PRE-PUBLICATION NOTICE

On December 6, 2024, Michael S. Regan, the EPA Administrator, signed the following document:

Action:	**Final Rule**
Title:	**Perchloroethylene (PCE); Regulation under the Toxic Substances Control Act (TSCA)**
FRL #:	**8329-01-OCSPP**
Docket ID #:	**EPA-HQ-OPPT-2020-0270**

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For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the Federal Register document.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA-HQ-OPPT-2020-0720; FRL-8329-01-OCSPP]

RIN 2070-AK84

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is finalizing a rule to address the unreasonable risk of injury to health presented by perchloroethylene (PCE) under its conditions of use. 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 that the chemical no longer presents unreasonable risk. EPA's final rule will, among other things, prevent serious illness associated with uncontrolled exposures to the chemical by preventing consumer access to the chemical, restricting the industrial and commercial use of the chemical while also allowing for a reasonable transition period where the industrial and commercial use of the chemical is being prohibited, providing a time-limited exemption for a critical or essential use of PCE for which no technically and economically feasible safer alternative is available, and protecting workers from the unreasonable risk of PCE while on the job.

DATES: This final rule is effective on **[DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0720, is available online at *https://www.regulations.gov*. Additional information

about dockets generally, along with instructions for visiting the docket in-person, is available at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT:

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For general information: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620-1103; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. *Does this action apply to me?*

1. *General applicability*.

You may be affected by this rule if you manufacture, process, distribute in commerce, use, or dispose of PCE or products containing PCE. TSCA section 3(9) defines the term "manufacture" to mean "to import into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedule of the United States), produce, or manufacture." Therefore, unless expressly stated otherwise, importers of PCE are subject to provisions regulating manufacture of 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 might apply 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).

2. *Applicability to importers and exporters.*

This action may also affect certain entities subject to import certification and export notification requirements under TSCA (*https://www.epa.gov/tsca-import-export-requirements*). Persons who import any chemical substance in bulk form, as part of a mixture, or as part of an article (if required by rule) are subject to 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(i)). Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA (see 19 CFR 12.121). 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 final 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. Any person who exports or intends to export PCE must comply with the export notification requirements in 40 CFR part 707, Subpart D.

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

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if 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). A description of the conditions of use that contribute to EPA's determination that PCE presents an unreasonable risk is in Unit III.B.1. of the 2023 PCE proposed rule, with a summary in Unit II.C.4. of this final rule. Accordingly, to address the unreasonable risk, EPA is finalizing a rule 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.D.1.;

(ii) Prohibit the manufacture (including import), processing, and distribution in commerce of PCE for all consumer use, outlined in Unit IV.D.2.;

(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.D.3.;

(iv) Require a Workplace Chemical Protection Program (WCPP), including an inhalation exposure concentration limit, direct dermal contact controls, and related workplace exposure controls, for many occupational conditions of use of PCE not prohibited, outlined in Unit IV.B.;

(v) Require prescriptive workplace controls for use of PCE in laboratories and energized electrical cleaners, outlined in Unit IV.C.;

(vi) Establish recordkeeping and downstream notification requirements, outlined in Unit

IV.E.;

(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 (NASA) 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.F.; and

(viii) Identify a regulatory threshold for products containing PCE for the prohibitions and restrictions on PCE, as outlined in Unit IV.A.

EPA notes that all TSCA conditions of use of PCE are subject to this final rule. "Conditions of use" is defined in TSCA section 3(4) to mean the circumstances, as determined by EPA, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

In addition, EPA is amending the general provision of 40 CFR part 751, Subpart A, to define "Designated representative," "Direct dermal contact," "ECEL," and "Exposure group" 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.

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. On June 16, 2023, EPA issued a proposed rule (88 FR 39652) (FRL-8329-02-OCSPP)) under TSCA section 6(a) to regulate PCE, so that it no longer presents unreasonable risk (hereinafter "2023 PCE proposed rule"). The Agency received public comment on the proposal. With this action, EPA is finalizing with modifications the 2023 PCE proposed rule as described in this final rule. The conditions of use that contribute to the unreasonable risk from PCE are described in Unit III.B.1. of the 2023 PCE proposed rule.

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 rule is neurotoxicity from chronic exposure. It was selected 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. 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 action, 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 final rule will 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.

Although EPA is prohibiting many conditions of use of the chemical where it cannot be used without continuing to present unreasonable risk as described in Unit IV., EPA is not finalizing 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 final rule allows 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 15-year phasedown under the AIM Act. 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 away from 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. It 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 United States gasoline pool. Therefore, this final rule allows 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 finalizing 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 (called the existing chemical exposure limit (ECEL)) in this rulemaking or to prevent direct dermal contact with PCE. For many of the conditions of use for which EPA is finalizing workplace controls under a WCPP, data to support the industry's position that certain uses could meet the exposure limit and ancillary requirements of an effective WCPP in addressing unreasonable risk were submitted during the risk evaluation, the Small Business Advocacy Review (SBAR) Panel process, the comment period following publication of the 2023 PCE proposed rule, or stakeholder outreach, and are available in the corresponding public dockets (Docket ID Nos. EPA-HQ-OPPT-2020-0720; EPA-HQ-OPPT-2019-0502; EPA-HQ-OPPT-2016-0732).

Accordingly, EPA is finalizing workplace controls to address the unreasonable risk and allow continued manufacture (including import), processing for conditions of use that are not prohibited, repackaging, recycling, and disposal of PCE as well as continued use of PCE for processing as a reactant/intermediate, certain uses in vapor degreasing and cold cleaning, use as a maskant for chemical milling, use in adhesives and sealants, use as a processing aid, use as energized electrical cleaner, and use as a laboratory chemical, which comprise more than an estimated 80% of the current production volume of PCE. EPA is finalizing a prohibition or phaseout for most conditions of use of PCE, including use in dry cleaning and spot cleaning, general 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 are not prohibited, EPA generally 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. The rationale for the final regulatory action, including the TSCA section 6 requirements considered in developing the regulatory action, is described in Units II.D. and III.

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 V.D. and VIII.C., EPA was unable to quantify all incremental costs of this final rule. The quantifiable cost of the final rule is estimated to be $43.43 million annualized over 20 years at a 2% discount rate. These costs take compliance with implementation of a WCPP into consideration, which would include meeting an 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 Economic Analysis notes various unquantified costs and uncertainty in the cost estimates (Sec. 7.14). The condition of use with the most expensive and uncertain compliance costs is the commercial use of PCE in energized electrical cleaning, which EPA estimates would result in about $20 million out of $43 million of estimated compliance costs. These estimates are based on assumptions regarding how much PCE is used for energized electrical cleaning and the types of locations of that use. Almost all of these compliance cost estimates are from respirator

requirements for the use of PCE in energized electrical cleaning in confined spaces, which would require expensive respirators. Because there is no consensus industry estimate for what fraction of PCE use in energized electrical cleaning is in confined spaces, as described in Unit III.A.2.e., EPA estimated 5% of energized electrical cleaning use of PCE was in confined spaces.

In addition, EPA estimates that 6,000 dry cleaners still use PCE, a majority of which are small businesses. 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 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 7-11 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 are generalizable to other states; industry has informed the Agency that very few PCE machines have been purchased in recent years. See sections 7.7 and 11 of the Economic Analysis for additional detail on EPA's analysis, including uncertainties associated with estimating the economic impact.

In alignment with the goals of President Biden's Cancer Moonshot, the rule will protect people from cancer and other adverse health effects of PCE by prohibiting most uses of PCE while ensuring essential uses can safely continue (Ref. 4). The actions in this final 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 $32.6 million to $84.6 million annualized over 20 years at a 2% 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 associated with PCE exposure in human studies include visual deficits, impaired cognition, and neurodevelopmental outcomes from prenatal and early

childhood exposure to PCE such as increased affinity of engaging in drug, alcohol, and tobacco use as a teen or adult (Ref. 1). Reductions in PCE exposure therefore may also be associated with additional important, but currently unmonetized, benefits.

Additionally, the Agency expects that the dry cleaning phaseout will decrease significant adverse health risks for affected populations that may own, operate, or work at dry cleaning facilities, as well as children of workers present at dry cleaners. 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). For the public's understanding, this document notes that based on reasonably available information, a significant number of members of minority populations may own or work at dry cleaning facilities.

II. Background

A. *Overview of Perchloroethylene (PCE)*

As described in more detail in the 2023 PCE proposed rule, PCE is a neurotoxicant and considered "likely to be carcinogenic in humans" This final 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 II.C. 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 Unit II.C.4., 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 United States decreased from 388 million pounds to around 324 million pounds between 2012 and 2015 (Ref. 5). The total aggregate annual production volume ranged from 250 to 500 million pounds between 2016 and 2019 according to CDR (Ref. 6).

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 as other Federal, State, and international regulations, is in the docket (Refs. 1, 7).

As described in more detail in Unit II.C. of 2023 PCE proposed rule, and the Response to Public Comments document (Ref. 8), EPA considered the adequacy of the current occupational safety and health standards from the Occupational Safety and Health Administration (OSHA) (29 CFR part 1910) for protection of workers. EPA notes that the standards for chemical hazards that OSHA promulgates under the Occupational Safety and Health (OSH) Act share a broadly similar purpose with the worker protection-related regulations 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, 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 when evaluating and addressing potential unreasonable risk to workers so that compliance requirements are clearly explained to the regulated community. TSCA risk evaluations are subject to statutory science standards, an explicit requirement to consider risks to

potentially exposed or susceptible subpopulations, and a prohibition on considering costs and other non-risk factors when determining whether a chemical presents an unreasonable risk that warrants regulatory actions—all requirements that do not apply to development of OSHA regulations. As such, EPA may find unreasonable risk for purposes of TSCA notwithstanding OSHA requirements. 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. 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, 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. Additional considerations of OSHA standards in the revised unreasonable risk determination are discussed further in the 2022 Revised Unreasonable Risk Determination for PCE, published in the *Federal Register* of

December 14, 2022 (87 FR 76481 (FRL-9942-02-OCSPP)).

EPA intends for this regulation to be as consistent as possible with OSHA regulations for toxic and hazardous substances, with additional requirements as necessary to address the unreasonable risk identified under TSCA. 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 enforcement of TSCA while imposing the least burdens of duplicative requirements.

C. *Summary of EPA's Risk Evaluation Activities on PCE*

EPA published the scope of the PCE risk evaluation in July 2017 (82 FR 31592 (FRL-9963-57)), and, after receiving public comments, published the problem formulation on June 11, 2018 (83 FR 26998 (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 Risk Determination for PCE in December 2022 (87 FR 76481, December 14, 2022 (FRL-9942-01-OCSPP)). The 2020 Risk Evaluation for PCE and supplemental materials are in Docket ID No. EPA-HQ-OPPT-2019-0502, and the December 2022 revised unreasonable risk determination and additional materials supporting the risk evaluation process in Docket ID No. EPA-HQ-OPPT-2016-0732.

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 (Ref. 1). Descriptions of these conditions of use are in Unit III.B.1. of the 2023 PCE proposed rule. The 2020 Risk Evaluation for PCE identified significant adverse health effects associated with short- and long-term exposure to PCE. A further discussion of the hazards of PCE is in Unit III.B.2. of the 2023 PCE proposed rule.

2. *2022 Revised Unreasonable Risk Determination.*

As described in more detail in the 2023 PCE proposed rule, 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 (titled "Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis") and other Administration priorities (Refs. 9, 10, and 11). The revisions consisted of making the risk determination based on the whole-chemical substance instead of making the risk determination for each individual condition of use, which resulted in the revised risk determination superseding the prior "no unreasonable risk" determinations for specific conditions of use (Ref. 2), the withdrawal of the associated TSCA section 6(i)(1) "no unreasonable risk" order, and clarification that the risk determination does not reflect an assumption that all workers are always provided and appropriately wear PPE (Ref. 2).

EPA determined that PCE presents an unreasonable risk of injury to health, and EPA did not identify risks of injury to the environment that contribute to the unreasonable risk determination for PCE. The PCE conditions of use that contribute to 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. of the 2023 PCE proposed rule, with descriptions to aid chemical manufacturers, processors, and users in determining how their particular use or

activity would be addressed under the final regulatory action.

3. *Description of unreasonable risk.*

EPA has determined that PCE presents an unreasonable risk of injury to health under the conditions of use, based on acute and chronic non-cancer risks and chronic cancer risks. As described in more detail in the 2023 PCE proposed rule and as described in the TSCA section 6(b) 2020 Risk Evaluation for PCE, EPA identified non-cancer effects from both 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). Other adverse effects associated with exposure to PCE include kidney and liver effects, immune system toxicity, and developmental toxicity. By targeting the sensitive chronic neurotoxicity effects endpoint for risk management, EPA's final rule will also prevent the unreasonable risks from acute, chronic non-cancer and cancer endpoints associated with inhalation and dermal exposure to PCE.

EPA considered potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by the Agency, which are included in the quantitative and qualitative analyses described in the 2020 Risk Evaluation for PCE (Ref. 1) and were considered in the determination of unreasonable risk for PCE.

4. *Conditions of use subject to this regulatory action.*

As noted in Unit I.C. "conditions of use" is defined in TSCA section 3(4). Condition of use descriptions for PCE are provided in Unit III.B.1. of the 2023 PCE proposed rule and were obtained from EPA sources such as CDR codes, the 2020 Risk Evaluation for PCE and related documents, as well as the Organisation for Economic Co-operation and Development (OECD)

harmonized use codes, and stakeholder engagements. EPA received public comments requesting minor clarifications of the descriptions for some industrial and commercial uses, and EPA has clarified those descriptions in Unit IV. A description of the minor changes can be found in the response to comments document and in Unit III.D. (Ref. 8). To assist with the implementation and compliance with the final rule, in Unit IV., EPA has provided a description of the conditions of use subject to the WCPP and to prescriptive controls.

As in the 2023 PCE proposed rule, for the purposes of this final rule, "occupational conditions of use" refers to the TSCA conditions of use described in Units III.B.1.a., b., c., and e. of the 2023 PCE proposed rule. Although EPA identified both industrial and commercial uses in the 2020 Risk Evaluation for PCE (Ref. 1) 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, as described in the 2023 PCE proposed rule, in the 2020 Risk Evaluation for PCE (Ref. 1), EPA identified and assessed all known, intended, and reasonably foreseen industrial, commercial, and consumer uses of PCE. EPA determined that all industrial, commercial, and consumer uses of PCE evaluated in the 2020 Risk Evaluation for PCE contribute to the unreasonable risk of injury to health. As such, for purposes of this risk management rule, "consumer use" refers to all known, intended, or reasonably foreseen PCE consumer uses. Likewise, for the purpose of this risk management rule, "industrial and commercial use" refers to all known, intended, or reasonably foreseen PCE industrial and commercial uses.

EPA further notes that this 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, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device.

D. *EPA's Proposed Rule under TSCA Section 6(a) for PCE.*

1. *Description of TSCA section 6(a) requirements.*

Under TSCA section 6(a), if the Administrator determines through 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 non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the Agency's risk evaluation, under the conditions of use, EPA must by rule apply one or more of the section 6(a) requirements to the extent necessary so that the chemical substance no longer presents such risk.

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

• Prohibit or otherwise restrict the manufacturing (including import), 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 (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 (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 (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 (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 (section 6(a)(4)).

• Prohibit or otherwise regulate any manner or method of commercial use of the substance or mixture (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 (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 (section 6(a)(7)).

In the 2023 PCE proposed rule under TSCA section 6(a), EPA analyzed how the TSCA section 6(a) requirements could be applied to address the unreasonable risk from PCE so that it no longer presents such risk. Unit II.D.1. of this final rule summarizes the TSCA section 6 considerations for issuing regulations under TSCA section 6(a). Unit V. of the 2023 PCE proposed rule outlines how EPA applied these considerations specifically to managing the unreasonable risk from PCE.

As required, EPA developed a proposed regulatory action and alternative regulatory actions, which are described in Units IV.A. and IV.B., respectively, of the 2023 PCE proposed rule. 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, 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 also 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 levels 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 the identified unreasonable risk, when selecting among possible TSCA section 6(a) regulatory requirements for the 2023 PCE proposed rule. EPA's considerations regarding TSCA section 6(c)(2)(A) for PCE are discussed in full in Unit VI. of the 2023 PCE proposed rule, including the statement of effects with respect to these considerations. After review of public comments received, EPA has revised its statement of effects considerations in Unit V. of this final rule.

Additionally, as described in more detail in the 2023 PCE proposed rule, EPA considered the availability of alternatives when finalizing a prohibition or a substantial restriction (TSCA section 6(c)(2)(C)) (Ref. 12), and in setting final compliance dates in accordance with the requirements in TSCA section 6(d)(1).

To the extent information was reasonably available, EPA considered pollution prevention strategies and the hierarchy of controls adopted by OSHA and the National Institute for Occupational Safety and Health (NIOSH) when developing its 2023 PCE proposed rule, with the goal of identifying risk management control methods that would be permanent, feasible, and effective. EPA also considered how to address the unreasonable risk while providing flexibility to the regulated community where appropriate and took into account the information presented in the 2020 Risk Evaluation for PCE (Ref. 1), input from stakeholders, insight received during consultations, and anticipated compliance strategies from regulated entities.

Taken together, these considerations led EPA to the proposed regulatory action and alternative actions described in Unit II.D.3. Additional details related to how the requirements described in this Unit II.D.1. were incorporated into development of the 2023 PCE proposed rule and alternative actions are in Unit V. of the 2023 PCE proposed rule.

2. *Consultations and other engagement.*

a. *Consultations.*

EPA conducted consultations and outreach as part of the development of the 2023 PCE proposed rule. The Agency held a federalism consultation from July 22, 2021, to October 22, 2021, as part of the rulemaking process and pursuant to Executive Order 13132 (Ref. 13).

EPA also consulted with Tribal officials during the development of the 2023 PCE proposed rule (Ref. 14). The Agency held a Tribal consultation from May 17, 2021, to August 20, 2021, with meetings on June 15 and July 8, 2021 (Ref. 14). EPA received no written comments as part of this consultation.

EPA's Environmental Justice (EJ) consultation occurred from June 3, 2021, to 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 Executive Orders 12898 and 14008. EPA received five written comments following the EJ meetings, in addition to oral comments provided during the consultation (Refs. 15, 16, 17, 18, 19). The 2023 PCE proposed rule presents a brief summary of the comments in Unit III.A.1. of the 2023 PCE proposed rule.

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 the rule's requirements. EPA met with SERs before and during Panel proceedings, on September 26, 2022, and November 10, 2022. Panel recommendations were addressed in Unit X.C. of the 2023 PCE

proposed rule and in the Initial Regulatory Flexibility Analysis (IRFA) (Ref. 20); the Panel report is in the docket (Ref. 21). EPA has also prepared a Final Regulatory Flexibility Analysis (FRFA) (Ref. 22).

The Agency presents more information regarding the consultations in Units X.C., X.E., X.F., and X.J. of the 2023 PCE proposed rule.

b. *Other stakeholder consultations.*

For development of the 2023 PCE proposed rule, in addition to the formal consultations described in Unit X. of the 2023 PCE proposed rule, EPA held a webinar on January 14, 2021, providing an overview of the TSCA risk management process and the risk evaluation findings for PCE (Ref. 23). EPA also presented on the TSCA risk management process and the findings in the 2020 Risk Evaluation for PCE (Ref. 24) at a Small Business Administration (SBA) Office of Advocacy Environmental Roundtable on January 15, 2021. Attendees of these meetings were given an opportunity to voice their concerns regarding the risk evaluation and risk management.

Furthermore, during development of the 2023 PCE proposed rule, EPA engaged in discussions with representatives from different industries, non-governmental organizations, organized labor, technical experts, and users of PCE. A list of external meetings held during the development of the 2023 PCE proposed rule is available in the docket (Ref. 25); meeting materials and summaries are also available in the docket. A summary of the topics discussed during these meetings is in Unit III.A.2. of the 2023 PCE proposed rule.

c. *Children's Environmental Health.*

The Agency's 2021 Policy on Children's Health (Ref. 26) 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." 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 (which includes unreasonable risk to any relevant potentially exposed or susceptible subpopulations). Information on how the 2021 Policy was applied and on the health and risk assessments supporting this action is available under Units II.C., II.D., and V.A., as well as in Unit III.A.3. of the 2023 PCE proposed rule, the 2020 Risk Evaluation for PCE (Ref. 1), and the Economic Analysis (Ref. 3).

3. *Proposed regulatory action.*

EPA's 2023 PCE proposed rule under TSCA section 6(a) to address the unreasonable risk presented by PCE under its conditions of use included the following:

• Prohibition of most industrial and commercial uses and the manufacture (including import), processing, and distribution in commerce, of PCE for those uses;

• Prohibition of the manufacture (including import), processing, and distribution in commerce of PCE for all consumer use;

• Prohibition of the manufacture (including import), processing, distribution in commerce, and commercial use of PCE in dry cleaning and spot cleaning through a 10-year phaseout;

• Requirements for 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 the 16 occupational conditions of use not prohibited;

• Requirements for prescriptive workplace controls for laboratory use;

• Establishments of recordkeeping and downstream notification requirements; and

• A 10-year time-limited exemption under TSCA section 6(g) for certain emergency uses of PCE in furtherance of NASA's mission, for specific conditions of use which are critical or essential and for which no technically and economically feasible safer alternative is available.

EPA notes that all TSCA conditions of use of PCE were subject to the 2023 PCE proposed rule and are subject to this final rule.

The 2023 PCE proposed rule included proposed timeframes for implementation. The prohibitions EPA proposed for most conditions of use would take effect in phases, beginning at the top of the supply chain, and coming into full effect after 24 months, as described in Units IV.A.1.a. and IV.A.1.b. of the 2023 PCE proposed rule. The phaseout period for dry cleaning that EPA proposed would take full effect after 10 years, as described in Unit IV.A.1.c. of the 2023 PCE proposed rule. Likewise, for the WCPP, EPA proposed timeframes for phases of compliance, beginning with monitoring at six months and full implementation after 12 months, as described in Unit IV.A.2. of the 2023 PCE proposed rule. EPA also proposed a compliance timeframe of 12 months for prescriptive controls for laboratory use.

Under TSCA section 6(c)(2)(A)(iv)(II) through (III), EPA is mandated to consider one or more alternative regulatory actions. These were included in the 2023 PCE proposed rule in Unit IV.B. Similar to the proposed regulatory action, both the primary and second alternative regulatory actions combined prohibitions, requirements for a WCPP, and prescriptive controls to address the unreasonable risk from PCE under its conditions of use.

The primary alternative regulatory action combined prohibitions, a WCPP, and prescriptive controls to address the unreasonable risk from PCE driven by its conditions of use. At the time of publication of the 2023 PCE proposed rule, uncertainties regarding 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, availability of alternatives, or whether the use is ongoing or phased out for most of these conditions of use led EPA to propose prohibition. At the time of proposal, EPA did not have reasonably available information to confidently conclude that these conditions of use could meet requirements of a WCPP. The alternative regulatory action also considered and included WCPP for laboratory use to seek input on requiring the non-prescriptive WCPP instead of the prescriptive workplace controls included in the proposed regulatory action. The primary alternative regulatory action also considered 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. Additionally, the primary alternative regulatory action included requirements for a concentration limit for PCE in industrial and commercial use in solvent-based adhesives and sealants.

The primary alternative regulatory action also included longer timeframes for prohibitions and implementation of WCPP and prescriptive controls. Those timeframes were described in Unit IV.B. of the 2023 PCE proposed rule.

The second alternative regulatory action combined prohibitions, requirements for a WCPP, prescriptive controls, and two time-limited exemptions to address the unreasonable risk from PCE driven by its conditions of use. This second alternative regulatory action included prohibitions on some conditions of use that would have requirements for a WCPP under the proposed regulatory action.

The second alternative regulatory action also included shorter compliance timeframes for prohibition and a WCPP. Additionally, this second alternative regulatory action did not include staggered prohibition compliance dates for manufacturers, processors, and distributors. The

secondary alternative regulatory action compliance timeframes are described in Unit IV.B. of the 2023 PCE proposed rule.

For a comprehensive overview of the alternative regulatory actions, refer to Unit IV.B. of the 2023 PCE proposed rule, with the rationale for the alternative regulatory actions provided in Unit V.A.2. of the 2023 PCE proposed rule.

4. *Public comments received.*

EPA requested comment on all aspects of the 2023 PCE proposed rule, and during the public comment period, EPA held a webinar on July 19, 2023, providing an overview of the 2023 PCE proposed rule and TSCA section 6; during the webinar, members of the public had the opportunity to share their perspectives (Ref. 27). The comment period closed on August 15, 2023. EPA received 749 public comments, with a majority received from individuals participating in mass mailer campaigns organized by non-governmental organizations. The public comments also include approximately 89 unique comments from industry stakeholders, trade associations, environmental groups, unions, academic institutions, a State government agency, a Federal Government agency, and members of the regulated community. A summary of the comments as well as EPA's responses is in the docket for this rulemaking (Ref. 8). Additionally, Unit III. contains summaries of public comments that informed EPA's regulatory approach in this final rule.

After the close of the public comment period for the 2023 PCE proposed rule, EPA held meetings with stakeholders to receive clarifying information on their comments, including affected industry and interested groups, related to the use of PCE. Topics of these meetings included exposure controls, process descriptions, monitoring data, and specific conditions of use. EPA received data as part of and following these stakeholder meetings and has made the information available to the public in the rulemaking docket (Docket ID No. EPA-HQ-OPPT-

2020-0720) (Ref. 28).

After review of the public comments received on the 2023 PCE proposed rule, EPA revised certain preliminary considerations that impacted which conditions of use were proposed by EPA to be prohibited or that could continue under the WCPP or prescriptive controls (Ref. 8). Similarly, based on public comments received, EPA modified for this final rule several proposed compliance timeframes, with details in Unit III.

III. Changes from the Proposed Rule based on Public Comment

Unit III. summarizes the main changes from the 2023 PCE proposed rule to this final rule, based on the consideration of the public comments.

A. *Changes to the risk management approach for certain conditions of use.*

As described in Units III.A.1. and 2., when compared to the 2023 PCE proposed rule, EPA's final rule prohibits two additional conditions of use (Unit III.A.1.), allows three additional conditions of use under the WCPP (Units III.A.2.a. through c.), broadens the types of prescriptive controls required for one condition of use (Unit III.A.2.d.), and allows one additional condition of use to continue under specific prescriptive controls or the WCPP (Unit III.A.2.e.). The rationale for these changes is described in this unit. EPA emphasizes that implementation of the WCPP or prescriptive controls can fully address the unreasonable risk from PCE for the conditions of use allowed to continue, and that these changes do not significantly impact the production volume of PCE expected to remain in commerce when compared to the proposed regulatory action. Taken together, the conditions of use described in Unit III.A.1. and 2. account for less than an estimated 5% of the total production volume of PCE.

1. *Additional conditions of use subject to prohibition: Industrial and commercial uses of PCE as a solvent for in-line vapor degreasing.*

EPA is finalizing a prohibition for the industrial and commercial use of PCE as a solvent

for in-line conveyorized vapor degreasing and for in-line web cleaner vapor degreasing, which were considered for prohibition in the second alternative regulatory action of the 2023 PCE proposed rule. As described in section 6 of the Economic Analysis for the 2023 PCE proposed rule (Ref. 29), EPA estimated that approximately two conveyorized vapor degreasers and no web vapor degreasers use PCE. One public commenter, a critical cleaning consultant, stated they no longer encounter in-line conveyorized or in-line web vapor degreasers using PCE (Ref. 30). Additionally, commenters identified alternative types of degreaser technologies, such as open-top batch vapor degreasers, closed-loop batch vapor degreasers, and airless batch vapor degreasers, that clean effectively and for which monitoring data and detailed process descriptions of PCE activities for these types of degreasers confirm that compliance with an ECEL of 0.14 ppm as an 8-hr TWA is possible (Refs. 30, 31). As described in Unit V.A.1. of the 2023 PCE proposed rule, prohibition is the preferred risk management option for occupational conditions of use where reasonably available information suggest minimal ongoing use or when feasible safer alternatives are reasonably available. Based on information provided by commenters and other information reasonably available to the Agency indicating that the use of PCE in in-line conveyorized and in-line web vapor degreasing is no longer ongoing, and availability of technologically feasible alternative vapor degreasing technology, EPA has determined that the unreasonable risk from PCE when used in both types of in-line vapor degreasers is best addressed with a prohibition.

2. *Additional conditions of use subject to restrictions: WCPP and prescriptive controls.*

a. *Processing PCE into formulation, mixture, or reaction product in other chemical products and preparations.*

EPA is finalizing a WCPP for processing PCE into formulation, mixture, or reaction product in other chemical products and preparations, as included in the primary alternative

regulatory action of EPA's proposal (88 FR 39652, June 16, 2023)(FRL-8329-02-OCSPP)). While EPA proposed to prohibit processing PCE into formulation, mixture or reaction product in other chemical products and preparations, this was because EPA proposed to prohibit the downstream industrial, commercial, and consumer uses associated with other chemical products and preparations. EPA included this condition of use under the WCPP in the primary alternative regulatory action.

EPA received several comments regarding processing PCE into formulation, mixture, or reaction product. One commenter stated that there appeared to be a disconnect between the proposed prohibitions on processing PCE versus prohibitions on distribution and/or use of PCE and requested that EPA clarify the prohibitions throughout all steps in the supply chain for each particular condition of use (Ref. 32). For example, the commenter stated that EPA proposed that PCE may be processed into a formulation, mixture, or reaction product in paint and coating mixtures but also proposed to prohibit the manufacturing, processing, distribution in commerce, and use of PCE in solvent-based paints and coatings. The commenter also stated that EPA proposed that PCE could be used for industrial and commercial use in maskants for chemical milling but did not explicitly permit the manufacturing or processing of PCE for use in maskants. Another commenter expressed opposition to EPA's proposed prohibition on processing of PCE for other chemical products and preparations, and stated that the proposed prohibition appeared to be based on an overly broad assumption that exposures to PCE in this condition of use correspond to aerosol packing (Ref. 33).

In Unit III.B.1.b.iv. of the 2023 PCE proposed rule, EPA described how the condition of use of processing PCE into formulation, mixture, or reaction products in paint and coating products refers to when PCE is added to a paint or coating product for further distribution, including when PCE is incorporated into coating products such as maskant (88 FR 39652, June

16, 2023)(FRL-8329-02-OCSPP)). However, to avoid confusion regarding which processing into formulation, mixture, or reaction product condition of use of PCE is associated with each downstream industrial and commercial condition of use of PCE, and, in particular, confusion regarding which products may fall under the category of "other chemical products and preparations," EPA is finalizing WCPP for all PCE processing into formulation, mixture, or reaction products, including in other chemical products and preparations, to make clear that all processing of PCE into formulation, mixture, or reaction product conditions of use, including in cleaning and degreasing products, in adhesive and sealant products, and in paint and coating products that are not prohibited by virtue of the downstream use being prohibited, are subject to the WCPP. As in the 2023 PCE proposed rule, all manufacturing, processing, and distribution in commerce of PCE for any downstream industrial, commercial, or consumer condition of use that is prohibited under the final rule would also be prohibited. In response to a comment requesting clarity regarding prohibitions throughout all steps of the value chain for each condition of use, EPA clarifies that the final rule includes prohibitions (staggered by lifecycle stage) for the manufacture, processing, distribution in commerce, and for all consumer, industrial and commercial use of PCE and PCE-containing products, except for those industrial and commercial uses which will continue under the WCPP or prescriptive controls, or are otherwise not prohibited. Therefore, in this final rule, WCPP applies to processing PCE for uses that are not prohibited.

b. *Industrial and commercial use of PCE as a processing aid.*

EPA is finalizing a WCPP for industrial and commercial use of PCE as a processing aid in pesticide, fertilizer, and other agricultural manufacturing, as included in the primary alternative regulatory action of the 2023 PCE proposal rule. While EPA proposed to prohibit the industrial and commercial use of PCE as a processing aid in pesticide, fertilizer, and other

agricultural manufacturing, this was due to insufficient information at the time of proposal to determine that compliance with the WCPP would be possible. For example, at the time of proposal, EPA was not aware of any monitoring data or detailed description of PCE activities for this use to confirm that compliance with an ECEL of 0.14 ppm as an 8-hr TWA would be possible. EPA requested comment on the ability of facilities in this sector to successfully implement the WCPP for this particular use because of the industrial nature of the use.

EPA received a few comments regarding the industrial and commercial use as a processing aid in pesticide, fertilizer, and other agricultural manufacturing. Two commenters disagreed with EPA's proposal to prohibit PCE use as a processing aid in the manufacture of agricultural chemicals and stated that it is unclear what information EPA relied on to conclude that this use could not meet the WCPP requirements (Refs. 33, 34). One commenter stated that this use of PCE is critical to the manufacture of certain agricultural products and described how they limit PCE exposure and manage production risks through strong product stewardship and industrial hygiene practices. Following a meeting to receive clarifying information on their comment, one commenter submitted information on worker activities and safety measures in place that provide worker protection for this use (Ref. 35). As described in the submitted information, activities associated with potential exposure to PCE include transfer, sample, and maintenance, where control measures such as purging lines/vessels prior to opening, closed sampling box, and PPE reduce exposures. Based on the information received, EPA believes such control measures that indicate the ability to comply with the WCPP requirements may be implementable for all those using PCE as a processing aid in pesticide, fertilizer, and other agricultural chemical manufacturing.

Additionally, information submitted to EPA indicates that PCE may be used as a processing aid in industrial sectors other than petrochemical manufacturing and pesticide,

fertilizer, and other agricultural chemical manufacturing (Refs. 33, 36). The 2020 Risk Evaluation assessed occupational exposures for "processing aids, specific to petroleum production – catalyst regeneration in petrochemical manufacturing" and "processing aids, not otherwise listed – pesticide, fertilizer and other agricultural chemical manufacturing" under the industrial processing aid Occupational Exposure Scenario (Ref. 1). While other specific processing aid uses of PCE were not identified in the 2020 Risk Evaluation, EPA expects the exposure assessment, including the worker activities, to be consistent across all processing aid type uses. For example, as assessed in the risk evaluation, worker activities that may result in exposure for use as a processing aid include unloading PCE into process equipment and maintenance. Similar to control measures that reduce the potential for exposure and indicate the ability to comply with the WCPP for use as a processing aid in the pesticide, fertilizer, and other agricultural chemical manufacturing sector, EPA has determined that control measures such as use occuring in a highly specialized closed system with minimal exposure to PCE during infrequent worker activity limit the potential for exposure and indicate the ability to comply with the WCPP for use as a processing aid in other industrial sectors. Therefore, EPA believes the WCPP requirements are practicable and implementable for all processing aid uses which occur at sophisticated industrial sites. EPA's determination is based on reasonably available information included in submissions to EPA related to process descriptions, worker activities, and exposure mitigation practices for use of PCE as an industrial processing aid in sectors other than petrochemical manufacturing and pesticide, fertilizer, and agricultural chemical manufacturing (Refs. 1, 36).

The information submitted to EPA as part of the comment period regarding the industrial and commercial use of PCE as a processing aid in sectors other than petrochemical manufacturing (including industrial and commercial use as a processing aid in pesticide,

fertilizer and agricultural chemical manufacturing) and supported by subsequent discussions, demonstrated the users' ability to comply with the WCPP. For this reason, EPA has determined that the unreasonable risk from PCE when used as a processing aid, even in sectors other than petrochemical manufacturing and pesticide, fertilizer, and agricultural chemical manufacturing, could be addressed with a WCPP. Therefore, in this final rule, EPA is finalizing a WCPP for all industrial and commercial use of PCE as a processing aid in sectors other than petrochemical manufacturing and a WCPP for industrial and commercial use of PCE as a processing aid in catalyst regeneration in petrochemical manufacturing.

c. *Industrial and commercial use of PCE as solvent for cold cleaning of tanker vessels.*

EPA is finalizing a WCPP for industrial and commercial use of PCE as solvent for cold cleaning of tanker vessels, which is a sub-use of the industrial and commercial use of PCE as solvent for cold cleaning, which EPA proposed to prohibit in the proposal (88 FR 39652, June 16, 2023) (FRL-8329-02-OCSPP)). While EPA proposed to prohibit industrial and commercial use of PCE as solvent for cold cleaning, this was due to insufficient information at the time of proposal to determine that compliance with the WCPP would be possible and EPA believed alternatives were reasonably available. EPA requested comment on whether to consider a regulatory alternative that would subject more conditions of use of PCE to a WCPP, instead of a prohibition, than those contemplated in the primary alternative regulatory action. EPA also requested 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 received one comment regarding the industrial and commercial use of PCE in cold cleaning of tanker vessels. The commenter requested that EPA not prohibit this use because entities utilize PCE and other solvents, such as methylene chloride, ortho-dichlorobenzene,

monochlorobenzene, and toluene, to clean tanks safely and effectively, when water and detergents are not compatible with the cargo material (Ref. 37). The commenter suggested that EPA establish the WCPP to maintain this use. Following a September 26, 2023, meeting with an industry user to receive clarifying information on their comment, the commenter submitted information on worker activities and safety measures in place that provide worker protection for this use (Ref. 38). As described in the submitted information, tank cleaning with a solvent is typically infrequent (about every two years) and worker exposure occurs during sampling and connecting or disconnecting of hoses to or from the ship manifold or waste truck, activities during which control measures are in place. Based on the information submitted regarding this condition of use, and supported by subsequent discussions, EPA believes such controls and safety measures may be implementable industry wide.

EPA received two comments regarding industrial and commercial use of PCE in cold cleaning generally. One commenter stated that the empirical and modeled exposure data for cold cleaning in the risk evaluation are very similar to that for degreasing, but EPA proposed to allow continued use of PCE under the WCPP in vapor degreasing and not cold cleaning (Ref. 33). Another commenter associated with the aerospace and defense sector urged EPA to permit ongoing use under the WCPP for PCE as a cold, immersion cleaner (Ref. 32). However, for all cold cleaning other than cold cleaning of tanker vessels, EPA does not have any reasonably available information, including monitoring or detailed process description, that supports the ability to comply with a WCPP such that the risks are no longer unreasonable. EPA does not have any reasonably available information that indicates the exposure frequency, worker activities, and safety measures associated with cold cleaning of tanker vessels, as described by the commenter, are applicable to other cold cleaning operations, which may vary in equipment design or worker activities (Ref. 37, 38).

The information submitted to EPA during the comment period regarding the industrial and commercial use of PCE as a solvent for cold cleaning of tanker vessels, supported by subsequent discussions, demonstrated the users' ability to comply with the WCPP. For this reason, EPA has determined that the unreasonable risk from PCE when used in cold cleaning of tanker vessels could be addressed with a WCPP. EPA is finalizing a prohibition for all other cold cleaning applications of PCE.

d. *Industrial and commercial use of PCE as a laboratory chemical.*

In general, EPA is finalizing the prescriptive control requirements for the industrial and commercial use of PCE as a laboratory chemical as proposed, with some modifications, based on consideration of public comments. As described in the 2023 PCE proposed rule, to address the unreasonable risk of injury to health resulting from dermal exposures to PCE for the industrial and commercial use as a laboratory chemical, EPA proposed to require dermal PPE in combination with comprehensive training for tasks related to the use of PCE in a laboratory setting for each potentially exposed person in direct dermal contact with PCE. EPA also proposed to require the use of fume hoods 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). EPA requested comment relative to the ability of owners and operators to implement laboratory chemical fume hood and dermal PPE-related requirements within 12 months of publication of the final rule. Under the primary alternative regulatory action, EPA included the WCPP for laboratory use of PCE and solicited comment on non-prescriptive requirements to meet an ECEL and Direct Dermal Contact Control (DDCC) as compared to the prescriptive workplace controls of using a fume hood and dermal PPE.

EPA received several comments regarding the industrial and commercial use of PCE as a laboratory chemical. Several commenters stated that the proposed regulation would result in

confusion and duplication with the OSHA standard for occupational exposure to hazardous chemicals in laboratories under 29 CFR 1910.1450 that is already in effect (Refs. 39, 40, 41). The commenters urged EPA to more closely align its requirements for laboratory use of PCE with OSHA's laboratory standard to reduce the compliance burden. Some commenters expressed support for the use of fume hoods and other engineering controls over the WCPP and suggested that EPA include flexibility for engineering controls beyond a fume hood for consistency with the OSHA laboratory standard (Refs. 40, 42). The commenters stated that while fume hoods are considered best practice and are commonly used to reduce exposure in laboratories, some experiment designs utilizing PCE may not be able to be accommodated within a fume hood. Commenters described other alternative controls that can be designed and implemented to reduce exposure, such as glove boxes, exhausted enclosures, air-free solvent purification systems, and fume extractors. One commenter described other laboratory standards, including the American National Standards Institute (ANSI)/American Society of Safety Professionals (ASSP) Z9.5 Laboratory Ventilation standard and the ANSI/American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) 62.1 Ventilation and Acceptable Indoor Air Quality standard, that laboratories adhere to in addition to OSHA's laboratory standard that they state meet or exceed the worker protections under EPA's proposed WCPP and prescriptive controls (Refs. 41, 43, 44).

Based on information provided by commenters related to exposure mitigation controls to comply with the OSHA laboratory standard and best management practices available to laboratories, EPA has determined that requiring laboratory ventilation devices such as fume hoods or glove boxes would better align with the OSHA laboratory standard and existing good laboratory practices. As described in Unit V.A.1. of the 2023 PCE proposed rule, EPA proposed to require fume hoods in laboratory settings to codify assumptions made in the 2020 Risk

Evaluation for PCE, where EPA's risk estimates and determination that inhalation exposures from the industrial and commercial use of PCE as a laboratory chemical did not contribute to the unreasonable risk were predicated on its findings that expected safety practices of using PCE in small amounts under a fume hood reduce the potential for inhalation exposures. For the industrial and commercial use of PCE as a laboratory chemical, EPA concurs with the commenters that indicated EPA's requirements should align more closely with the OSHA laboratory standard wherever possible to prevent confusion. The requirement in this final rule that laboratory ventilation devices, such as fume hoods or glove boxes, 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 PCE is used in a laboratory setting aligns with existing requirements from 29 CFR 1910.1450(e)(3)(iii).

As detailed in Unit IV.C. of this final rule, EPA is finalizing as proposed the requirements for dermal PPE in combination with comprehensive training for tasks related to the use of PCE in a laboratory setting. EPA believes these requirements align with OSHA's laboratory standard and OSHA's General Requirements for Personal Protective Equipment at 29 CFR 1910.132 to the extent possible while still addressing the unreasonable risk of injury to health resulting from dermal exposures to PCE identified for the industrial and commercial use as a laboratory chemical.

e. *Industrial and commercial use of PCE as energized electrical cleaner.*

EPA is finalizing requirements to comply with *either* specific prescriptive controls *or* the WCPP for the industrial and commercial use of PCE as energized electrical cleaner, which is a sub-use of the industrial and commercial use of PCE as solvent for aerosol spray degreaser/cleaner, as described in Unit III.B.1.c.vi. of the 2023 PCE proposed rule. In the proposal, EPA proposed to prohibit the industrial and commercial use of PCE as solvent for

aerosol spray degreaser/cleaner because the Agency was not able to identify reasonably available information such as monitoring data or detailed activity descriptions to indicate with certainty that relevant regulated entities could mitigate the identified unreasonable risk through a WCPP. EPA considered requiring a WCPP for this condition of use under the primary alternative regulatory action because of uncertainties regarding the availability of alternatives for all aerosol spray degreasing/cleaning applications, including for energized electrical cleaning. EPA requested comment on the ways PCE may be used, including the likelihood of successful compliance with the WCPP for this condition of use. EPA also requested 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. Additionally, EPA requested comment on whether to include a self-certification requirement for purchasing PCE or PCE-containing products.

EPA received several comments expressing concern over the proposed prohibition on energized electrical cleaning (Refs. 45, 46, 33, 47, 48, 49). Several commenters stated that safer alternatives are not available because alternative products not containing PCE likely present a flammability safety issue (Refs. 45, 48, 47, 50). A commenter also stated that some cleaning in the electrical utility industry is conducted underground in confined spaces where respiratory protection is used and a non-flammable product, such as those containing PCE, is needed to control a potential fire hazard (Ref. 45). In addition to describing the need for PCE in energized electrical cleaning, commenters described the work practices and context that support the potential for exposure reduction to PCE through workplace controls, rather than prohibition. As an example, one commenter described work practices and controls for energized electrical cleaning, stating that facilities that require cleaning of energized equipment rely on skilled technicians or other professional users who typically have education and training that may

include two years at lineman school, time as an apprentice, licensing or certifications, and continuing education (Ref. 45).

Additionally, the commenter stated that OSHA General Industry and Construction standards include requirements specific to electrical work under 29 CFR part 1926, Subparts E, K, and V. Commenters also described State-level regulations that exclude energized electrical cleaners from prohibitions on the manufacture and sale of PCE-containing general purpose degreasing products, electrical cleaners, and electronic cleaners (Refs. 45, 49). Another commenter stated that EPA should not prohibit energized electrical cleaning because petroleum refineries safely use energized electrical cleaners on a regular basis (Ref. 48).

While many commenters advocated for continued use of PCE for this condition of use, they differed in whether the WCPP or other workplace controls would be most suitable. Some commenters stated that the WCPP would be impractical for energized electrical cleaning because trained technicians often travel to different facilities to conduct work, including facilities that may not otherwise use PCE, and suggested that instead of a WCPP, a training and certification program would be sufficient to address the unreasonable risk (Refs. 45). Other commenters suggested PCE use for cleaning of energized electrical equipment should be exempt from the rule under a TSCA section 6(g) exemption (Refs. 45, 46, 33, 47).

Based on the information submitted to EPA as part of the comment period regarding this condition of use, supported by subsequent discussions, and in consideration of existing best practices and regulations for work in electrical spaces as well as the lack of reasonably available technically and economically feasible alternatives to PCE that also do not present a potential flammability concern for energized electrical cleaning, EPA has determined that the unreasonable risk from PCE when used as energized electrical cleaner could be addressed with a combination of labeling, self-certification, and either the WCPP or specific prescriptive controls,

including dermal PPE and respiratory protection. EPA notes the importance of existing OSHA regulations designed to protect workers exposed to dangers such as electric shock, electrocution, fires, and explosions. Specifically, in addition to the requirements for electrical work under OSHA General Industry and Construction standards at 29 CFR part 1926, Subparts E, K, and V that one commenter mentioned in their public comment, OSHA regulates electrical work under Occupational Safety and Health standards at 29 CFR part 1910. For example, OSHA requires safety-related work practices on electrical equipment under the Electrical Standard at 29 CFR part 1910, Subpart S (29 CFR 1910.301 to 1910.399), which was significantly updated in 2007. OSHA also sets forth requirements for the operation and maintenance of electrical power generation, control, transformation, transmission, and distribution lines and equipment under the Electric Power Generation, Transmission, and Distribution Standard at 29 CFR part 1910, Subpart R (29 CFR 1910.269), last amended in 2015. Additionally, OSHA regulates electrical protective equipment under the Electrical Protective Equipment Standard at 29 CFR part 1910, Subpart I (29 CFR 1910.137), which was significantly updated in 2014. Other standards and best practices apply to electrical safety in the workplace, for example the National Fire Protection Association 70E Standard for Electrical Safety in the Workplace (Ref. 51).

Under the Electrical Standard at 29 CFR 1910.333 and the Electric Power Generation, Transmission, and Distribution Standard at 29 CFR 1910.269, OSHA requires employers to establish minimum approach distances from exposed energized parts, depending on the voltage, that persons must maintain unless they are a qualified employee that meets certain requirements under 29 CFR 1910.269(l)(3)(iii)(A) through (C) or 29 CFR 1910.333(c)(3)(ii)(A) through (C). In instances where persons need to clean or degrease energized equipment in an area that is not considered a confined space, as defined in 29 CFR 1910.146(b), or an enclosed space (such as a manhole or vault) as described in 29 CFR 1910.269(e), for example housekeeping overhead

lines, but are not permitted to approach or take conductive objects closer to the exposed energized part than the employer's established minimum approach distance, persons may be able to use tools, such as a hotstick with an aerosol spray can holder adapter or other live-line tools to clean the energized equipment (Ref. 52). In such instances where persons are maintaining the established minimum approach distance while conducting energized electrical cleaning in an area that is not confined or enclosed, EPA believes the potential for inhalation exposures is minimal.

As noted earlier, EPA has determined that the unreasonable risk from PCE when used as energized electrical cleaner could be addressed with a combination of labeling, self-certification, and either (i) specific prescriptive controls, including dermal PPE and respiratory protection, or (ii) the WCPP. EPA's finalized requirements for industrial and commercial use of PCE as energized electrical cleaner are described in Unit IV.C.2. Other industrial and commercial use as a solvent for aerosol spray degreasers/cleaners is prohibited in the final rule, consistent with the proposal for that condition of use. EPA's workplace requirements to address the unreasonable risk for PCE as an energized electrical cleaner are consistent to the extent possible with existing regulations and best practices for work in electrical spaces such as OSHA's Electrical Standard at 29 CFR part 1910, Subpart S and the Electric Power Generation, Transmission, and Distribution Standard at 29 CFR part 1910, Subpart R.

In this final rule, EPA is also adding a definition of "energized electrical cleaner" to 40 CFR 751.603, consistent with the definition promulgated in States such as California (*Title 17, California Code of Regulations, Article 2, section 94508*), New York (*6 CRR-NY III A 235*), Maine (*06 ME Code Rules § 096-152*), Rhode Island (*250-RICR-120-05-31*), Connecticut (*section 22a-174-40*), Delaware (*7 Del. Admin. Code § 1141-1.0*), Washington, D.C. (*20 DCMR, Chapter 7, section 718*), Maryland (*COMAR 26.11.32*), New Jersey (*New Jersey Administrative*

Code 5:23-6.1), Indiana (*Standards for Consumer and Commercial Products (CCP)—VOC Rule 326 IAC 8-15*), Illinois (*Administrative Cod Title 35, § 223.265*), and Massachusetts (*310 CMR 7.25*).

B. *Changes to timeframes.*

1. *Changes to the WCPP timeframe.*

For the conditions of use for which EPA proposed the WCPP, EPA proposed several compliance timeframes, including the following requirements:

• Initial exposure monitoring must be conducted within six months of publication of the final rule or within 30 days of introduction of PCE into the workplace if PCE use commences at least six months after the date of publication;

• Each owner or operator ensure that exposure to PCE does not exceed the ECEL as an 8-hour TWA for all potentially exposed persons within nine months of publication of the final rule; and

• Owners and operators implement an exposure control plan within 12 months of publication of the final rule.

In the primary alternative regulatory action described in the 2023 PCE proposed rule, EPA described slightly longer timeframes that included the following:

• Initial exposure monitoring be conducted within 12 months of publication of the final rule;

• Each owner or operator ensures that the exposure to PCE does not exceed the ECEL as an 8-hour TWA for all potentially exposed persons within 15 months of publication of the final rule; and

• Owners and operators implement an exposure control plan within 18 months of publication of the final rule.

EPA requested comment regarding the ability of owners or operators to comply with the various provisions of the WCPP, including initial exposure monitoring, within the compliance timelines included in the proposal, and anticipated timelines for any procedural adjustments needed to comply with the establishment of a respiratory protection program and development of an exposure control plan. EPA further requested comment on any advantages or drawbacks associated with the longer timeframes outlined in the primary alternative regulatory action, and noted that the Agency may finalize significantly shorter or longer compliance timeframes based on consideration of public comments. EPA also requested comment regarding issues around the viability of current analytical methods and detection limits for occupational PCE sampling and/or monitoring methods.

Public comments highlighted challenges with the proposed timeframes and suggested longer timeframes for initial exposure monitoring. For example, some commenters stated that the proposed 6-month timeframe within which to conduct initial exposure monitoring may not be possible because PCE use may be infrequent and occur only periodically or annually, such as in maintenance exercises or in batch manufacturing operations (Refs. 53, 54, 32). One commenter expressed concern that requirements to comply with a new exposure limit would stress industrial hygiene consultants and laboratories that analyze the samples, and urged EPA to ensure that there would be adequate time for consultant firms and laboratories to establish sufficient capacity (Ref. 55). Some commenters described how entities need more time than what was proposed to assess exposures to various products and processes and noted that the complexity of the WCPP provisions would require taking multiple measurements for the presence of PCE in various operations across multiple facilities, which will be challenging to layer on top of the employer's OSHA compliance practices (Refs. 32, 47, 54). Other commenters stated the proposed 6-month timeframe for initial monitoring would be untenable and suggested that the deadline be extended

to 12 months (Refs. 31, 33, 56, 49). Two commenters reasoned that at least 12 months would be necessary to revalidate methods and determine whether revision to corporate exposure assessment strategy would be necessary to address the new ECEL (Refs. 33, 49). Commenters stated that a corporate exposure assessment strategy or similar mechanism would necessitate the procurement of professional services, adding logistical demand for these specialized services. The commenters also noted that monitoring at the proposed ECEL and action level would likely require laboratory analysis (rather than direct measurement) that will delay the availability of results and make meeting a 6-month timeframe challenging.

In consideration of public comments and the challenges of initiating the WCPP, even for facilities with industrial hygiene programs in place, and the difference in the occupational exposure limits between the OSHA permissible exposure limit (PEL) and the EPA ECEL and the challenges associated with monitoring to new, lower EPA exposure thresholds that may spur an increase in the need for monitoring or other exposure control assessment infrastructure, EPA has determined that a longer compliance deadline of 360 days, as provided in the primary alternative regulatory action described in the proposal, is as soon as practicable to conduct initial monitoring for PCE, which likely would require regulated entities to contract new services or realign current industrial hygiene professionals towards WCPP compliance. Adopting this timeframe from the primary alternative approach (providing 360 days for initial monitoring) is intended to: 1) prevent professional safety service sectors from being overwhelmed by new EPA requirements; 2) provide time to procure the necessary services while ensuring the preservation of safety quality, standards, and practices; and 3) provide sufficient time for a comprehensive exposure evaluation, increasing the likelihood of successful implementation of the WCPP. Following initial monitoring, EPA is finalizing the requirement that each owner or operator supply a respirator to each person who enters a regulated area within three months after the receipt of any

exposure monitoring that indicates exposures exceeding the ECEL. Therefore, the requirements for each owner or operator to ensure that exposures to PCE do not exceed the ECEL as an 8-hour TWA for all potentially exposed persons, including by providing respiratory protection, take effect 450 days after publication of the final rule. Given the full WCPP requirements (including the exposure control plan) are required after owners or operators are required to ensure that no person is exposed to an airborne concentration that exceeds the TWA ECEL, EPA acknowledges that compliance with the ECEL may include temporary PPE use (*e.g.,* respiratory protection) until comprehensive engineering and administrative controls are fully implemented. As described in the 2023 PCE proposed rule, EPA believes that three months after receipt of exposure monitoring results is as soon as practicable, while also providing a reasonable transition period for entities to evaluate exposure monitoring results, acquire the correct respiratory protection, and establish the PPE program, including training, fit-testing, and medical evaluation. Additionally, for clarity in regulatory requirements and reduced burden in implementation, EPA is finalizing a compliance date for preventing direct dermal contact, including by use of dermal PPE, that is 450 days after publication of the final rule, so that this compliance timeframe is consistent with timeframe to ensure inhalation exposures do not exceed the ECEL. EPA believes that 450 days is as soon as practicable and provides a reasonable transition period for regulated entities to evaluate potential for direct dermal contact with PCE, establish a PPE program, acquire the appropriate dermal PPE, and conduct the required training.

EPA also received public comment regarding the compliance timeframe for full implementation of the WCPP, including detailing the evaluation steps that would be required to assess a facility and develop, document, and implement an exposure control plan. To allow time for orderly transitions and training to comply with an ECEL (0.14 ppm (8-hr TWA)) that is significantly lower than the OSHA PEL of 100 ppm (8-hr TWA) and the American Conference

of Governmental Industrial Hygienists (ACGIH) threshold limit value (TLV) of 25 ppm (8-hr TWA) for PCE, some commenters suggested that EPA adopt a graduated implementation approach for ECEL implementation by first requiring entities that already meet the OSHA PEL to comply with the ACGIH TLV within two years from the effective date of the final rule and then permitting those facilities meeting the ACGIH standard two years to transition to the ECEL (Refs. 57, 54). Two commenters expressed concern that the proposed timeframes would be insufficient for owners or operators to document their efforts to implement the hierarchy of controls as required under the WCPP, and recommended that the time required to develop the exposure control plan be extended to two years from completion of initial monitoring, for a total of 24 to 36 months from the effective date of the final rule, to provide adequate time for entities to evaluate and implement appropriate compliance approaches that are the least burdensome and most effective for workers (Refs. 49, 33).

Based on comments, outreach, reasonably available information, existing OSHA standards, and industry best practices, EPA maintains that the majority of the exposure reduction and worker safety infrastructure needed for compliance is currently in place, but recognizes the fundamental challenge of building a new exposure control strategy around the new, lower EPA exposure limit. Additionally, based on consideration of public comment and given that OSHA has not promulgated a detailed standard specific to PCE, EPA has determined that a longer compliance timeframe of 900 days for development and implementation of an exposure control plan is as soon as practicable to ensure that the regulated community has adequate time to evaluate monitoring data, assess and develop an exposure strategy, procure appropriate control technology and PPE, and implement the required chemical safety program for PCE.

Therefore, EPA is finalizing the compliance timeframes for the WCPP provisions as follows: 1) The requirements for each owner or operator to conduct initial baseline monitoring

must be met within 360 days of the publication date for this final rule or within 30 days of introduction of PCE into the workplace, whichever is later; 2) The requirements for each owner or operator to ensure that exposure to PCE does not exceed the ECEL as an 8-hour TWA for all potentially exposed persons, including by providing respiratory protection to all potentially exposed persons in the regulated area must be met within 450 days of the publication date for this final rule or within three months after receipt of the results of any exposure monitoring that indicates an exceedance of the ECEL; 3) The requirements that each owner or operator ensure all persons are separated, distanced, physically removed, or isolated from direct dermal contact with PCE, including by providing dermal PPE, must be met within 450 days of the publication date of this final rule; and 4) The requirements for development and implementation of an exposure control plan must be met within 900 days of the publication date of this final rule. EPA is also finalizing as proposed, with a slight modification, the requirement that owners and operators institute a training and information program for potentially exposed persons and assure their participation in the training and information program, and that this requirement be met within 450 days of the publication date of this final rule (see Unit IV.B.7.a.).

However, EPA understands that understands that certain departments and agencies of the Federal government, as well as Federal contractors acting for or on behalf of the Federal government, need additional time to comply with these timeframes. For example, complying with these timeframes could impact the ability of the Department of Defense to continue to engage in vapor degreasing. While, for example, 29 CFR part 1960 sets forth procedures and guidelines for ensuring that Federal workers are protected in comparable ways to their non-Federal counterparts, EPA believes that compliance with this final rule will require increased and different preparations on the part of Federal agencies. For example, Federal agencies must follow procurement requirements which will likely result in increased compliance timelines. In addition,

these requirements will require support in the Federal budget, which, for some agencies, is a multi-year process. Therefore, EPA is providing additional time for agencies of the Federal government and their contractors, when acting for or on behalf of the Federal government, to comply with the WCPP, including 915 days for initial monitoring, 1,005 days to ensure that no person is exposed to an airborne concentration of PCE that exceeds the ECEL, and 1,095 days to implement an exposure control plan.

2. *Changes to prohibition timeframes.*

For most occupational conditions of use that EPA proposed to prohibit, EPA proposed that prohibitions would become effective in a staggered schedule for each stage of the supply chain and would come into effect after the publication of this final rule: In 12 months for manufacturers, 15 months for processors, 18 months for distributors to retailers, 21 months for all other distributors (including retailers), and 24 months for industrial and commercial users. For consumer uses, EPA proposed that the prohibitions of manufacturing, processing, and distribution in commerce of PCE for consumer use would take effect after the publication of this final rule: In 12 months for manufacturers, 15 months for processors, 18 months for distributing to retailers, and 21 months for all other distributors and retailers. EPA's primary alternative regulatory action, discussed in the 2023 PCE proposed rule, included slightly longer timeframes, which begin after the publication of this final rule: In 18 months for manufacturers, 21 months for processors, 24 months for distributing to retailers, 27 months for all other distributors (including retailers), and 30 months for industrial and commercial uses. EPA requested comment regarding the proposed and alternative compliance dates for prohibitions and whether additional time is needed.

Several commenters raised concerns about the timeframe for complying with prohibitions from the proposed regulatory action, stating that EPA should consider longer timeframes for

prohibition to avoid disruptions to the supply chain for continuing uses, help minimize disposal of products left on retail shelves, and provide sufficient time to identify, research, test, qualify, and implement cost-effective alternative substances or processes (Refs. 32, 50, 33). One commenter expressed concern that the proposed compliance timeframes would cause certain products containing PCE to leave the market, potentially cutting off PCE supply for continuing critical uses and creating a risk of obsolescence for essential equipment that is reliant on PCE.

Some commenters expressed that there may be circumstances in which a chemical alternative is not an exact, drop-in replacement for certain conditions of use, or in which new, additional, or modifications to existing engineering equipment could be necessary (Refs. 33, 50, 45). These commenters further expressed concerns regarding coordination with suppliers or customers across the supply chain (including with certifying entities in circumstances where a formulation change may require recertifying a product to meet performance standards, for example) that may require a transitioning process. Due to these and other concerns, some commenters supported longer timeframes for prohibition than what was proposed, which would provide additional time that commenters described as necessary for seeking alternatives, successfully implementing their use, and mitigating supply chain impacts (Refs. 33, 50, 45). One commenter stated that the proposed 24-month prohibition is significantly shorter than for other EPA programs, such as EPA's National Emission Standards for Hazardous Air Pollutants (NESHAP) which typically provide 36 months for compliance, and suggested that EPA extend the deadlines to 12 months for manufacturing, 21 months for processing, 24 months for distribution to retailers, and 30 months for retail distribution (Ref. 50). Other commenters recommended that EPA double the proposed prohibition timeframes for manufacturers and processors, suggested longer timeframes, and suggested that EPA extend the sell-through period of products already in commerce by six months (Refs. 45, 46, 33).

After reviewing all of the comments, in this final rule EPA is modifying the proposed prohibition compliance timeframes for most uses to lengthen them to the prohibition compliance timeframes included in the primary alternative regulatory action, which will allow for successful implementation of the prohibitions in a manner that is as soon as practicable while providing for a reasonable transition period. This extension will also provide additional time for regulated entities to consult with their upstream suppliers and downstream customers and to make necessary adjustments, thereby mitigating immediate concerns for operational continuity for conditions of use identified in Units IV.B. and C. The timeframes for prohibition EPA is finalizing are described in detail in Unit IV.D.

EPA is finalizing as proposed the prohibition on the manufacturing, processing, distribution in commerce, and industrial and commercial use of PCE for dry cleaning and spot cleaning through a 10-year phaseout, as outlined in Unit IV.D.3.

C. *Changes to WCPP requirements.*

1. *Exposure monitoring requirements.*

As part of the WCPP, EPA proposed to require owners or operators to meet certain documentation requirements for each monitoring event of PCE, including compliance with the Good Laboratory Practice (GLP) Standards in accordance with 40 CFR part 792.

Numerous commenters expressed concern regarding the requirement that the WCPP include compliance with the GLP Standards at 40 CFR part 792 (Refs. 46, 54, 53, 56, 48, 55, 49). Commenters stated that it is atypical, for industrial hygiene purposes, to use this standard for air sampling of PCE (Refs. 33, 55, 49). According to the commenters, it is common practice within the industrial hygiene community to have analyses performed by American Industrial Hygiene Association (AIHA) accredited laboratories (Ref. 49). Some commenters recommended that provisions of monitoring results and recordkeeping in the final rule be allowed from any

accredited laboratory, without regard to a specific type, or allowing any number of approved monitoring methods, especially AIHA accredited laboratories (Refs. 56, 46). Commenters also suggested applying the policy described in typical TSCA section 5(e) orders that establish a New Chemical Exposure Limit under the TSCA New Chemicals Program, which state that compliance with TSCA GLP Standards is not required where exposure monitoring samples are analyzed by a laboratory accredited by either: (A) the AIHA Industrial Hygiene Laboratory Accreditation Program; or (B) another comparable program approved in advance in writing by EPA (Refs. 33, 55, 49). Another commenter reasoned the GLP Standards were not intended for air monitoring in a workplace when compliance with such standards would mean that real-time assessments could not be made, as air samples would need to be processed and analyzed in a laboratory (Ref. 53).

EPA agrees with the commenter that the WCPP is incompletely served by solely relying on the GLP Standard initially put forth in the 2023 PCE proposed rule. Given the concern from commenters regarding potential increases in demand for professional safety services and sampling laboratories having a negative impact due to anticipated industry strain and sampling limitations (Refs. 33, 55, 49), EPA has broadened the scope of laboratory accreditation accordingly. EPA has considered this laboratory capacity issue, in addition to other revisions for finalization in this rule, so that the additional infrastructure is in place for the regulated community to successfully implement the WCPP. For the final rule, EPA is requiring that exposure samples be analyzed using an appropriate analytical method, and related records retained, by a laboratory that complies with the GLP Standards in 40 CFR part 792 or that otherwise maintains a relevant third-party laboratory accreditation (e.g., under the AIHA Laboratory Accreditation Programs, LLC Policy Module 2A/B/E of Revision 17.3), or other analogous industry-recognized programs.

Another commenter stated that EPA's proposal did not make clear that "personal breathing zone" air samples to monitor exposures are to be taken without regard to respirator use. The commenter noted that OSHA requires exposure monitoring to be conducted without regard to respirator use (citing as an example OSHA's definition of "employee exposure" at 29 CFR 1910.1052(b)) and asserted that this important element of OSHA's monitoring program was omitted from EPA's proposal (Ref. 58). EPA agrees with the commenter that exposure monitoring should be conducted without regard to respiratory protection to inform engineering control options and respiratory protection considerations. Therefore, EPA is finalizing this rule to explicitly state that air sampling is required to measure ambient concentrations for PCE without taking respiratory protections into account when being performed. This will ensure the highest degree of protection to potentially exposed persons by logging accurate ambient air concentrations of PCE, thus empowering owners or operators to appropriately consider the hierarchy of controls.

As part of the WCPP, EPA also proposed to establish an ECEL action level of 0.07 ppm as an 8-hour TWA for PCE. As described in Unit IV.A.2.b. of the 2023 PCE proposed rule, air concentrations at or above the action level would trigger more frequent periodic monitoring of exposures to PCE, consistent with the action level approach utilized by OSHA in the implementation of OSHA standards, although the values differ due to differing statutory authorities. EPA proposed an action level that would be half the 8-hour ECEL, which is in alignment with the precedented approach established under most OSHA standards. EPA solicited 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. EPA also requested comment on viability of current analytical methods and detection limits for PCE sampling.

EPA received several comments regarding an action level that is half the ECEL and the viability of detecting to the action level with existing analytical methods. One commenter supported the establishment of an action level that is one-half the ECEL as this stratified approach will impose appropriate controls based on the particulars of each workplace (Ref. 58). Other commenters expressed concern regarding the proposed ECEL action level, stating that the action level should not be included in the regulation because of challenges to reliably measure to the proposed value and suggesting EPA consider best practice for industrial hygiene exposure assessment published by the AIHA (Refs. 33, 57). Commenters warned that implementing a monitoring methodology for the proposed ECEL would not be seamless because existing monitoring methods are not adequate. As an example, commenters stated that the NIOSH 1003 method, as currently validated, will not achieve the limit of detection required for evaluating to the proposed ECEL or action limit (Refs. 33, 49). Commenters stated that passive sampling methods cannot measure to below the ECEL, and thus entities would need to rely on active sampling with a pump with samples sent out to laboratories for analysis (Refs. 45, 47). Another commenter asserts that the proposed ECEL action level of 0.07 ppm is not detectable and stated that the best way to ensure reliable and comparable results is to use a digital measuring device, which can currently detect concentrations up to 10 ppm and are in development to detect concentrations as low as 0.1 ppm, which is the lowest on the global market (Ref. 59). Additionally, other commenters stated that NIOSH recommends a detection limit of 10% of the occupational exposure limit (Refs. 33, 49, 60).

EPA acknowledges the challenges of occupational personal breathing zone monitoring to levels consistent with the ECEL action level and ECEL. As noted earlier, EPA intends for the WCPP to align with, to the extent possible, certain elements of the existing OSHA standards for regulating toxic and hazardous substances under 29 CFR part 1910, Subpart Z and is therefore

finalizing an action level different from the proposed 0.07 ppm ECEL action level to support a trigger for more frequent periodic monitoring. In consideration of public comment, reasonably available information, and outreach, EPA has determined that revising the ECEL action level to 0.10 ppm as an 8-hr TWA for PCE is appropriate given the limits of detection and limits of quantification for existing monitoring methods. EPA notes that while real-time monitoring with a digital measuring device is not required for rule compliance, EPA understands the practical benefits of real-time occupational exposure monitoring. EPA also notes that the reliable limits of quantification for available analytical methods (e.g., NIOSH 1003 and OSHA 5000) are below the ECEL action level of 0.10 ppm.

Additionally, as part of the WCPP, EPA proposed to require owners and operators to re-monitor within 15 working days after receipt of any exposure monitoring if results indicated 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 received several comments disagreeing with the proposed requirement to review non-detect air monitoring samples. The commenters stated that the requirement is inconsistent with OSHA rules, is an unnecessary step that adds no value to reduce risk to workers, and could be costly, especially for smaller companies (Refs. 56, 32, 57, 33, 47, 48, 49). One commenter suggested that EPA incorporate a six-sample rolling average, as the statistical evaluation would incorporate ongoing validation of exposure levels for a particular task and thus remove any need for resampling based on a non-detect result.

EPA disagrees with commenters that expressed the opinion that re-evaluating a non-detect result adds no value and is inappropriate. While in some cases a non-detect result may accurately indicate that the chemical is not present and that air concentrations are below the ECEL action level, in other cases it may not necessarily imply negligible occupational exposure

to the chemical. For example, interference from another chemical during sampling may result in an incorrect result of non-detect. This interference may not be recognized at the time of sampling or analysis. Owners and/or operators also may not be using sampling techniques or analytical procedures that are effective or appropriate for the particular chemical of interest. In each of these cases, non-detect results, along with supporting documentation about the sampling and analytical methods used to get those results, is a meaningful part of the potentially exposed person's exposure record required under the WCPP. The WCPP in the 2023 PCE proposed rule and in this final rule does not require re-monitoring in all cases. Re-monitoring may be necessary based on a professional evaluation by an Environmental Professional as defined at 40 CFR 312.10 or a Certified Industrial Hygienist. This flexibility allows owners or operators options in terms of revisiting occupational sampling in the event of a non-detect result, or evaluation by a qualified professional.

From an owner/operator's perspective, a non-detect sampling result when effective sampling and analysis procedures are used is valuable in that it suggests effective implementation of exposure controls. Potentially exposed persons may also use these records in discussions with owner/operators, in collective bargaining situations, or in compliance assistance inquiries to EPA or other federal agencies. Exposure monitoring results may also improve overall workplace health and reducing owner/operator liability in the effective detection, treatment, and prevention of occupational disease or illness. All of the above scenarios are valuable for owner/operators, potentially exposed persons, and for effective mitigation of occupational exposures. In consideration of these factors, EPA has removed the air monitoring equipment malfunction from the monitoring activities that do not require resampling based on professional evaluation by an Environmental Professional or Certified Industrial Hygienist. While professional discretion may be warranted in determining whether re-monitoring is needed

following results that indicate non-detect, EPA has determined this is not appropriate in the event of air monitoring equipment malfunction. This is due to the importance of air monitoring in ensuring that the requirements of the WCPP are met, and the importance of the WCPP in reducing risks from exposures to PCE in the workplace. Monitoring results from malfunctioning air monitoring equipment are not valid monitoring and therefore not sufficient to meet the monitoring requirements under the WCPP.

Additionally, while statistical methods may be useful in establishing and analyzing an occupational monitoring program, EPA is not persuaded by information commenters presented in support of relying on a six-sample rolling average of exposure measurements in place of the proposed requirement to evaluate re-monitoring. See section 5.5.3 of the Response to Comments document for a more detailed response (Ref. 8). EPA may consider developing additional guidance regarding occupational monitoring in the future. Therefore, after consideration of public comment, EPA is finalizing the requirement to re-monitor within 15 working days after receipt of any exposure monitoring if results indicated non-detect, 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. However, EPA agrees with comments that raised concern that the 2023 PCE proposed rule lacked clarity on what would suffice for justification that re-monitoring is not necessary, and has therefore updated the recordkeeping requirements associated with the WCPP exposures records required under 40 CFR 751.615(b)(1)to require documentation of the determination by the Environmental Professional as defined at 40 CFR 312.10 or a Certified Industrial Hygienist to be maintained as a record. Occupational monitoring (and associated recordkeeping) is an area that EPA may develop guidance as part of final rule implementation efforts.

In the 2023 PCE proposed rule, EPA proposed to require under the WCPP 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 occurred. In the event of start-ups, shutdowns, spills, leaks, ruptures or other breakdowns that may lead to employee exposure, EPA proposed to require that each owner or operator 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. EPA is finalizing the requirement to conduct this additional exposure monitoring, with a compliance timeframe requiring that this monitoring be conducted within 30 days after the relevant change or conclusion of the event and/or cleanup (see Unit IV.B.3.b.iii.), which is a clarification of the proposal, in which a timeframe was not specified.

As part of the WCPP exposure monitoring, EPA proposed to require owners or operators to determine each potentially exposed person's exposure by either taking a personal breathing zone air sample of each potentially exposed person's exposure or by taking personal breathing zone air samples that are representative of each potentially exposed person's exposure group, which EPA proposed to mean 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. EPA received a comment that suggested EPA revise the proposed definition of "exposure group" to more closely align with the similar exposure group approach used by industrial hygienists to refer to a group of workers who have common risks and similar exposure profiles (Ref. 56). EPA agrees that the definition of "exposure group" should align with standard practice for occupational safety and industrial hygiene and is therefore finalizing the definition of "exposure group" in 40 CFR 751.5

to mean a group of potentially exposed persons with a similar exposure profile to a chemical substance or mixture based on the substantial similarity of tasks performed, the manner in which the tasks are performed, and the materials and processes with which they work.

2. *Designated representative and workplace participation.*

As part of the WCPP in Unit IV.A.2.e.iii. of the 2023 PCE proposed rule, EPA proposed to require that owners or operators (i.e., any person who owns, leases, operates, controls, or supervises a workplace covered by the rule) provide potentially exposed persons or their designated representatives regular access to the exposure control plans, exposure monitoring records, and PPE program implementation and documentation. Additionally, EPA proposed to require that owners or operators document the notice to and ability of any potentially exposed person that may reasonably be affected by PCE inhalation or dermal exposure to readily access the exposure controls plans, facility exposure monitoring records, PPE program implementation, or any other information relevant to PCE inhalation exposure in the workplace. EPA also requested comment on how owners and operators could engage with potentially exposed persons on the development and implementation of an exposure control plan and PPE program. Additional details of EPA's worker participation proposal can be found in Unit IV.A.2.e. of the 2023 PCE proposed rule.

EPA received public comment on the role of designated representatives in the WCPP. One commenter, a group of labor unions, urged EPA to incorporate requirements similar to OSHA's access standard at 29 CFR 1910.1020 (titled, "Access to employee exposure and medical records") in EPA's proposed requirements at 40 CFR 751.613 to ensure that exposure information is promptly and fully shared with both potentially exposed persons and their designated representatives (Ref. 58). The commenter pointed out that while the preamble to the 2023 PCE proposed rule stated that EPA was proposing to provide designated representatives

regular access to specified information, the proposed regulatory text at 40 CFR 751.613(b)(4) did not do so. The commenter also suggested that EPA include a requirement that employers provide employees or their designated representatives an opportunity to observe monitoring events. The commenter observed that workers and their designated representatives have a critical role to play in ensuring effective control of toxic substances and further noted that, often, unions are the organizations with expertise in understanding occupational exposure information. The commenter also urged EPA to require that owners and operators consult with workers and their designated representatives in developing and implementing their plans.

Following review of the comments received, EPA recognizes the importance of having the ability for potentially exposed persons and their designated representative(s), such as labor union representatives, to observe exposure monitoring and have prompt access to exposure records. EPA additionally recognizes that, in some instances, individual workers may be hesitant to ask owners or operators for information relating to their chemical exposure or may be less familiar with discipline-specific industrial hygiene practices. EPA determined that it is appropriate in this final rule to revise to some extent the requirements regarding designated representatives included in the proposal, consistent with existing OSHA precedent in certain 29 CFR part 1910, Subpart Z regulations, to allow designated representatives the ability to observe occupational exposure monitoring and have access to exposure monitoring records. In EPA's final rule, the WCPP includes a requirement that owners and operators provide potentially exposed persons or their designated representatives an opportunity to observe any exposure monitoring that is designed to characterize their exposures and is conducted under the WCPP. With respect to facilities classified in the interest of national security, only persons authorized to have access to such facilities will be allowed to observe exposure monitoring.

EPA is also finalizing a requirement that designated representatives have access to

relevant exposure records, similar to provisions in certain OSHA regulations under 29 CFR part 1910, Subpart Z, such as 29 CFR 1910.1200 and 29 CFR 1910.1020. EPA is requiring owners and operators to notify potentially exposed persons and their designated representatives of the availability of the exposure control plan and associated records of exposure monitoring and PPE program implementation within 30 days of the date that the exposure control plan is completed and at least annually thereafter. EPA is also requiring, consistent with the proposed requirement for notification of exposure monitoring results, that the notice of the availability of the exposure control plan and associated records be provided in plain language writing to each potentially exposed person in a language that the person understands 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. While EPA encourages owners or operators to consult with persons that have potential for exposure and their designated representatives on the development and implementation of the exposure control plan, EPA has determined that it is not necessary to include this as a requirement in the final rule because OSHA does not typically require consultations with designated representatives. However, EPA believes that the notification of the exposure control plan and associated records may help facilitate participation from potentially exposed persons and their designated representatives in the implementation and further development of that plan.

In this final rule, EPA is defining "designated representative" in 40 CFR 751.5 to mean any individual or organization to whom a potentially exposed person gives explicit, written authorization to exercise a right of access. A recognized or certified collective bargaining agent must be treated automatically as a designated representative without regard to written authorization. Additionally, with respect to federal employees, EPA, like OSHA at 29 CFR

1960.2(e), will interpret these designated representative requirements consistent with the Federal Service Labor Management Relations Statute (5 U.S.C. 71), or collective bargaining or other labor-management arrangements that cover the affected employees.

Should a request be initiated for such records by the potentially exposed person or their designated representative(s), the owner or operator will be required to provide the specified records at a reasonable time, place, and manner, analogous to provisions outlined in OSHA's 29 CFR 1910.1020(e)(1)(i). If the owner or operator is unable to provide the requested records within 15 working days, the owner or operator must, within those 15 working days, inform the potentially exposed person or designated representative(s) requesting the record of the reason for the delay and the earliest date when the record can be made available. Additionally, in the event that a designated representative is observing exposure monitoring, the owner or operator must ensure that designated representatives are provided with PPE appropriate for the observation of monitoring. Finally, this rule requires owners or operators to provide notice to potentially exposed persons and their designated representatives of exposure monitoring results and of the availability of the exposure control plan and associated records. For purposes of this requirement, the owner or operator is only required to provide notice to those designated representatives that the owner or operator is aware of, such as representatives designated in writing or a recognized collective bargaining agent for the owner or operator's own employees.

3. *Other changes to the WCPP.*

As part of the WCPP in the 2023 PCE proposed rule, EPA proposed various requirements for owners or operators to provide PPE, including respiratory protection and dermal protection, to potentially exposed persons and to establish a PPE program. For greater clarity in this final rule, EPA has revised the PPE requirements with respect to the cross-references to the relevant OSHA regulations. While the language appears different than the requirements included in the

2023 PCE proposed rule, it remains EPA's intention that owners and operators implement PPE programs that are consistent with OSHA requirements. The PPE requirements as part of the WCPP in this final rule are described in Unit IV.B.6.

D. *Other changes.*

EPA is slightly modifying the provisions related to the de minimis regulatory threshold in the 2023 PCE proposed rule, where EPA proposed that products containing PCE at concentrations less than 0.1% by weight are not subject to the prohibitions. EPA requested comment on the de minimis concentration limit of PCE in products or formulations and received numerous comments in support of the inclusion of a de minimis regulatory threshold (Refs. 48, 32, 46, 33, 61, 56, 47, 55, 62, 53, 54, 31, 63). One commenter urged EPA to make clear that the proposed de minimis exemption applies to all the provisions in the 2023 PCE proposed rule, and not just the prohibitions (Ref. 54). Some commenters expressed opposition to the de minimis level identified because they state EPA has not shown that a de minimis concentration is protective of workers (Refs. 64, 65, 66). EPA's approach for a de minimis concentration of 0.1% for PCE is consistent with OSHA's Hazard Communication Standard, as urged by several commenters who asserted that consistency with the existing hazard communication framework is important to avoid companies being out of compliance with EPA's regulations without their knowledge, or having to engage in impractical and burdensome changes to hazard communication programs that are not necessary to protect against unreasonable risk (Ref. 33, 47, 48, 55). OSHA recently reaffirmed its approach of 0.1% threshold for carcinogens with its 2024 modification of its Hazard Communication Standard (89 FR 44144, May 20, 2024). The OSHA Hazard Communication standard, at 29 CFR 1910.1200, which requires employers to communicate to employees and downstream employers about the hazards of chemicals employees are exposed to, including through safety data sheets, defines "health hazard" as "a

chemical which is classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); or aspiration hazard" (29 CFR 1910.1200(c)). The criteria for determining whether a chemical is classified as a health hazard are detailed in Appendix A to 29 CFR 1910.1200 – Health Hazard Criteria. Section A.6.3.1 of Appendix A of 29 CFR 1910.1200 indicates that a substance is considered a health hazard if it includes greater than 0.1% of a substance that, like PCE, is classified as a carcinogen. OSHA's Hazard Communication Standard is intended to be consistent with the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (29 CFR 1910.1200(a)(1); 89 FR 44144, May 20, 2024). Other EPA programs, such as the Toxics Release Inventory (TRI) program, have adopted a de minimis threshold of 0.1% for chemicals which are defined as carcinogens or as a potential carcinogen under the National Toxicology Program, International Agency for Research on Cancer, or OSHA, with limited exceptions not relevant to PCE (see 40 CFR 372.38(a)).

In consideration of public comment and the implementability of the PCE rule, as well as the analysis described in Unit V.A. of the 2023 PCE proposed rule, EPA is finalizing as proposed a de minimis threshold of 0.1%, which EPA is referring to in this final rule as a regulatory threshold, so that products containing PCE at concentrations less than 0.1% by weight are not subject to the prohibitions of this final rule, and is also adding clarification that products below the regulatory threshold are not subject to other restrictions of this final rule. While EPA conducted analysis regarding residual amounts of PCE in products (described in Unit V.A.1. of the 2023 PCE proposed rule), which confirmed that the use of the 0.1% value for carcinogens was an appropriate cut off, consistent with the OSHA's Hazard Communication Standard. EPA

generally expects to align with the OSHA's Hazard Communication Standard approach regarding threshold amounts of chemicals going forward, with some exceptions as warranted by chemical-specific considerations (Ref. 67). EPA is confident that adopting a regulatory threshold of 0.1% for chemicals which are defined as carcinogens or as a potential carcinogen will increase regulatory certainty and enhance compliance. The manufacturing (including import), processing, and distribution in commerce of products that contain PCE at concentrations equal to or above the regulatory threshold of 0.1% are still subject to the prohibitions and restrictions of this final rule, regardless of the concentration of PCE in the end product.

As an additional change, EPA has revised its proposed description of industrial and commercial use of PCE as a laboratory chemical to provide additional clarity as suggested by a commenter (Ref. 62). The revised description for industrial and commercial use as a laboratory chemical appears in Unit IV.C.1. Similarly, for greater clarity and in response to comment that suggested EPA include terminology for "airless degreasers" in the final rule, EPA has revised its proposed description of industrial and commercial use as solvent for closed-loop batch vapor degreasing by clarifying that this use includes use of airless degreasers (Ref. 30). EPA has also revised the proposed description for industrial and commercial use of PCE in maskant for chemical milling to provide additional clarity as recommended by a commenter (Ref. 31). Additionally, in response to a comment that EPA should ensure that uses of PCE required for environmental, health, and safety permit compliance, such as performance testing requirements in the NESHAP for hazardous waste combustors (HWCs) (40 CFR part 63, Subpart EEE), are permitted to continue and are not inadvertently prohibited, EPA has revised its proposed description of disposal (Ref. 55). For purposes of this final rule, disposal includes the use of PCE to comply with requirements for HWC facilities under the Clean Air Act (CAA) and the Resource Conservation and Recovery Act (RCRA) (40 CFR parts 260 and 270), including use of

PCE as a representative principal organic hazardous constituent (POHC) in destruction and removal efficiency (DRE) tests required under 40 CFR 63.1216–63.1221 and for chlorine feedrate operating conditions during comprehensive and confirmatory performance tests required under 40 CFR 63.1207(g)(1) and 40 CFR 63.1207(g)(2). The revised descriptions for industrial and commercial use as solvent for batch vapor degreasing, industrial and commercial use in maskant for chemical milling, and for disposal appear in Unit IV.B.1.

Additionally, in this final rule, EPA is not finalizing as proposed to amend the general provision of 40 CFR part 751, Subpart A, to define "authorized person," "owner or operator," "potentially exposed person," "regulated area," and "retailer," because those definitions are finalized in the TSCA section 6 final rule for methylene chloride (89 FR 39254, May 8, 2024) (FRL-8155-01-OCSPP) 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. In response to one commenter that suggested EPA describe "distribution in commerce" in the preamble, EPA is finalizing the definition for "distribute in commerce" in § 751.603 so that it has the same meaning as in section 3 of the Act, except that the term does not include retailers for purposes of §§ 751.613 and 751.615 (Ref. 33).

IV. Provisions of the Final Rule

EPA intends that each provision of this rulemaking be severable. In the event of litigation staying, remanding, or invalidating EPA's risk management approach for one or more conditions of use in this rule, EPA intends to preserve the risk management approaches in the rule for all other conditions of use to the fullest extent possible. The Agency evaluated the risk management options in TSCA section 6(a)(1) through (7) for each condition of use and generally EPA's regulation of one condition of use to address its contribution to the unreasonable risk from PCE functions independently from EPA's regulation of other conditions of use, which may have

different characteristics leading to EPA's risk management decisions. Further, the Agency crafted this rule so that different risk management approaches are reflected in different provisions or elements of the rule that are capable of operating independently. Accordingly, the Agency has organized the rule so that if any provision or element of this rule is determined by judicial review or operation of law to be invalid, that partial invalidation will not render the remainder of this rule invalid.

There are many permutations of this. For example, as discussed in Unit IV.D., this final rule prohibits the industrial and commercial use of PCE in dry cleaning and spot cleaning, and also the industrial and commercial use of PCE in general aerosol degreasing/cleaning products that contain PCE (although a subset of this use is permitted to continue under specific prescriptive controls or the WCPP as described in Unit III.A.3.b.). For use of PCE in general aerosol degreasing/cleaning products as well as dry cleaning, EPA's risk management approach is prohibition. To the extent that a court were to find that EPA lacked substantial evidence to support its prohibition of general aerosol degreasing/cleaning or otherwise found legal issues with EPA's approach to that condition of use, it would have no bearing on other similarly situated conditions of use such as dry cleaning unless the specific issue also applies to the particular facts associated with dry cleaning. This is reflected in the structure of the rule, which describes these specific prohibitions separately by compliance date.

As another example, for industrial and commercial use of PCE as a processing aid in catalyst regeneration in petrochemical manufacturing and industrial and commercial use of PCE in automotive care products (*e.g.,* engine degreaser and brake cleaner), EPA took different risk management approaches— application of the WCPP for the industrial and commercial use of PCE as a processing aid in catalyst regeneration in petrochemical manufacturing and prohibition for industrial and commercial use in automotive care products. To the extent that a court were to

find a legal issue with EPA's approach to the WCPP, impacting industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing, it would have no bearing on EPA's decision to prohibit the industrial and commercial use in automotive care products, and vice versa. This is reflected in the structure of the rule, which organizes the prohibitions and the WCPP into different sections of the regulation.

EPA also intends all TSCA section 6(a) risk management elements in this rule to be severable from each regulatory exclusion from those requirements, including each TSCA section 6(g) exemption. EPA has the authority to promulgate TSCA section 6(g) exemptions "as part of a rule promulgated under [TSCA section 6(a)]." However, EPA's risk management decisions under TSCA sections 6(a) and 6(c) are independent from EPA's consideration of whether it is appropriate, based on the factors in TSCA section 6(g), to exempt specific conditions of use from the requirements of the TSCA section 6(a) risk management elements in the rule. In other words, EPA first decides whether and how to regulate each condition of use, per TSCA sections 6(a) through (c), and only then determines whether an exemption under TSCA section 6(g) is appropriate. Accordingly, the underlying TSCA section 6(a) risk management elements would not be impacted if a TSCA section 6(g) exemption is determined by judicial review or operation of law to be invalid. Rather, the exempted condition of use would become subject to the underlying TSCA section 6(a) risk management element(s). Similarly, to the extent a court were to find a legal issue with the regulatory threshold established in the rule, the underlying risk management requirements would not be impacted. Rather, the excluded products would become subject to the underlying TSCA section 6(a) risk management requirements applicable to the condition of use. EPA further notes that the specific examples of severability described in this Unit are not intended to be exhaustive, but rather illustrative of a wide variety of scenarios that reflect EPA's overarching intent that each provision of this rulemaking be severable.

To that end, EPA acknowledges that after the issuance of this rule, Federal agencies, their contractors, and other related entities may become aware of important information which indicates a particular use, that would otherwise be prohibited, could meet the criteria of section 6(g) or the requirements of a WCPP. EPA also notes that there are multiple avenues to ask EPA to revisit issues in this TSCA section 6(a) rulemaking, both before and after the mandatory compliance dates are set consistent with TSCA section 6(d). EPA has the authority under TSCA section 6(g) to consider whether a time limited exemption is appropriate and consistent with TSCA section 6(g)(1), could expeditiously promulgate such exemptions independently from this rulemaking, including consideration of emergency or interim rulemaking. EPA has initiated a notice of proposed rulemaking for public comment on this topic, included in the Spring 2024 Regulatory Agenda (RIN 2070-AL17). Additionally, any person could petition EPA to request that EPA issue or amend a rule under TSCA section 6.

A. *Applicability*

This final rule sets prohibitions and restrictions on the manufacture (including import), processing, distribution in commerce, commercial use, and disposal of PCE to prevent unreasonable risk of injury to health in accordance with TSCA section 6(a), 15 U.S.C. 2605(a).

Additionally, pursuant to TSCA section 12(a)(2), this rule applies to PCE even if being manufactured, processed, or distributed in commerce solely for export from the United States because EPA has determined that PCE presents an unreasonable risk to health within the United States. Several commenters expressed concern that an unclear statement in the 2023 PCE proposed rule preamble, and a proposed regulatory requirement for downstream notification of permissible purposes for distribution in commerce, appeared to indicate that manufacture, processing, and distribution for export would be prohibited under the 2023 PCE proposed rule if the intended use in the destination country is prohibited in the United States, even if it is

permissible under other risk mitigation rules in the destination country (Refs. 47, 33, 55, 49, 68). This was not EPA's intent. Because distribution in commerce did not contribute to EPA's unreasonable risk determination for PCE, and because this final rule permits manufacturing and processing, including recycling, for various uses to continue under the WCPP, EPA intends this final rule to permit manufacturing and processing in compliance with the WCPP for export, as well as distribution in commerce for export, without regard for the intended use in the destination country. EPA has clarified the regulatory text accordingly.

As discussed in Unit III.D., EPA is finalizing a regulatory threshold of 0.1% to account for impurities and the unintended presence of PCE (in the 2023 proposed rule, this was referred to as a de minimis threshold). In other words, the provisions of this rulemaking only apply when PCE is present in a formulation at 0.1% or greater. Additionally, the provisions of this final rule only apply to chemical substances as defined under TSCA section 3. Notably, TSCA section 3(2) excludes from the definition of chemical substance "any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device" and "any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide." Additional details regarding TSCA statutory authorities can be found in section 2 of the response to comments document (Ref. 8).

EPA uses the term "potentially exposed person" in Unit IV. and in the regulatory text to include workers, occupational non-users, 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 or specific prescriptive controls would apply. (EPA notes that this definition is intended to apply to occupational workspaces as part of implementation of

the WCPP and other restrictions, and recognizes that other individuals or communities may be exposed to PCE as consumers, members of fenceline communities, or members of the general population.) For certain conditions of use, EPA requires a comprehensive WCPP or specific prescriptive controls to address the unreasonable risk from PCE to workers directly handling the chemical or in the area where the chemical is being used. Similarly, the 2020 Risk Evaluation for PCE (Ref. 1) did not distinguish between employers, contractors, or other legal entities or businesses that manufacture, process, distribute in commerce, use, or dispose of PCE. For this reason, EPA uses the term "owner or operator" to describe the entity responsible for implementing the WCPP or specified prescriptive controls in any workplace where an applicable condition of use is identified in Unit IV. and subject to the WCPP or prescriptive controls is occurring. The term includes any person who owns, leases, operates, controls, or supervises such a workplace. While owners or operators remain responsible for ensuring compliance with the WCPP or prescriptive controls requirements in the workplace, they may contract with others to provide training or implement a respiratory protection program, for example. EPA is also clarifying its intent that for the provisions in this rule, any requirement for an owner or operator, or an owner and operator, is a requirement for any individual that is either an owner or an operator.

EPA emphasizes that this approach is essential for addressing the unreasonable risk presented by PCE, including to individuals who may not be covered by OSHA requirements, such as volunteers, self-employed persons, and state and local government workers who are not covered by a state plan. EPA uses the term "owner or operator" in TSCA programs because the term is used in other EPA programs to describe persons with responsibilities for implementing statutory and regulatory requirements at particular locations. See, for example, CAA section 113, 42 U.S.C. 7412, which defines "owner or operator" as a person who owns, leases, operates,

controls, or supervises a stationary source. There is a similar definition in section 306 of the Clean Water Act (CWA), 33 U.S.C. 1316. EPA understands that the use of this term may result in multiple persons' bearing responsibility for complying with provisions of this final rule, including the WCPP. However, this is also the case for workplaces regulated by OSHA, including those regulated under OSHA's general industry standards at 29 CFR part 1910. OSHA's 1999 Multi-Employer Citation Policy explains which employers should be cited for a hazard that violates an OSHA standard (Ref. 69). The OSHA Policy describes four different roles that employers may fill at a workplace and describes who should be cited for a violation based on factors such as whether the employer created the hazard, had the ability to prevent or correct the hazard, and knew or should have known about the hazard. More than one employer may be cited for the same hazard. This final rule will have similar results, in that more than one owner or operator may be responsible for compliance.

The OSHA multi-employer citation policy is an example of a guidance governing situations where more than one regulated entity is present. EPA has received several requests for clarification of the applicability of the term "owner or operator" to sites where more than one entity owns, leases, or controls a workplace where a PCE condition of use is ongoing and where implementation of the WCPP or prescriptive controls is required. EPA understands that there are a wide variety of situations where these questions could arise, and plans to issue guidance consistent with TSCA authorities that explains how EPA will approach the issue of responsibility for implementation of, and compliance with, the WCPP requirements in practice.

B. *Workplace Chemical Protection Program (WCPP)*

1. *Applicability.*

EPA is finalizing the WCPP for most of the conditions of use for which it was proposed, as well as for additional conditions of use for which prohibition was proposed. EPA has removed

from the WCPP two conditions of use proposed to be included, as described in Unit III.A.1. EPA's descriptions of changes from the 2023 PCE proposed rule are in Unit III. and EPA's rationale for why the WCPP addresses the unreasonable risk for certain conditions of use is in Unit V. of the 2023 PCE proposed rule. EPA is additionally requiring that uses receiving an exemption under TSCA section 6(g), as outlined in Unit IV.F., comply with the WCPP to the extent feasible.

EPA is finalizing the WCPP for the following conditions of use where manufacture and processing are not otherwise prohibited: domestic manufacturing; import; processing as a reactant/intermediate; processing into formulation, mixture, or reaction product; processing by repackaging; recycling; 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 in maskant for chemical milling; industrial and commercial use in solvent-based adhesives and sealants; industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing; industrial and commercial use as a processing aid in sectors other than petrochemical manufacturing; industrial and commercial use for cold cleaning of tanker vessels; and disposal. This Unit provides a description of the uses subject to the WCPP to assist with compliance.

a. *Manufacturing (includes 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. For purposes of this rule, 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. 70).

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 processed as a reactant in the production of HFCs, hydrochlorofluorocarbons, and chlorofluorocarbons. 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.*

This condition of use refers to when PCE is added or incorporated into a product (or product mixture) prior to further distribution of the product, including in cleaning and degreasing products, adhesive and sealant products, paint and coating products, and other chemical products and preparations.

iii. *Processing by repackaging.*

This condition of use refers to the preparation of PCE for distribution in commerce in a different form, state, or quantity. This includes transferring the chemical from a bulk container into smaller containers.

iv. *Recycling.*

This condition of use refers to the process of treating generated waste streams (*i.e.*, which

would otherwise be disposed of as waste) that are collected, either onsite or transported to a third-party site, for commercial purpose. Waste solvents can be restored to a condition that permits reuse 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 uses.*

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 systems.

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 or airless vapor degreasing systems.

iii. *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. This condition of use includes use of peelable maskant to act as temporary protection during transportation.

iv. *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.

v. *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.

vi. *Industrial and commercial use as a processing aid in sectors other than petrochemical manufacturing.*

This condition of use refers to the industrial and commercial use of PCE outside of petrochemical manufacturing to improve the processing characteristics or the operation of process equipment or to alter or buffer the pH of the substance or mixture, when added to a process or to a substance or mixture to be processed. For example, PCE is used in pesticide, fertilizer and other agricultural manufacturing 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 not intended to remain in or become part of the product or product mixture or affect the function of a substance or article created.

vii. *Industrial and commercial use as solvent for cold cleaning of tanker vessels.*

This condition of use refers to the industrial and commercial use of PCE as a non-boiling solvent in cold cleaning to remove dirt, oils, greases, and other surface contaminants from tanker vessels.

d. *Disposal.*

This condition of use refers to the process of disposing waste streams of PCE that are collected either onsite or and transported to a third-party site for treatment or their final disposition, such as waste incineration or landfilling. This condition of use includes the use of PCE to comply with requirements for HWC facilities under the CAA (40 CFR part 63, Subpart EEE) and RCRA (40 CFR parts 260 and 270), including as a representative POHC in DRE tests required under 40 CFR 63.1216-63.1221 and for chlorine feedrate operating conditions during comprehensive and confirmatory performance tests required under 40 CFR 63.1207(g)(1) and 40 CFR 63.1207(g)(2).

2. *Overview.*

The WCPP for PCE encompasses an inhalation exposure limit and action level, DDCC, 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 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 limit threshold and implementing the DDCC requirements for certain occupational conditions of use would address the unreasonable risk to potentially exposed persons from inhalation and dermal exposure.

EPA is finalizing the WCPP requirements to start to take effect by [**INSERT DATE 360 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***] for non-Federal owners or operators, or by [**INSERT DATE 915 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***] for Federal agencies and Federal contractors acting for or on behalf of the Federal government, or within 30 days of introduction of PCE into the workplace, whichever is later, at which point entities would be required to

complete initial monitoring (as described in Unit IV.B.3.b.). Additionally, EPA requires that each owner or operator ensure that no person is exposed to an airborne concentration of PCE that exceeds the ECEL as an 8-hour TWA, including by providing respirators to potentially exposed persons in the regulated area, no later than [**INSERT DATE 450 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***] for non-Federal owners or operators, or no later than [**INSERT DATE 1005 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***] for Federal agencies and Federal contractors acting for or on behalf of the Federal government, or beginning four months after introduction of PCE into the workplace, whichever is later. EPA also requires each owner or operator to ensure all persons are separated, distanced, physically removed, or isolated from direct dermal contact with PCE, including by providing dermal PPE, by [**INSERT DATE 450 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***] for non-Federal owners or operators, or no later than [**INSERT DATE 1005 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**] for Federal agencies and Federal contractors acting for or on behalf of the Federal government. EPA also requires implementation of any needed exposure controls based on initial monitoring and development of an exposure control plan, which requires consideration and documented application of the hierarchy of controls, no later than [**INSERT DATE 900 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***] for non-Federal owners or operators, or [**INSERT DATE 1095 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***] for Federal agencies and Federal contractors acting for or on behalf of the Federal government (as described in Unit IV.B.5).

EPA's implementation of the requirement to meet an ECEL as part of a WCPP aligns with, to the extent possible, certain elements of the existing OSHA standards for regulating toxic and hazardous substances under 29 CFR part 1910, Subpart Z. However, EPA is finalizing as

proposed a new, lower occupational exposure limit, derived from the TSCA 2020 Risk Evaluation for PCE (Refs. 1, 71). For PCE, this final rule will eliminate the unreasonable risk from PCE contributed to by the conditions of use subject to the WCPP, enable continued industry use where appropriate, and provide the familiarity of a pre-existing framework for the regulated community.

EPA's requirements include specific exposure limits and ancillary requirements necessary for successful implementation of an ECEL as part of a WCPP. Taken together, these WCPP requirements apply to the extent necessary so that the unreasonable risk from PCE under the conditions of use listed earlier in this Unit would no longer be presented.

Unit IV. includes a summary of the WCPP, including a description of the finalized exposure limits including an ECEL and ECEL action level; implementation requirements including monitoring requirements; a description of potential exposure controls in accordance with the hierarchy of controls, including engineering controls, administrative controls, and PPE as it relates to respirator selection; and additional finalized requirements for recordkeeping and workplace participation. Additionally, Unit IV. describes DDCC requirements for PCE, including potential exposure controls, which consider the hierarchy of controls; PPE as it relates to dermal protection; and additional requirements finalized for recordkeeping. Unit IV. also describes compliance timeframes revised from the 2023 PCE proposed rule, changes by EPA to certain provisions of the WCPP based on public comments, and addition of new provisions in the WCPP based on public comments used to inform this final rule.

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

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 requiring an ECEL and ancillary

requirements for all of the conditions of use identified in Unit IV.B.1. except recycling and disposal. As described in Unit V.A.1.b. of the 2023 PCE proposed rule, for recycling and disposal, EPA did not identify human health risk from inhalation exposure as contributing to the unreasonable risk of PCE and is therefore not requiring an ECEL and related implementation measures identified in Unit IV. for recycling and disposal activities.

a. *ECEL and ECEL Action Level (AL).*

EPA is finalizing as proposed an ECEL under TSCA section 6(a) of 0.14 ppm (0.98 mg/m3) as an 8-hour TWA based on the chronic non-cancer human equivalent concentration for neurotoxicity. EPA has determined that ensuring exposures remain at or below the 8-hour TWA ECEL of 0.14 ppm will eliminate the unreasonable risk of injury to health resulting from acute and chronic inhalation exposures for certain occupational conditions of use of PCE (Ref. 71). If ambient exposures are kept at or below the 8-hour TWA ECEL of 0.14 ppm, a potentially exposed person will be protected against the effects described in Unit IV., including effects resulting from acute exposure, chronic non-cancer effects, and cancer. EPA is finalizing requirements that each owner or operator ensure that exposure to PCE does not exceed the ECEL as an 8-hour TWA for all potentially exposed persons within 450 days after publication of the final rule or beginning four months after introduction of PCE into the workplace, whichever is later.

EPA is finalizing an ECEL action level at 0.10 ppm as an 8-hour TWA, which is a modification from the ECEL action level EPA proposed, as described in Unit III.C.1. Below the ECEL action level, certain compliance activities, such as periodic monitoring, would be required less frequently, as described further in this Unit. In this way, EPA's WCPP for PCE is consistent with the familiar framework that is in place in OSHA standards for regulating toxic and hazardous substances under 29 CFR part 1910, Subpart Z that establish an action level, although

the values differ due to differing statutory authority. As explained by OSHA, the action level provides employers and employees with greater assurance that their employees will not be exposed to concentrations above the PELs (Ref. 72).

In summary, EPA is finalizing with slight modification that owners or operators must ensure the airborne concentration of PCE within the personal breathing zone of potentially exposed persons remains at or below 0.14 ppm as an 8-hour TWA ECEL, with an action level finalized as 0.10 ppm as an 8-hour TWA. For purposes of this rulemaking, the personal breathing zone is consistent with how OSHA defines it as a hemispheric area forward of the shoulders within a six-to-nine-inch radius of a worker's nose and mouth and requires that exposure monitoring air samples be collected from within this space (Ref. 73). EPA is finalizing the ECEL for certain occupational conditions of use to ensure that no person is exposed to inhalation of PCE in excess of these concentrations resulting from those conditions of use. For the identified conditions of use for which the concentration thresholds are being finalized, EPA recognizes that the regulated community has the ability to detect the values for the ECEL and ECEL action level because of viable detection limits and analytical methods of PCE for monitoring devices that are available in commerce, currently in use, and approved by EPA, NIOSH, and OSHA, which can range from ≤0.5 parts per billion (ppb) to 9 ppm (Ref. 71). Based on the ECEL and ECEL action level established in this final rule, EPA confirmed there are adequate sampling methods available for personal breathing zone monitoring for PCE based on consultation with NIOSH and OSHA (Refs. 74, 75). While sampling methods may have some limitations, EPA notes that new and alternative methods may be developed as long as they are consistent with the performance criteria in the final PCE rule (accurate to a confidence level of 95% and are within (plus or minus) 25% of airborne concentrations of PCE above the 8-hour TWA ECEL). Multiple existing methods are available. OSHA, NIOSH, and EPA have available sampling methods (both active

and passive) with sufficient limits of quantification to support WCPP implementation.

b. *Monitoring requirements.*

i. *Exposure sampling.*

Initial monitoring for PCE is critical for establishing a baseline of exposure for potentially exposed persons; similarly, periodic exposure monitoring assures continued compliance over time so that potentially exposed persons are not exposed to levels that would result in an unreasonable risk of injury to health. Exposure monitoring could be suspended if certain conditions described in Unit IV. are met. Also, in some cases, a change in workplace conditions with the potential to impact exposure levels would warrant additional monitoring, which is also described.

EPA is finalizing with modifications from proposal its requirement that owners or operators determine each potentially exposed person's exposure by either taking a personal breathing zone air sample of each potentially exposed person's exposure or by taking personal breathing zone air samples that are representative of each potentially exposed person with a similar exposure profile to a chemical substance or mixture based on the substantial similarity of tasks performed, the manner in which the tasks are performed, and the materials and processes with which they work (hereinafter identified as an "exposure group"). Personal breathing zone air samples are representative of the 8-hour TWA of all potentially exposed persons in an exposure group if the samples are of the full shift-exposure of at least one person who represents the highest potential PCE exposures in that exposure group. In addition, the initial monitoring will be required when and where the operating conditions are best representative of each potentially exposed person's work-shift exposures. Personal breathing zone air samples taken during one work shift may be used to represent potentially exposed person exposures on other work shifts where the owner or operator can document that the tasks performed and conditions in

the workplace are similar across shifts. Additionally, air sampling is required to measure ambient concentrations for PCE without taking respiratory protections into account as sampling is being performed. For purposes of exposure monitoring requirements, owners and operators are only required to monitor potentially exposed persons that are expected to be present in the workplace.

EPA is also finalizing requirements that the owner or operator ensure that their exposure monitoring methods are accurate to a confidence level of 95% and are within (plus or minus) 25% of airborne concentrations of PCE above the 8-hour TWA ECEL. To ensure compliance for monitoring activities, EPA is finalizing recordkeeping requirements and will require that owners or operators document their choice of monitoring method outlined in this Unit. As described in Unit III.C.1., EPA is finalizing the requirement that owners or operators meet certain documentation requirements for each monitoring event of PCE, including compliance with GLP Standards in accordance with 40 CFR part 792 or use of a laboratory accredited by the AIHA (*e.g.,* AIHA LAP, LLC Policy Module 2A/B/E of Revision 17.3), or other analogous industry-recognized program. Additionally, as described in Unit III.C.1., EPA is finalizing the requirement that owners or operators must re-monitor within 15 working days after receipt of any exposure monitoring when results indicate non-detect, 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 finalizing the requirement that each owner or operator maintain exposure monitoring records that include the following information for each monitoring event:

• Dates, duration, and results of each sample taken.

• The quantity, location(s) and manner of PCE use at the time of each monitoring event.

• 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.

• Name, workplace address, work shift, job classification, work area, and type of respiratory protection (if any) of each monitored person.

• Identification of all potentially exposed persons that a monitored person is intended to represent if using a representative sample.

• Use of appropriate sampling and analytical methods.

• Compliance with GLP Standards in accordance with 40 CFR part 792 or use of a laboratory accredited by AIHA (*e.g.,* AIHA LAP, LLC Policy Module 2A/B/E of Revision 17.3), or another analogous industry-recognized program.

• Information regarding air monitoring equipment, including: Type, maintenance, calibrations, performance tests, limits of detection, and any malfunctions.

• Notification of exposure monitoring results to each person whose exposures are monitored or who is part of a monitored exposure group.

ii. *Initial exposure monitoring.*

Under the final regulation, each non-Federal owner or operator of a facility that is engaged in one or more of the conditions of use listed in Unit IV.B.1., except recycling and disposal, will be required to perform initial exposure monitoring within 360 days of the publication of this final rule or within 30 days of introduction of PCE into the workplace, whichever is later, to determine the extent of exposure of potentially exposed persons to PCE. As discussed in Unit III.B.1., EPA is providing additional time for Federal agencies and Federal contractors acting for or on behalf of the Federal government to comply with the provisions of the WCPP, so they will be required to conduct initial monitoring within 915 days after publication. Initial monitoring will notify owners and operators of the magnitude of possible exposures to potentially exposed persons with respect to their work conditions and environments.

Based on the magnitude of possible exposures in the initial exposure monitoring, the owner or operator may need to increase or decrease the frequency of future periodic monitoring or adopt new exposure controls (such as engineering controls, administrative controls, and/or a respiratory protection program). In addition, the initial monitoring will be required when and where the operating conditions are best representative of each potentially exposed person's work-shift exposures. If the owner or operator chooses to use a sample that is representative of potentially exposed persons' full shift exposures (rather than monitor every individual), such sampling should be representative (i.e., taken from the breathing zone of potentially exposed persons and reflect duration appropriate exposure) of the most highly exposed persons in the workplace. Additionally, EPA expects that owners and operators will conduct initial exposure monitoring representative of all tasks that a potentially exposed person will be expected to do. EPA understands that certain tasks may occur less frequently or may reflect accidental exposure (for example, due to malfunction).

EPA also recognizes that some entities may already have objective exposure monitoring data. If the owner or operator has monitoring data conducted within five years prior to 60 days following publication of the final rule in the *Federal Register* and the monitoring satisfies all other requirements in Unit IV., 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. Prior monitoring data cannot be used where there has been a change in work conditions or practices that is expected to result in new or additional exposures.

As described in more detail later in Unit IV., the owner or operator must conduct periodic monitoring at least once every five years since its last monitoring. This periodic monitoring must be representative of all the potentially exposed persons in the workplace and the tasks that they

are expected to do.

iii. *Periodic exposure monitoring.*

EPA is finalizing as proposed the following periodic monitoring for owners or operators. These finalized requirements are also outlined in table 1.

• If samples taken during the initial exposure monitoring reveal a concentration below the ECEL action level (<0.10 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 three 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 (≥ 0.10 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 six 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 six months of the most recent monitoring until two consecutive monitoring measurements, taken at least seven days apart, are below the ECEL action level (<0.10 ppm 8-hour TWA), at which time the owner or operator must repeat the periodic exposure monitoring at least once every five years.

• 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 required over the entirety of time since the last required periodic monitoring event, EPA is requiring 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 when the owner or operator restart any of the conditions of use listed in Unit IV.B.1., except recycling and disposal.

Table 1 – Periodic Monitoring Requirements

Air Concentration Condition	Periodic Monitoring Requirement
If initial exposure monitoring is below the ECEL action level (< 0.10 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 three 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 (≥ 0.10 ppm 8-hour TWA, ≤ 0.14 ppm 8-hour TWA).	Periodic exposure monitoring is required within six 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 (< 0.10 ppm 8-hour TWA).	Periodic exposure monitoring is required within five 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 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 is required when the owner or operator resumes the condition of use.

Table Note: Additional scenarios in which monitoring may be required are discussed in Unit IV.B.3.b.iv.

iv. *Additional exposure monitoring.*

EPA is finalizing that each owner or operator conduct additional exposure monitoring within 30 days after 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 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, for example if an owner or operator receives information from potentially exposed person(s)

suggesting that such new or additional exposures may have occurred. In the event of start-up or shutdown, or spills, leaks, ruptures, or other breakdowns or unexpected releases that may lead to exposure to potentially exposed persons, EPA is finalizing that each owner or operator must conduct exposure monitoring of potentially exposed persons (using personal breathing zone sampling) within 30 days after the conclusion of the start-up or shutdown and/or 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 six 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 three 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.

c. *Regulated area.*

EPA is finalizing its requirement that the owner or operator demarcate any area where airborne concentrations of PCE exceed, or are reasonably expected to exceed, the ECEL. To provide more clarity regarding how regulated areas must be demarcated, EPA has incorporated the language analogous to OSHA's regulated area requirements under the standards for toxic and hazardous substances (29 CFR part 1910, Subpart Z) into this final rule. Owners and operators must demarcate regulated areas from the rest of the workplace in any manner that adequately establishes and alerts potentially exposed persons to the boundaries of the area and minimizes the number of authorized persons exposed to PCE within the regulated area. This can be accomplished using administrative controls (*e.g.,* highly visible signifiers) in multiple languages as appropriate (*e.g.,* whenever potentially exposed persons who are primarily Spanish-speaking

are likely to be present, owners and operators should post additional highly visible signifiers in Spanish), placed in conspicuous areas. The owner or operator is required to restrict access to the regulated area from any potentially exposed person that lacks proper training or is otherwise unauthorized to enter.

d. *Notification of monitoring results.*

EPA is finalizing the requirement that the owner or operator must, within 15 working days after receipt of the results of any exposure monitoring, notify each potentially exposed person whose exposure is represented by that monitoring and their designated representatives in writing, either individually to each potentially exposed person or by posting the information in an appropriate and accessible location, such as public spaces or common areas, for potentially exposed persons outside of the regulated area. The notice would be required to identify the exposure monitoring results, the ECEL and ECEL action level and what they mean in plain language, statement of whether the monitored airborne concentration of PCE exceeds the ECEL and the ECEL action level, and any corresponding respiratory protection required. If the ECEL is exceeded, the notice must also include a description of the actions taken by the owner or operator to reduce inhalation exposures to or below the ECEL. The notice must also include the quantity, location, manner of PCE use, and identified releases of PCE that could result in exposure to PCE at the time of monitoring.The notice must 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).

4. *Direct dermal contact control (DDCC).*

To reduce exposures in the workplace and address the unreasonable risk of injury to health resulting from dermal exposures to PCE identified under the occupational conditions of

use in the TSCA 2020 Risk Evaluation for PCE, EPA is finalizing largely as proposed, with modification to the compliance timeframe as described in Unit III.B., the DDCC requirements for all of the conditions of use identified in Unit IV.B.1. EPA is finalizing requirements that owners or operators must 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) within 450 days after publication of the final rule. For purposes of this rulemaking, 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 has determined that preventing direct dermal contact will eliminate the unreasonable risk of injury to health resulting from dermal exposures for certain occupational conditions of use of PCE. See 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 in Units III.B.3. and V.A. of the 2023 PCE proposed rule.

5. *Exposure control plan.*

EPA is finalizing its requirement that owners or operators implementing the WCPP use feasible exposure controls, including one or a combination of elimination, substitution, engineering controls, and administrative controls, prior to requiring the use of PPE (*i.e.*, respirators or gloves) as a means of controlling exposures below EPA's ECEL and/or prevent

direct dermal contact with PCE for all potentially exposed persons, in accordance with the hierarchy of controls (Ref. 76). If an owner or operator chooses to replace PCE with a substitute, EPA recommends careful review of the available hazard and exposure information on the potential substitutes to avoid a substitute chemical that might later be found to present an unreasonable risk of injury to health or the environment or be subject to regulation (sometimes referred to as a "regrettable substitution"). EPA expects that, for conditions of use for which EPA is finalizing a WCPP, compliance at most workplaces would be part of an established industrial hygiene program that aligns with the hierarchy of controls.

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 is finalizing the requirement that regulated entities use the hierarchy of controls, instituting one or a combination of controls to the extent feasible, and supplement such protections using PPE, where necessary, including respirators for potentially exposed persons at risk of inhalation exposure above the ECEL and dermal PPE for persons potentially exposed through direct dermal contact to PCE. If efforts of elimination, substitution, engineering controls, and administrative controls are not sufficient to reduce exposures to or below the ECEL or prevent direct dermal contact for all potentially exposed persons in the workplace, EPA requires

that the owner or operator use feasible controls to reduce PCE concentrations in the workplace to the lowest levels achievable and supplement these controls with respiratory protection and dermal PPE as needed to achieve the ECEL or prevent direct dermal contact. In such cases, EPA requires that the owner or operator provide potentially exposed persons reasonably likely to be exposed to PCE by inhalation to concentrations above the ECEL with respirators affording sufficient protection against inhalation risk and appropriate training on the proper use of such respirators, to ensure that their exposures do not exceed the ECEL as described in Unit IV. EPA also requires that the owner or operator provides potentially exposed persons reasonably likely to be exposed to PCE by direct dermal contact with dermal protection affording sufficient protection against dermal risk and appropriate training on the proper use of dermal protection, as described in Unit IV. As part of the training requirement, the owner or operator is required to provide information and comprehensive training in an understandable manner (*i.e.,* plain language), considering factors such as the skills required to perform the work activity and the existing skill level of the staff performing the work, and in multiple languages as appropriate (*e.g.,* based on languages spoken by potentially exposed persons) to potentially exposed persons. This training must be provided prior to or at the time of initial assignment to a job involving potential exposure to PCE. Furthermore, EPA also requires that the owner or operator document their efforts in using elimination, substitution, engineering controls, and administrative controls to reduce exposure to or below the ECEL in an exposure control plan.

EPA is finalizing its requirement that the owner or operator include and document in the exposure control plan or through any existing documentation of the facility's safety and health program developed as part of meeting OSHA requirements or other safety and health standards, the following:

• Identification in the exposure control plan of available exposure controls that were

considered and rationale for using or not using available exposure controls in the following sequence (*i.e.,* elimination and substitution, then 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;

• For each exposure control considered, exposure controls selected based on feasibility, effectiveness, and other relevant considerations;

• A description of actions the owner or operator must take to implement exposure controls selected, including proper installation, regular inspections, maintenance, training, or other steps taken;

• A description of regulated areas, how they are demarcated, and persons authorized to enter the regulated areas;

• A description of activities conducted by the owner or operator to review and update the exposure control plan to ensure effectiveness of the exposure controls, identify any necessary updates to the exposure controls, and confirm that all persons are properly implementing the exposure controls; and

• An explanation of the procedures for responding to any change that may reasonably be expected to introduce additional sources of exposure to PCE, or otherwise result in increased exposure to PCE, including procedures for implementing corrective actions to mitigate exposure to PCE.

Under this final rule, owners or operators are prohibited from using rotating work schedules to comply with the ECEL 8-hour TWA, in alignment with certain elements of existing OSHA's standards for toxic and hazardous substances under 29 CFR part 1910, Subpart Z. Owners or operators must maintain the effectiveness of any engineering controls and administrative controls instituted as part of the exposure control plan. They must also review and

update the exposure control plan as necessary, but at least every five years, to reflect any significant changes in the status of the owner or operator's approach to compliance with the exposure control requirements. EPA intends that the exposure control plan identify the available exposure controls and, for the exposure controls not selected, document the efforts identifying why these are not feasible, not effective, or otherwise not implemented. For entities for which significant amounts of time are needed to verify suitability of alternatives or procure funds or authorization for additional engineering controls, for example, EPA expects that as those controls become available the exposure control plan would be updated accordingly. EPA requires that the exposure control plan be revisited under certain conditions (and at least every five years) and encourages updates as more sophisticated controls are available.

This final rule requires owners or operators to make the exposure control plan and associated records, including ECEL exposure monitoring records, ECEL compliance records, DDCC compliance records, and workplace participation records, available to potentially exposed persons and their designated representatives. Owners or operators must notify potentially exposed persons and their designated representatives of the availability of the exposure control plan and associated records within 30 days of the date that the exposure control plan is completed and at least annually thereafter. The notice of the availability of the plan and associated records must be provided in plain language writing to each potentially exposed person in a language that the person understands or posted in an appropriate and accessible location outside the regulated area with an English-language version and a non-English version representing the language of the largest group of workers who do not read English. This final rule also requires the owner or operator to provide the exposure control plan and associated records at a reasonable time, place, and manner to a potentially exposed person or their designated representative upon request. As explained in Unit III.C.2., if the owner or operator is

unable to provide the specified records within 15 working days, the owner or operator must inform the potentially exposed person or designated representative requesting the record within 15 working days that reason for the delay and the earliest date when the record can be made available.

6. *Personal Protective Equipment (PPE).*

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 finalizing as proposed with slight modifications to improve clarity or for greater consistency with OSHA's regulations to require owners and operators to provide PPE, including respiratory protection and dermal protection selected in accordance with the guidelines described in this unit, and to implement a PPE program. Unit IV. includes a description of the PPE Program, including required PPE as it relates to respiratory protection, required PPE as it relates to dermal protection, and other requirements such as additional training for respirators and recordkeeping to support implementation of a PPE program.

a. *Respiratory protection.*

Where elimination, substitution, engineering, and administrative controls are not feasible or sufficiently protective to reduce the air concentration to or below the ECEL, or if inhalation exposure above the ECEL is still reasonably likely, EPA is finalizing, with slight modification from the proposal, minimum respiratory PPE requirements based on an owner or operator's most recent measured air concentration for one or more potentially exposed persons and the level of PPE needed to reduce exposure to or below the ECEL. In those circumstances, EPA is finalizing requirements for a respiratory protection PPE program with worksite-specific procedures and elements for required respirator use. Owners or operators must develop and administer a written

respiratory protection program in accordance with OSHA's Respiratory Protection Standard under 29 CFR 1910.134(c)(1), (c)(3), and (c)(4). EPA is finalizing requirements that owners and operators provide training to all persons required to use respiratory protection consistent with 29 CFR 1910.134(k) prior to or at the time of initial assignment to a job involving potential exposure to PCE. Owners and operators must retrain all persons required to use PPE at least 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.

EPA is finalizing requirements that each owner or operator supply a respirator, selected in accordance with requirements described in Unit IV., to each person who enters a regulated area within 450 days after publication of the final rule, or within three 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.

EPA is also finalizing requirements that owners or operators who are required to administer a respiratory protection PPE program must supply a respirator selected based on a medical evaluation consistent with the requirements of 29 CFR 1910.134(e). If a potentially exposed person cannot use a negative-pressure respirator, then the owner or operator must provide that person with an alternative respirator. The alternative respirator must have less breathing resistance than the negative-pressure respirator and provide equivalent or greater protection. If the person is unable to use an alternative respirator, then the person must not be permitted to enter the regulated area. Additionally, EPA is requiring owners and operators to select respiratory protection that properly fits each affected person and communicate respirator selections to each affected person in accordance with the requirements of 29 CFR 1910.134(f).

Consistent with requirements of 29 CFR 1910.134(g) through (j), EPA is requiring owners and operators to provide, ensure use of, and maintain (in a sanitary, reliable, and undamaged condition), respiratory protection that is of safe design and construction. EPA is also requiring owners and operators to provide training to all persons required to use respiratory protection consistent with the requirements of 29 CFR 1910.134(k).

EPA is finalizing the requirements to establish minimum respiratory protection requirements, such that any respirator affording a higher degree of protection than the following requirements may be used. EPA is finalizing the following requirements for respiratory protection, based on the most recent exposure monitoring concentrations results measured as an 8-hour TWA that exceed the ECEL (0.14 ppm):

• 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 1.4 ppm (10 times ECEL): Any NIOSH Approved® air-purifying half mask respirator equipped with organic vapor cartridges or canisters; or any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator operated in demand mode equipped with a half mask; or any NIOSH Approved® Self-Contained Breathing Apparatus (SCBA) in a demand mode equipped with a half mask [Assigned Protection Factor (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 Approved® Powered Air-Purifying Respirator (PAPR) equipped with a loose-fitting facepiece or hood/helmet equipped with organic vapor cartridges or canisters; or any NIOSH Approved® SAR or Airline Respirator in a continuous-flow mode equipped with a loose-fitting facepiece or helmet/hood [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 Approved® air-purifying full facepiece respirator equipped with organic vapor cartridges or canisters; any NIOSH Approved® PAPR with a half mask equipped with organic vapor cartridges or canisters; any NIOSH Approved® SAR or Airline Respirator in a continuous flow mode equipped with a half mask; any NIOSH Approved® SAR or Airline Respirator operated in a pressure-demand or other positive-pressure mode with a half mask; or any NIOSH Approved® SCBA in demand-mode equipped with a full facepiece or helmet/hood [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 Approved® PAPR equipped with a full facepiece equipped with organic vapor cartridges or canisters; any NIOSH Approved® SAR or Airline Respirator in a continuous-flow mode equipped with full facepiece; any NIOSH Approved® SAR or Airline Respirator in pressure-demand or other positive-pressure mode equipped with a full facepiece and an auxiliary self-contained air supply; or any NIOSH Approved® SAR or Airline Respirator in a continuous-flow mode equipped with a helmet/hood and has been tested to demonstrate performance at a level of a protection of APF 1,000 or greater. [APF 1,000].

• If the measured exposure concentration is greater than 140 ppm (1,000+ times ECEL): Any SCBA in a pressure-demand or other positive-pressure mode equipped with a full facepiece or helmet/hood [APF 10,000].

• If the exposure concentration is unknown: Any NIOSH Approved® combination supplied air respirator equipped with a full facepiece and operated in pressure demand or other positive pressure mode with an auxiliary self-contained air supply; or any NIOSH Approved® SCBA operated in pressure demand or other positive pressure mode and equipped with a full facepiece or helmet/hood [APF 1000+].

Additionally, EPA is finalizing requirements that owners or operators select and provide

respirators in accordance with the requirements of 29 CFR 1910.134(d)(1)(iv) and with consideration of workplace and user factors that affect respirator performance and reliability. EPA is requiring 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. Consistent with 29 CFR 1910.134(d)(3)(iii), EPA is requiring 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 also requiring owners and operators to ensure that respirators are used in compliance with the terms of the respirator's NIOSH certification.

EPA is finalizing requirements that owners and operators must conduct regular evaluations of the workplace, including consultations with potentially exposed persons using respiratory protection, consistent with the requirements of 29 CFR 1910.134(l), to ensure that the provisions of the written respiratory protection program described in this Unit are being effectively implemented.

EPA is finalizing the requirement that owners and operators document respiratory protection used and PPE program implementation. EPA is finalizing requirements that owners and operators document in the exposure control plan or other documentation of the facility's safety and health program information relevant to the 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, fit-testing, and training as described in this unit.

b. *Dermal protection.*

As described in Unit III.B.1., EPA is finalizing requirements that each owner or operator

supply dermal PPE that separates and provides a barrier to prevent direct dermal contact with PCE, selected in accordance with requirements described in this Unit, to each person who is reasonably likely to be dermally exposed in the work area through direct dermal contact, to be effective within 450 days of the publication of this final rule. Where elimination, substitution, engineering controls, and administrative controls are not feasible or sufficient to fully prevent direct dermal contact with PCE, EPA is finalizing requirements that appropriate dermal PPE be provided by owners and operators to, and be worn by, persons potentially exposed to direct dermal contact with PCE. EPA is requiring owners and operators to provide dermal PPE that is of safe design and construction for the work to be performed. EPA is also requiring owners and operators ensure each potentially exposed person who is required to wear PPE to use and maintain PPE in a sanitary, reliable, and undamaged condition. Additionally, EPA is requiring owners and operators to select and provide PPE that properly fits each potentially exposed person who is required to use PPE and communicate PPE selections to each affected person.

In choosing appropriate dermal PPE, EPA is requiring owners and operators 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 or individually prepared third party testing 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. EPA is also requiring that owners and operators demonstrate 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. In alignment with the OSHA Hand Protection PPE Standard (29 CFR

1910.138), EPA is requiring owners and operators 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. EPA is also requiring owners and operators 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. Further information related to choosing appropriate PPE can be found in the summary of suitable gloves for PCE memo (Ref. 67).

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 finalizing as proposed 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 impervious during expected durations of use and conditions of exposure. EPA is finalizing requirements 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. 77). EPA is also finalizing requirements that replacement PPE must be provided immediately 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 finalizing as proposed requirements 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.

Additionally, as part of the PPE program, EPA is also finalizing as proposed 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 dermal 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 finalizing that owners and operators provide PPE training to all persons required to use dermal PPE prior to or at the time of initial assignment to a job involving potential exposure to PCE. Owners and operators 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.

EPA is also finalizing as proposed requirements that owners and operators retain records of dermal PPE used and program implementation. EPA is requiring 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:

• 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 be present and the type of PPE selected to be worn by each of these persons;

• 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);

• Appropriately sized PPE and training on proper application, wear, and removal of PPE,

and proper care/disposal of PPE;

• 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

• Training described in this unit.

7. *Additional finalized requirements.*

a. *Workplace information and training.*

EPA is also finalizing its requirements to implement 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 finalizing as proposed with slight modification 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 within 450 days after publication of the final rule. For purposes of workplace information and training, owners and operators are only required to train potentially exposed persons that are expected to be present in the workplace or to directly handle PCE or handle equipment or materials on which PCE may be present.

As part of the training and information program, the owner or operator is required to provide information and comprehensive training in an understandable manner (*i.e.,* plain language) and in multiple languages 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. Owners and operators are required to

provide information and training, as referenced in the OSHA Hazard Communication Standard, to all potentially exposed persons that includes:

• The requirements of the PCE WCPP and how to access or obtain a copy of the requirements of the WCPP, including but not limited to the exposure control plan, monitoring requirements, and PPE program;

• The quantity, location, manner of use, release, and storage of PCE and the specific operations in the workplace that could results in PCE exposure, particularly noting where each regulated area is located;

• Principles of safe use and handling of PCE in the workplace, including specific measures the owner or operator has implemented to reduce inhalation exposure at or below the ECEL or prevent dermal contact with PCE, such as work practices and PPE used;

• 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

• The acute and chronic health hazards of PCE as detailed on relevant Safety Data Sheets (SDSs).

In addition to providing training at the time of initial assignment to a job involving potential exposure to PCE, owners and operators subject to the PCE WCPP are 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. EPA is finalizing its requirements that owners and 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 finalizing as proposed 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.

b. *Workplace participation.*

EPA encourages owners and operators to consult with potentially exposed persons and their designated representatives on the development and implementation of exposure control plans and PPE/respirator programs. EPA is finalizing the requirement that owners and operators provide potentially exposed persons and their designated representatives regular access to the exposure control plans, exposure monitoring records, and PPE program implementation. To ensure compliance with workplace participation, EPA is finalizing its requirement that the owner or operator document the notice to and ability of any potentially exposed person that may reasonably be affected by PCE exposure 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.

c. *Recordkeeping.*

For owners and operators to demonstrate compliance with the WCPP provisions, EPA is requiring that owners and operators must retain compliance records for five years (although this requirement does not supplant any longer recordkeeping retention time periods such as those required under 29 CFR 1910. 1020 or other applicable regulations). EPA is requiring the owner or operator to retain records of:

• Exposure control plan;

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

• Information and training provided to each person prior to or at the time of initial

assignment and any retraining.

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

• Regulated areas and authorized personnel;

• The exposure monitoring records;

• Notification of exposure monitoring results; and

• 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, are required to make all records that are maintained as described in Unit IV. available to EPA for examination and copying in accordance with EPA requirements. EPA emphasizes that all records required to be maintained can be kept in the most administratively convenient form such as electronic record form or paper form.

8. *Compliance timeframes.*

With regard to the compliance timeframe for those occupational conditions of use which are subject to the WCPP, EPA is not finalizing the timeframes proposed. Rather, as discussed in Unit III.B.1, based on consideration of public comments and reasonably available information, EPA is finalizing longer timeframes for non-Federal owners or operators, and is providing Federal agencies and Federal contractors acting for or on behalf of the Federal government additional time to comply with each of the provisions of the WCPP. Specifically, EPA is finalizing its requirement that non-Federal owners and operators perform initial exposure monitoring according to the process outlined in Unit IV. within 360 days after publication of the final rule in the *Federal Register*, or within 30 days of introduction of PCE into the workplace, whichever is later. Federal agencies and Federal contractors acting for or on behalf of the Federal government must conduct initial exposure monitoring within 915 days after the date of

publication, or within 30 days of introduction of PCE into the workplace, whichever is later. EPA is also finalizing its requirement that each non-Federal owner or operator ensure that exposure to PCE does not exceed the ECEL as an 8-hour TWA for all potentially exposed persons within 450 days after publication of the final rule, while Federal agencies and Federal contractors acting for or on behalf of the Federal government must comply with the ECEL within 1005 days after the date of publication. If applicable, 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 three months after receipt of the results of any exposure monitoring that indicates an exceedance of the ECEL. For non-Federal owners or operators, this will be within 450 days after publication of the final rule in the *Federal Register*. For Federal agencies and Federal contractors acting for or on behalf of the Federal government, this will be within 1005 after the date publication. EPA is also finalizing the requirement that owners and operators demarcate a regulated area within three months after receipt of any exposure monitoring that indicates exposures exceeding the ECEL. Additionally, EPA is finalizing requirements that each non-Federal owner or operator ensure all persons are separated, distanced, physically removed, or isolated from direct dermal contact with PCE, including by providing dermal PPE within 450 days after publication of the final rule, while Federal agencies and Federal contractors acting for or on behalf of the Federal government must comply with dermal controls no later than 1005 days after publication of the final rule. Non-Federal owners or and operators shall proceed accordingly to implement an exposure control plan, including institution of feasible exposure controls other than PPE, within 900 days of the publication of this final rule, while Federal agencies and Federal contractors acting for or on behalf of the Federal government must implement an exposure control plan within 1095 days after the date of publication.

C. *Prescriptive Controls*

In contrast to the non-prescriptive requirements of the WCPP, including DDCC, where regulated entities would have flexibility to select controls in accordance with the hierarchy of controls to comply with the parameters outlined in Unit IV.B., EPA has found it appropriate in certain circumstances to require specific prescriptive controls for certain occupational conditions of use. In general, EPA is finalizing the prescriptive controls as proposed, with some modifications, for the industrial and commercial use of PCE as a laboratory chemical, as described in Unit III.A.2.d. Additionally, EPA is finalizing prescriptive controls for the industrial and commercial use in energized electrical cleaning. The rationale for these changes from the 2023 PCE proposed rule, after consideration of public comments, is in Unit III.A.2.e. This unit provides a description of the conditions of use subject to specific prescriptive controls, the specific prescriptive control requirements, and the compliance timeframes for the requirements.

1. *Workplace requirements for laboratory use.*

a. *Applicability.*

The industrial and commercial use of PCE as a laboratory chemical refers to the industrial or 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, such as use as a solvent, reagent, analytical standard, or other experimental use.

EPA recognizes that potentially exposed persons in a laboratory setting may include students, researchers, visiting scholars, or others whose job classifications may vary, such as depending on the academic period in university laboratories. The requirements described in Unit IV. apply to all potentially exposed persons in all laboratory settings, including academic and

research laboratories, regardless of job classification.

b. Workplace requirements.

To 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 requiring dermal PPE, including impermeable gloves and protective clothing, 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 with direct dermal contact to PCE in the work area through direct handling of the substance or from contact with surfaces that may be contaminated with PCE. For dermal PPE, EPA is requiring that each owner or operator comply with the requirements outlined in Units IV.B.6.b. for selection of dermal PPE and training for all potentially exposed persons. EPA's description for how the requirements for the industrial and commercial use as a laboratory chemical address the unreasonable risk resulting from dermal exposures under the conditions of use and the rationale for this regulatory approach is outlined in Unit V. of the 2023 PCE proposed rule.

In addition, EPA is requiring the use of laboratory ventilation devices, such as fume hoods, glove boxes, air handling units, exhaust fans, biological safety devices, airflow controls, and other local exhaust devices, in workplace laboratory settings for the industrial and commercial use of PCE as a laboratory chemical, to codify existing good laboratory practices. EPA is requiring each owner or operator of a workplace laboratory setting, to ensure laboratory ventilation devices are in use and functioning properly to minimize exposures to 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, for National Research Council recommendations concerning laboratory chemical hood ventilation system characteristics and practices and to

ANSI's and ASSP's Z9.5-2022 for recommendations on additional laboratory ventilation controls to minimize exposures to potentially exposed persons in the work area.

c. *Recordkeeping.*

To support and demonstrate compliance, EPA is requiring that each owner or operator of a laboratory workplace subject to the requirements of this unit retain compliance records for five years. In alignment with 29 CFR 1910.1450(e)(3)(ii) and (iii) and 29 CFR 1910.132(d)(2), EPA is requiring that owners and operators must retain records of:

• Dermal protection used by each potentially exposed person and PPE program implementation as outlined in this unit;

• Criteria that the owner or operator will use to determine and implement control measures to reduce potentially exposed persons' exposure to PCE including laboratory ventilation devices as outlined in this unit; and

• Implementation of properly functioning laboratory ventilation devices using manufacturer's instructions for installation, use, and maintenance of the systems, 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 must re-assess and update these records.

d. *Compliance timeframes.*

With regards to the compliance timeframe, EPA is requiring that each owner or operator of a workplace engaged in the industrial and commercial of PCE as a laboratory chemical ensure laboratory ventilation devices are in use and functioning properly and that dermal PPE is provided to all potentially exposed persons with direct dermal contact with PCE within 360 days after publication of the final rule.

2. *Workplace requirements for energized electrical cleaner.*

To address the unreasonable risk of injury to health resulting from inhalation and dermal exposures to PCE identified for the industrial and commercial use as an energized electrical cleaner, which is a sub-use of the industrial and commercial use as an aerosol spray degreaser/cleaner, and in consideration of the lack of reasonably available technically and economically feasible alternatives to PCE for energized electrical cleaning, EPA is requiring (i) specific prescriptive controls outlined in this Unit, including dermal PPE and respiratory protection, or (ii) implementation of the WCPP outlined in Unit IV.B. EPA is also requiring labels and self-certification. As described in Unit III.A.2.e., EPA's workplace requirements to address the unreasonable risk for industrial and commercial use as an energized electrical cleaner are consistent to the extent possible with existing regulations and best practices for work in electrical spaces. EPA acknowledges the existing OSHA requirements for electrical protective equipment under 29 CFR 1910.137 and does not believe the requirements in this rule interfere with a potentially exposed person's ability to safely use electrical protective equipment, such as rubber insulating gloves and rubber insulating sleeves, as required under OSHA.

a. *Applicability.*

The industrial and commercial use of PCE as an energized electrical cleaner refers to the use of PCE in a product that meets both of the following criteria: 1) the product is labeled to clean and/or degrease electrical equipment, where cleaning and/or degreasing is accomplished when electrical current exists, or when there is a residual electrical potential from a component, such as a capacitor; and; 2) the product label clearly displays the statements: "Energized Equipment use only. Not to be used for motorized vehicle maintenance, or their parts."

b. *Workplace requirements for energized electrical cleaner.*

EPA is requiring that owners or operators must either implement (i) specific prescriptive controls that provide dermal PPE and respiratory protection, or (ii) implement the WCPP for

industrial and commercial use as energized electrical cleaner. Owners and operators must maintain a statement regarding whether the business is complying with the specified prescriptive controls or with the WCPP.

i. *Prescriptive controls.*

A. *Dermal protection.* To address the unreasonable risk of injury to health resulting from dermal exposures to PCE identified for the industrial and commercial use as an energized electrical cleaner, EPA is requiring dermal PPE, including impermeable gloves and protective clothing, in combination with comprehensive training for each potentially exposed person with direct dermal contact to PCE in the work area through direct handling of the substance or from contact with surfaces that may be contaminated with PCE. For dermal PPE, EPA is requiring that each owner or operator comply with the requirements outlined in Unit IV.B.6.b. for selection of dermal PPE and training for all potentially exposed persons.

B. *Respiratory protection.* Based on the 2020 Risk Evaluation for PCE, EPA determined that the use of respirators with an APF of 50 could control PCE air concentrations to levels that address the unreasonable risk from inhalation exposure based on high-end exposures for the industrial and commercial use in aerosol spray degreaser/cleaner. Therefore, EPA is requiring use of specific respiratory protection, in combination with comprehensive training, for use of an energized electrical cleaner containing PCE in confined spaces, as defined in 29 CFR 1910.146(b), or in an enclosed space (such as a manhole or vault), as described in 29 CFR 1910.269(c). Specifically, EPA is requiring owners or operators to provide to potentially exposed persons, and potentially exposed persons to use, the following: any NIOSH Approved® air-purifying full facepiece respirator equipped with organic vapor cartridges or canisters; any NIOSH Approved® Powered Air-Purifying Respirator (PAPR) with a half mask equipped with organic vapor cartridges or canisters; any NIOSH Approved® Supplied-Air Respirator (SAR) or

Airline Respirator in a continuous flow mode equipped with a half mask; any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator operated in a pressure-demand or other positive-pressure mode with a half mask; or any NIOSH Approved® SCBA in demand-mode equipped with a full facepiece or helmet / hood [APF 50]; or any respirator affording a higher degree of protection. In providing the specified respirators and training to potentially exposed persons, EPA is requiring owners or operators to administer a PPE program with procedures and elements for required respirator use as outlined in Unit IV.B.6.a. for proper respirator use, maintenance, fit-testing, medical evaluation, and training. EPA is requiring 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.

For energized electrical cleaning in spaces that are not enclosed or confined, EPA is requiring use of respiratory protection described in Unit IV. if the potentially exposed person is permitted to approach exposed energized parts closer than the employer's established minimum approach distance by meeting the requirements of 29 CFR 1910.269(l)(3)(iii)(A) through (C) or 29 CFR 1910.333(c)(3)(ii)(A) through (C), or if there is no established minimum approach distance.

ii. *WCPP.*

EPA understands that there may be instances where a performance-based standard is more appropriate to address the unreasonable risk for the industrial and commercial use of PCE as an energized electrical cleaner, instead of the specific prescriptive dermal and respiratory protection requirements described in Unit IV.C.2.b.i. For example, the WCPP may be preferred by owners or operators that regularly use PCE to clean energized electrical equipment onsite at their facility or by owners or operators that are implementing the WCPP at their facility for

another condition of use of PCE. In these instances, EPA is requiring owners or operators to comply with the WCPP requirements, including the ECEL, direct dermal contact controls, and ancillary provisions, outlined in Univ IV.B. Owners and operators who choose to follow the WCPP as an alternative to the specific prescriptive controls must also document and maintain a statement that they are electing to comply with the WCPP.

c. *Labeling requirements for energized electrical cleaner.*

To prevent the use of an energized electrical cleaner containing PCE for unintended applications, such as automotive maintenance or electrical cleaner, EPA is requiring that all manufacturers (including importers), processors, and distributors in commerce of energized electrical cleaner containing PCE provide a label securely attached to each product. Label information is required to be clearly displayed in an easily readable font size, and containing the following text: "This product contains perchloroethylene (PCE) (CASRN 127-18-4), a chemical determined by the Environmental Protection Agency to present unreasonable risk of injury to health under the Toxic Substances Control Act (TSCA), based on neurotoxicity and other adverse health effects. The use of PCE is restricted under 40 CFR part 751, Subpart G. This product is for Energized Equipment use only. Not to be used for motorized vehicle maintenance, or their parts."

d. *Self-certification for energized electrical cleaner.*

To ensure safe and appropriate use of PCE as an energized electric cleaner and to prevent use of an energized electrical cleaner containing PCE for unintended applications, EPA is requiring a point-of-sale self-certification requirement in order to purchase and subsequently use PCE as an energized electrical cleaner. Under this self-certification requirement, EPA is requiring owners or operators, or persons specifically authorized by the owner or operator to purchase energized electrical cleaner, to submit a self-certification to the distributor each time

energized electrical cleaner containing PCE is purchased. The self-certification consists of a statement indicating the owner or operator is implementing the prescriptive controls described in Unit IV. or the WCPP described in Unit IV.B. at their business. The self-certification must be signed and presented by a person authorized to do so by the owner or operator of the business entity. EPA is requiring that copies of the self-certification be maintained as records by both the owner or operator and the distributor where PCE was purchased.

Owners or operators who wish to continue or begin purchasing energized electrical cleaners containing PCE must self-certify that the business is implementing and complying with all aspects of the workplace controls (specified respiratory and dermal PPE or the WCPP) described in Unit IV., with the following self-certification statement:

> I certify each of the following statements under penalty of law. This document was prepared under my direction and supervision. This energized electrical cleaner will be used for energized equipment use only. This business entity has implemented and complies with the EPA requirements for energized electrical cleaner that contains perchloroethylene under 40 CFR § 751.611 and only trained and qualified persons will handle the energized electrical cleaner product. Based on my inquiry of the person or persons who manage the business entity and/or those persons directly responsible for implementing the EPA requirements for energized electrical cleaner that contains perchloroethylene, and to the best of my knowledge and belief, this business entity is in compliance with the EPA requirements for energized electrical cleaner. I am aware that there are significant penalties, including the possibility of civil penalties for failing to comply with these requirements and criminal fines and imprisonment, for knowingly failing to comply with these requirements. I understand that this certification shall serve as a certification that this business entity will properly implement and comply with the requirements for energized electrical cleaner consistent with the applicable regulatory timelines.

The self-certification statement must be signed and dated by the owner or operator, including a name, title, email address, and phone number for the owner or operator who is self-certifying. The self-certification statement must also list the name and address of the business entity that is being certified and indicate if this is the business entity's first purchase of energized electrical cleaner containing PCE, after publication of the final rule. The self-certification

statement would be valid for one year, unless the business entity has changed processes or there is an indication that exposures to PCE have changed.

To ensure distributors are only selling PCE to owners or operators, or to persons specifically authorized by the owner or operator to purchase energized electrical cleaners, of business entities able to implement and comply with the workplace requirements for energized electrical cleaner, EPA is requiring owners or operators who self-certify to provide a copy of the business entity's current self-certification statement to the distributor from whom energized electrical cleaner containing PCE is being purchased, for every purchase of PCE. EPA is also requiring the distributors to collect, maintain, and retain a copy of the self-certification statement. EPA is also requiring distributors to keep records, such as invoices, that indicate the name of the purchaser and business entity, date of sale, and quantity of PCE purchased. Distributors of PCE as an energized electrical cleaner may only distribute to those companies that provide the correct self-certification statement for purchasing. EPA realizes that some companies may not engage in or use energized electrical cleaners containing PCE at the time this rule is finalized. Owners or operators that may wish to purchase energized electrical cleaners containing PCE after the publication of the final rule are required to submit the self-certification statement to the distributor from whom PCE was initially purchased in order to purchase PCE, certifying that the business for which PCE is being purchased will implement and comply with the workplace requirements for industrial and commercial use as an energized electrical cleaner. EPA is also requiring that sellers and distributors review the self-certification statement to ensure it is appropriately completed to include the business entity's information, as outlined in Unit IV. Distributors of PCE for use in energized electrical cleaners must have a complete and valid self-certification statement in accordance with this section for each sale of PCE for such use. EPA is requiring that the distributors and owners or operators maintain and retain the self-certification

statement and related invoices in the most administratively convenient form (electronic or paper) and retain the statement and supporting documentation for five years.

e. *Recordkeeping.*

To support and demonstrate compliance, EPA is requiring that each owner or operator subject to the requirements of this Unit retain compliance records for five years. EPA is requiring that owners and operators must retain records of:

• The self-certification statement and related invoices, including: (A) the written statement required in Unit IV.C.2.d.; (B) printed name and signature, job classification, email address, and phone number of the owner or operator who is self-certifying; (C) date of self-certification; and (D) name and address of business entity; and

• Statement regarding whether the owner or operator is complying with the prescriptive dermal and respiratory protection requirements or with the WCPP.

Additionally, for owners or operators that elect to comply with the prescriptive dermal and respiratory protection requirements outlined in Unit IV.C.2.b.i., EPA is requiring that owners and operators must retain records of:

• Dermal protection used by each potentially exposed person and program implementation;

• Respiratory protection used by each potentially exposed person and program implementation;

For owners or operators that elect to comply with the WCPP instead of the prescriptive dermal and respiratory protection outlined in Unit IV.C.2.b.i., owners and operators must retain the records described in Unit IV.B.7.c.

EPA is also requiring sellers and distributors of energized electrical cleaner containing PCE to retain the following:

• Invoices that include: (A) name of purchaser; (B) date of sale; and (C) quantity of PCE or PCE containing products sold; and

• Self-certification statement for each purchase of PCE; and

• Copies of the labels required in Unit IV.C.2.c.

f. *Compliance timeframes.*

With regards to the compliance timeframe, EPA is requiring that each owner or operator of a business entity engaged in the industrial and commercial use of PCE as an energized electrical cleaner either: (1) Implement the specific prescriptive controls of dermal and respiratory protection for energized electrical cleaner described in this unit within 450 days of the publication of this final rule or (2) implement the WCPP in accordance with the compliance timeframes described in Unit IV.B.8., which includes requiring owners and operators to establish initial monitoring within 360 days of the publication of this final rule and providing PPE within 450 days of the publication of this final rule. Additionally, EPA is requiring that the labeling requirement take effect 450 days after publication of this final rule for manufacturers (including importers), processors, and distributors of energized electrical cleaner containing PCE. EPA is also requiring the self-certification requirements take effect 450 days after publication of this final rule for owners or operators and distributors.

D. *Prohibition of Manufacture, Processing, Distribution, and Use of PCE*

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

In general, EPA is finalizing the prohibitions as proposed, with some modifications, including for compliance timeframes to provide for reasonable transitions, based on consideration of the public comments. The rule prohibits the manufacture, processing, distribution in commerce, and use of PCE for all industrial and commercial use, except for those

industrial and commercial uses which would continue under the WCPP (as identified in Unit IV.A.2.), laboratory use (as identified in Unit IV.A.3.) and use as an energized electrical cleaner (as identified in Unit IV.A.3). Based on comments, EPA is finalizing timeframes longer than proposed for prohibitions of manufacture, processing, distribution, and most industrial and commercial use of PCE broadly. The rationale for these changes from the 2023 PCE proposed rule is in Unit III.B.2. EPA is also finalizing as proposed the phaseout timeframes for the industrial and commercial use of PCE in dry cleaning and related spot cleaning as described in Unit IV.D.3.

As discussed in Unit II.C.4., the prohibitions do not apply to any substance that is excluded from the definition of "chemical substance" under TSCA section 3(2)(B)(ii) through (vi) (Ref. 8).

The final regulation will impose prohibitions in a staggered timeframe, beginning at the top of the supply chain, as proposed. As discussed in Unit III.B.2., in response to comments received, EPA is finalizing timeframes for prohibitions according to the following staggered timeframe:

- Within 540 days of publication of this final rule for prohibitions on manufacturers;
- Within 630 days of publication of this final rule for prohibitions on processors;
- Within 720 days of publication of this final rule for prohibitions on distributing to retailers;
- Within 810 days of publication of this final rule for prohibitions on all other distributors (including retailers); and
- Within 900 days of publication of this final rule for prohibitions on industrial and commercial users.

Additionally, EPA had proposed a WCPP for the industrial and commercial use of PCE

for in-line conveyorized and web vapor degreasing. After receiving public comments that clarified that these uses are no longer ongoing, EPA is finalizing the prohibition of these uses.

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

The final rule prohibits the manufacture, processing, and distribution in commerce of PCE and PCE-containing products for all consumer use. As discussed in the 2023 PCE proposed rule and in this final rule, "consumer use" refers to all known, intended, or reasonably foreseen PCE consumer uses.

EPA is also finalizing the proposed prohibitions on distributing in commerce to retailers, and on retailers from distributing in commerce, PCE and all PCE-containing products for any use (with the exception of dry cleaning, which is subject to a separate phaseout described in Unit IV.D.3), in order to prevent products intended for industrial and commercial use under the WCPP or prescriptive controls from being purchased by consumers. The prohibitions described in this unit will take effect in the following timeframes:

• Within 540 days of publication of this final rule for prohibitions on manufacturers;

• Within 630 days of publication of this final rule for prohibitions on processors, within 720 days of publication of this final rule for prohibitions on distributing to retailers; and

• Within 810 days of publication of this final rule for prohibitions on all other distributors (including retailers).

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 (40 CFR 751.5). For a distributor not to be considered a retailer, the distributor must distribute or make available products 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 prevents retailers from making these products available to consumers, which helps address that part of the unreasonable risk from PCE contributed by consumer use.

3. *Prohibition and phaseout of PCE in dry cleaning.*

EPA is finalizing as proposed the prohibition on the manufacturing, processing, distribution of 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. A prohibition on the manufacturing, processing, distribution in commerce, and industrial and commercial use of PCE in dry cleaning and spot cleaning addresses the unreasonable risk for the following conditions of use as described in Unit III.B.1 of the 2023 PCE proposed rule:

• *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.

• *Industrial and commercial use in dry cleaning and spot cleaning 4th/5th generation 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.

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

EPA is finalizing a phaseout period following the publication of the final rule. The phaseout starts with a prohibition on the industrial or commercial use of PCE in any dry cleaning machine acquired 180 days or later after publication of the final rule, followed by a prohibition on the industrial or commercial use of PCE in 3rd generation machines 3 years after publication of the final rule. Full implementation of the phaseout will be achieved with a prohibition on the industrial or commercial use of PCE in all dry cleaning and spot cleaning, including in 4th and 5th generation machines, 10 years after publication 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 publication of the final rule. 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 United

States market (Ref. 21). 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. 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. EPA believes that the 180-day and 3-year compliance dates for the start of the phaseout, and the 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 five 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).

E. *Other Requirements*

1. *Recordkeeping.*

For conditions of use that are not otherwise prohibited under this final rule, EPA is finalizing as proposed the requirement 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. This requirement begins 60 days following publication of the final rule in the *Federal Register*. For enforcement purposes, EPA will have access to such businesses records plus additional records required under 40 CFR 751.615. Recordkeeping requirements would ensure that owners or operators can demonstrate compliance with the regulations if necessary.

2. *Downstream notification.*

For conditions of use that are not otherwise prohibited or are subject to delayed prohibition compliance timeframes under this final regulation, EPA is finalizing as proposed, with slight modification, the requirements that manufacturers (including importers), processors, and distributors, excluding retailers, of PCE and PCE-containing products provide downstream notification of the prohibitions through the SDSs by adding to sections 1(c) and 15 of the SDS the following language:

> After **[INSERT DATE 720 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** this chemical/product (as defined in TSCA section 3(2)) cannot be distributed in commerce to retailers. After **[INSERT DATE 810 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, this chemical/product is and can only be distributed in commerce or processed with a concentration of PCE equal to or greater than 0.1% by weight for the following purposes: (1) Processing as a reactant/intermediate; (2) Processing into formulation, mixture or reaction product (3) Processing by repackaging; (4) Recycling; (5) Industrial and commercial use as solvent in open-top batch vapor degreasing; (6) Industrial and commercial use as solvent in closed-loop batch vapor degreasing; (7) Industrial and commercial use in maskant for chemical milling; (8) Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing; (9) Industrial and commercial use as a processing aid in sectors other than petrochemical manufacturing; (10) Industrial and commercial use in laboratory chemicals; (11) Industrial and commercial use in solvent-based adhesives and sealants; (12) Industrial and commercial use as solvent for cold cleaning of tanker vessels; (13) Industrial and commercial use as energized electrical cleaner; (14) Industrial and commercial use in dry cleaning in 3rd generation machines until **[INSERT DATE 3 YEARS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**; (15) Industrial and commercial use in dry cleaning and related spot cleaning until **[INSERT DATE 10 YEARS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**; (16) Export; and (17) Disposal.

To provide adequate time to update the SDS and ensure that all products in the supply chain include the revised SDS, EPA's final rule requires manufacturers to revise their SDS

within two months of rule publication and processors and distributors to revise their SDS within six months of rule publication. EPA did not receive public comments asserting that these compliance dates for updating the SDS were impracticable, and is therefore finalizing the compliance dates as proposed. The intention of downstream notification is to spread awareness throughout the supply chain of the restrictions on PCE under TSCA and to provide information to commercial end-users about allowable uses of PCE.

F. *TSCA Section 6(g) Exemptions*

EPA is finalizing with minor clarifications the proposed 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; and Industrial and commercial use in wipe cleaning. The exemption includes conditions, pursuant to TSCA section 6(g)(4), including required notification and controls for exposure, to the extent feasible. Specifically, this regulation requires the following: (1) NASA and its contractors must provide notice to the EPA Assistant Administrators of both the Office of Enforcement and Compliance Assurance and the Office of Chemical Safety and Pollution Prevention of each instance of emergency use within 15 days; and (2) NASA and its contractors must comply with the WCPP described in Unit IV.B to the extent feasible. The notification must 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 finalized, 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 safer alternatives. EPA notes that in the event that sensitive information clearly marked as such relating to national security or critical infrastructure is submitted to EPA at any point during the TSCA section 6 process, the Agency will protect such information in accordance with applicable authorities.

EPA expects NASA and its contractors have the ability to implement a WCPP as

described in Unit IV.B. for the identified uses in the context of an emergency, to some extent even if not to the full extent of WCPP implementation. Therefore, NASA must comply with the WCPP to the extent technically feasible in light of the particular emergency. NASA and its contractors would still be subject to the general recordkeeping requirements discussed in Unit IV.E.1.

V. 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 and the 2022 revised unreasonable risk determination for PCE (Refs. 1, 2). A summary is presented in Unit V.

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. Prenatal and early childhood exposure to PCE has also been linked to statistically significant increased risk of engaging in risky behaviors. 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. 78), 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 259,609 workers and 31,449 occupational non-users (ONUs) (Ref. 3). The number of consumers that use the approximately 115 types of products containing PCE each year is unknown. See section 6.1.9 of the Economic Analysis and section 8.4.1 of the response to comment document for additional detail, including a description of changes made from the 2023 PCE proposed rule to EPA's estimates in response to public comment (Refs. 3, 8).

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 these estimates of numbers of workers, occupational non-users, 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. (While bystanders are individuals in proximity to a consumer use of PCE, fenceline communities are a subset of the general population who may be living in proximity to a facility where PCE is being used in an

occupational setting). EPA separately conducted a screening approach to assess whether there may be potential risks to the general population from these exposure pathways. This analysis is summarized in full in the 2023 PCE proposed rule, which includes information on the SACC peer review. This unit addresses those areas where some risk was indicated at the fenceline, and the condition of use will be continuing under the rule.

EPA's analysis methodology was presented to the SACC peer review panel in March 2022, and EPA is including SACC recommendations, as appropriate, in assessing general population exposures in upcoming risk evaluations. 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. 79). EPA therefore does not intend to revisit or conduct an analysis of the water pathway for PCE as part of a supplemental risk evaluation.

EPA's analysis for the air pathway for PCE using methodology presented to SACC and the multi-year analysis conducted in response indicated potential exposure and associated risks to select populations within the general population at particular facilities (Ref. 80). As described in Unit VI.A. of the 2023 PCE proposed rule, 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. 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 screening analysis whether those risks drive the unreasonable risk of injury to health presented by PCE. Although EPA did not make a determination of unreasonable risk based on the fenceline screening analysis, this final regulatory action is expected to reduce the risks identified in the screening approach. Additionally, while the fenceline screening analysis identified facilities with some indication of

releases and potential exposures with associated increased cancer risk that exceeds the $1x10^{-6}$ benchmark, the analysis did not identify any facilities exceeding the $1x10^{-4}$ benchmark; the highest risk estimate identified is in the $1x10^{-5}$ range (Ref. 80). 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 $1x10^{-4}$). For example, when setting standards under CAA section 112(f)(2), EPA uses a two-step process, with "an analytical first step to determine an `acceptable risk' that considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual risk (MIR) of approximately 1-in-10 thousand" (Ref. 81, referencing the interpretation set forth in the 1989 final National Emission Standards for Benzene rule (54 FR 38044 Sept. 14, 1989)).

EPA believes that the prohibitions being finalized for manufacturing (including importing), processing, and distribution in commerce for all consumer use and most commercial use would reduce exposures to the general population, including fenceline communities. Of the 29 facilities which indicated potential exposure and associated increased cancer risk to fenceline communities, under the final regulation, 20 may be associated with conditions of use that EPA is not prohibiting, and thus exposures at the fenceline at the remaining 9 facilities would be addressed.

Under the final rule, only 16 conditions of use will continue (see Units IV.B. and IV.C. for a summary). For many of these conditions of use, EPA expects use and associated production volume of PCE to decline over time. For example, the manufacturing and processing: incorporation into a formulation, mixture, or reaction product conditions of use can reasonably be expected to decline. While EPA is permitting the continued manufacturing and processing of PCE subject to the WCPP, the downstream distribution and use of formulations, mixtures, or reaction products for most conditions of use would be prohibited. Exceptions include the

distribution and use of products for conditions of use that EPA is not prohibiting in this final regulation, including certain degreasing applications (*e.g.,* vapor degreasing, cold cleaning, and energized electrical cleaning), chemical milling, adhesives and sealants, processing aid, and laboratory use. Additionally, EPA expects the processing 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. HFC-125 and HFC-134a are two of the regulated substances that are subject to the AIM Act phasedown.

For the conditions of use that are not prohibited, this final rule requires exposure controls via implementation of a WCPP or prescriptive controls as described in Units IV.B. and IV.C. While it is possible that 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 predicts that this potential exposure would be limited as a result of the existing NESHAP that cover PCE for these conditions of use under the CAA. Applicable NESHAPs 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, and any exceedances would be an enforcement issue. The CAA establishes a two-phase process for the EPA's development, review, and potential revision of NESHAP that impose emission standards and work practice requirements on subject categories of sources of hazardous air pollutants. First, the EPA sets technology-based or performance-based standards reflecting the maximum achievable control technology (MACT) for major sources (CAA section 112(d)(2)-(3)) and generally available control technology (GACT) for area or non-major sources (CAA section 112(d)(5)). In the second phase, eight years

after adoption of the first phase standards, the EPA performs a residual risk review of major source MACT standards to ensure that they provide an ample margin of safety to protect public health (CAA section 112(f)(2)), and a technology review of all NESHAP to account for developments in practices, processes and control technologies (CAA section 112(d)(6)). The CAA only requires the EPA to conduct the residual risk review one time for each MACT standard, although the EPA has discretion to conduct additional risk reviews where warranted. The technology review, instead, is a recurring duty, and the EPA must perform it no less often than every eight years.

Thus, the prohibitions and restrictions on PCE in this final rule, combined with the expected decline in production volume for PCE and the CAA requirements described above, are expected to sufficiently address the emissions of PCE, and thus the resulting risks identified in the screening analysis to any general population or fenceline communities close to facilities engaging in PCE use. EPA therefore does not intend to revisit or conduct an analysis of the air pathway for PCE as part of a supplemental risk evaluation.

B. *Environmental Effects of PCE and the Magnitude of Environmental Exposure 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 and the 2022 revised unreasonable risk determination for PCE (Refs. 1, 2). 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 in Unit V.

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 (Ref. 82), as well as monitored data from the Water Quality Portal (Ref. 83), 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*

As described in the 2023 PCE proposed rule, 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, 84).

D. *Reasonably Ascertainable Economic Consequences of the Final 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 final rule include several components, all of which are described in the Economic Analysis (Ref. 3). With respect to the anticipated effects of this final 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 final rule would be $43.4 million annualized over 20 years at a 2% 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 final rule, and found that the direction of change in employment is uncertain, but EPA expects the short-term and longer-term employment effects to be small.

There are an estimated 154,683 small entities affected by the final rule with a per firm and total estimated cost impact of $177 and $27.4 million, respectively. Of the small businesses potentially impacted by this final rule, almost 100% (154,671 out of 154,683) are expected to have impacts of less than 1% to their firm revenues, 8 (0.00005%) are expected to have impacts between 1 and 3% to their firm revenues, and 5 (0.00003%) are expected to have impacts greater than 3% to their firm revenues. Most of these small entities (94%) are users of PCE in aerosol degreasing with an estimated 119,523 small entities using PCE in energized electrical cleaning and an estimated 26,050 small entities using PCE in other aerosol spray cleaning/degreasing uses like brake cleaning.

EPA estimates that there are 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 maintains 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 phaseout date.

In addition to dry cleaners, other users of PCE (such as in vapor degreasing and use as maskant in chemical milling) could be strongly impacted because they may have no economical alternative to the use of PCE.

With respect to this 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 final rule may increase demand for safer chemical substitutes. This rule is not likely to have significant effects on the environment because PCE does not present an unreasonable risk to the environment, though this 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 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 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 rule are described at length in the Economic Analysis (Ref. 3). The monetized costs for this final rule are estimated to be $43.4 million annualized over 20 years at a 2% discount rate. The monetized benefits are estimated to be $32.6 to $84.6 million annualized over 20 years at a 2% discount rate.

EPA considered the estimated costs to regulated entities as well as the cost to administer and enforce an alternative regulatory action. The alternative regulatory action is described in detail in Unit IV.B of the 2023 PCE proposed rule. The estimated annualized cost of the alternative regulatory action is $62.1 million at a 2% discount rate over 20 years (Ref. 3). The monetized benefits of the alternative action are estimated to be $32.5 to $84.4 million annualized over 20 years at a 2% discount rate (Ref. 3).

This final rule 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 Units II.A. (overview), III.B.2. (description of the unreasonable risk), V.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 previously. 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 2023 PCE proposed rule.

3. *Cost effectiveness of the regulatory action and of one 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 regulatory action is to prevent unreasonable risk resulting from exposure to PCE. The regulatory action would cost $3.1 million per potential prevented cancer case while the primary alternative regulatory action would cost $4.4 million (using the 2% discount rate) (Ref. 3).

VI. TSCA Section 9 Analysis and Section 14 and 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. TSCA section 9(a) describes additional procedures and requirements to be followed by EPA and the other Federal agency after submission of the report. As discussed in

Unit VI., the Administrator does not determine that 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. EPA's section 9(a) analysis can be found in full in Unit VII.A. of the 2023 PCE proposed rule, and responses to comments on that 9(a) analysis can be found in the Response to Comments, section 9.1 (Ref. 8).

TSCA section 9(d) instructs the Administrator to consult and coordinate TSCA activities with other Federal agencies for the purpose of achieving the maximum enforcement of TSCA while imposing the least burden of duplicative requirements. For this rulemaking, EPA has coordinated with appropriate Federal executive departments and agencies including but not limited to OSHA and the Consumer Product Safety Commission (CPSC), to, among other things, identify their respective authorities, jurisdictions, and existing laws with regard to risk evaluation and risk management of PCE.

As discussed in more detail in the 2023 PCE proposed rule, OSHA requires that employers provide safe and healthful working conditions by setting and enforcing standards and by providing training, outreach, education, and assistance. 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. The U.S. CPSC, under authority provided to it by Congress in the Consumer Product Safety Act (CPSA), protects

the public from unreasonable risk of injury or death associated with consumer products. Under the CPSA, CPSC has the authority to regulate PCE in consumer products, but not in other sectors such as automobiles, some industrial and commercial products, or aircraft for example.

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. An action under TSCA is also able to address occupational unreasonable risk and would reach entities that are not subject to OSHA. Moreover, the timeframe and any exposure reduction as a result of updating OSHA or CPSC regulations for PCE cannot be estimated, while TSCA imposes a much more accelerated two-year statutory timeframe for proposing and finalizing requirements to address unreasonable risk. Regulating PCE's unreasonable risk utilizing TSCA authority will also avoid the situation where a patchwork of regulations amongst several Agencies using multiple laws and differing legal standards would occur and is therefore a more efficient and effective means of addressing the unreasonable risk of PCE. Finally, as discussed in greater detail in the 2023 PCE proposed rule, the 2016 amendments to TSCA altered both the manner of identifying unreasonable risk and EPA's authority to address unreasonable risk, such that risk management is increasingly distinct from provisions of the CPSA, Federal Hazardous Substances Act (FHSA), or OSH Act (88 FR 39652) (FRL-8329-01-OCSPP)). 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.

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 (Refs. 3, 5), regulations under those EPA statutes 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.*, RCRA, CAA, CWA). Updating regulations under other EPA statutes would not be sufficient to address the unreasonable risk of injury to the health of workers, occupational non-users, consumers, and bystanders who are exposed to PCE under its conditions of use. EPA's section 9(b) analysis can be found in full in Unit VII.B. of the 2023 PCE proposed rule, and responses to comments on that 9(b) analysis can be found in the Response to Comments, section 9.2 (Ref. 8).

For these reasons, the Administrator does not determine that unreasonable risk from PCE under its conditions of use, as evaluated in the 2020 Risk Evaluation for PCE (Ref. 1), 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. Under TSCA sections 14(a) and 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). Pursuant to TSCA section 14(b)(4)(B)(iii), the presumption against protection from disclosure will apply only to information about the specific conditions of use that this rule prohibits or phases out. Per TSCA section 14(b)(4)(B)(i), the presumption against protection will not apply to information about certain emergency uses that this rule exempts from a ban or phase-out pursuant to TSCA section 6(g). Manufacturers or processors seeking to protect such information may submit a request for nondisclosure as provided by TSCA sections 14(b)(4)(C) and 14(g)(1)(E). Any request for nondisclosure must be submitted within 30 days after receipt of notice from EPA under TSCA section 14(g)(2)(A) stating EPA will not protect the information from disclosure. EPA anticipates providing such notice via the Central Data Exchange (CDX).

D. *TSCA Section 26 Considerations*

As explained in the 2023 PCE proposed rule, EPA fulfilled TSCA section 26(h) by using scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science. Comments received on the 2023 PCE proposed rule about whether EPA adequately assessed reasonably available information under TSCA section 26 on the risk evaluation, and responses to those comments, can be found in Section 9.3 of the Response to Comments document (Ref. 8).

VII. 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**.

1. EPA. Risk Evaluation for Perchloroethylene. Document ID No. EPA-HQ-OPPT-2020-0720-0035. EPA Publication No. 740-R1-8011. December 2020. *https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0502-0058*.

2. EPA. Perchloroethylene. Unreasonable Risk Determination. Document ID No. EPA-HQ-OPPT-2020-0720-0036. December 2022.

3. EPA. Economic Analysis of the Final Regulation of Perchloroethylene Under TSCA Section 6(a). RIN 2070-AK84. December 2024.

4. President Biden. The President and First Lady's Cancer Moonshot: Ending Cancer As We Know It. Accessed February 26, 2024. *https://www.whitehouse.gov/cancermoonshot/*.

5. EPA. Access Chemical Data Reporting Data: 2016 CDR Data (Updated May 2020). Document ID No. EPA-HQ-OPPT-2020-0720-0037. Last Updated on May 16, 2022. *https://www.epa.gov/chemical-data-reporting/access-cdr-data#2016*.

6. EPA. Access Chemical Data Reporting Data: 2020 CDR Data (up-to-date as of April 2022). Document ID No. EPA-HQ-OPPT-2020-0720-0038. Last Updated on May 16, 2022. *https://www.epa.gov/chemical-data-reporting/access-cdr-data*.

7. EPA. Regulatory Actions Pertaining to Perchloroethylene. Document ID No. EPA-HQ-OPPT-2020-0720-0039. 2022.

8. EPA. Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA); Response to Public Comments. December 2024.

9. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *Federal Register.* 86 FR 7009, January 20, 2021.

10. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. *Federal Register.* 86 FR 7037, January 25, 2021.

11. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. *Federal Register.* 86 FR 7619, February 1, 2021.

12. EPA. An Alternatives Assessment for Use of Perchloroethylene. Document ID No. EPA-HQ-OPPT-2020-0720-0104. RIN 2070-AK84. November 2022.

13. EPA. Notes from Federalism Consultation on Forthcoming Proposed Rulemakings for Trichloroethylene, Perchloroethylene, and n-Methylpyrrolidone under TSCA Section 6(a). Document ID No. EPA-HQ-OPPT-2020-0720-0058. July 22, 2021.

14. EPA. Notes from Tribal Consultations on Forthcoming Proposed Rulemakings for Trichloroethylene (TCE) and Perchloroethylene (PCE). Document ID No. EPA-HQ-OPPT-2020-0720-0059. June 15, 2021 and July 8, 2021.

15. Peter Sinsheimer; Green Analytics. Comments on Environmental Justice Consultation for TSCA PCE Risk Management of Dry Cleaning. Document ID No. EPA-HQ-OPPT-2020-0720-0060. August 20, 2021.

16. Hans Kim; AQUA Wet Clean. Letter re: Environmental Justice Consultation USEPA TSCA PCE Risk Management. Document ID No. EPA-HQ-OPPT-2020-0720-0061. August 20, 2021.

17. W. Heiger-Bernays and G. Nielsen. Comments on Environmental Justice Consultation #2 for TCE and PCE. Document ID No. EPA-HQ-OPPT-2020-0720-0062. July 5, 2021.

18. Martin Argüello; Physicians for Social Responsibility. USEPA EJ Consultation Meeting Comments on PCE and TCE TSCA Regulations. Document ID No. EPA-HQ-OPPT-2020-0720-0063. August 20, 2021.

19. Sa Liu; School of Health Sciences Purdue University. Letter re: Environmental Justice Consultation on Forthcoming Proposed Rulemakings under TSCA Section 6(a). Document ID No. EPA-HQ-OPPT-2020-0720-0064. August 20, 2021.

20. EPA. Initial Regulatory Flexibility Analysis for Perchloroethylene; Regulation of Perchloroethylene under TSCA §6(a) Proposed Rule; RIN 2070-AK84. Document ID No. EPA-HQ-OPPT-2020-0720-0126. February 2023.

21. EPA. Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule Toxic Substances Control Act (TSCA) Section 6(a) Perchloroethylene. Document ID No. EPA-HQ-OPPT-2020-0720-0066. February 1, 2023.

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37. Dow Chemical. Comments on the Proposed Rulemaking for Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA). Document ID No. EPA-HQ-OPPT-2020-0720-0284. August 15, 2023.

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39. The Campus Safety Health and Environmental Management Association (CSHEMA). Comments on the Proposed Rulemaking for Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA). Document ID No. EPA-HQ-OPPT-2020-0720-0248. August 10, 2023.

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VIII. 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 the Office of Management and Budget (OMB) for Executive Order 12866 review. Documentation of any changes made in response to Executive Order 12866 review is available in the docket. EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis (Ref. 3) is available in the docket and summarized in Unit I.E.

B. *Paperwork Reduction Act (PRA).*

The information collection activities in this rule will be submitted to OMB for approval 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. 2740.02, and OMB Control No. 2070-0233 (Ref. 85).) The ICR is available in the docket and is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

There are four primary provisions of the final 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 will be required for manufacturers, processors, and distributors in commerce of PCE, who will provide notice to companies downstream upon shipment of PCE about the prohibitions. The information submitted to downstream companies through the SDS will provide knowledge and awareness of the restrictions to these companies. The second primary provision

of the 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). The third primary provision of the rule that is expected to increase burden under the PRA is information generation related to workplace requirements for laboratory use-related information and generation, (including development of documentation for a PPE program, related recordkeeping, and development of documentation demonstrating implementation of a properly functioning ventilated laboratory safety device). The fourth primary provision of the rule that is expected to increase burden under the PRA is information generation related to energized electrical cleaning, including self-certification, recordkeeping, and notification requirements (including development and documentation of those requirements under the specific prescriptive controls or WCPP and related recordkeeping; development of documentation of a self-certification statement and related recordkeeping; notification of self-certification; and labeling).

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: 157,760.

Frequency of response: On occasion.

Total estimated burden: 432,203 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $34,515,086 (per year), includes $2,922,680 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. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the ***Federal Register*** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. *Regulatory Flexibility Act (RFA).*

Pursuant to section 603 and 609(b) of the RFA, 5 U.S.C. 601 *et seq.*, EPA prepared an IRFA for the 2023 PCE proposed rule and convened a SBAR Panel to obtain advice and recommendations from SER that potentially would be subject to the rule's requirements. Summaries of the IRFA and Panel recommendations are presented in the 2023 PCE proposed rule (88 FR 39652, June 16, 2023) (FRL-8329-02-OCSPP).

As required by section 604 of the RFA, EPA prepared a FRFA for this action (Ref. 22). The FRFA addresses issues raised by public comments on the IRFA for the 2023 PCE proposed rule. The complete FRFA is available for review in the docket and is summarized here.

1. *Statement of need and rule objectives.*

Under section of TSCA 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 non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more

requirements 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 taking action to the extent necessary so that PCE no longer presents such risk.

EPA developed this final rule after considering EPA's unreasonable risk determination for PCE, information provided in public comments on the 2023 PCE proposed rule, findings from and comments on the SBAR panel, other required consultations, and additional public outreach. For more information on the 2023 PCE proposed rule, SBAR panel, and outreach efforts for this action, see the docket for this rulemaking (EPA-HQ-OPPT-2020-0720).

To address the identified unreasonable risk, this rule (1) prohibits most industrial and commercial uses and the manufacture (including import), processing and distribution in commerce, of PCE for those uses; (2) prohibits the manufacture (including import), processing, and distribution in commerce of PCE for all consumer use; (3) prohibits the manufacture (including import), processing, distribution in commerce, and use of PCE in dry cleaning and related spot cleaning through a 10-year phaseout; (4) requires a WCPP, including an inhalation exposure concentration limit, direct dermal contact controls, and related workplace exposure controls for many occupational conditions of use of PCE not prohibited; (5) require prescriptive workplace controls for laboratory use and energized electrical cleaner; (6) establish recordkeeping and downstream notification requirements; (7) provides certain time-limited exemptions from requirements for uses of PCE which are critical that have no technically feasible, safer alternative available; and (8) identifies a regulatory threshold for products containing PCE for the prohibitions and restrictions on PCE.

2. *Significant issues raised by the public comments in response to the IRFA and EPA response.*

A summary of significant issues raised by comments about the IRFA (Ref. 20) and EPA's response is in the Response to Comments document (Ref. 8) in section 11.3.

3. *SBA Office of Advocacy comments and EPA response.*

SBA Office of Advocacy provided comments on the 2023 PCE proposed rule (EPA-HQ-OPPT-2020-0720). A summary of these comments and EPA's response is in the Response to Comments document (Ref. 8) in sections 5.1.3, 5.3.2, 5.3.3, 5.8.2, 7.1, and 8.4.3.

4. *Estimate of the number of small entities to which the final rule applies.*

The final 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 rule would affect approximately 157,760 firms using PCE, of which 154,683 small entities (based on SBA definitions in March 2023) have estimated impacts. EPA estimates that most small entities that use PCE use it in aerosol spray degreasing and cleaning; 119,523 in energized electrical cleaning and 26,050 in other aerosol spray cleaning/degreasing (include brake cleaners). An estimated 5,949 of these entities are commercial users of PCE in dry cleaning applications. Users of products containing PCE, including adhesives and sealants, liquid cleaners/degreasers, mold cleaners, and other products also account for some of the affected small entities. EPA also estimates that 69 small entities use PCE in chemical milling, 87 use PCE in recycling and disposal, and 25 incorporate PCE into other formulations, mixtures, and reaction products. For a full description of the estimated number of small entities affected by this rule, see the FRFA (Ref. 22).

5. *Projected reporting, recordkeeping and other compliance requirements of the final rule.*

a. *Compliance requirements.*

EPA is prohibiting most conditions of use of PCE. As described in the final rule, EPA is prohibiting all manufacturing (including import), processing, and distribution in commerce of PCE for consumer use. After the publication of the final rule, prohibitions on manufacturing, processing, and distribution in commerce of PCE for consumer use will occur in 540 days for manufacturers, 630 days for processers, 720 days for distributing to retailers, and 810 days for all other distributors and retailers.

EPA is also prohibiting most industrial and commercial uses and the manufacture (including import), processing and distribution in commerce of PCE for those uses. The prohibitions for these commercial uses will become effective following prohibitions relevant to these uses in stages of the supply chain before the industrial and commercial use (e.g., manufacturing and processing). The restrictions follow a staggered schedule for each stage of the supply chain. After the publication of the final rule, prohibitions come into effect in 540 days for manufacturers, 630 days for processers, 720 days for distributing to retailers, 810 days for all other distributors and retailers, and 900 days for industrial and commercial use.

EPA is finalizing a prohibition compliance date for commercial use of PCE in any dry cleaning machine acquired 180 days or later after the publication of this final rule, followed by a prohibition on the use of PCE in 3rd generation machines 3 years after the publication of this final rule. Full implementation of the phaseout will 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 of this 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 of this final rule.

For most other conditions of use that contribute to the unreasonable risk from PCE, EPA

is finalizing a WCPP to address the unreasonable risk as outlined in Unit IV.B. The WCPP includes a combination of requirements to address unreasonable risk driven by inhalation and dermal exposures in the workplace. The PCE WCPP encompasses restrictions on certain occupational conditions of use and includes 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 WCPP that is necessary to address the unreasonable risk from PCE, EPA identified certain conditions of use where the Agency expects a WCPP can be successfully implemented.

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

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 requirements include the specific exposure limits that are 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 also finalizing a requirement for specific prescriptive controls for the industrial and commercial use of PCE in laboratory chemicals and specific prescriptive controls for energized electrical cleaner as outlined in Unit IV.C. For laboratory use, EPA is requiring 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 requiring the use of laboratory ventilation devices in workplaces engaged in the laboratory chemical condition of use. To support and demonstrate compliance, EPA is finalizing that each owner or operator of a laboratory workplace subject to the workplace controls for laboratory use requirements retain compliance records for five years. For energized electrical cleaner, EPA is requiring labeling, self-certification, and either the WCPP or prescriptive controls that include respiratory and dermal PPE in combination with comprehensive training for tasks.

EPA is not requiring reporting requirements beyond downstream notification or labeling (third-party notifications). Regarding recordkeeping requirements, three primary provisions of the final 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 final rule, facilities complying with the rule through the WCPP are required to develop and maintain records associated with ECEL exposure monitoring (including measurements, compliance with GLP Standards or use of a laboratory accredited by the AIHA or another industry-recognized program 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. The third is recordkeeping for business entities complying with the prescriptive controls for laboratory use or for energized electrical cleaning. To support and demonstrate compliance, EPA is finalizing that each owner or

operator of a workplace subject to the WCPP or specific prescriptive controls retain compliance records for five years.

b. *Classes of small entities subject to the compliance requirements.*

The small entities that would be potentially directly regulated by this rulemaking are small entities that manufacture (including import), process, distribute in commerce, use, or dispose of PCE, including retailers of PCE for end-consumer uses.

c. *Professional skills needed to comply.*

Entities subject to this rule that manufacture (including import), process, or distribute PCE in commerce for consumer use would be required to cease such activity. The entity would be required to modify their SDS 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 final rule. None of these activities require any special skills.

Entities that use PCE in any industrial and commercial capacity that is prohibited would be required to cease that activity. 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 are permitted to continue to manufacture, process, distribute, use (with the exception for use as a laboratory chemical or use in energized electrical cleaning), or dispose of PCE are 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 or in energized electrical cleaning are required to implement prescriptive workplace controls for those uses and would have to meet the provisions of the workplace restrictions for continued use of PCE. Adaption to a WCPP or prescriptive workplace controls may require persons with specialized skills such as an engineer, chemist, health and safety professional, or laboratory technicians to process monitoring samples. Instead of implementing the WCPP or workplace controls 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, 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 or laboratory technician. Additionally, potentially exposed persons reasonably likely to be exposed to PCE by inhalation to concentrations above the ECEL are required to be trained for the proper use of respirators. Potentially exposed persons reasonably likely to have direct dermal contact to PCE are required to be trained for proper use of dermal protection. While this does not necessarily entail a specialized skill, it does require specialized training for those handling PCE within regulated areas and includes activity-specific training for proper PPE use.

6. *Steps taken to minimize economic impact to small entities.*

a. *Small Business Advocacy Review Panel.*

As required by section 609(b) of the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), EPA conducted outreach to small entities and convened a SBAR Panel on October 27, 2022, to obtain advice and recommendations of representatives of the small entities that potentially would be subject to the rule's requirements. The Panel solicited input on all aspects of these proposed regulations. Ten potentially impacted small entities served as small-entity representatives (SERs) to the Panel, representing a broad range of small entities

from diverse geographic locations. The Panel Report was signed on February 1, 2023.

Consistent with the RFA/SBREFA requirements, the Panel evaluated the assembled materials and small-entity comments on issues related to elements of the regulatory flexibility analysis. It is important to note that the Panel's findings and discussion were based on the information available at the time the final report was prepared. For the full list of Panel recommendations, see section 7.A. of the FRFA (Ref. 22).

EPA detailed the SBAR Panel's request for comment on these specific topics in the IRFA and 2023 PCE proposed rule and solicited comment from the public. During the comment period, the public provided comment on some of these areas. Those comments and others received on the 2023 PCE proposed rule and EPA's responses are in the Response to Comments document in the docket (Ref. 8).

b. *Alternatives considered.*

To identify the regulatory approach that would address the unreasonable risk from PCE, 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 list 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. of the 2023 PCE proposed rule, and Unit II.D. of the final rule, 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. As part of this analysis, EPA considered a wide variety of control measures to address the unreasonable risk from PCE such as weight fractions, prescriptive

controls, and a certification and limited access program. EPA's consideration of these alternative control measures is described in detail in the IRFA for the 2023 PCE proposed rule, and throughout Unit V.A. of the 2023 PCE proposed rule.

Based on consideration of public comments received on the 2023 PCE proposed rule, EPA has made some changes from the 2023 PCE proposed rule to the final rule. These changes include the finalization of additional conditions of use under the WCPP or prescriptive controls rather than prohibition, prohibition of additional conditions of use rather than the WCPP, and changes to compliance timeframes for prohibition and the WCPP. Additional changes to the rule based on consideration of public comments are detailed Unit III. of the final rule and include modifications to provisions of the WCPP. For additional information and rationale towards alternative actions, see Unit III.D. of this final rule and section 7.B. of the FRFA (Ref. 22).

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

D. *Unfunded Mandates Reform Act (UMRA).*

This action does not contain an unfunded mandate of $100 million (adjusted annually for inflation) or more (in 1995 dollars) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action will 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. The costs involved in this action are estimated not to exceed $183 million in 2023$ ($100 million in 1995$ adjusted for inflation using the GDP implicit price deflator) or more in any one year.

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. EPA provides the following federalism summary impact statement. The Agency consulted with State and local officials early in the process of developing the proposed action to permit them to have meaningful and timely input into its development. 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. A summary of the meeting with these organizations, including the views that they expressed, is available in the docket (Ref. 13). 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. PCE is not manufactured, processed, or distributed in commerce by Tribes, and therefore, this rulemaking would not impose substantial direct compliance costs on Tribal governments.

Notwithstanding the lack of Tribal implications as specified by Executive Order 13175, EPA consulted with Tribal officials during the development of this action, consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, which EPA applies more

broadly than Executive Order 13175.

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 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 sought from Tribes (Ref. 14). EPA briefed Tribal officials on the Agency's risk management considerations and Tribal officials raised no related issues or concerns to EPA during or in follow-up to those meetings (Ref. 14). EPA received no written comments as part of this consultation.

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

Executive Order 13045 (62 FR 19885, April 23, 1997) directs federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) 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. EPA did not find that the adverse health impacts for children and for men and women of reproductive age was disproportionate in comparison to other populations. EPA's Policy on Children's Health applies to this action. Information on how the Policy was applied and on the action's health and risk assessments are contained in Units III.A.3. and B.2., VI.A. and B., and the 2020 Risk Evaluation for PCE (Ref. 1) and the Economic Analysis for the 2023 PCE proposed rule (Ref. 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), EPA will not 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. 71). EPA recognizes that there may be voluntary consensus standards that meet the criteria (Ref. 86).

J. *Executive Orders 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations and 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All.*

EPA believes that the human health or environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with environmental justice concerns in accordance with Executive Order 12898 (59 FR 7629, February 16, 1994) and Executive Order 14096 (88 FR 25251, April 26, 2023). As described more fully in the Economic Analysis for this rulemaking (Ref. 3), 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 communities with environmental justice concerns using information about the facilities, workforce, and communities potentially affected by the regulatory options under current conditions, before the regulation would go into effect. The analysis drew on publicly available data provided by EPA, U.S. Census Bureau, and Centers for Disease Control and Prevention, including data from TRI, EPA Enforcement and Compliance History Online, National Air Toxics Assessment, the American Community Survey, and the Behavioral Risk Factor Surveillance System. 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 effect on communities with environmental justice concerns. This regulatory action would apply requirements to the extent necessary so that PCE no longer presents an unreasonable risk, EPA is not able to quantify the distribution of the change in risk across affected populations due to data limitations that prevented EPA from conducting a more comprehensive analysis of such a change.

EPA additionally identified and addressed environmental justice concerns by conducting outreach to communities with environmental justice concerns. For example, on June 16 and July 6, 2021, EPA held public meetings as part of this consultation (Ref. 87). These meetings were held pursuant to and in compliance with Executive Order 12898 and Executive Order 14008, Tackling the Climate Crisis at Home and Abroad (86 FR 7619, February 1, 2021). EPA received five written comments following the EJ meetings, 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 and Executive Order 14096 is contained in Units I.E., II.D., III.A.1., VI.A., and in the Economic Analysis (Ref. 3). EPA's presentations, a summary of EPA's presentation and public comments made, 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.

K. *Congressional Review Act (CRA)*

This action is subject to the CRA, 5 U.S.C. 801 et seq., and EPA will submit a rule report

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

List of Subjects in 40 CFR part 751

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

Michael S. Regan,

Administrator.

Therefore, for the reasons stated in the preamble, EPA amends 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 "Designated representative," "Direct dermal contact," "ECEL," and "Exposure group" to read as follows:

§ 751.5 Definitions.

* * * * *

Designated representative means any individual or organization to whom a potentially exposed person gives written authorization to exercise a right of access. A recognized or certified collective bargaining agent must be treated automatically as a designated representative without regard to written authorization.

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 calculated as an eight (8)-hour time-weighted average (TWA).

Exposure group means a group of potentially exposed persons with a similar exposure profile to a chemical substance or mixture based on the substantial similarity of tasks performed, the manner in which the tasks are performed, and the materials and processes with which they work.

* * * * *

3. Amend part 751 by adding Subpart G to read as follows:

Subpart G—Perchloroethylene (PCE)

Sec.

§ 751.601 General.

(a) *Applicability.*

This Subpart establishes prohibitions and restrictions on the manufacture (including import), processing, distribution in commerce, use, and disposal of perchloroethylene (CASRN 127-18-4) (PCE), also known as tetrachloroethylene, to prevent unreasonable risk of injury to health in accordance with TSCA section 6(a).

(b) *Regulatory threshold.*

Unless otherwise specified in this Subpart, the prohibitions and restrictions of this Subpart do not apply to products containing PCE at thresholds less than 0.1 percent by weight.

(c) *Owner and operator requirements.*

Any requirement for an owner *or* operator, or an owner *and* operator, is a requirement for any individual that is either an owner or an operator.

§ 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 to this Subpart:

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.

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 §§ 751.613 and 751.615.

ECEL has the same meaning as in § 751.5 and, for PCE, is an airborne concentration of PCE of 0.14 part per million (ppm).

ECEL action level means a concentration of airborne PCE of 0.10 part per million (ppm) calculated as an eight (8)-hour time-weighted average (TWA).

Energized electrical cleaner means a product that meets both of the following criteria: (1) the product is labeled to clean and/or degrease electrical equipment, where cleaning and/or degreasing is accomplished when electrical current exists, or when there is a residual electrical potential from a component, such as a capacitor; and (2) the product label clearly displays the statements: "Energized Equipment use only. Not to be used for motorized vehicle maintenance, or their parts."

§ 751.605 Prohibitions of Manufacturing, Processing, Distribution in Commerce, and Use.

(a) *Applicability.*

(1) The provisions of this section apply as indicated in paragraph (b) to all manufacturing (including import), processing, and distribution in commerce of PCE for consumer use.

(2) The provisions of this section apply as indicated in paragraph (b) to:

(i) All manufacturing (including import), processing, and distribution in commerce of PCE for industrial and commercial use, other than for the industrial and commercial uses addressed under §§ 751.607(a), 751.609(a), and 751.611(a), or covered by paragraph (a)(3) of this section; and

(ii) All industrial and commercial use of PCE, other than the industrial and commercial uses addressed under §§ 751.607(a), 751.609(a), and 751.611(a), or covered by paragraph (a)(3) of this section.

(3) The provisions of this section apply as indicated in paragraph (b) to all manufacturing (including import), processing, distribution in commerce, and industrial and commercial use of PCE in dry cleaning and related spot cleaning, 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) This section does not apply to the distribution in commerce or use of clothing and articles that have been commercially dry cleaned with PCE.

(5) This section does not apply to manufacturing, processing, or distribution in commerce of PCE solely for export that meets the conditions described in TSCA section 12(a)(1)(A) and (B).

(b) *Prohibitions.*

(1) After **[INSERT DATE 540 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, all persons are prohibited from manufacturing (including importing) PCE for the uses listed in paragraphs (a)(1) and (a)(2)(ii) of this section.

(2) After **[INSERT DATE 630 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, all persons are prohibited from processing PCE, including any PCE-containing products, for the uses listed in paragraphs (a)(1) and (a)(2)(ii) of this section.

(3) After **[INSERT DATE 720 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, all persons are prohibited from distributing in commerce (including

making available) PCE, including any PCE-containing products, to retailers for any use other than commercial dry cleaning.

(4) After **[INSERT DATE 810 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, all retailers are prohibited from distributing in commerce (including making available) PCE, including any PCE-containing products.

(5) After **[INSERT DATE 810 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, all persons are prohibited from distributing in commerce (including making available) PCE, including any PCE-containing products, for the uses described in paragraphs (a)(1) and (a)(2)(ii) of this section.

(6) After **[INSERT DATE 900 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, all persons are prohibited from industrial or commercial use of PCE, including any PCE-containing products, for the uses listed in paragraph (a)(2)(ii) of this section.

(7) All persons are prohibited from industrial or commercial use of PCE in dry cleaning machines acquired after **[INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

(8) After **[INSERT DATE 3 YEARS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, all persons are prohibited from industrial or commercial use of PCE for the use listed in paragraph (a)(3)(i) of this section.

(9) After **[INSERT DATE 10 YEARS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, all persons are prohibited from the manufacturing (including importing), processing, distribution in commerce, or industrial or commercial use of PCE for dry cleaning and spot cleaning, including for the use listed in paragraph (a)(3)(ii) of this section.

(10) After **[INSERT DATE 10 YEARS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, all persons are prohibited from manufacturing (including import),

processing, distribution in commerce, or use of PCE, including any PCE containing products, for industrial or commercial use in an emergency by the National Aeronautics and Space Administration or its contractors as described in § 751.117(b).

§ 751.607 Workplace Chemical Protection Program (WCPP).

(a) *Applicability.*

The provisions of this section apply to the following conditions of use of PCE, including manufacturing and processing for export, 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;

(5) Repackaging;

(6) Industrial and commercial use as solvent for open-top batch vapor degreasing;

(7) Industrial and commercial use as solvent for closed-loop batch vapor degreasing

(8) Industrial and commercial use in maskant for chemical milling;

(9) Industrial and commercial use in solvent-based adhesives and sealants;

(10) Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing;

(11) Industrial and commercial use as a processing aid in sectors other than petrochemical manufacturing;

(12) Industrial and commercial use for cold cleaning of tanker vessels;

(13) Recycling; and

(14) 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 (12) of this section and not prohibited by § 751.605.

(2) *Eight-hour time-weighted average (TWA) ECEL*. Beginning **[INSERT DATE 1005 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government, **[INSERT DATE 450 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for non-Federal owners and operators, or beginning four months after introduction of PCE into the workplace if PCE use commences after **[INSERT DATE 360 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*],** the owner or operator must ensure that no person is exposed to an airborne concentration of PCE in excess of the ECEL, consistent 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, without regard to respiratory protection, 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 exposure group.

(B) Personal breathing zone air samples are representative of the 8-hour TWA of all potentially exposed persons in an exposure group if the samples are of at least one person's full-

shift exposure who represents the highest potential PCE exposures in that exposure group. Personal breathing zone air samples taken during one work shift may be used to represent potentially exposed person exposures on other work shifts where the owner or operator can document that the tasks performed and conditions in the workplace are similar across shifts.

(C) Exposure samples must be analyzed using an appropriate analytical method by a laboratory that complies with the Good Laboratory Practice (GLP) Standards in 40 CFR Part 792 or a laboratory accredited by the American Industrial Hygiene Association (AIHA) or another industry-recognized program.

(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 PCE.

(E). Owners and operators must re-monitor within 15 working days after receipt of any exposure monitoring when results indicate non-detect, 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*.

By **[INSERT DATE 915 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government, by **[INSERT DATE 360 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for non-Federal owners and operators, or within 30 days of introduction of PCE into the workplace, whichever is later, each owner or operator covered by this section must perform initial monitoring of potentially exposed persons. Where the owner or operator has monitoring results from monitoring conducted within five years prior to **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** 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 this paragraph.

(iii) *Periodic monitoring.*

The owner or operator must establish an exposure monitoring program for periodic monitoring of exposure to PCE in accordance with table 1.

Table 1 to § 751.607(b)(3)(iii) – Periodic Monitoring Requirements

Air Concentration Condition	**Periodic Monitoring Requirement**
If initial exposure monitoring is below ECEL action level (< 0.10 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 three 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 (≥ 0.10 ppm 8-hour TWA, ≤ 0.14 ppm 8-hour TWA).	Periodic exposure monitoring is required within six 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 (< 0.10 ppm 8-hour TWA).	Periodic exposure monitoring is required within five 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 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 is required when the owner or operator resumes the condition of use.

(iv) *Additional monitoring*.

(A) The owner or operator must conduct the exposure monitoring required by paragraph (b)(3)(ii) of this section within 30 days after 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.

Prior monitoring data cannot be used to meet this requirement.

(B) Whenever start-ups or shutdowns, or spills, leaks, ruptures or other breakdowns or unexpected releases occur that may lead to exposure to potentially exposed persons, the owner or operator must conduct the exposure monitoring required by paragraph (b)(3)(ii) of this section within 30 days after the conclusion of the start-up or shutdown and/or the cleanup of the spill or repair of the leak, rupture or other breakdown. Prior monitoring data cannot be used to meet this requirement.

(v) *Observation of monitoring*.

(A) Owners and operators must provide potentially exposed persons or their designated representatives an opportunity to observe any monitoring of occupational exposure to PCE that is conducted under this section and designed to characterize their exposure.

(B) When monitoring observation requires entry into a regulated area, the owner or operator must provide the observers with the required PPE.

(C) Only persons who are authorized to have access to facilities classified in the interest of national security must be permitted to observe exposure monitoring conducted in such facilities.

(vi) *Notification of monitoring results*.

(A) The owner or operator must inform each person whose exposures are monitored or who is part of a monitored exposure group and their designated representatives of any monitoring results within 15 working days of receipt of those monitoring results.

(B) This notification must include the following:

(*1*) Exposure monitoring results;

(*2*) Identification and explanation of the ECEL and ECEL action level;

(3) Statement of whether the monitored airborne concentration of PCE exceeds the ECEL action level or ECEL;

(*4*) If the ECEL is exceeded, descriptions of any exposure controls implemented by the owner or operator to reduce exposures to or below the ECEL, as required by paragraph (d)(1) of this section;

(*5*) Explanation of any respiratory protection provided in accordance with paragraphs (b)(4)(iv), (d)(1)(i), and (f) of this section;

(*6*) Quantity of PCE in use at the time of monitoring;

(*7*) Location of PCE use at the time of monitoring;

(*8*) Manner of PCE use at the time of monitoring; and

(*9*) Identified releases of PCE.

(C) Notice must be written in plain language and either provided to each potentially exposed person and their designated representatives individually in a language that the person understands, 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) *Establishment.*

By [**INSERT DATE 1005 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER***] for Federal agencies and Federal contractors acting for or on behalf of the Federal government and by **[INSERT DATE 450 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for non-Federal owners and operators, or within three months after receipt of any exposure monitoring that indicates exposures exceeding the ECEL, the owner or operator must establish and maintain a regulated area wherever airborne

concentrations of PCE exceed or can reasonably be expected to exceed, the ECEL.

(ii) *Access.*

The owner or operator must limit access to regulated areas to authorized persons.

(iii) *Demarcation.*

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 PCE within the regulated area.

(iv) *Provisions of respirators.*

(A) The owner or operator must ensure that each person who enters a regulated area is supplied with a respirator selected in accordance with paragraph (f) of this section and must ensure that all persons within the regulated area are using the provided respirators whenever PCE exposures may exceed the ECEL.

(B) An owner or operator who has implemented all feasible 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 PCE 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.

(v) *Prohibited activities.*

(A) The owner or operator must ensure that, within a regulated area, persons do not engage in non-work activities which may increase PCE exposure.

(B) 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 performance.

(c) *DDCC.*

Beginning **[INSERT DATE 1005 DAYS AFTER DATE OF PUBLICATION IN**

THE *FEDERAL REGISTER*] for Federal agencies and Federal contractors acting for or on behalf of the Federal government and beginning **[INSERT DATE 450 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for non-Federal owners and operators, owners or operators must ensure that all persons are separated, distanced, physically removed, or isolated from direct dermal contact with PCE consistent 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) By **[INSERT DATE 1095 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government, or by **[INSERT DATE 900 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for non-Federal owners and operators, 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, in accordance with the hierarchy of controls.

(B) If the feasible controls required under paragraph (d)(1)(i)(A) of this section that can be instituted do not reduce exposures for potentially exposed persons to or below the ECEL, then the owner or operator must use such controls to reduce exposure to the lowest levels achievable by these controls and must supplement those controls with the use of respiratory protection that complies with the requirements of paragraph (f) of this section.

(C) Where an owner or operator cannot demonstrate exposure to PCE has been reduced to or below the ECEL through the use of controls required under paragraphs (d)(1)(i)(A) and (B)

of this section, and has not demonstrated that it has appropriately supplemented with respiratory protection that complies with the requirements of paragraph (f) of this section, this will constitute a failure to comply with the ECEL.

(ii) *DDCC requirements.*

(A) By **[INSERT DATE 1095 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government, or by **[INSERT DATE 900 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for non-Federal owners and operators, 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 PCE except to the extent that the owner or operator can demonstrate that such controls are not feasible.

(B) If the feasible controls required under paragraph (d)(1)(ii)(A) of this section that can be instituted do not prevent direct dermal contact, then the owner or operator must use such controls to reduce direct dermal contact to the extent achievable by these controls and must supplement those controls with the use of dermal protection that complies with the requirements of paragraph (f) of this section.

(C) Where an owner or operator cannot demonstrate direct dermal contact to PCE is prevented through the use of controls required under paragraphs (d)(1)(ii)(A) and (B) of this section, and has not demonstrated that it has appropriately supplemented with dermal protection 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.

(2) *Exposure control plan*.

By **[INSERT DATE 1095 DAYS AFTER DATE OF PUBLICATION IN THE**

***FEDERAL REGISTER*]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government, or by **[INSERT DATE 900 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for non-Federal owners and operators, each owner and operator must establish and implement an exposure control plan.

(i) *Exposure control plan contents*.

The exposure control plan must include documentation of the following:

(A) Identification of exposure controls that were considered, including those that were used or not used to meet the requirements of paragraphs (d)(1)(i)(A) and (d)(1)(ii)(A) of this section, in the following sequence: elimination, substitution, engineering controls and administrative controls;

(B) For each exposure control considered, a rationale for why the exposure control was selected or not selected based on feasibility, effectiveness, and other relevant considerations;

(C) A description of actions the owner or operator must take to implement exposure controls selected, including proper installation, regular inspections, maintenance, training or other actions;

(D) A description of regulated areas, how they are demarcated, and persons authorized to enter the regulated areas;

(E) Description of activities conducted by the owner or operator to review and update the exposure control plan to ensure effectiveness of the exposure controls, identify any necessary updates to the exposure controls, and confirm that all persons are properly implementing the exposure controls; and

(F) An explanation of the procedures for responding to any change that may reasonably be expected to introduce additional sources of exposure to PCE, or otherwise result in increased exposure to PCE, including procedures for implementing corrective actions to mitigate exposure

to PCE.

(ii) *Exposure control plan requirements.*

(A) The owner or operator must not implement a schedule of personnel rotation as a means of compliance with the ECEL.

(B) The owner or operator must maintain the effectiveness of any controls instituted under this paragraph (d).

(C) The exposure control plan must be reviewed and updated as necessary, but at least every 5 years, to reflect any significant changes in the status of the owner or operator's approach to compliance with paragraphs (b) through (d) of this section.

(iii) *Availability of exposure control plan.*

(A) Owners or operators must make the exposure control plan and associated records, including ECEL exposure monitoring records, ECEL compliance records, DDCC compliance records, and workplace participation records described in § 751.615(b), available to potentially exposed persons and their designated representatives.

(B) Owners or operators must notify potentially exposed persons and their designated representatives of the availability of the exposure control plan and associated records within 30 days of the date that the exposure control plan is completed and at least annually thereafter.

(C) Notice of the availability of the exposure control plan and associated records must be provided in plain language writing to each potentially exposed person in a language that the person understands 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.

(D) Upon request by the potentially exposed person or their designated representative(s), the owner or operator must provide the specified records at a reasonable time, place, and manner.

If the owner or operator is unable to provide the requested records within 15 working days, the owner or operator must, within those 15 working days, inform the potentially exposed person or designated representative(s) requesting the record(s) of the reason for the delay and the earliest date when the record will be made available.

(e) *Workplace information and training.*

(1) By **[INSERT DATE 450 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*],** the owner or operator must institute a training program and ensure that persons potentially exposed to PCE participate in the program according to the requirements of this paragraph (e).

(2) The owner or operator must ensure that each potentially exposed person is trained prior to or at the time of a potential exposure to PCE.

(3) 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.

(4) The following information and training must be provided to all persons potentially exposed to PCE:

(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 PCE and the specific operations in the workplace that could result in exposure to PCE, particularly noting where each regulated area is located;

(iii) 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);

(iv) The acute and chronic health hazards of PCE as detailed on relevant Safety Data

Sheets; and

(v) The principles of safe use and handling of PCE and measures potentially exposed persons can take to protect themselves from PCE, including specific procedures the owner or operator has implemented to protect potentially exposed persons from exposure to PCE, such as appropriate work practices, emergency procedures, and personal protective equipment to be used.

(5) 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 PCE in the workplace.

(6) Whenever there are workplace changes, such as modifications of tasks or procedures or the institution of new tasks or procedures, that increase exposure, and where such exposure exceeds 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 and ensure that each potentially exposed person is re-trained.

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

(1) *Protection.*

The provisions of paragraph (f) apply to any owner or operator that is required to provide respiratory protection pursuant to paragraphs (b)(4)(iv) or (d)(1)(i)(B) of this section or § 751.611(b), or dermal protection pursuant to paragraphs (c) or (d)(1)(ii)(B) of this section, § 751.609(b)(2), or § 751.611(b).

(2) *Respiratory protection.*

(i) By **[INSERT DATE 1005 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government, by **[INSERT DATE 450 DAYS AFTER DATE OF PUBLICATION**

IN THE *FEDERAL REGISTER*] for non-Federal owners and operators, or within three months after receipt of any exposure monitoring that indicates exposures exceeding the ECEL, if an owner or operator is required to provide respiratory protection pursuant to paragraph (f)(1) of this section, the owner or operator must ensure that each potentially exposed person is provided with a respirator according to the requirements of this section.

(ii) For purposes of this paragraph (f)(2), cross-referenced provisions in 29 CFR 1910.134 applying to an "employee" apply equally to potentially exposed persons and cross-referenced provisions applying to an "employer" also apply equally to owners or operators. Other terms in cross-referenced provisions in 29 CFR 1910.134 that are defined in 29 CFR 1910.134(b) have the meaning assigned to them in that paragraph.

(iii) By **[INSERT DATE 1005 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government, or by [**INSERT DATE 450 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for non-Federal owners and operators, or within three months after receipt of any exposure monitoring that indicates exposures exceeding the ECEL, if an owner or operator is required to provide respiratory protection pursuant to paragraph (f)(1) of this section, the owner or operator must develop and administer a written respiratory protection program consistent with the requirements of 29 CFR 1910.134(c)(1), (c)(3) and (c)(4).

(iv) Owners and operators must select respiratory protection required by paragraph (f)(2)(i) of this section based on a medical evaluation consistent with the requirements of 29 CFR 1910.134(e). If a potentially exposed person cannot use a negative-pressure respirator that would otherwise be required by paragraph (f)(1) of this section, then the owner or operator must provide that person with an alternative respirator. The alternative respirator must have less

breathing resistance than the negative-pressure respirator and provide equivalent or greater protection. If the person is unable to use an alternative respirator, then the person must not be permitted to enter the regulated area.

(v) Owners and operators must select respiratory protection that properly fits each affected person and communicate respirator selections to each affected person consistent with the requirements of 29 CFR 1910.134(f),1910.134 App A.

(vi) Owners and operators must provide, ensure use of, and maintain (in a sanitary, reliable, and undamaged condition) respiratory protection that is of safe design and construction for the applicable condition of use consistent with the requirements of 29 CFR 1910.134(g) through (j),1910.134 App. B-1 to B-2.

(vii) Prior to or at the time of initial assignment to a job involving potential exposure to PCE, owners and operators must provide training to all persons required to use respiratory protection consistent with 29 CFR 1910.134(k), 1910.134 App. D.

(viii) Owners and operators must retrain all persons required to use PPE at least 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.

(ix) 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 1.4 ppm (10 times ECEL): Any National Institute for Occupational Safety and Health (NIOSH) Approved® air-purifying half mask respirator equipped with organic vapor cartridges or

canisters; or any NIOSH Approved® Supplied-Air Respirator (SAR) or Airline Respirator operated in demand mode equipped with a half mask; or any NIOSH Approved® Self-Contained Breathing Apparatus (SCBA) in a demand mode equipped with a half mask [APF 10].

(C) If the measured exposure concentration is above 1.4 ppm and less than or equal to 3.5 ppm (25 times ECEL): Any NIOSH Approved® Powered Air-Purifying Respirator (PAPR) equipped with a loose-fitting facepiece or hood/helmet equipped with organic vapor cartridges or canisters; or any NIOSH Approved® SAR or Airline Respirator in a continuous-flow mode equipped with a loose-fitting facepiece or helmet/hood [APF 25].

(D) If the measured exposure concentration is above 3.5 ppm and less than or equal to 7.0 ppm (50 times ECEL): Any NIOSH Approved® air-purifying full facepiece respirator equipped with organic vapor cartridges or canisters; any NIOSH Approved® PAPR with a half mask equipped with organic vapor cartridges or canisters; any NIOSH Approved® SAR or Airline Respirator in a continuous flow mode equipped with a half mask; any NIOSH Approved® SAR or Airline Respirator operated in a pressure-demand or other positive-pressure mode with a half mask; or any NIOSH Approved® SCBA in demand-mode equipped with a full facepiece or helmet / hood [APF 50].

(E) If the measured exposure concentration is above 7.0 ppm and less than or equal to 140 ppm (1,000 times ECEL): Any NIOSH Approved® PAPR equipped with a full facepiece equipped with organic vapor cartridges or canisters; any NIOSH Approved® SAR or Airline Respirator in a continuous-flow mode equipped with full facepiece; any NIOSH Approved® SAR or Airline Respirator in pressure-demand or other positive-pressure mode equipped with a full facepiece and an auxiliary self-contained air supply; or any NIOSH Approved® SAR or Airline Respirator in a continuous-flow mode equipped with a helmet or hood and that has been tested to demonstrated performance at a level of a protection of APF 1,000 or greater [APF

1000].

(F) If the measured exposure concentration is greater than 140 ppm (1,000+ times ECEL): Any NIOSH Approved® Self-Contained Breathing Apparatus (SCBA) in a pressure-demand or other positive-pressure mode equipped with a full facepiece or helmet/hood [APF 10,000].

(G) If the exposure concentration is unknown: Any NIOSH Approved® combination supplied air respirator equipped with a full facepiece and operated in pressure demand or other positive pressure mode with an auxiliary self-contained air supply; or any NIOSH Approved® SCBA operated in pressure demand or other positive pressure mode and equipped with a full facepiece or hood/helmet [APF 1000+].

(x) Owners and operators must select and provide respirators as required in paragraph (f)(2) of this section consistent with the requirements of 29 CFR 1910.134(d)(1)(iv), and with consideration of workplace and user factors that affect respirator performance and reliability.

(xi) Owners and operators who select air-purifying respirators must either:

(A) Select respirators that have an end-of-service-life indicator (ESLI) that is NIOSH Approved® for PCE; or

(B) Implement a change schedule for canisters and cartridges based on objective information or data that ensures that canisters and cartridges are changed before the end of their service life. The written respiratory protection program required by paragraph (f)(2)(iii) of this section must include a description of the information and data relied upon, the basis for reliance on the information and data, and the basis for the canister and cartridge change schedule.

(xii) Owners and operators must ensure that respirators are used in compliance with the terms of the respirator's NIOSH certification.

(xiii) Owners and operators must conduct regular evaluations of the workplace, including

consultations with potentially exposed persons using respiratory protection, consistent with the requirements of 29 CFR 1910.134(l), to ensure that the provisions of the written respiratory protection program required under paragraph (f)(2)(iii) of this section are being effectively implemented.

(xiv) The respiratory protection requirements in this paragraph (f)(2) represent the minimum respiratory protection requirements, such that any respirator affording a higher degree of protection than the required respirator may be used.

(3) *Dermal protection.*

(i) By **[INSERT DATE 1005 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for Federal agencies and Federal contractors acting for or on behalf of the Federal government, or by **[INSERT DATE 450 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** for non-Federal owners and operators, if an owner or operator is required to provide dermal protection pursuant to paragraph (f)(1) of this section, the owner or operators must ensure that each potentially exposed person is provided with dermal PPE according to the requirements of this section.

(ii) Owners or operators must supply and require the donning of dermal PPE that separates and provides a barrier to prevent direct dermal contact with PCE in the specific work area where it is selected for use, selected in accordance with this paragraph (f)(3) 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 PCE. For the purposes of this paragraph (f)(3)(ii), provisions in 29 CFR 1910.132(h) 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 dermal PPE in accordance with 29 CFR

1910.133(b) and additionally as specified in this paragraph (f)(3) to each person who is reasonably likely to be dermally exposed in the work area through direct dermal contact with PCE. For the purposes of this paragraph (f)(3)(iii), provisions in 29 CFR 1910.133(b) applying to an "employer" also apply equally to owners or operators. (iv) 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. Replacement PPE must be provided immediately 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. Dermal PPE must include, but is not limited to, the following items:

(A) Impervious gloves selected based on specifications from the manufacturer or supplier or by individually prepared third-party testing.

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

(v) Owners or operators must demonstrate that each item of gloves and other clothing selected provides an impervious barrier to prevent direct dermal contact with PCE during normal and expected duration and conditions of exposure within the work area by evaluating the specifications from the manufacturer or supplier or individually prepared third-party testing of the dermal PPE or of the material used in construction of the dermal PPE, to establish that the dermal PPE will be impervious to PCE alone and in likely combination with other chemical substances in the work area.

(vi) Dermal PPE 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.

(vii) Owners or operators must provide training in accordance with 29 CFR 1910.132(f) to all persons required to use dermal protection prior to or at the time of initial assignment to a job involving exposure to PCE. For the purposes of this paragraph (f)(3)(vii), 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.

(viii) Owners and operators must retrain each person required to use dermal protection at least 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 dermal protection, or when changes in the workplace or in dermal protection to be used render the previous training obsolete.

§ 751.609 Workplace Requirements for Laboratory Use

(a) *Applicability.*

The provisions of this section apply to the industrial and commercial use of PCE as a laboratory chemical.

(b) *Laboratory use requirements.*

(1) After **[INSERT DATE 360 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, owners or operators must ensure laboratory ventilation devices such as fume hoods or glove boxes 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 potentially exposed persons in the area when PCE is used in a laboratory setting.

(2) After **[INSERT DATE 360 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, owners or operators must ensure that all persons reasonably likely to be exposed from direct dermal contact to PCE in a laboratory setting are provided with dermal

personal protective equipment and training on proper use of PPE in a manner consistent with § 751.607(f)(3), except that the date listed in paragraph (f)(3)(i) does not apply.

§ 751.611 Workplace Requirements for Energized Electrical Cleaner

(a) *Applicability.*

The provisions of this section apply as indicated in paragraphs (b) through (d) of this section to:

(1) All manufacturing (including importing), processing, and distribution in commerce of PCE for industrial and commercial use as energized electrical cleaner, and

(2) Industrial and commercial use of PCE as energized electrical cleaner.

(b) *Energized electrical cleaner requirements.*

The provisions of this paragraph (b) apply to any workplace engaged in the condition of use listed in paragraph (a)(2).

(1) *PPE*.

(i) The provisions of this paragraph (b)(1) apply after **[INSERT DATE 450 DAYS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*]**.

(ii) Owners or operators must ensure that all potentially exposed persons using PCE, including any PCE containing products, are provided with dermal PPE and training on proper use of PPE in accordance with § 751.607(f)(3).

(iii) If any of the criteria in paragraphs (b)(1)(iii)(A) or (B) are met, then owners or operators must ensure that all persons using PCE, including any PCE containing products, are provided with respiratory PPE and training on proper use of PPE in accordance with § 751.607(f)(2), except that instead of selecting appropriate respirators based on monitoring results pursuant to paragraph (f)(2)(ix), owners or operators must select from and provide the following

types of respirators: any NIOSH Approved® air-purifying full facepiece respirator equipped with organic vapor cartridges or canisters; any NIOSH Approved® PAPR with a half mask equipped with organic vapor cartridges or canisters; any NIOSH Approved® SAR or Airline Respirator in a continuous flow mode equipped with a half mask; any NIOSH Approved® SAR or Airline Respirator operated in a pressure-demand or other positive-pressure mode with a half mask; any NIOSH Approved® SCBA in demand-mode equipped with a full facepiece or helmet / hood [APF 50]; or any respirator affording a higher degree of protection.

(A) The potentially exposed person is in a confined space, as defined in 29 CFR 1910.146(b), or in an enclosed space, as described in 29 CFR 1910.269(e); or

(B) The potentially exposed person approaches the exposed energized equipment closer than the employer's established minimum approach distance required under 29 CFR 1910.269(l)(3) or when there is no established minimum approach distance.

(2) *Alternative to PPE Requirements*.

(i) As an alternative to the requirements in paragraph (b)(1) of this section, the owner or operator may choose to follow the WCPP provisions in § 751.607.

(ii) Owners or operators who choose to follow the WCPP as an alternative to the requirements in paragraph (b)(1) of this section must:

(A) Document and maintain a statement that they are electing to comply with the WCPP.

(B) Comply with the WCPP provisions in § 751.607 and document compliance in accordance with § 751.615(b).

(c) *Label.*

After **[INSERT DATE 450 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, all manufacturers (including importers), processors and distributors in commerce of PCE or PCE-containing products for industrial and commercial use as energized

electrical cleaner must provide a label securely attached to each product. Label information must be prominently displayed and in an easily readable font size, with the sentences: "This product contains perchloroethylene (PCE) (CASRN 127-18-4), a chemical determined by the Environmental Protection Agency to present unreasonable risk of injury to health under the Toxic Substances Control Act (TSCA), based on neurotoxicity and other adverse health effects. The use of PCE is restricted under 40 CFR part 751, Subpart G. This product is for Energized Equipment use only. Not to be used for motorized vehicle maintenance, or their parts."

(d) *Self-certification.*

After **[INSERT DATE 450 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, the owner or operator of the business entity purchasing and using PCE, including any PCE containing products, for the industrial and commercial use as energized electrical cleaner must self-certify that use is in compliance with requirements of paragraph (b) of this section with the following written statement.

(1) The self-certification must include the following written statement:

> I certify each of the following statements under penalty of law. This document was prepared under my direction and supervision. This energized electrical cleaner will be used for energized equipment use only. This business entity has implemented and complies with the EPA requirements for the use of energized electrical cleaner that contains perchloroethylene under 40 CFR § 751.611 and only trained and qualified persons will handle the energized electrical cleaner. Based on my inquiry of the person or persons who manages this business entity and/or those persons directly responsible for implementing the EPA requirements for energized electrical cleaner that contains perchloroethylene, and to the best of my knowledge and belief, this business entity is in compliance with the EPA requirements for energized electrical cleaner. I am aware that there are significant penalties, including the possibility of civil penalties for failing to comply with these requirements and criminal fines and imprisonment, for knowingly failing to comply with these requirements. I understand that this certification shall serve as a certification that this business entity will properly implement and comply with the EPA requirements for energized electrical cleaner consistent with the applicable regulatory timelines.

(2) The self-certification must also include the following:

(i) Printed name and signature, job classification, title, email address, and phone number of the owner or operator who is self-certifying.

(ii) Date of self-certification.

(iii) Name and address of the business entity.

(iv) Indication of whether this is the business entity's first purchase of PCE, including PCE containing products, after publication of the final rule.

(3) Owners or operators or persons specifically authorized by the owner or operator to purchase energized electrical cleaner must provide a copy of the self-certification statement for each business entity to the distributor from whom PCE, including PCE containing products, is being purchased, for every purchase.

(4) Distributors of PCE, including PCE containing products, must review the self-certification statement to ensure it is appropriately completed to include the owner or operator's and the business entity's information required by this section.

(5) Distributors of PCE, including PCE containing products, must have a complete and valid self-certification statement in accordance with this section for each sale of PCE, including PCE containing products, for use in energized electrical cleaning.

§ 751.613 Downstream Notification.

(a) Beginning on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, each person who manufactures (including imports) PCE for any use must, prior to or concurrent with the shipment, notify companies to whom PCE is shipped, in writing, of the restrictions described in this Subpart in accordance with paragraph (c) of this section.

(b) Beginning on **[INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*],** each person who processes or distributes in commerce PCE or

any PCE-containing products for any use must, prior to or concurrent with the shipment, notify companies to whom PCE 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 PCE or with any PCE-containing product:

> After **[INSERT DATE 720 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** this chemical substance (as defined in TSCA section 3(2))/product cannot be distributed in commerce to retailers for any use. After **[INSERT DATE 810 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, this chemical substance (as defined in TSCA section 3(2))/product is and can only be distributed in commerce or processed with a concentration of PCE equal to or greater than 0.1% by weight for the following purposes: (1) Processing as a reactant/intermediate; (2) Processing into formulation, mixture or reaction product; (3) Processing by repackaging; (4) Recycling; (5) Industrial and commercial use as solvent in open-top batch vapor degreasing; (6) Industrial and commercial use as solvent in closed-loop batch vapor degreasing; (7) Industrial and commercial use in maskant for chemical milling; (8) Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing; (9) Industrial and commercial use as a processing aid in sectors other than petrochemical manufacturing; (10) Industrial and commercial use as solvent for cold cleaning of tanker vessels; (11) Industrial and commercial use as energized electrical cleaner; (12) Industrial and commercial use in laboratory chemicals; (13) Industrial and commercial use in solvent-based adhesives and sealants; (14) Industrial and commercial use in dry cleaning in 3rd generation machines until **[INSERT DATE 3 YEARS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**; (15) Industrial and commercial use in all dry cleaning and related spot cleaning until **[INSERT DATE 10 YEARS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**; (16) Export; and (17) Disposal.

§ 751.615 Recordkeeping Requirements.

(a) *General records.*

After **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, all persons who manufacture (including import), process, distribute in commerce, or engage in industrial or commercial use of PCE or PCE-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) *WCPP compliance.*

(1) *ECEL exposure monitoring*.

For each monitoring event, owners or operators subject to the ECEL described in § 751.607(b) must document and retain records of the following:

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

(ii) The quantity, location(s) and manner of PCE use at the time of each monitoring event;

(iii) All measurements that may be necessary to determine the conditions that may affect the monitoring results;

(iv) Name, workplace address, work shift, job classification, work area, and type of respiratory protection (if any) by each monitored person;

(v) Identification of all potentially exposed persons that a monitored person is intended to represent if using a representative sample, consistent with § 751.607(b)(3)(i)(A) and (B);

(vi) Sampling and analytical methods used as described in § 751.607(b)(3)(i)(D);

(vii) Compliance with the GLP Standards in 40 CFR part 792, or use of a laboratory accredited by the AIHA or another industry-recognized program, as required by § 751.607(b)(3)(i)(C); and

(viii) Information regarding air monitoring equipment, including: Type, maintenance, calibrations, performance tests, limits of detection, and any malfunctions;

(ix) Re-monitoring determinations conducted by an Environmental Professional as defined at 40 CFR 312.10 or a Certified Industrial Hygienist, if results indicated non-detect; and

(x) Notification of exposure monitoring results in accordance with § 751.607(b)(3)(v).

(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) Implementation of the exposure control plan as described in § 751.607(d)(2), including:

(A) Any regular inspections, evaluations, and updating of the exposure controls to maintain effectiveness;

(B) Confirmation that all persons are implementing the exposure controls; and

(C) Each occurrence and duration of any start-up, shutdown, or malfunction of the facility that causes an exceedance of the ECEL and any subsequent corrective actions taken by the owner or operator during the start-up, shutdown, or malfunctions to mitigate exposures to PCE.

(iii) Respiratory protection used by each potentially exposed person and PPE program implementation as described in § 751.607(f)(2) including:

(A) The name, workplace address, work shift, job classification, work area of each potentially exposed person, and the type of respiratory protection provided to each potentially exposed person;

(B) The basis for the specific respiratory protection selection in accordance with § 751.607(f)(2); and

(C) Fit testing and training in accordance with § 751.607(f)(2).

(iv) Information and training provided 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)(2);

(ii) Dermal protection used by each potentially exposed person and PPE program implementation as described in § 751.607(f)(3), 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 be 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 § 751.607(f)(3).

(iii) Information and training provided 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 PCE inhalation exposure or direct dermal contact and their designated representatives to readily access the exposure control plans, facility exposure

monitoring records, PPE program implementation records, or any other information relevant to PCE 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 § 751.615(b)(3)(ii);

(2) Documentation identifying: Criteria that the owner or operator will use to determine and implement control measures to reduce potentially exposed persons' exposure to PCE including laboratory ventilation devices;

(3) Documentation identifying: Implementation of properly functioning laboratory ventilation devices using manufacturer's instructions for installation, use, and maintenance of the devices including inspections, tests, development of maintenance procedures, the establishment of criteria for acceptable test results, and documentation of test and inspection results; and

(d) *Workplace requirements for energized electrical cleaner.*

(1) Owners and operators subject to the energized electrical cleaner requirements described in § 751.611 must retain records of:

(i) Statement regarding whether the owner or operator is complying with the prescriptive PPE requirements described in § 751.611(b)(1) or with the WCPP described in § 751.611(b)(2).

(ii) Dermal and respiratory protection used by each potentially exposed person and program implementation as described in § 751.611(b)(1) or WCPP records described in § 751.615(b).

(iii) Labels used as described in § 751.611(c).

(iv) Self-certification statements provided as described in § 751.611(d)(1)-(3).

(2) Distributors of PCE, including PCE containing products, for use in energized electrical cleaning must retain sale records, including:

(i) Name of purchaser;

(ii) Date of sale;

(iii) Quantity of PCE or PCE containing products sold;

(iv) Self-certification statement for each purchase of PCE; and

(v) Copies of labels required in § 751.611(c).

(e) *Records related to exemptions.*

To maintain eligibility for an exemption described in § 751.617, the records maintained by the owners or operators must demonstrate compliance with the specific conditions of the exemption.

(f) *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.

§ 751.617 Exemptions.

(a) *General applicability.*

(1) Time-limited exemptions described in this section are established in accordance with 15 U.S.C. 2605(g)(1).

(2) To be eligible for the exemptions established in this section, regulated parties must comply with all conditions promulgated in this section for such exemptions in accordance with 15 U.S.C. 2605(g)(4).

(b) *Time-limited exemption for emergency use by the National Aeronautics and Space Administration.*

Under 15 U.S.C. 2605(g)(1)(A), use of PCE or PCE containing products for the

conditions of use identified in paragraph (b)(1) of this section in an emergency by the National Aeronautics and Space Administration (NASA) and its contractors operating within the scope of their contracted work is exempt from the requirements of § 751.605 until **[INSERT DATE 10 YEARS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

(1) *Applicability*.

This exemption shall apply to the following specific conditions of use:

(i) Industrial and commercial use as solvent for cold cleaning; and

(ii) Industrial and commercial use in wipe cleaning.

(2) *Emergency use*.

(i) An emergency is a serious and sudden situation requiring immediate action, within 15 days or less, necessary to protect:

(A) Safety of NASA's or their contractors' personnel;

(B) NASA's missions;

(C) Human health, safety, or property, including that of adjacent communities; or

(D) The environment.

(ii) Each emergency is a separate situation; if use of PCE exceeds 15 days, then justification must be documented.

(3) *Eligibility*. To be eligible for the exemption, NASA and its contractors must:

(i) Select PCE because there are no technically and economically feasible safer alternatives available during the emergency.

(ii) Perform the emergency use of PCE at locations controlled by NASA or its contractors.

(iii) Comply with the following conditions:

(A) Within 15 working days of the emergency use by NASA or its contractors, NASA

and its contractors must provide notice to the EPA Assistant Administrators of both the Office of Enforcement and Compliance Assurance and the Office of Chemical Safety and Pollution Prevention that includes the following:

(*1*) Identification of the conditions of use detailed in paragraph (b)(1) that the emergency use fell under;

(*2*) An explanation for why the emergency use met the definition of emergency in paragraph (b)(2)(i) of this section; and

(*3*) An explanation of why PCE was selected, including why there were no technically and economically feasible safer alternatives available in the particular emergency.

(iv) The owner or operator must comply with and document such compliance efforts under the WCPP provisions in § 751.607, to the extent technically feasible in light of the particular emergency.

(v) The owner or operator of the location where the use takes place must comply with the recordkeeping requirements in § 751.615.