to, the RCRA, the Comprehensive Environmental Response, Compensation, and Liability Act, the Safe Drinking Water Act, and the CWA, classify PCE as a characteristic and listed hazardous waste (40 CFR 261.24, 40 CFR 261.31, 40 CFR 261.33), a hazardous substance (40 CFR 302.4), a contaminant subject to National Primary Drinking Water Regulations (40 CFR 141.61), and a toxic pollutant (40 CFR 401.15, 40 CFR part 423 Appendix A, 40 CFR 131.36) or the program requires reportable criteria of releases into the environment involving PCE. While TSCA shares equity in the regulation of PCE, EPA does not anticipate this rule to duplicate nor conflict with the aforementioned programs' classifications and associated rules.

In addition to EPA actions, PCE is also subject to other Federal regulations. Under the OSH Act, OSHA established the PEL for PCE at 100 ppm as an 8-hour TWA with an acceptable ceiling concentration of 200 ppm and an acceptable maximum peak above the acceptable ceiling concentration for an 8-hour shift of 300 ppm, maximum duration of 5 minutes in any 3 hours. However, EPA recognizes that the existing PEL does not eliminate the unreasonable risk identified by EPA under TSCA, and EPA is therefore proposing to apply new, lower exposure thresholds, derived from the TSCA 2020 Risk Evaluation for PCE, while aligning with existing OSHA requirements where possible. For PCE, this approach would eliminate the unreasonable risk driven by certain conditions of use, reduce burden for complying with the regulations, and provide the familiarity of a pre-existing framework for the regulated community.

Under the FHSA, visual novelty devices containing PCE are regulated by the CPSC (16 CFR 1500.83(a)(31)). Under the FFDCA, the Food and Drug Administration regulates PCE in bottled water and set the maximum permissible level of PCE in bottled water to 0.005 mg/L (21 CFR 165.110). Under the Atomic Energy Act, the Department of Energy Worker Safety and

Health Program requires its contractor employees to use the 2005 ACGIH TLV for PCE, which is 25 ppm (8-hour TWA) and 100 ppm Short Term Exposure Limit. Under the Federal Hazardous Material Transportation Act, the Department of Transportation has designated PCE as a hazardous material, and there are special requirements for marking, labeling, and transporting it (49 CFR part 171, 49 CFR part 172, 40 CFR 173.202, and 40 CFR 173.242).

6. *Significant alternatives to the proposed rule.*

EPA analyzed alternative regulatory approaches to identify which would be feasible, reduce burden to small businesses, and achieve the objective of the statute (i.e., applying one or more requirements listed in TSCA section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents an unreasonable risk). As described in more detail in Unit V., EPA considered several factors, in addition to identified unreasonable risk, when selecting among possible TSCA section 6(a) requirements. To the extent practicable, EPA factored into its decisions: the effects of PCE on health and the environment, the magnitude of exposure to PCE of human beings and the environment, the benefits of PCE for various uses, and the reasonably ascertainable economic consequences of the rule. EPA also considered input provided by the SERs in selecting among possible TSCA section 6(a) requirements as part of the proposed regulatory action and alternative regulatory actions, particularly as it related to dry cleaners' compliance timeframes. Overall, EPA expects few dry cleaning facility closures because EPA estimates that only about 60 PCE machines are expected to be in use at the end of the proposed phaseout period, based on SER input and given the age of the machines and the declining trend of use. Additionally, as s part of this analysis, EPA considered – in addition to prohibition, WCPP, and prescriptive controls described earlier – a wide variety of control measures to address the unreasonable risk from PCE such as weight fractions and a point-of-sale self-certification requirement. EPA's analysis of these risk management approaches is detailed in

Unit V.A.3. In general, EPA determined that these approaches alone would either not be able to address the unreasonable risk, or, in the case of a weight fraction limit, would result in a product containing so little PCE that it would have the effect of a prohibition.

Weight Fractions: As discussed in Unit V.A.3., EPA considered limiting the weight fraction of PCE in industrial/commercial and consumer products and conducted an analysis to estimate to what extent this would reduce risks from conditions of use that drive the unreasonable risk for PCE. EPA determined that the unreasonable risk from PCE would not be driven by use of products containing PCE at less than 0.1% by weight. Therefore, EPA is proposing a de minimis level for products containing PCE at levels of less than 0.1% to account for impurities that do not drive the unreasonable risk., as described in Unit IV.A.1.d. For most industrial/commercial and consumer conditions of use, the weight fraction or concentration identified through this modeling that would address the unreasonable risk through inhalation or dermal pathways was so low that it was highly unlikely that PCE would still serve its functional purpose in the formulation. EPA thus concluded that a weight fraction limit would essentially function as a prohibition yet with a greater amount of uncertainty regarding compliance and no increased benefit to users; it was therefore not a preferred option. For the industrial and commercial use in solvent-based adhesives and sealants, EPA identified several products available on the market at concentrations of PCE between 0.1% and 1% by weight in the 2020 Risk Evaluation for PCE. As part of the primary alternative regulatory action, EPA would set a concentration limit of PCE in adhesive and sealant products for industrial and commercial use to 1%, as described in Unit IV.B.1.c.

Point-of-sale self-certification: As discussed in Unit V.A.3., EPA also examined the extent to which a point-of-sale self-certification requirement in order to purchase and subsequently use PCE would further ensure that only facilities able to implement and comply

with a WCPP or prescriptive controls are able to purchase and use PCE, and self-certify to that. Under a self-certification requirement, entities would submit a self-certification to the distributor or retailer each time PCE is purchased. The self-certification would consist of a statement indicating that the facility is implementing a WCPP or required prescriptive controls to control exposures to PCE; the self-certification would be signed and presented by a person authorized to do so by the facility owner or operator. Copies of the self-certification would be maintained as records by both the owner or operator and the distributor or retailer where PCE was purchased. However, because of the number and types of entities where users can obtain PCE or PCE-containing products, EPA does not believe the added requirement and subsequent burden of a point-of-sale self-certification requirement for the use of PCE would be an effective tool for preventing facilities that may be unable to comply with the WCPP or prescriptive controls of this proposed rulemaking from accessing PCE or PCE-containing products. As such, EPA is not proposing a self-certification requirement as an additional component of the requirements for addressing the unreasonable risk of occupational exposures to PCE.

Prescriptive controls: As discussed in Unit V.A.1., EPA considered prescriptive controls (i.e., engineering or administrative controls, or PPE) and has determined that prescriptive controls may not be able to eliminate unreasonable risk for some conditions of use when used in isolation. In the 2020 Risk Evaluation for PCE, analysis of occupational exposure scenarios (OES) indicated that many conditions of use still posed risk concerns even with the application of respirators with APF 25 or 50. Because of the uncertainty regarding the feasibility of exposure reductions through engineering controls alone, EPA determined that a PCE WCPP ECEL, which would be accompanied by monitoring requirements in tandem with the implementation of engineering controls, administrative controls, and/or PPE as elements of the program, as appropriate, would more successfully reduce exposure so that the unreasonable risk is addressed.

Additionally, relying primarily on respirators and gloves to reduce exposures does not consider other more protective controls in the hierarchy, including elimination, substitution, engineering controls, and administrative controls. For occupational conditions of use where compliance with the PCE WCPP ECEL and DDCC is unlikely to be successful, in most cases prohibitions (rather than prescribed controls) would be more appropriate to ensure that PCE does not present unreasonable risk under the conditions of use. EPA is proposing prescriptive workplace controls for laboratory use to codify assumptions made in the 2020 Risk Evaluation for PCE regarding the use of fume hoods in laboratory settings and because EPA has preliminarily determined that chemically resistant gloves in combination with specific activity training for tasks where dermal exposure can be expected to occur in laboratory settings would address the unreasonable risk resulting from dermal exposures. Additionally, as part of the primary alternative regulatory action, EPA includes certain prescriptive controls (PPE in combination with monitoring, regulated area, and training) for conditions of use for which EPA is proposing WCPP as the regulatory action.

As indicated by this overview, and detailed in Unit V.A, in the review of alternatives, EPA determined that some methods either did not effectively eliminate the unreasonable risk presented by PCE or, for many conditions of use, there was a high degree of uncertainty regarding whether compliance with a comprehensive WCPP or prescriptive controls would be possible to adequately protect potentially exposed persons. The primary alternative regulatory action and second regulatory action were considered and found to provide greater uncertainty in addressing the unreasonable risk from PCE under the conditions of use, resulting in EPA's proposed action. Information on the costs and benefits of the proposed and alternative regulatory actions is available in Chapters 7 and 8 of the Economic Analysis Analysis and analysis on small entity impacts is in Chapter 10 of the Economic Analysis.

EPA considered its authority under TSCA section 6(g) to grant a time-limited exemption for conditions of use where compliance with a requirement would significantly disrupt the national economy, national security, or infrastructure. As described in Units IV.B.2.b. and V.A.2., based on reasonably available information, EPA analyzed the need for an exemption and has found that a TSCA section 6(g) exemption may be warranted under the second alternative regulatory action for the industrial and commercial use in maskant for chemical milling and for the industrial and commercial use in vapor degreasing if the workplaces engaged in those conditions of use cannot meet the requirements of the proposed regulatory action (PCE WCPP) or primary alternative regulatory action (prescriptive controls) such that those conditions of use would no longer drive the unreasonable risk. A section 6(g) exemption may mean that the unreasonable risk will not be fully addressed.

As required under TSCA section 6(c)(2)(C) and detailed in Unit V.B., EPA also considered to the extent practicable whether technically and economically feasible alternatives that benefit human health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect. To that end, in addition to the Economic Analysis (Ref. 3), EPA conducted an Alternatives Assessment, using reasonably available information (Ref. 56). For this assessment, EPA identified and analyzed alternatives to PCE in products relevant to industrial, commercial, and consumer conditions of use. Based on reasonably available information, including information submitted by industry, EPA understands viable alternatives to PCE may not be available for several conditions of use—for example, the industrial and commercial use in vapor degreasing for certain applications (Refs. 57, 58)—and considered that information to the extent practicable in the development of the regulatory options.

Regarding timeframes for compliance, as described in Unit IV.A.1, 2, and 3, the

proposed compliance dates incorporate EPA's consideration of sustained awareness of risks resulting from PCE exposure as well as precedent established by the OSHA standards (62 FR 1494, January 10, 1997). TSCA requires that EPA propose timeframes that are "as soon as practicable" under TSCA section 6(d)(1)(B) and 6(d)(1)(D). TSCA section 6(d)(1)(C) also requires that EPA specify mandatory compliance dates for the start of ban or phase-out requirements "as soon as practicable" but not later than five years after the promulgation date of a rule. In developing the proposed compliance timeframes, including for the prohibition and phaseout of PCE in dry cleaning as outlined in Unit IV.A.1.c., EPA considered reasonably available information. EPA has no information indicating that the proposed compliance dates are not practicable for the activities that would be prohibited, or that additional time is needed for products affected by the proposed restrictions to clear the channels of trade. As noted earlier, EPA is seeking public comment on whether additional time is needed for compliance with prohibitions, for products to clear the channels of trade, or for implementing a WCPP or prescriptive controls. EPA may finalize shorter or longer compliance timeframes based on public comment. Regarding potential regulatory flexibilities for compliance dates and timeframes, EPA notes that the primary alternative regulatory action would include longer compliance timeframes for prohibitions. Given the potential severity of impacts from exposure to PCE, EPA's proposed regulatory action and second alternative regulatory action would include relatively rapid compliance timeframes. However, it is possible that longer timeframes would be needed for entities to come into compliance; therefore, the primary alternative regulatory action described in the proposed rule would include longer timeframes for implementation than the proposed regulatory action. These timeframes are detailed in Unit IV. Information on the estimated costs of the shorter and longer timeframes for the dry cleaning phaseout are in Chapter 7.7.3 of the Economic Analysis.

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 action would affect entities that use PCE. It is not expected to affect State, local, or Tribal governments because the use of PCE by government entities is minimal. This action is not expected to result in expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (when adjusted annually for inflation) in any 1 year. Accordingly, this action is not subject to the requirements of sections 202, 203, or 205 of UMRA.

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

EPA provides the following preliminary federalism summary impact statement. The Agency consulted with State and local officials early in the process of developing the proposed action to permit them to have meaningful and timely input into its development. This included background presentation on September 9, 2020, and a consultation meeting on July 22, 2021.

EPA invited the following national organizations representing State and local elected officials to these meetings: American Water Works Association, Association of Clean Water Administrators, Association of Metropolitan Water Agencies, Association of State Drinking Water Administrators, Environmental Council of the States, National Association of Counties, National Conference of State Legislatures, National Governors Association, National League of Cities, National Water Resources Association, and United States Conference of Mayors. During the consultation, stakeholders in attendance asked about the differences between PCE and TCE, recommended additional reporting requirements as a risk management tool to address the unreasonable risk, suggested EPA look into safer alternatives, and described concerns related to current impacts on drinking water utilities from PCE (Ref. 25). A summary of the meeting with these organizations, including the views that they expressed, is available in the docket (Ref. 25). EPA provided an opportunity for these organizations to provide follow-up comments in writing but did not receive any such comments.

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

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes. This rulemaking would not have substantial direct effects on Tribal governments because PCE is not manufactured, processed, or distributed in commerce by Tribes. PCE is not regulated by Tribes, and this rulemaking would not impose substantial direct compliance costs on Tribal governments. Thus, Executive Order 13175 does not apply to this action.

Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, EPA consulted with Tribal officials during the development of this action. The Agency held a

Tribal consultation from May 17, 2021, to August 20, 2021, with meetings on June 15, 2021, and July 8, 2021. Tribal officials were given the opportunity to meaningfully interact with EPA risk managers concerning the current status of risk management. During the consultation, EPA discussed risk management under TSCA section 6(a), findings from the 2020 Risk Evaluation for PCE, types of information to inform risk management, principles for transparency during risk management, and types of information EPA is seeking from Tribes (Ref. 26). EPA briefed Tribal officials on the Agency's risk management considerations and encouraged Tribal officials to provide additional comments after the teleconferences. Tribal officials raised no related issues or concerns to EPA during or in follow-up to those meetings (Ref. 26).

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

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children as reflected by the conclusions of the PCE risk evaluation. This action's health and risk assessments are contained in Unit III.A.3, III.B.2, VI.A. and B., and the 2020 Risk Evaluation for PCE and the Economic Analysis for this proposed rulemaking (Refs. 1 and 3).

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

This action is not a "significant energy action" under Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution or use of energy and has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.

I. National Technology Transfer and Advancement Act (NTTAA)

Pursuant to the NTTAA section 12(d), 15 U.S.C. 272., the Agency has determined that this rulemaking involves environmental monitoring or measurement, specifically for occupational inhalation exposures to PCE. Consistent with the Agency's Performance Based Measurement System (PBMS), the Agency proposes not to require the use of specific, prescribed analytic methods. Rather, the Agency plans to allow the use of any method that meets the prescribed performance criteria. The PBMS approach is intended to be more flexible and cost-effective for the regulated community; it is also intended to encourage innovation in analytical technology and improved data quality. EPA is not precluding the use of any method, whether it constitutes a voluntary consensus standard or not, as long as it meets the performance criteria specified.

For this rulemaking, the key consideration for the PBMS approach is the ability to accurately detect and measure airborne concentrations of PCE at the ECEL and the ECEL action level. Some examples of methods which meet the criteria are included in appendix B of the ECEL memo (Ref. 10). EPA recognizes that there may be voluntary consensus standards that meet the proposed criteria (Ref. 81). EPA requests comments on whether it should incorporate such voluntary consensus standards in the rule and seeks information in support of such comments regarding the availability and applicability of voluntary consensus standards that may achieve the sampling and analytical requirements of the rule in lieu of the PBMS approach.

J. Executive Orders 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make EJ part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or

environmental effects of their programs, policies, and activities on minority populations (people of color and/or indigenous peoples) and low-income populations.

EPA believes that the human health or environmental conditions that exist prior to this action result in or have the potential to result in disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples. As described more fully in the Economic Analysis, EPA conducted an analysis to characterize the baseline conditions faced by communities and workers affected by the regulation to identify the potential for disproportionate impacts on minority and low-income populations. The baseline characterization suggests that workers in affected industries and regions, as well as residents of nearby communities, are more likely to be people of color than the general population in affected states, although this varied by use assessed. Additionally, based on reasonably available information, the Agency understands that most dry cleaning workers are members of minority populations.

EPA believes that this action is likely to reduce existing disproportionate and adverse effects on people of color, low-income populations and/or Indigenous peoples. While the regulatory options are anticipated to address the unreasonable risk from exposure to PCE to the extent necessary so that it is no longer unreasonable, EPA is not able to quantify the distribution of the change in risk across affected workers, communities, or demographic groups. EPA is also unable to quantify the changes in risks to workers, communities, and demographic groups from non-PCE-using technologies or practices that firms may adopt in response to the regulation to determine whether any such changes could pose EJ concerns. Data limitations that prevent EPA from conducting a more comprehensive analysis are summarized in the Economic Analysis (Ref. 3).

EPA additionally identified and addressed EJ concerns by conducting outreach to

advocates of communities that might be subject to disproportionate exposure to PCE, such as minority populations, low-income populations and indigenous peoples. On June 16, 2021, and July 6, 2021, EPA held public meetings as part of this consultation (Ref. 32). See also Unit III.A.1. These meetings were held pursuant to and in compliance with Executive Order 12898 and Executive Order 14008, entitled "Tackling the Climate Crisis at Home and Abroad" (86 FR 7619, February 1, 2021).

Following the EJ meetings, EPA received five written comments, in addition to oral comments provided during the consultations. In general, commenters supported strong outreach to affected communities, encouraged EPA to follow the hierarchy of controls, favored prohibitions, and noted the uncertainty, and in some cases inadequacy, of PPE. Commenters also urged the EPA to extend the rulemaking into ongoing releases from hazardous waste and disposal sites, in particular vapor intrusion of PCE from contaminated groundwater, soil, and indoor air. Additionally, commenters expressed concern that the adverse health impacts of PCE dry cleaning fall disproportionately to owners and employees of minority owned small businesses, noted the viability of professional wet cleaning as an alternative to PCE dry cleaning, and urged EPA to consider economic impacts and a financial program to offset transition costs to local communities.

The information supporting the review under Executive Order 12898 is contained in Units I.E., II.D., III.A.1., VI.A., and in the Economic Analysis (Ref. 3). EPA's presentations and fact sheets for the EJ consultations related to this rulemaking, are available at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/materials-june-and-july-2021-environmental-justice.* These materials and a summary of the consultation are also available in the public docket for this rulemaking (Ref. 32).

List of Subjects in 40 CFR Part 751

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

Dated: June 7, 2023.

Michael S. Regan,

Administrator.

Therefore, for the reasons stated in the preamble, EPA proposes to amend 40 CFR part 751 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, 15 U.S.C. 2625(l)(4)

2. Amend § 751.5 by adding in alphabetical order definitions for “authorized person”, “direct dermal contact”, “ECEL”, “exposure group”, “owner or operator”, “potentially exposed person”, “regulated area”, and “retailer” to read as follows:

§ 751.5 Definitions.

* * * * *

Authorized person means any person specifically authorized by the owner or operator to enter, and whose duties require the person to enter, a regulated area.

* * * * *

Direct dermal contact means direct handling of a chemical substance or mixture or skin contact with surfaces that may be contaminated with a chemical substance or mixture.

ECEL is an Existing Chemical Exposure Limit and means an airborne concentration generally calculated as an eight (8)-hour time-weighted average (TWA).

* * * * *

Exposure group means a group consisting of every person performing the same or substantially similar operations in each work shift, in each job classification, in each work area where exposure to chemical substances or mixtures is reasonably likely to occur.

Owner or operator means any person who owns, leases, operates, controls, or supervises a workplace covered by this part.

* * * * *

Potentially exposed person means any person who may be occupationally exposed to a chemical substance or mixture in a workplace as a result of a condition of use of that chemical substance or mixture.

Regulated area means an area established by the regulated entity to demarcate areas where airborne concentrations of a specific chemical substance exceed, or there is a reasonable possibility they may exceed, the ECEL or the EPA STEL.

Retailer means a person who distributes in commerce or makes available a chemical substance or mixture to consumer end users, including e-commerce internet sales or distribution. Any distributor with at least one consumer end user customer is considered a retailer. A person who distributes in commerce or makes available a chemical substance or mixture solely to commercial or industrial end users or solely to commercial or industrial businesses is not considered a retailer.

3. Add new subpart G to read as follows:

Subpart G—Perchloroethylene

Sec.

Subpart G—Perchloroethylene

§ 751.601 General.

This subpart establishes prohibitions and restrictions on the manufacture (including import), processing, distribution in commerce, use, and disposal of perchloroethylene (CASRN

127-18-4), also known as tetrachloroethylene, to prevent unreasonable risk of injury to health in accordance with TSCA section 6(a).

§ 751.603 Definitions.

The definitions in subpart A of part 751 apply to this subpart unless otherwise specified in this section. In addition, the following definitions apply:

Distribute in commerce has the same meaning as in section 3 of the Act, except that the term does not include retailers for purposes of §§ 751.611 and 751.613.

ECEL action level means a concentration of airborne perchloroethylene of 0.07 part per million (ppm) calculated as an eight (8)-hour time-weighted average (TWA).

3rd generation machine means a dry-to-dry machine with a refrigerated condenser, as those terms are defined in 40 CFR Part 63 Subpart M.

4th or 5th generation machine means a dry-to-dry machine with a carbon adsorber and refrigerated condenser, as those terms are defined in 40 CFR Part 63 Subpart M.

§ 751.605 Prohibitions of Manufacturing, Processing, Distribution in Commerce, and Use.

(a) *Applicability.*

The provisions of this section apply to the following uses as indicated in each paragraph of this section:

(1) All consumer use, excluding use of clothing and articles that have been commercially dry cleaned with perchloroethylene.

(2) Processing into formulation, mixture or reaction product in other chemical products and preparations.

(3) Dry cleaning use, including:

(i) Industrial and commercial use in dry cleaning and related spot cleaning in 3rd generation machines; and

(ii) Industrial and commercial use in dry cleaning and related spot cleaning in 4th and 5th generation machines.

(4) All other industrial and commercial use, except for the following:

(i) Those industrial and commercial uses presented in § 751.607(a);

(ii) Laboratory use as described in § 751.609(a); and

(iii) Any industrial and commercial use of clothing and articles that have been commercially dry cleaned with perchloroethylene.

(5) Distribution in commerce.

(b) *Prohibitions.*

(1) After [DATE 12 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from manufacturing (including importing) perchloroethylene for the uses listed in paragraphs (a)(1), (2) and (4) of this section.

(2) After [DATE 15 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from processing perchloroethylene, including any perchloroethylene-containing products, for the uses listed in paragraphs (a)(1), (2) and (4) of this section.

(3) After [DATE 18 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from distributing in commerce (including making available) perchloroethylene, including any perchloroethylene-containing products, to retailers for any use, other than commercial dry cleaning or consumer use of clothing and articles that have been commercially dry cleaned with perchloroethylene.

(4) After [DATE 21 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all retailers are prohibited from distributing in

commerce (including making available) perchloroethylene, including any perchloroethylene-containing products. Distribution in commerce by retailers of clothing and articles that have been commercially dry cleaned with perchloroethylene is not subject to the prohibitions described in this paragraph.

(5) After [DATE 21 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from distributing in commerce (including making available) perchloroethylene, including any perchloroethylene-containing products, for the uses described in paragraphs (a)(1) and (4) of this section.

(6) After [DATE 24 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from industrial or commercial use of perchloroethylene, including any perchloroethylene-containing products, for the uses listed in paragraph (a)(4) of this section.

(7) All persons are prohibited from industrial or commercial use of perchloroethylene in dry cleaning machines acquired after [DATE 6 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*].

(8) After [DATE 3 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from industrial or commercial use of perchloroethylene for the use listed in paragraph (a)(3)(i) of this section.

(9) After [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from the manufacturing (including importing), processing, distribution in commerce, or industrial or commercial use of perchloroethylene for dry cleaning and spot cleaning, including for the use listed in paragraph (a)(3)(ii) of this section.

(c) *De minimis level.*

Products containing perchloroethylene at levels less than 0.1 percent by weight are not subject to the prohibitions described in paragraph (b) of this section.

§ 751.607 Workplace Chemical Protection Program.

(a) *Applicability.*

The provisions of this section apply to workplaces engaged in the following conditions of use of perchloroethylene, unless otherwise indicated in this section, except to the extent the conditions of use are prohibited by § 751.605:

(1) Manufacturing (domestic manufacture);

(2) Manufacturing (import);

(3) Processing as a reactant/intermediate;

(4) Processing into formulation, mixture or reaction product in paint and coating products;

(5) Processing into formulation, mixture or reaction product in cleaning and degreasing products;

(6) Processing into formulation, mixture or reaction product in adhesive and sealant products

(7) Repackaging;

(8) Industrial and commercial use as solvent for open-top batch vapor degreasing;

(9) Industrial and commercial use as solvent for closed-loop batch vapor degreasing;

(10) Industrial and commercial use as solvent for in-line conveyorized vapor degreasing;

(11) Industrial and commercial use as solvent for in-line web cleaner vapor degreasing;

(12) Industrial and commercial use in maskant for chemical milling;

(13) Industrial and commercial use in solvent-based adhesives and sealants;

(14) Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing;

(15) Recycling; and

(16) Disposal.

(b) *Existing chemical exposure limit (ECEL).*

(1) *Applicability.* The provisions of this paragraph (b) apply to any workplace engaged in a condition of use that is listed in paragraph (a)(1) through (14) of this section and not prohibited by § 751.605.

(2) *Eight-hour time-weighted average (TWA) ECEL*. Beginning [DATE 9 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], or beginning 4 months after introduction of perchloroethylene into the workplace if perchloroethylene use commences after [DATE 6 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], the owner or operator must ensure that no person is exposed to an airborne concentration of perchloroethylene in excess of 0.14 parts of perchloroethylene per million parts of air (0.14 ppm) as an eight (8)-hour TWA, in accordance with the requirements of paragraph (d)(1)(i) of this section and, if necessary, paragraph (f) of this section.

(3) *Exposure monitoring.*

(i) *General.*

(A) Owners or operators must determine each potentially exposed person's exposure by either:

(*1*) Taking a personal breathing zone air sample of each potentially exposed person's exposure; or

(*2*) Taking personal breathing zone air samples that are representative of the 8-hour TWA

of each person whose exposure must be monitored.

(B) Representative 8-hour TWA exposures must be determined on the basis of one or more full-shift exposure of at least one person that represents, and does not underestimate, the potential exposure of every person in each exposure group and that represents the highest perchlorethylene exposures likely to occur under reasonably foreseeable conditions of use.

(C) Exposure samples must be analyzed using an appropriate analytical method by a laboratory that complies with the Good Laboratory Practice Standards in 40 CFR Part 792.

(D) Owners or operators must ensure that methods used to perform exposure monitoring produce results that are accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of perchloroethylene.

(E) Owners and operators must re-monitor within 15 working days after receipt of any exposure monitoring when results indicate non-detect or air monitoring equipment malfunction, unless an Environmental Professional as defined at 40 CFR 312.10 or a Certified Industrial Hygienist reviews the monitoring results and determines re-monitoring is not necessary.

(ii) *Initial monitoring*.

(A) Each owner or operator who has a workplace or work operation covered by this section, except as provided for in paragraph (b)(3)(ii)(B) of this section, must perform initial monitoring of potentially exposed persons regularly working in areas where perchloroethylene is present.

(B) The initial monitoring required in paragraph (b)(3)(ii)(A) of this section must be completed by [DATE 6 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] or within 30 days of introduction of perchloroethylene into the workplace, whichever is later. Where the owner or operator has monitoring within five years prior to [the effective date of the final rule] and the monitoring satisfies all other requirements of

this section, the owner or operator may rely on such earlier monitoring results to satisfy the requirements of paragraph (b)(3)(ii)(A) of this section.

(iii) *Periodic monitoring.* The owner or operator must establish an exposure monitoring program for periodic monitoring of exposure to perchloroethylene in accordance with table 1 to this paragraph (b)(3)(iii).

Table 1 to § 751.607(b)(3)(iii) – Periodic Monitoring Requirements

Air Concentration Condition	**Periodic Monitoring Requirement**
If all initial exposure monitoring is below ECEL action level (< 0.07 ppm 8-hour TWA)	Periodic exposure monitoring is required at least once every five years.
If the most recent exposure monitoring indicates that airborne exposure is above the ECEL (> 0.14 ppm 8-hour TWA)	Periodic exposure monitoring is required within 3 months of the most recent exposure monitoring.
If the most recent exposure monitoring indicates that airborne exposure is at or above the ECEL action level but at or below the ECEL (≥ 0.07 ppm 8-hour TWA, ≤ 0.14 ppm 8-hour TWA)	Periodic exposure monitoring is required within 6 months of the most recent exposure monitoring.
If the two most recent (non-initial) exposure monitoring measurements, taken at least seven days apart within a 6 month period, indicate exposure is below the ECEL action level (< 0.07 ppm 8-hour TWA)	Periodic exposure monitoring is required within 5 years of the most recent exposure monitoring.
If the owner or operator engages in a condition of use for which WCPP ECEL is required but does not manufacture, process, use, or dispose of perchlorethylene in that condition of use over the entirety of time since the last required monitoring event	The owner or operator may forgo the next periodic monitoring event. However, documentation of cessation of use of perchlorethylene is required; and periodic monitoring would be required when the owner or operator resumes the condition of use.

(iv) *Additional monitoring*.

(A) The owner or operator must conduct additional initial exposure monitoring whenever there has been a change in the production, process, control equipment, personnel or work practices that may reasonably be expected to result in new or additional exposures above the ECEL action level or when the owner or operator has any reason to believe that new or

additional exposures above the ECEL action level have occurred.

(B) Whenever start-ups, shutdown, spills, leaks, ruptures or other breakdowns occur that may lead to exposure to potentially exposed persons, the owner or operator must conduct additional initial exposure monitoring (using personal breathing zone sampling) after the cleanup of the spill or repair of the leak, rupture or other breakdown.

(v) *Notification of monitoring results*.

(A) The owner or operator must inform persons whose exposures are represented by the monitoring of the monitoring results within 15 working days.

(B) This notification must include the following:

(*1*) Exposure monitoring results;

(*2*) Identification and explanation of the ECEL and ECEL action level in plain language;

(*3*) Explanation of any corresponding required respiratory protection as described in paragraph (f) of this section;

(*4*) Descriptions of actions taken by the regulated entity to reduce exposure to or below the ECEL;

(*5*) Quantity of perchloroethylene in use;

(*6*) Location of perchloroethylene use;

(*7*) Manner of perchloroethylene use;

(*8*) Identified releases of perchloroethylene; and

(*9*) Whether the airborne concentration of perchloroethylene exceeds the ECEL limit.

(C) Notice must be provided in plain language writing, in a language that the person understands, to each potentially exposed person or posted in an appropriate and accessible location outside the regulated area with an English-language version and a non-English language version representing the language of the largest group of workers who do not read English.

(4) *Regulated areas.*

(i) Beginning [DATE 9 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], or beginning 4 months after introduction of perchloroethylene into the workplace if perchloroethylene use commences after [DATE 6 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], the owner or operator must establish and maintain a regulated area wherever any person's exposure to airborne concentrations of perchloroethylene exceeds or can reasonably be expected to exceed the ECEL.

(ii) The owner or operator must limit access to regulated areas to authorized persons.

(iii) The owner or operator must demarcate regulated areas from the rest of the workplace in a manner that adequately establishes and alerts persons to the boundaries of the area and minimizes the number of authorized persons exposed to perchloroethylene within the regulated area.

(iv) The owner or operator must supply a respirator that complies with the requirements of paragraph (f) of this section and must ensure that all persons within the regulated area are using the provided respirators whenever perchloroethylene exposures may exceed the ECEL.

(v) An owner or operator who has implemented all feasible engineering, work practice and administrative controls as required in paragraph (d)(1)(i) of this section, and who has established a regulated area as required by paragraph (b)(4)(i) of this section where perchloroethylene exposure can be reliably predicted to exceed the ECEL only on certain days (for example, because of work or process schedule) must have persons use respirators in that regulated area on those days.

(vi) The owner or operator must ensure that, within a regulated area, persons do not

engage in non-work activities which may increase perchloroethylene exposure.

(vii) The owner or operator must ensure that while persons are wearing respirators in the regulated area, they do not engage in activities which interfere with respirator seal or performance.

(c) *Direct dermal contact controls.*

(1) The provisions of this paragraph (c) apply to any workplace engaged in the conditions of use that are listed in paragraph (a)(1) through (16) of this section and are not prohibited by § 751.605.

(2) Owners or operators must ensure that all persons are separated, distanced, physically removed, or isolated from direct dermal contact with perchloroethylene in accordance with the requirements of paragraph (d)(1)(ii) of this section and, if necessary, paragraph (f) of this section.

(d) *Exposure control procedures and plan.*

(1) *Methods of compliance.*

(i) *ECEL.*

(A) The owner or operator must institute one or a combination of elimination, substitution, engineering controls or administrative controls to reduce exposure to or below the ECEL except to the extent that the owner or operator can demonstrate that such controls are not feasible.

(B) Wherever the feasible exposure controls, including one or a combination of elimination, substitution, engineering controls or administrative controls, which can be instituted are not sufficient to reduce exposure to or below the ECEL, the owner or operator must use them to reduce exposure to the lowest levels achievable by these controls and must supplement them by the use of respiratory protection that complies with the requirements of paragraph (f) of this

section. Where an owner or operator cannot demonstrate exposure below the ECEL, including through the use of engineering controls or work practices, and has not demonstrated that it has supplemented feasible exposure controls with respiratory protection that complies with the requirements of paragraph (f) of this section, this will constitute a failure to comply with the ECEL.

(C) The owner or operator must maintain the effectiveness of engineering controls and administrative controls instituted under paragraph (d)(1)(i)(A) of this section.

(D) The owner or operator must not implement a schedule of personnel rotation as a means of compliance with the ECEL.

(E) The owner or operator must document their exposure control strategy and implementation in an exposure control plan in accordance with paragraph (d)(2) of this section.

(ii) *Direct dermal contact control requirements.*

(A) The owner or operator must institute one or a combination of elimination, substitution, engineering controls, or administrative controls to prevent all persons from direct dermal contact with perchloroethylene except to the extent that the owner or operator can demonstrate that such controls are not feasible.

(B) Wherever the feasible exposure controls, including one or a combination of elimination, substitution, engineering controls or administrative controls, which can be instituted are not sufficient to prevent direct dermal contact, the owner or operator must use them to reduce direct dermal contact to the extent achievable by these controls and must supplement them by the use of dermal personal protective equipment that complies with the requirements of paragraph (f) of this section. Where an owner or operator cannot demonstrate direct dermal contact is prevented, including through the use of engineering controls or work practices, and has not demonstrated that it has supplemented feasible exposure controls with dermal personal protective

equipment that complies with the requirements of paragraph (f) of this section, this will constitute a failure to comply with the direct dermal contact control requirements.

(C) The owner or operator must maintain the effectiveness of engineering controls and administrative controls instituted under paragraph (d)(1)(ii)(A) of this section.

(D) The owner or operator must document their exposure control strategy and implementation in an exposure control plan in accordance with paragraph (d)(2) of this section.

(2) *Exposure control plan requirements*.

Beginning [DATE 12 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], owners and operators must include and document in an exposure control plan the following:

(i) Identification and rationale of exposure controls used or not used in the following sequence: elimination of perchloroethylene, substitution of perchloroethylene, engineering controls and administrative controls to reduce exposures in the workplace to either at or below the ECEL or to the lowest level achievable and to prevent or reduce direct dermal contact with perchloroethylene in the workplace;

(ii) The exposure controls selected based on feasibility, effectiveness, and other relevant considerations;

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

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

(v) Description of any regulated area and how it is demarcated, and identification of authorized persons; and description of when the owner or operator expects exposures may be likely to exceed the ECEL;

(vi) Regular inspections, evaluations, and updating of the exposure controls to ensure effectiveness and confirmation that all persons are implementing them as required;

(vii) Occurrence and duration of any start-up, shutdown, or malfunction of the facility that causes air concentrations to be above the ECEL or any direct dermal contact with perchloroethylene and subsequent corrective actions taken during start-up, shutdown, or malfunctions to mitigate exposures to perchloroethylene; and

(viii) Availability of the exposure control plan and associated records for potentially exposed persons.

(e) *Workplace information and training.*

(1) The owner or operator must provide information and training for each person prior to or at the time of initial assignment to a job involving potential exposure to perchloroethylene.

(2) The owner or operator must ensure that information and training is presented in a manner that is understandable to each person required to be trained.

(3) The following information and training must be provided to all persons assigned to a job involving potential exposure to perchloroethylene:

(i) The requirements of this section, as well as how to access or obtain a copy of these requirements in the workplace;

(ii) The quantity, location, manner of use, release, and storage of perchloroethylene and the specific operations in the workplace that could result in exposure to perchloroethylene, particularly noting where exposures may be above the ECEL or where there is potential for direct dermal contact with perchloroethylene;

(iii) Methods and observations that may be used to detect the presence or release of perchloroethylene in the workplace (such as monitoring conducted by the owner or operator, continuous monitoring devices, visual appearance or odor of perchloroethylene when being

released, etc.);

(iv) The health hazards of perchloroethylene in the workplace; and

(v) The principles of safe use and handling of perchloroethylene and measures potentially exposed persons can take to protect themselves from perchloroethylene, including specific procedures the owner or operator has implemented to protect potentially exposed persons from exposure to perchloroethylene, such as appropriate work practices, emergency procedures, and personal protective equipment to be used.

(4) The owner or operator must re-train each potentially exposed person annually to ensure that each such person maintains the requisite understanding of the principles of safe use and handling of perchloroethylene in the workplace.

(5) Whenever there are workplace changes, such as modifications of tasks or procedures or the institution of new tasks or procedures, which increase exposure, and where those exposures exceed or can reasonably be expected to exceed the ECEL action level or increase potential for direct dermal contact, the owner or operator must update the training as necessary to ensure that each potentially exposed person has the requisite proficiency.

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

(1) The provisions of paragraph (f) apply to any owner or operator that is required to provide respiratory protection or dermal protection pursuant to paragraphs (d)(1)(i)(B) or (d)(1)(ii)(B) of this section or § 751.609(b)(2).

(2) PPE, including respiratory and dermal protection, that is of safe design and construction for the work to be performed must be provided, used, and maintained in a sanitary, reliable, and undamaged condition. Owners and operators must select PPE that properly fits each affected person and communicate PPE selections to each affected person.

(3) Owners and operators must provide PPE training in accordance with 29 CFR

1910.132(f) to all persons required to use PPE prior to or at the time of initial assignment to a job involving potential exposure to perchloroethylene. For the purposes of this subsection, provisions in 29 CFR 1910.132(f) applying to an "employee" also apply equally to potentially exposed persons, and provisions applying to an "employer" also apply equally to owners or operators.

(4) Owners and operators must retrain each potentially exposed person required to use PPE annually or whenever the owner or operator has reason to believe that a previously trained person does not have the required understanding and skill to properly use PPE, or when changes in the workplace or in PPE to be used render the previous training obsolete.

(5) *Respiratory protection.*

(i) Beginning [DATE 9 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], or within 3 months after receipt of any exposure monitoring that indicates exposures exceeding the ECEL, the owner or operator must supply a respirator, selected in accordance with this paragraph, to each person who enters a regulated area and must ensure that all persons within the regulated area are using the provided respirators whenever perchloroethylene exposures may exceed the ECEL.

(ii) Owners or operators must provide respiratory protection in accordance with the provisions outlined in 29 CFR 1910.134(a) through (l) (except (d)(1)(iii)) and as specified in this paragraph for persons exposed or who may be exposed to perchloroethylene in concentrations above the ECEL. For the purpose of this paragraph (f), the maximum use concentration (MUC) as used in 29 CFR 1910.134 must be calculated by multiplying the assigned protection factor (APF) specified for a respirator by the ECEL. For the purposes of this subsection, provisions in 29 CFR 1910.134(a) through (l) (except (d)(1)(iii)) applying to an "employee" also apply equally to potentially exposed persons, and provisions applying to an "employer" also apply equally to

owners or operators.

(iii) Owners or operators must select and provide to persons appropriate respirators as indicated by the most recent monitoring results as follows:

(A) If the measured exposure concentration is at or below 0.14 ppm: no respiratory protection is required.

(B) If the measured exposure concentration is above 0.14 ppm and less than or equal to 0.7 ppm (5 times ECEL): Any NIOSH-certified air-purifying quarter mask respirator (APF 5).

(C) If the measured exposure concentration is above 0.7 ppm and less than or equal to 1.4 ppm (10 times ECEL): Any NIOSH-certified air-purifying half mask or full facepiece respirator equipped with NIOSH-approved organic vapor cartridges or canisters (APF 10).

(D) If the measured exposure concentration is above 1.4 ppm and less than or equal to 3.5 ppm (25 times ECEL): Any NIOSH-certified air-purifying full facepiece respirator equipped with NIOSH-approved organic vapor cartridges or canisters; any NIOSH-certified powered air-purifying respirator equipped with NIOSH-approved organic vapor cartridges; or any NIOSH-certified continuous flow supplied air respirator equipped with a hood or helmet (APF 25).

(E) If the measured exposure concentration is above 3.5 ppm and less than or equal to 7.0 ppm (50 times ECEL): Any NIOSH-certified air-purifying full facepiece respirator equipped with NIOSH-approved organic vapor cartridges or canisters; or any NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece and a NIOSH-approved organic vapor cartridge (APF 50).

(F) If the measured exposure concentration is above 7.0 ppm and less than or equal to 140 ppm (1,000 times ECEL): Any NIOSH-certified supplied air respirator equipped with a half mask or full facepiece and operated in a pressure demand or other positive pressure mode (APF 1,000).

(G) If the measured exposure concentration is greater than 140 ppm (1,000 times ECEL) or the concentration is unknown: Any NIOSH-certified self-contained breathing apparatus equipped with a full facepiece and operated in a pressure demand or other positive pressure mode; or any NIOSH-certified supplied air respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode (APF 10,000).

(iv) The respiratory protection requirements in this paragraph represent the minimum respiratory protection requirements, such that any respirator affording a higher degree of protection than the required respirator may be used.

(v) When a person whose job requires the use of a respirator cannot use a negative-pressure respirator, the owner or operator must provide that person with a respirator that has less breathing resistance than the negative-pressure respirator, such as a powered air-purifying respirator or supplied-air respirator, when the person is able to use it and if it provides the person with adequate protection.

(6) *Dermal protection.*

(i) The owner or operator must supply and require the donning of dermal PPE that separates and provides a barrier to prevent direct dermal contact with perchloroethylene in the specific work area where it is selected for use, selected in accordance with this paragraph and provided in accordance with 29 CFR 1910.132(h), to each person who is reasonably likely to be dermally exposed in the work area through direct dermal contact with perchloroethylene. For the purposes of this subsection, provisions in 29 CFR 1910.132(h) applying to an "employer" also applies equally to owners or operators.

(ii) Owners or operators must select and provide dermal PPE in accordance with 29 CFR

1910.133(b) and additionally as specified in this paragraph to each person who is reasonably likely to be dermally exposed in the work area through direct dermal contact with perchloroethylene. For the purposes of this subsection, provisions in 29 CFR 1910.133(b) applying to an "employer" also apply equally to owners or operators.

(iii) Owners or operators must select and provide to persons appropriate dermal PPE based on an evaluation of the performance characteristics of the PPE relative to the task(s) to be performed, conditions present, and the duration of use. Dermal PPE must include, but is not limited to, the following items:

(A) Impervious gloves selected based on specifications from the manufacturer or supplier.

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

(iv) *Demonstration of imperviousness.* Owners or operators must demonstrate that each item of gloves and other clothing selected provides an impervious barrier to prevent direct dermal contact with perchloroethylene during normal and expected duration and conditions of exposure within the work area by evaluating the specifications from the manufacturer or supplier of the clothing, or of the material used in construction of the clothing, to establish that the clothing will be impervious to perchloroethylene alone and in likely combination with other chemical substances in the work area.

§ 751.609 Workplace Requirements for Laboratory Use

(a) *Applicability.*

The provisions of this section apply to workplaces engaged in the industrial and commercial use of perchloroethylene as a laboratory chemical.

(b) *Laboratory use requirements.*

(1) After [DATE 12 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], owners or operators must ensure fume hoods are in use and functioning properly and that specific measures are taken to ensure proper and adequate performance of such equipment to minimize exposures to persons in the area when perchloroethylene is used in a laboratory setting.

(2) After [DATE 12 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], owners or operators must ensure that all persons reasonably likely to be exposed from direct dermal contact to perchloroethylene in a laboratory setting are provided with dermal personal protective equipment as outlined in § 751.607(f)(2) and (6) and training on proper use of PPE as outlined in § 751.607(f)(3) and (4).

§ 751.611 Downstream Notification.

(a) Beginning on [DATE 2 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], each person who manufactures (including imports) perchloroethylene for any use must, prior to or concurrent with the shipment, notify companies to whom perchloroethylene is shipped, in writing, of the restrictions described in this subpart in accordance with paragraph (c) of this section.

(b) Beginning on [DATE 6 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], each person who processes or distributes in commerce perchloroethylene or any perchloroethylene-containing products for any use must, prior to or concurrent with the shipment, notify companies to whom perchloroethylene is shipped, in writing, of the restrictions described in this subpart in accordance with paragraph (c) of this section.

(c) The notification required under paragraphs (a) and (b) of this section must occur by inserting the following text in Section 1(c) and 15 of the Safety Data Sheet (SDS) provided with

the perchloroethylene or with any perchloroethylene-containing product:

> After [DATE 18 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] this chemical/product cannot be distributed in commerce to retailers for any use. After [DATE 21 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], this chemical/product is and can only be distributed in commerce or processed for the following purposes: Processing as a reactant/intermediate; Processing into formulation, mixture or reaction product in cleaning and vapor degreasing products; Processing into formulation, mixture or reaction product in paint and coating products; Processing into formulation, mixture or reaction product in adhesive and sealant products; Processing by repackaging; Recycling; Industrial and commercial use as solvent in vapor degreasing; Industrial and commercial use in maskant for chemical milling; Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing; Industrial and commercial use in laboratory chemicals; Industrial and commercial use in solvent-based adhesives and sealants; Industrial and commercial use in dry cleaning in 3rd generation machines until [DATE 3 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*]; Industrial and commercial use in all dry cleaning and related spot cleaning until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*]; and Disposal.

§ 751.613 Recordkeeping Requirements.

(a) *General records.*

After [DATE 60 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons who manufacture, process, distribute in commerce, or engage in industrial or commercial use of perchloroethylene or perchloroethylene-containing products must maintain ordinary business records, such as downstream notifications, invoices and bills-of-lading related to compliance with the prohibitions, restrictions, and other provisions of this subpart.

(b) *Workplace Chemical Protection Program compliance.*

(1) *ECEL exposure monitoring*. For each monitoring event, owners or operators subject to the ECEL described in § 751.607(b) must document the following:

(i) Dates, duration, and results of each sample taken;

(ii) All measurements that may be necessary to determine the conditions that may affect

the monitoring results;

(iii) Name, workplace address, work shift, job classification, and work area of the person monitored; documentation of all potentially exposed persons whose exposures the monitoring is intended to represent if using a representative sample; and type of respiratory protective device worn by the monitored person, if any

(iv) Use of appropriate sampling and analytical methods, such as analytical methods already approved by EPA, OSHA or NIOSH, or compliance with an analytical method verification procedure;

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

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

(2) *ECEL compliance*. Owners or operators subject to the ECEL described in § 751.607(b) must retain records of:

(i) Exposure control plan as described in § 751.607(d)(2);

(ii) Facility exposure monitoring records;

(iii) Notifications of exposure monitoring results;

(iv) The name, workplace address, work shift, job classification, work area and respiratory protection used by each potentially exposed person and PPE program implementation as described in § 751.607(f), including fit-testing and training; and

(v) Information and training provided by the regulated entity to each person prior to or at the time of initial assignment to a job involving potential exposure to perchloroethylene and any re-training as required in § 751.607(e).

(3) *DDCC compliance.* Owners or operators subject to DDCC requirements described in

§ 751.607(c) must retain records of:

(i) Exposure control plan as described in § 751.607(d);

(ii) Dermal protection used by each potentially exposed person and PPE program implementation as described in § 751.607(f), including:

(A) The name, workplace address, work shift, job classification, and work area of each person reasonably likely to directly handle perchloroethylene or handle equipment or materials on which perchloroethylene may present and the type of PPE selected to be worn by each of these persons;

(B) The basis for specific PPE selection (e.g., demonstration based on permeation testing or manufacturer specifications that each item of PPE selected provides an impervious barrier to prevent exposure during expected duration and conditions of exposure, including the likely combinations of chemical substances to which the PPE may be exposed in the work area);

(C) Appropriately sized PPE and training on proper application, wear, and removal of PPE, and proper care/disposal of PPE;

(D) Occurrence and duration of any direct dermal contact with perchloroethylene that occurs during any activity or malfunction at the workplace that causes direct dermal exposures to occur and/or glove breakthrough, and corrective actions to be taken during and immediately following that activity or malfunction to prevent direct dermal contact to perchloroethylene; and

(E) Training in accordance with § 751.607(f)(3).

(iii) Information and training provided by the regulated entity to each person prior to or at the time of initial assignment to a job involving potential direct dermal contact with perchloroethylene and any re-training as required in § 751.607(e).

(4) *Workplace participation*.

Owners or operators must document the notice to and ability of any potentially exposed

person that may reasonably be affected by perchloroethylene inhalation exposure or direct dermal contact to readily access the exposure control plans, facility exposure monitoring records, PPE program implementation, or any other information relevant to perchloroethylene exposure in the workplace.

(c) *Workplace requirements for laboratory use compliance.*

Owners and operators subject to the laboratory chemical requirements described in § 751.609 must retain records of:

(1) Dermal protection used by each potentially exposed person and PPE program implementation, as described in § 751.613(b)(3)(ii); and

(2) Documentation identifying: implementation of a properly functioning fume hood using manufacturer's instructions for installation, use, and maintenance of the fume hood, including inspections, tests, development of maintenance procedures, the establishment of criteria for acceptable test results, and documentation of test and inspection results.

(d) *Records related to § 751.615 exemptions.*

To maintain eligibility for an exemption described in § 751.615, the records maintained by the owners or operators must demonstrate compliance with the specific conditions of the exemption.

(e) *Retention.*

Owners or operators must retain the records required under this section for a period of 5 years from the date that such records were generated.

§ 751.615 Exemptions.

(a) *In general.*

(1) As provided in paragraph (b) of this section, a time-limited exemption from the requirements of § 751.605 is established in this section in accordance with 15 U.S.C.

2605(g)(1)(A).

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

(b) *Time-limited exemption.*

Use of perchloroethylene or perchloroethylene containing products identified in paragraph (b)(1) of this section in an emergency by the National Aeronautics and Space Administration and its contractors operating within the scope of their contracted work until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*].

(1) *Applicability*.

The emergency use exemption described in this paragraph (b) shall apply to the following specific conditions of use as described in paragraph (b)(1)(i).

(i) *Conditions of use subject to this exemption*.

(A) Industrial and commercial use as solvent for cold cleaning.

(B) Industrial and commercial use in wipe cleaning.

(ii) *Emergency use*.

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

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

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

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

(*4*) The environment.

(B) *Duration*. Each emergency is a separate situation; if use of perchloroethylene exceeds 15 days, then justification must be documented.

(C) *Eligibility*. To be eligible for the exemption, the National Aeronautics and Space Administration and its contractors must:

(*1*) Select perchloroethylene because there are no technically and economically feasible safer alternatives available during the emergency.

(*2*) Perform the emergency use of perchloroethylene at locations controlled by National Aeronautics and Space Administration or its contractors.

(2) *Requirements*.

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

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

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

(B) An explanation for why the emergency use met the definition of emergency in paragraph (b)(1)(ii)(A); and

(C) An explanation of why perchloroethylene was selected, including why there were no technically and economically feasible safer alternatives available in the particular emergency.

(ii) *Exposure control*. The owner or operator must comply with the Workplace Chemical Protection Program provisions in § 751.607, to the extent technically feasible in light of the particular emergency. (iii) *Recordkeeping*. The owner or operator of the location where the use

takes place must comply with the recordkeeping requirements in § 751.613.