PRE-PUBLICATION NOTICE

On October 12, 2023, Michael S. Regan, the EPA Administrator, signed the following document:

Action:	Proposed Rule
Title:	Trichloroethylene; Regulation under the Toxic Substances Control Act (TSCA)
FRL #:	8317-01-OCSPP
Docket ID #:	EPA-HQ-OPPT-2020-0642

EPA is submitting this document for publication in the *Federal Register* (FR). EPA is providing this document solely for the convenience of interested parties. It is not the official version of the document for purposes of public notice and comment under the Administrative Procedure Act. This document is not disseminated for purposes of EPA's Information Quality Guidelines and does not represent an Agency determination or policy. While we have taken steps to ensure the accuracy of this Internet version of the document that was signed, the official version will publish in a forthcoming FR publication, which will appear on the Government Printing Office's govinfo website (https://www.govinfo.gov/app/collection/fr) and on Regulations.gov (https://www.regulations.gov) in the docket identified above.

Once the official version of this document is published in the *Federal Register*, this version will be removed from the Internet and replaced with a link to the official version. At that time, you will also be able to access the on-line docket for this *Federal Register* document at http://www.regulations.gov.

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-2020-0642; FRL-8317-01-OCSPP]

RIN 2070-AK83

Trichloroethylene (TCE); Regulation under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to address the unreasonable risk of injury to human health presented by trichloroethylene (TCE) under its conditions of use as documented in EPA's November 2020 Risk Evaluation for TCE and January 2023 revised risk determination for TCE pursuant to the Toxic Substances Control Act (TSCA). TCE is widely used as a solvent in a variety of industrial, commercial and consumer applications including for hydrofluorocarbon (HFC) production, vapor and aerosol degreasing, and in lubricants, greases, adhesives, and sealants. TSCA requires that when EPA determines a chemical substance presents unreasonable risk that EPA address by rule the unreasonable risk of injury to health or the environment and apply requirements to the extent necessary so the chemical no longer presents unreasonable risk. EPA determined that TCE presents an unreasonable risk of injury to health due to the significant adverse health effects associated with exposure to TCE, including non-cancer effects (liver toxicity, kidney toxicity, neurotoxicity, immunotoxicity, reproductive toxicity, and developmental toxicity) as well as cancer (liver, kidney, and non-Hodgkin lymphoma) from chronic inhalation and dermal exposures to TCE. TCE is a neurotoxicant and is carcinogenic to humans by all routes of exposure. The most sensitive adverse effects of TCE exposure are non-cancer effects (developmental toxicity and

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immunosuppression) for acute exposures and developmental toxicity and autoimmunity for chronic exposures. To address the identified unreasonable risk, EPA is proposing to: prohibit all manufacture (including import), processing, and distribution in commerce of TCE and industrial and commercial use of TCE for all uses, with longer compliance timeframes and workplace controls for certain processing and industrial and commercial uses (including proposed phaseouts and time-limited exemptions); prohibit the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works, with a time-limited exemption for cleanup projects; and establish recordkeeping and downstream notification requirements.

DATES: Comments must be received on or before **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0465, through the Federal eRulemaking Portal at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Gabriela Rossner, Existing Chemicals Risk Management Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC

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20460-0001; telephone number (202) 565-2426; email address: *TCE.TSCA@epa.gov*.

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

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

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

- Crude Petroleum Extraction (NAICS code 211120);
- Fossil Fuel Electric Power Generation (NAICS code 221112);
- Other Electric Power Generation (NAICS code 221118);
- Broadwoven Fabric Mills (NAICS code 313210);
- Narrow Fabric Mills and Schiffli Machine Embroidery (NAICS code 313220);
- Nonwoven Fabric Mills (NAICS code 313230);
- Textile and Fabric Finishing Mills (NAICS code 313310);
- Fabric Coating Mills (NAICS code 313320);
- Wood Window and Door Manufacturing (NAICS code 321911);
- Prefabricated Wood Building Manufacturing (NAICS code 321992);
- Paper Bag and Coated and Treated Paper Manufacturing (NAICS code 322220);
- Petroleum Refineries (NAICS code 324110);

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• All Other Petroleum and Coal Products Manufacturing (NAICS code 324199);

• Petrochemical Manufacturing (NAICS code 325110);

• Other Basic Inorganic Chemical Manufacturing (NAICS code 325180);

• Ethyl Alcohol Manufacturing (NAICS code 325193);

• All Other Basic Organic Chemical Manufacturing (NAICS code 325199);

• Plastics Material and Resin Manufacturing (NAICS code 325211);

• Medicinal and Botanical Manufacturing (NAICS code 325411);

• Pharmaceutical Preparation Manufacturing (NAICS code 325412);

• Paint and Coating Manufacturing (NAICS code 325510);

• Adhesive Manufacturing (NAICS code 325520);

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

• Photographic Film, Paper, Plate and Chemical Manufacturing (NAICS code 325992);

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

• Polystyrene Foam Product Manufacturing (NAICS code 326140);

• Urethane and Other Foam Product (except Polystyrene) Manufacturing (NAICS code 326150);

• Tire Manufacturing (except Retreading) (NAICS code 326211);

• Tire Retreading (NAICS code 326212);

• 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);

• Gypsum Product Manufacturing (NAICS code 327420);

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• Iron and Steel Mills and Ferroalloy Manufacturing (NAICS code 331110);

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

• Rolled Steel Shape Manufacturing (NAICS code 331221);

• Steel Wire Drawing (NAICS code 331222);

• Nonferrous Metal (except Aluminum) Smelting and Refining (NAICS code 331410);

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

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

• Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum) (NAICS code 331492);

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

• Iron and Steel Forging (NAICS code 332111);

• Nonferrous Forging (NAICS code 332112);

• Custom Roll Forming (NAICS code 332114);

• Powder Metallurgy Part Manufacturing (NAICS code 332117);

• 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);

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

• Sheet Metal Work Manufacturing (NAICS code 332322);

• Ornamental and Architectural Metal Work Manufacturing (NAICS code 332323);

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

• Metal Tank (Heavy Gauge) Manufacturing (NAICS code 332420);

• Metal Can Manufacturing (NAICS code 332431);

• Other Metal Container Manufacturing (NAICS code 332439);

• Hardware Manufacturing (NAICS code 332510);

• Spring Manufacturing (NAICS code 332613);

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

• Machine Shops (NAICS code 332710);

• Precision Turned Product Manufacturing (NAICS code 332721);

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

• Metal Heat Treating (NAICS code 332811);

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

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

• 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);

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

• Farm Machinery and Equipment Manufacturing (NAICS code 333111);

• Lawn and Garden Tractor and Home Lawn and Garden Equipment Manufacturing (NAICS code 333112);

• Construction Machinery Manufacturing (NAICS code 333120);

• Mining Machinery and Equipment Manufacturing (NAICS code 333131);

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

• Food Product Machinery Manufacturing (NAICS code 333241);

• Semiconductor Machinery Manufacturing (NAICS code 333242);

• Sawmill, Woodworking, and Paper Machinery Manufacturing (NAICS code 333243);

• Printing Machinery and Equipment Manufacturing (NAICS code 333244);

• Other Industrial Machinery Manufacturing (NAICS code 333249);

• Optical Instrument and Lens Manufacturing (NAICS code 333314);

• Photographic and Photocopying Equipment Manufacturing (NAICS code 333316);

• Other Commercial and Service Industry Machinery Manufacturing (NAICS code 333318);

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

• Heating Equipment (except Warm Air Furnaces) Manufacturing (NAICS code 333414);

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

• Industrial Mold Manufacturing (NAICS code 333511);

• Special Die and Tool, Die Set, Jig and Fixture Manufacturing (NAICS code 333514);

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

• Machine Tool Manufacturing (NAICS code 333517);

• Rolling Mill and Other Metalworking Machinery Manufacturing (NAICS code 333519);

• Turbine and Turbine Generator Set Unit Manufacturing (NAICS code 333611);

• Speed Changer, Industrial High-Speed Drive and Gear Manufacturing (NAICS code 333612);

• Mechanical Power Transmission Equipment Manufacturing (NAICS code 333613);

• Other Engine Equipment Manufacturing (NAICS code 333618);

• Air and Gas Compressor Manufacturing (NAICS code 333912);

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

• Elevator and Moving Stairway Manufacturing (NAICS code 333921);

• Conveyor and Conveying Equipment Manufacturing (NAICS code 333922);

• Overhead Traveling Crane, Hoist and Monorail System Manufacturing (NAICS code 333923);

• Industrial Truck, Tractor, Trailer and Stacker Machinery Manufacturing (NAICS code 333924);

• Power-Driven Hand Tool Manufacturing (NAICS code 333991);

• 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);

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• Scale and Balance Manufacturing (NAICS code 333997);

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

• Audio and Video Equipment Manufacturing (NAICS code 334310);

• Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing (NAICS code 334416);

• Electronic Connector Manufacturing (NAICS code 334417);

• Printed Circuit Assembly (Electronic Assembly) Manufacturing (NAICS code 334418);

• Other Electronic Component Manufacturing (NAICS code 334419);

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

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

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

• Instrument Manufacturing for Measuring and Testing Electricity and Electrical Signals (NAICS code 334515);

• Electric Lamp Bulb and Part Manufacturing (NAICS code 335110);

• Residential Electric Lighting Fixture Manufacturing (NAICS code 335121);

• Commercial, Industrial and Institutional Electric Lighting Fixture Manufacturing (NAICS code 335122);

• Other Lighting Equipment Manufacturing (NAICS code 335129);

• Major Household Appliance Manufacturing (NAICS code 335220);

• Power, Distribution and Specialty Transformer Manufacturing (NAICS code 335311);

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• Motor and Generator Manufacturing (NAICS code 335312);

• Switchgear and Switchboard Apparatus Manufacturing (NAICS code 335313);

• Relay and Industrial Control Manufacturing (NAICS code 335314);

• Storage Battery Manufacturing (NAICS code 335911);

• Fiber Optic Cable Manufacturing (NAICS code 335921);

• Current-Carrying Wiring Device Manufacturing (NAICS code 335931);

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

• Automobile Manufacturing (NAICS code 336111);

• Light Truck and Utility Vehicle Manufacturing (NAICS code 336112);

• Heavy Duty Truck Manufacturing (NAICS code 336120);

• Motor Vehicle Body Manufacturing (NAICS code 336211);

• Truck Trailer Manufacturing (NAICS code 336212);

• Motor Home Manufacturing (NAICS code 336213);

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

• Motor Vehicle Gasoline Engine and Engine Parts Manufacturing (NAICS code 336310);

• Motor Vehicle Electrical and Electronic Equipment Manufacturing (NAICS code 336320);

• Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing (NAICS code 336330);

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

• Motor Vehicle Transmission and Power Train Parts Manufacturing (NAICS code 336350);

• Motor Vehicle Seating and Interior Trim Manufacturing (NAICS code 336360);

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• Motor Vehicle Metal Stamping (NAICS code 336370);

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

• Aircraft Manufacturing (NAICS code 336411);

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

• Other Aircraft Part 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);

• Railroad Rolling Stock Manufacturing (NAICS code 336510);

• Ship Building and Repairing (NAICS code 336611);

• Boat Building (NAICS code 336612);

• Motorcycle, Bicycle and Parts Manufacturing (NAICS code 336991);

• Military Armored Vehicle, Tank and Tank Component Manufacturing (NAICS code 336992);

• All Other Transportation Equipment Manufacturing (NAICS code 336999);

• Wood Kitchen Cabinet and Counter Top Manufacturing (NAICS code 337110);

• Upholstered Household Furniture Manufacturing (NAICS code 337121);

• Nonupholstered Wood Household Furniture Manufacturing (NAICS code 337122);

• Metal Household Furniture Manufacturing (NAICS code 337124);

• Institutional Furniture Manufacturing (NAICS code 337127);

• Wood Office Furniture Manufacturing (NAICS code 337211);

• Surgical Appliance and Supplies Manufacturing (NAICS code 339113);

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

• Jewelry and Silverware Manufacturing (NAICS code 339910);

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

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

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

• All Other Miscellaneous Manufacturing (NAICS code 339999);

• Metal Service Centers and Other Metal Merchant Wholesalers (NAICS code 423510);

• Industrial Supplies Merchant Wholesalers (NAICS code 423510);

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

• Paint, Varnish, and Supplies Merchant Wholesalers (NAICS code 424950);

• New Car Dealers (NAICS code 441110);

• Used Car Dealers (NAICS code 441120);

• Sporting Goods Stores (NAICS code 451110);

• Scheduled Passenger Air Transportation (NAICS code 481111);

• Other Support Activities for Air Transportation (NAICS code 481111);

• Other Warehousing and Storage (NAICS code 493190);

• Motion Picture and Video Production (NAICS code 512110);

• Other Financial Vehicles (NAICS code 525990);

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

• Research and Development in the Social Sciences and Humanities (NAICS code 541720);

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

• Carpet and Upholstery Cleaning Services (NAICS code 561740);

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

• Solid Waste Landfill (NAICS code 562212);

• Materials Recovery Facilities (NAICS code 562920);

• Junior Colleges (NAICS code 611210);

• Colleges, Universities and Professional Schools (NAICS code 611310);

• 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);

• Coin-Operated Laundries and Drycleaners (NAICS code 812310);

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

• Industrial Launderers (NAICS code 812332).

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

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

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

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines through a TSCA section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must by rule apply one or more requirements listed in 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 TCE 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 TCE by EPA, under the conditions of use (Refs. 1, 2). The term "conditions of use" is defined at TSCA section 3(4) (15 U.S.C. 2602(4)) to mean the circumstances under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. A detailed description of the conditions of use that EPA evaluated in reaching its determination that TCE presents an unreasonable risk is included in Unit III.B.1. EPA notes that all TSCA conditions of use of TCE are subject to this proposal. Accordingly, to address the unreasonable risk, EPA is proposing, under TSCA section 6(a), to:

(i) Prohibit the manufacture (including import), processing, and distribution in commerce of TCE for all uses (including all consumer uses (see Unit III.B.1.f)), as described in Unit V.A.1., with longer compliance timeframes for manufacture and processing related to certain uses;

(ii) Prohibit the industrial and commercial use of TCE, as described in Unit V.A.1., with longer compliance timeframes for certain uses;

(iii) Prohibit the manufacture (including import) and processing of TCE as an intermediate for the manufacturing of hydrofluorocarbon134a (HFC-134a), following an 8.5-year phaseout, as described in Unit V.A.1.d.;

(iv) Prohibit the industrial and commercial use of TCE as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production by Federal agencies and their contractors, following a 10-year phaseout, outlined in Unit V.A.1.e.;

(iv) For Department of Defense (DoD) naval vessels and their systems, and in the maintenance, fabrication, and sustainment for and of such vessels and systems, prohibit the industrial and commercial use of TCE as potting compounds for naval electronic systems and

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equipment; sealing compounds for high and ultra-high vacuum systems; bonding compounds for materials testing and maintenance of underwater systems and bonding of nonmetallic materials; and cleaning requirements (which includes degreasing using wipes, sprays, solvents and vapor degreasing) for: materials and components required for military ordinance testing; temporary resin repairs in vessel spaces where welding is not authorized; ensuring polyurethane adhesion for electronic systems and equipment repair and installation of elastomeric materials; various naval combat systems, radars, sensors, equipment; fabrication and prototyping processes to remove coolant and other residue from machine parts; machined part fabrications for naval systems; installation of topside rubber tile material aboard vessels; and vapor degreasing required for substrate surface preparation prior to electroplating processes, following a 10-year TSCA section 6(g) exemption, outlined in Unit V.A.3.;

(v) Prohibit the manufacture (including import), processing, distribution in commerce, and use of TCE as a processing aid for battery separator manufacturing, following a 10-year TSCA section 6(g) exemption, as described in Unit V.A.3.;

(vi) Prohibit the manufacture (including import), processing, distribution in commerce, and use of TCE as a laboratory chemical for essential laboratory activities and some research and development activities, following a 50-year TSCA section 6(g) exemption, as described in Unit V. A.3.;

(vii) Prohibit the manufacture (including import), processing, distribution in commerce, and industrial and commercial use of TCE as a solvent in closed loop vapor degreasing necessary for human-rated rocket engine cleaning by the National Aeronautics and Space Administration (NASA) and its contractors, following a 7-year TSCA section 6(g) exemption, as described in Unit V.A.3.;

(viii) Prohibit the emergency industrial and commercial use of TCE in furtherance of the

NASA mission for specific conditions that are critical or essential and for which no technically and economically feasible safer alternative is available, following a 10-year TSCA section 6(g) exemption, as described in Unit V.A.3.;

(ix) Require strict workplace controls, including compliance with a TCE workplace chemical protection program (WCPP), which would include requirements for an inhalation exposure limit and dermal protection to limit exposure to TCE, for conditions of use with long term phaseouts or time-limited exemptions under TSCA section 6(g), as described in Unit V.A.2.;

(x) Prohibit, due to worker risks, the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works, with a 50-year TSCA section 6(g) exemption for cleanup projects, as described in Unit V.A.3.; and

(xi) Establish recordkeeping and downstream notification requirements, as described in Unit V.A.4.

In addition, EPA is proposing to amend the general provisions of 40 CFR part 751, Subpart A, to define the following terms 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: "authorized person," "ECEL," "exposure group," "owner or operator," "potentially exposed person," "regulated area," and "retailer."

EPA seeks public comment on all aspects of this proposed rule.

D. Why is the Agency taking this action?

Under TSCA section 6(a), "[i]f the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule… apply

one or more of the [section 6(a)] requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk." TCE was the subject of a risk evaluation under TSCA section 6(b)(4)(A) that was issued in November 2020 (Ref. 1). In addition, EPA issued a revised unreasonable risk determination in January 2023 (Ref. 2), determining that TCE, as a whole chemical substance, presents an unreasonable risk of injury to health under the conditions of use. As a result, EPA is proposing to take action to the extent necessary so that TCE no longer presents such risk. The unreasonable risk is described in Unit III.B.2. and the conditions of use EPA evaluated in reaching its conclusion that TCE presents unreasonable risk are described in Unit III.B.1.

TCE's hazards are well established. EPA's 2020 Risk Evaluation for TCE considered the hazards associated with exposure to TCE and determined that TCE presents an unreasonable risk of injury to health due to the significant adverse health effects associated with exposure to TCE. While some of the risks of adverse effects from TCE exposure are experienced following acute single exposures, other risks are incurred following long-term repeated exposures. Risk of non-cancer effects, specifically fetal cardiac defects and autoimmunity following chronic exposure, are the most sensitive adverse effects. In addition, risks of other significant adverse outcomes associated with TCE exposure include: Non-cancer effects (liver toxicity, kidney toxicity, neurotoxicity, immunosuppression, reproductive toxicity, and developmental toxicity), as well as cancer effects (liver, kidney, and non-Hodgkin lymphoma). EPA is proposing requirements so that TCE would no longer present unreasonable risk to human health.

While EPA's proposal would ultimately result in a complete ban on TCE, the Agency recognizes that a phaseout of TCE for some TSCA conditions of use may be appropriate. The timeframes for the phaseouts differ across conditions of use and are described in fuller detail in Unit V.A.1.d. and e. One phaseout is for uses that may impact the Agency's efforts to address

climate-damaging HFCs (and the associated adverse impacts on human health and the environment) under the American Innovation and Manufacturing Act of 2020 (AIM Act) (42 U.S.C. 7675). EPA proposes to implement a longer phaseout in tandem with strict workplace controls for the manufacturing (including import) and processing of TCE as an intermediate in the generation of HFC-134a, one of the regulated substances subject to a phasedown under the AIM Act (More information on HFC-134a is in Unit V.A.1.). While HFC-134a is one of the regulated substances subject to AIM Act 85% phasedown in generation and consumption by 2023, HFC-134a can be mixed with other substances to make lower global warming potential (GWP) blends that are likely to be used to facilitate the transition from certain other HFCs and HFC blends with higher global warming potentials in certain applications.

Additionally, the Agency recognizes that some conditions of use may not have alternatives readily available. As an example, EPA is proposing a longer phaseout timeframe for industrial and commercial use as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production by Federal agencies and their contractors, in addition to the uses of TCE necessary for DoD vessels. Currently, substitutes and alternative processes do not meet the technical specifications required to clean the rayon fabric in order to safely produce rockets.

Additionally, EPA recognizes that some conditions of use may be important for national security applications or for other critical needs. For these reasons, EPA's proposal includes a 10-year exemption under TSCA section 6(g) for industrial and commercial use of TCE as a processing aid for battery separator manufacturing in the production of lead-acid and lithium battery separators, as well as for the manufacturing, processing, and distribution in commerce of TCE for this use (See Unit V.A.3.a.i.). EPA recognizes that lead-acid and lithium battery separators are essential components of batteries that power vehicles and systems in the U.S.

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supply chain for multiple critical infrastructure sectors within the national economy. Further, there are a number of critical uses required for DoD vessels. EPA is proposing a 10-year exemption under TSCA section 6(g) for DoD vessel requirements for potting, bonding and sealing compounds, and bonding and cleaning requirements for naval combat systems, radars, sensors, equipment, and fabrication and prototyping processes. Additionally, EPA is proposing a 50-year exemption under TSCA section 6(g) for the industrial and commercial use of TCE in laboratory use for essential laboratory activities which are particularly critical; for example, laboratory activities associated with ongoing environmental cleanup projects that fall under the Superfund program or other similar EPA authorities, in which it is necessary to use TCE as a laboratory chemical for the analysis of contaminated soil, air, and water samples (See Unit V.A.3.a.iii.).

EPA considered the potential impact of the prohibition of the total production volume of TCE regulated under TSCA on the availability of TCE for critical or essential uses, for uses essential to the national economy, national security, or critical infrastructure, and for uses for which longer phase-out timeframes are proposed. EPA concluded, based on information received through stakeholder engagement and professional judgment, that there would remain a sufficient supply of TCE in circulation for these uses. EPA requests comment on whether there would remain a sufficient supply of TCE in circulation to provide a source for those limited critical or essential uses exempted under TSCA section 6(g), as described in Unit V. (Ref. 3).

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 VII.D. and XI.D., EPA was unable to quantify all incremental costs of this proposed rule. The quantifiable cost of the proposed rule is

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estimated to be $33.1 million annualized over 20 years at a 3% discount rate and $40.6 million annualized over 20 years at a 7% discount rate. These costs take compliance with implementation of a WCPP into consideration, which would include an existing chemical exposure limit (ECEL) of 0.0011 ppm (1.1 ppb; 0.0059 mg/m^3) for inhalation exposures as an 8-hour time-weighted average (TWA), applicable personal protective equipment (PPE) requirements, and reformulation costs of numerous products. There are a number of notable unquantified costs. These are described in this Unit and more fully in section 7.11 of the Economic Analysis (Ref. 3).

Alternative products with similar cost and efficacy are available for most of the products that are formulated with TCE. However, for some applications, there may be additional unquantified costs associated with the alternatives or in cases where alternatives are not currently available. For instance, in some cases, some effort might be required by firms using TCE products to identify suitable alternatives, test them for their desired applications, learn how to use them safely and effectively, and implement new processes for using the alternative products. There may also be some safety-critical applications where alternatives would need to undergo extensive safety reviews and testing before they could replace the TCE products. The information to estimate how often these costs might be incurred or what the specific costs would be per-user or per-firm when they are incurred is not available. Therefore, EPA is unable to consider these costs quantitatively.

There also may be some unquantified costs associated with the implementation of a WCPP. EPA estimated a distribution for air monitoring results but since these data were not collected in the same way monitoring data under a WCPP would be collected, these estimated distributions are uncertain and therefore, the costs of the WCPP are uncertain. The WCPP costs also assume that when the exposure levels exceed the ECEL, compliance is achieved by

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implementing a respirator PPE program. However, the options require that feasible engineering and administrative controls are implemented before resorting to PPE use. These costs would be specific to individual firms, and EPA does not have sufficient information to estimate these costs.

The costs of alternative identification, testing, and potential process changes to battery separator manufacturers could not be estimated. And, if battery separator manufacturers are unable to transition to TCE-free production processes within the 10-year timeframe, there could be battery separator supply chain disruptions. According to one battery separator manufacturer submitting an exemption request to EPA, 80% of lead-acid and lithium-ion batteries are built using battery separators manufactured with TCE. According to the Battery Council International, the U.S. lead-acid battery industry provides $13.7 billion in gross domestic product. Both battery separator manufacturers submitting exemption requests noted that there was only one domestic battery separator manufacturer that does not use TCE for each of lead-acid and lithium batteries, and they asserted that the manufacturers would not have sufficient capacity to meet domestic battery separator demand on their own and could likely support less than half of the U.S. battery production need. In addition, they also noted that the domestic battery separator manufacturer that does not use TCE for lithium batteries uses a “dry process” instead of a “wet process”, and the “dry process” does not allow for reliable manufacture of the 9-12 μm separators that are generally used for electric vehicle applications. However, the magnitude of economic impacts from a potential supply chain disruption is uncertain, particularly since EPA could take subsequent regulatory action to extend, modify, or eliminate the exemption on the basis of reasonably available information and adequate public justification.

EPA expects the processing of TCE as an intermediate for the manufacture of HFC-134a to decline over time, in light of the AIM Act requirements (Ref. 4). At some point, the domestic

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manufacture of HFC-134a may be discontinued. While the timing for this discontinuation is uncertain, it is unclear whether the proposed rule would hasten the closure of plants that use TCE to produce HFC-134a. There would be some unknown cost impacts associated with hastening the closure of these two plants.

Costs to both fluoroelastomer producers using TCE and those using TCE as an intermediate to manufacture hydrochloric acid (HCl) may include potential supply chain disruptions, which could not be estimated. It is expected that these facilities would need to adopt process and/or physical plant changes in order to comply with the proposed rule. EPA does not have sufficient information to estimate the costs of the prohibition to these sectors.

Additionally, EPA is proposing a 10-year phaseout for the industrial and commercial use of TCE as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production by Federal agencies and their contractors, conditioned on Federal agencies performing within 5 years a final pre-launch test of rocket booster nozzles that have been produced without using TCE. EPA does not have information to estimate the cost of such a test. The disposal of TCE from cleanup projects to industrial pre-treatment, industrial treatment, or publicly owned treatment work would be prohibited after the section 6(g) exemption ends, 50 years after the rule is finalized. Cleanup sites would need to identify and implement alternative disposal or treatment methods, and would likely also need to renegotiate RCRA permits or CERCLA agreements to include those changes. These approaches could be more costly to implement and/or increase the duration of cleanups allowing any potential environmental or human health impacts to continue for a longer period of time. The information to estimate how often these costs might be incurred or what the specific costs would be per site when they are incurred is not available. Furthermore, the number of sites affected by this prohibition is unknown.

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Finally, EPA could not estimate any potential business closures or off-shoring of businesses that might result from the proposed rule. Vapor degreasing is one use of TCE where switching to a suitable alternative may be challenging and where closing or off-shoring may be a compliance strategy. EPA estimates that 366 facilities still use TCE in vapor degreasers, a majority of which are small businesses. There is no standard generally accepted approach for estimating the cost impacts of a firm closure. Despite information EPA has sought from stakeholders, including through a Small Business Advocacy Review (SBAR) Panel, it is still unclear as to the entire impact of a prohibition of TCE vapor degreasing.

The actions proposed in this rulemaking are expected to achieve health benefits for the American public, some of which can be monetized and others that, while tangible and significant, cannot at present be monetized. The monetized benefits of this rulemaking are approximately $18.1 to $21.5 million annualized over 20 years at a 3% discount rate and $8.2 to $10.3 million annualized over 20 years at a 7% discount rate. The monetized benefits only include liver, kidney, and non-Hodgkin's lymphoma cancers.

There are a number of non-cancer endpoints associated with exposure to TCE, including liver toxicity, kidney toxicity, reproductive effects, neurotoxicity, immunotoxicity effects and fetal cardiac defects (Ref. 1). There is human evidence for hepatitis accompanying immune-related generalized skin diseases, jaundice, hepatomegaly, hepatosplenomegaly, and liver failure in TCE-exposed workers and changes in the proximal tubules of the kidney following exposure to TCE, and occupational studies have shown increased levels of kidney damage (proximal tubules) and end-stage renal disease in TCE-exposed workers. Evidence exists to associate TCE with reproductive effects. Most human studies support an association between TCE exposure and alterations in sperm density and quality, as well as changes in sexual drive or function and serum endocrine levels. Fewer epidemiological studies exist linking decreased incidence of

fecundability (time-to-pregnancy) and menstrual cycle disturbances in women with TCE exposures. Human studies have consistently reported vestibular system-related symptoms such as headaches, dizziness, and nausea following TCE exposure. Several newer epidemiological studies have found an association between TCE exposure and neurodegenerative disorders such as amyotrophic lateral sclerosis and Parkinson's disease (Ref. 1). EPA does not have sufficient information to estimate the monetized benefits of the proposed rule with respect to these non-cancer effects, and therefore monetized benefits are likely underestimated.

EPA does estimate that there are 52,595 workers and occupational non-users (ONUs, or people who do not directly handle the chemical, but are in close proximity) exposed to TCE and of those, approximately 982 pregnant workers and ONUs annually that may potentially benefit from a reduced risk of fetal cardiac defects resulting from reduced TCE exposure. Although EPA has not developed a complete estimate of the monetized benefits associated with avoiding fetal cardiac defects, as described in the Economic Analysis (Ref. 3), Arth, Tinker et al. (Ref. 5) estimated a mean annual cost of $41,166 (2013$) (median $14,552) for each fetal cardiac defects-associated hospitalization. For critical fetal cardiac defects, mean and median costs were estimated at $79,011 and $29,886 (2013$), respectively for each incidence. In addition to hospitalization costs, individuals with fetal cardiac defects will likely incur healthcare costs associated with physician visits and outpatient care. They are also more likely to require specialized healthcare such as medications, physical or speech therapy, or treatment for developmental or behavioral problems (Ref. 6). Additional social costs may include caregiver burden and mental health services (Ref. 7), as well as non-market costs such as pain and suffering and fetal cardiac defect-related mortality. Because these costs are not accounted for, monetized benefits are likely underestimated. The severity of specific types of fetal cardiac defects and associated costs will vary depending on the type of heart defect. EPA requests

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comment on information that would allow EPA to quantify the magnitude of avoided risk of fetal cardiac defects due to reductions in TCE exposure under the proposed rulemaking.

Additionally, to the extent that the proposed rule reduces the amount of TCE in drinking water systems and thereby exposures to populations using those drinking water sources, there could be potential health-related benefits related to improved drinking water quality that EPA was unable to quantify.

II. Background

A. Overview of TCE.

This proposed rule applies to TCE (CASRN 79-01-6) and is intended to address the unreasonable risk of injury to health that EPA has identified for TCE. TCE is a volatile organic compound (VOC) used in industry as well as in commercial and consumer products. The total aggregate annual production volume ranged from 100 to 250 million pounds between 2016 and 2019 according to CDR (Ref. 8). The majority of TCE is processed as an intermediate during the manufacture of refrigerants, specifically HFC-134a, which accounts for about 83.6% of TCE's annual production volume (Ref. 1). TCE is also used as a solvent, frequently in cleaning and degreasing (including spot cleaning, vapor degreasing, cold cleaning, and aerosol degreasing), which accounts for another 14.7% of TCE production volume, leaving approximately 1.7% for other uses. As outlined in Unit III.B.1., TCE is used as a solvent in a variety of commercial and consumer applications including lubricants, adhesives and sealants, paints and coatings, and other miscellaneous products.

B. Regulatory actions pertaining to TCE.

TCE 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 TCE, as well as other Federal, State, and international regulations (Ref. 9) is in the

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docket and in Appendix A of the 2020 Risk Evaluation for TCE (Ref. 1).

C. Consideration of Occupational Safety and Health Administration (OSHA) occupational health standards in TSCA risk evaluations and TSCA risk management actions.

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

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

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

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Thus, the standards for chemical hazards that OSHA promulgates under the OSH Act share a broadly similar purpose with the standards that EPA promulgates under TSCA section 6(a). The control measures OSHA and EPA require to satisfy the objectives of their respective statutes may also, in many circumstances, overlap or coincide. However, as this unit outlines, there are important differences between EPA's and OSHA's regulatory approaches and jurisdiction, and EPA considers these differences when deciding whether and how to account for OSHA requirements (Ref. 9) when evaluating and addressing potential unreasonable risk to workers so that compliance requirements are clearly explained to the regulated community.

1. OSHA requirements.

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

a. General Duty Clause of the OSH Act.

The General Duty Clause of the OSH Act requires employers to keep their workplaces free from recognized hazards that are causing or are likely to cause death or serious physical harm to employees. The General Duty Clause is cast in general terms, and does not establish specific requirements like exposure limits, PPE, or other specific protective measures that EPA could potentially consider when developing its risk evaluations or risk management requirements. OSHA, under limited circumstances, has cited the General Duty Clause for regulating exposure to chemicals. To prove a violation of the General Duty Clause, OSHA must prove employer or industry recognition of the hazard, the hazard was causing or likely to cause death or serious physical harm, and a feasible method to eliminate or materially reduce the hazard was available. In rare situations, OSHA has cited employers for violation of the General

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Duty Clause where exposures were below a chemical-specific permissible exposure limit (PEL), a TWA based on an employee's average airborne exposure in any 8-hour work shift of a 40-hour work week which shall not be exceeded (Ref. 10). In such situations, OSHA must demonstrate that the employer had actual knowledge that the PEL was inadequate to protect its employees from death or serious physical harm. Because of the heavy evidentiary burden on OSHA to establish violations of the General Duty Clause, it is not frequently used to cite employers for employee exposure to chemical hazards.

b. OSHA standards.

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

OSHA sets legally enforceable limits on the airborne concentrations of hazardous chemicals, referred to as PELs, established for employers to protect their workers against the health effects of exposure to hazardous substances (29 CFR part 1910, subpart Z, part 1915, subpart Z, and part 1926, subparts D and Z). Under section 6(a) of the OSH Act, OSHA was permitted an initial 2-year window after the passage of the Act to adopt "any national consensus standard and any established Federal standard." 29 U.S.C. 655(a). OSHA used this authority in 1971 to establish PELs that were adopted from Federal health standards originally set by the Department of Labor through the Walsh-Healy Act, in which approximately 400 occupational exposure limits (OELs) were selected based on the American Conference of Governmental Industrial Hygienists (ACGIH) 1968 list of Threshold Limit Values (TLVs). In addition, about

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25 exposure limits recommended by the American Standards Association (now called the American National Standards Institute or ANSI) were adopted as PELs.

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

Many OSHA PELs have not been updated since they were established in 1971, including the PEL for TCE. In many instances, scientific evidence has accumulated suggesting that the current limits of many PELs are not sufficiently protective. On October 10, 2014, OSHA published a *Federal Register* document in which it recognized that many of its PELs are outdated and inadequate for ensuring protection of worker health (79 FR 61384). In addition, health standards issued under section 6(b)(5) of the OSH Act must reduce significant risk only to the extent that it is technologically and economically feasible. OSHA's legal requirement to demonstrate that its section 6(b)(5) standards are technologically and economically feasible at the time they are promulgated often precludes OSHA from imposing exposure control requirements sufficient to ensure that the chemical substance no longer presents a significant risk to workers. As described in that document, while new advancements or developments in science and technology from the time a PEL is promulgated may improve the scientific basis for making findings of significant risk, technical feasibility or economic feasibility, OSHA has been unable to update most of the PELs established in 1971 and they remain at levels at which they were

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initially adopted (79 FR 61384, October 10, 2014). One example of how industries have evolved in the intervening 50 years as to what is technologically and economically feasible is the halogenated solvent cleaning industry, which, in response to EPA's National Emission Standards for Hazardous Air Pollutants (NESHAP) promulgated under section 112 of the 1990 Clean Air Act Amendments (see National Emissions Standards for Halogenated Solvent Cleaning, 40 CFR part 63, subpart T), has made equipment improvements that conserve solvent resources and reduce workplace exposure.

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

Because the requirements and application of TSCA and OSHA regulatory analyses differ, and because OSHA's chemical-specific standards are decades old and may include outdated assumptions regarding the most sensitive end-point and/or the technological and economic feasibility of the standards, it is necessary for EPA to conduct risk evaluations and, where it finds unreasonable risk to workers, develop risk management requirements for chemical substances that OSHA also regulates, and it is expected that EPA's findings and requirements may

sometimes diverge from OSHA's. However, it is also appropriate that EPA consider the chemical standards that OSHA has already developed to limit the compliance burden to employers by aligning management approaches required by the agencies, where alignment will adequately address unreasonable risk to workers. Unit II.C.2. discusses EPA's consideration of OSHA standards in its risk evaluation and management strategies under TSCA.

2. Consideration of OSHA standards in TSCA risk evaluations.

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

In addition, EPA believes it may be appropriate to also evaluate the levels of risk present in scenarios considering applicable OSHA requirements as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. EPA may evaluate risk under scenarios that consider industry or sector best practices for industrial hygiene that are clearly articulated to the Agency, when doing so serves to inform its

risk management efforts. Characterizing risks using scenarios that reflect different levels of mitigation can help inform potential risk management actions by providing information that could be used during risk management to tailor risk mitigation appropriately to address any unreasonable risk identified (see Unit II.C.2.b. and Unit II.C.3.).

a. Risk characterization for unreasonable risk determination.

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

Therefore, EPA makes its determinations of unreasonable risk based on scenarios that do not assume compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE. Making unreasonable risk determinations based on such scenarios should not be viewed as an indication that EPA believes

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there are no occupational safety protections in place at any location, or that there is widespread noncompliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by an OSHA State Plan, or because their employer is out of compliance with OSHA standards, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

b. Risk evaluation to inform risk management requirements.

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

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

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

Informed by the mitigation scenarios and information gathered during the risk evaluation

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

For evaluation scenarios which involve OSHA chemical-specific PELs, EPA's risk evaluation in some cases may illustrate that limiting exposure to OSHA's PEL would result in acceptable levels of risk under TSCA under certain conditions of use. In these cases, TSCA risk management requirements could incorporate and reinforce requirements in OSHA standards and ensure that risks are addressed, including for circumstances where OSHA requirements are not applicable (e.g., public sector workers not covered by an OSHA State plan, and self-employed workers) by asserting TSCA compliance/enforcement as well. EPA's risk evaluation may also find unreasonable risk under TSCA associated with some occupational conditions of use (see Unit III.B.1.f.), even when the applicable OSHA requirements are being met. In these cases, EPA would need to develop risk management requirements beyond those included in OSHA's standards.

4. TCE and OSHA requirements.

EPA incorporated the considerations described in Unit II.C. into the 2020 Risk Evaluation for TCE, the January 2023 revised unreasonable risk determination for TCE, and this rulemaking. Specifically, in the TSCA 2020 Risk Evaluation for TCE, EPA presented risk estimates based on workers' exposures with and without respiratory protection. EPA determined that even when respirators are used by workers, most of the conditions of use evaluated drove the unreasonable risk. Additional consideration of OSHA standards in the revised unreasonable risk

determination is discussed further in the *Federal Register* document announcing that document (Ref. 11). In Unit III.B.3. and Unit V.A.2.b.iii., EPA outlines the importance of considering the hierarchy of controls used by the industrial hygiene community (hereafter referred to as "hierarchy of controls") when developing risk management actions in general, and specifically when determining if and how regulated entities may meet a risk-based exposure limit for TCE. The hierarchy of controls is a prioritization of exposure control strategies from most preferred to least preferred techniques. The control strategies include elimination of the hazard, substitution with a less hazardous substance, engineering controls, administrative controls such as training or exclusion zones with warning signs, and, finally, use of PPE (Ref. 12). Under the hierarchy of controls, the use of respirators and dermal PPE should only be considered after all other steps have been taken to reduce exposures. As discussed in Units V.A. and VI.A.1., EPA's risk management approach would not rely solely or primarily on the use of respirators and dermal PPE to address unreasonable risk to workers; instead, EPA is proposing prohibitions for all conditions of use, with a WCPP for certain occupational conditions of use before the prohibitions are fully implemented. The WCPP would require consideration of the hierarchy of controls before use of respirators and other PPE. The WCPP is discussed in full in Units V.A.2. and VI.A.1.b.

In accordance with the approach described in Unit II.C.3., EPA intends for this regulation to be as compatible as possible with the existing OSHA standards, with additional requirements as necessary to address the unreasonable risk. One notable difference between the WCPP and the OSHA standards are the exposure limits. The WCPP would include an ECEL of either 0.0011 ppm (1.1 ppb) or 0.0040 ppm (4.0 ppb) as an 8-hour TWA; exposures at or below each ECEL would not result in unreasonable risk for chronic cancer and non-cancer and acute non-cancer inhalation endpoints (See Unit IV.A. for further discussion about an ECEL of 0.0011 ppm and

Unit IV.B. for further discussion about an ECEL of 0.0040 ppm. Refer to Unit VI.A. for discussion about why EPA is considering two TCE ECELs and EPA's related request for public comment). EPA recognizes that for TCE, either ECEL would be significantly lower than the OSHA PEL (100 ppm as an 8-hour TWA). In addition to the distinctions in statutory requirements described in this unit, EPA has identified several factors contributing to the differences in these levels, outlined here.

The TSCA ECEL value for TCE is a lower value than the OSHA PEL (and other existing OELs, discussed in Unit II.C.5.) for many reasons, including that the PEL, established in 1971, may not fully capture either the complete database of studies considered in the 2020 Risk Evaluation for TCE or more recent advances in modeling and scientific interpretation of toxicological data applied in the calculation of the TCE ECEL. The proposed numeric ECEL values considered for incorporation into the WCPP are derived from the analysis in the 2020 Risk Evaluation for TCE, which EPA considers to represent the best available science under TSCA section 26(h) because it was subject to peer review and is the result of a systematic review process that considered reasonably available information in order to identify relevant adverse health effects. Additionally, by using the information from the 2020 Risk Evaluation for TCE, the ECEL incorporates advanced modeling and peer-reviewed methodologies, and accounts for exposures to potentially exposed and susceptible subpopulations, as required by TSCA.

For TCE, the EPA ECEL is an 8-hour occupational inhalation exposure limit, and it takes into consideration the uncertainties identified in the 2020 Risk Evaluation for TCE. For TCE, EPA derived two distinct ECEL values.

The ECEL of 0.0011 ppm is based on the most sensitive overall human health endpoint of developmental toxicity, specifically, fetal cardiac defects based on rat data from Johnson et al., 2003 (Refs. 1, 13). It represents the concentration at which an individual, including a member

of a PESS, especially older pregnant workers and ONUs (the group identified as most susceptible to cardiac defects in their developing fetus based on epidemiological data), would be unlikely to suffer adverse effects if exposed for a single 8-hr workday. This value is also protective of health effects that could present following chronic or lifetime exposures under typical occupational exposure scenarios. The ECEL of 0.0011 ppm incorporates a benchmark margin of exposure of 10 to account for inter- and intra-species toxicodynamic variability. In addition to the ECEL, as part of this rulemaking, EPA is proposing an ECEL action level, which is a value equal to half of the ECEL, that would trigger additional monitoring to ensure that workers are not exposed to concentrations above the ECEL. Exposure monitoring and establishing a baseline of TCE exposure for potentially exposed persons, as well as identifying the lowest achievable exposure level in a facility, is further discussed in Unit V.A.2.

The ECEL of 0.0040 ppm is based on chronic autoimmunity, representing the most protective exposure limit from the best overall acute and chronic non-cancer endpoints under TSCA of immunosuppression and autoimmunity, respectively (Refs. 14, 46, 1). The ECEL of 0.0040 ppm is based on elevated anti-double stranded DNA (anti-dsDNA) and single-stranded DNA (ssDNA) antibodies following chronic exposure based on mouse data from Keil et al, 2009 (Ref. 1). The ECEL based on autoimmunity was derived from the PBPK model-adjusted assumptions of 8-hour daily exposure and elevated respiratory rate for workers, and it incorporates a benchmark MOE of 30 to account for inter- and intra-species toxicodynamic variability as well as the absence of a no-effect level in the study (Ref. 1).

The OSHA PEL for TCE of 100 ppm as an 8-hour TWA was established in 1971. OSHA is required to promulgate a standard that reduces significant risk to the extent that it is technologically and economically feasible to do so (81 FR 16285) at the time of promulgation. As part of a 1989 air contaminants standard for 428 toxic substances, OSHA lowered the PEL to

50 ppm based on a quantitative cancer risk assessment and technological feasibility analysis (See 54 FR 2332, 2432(1989)). This rulemaking was later vacated by court order, which held that OSHA failed to establish that: (1) the existing PELs presented a significant risk of material health impairment; (2) the new standards eliminated or substantially lessened the risk; and (3) the new PELs were economically or technologically feasible (Ref. 15). As a result, the PEL for TCE reverted to the original PEL of 100 ppm. The basis of the 100 ppm PEL is unclear; however, most original PELs were based on acute health effects only observable at higher concentrations and did not take into account more sensitive repeated dose studies, including the studies used to inform the TCE ECEL, that were not available at the time the PEL was established (see, e.g., 79 FR 61383, 61388). As discussed in Units II.D., III.B., and VIII.D., the TSCA ECELs for the TCE WCPP are based on the 2020 Risk Evaluation for TCE and represent the best available science. As described in Unit II.C.1., in a 2014 request for information OSHA described how, while new developments in science and technology from the time the PEL for TCE was established in 1971 may improve the scientific basis for making findings of significant risk, technical feasibility, or economic feasibility that is required under section 6(b)(5) of the OSH Act, OSHA has been unable to update the PEL for TCE and it remains at the level that was originally adopted in 1971 (79 FR 61383, October 10, 2014).

5. TCE and other occupational exposure limits.

EPA is aware of other OELs for TCE, including the ACGIH TLV, the California Division of Occupational Safety and Health (Cal/OSHA) PEL, and the National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL).

The 8-hour TWA TLV currently recommended by the ACGIH is 10 ppm, based on a most recent update in 2007. This TLV is based on central nervous system (CNS) effects occurring at 100 ppm and above (Ref. 16). Kidney toxicity, cancer, and developmental toxicity

were also indicated at high doses. Overall, the 10 ppm TLV does not seem to be directly derived from any particular endpoint and can be considered only a semi-quantitative estimate. The TLV report did not cite either the immune study used as the basis of EPA's alternative ECEL of 0.0040 ppm (Keil et al., 2009), nor did it cite Johnson et al., 2003, which is the basis of EPA's proposed ECEL of 0.0011 ppm. Notably, the most recent TLV report was released prior to publication of Keil et al., 2009, and the TLV was not directly derived from any particular endpoint or hazard value. Among other cited studies that are discussed in the 2020 Risk Evaluation, the TLV report only discusses LOAELs and did not apply benchmark dose modeling, PBPK modeling, or any uncertainty factors that would have contributed to a reduced exposure limit. The report does identify TCE as a suspected human carcinogen and discusses epidemiological evidence for several cancers, but there is no consideration of low-dose linear extrapolation that would have resulted in a substantially lower TLV.

The current NIOSH REL is based on the "lowest feasible level" standard applied to carcinogens, labeled as "Ca (potential occupational carcinogen), minimize exposure concentrations" (Ref. 17), as well as a 2 ppm 60-minute ceiling REL value when used as an anesthetic agent and a 25 ppm 10-hour TWA REL for other exposures. As described in NIOSH's Appendix A, the non-quantitative value applied to carcinogens is based on the lowest feasible concentration (Ref. 18). The 25 ppm TWA was based on concerns for CNS effects at higher doses and a review of industrial hygiene reports supporting the feasibility of a 25-ppm limit. Notably, this ceiling limit is from 1990, over a decade before publication of any of the key studies EPA used for risk determination or ECEL derivation.

The 2007 Cal/OSHA PEL is 25 ppm, lower than the OSHA PEL and equivalent to the NIOSH REL TWA (Ref. 19). According to Cal/OSHA, the origin of the Cal/OSHA PEL is not clear but is assumed to be based on the NIOSH REL threshold value, which cited CNS effects

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and liver cancer in animals (Ref. 20).

D. Summary of EPA's risk evaluation activities on TCE.

In December 2016, EPA selected TCE as one of the first 10 chemicals for risk evaluation under TSCA section 6 (15 U.S.C. 2605) (81 FR 91927, December 19, 2016) (FRL-9956-47). EPA published the scope of the TCE risk evaluation (82 FR 31592, July 7, 2017) (FRL-9963-57), and, after receiving public comments, published the problem formulation in June 2018 (83 FR 26998, June 11, 2018) (FRL-9978-40). In February 2020, EPA published a draft risk evaluation (85 FR 11079, February 26, 2020) (FRL-10005-52), and after public comment and peer review by the Science Advisory Committee on Chemicals (SACC), EPA issued the 2020 Risk Evaluation for TCE in November 2020 in accordance with TSCA section 6(b) (85 FR 75010, November 24, 2020) (FRL-10016-91). EPA subsequently issued a draft revised TSCA unreasonable risk determination for TCE (87 FR 40520, July 7, 2022) (FRL-9945-01-OCSPP) and after public notice and receipt of comments, published a final revised Unreasonable Risk Determination for TCE in January 2023 (88 FR 1222, January 9, 2023) (FRL-9945-02-OCSPP). The 2020 Risk Evaluation for TCE and supplemental materials are in docket EPA-HQ-OPPT-2019-0500, with the January 2023 final revised unreasonable risk determination and additional materials supporting the risk evaluation process in docket EPA-HQ-OPPT-2016-0737, on *https://www.regulations.gov*.

1. 2020 Risk Evaluation.

In the 2020 Risk Evaluation for TCE, EPA evaluated risks associated with 54 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.

The 2020 Risk Evaluation for TCE identified significant adverse health effects associated

with short- and long-term exposure to TCE, including non-cancer effects (immunosuppression and developmental toxicity) from acute inhalation exposures and dermal exposures, and non-cancer effects (liver toxicity, kidney toxicity, neurotoxicity, autoimmunity, reproductive toxicity, and developmental toxicity) and cancer (liver, kidney, and non-Hodgkin lymphoma) from chronic inhalation exposures to TCE. A further discussion of the hazards of TCE is in Unit III.B.2.

In the 2020 Risk Evaluation for TCE, EPA documented its unreasonable risk policy determination for TCE and based it on the immunotoxicity endpoint rather than the most sensitive endpoint (developmental toxicity). The 2020 Risk Evaluation for TCE included a robust scientific description of the developmental toxicity endpoint, specifically fetal cardiac defects, and the analysis in the risk evaluation supporting the developmental toxicity endpoint noted that this endpoint presents lower PODs (Ref. 1). EPA identified the risk of fetal cardiac defects most strongly associated with offspring of older mothers, and therefore included risk estimates for fetal cardiac defects that account for susceptible mothers and their offspring in addition to PESS groups with other susceptibilities (*e.g.,* diabetes, infection status, drug exposure, stress, and metabolic sensitivity due to increased enzymatic activity of cytochrome P450 2E1 (CYP2E1)) (Ref. 1). EPA recognizes that there are differing views about the appropriateness of EPA's policy decision in 2020 to use the immunotoxicity endpoint as the basis for EPA's unreasonable risk determination. EPA also notes that the endpoint selected as the basis for the TSCA section 6 unreasonable risk determination in the risk evaluation that is the basis for this proposed rule should not necessarily be construed as appropriate for or consistent with the basis for other Agency assessments such as the Integrated Risk Information System (IRIS) assessment for TCE or for actions taken by other agency programs. Further, EPA has received numerous comments on EPA's 2020 TSCA Risk Evaluation policy choice regarding

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endpoint selection that have raised concerns pertaining to political interference and scientific integrity, among other issues. In recognition of this history, EPA is therefore requesting comment on the use of the more sensitive developmental toxicity endpoint to inform TCE risk management decisions. In particular, EPA notes that this proposed rule for regulating the unreasonable risk of TCE demonstrates that both the immunotoxicity and developmental toxicity endpoints support the proposed prohibitions, discussed in detail in Unit IV.

2. Revised unreasonable risk determination.

EPA has been revisiting specific aspects of its first ten TSCA existing chemical risk evaluations, including the 2020 Risk Evaluation for TCE, to ensure that the risk evaluations upon which risk management decisions are made better align with TSCA's objective of protecting human health and the environment. For TCE, EPA revised the original unreasonable risk determination based on the 2020 Risk Evaluation for TCE and issued a final revised unreasonable risk determination in January 2023 (Ref. 2). EPA revised the risk determination for the 2020 Risk Evaluation for TCE pursuant to TSCA section 6(b) and Executive Order 13990, (entitled "Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis") and other Administration priorities (Refs. 21, 22, 23). The revisions consisted of making the risk determination for the whole chemical substance rather than for individual conditions of use (which resulted in the revised risk determination superseding the prior "no unreasonable risk" determinations and withdrawing the associated TSCA section 6(i)(1) "no unreasonable risk" order); and clarifying that the risk determination does not reflect an assumption that all workers are always provided and appropriately wear PPE. (Ref. 2).

In determining whether TCE presents unreasonable risk under the conditions of use, EPA considered relevant risk-related factors, including, but not limited to: the effects of the chemical substance on health (including cancer and non-cancer risks) and human exposure to the

substance under the conditions of use (including duration, magnitude, and frequency of exposure); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any PESS); the severity of hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties.

EPA determined that TCE presents an unreasonable risk of injury to health. The unreasonable risk determination, based on immunotoxicity and cancer, is driven by risks to workers and ONUs (workers who do not directly handle the chemical but perform work in an area where the chemical is present) due to occupational exposures to TCE (i.e., during manufacture, processing, industrial and commercial uses, and disposal); and to consumers and bystanders associated with consumer uses of TCE due to exposures from consumer use of TCE and TCE-containing products. Though the revised unreasonable risk determination was based on cancer and the best overall non-cancer endpoints for use in risk evaluation under TSCA (immunosuppression effects for acute inhalation and dermal exposures, and autoimmunity effects for chronic inhalation and dermal exposures), consistent with the 2020 Risk Evaluation for TCE, the Agency is proposing to base the risk management requirements for the WCPP on a more sensitive endpoint to account for particular health effects identified in the underlying 2020 Risk Evaluation for TCE relevant to PESS, as discussed in Unit IV.A. and V.A.2.

EPA did not identify unreasonable risk of injury to the environment for TCE. The TCE conditions of use that EPA evaluated and whose risk support 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.

3. Fenceline screening analysis.

The 2020 Risk Evaluation for TCE excluded the assessment of certain exposure pathways that were or could be regulated under another EPA-administered statute (see section 1.4.2 of the

November 2020 Risk Evaluation for TCE (Ref. 1). This resulted in the surface water, drinking water, and ambient air pathways for TCE exposure not being assessed for human health risk to the general population. In June 2021, EPA made a policy announcement on the path forward for TSCA chemical risk evaluations, indicating that EPA would, among other things, examine whether the exclusion of certain exposure pathways from the risk evaluations could lead to a failure to adequately protect fenceline communities (Ref. 24). EPA then conducted a screening analysis to identify whether there may be risks to people living near the fenceline of facilities releasing TCE.

In order to assess whether there are no risks of concern or whether there may be risks of concern to the general population in proximity to a facility releasing TCE, EPA developed the TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0, which was presented to the SACC in March 2022, with a report issued by the SACC on May 18, 2022 (Ref. 25). This screening level approach, which EPA believes is very effective in accurately assessing where fenceline exposures are of no concern is discussed in Unit VII.A.

III. Regulatory Approach

A. Background.

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

- Prohibit or otherwise restrict the manufacturing, processing, or distribution in

commerce of the substance or mixture, or limit the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce (TSCA section 6(a)(1)).

• Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of the substance or mixture for a particular use or above a specific concentration for a particular use (TSCA section 6(a)(2)).

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

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

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

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

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

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

As described in Unit III.B.3., EPA analyzed how the TSCA section 6(a) requirements could be applied to address the unreasonable risk, so that TCE no longer presents such unreasonable risk. EPA's proposed regulatory action and a primary alternative regulatory action

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are described in Unit V. EPA is requesting public comment on all elements of the proposed regulatory action and the alternative regulatory action and is providing notice that based on consideration of comments and any new information submitted to EPA during the comment period on this proposed rule, EPA may in the final rule modify elements of the proposed regulatory action. The public should understand that public comments could result in changes to elements of the proposed and alternative regulatory actions when this rulemaking is finalized. For example, elements such as timeframes for phase out could be lengthened or shortened, ECELs could be modified, or the WCPP could have conditions added or eliminated.

Under the authority of TSCA section 6(g), EPA may consider granting a time-limited exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use if EPA finds that: 1) The specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; 2) Compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or 3) The specific condition of use, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety. Based on reasonably available information, EPA has analyzed the need for an exemption and has found that TSCA section 6(g) exemptions are warranted for certain conditions of use, as detailed in Unit V.A.3. EPA is requesting public comment regarding the need for exemptions from the rule (and under what specific circumstances), including exemptions from the proposed regulatory action and the primary alternative regulatory action, pursuant to the provisions of TSCA section 6(g).

TSCA section 6(c)(2)(A) requires EPA, in proposing and promulgating TSCA section 6(a) rules, to consider and include a statement addressing certain factors, including the costs and

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

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

1. Consultations.

EPA conducted consultations and outreach in developing this proposed regulatory action. The Agency held a federalism consultation from July 22, 2021, until October 22, 2021, as part of this rulemaking process and pursuant to Executive Order 13132. This included a background presentation on September 9, 2021, and a consultation meeting on July 22, 2021. During the consultation, EPA met with State and local officials early in the process of developing the proposed action in order to receive meaningful and timely input into its development (Ref. 26). During the consultation, participants and EPA discussed preemption; the authority given under TSCA section 6 to regulate identified unreasonable risk; which activities would be potentially regulated in the proposed rule; TSCA reporting requirements; key local constituencies; and the

relationship between TSCA and existing statutes, particularly the Clean Water Act (CWA) and the Safe Drinking Water Act (SDWA) (Ref. 26).

TCE is not manufactured (including imported), processed, distributed in commerce, or regulated by Tribal governments. However, EPA consulted with Tribal officials during the development of this proposed action (Ref. 27). The Agency held a Tribal consultation from May 17, 2021, to August 20, 2021, with meetings on June 15 and July 8, 2021. Tribal officials were given the opportunity to meaningfully interact with EPA risk managers concerning the current status of risk management. During the consultation, participants and EPA discussed concerns from Tribal members about the TCE OSHA exposure limit being outdated, Tribal interest in seeing TCE banned, and concerns that third party disposal may be occurring near Tribal lands, with a particular interest in protecting workers at publicly owned treatment works (Ref. 27). EPA received no written comments as part of this consultation.

In addition to the formal consultations, EPA also conducted outreach to advocates of communities that might be subject to disproportionate risk from the exposures to TCE, such as communities with environmental justice concerns. EPA's Environmental Justice (EJ) consultation occurred from June 3, 2021, through August 20, 2021. On June 16 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 three written comments following the EJ meetings, in addition to oral comments provided during the consultation (Refs. 28, 29, 30). In general, commenters supported strong regulation of TCE to protect lower-income communities and workers, strong outreach to affected communities, encouraged EPA to follow the National Institute for Occupational Safety and Health (NIOSH) hierarchy of controls, favored prohibitions, and noted the uncertainty, and, in some cases, inadequacy, of personal protective equipment (Ref. 31).

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As required by section 609(b) of the Regulatory Flexibility Act (RFA), EPA convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations from small entity representatives (SERs) that potentially would be subject to this proposed rule's requirements (Ref. 32). EPA met with SERs before and during Panel proceedings, on October 28, 2022, and January 31, 2023. Panel recommendations are in Unit XI.C. and in the Initial Regulatory Flexibility Analysis (Ref. 33), the Panel report is in the docket (Ref. 32).

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

2. Other stakeholder engagement.

In addition to the formal consultations described in Unit XI., EPA held a webinar on December 15, 2020, providing an overview of the TSCA risk management process and the risk evaluation findings for TCE. EPA also presented on the risk evaluation and risk management under TSCA for TCE at a Small Business Administration small business roundtable on December 18, 2020. At both events EPA staff provided an overview of the TSCA risk management process and the findings in the 2020 Risk Evaluation for TCE (Ref. 34). Attendees of these meetings were given an opportunity to voice their concerns regarding the risk evaluation and risk management.

Furthermore, EPA engaged in discussions with representatives from different industries, non-governmental organizations, technical experts and users of TCE. A list of external meetings held during the development of this proposed rule is in the docket (Ref. 35); meeting materials and summaries are also in the docket. The purpose of these discussions was to create awareness and educate stakeholders and regulated entities on the provisions for risk management required under TSCA section 6(a); explain the risk evaluation findings; obtain input from manufacturers, processors, distributors, users, academics, advisory councils, and members of the public health community about uses of TCE; identify workplace practices, engineering controls, administrative

controls, PPE, and industrial hygiene plans currently in use or feasibly adoptable to reduce exposure to TCE under the conditions of use; understand the importance of TCE in the various uses subject to this proposed rule; compile knowledge about critical uses, substitute chemicals or alternative methods; identify various standards and performance specifications; and generate potential risk reduction strategies. EPA has met with, or otherwise communicated with, a variety of companies, trade associations and non-governmental public interest organizations to discuss the topics outlined in this paragraph; a list of external meetings held during the development of this proposed rule is in the docket (Ref. 35).

3. Children's environmental health.

The EPA 2021 Policy on Children's Health (Ref. 36) requires EPA to protect children from environmental exposures by consistently and explicitly considering early life exposures (from conception, infancy, early childhood and through adolescence until 21 years of age) and lifelong health in all human health decisions through identifying and integrating children's health data and information when conducting risk assessments. TSCA section 6(b)(4)(A) also requires EPA to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." Infants, children, and pregnant women are listed as examples of subpopulations based on lifestage that may be considered relevant "potentially exposed or susceptible subpopulations" in the TSCA section 3(12) definition of that term. In addition, TSCA section 6(a) requires EPA to apply one or more risk management requirements under TSCA section 6(a) so that TCE no longer presents an unreasonable risk (including unreasonable risk to PESS). Furthermore, TSCA 6(c)(2)(B) requires EPA to "factor in, to the extent practicable," the considerations under TSCA section 6(c)(2)(A) when selecting among

prohibitions and other restrictions in TSCA section 6(a) rules, including taking into consideration the magnitude of exposure to human health, as further discussed in Unit IV.

The 2020 Risk Evaluation for TCE evaluated the hazards of TCE to all lifestages. Evidence of developmental hazards were observed for increased resorptions, fetal cardiac defects and decreased rearing activity (i.e., neurotoxicity). These effects occur in the offspring exposed either *in utero* or postnatally, with older pregnant women identified as especially susceptible to cardiac defects in their developing fetus based on epidemiological data. Adverse health effects to reproduction following TCE exposure include decreased normal sperm morphology and hyperzoospermia along with delayed onset of birth. The most sensitive non-cancer hazard identified for non-reproductive or developmental effects is autoimmunity following chronic exposure to TCE.

The 2020 Risk Evaluation for TCE considered impacts on both children and adults from occupational and consumer use from inhalation and dermal exposures, as applicable. The 2020 Risk Evaluation for TCE identified consumers and bystanders associated with use of TCE-containing consumer products as potentially exposed and susceptible subpopulations due to greater exposure. Consumer users are considered to include adults as well as children as young as 11. Bystanders in the home exposed via inhalation are considered to include any age group from infant (including breast-fed infants) to adult (including elderly), including pregnant women and individuals of reproductive age. Younger lifestages are likely exposed to higher internal dose concentrations of TCE than adults due to relative physiological differences in body weight, breathing rate, and other parameters. A further discussion on the magnitude of health effects and EPA's consideration of these health effects in this proposed rule is in Unit IV.

B. Regulatory assessment of TCE.

1. Description of conditions of use.

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This unit describes the TSCA conditions of use whose risk EPA evaluated and considered in making its unreasonable risk determination for the chemical substance TCE. Condition of use descriptions were obtained from EPA sources such as CDR use codes, the 2020 Risk Evaluation for TCE and related documents, as well as the Organisation for Economic Co-operation and Development harmonized use codes and stakeholder engagements. For additional description of the conditions of use, including process descriptions and worker activities considered in the risk evaluation, see the Problem Formulation of the 2020 Risk Evaluation for TCE, the 2020 Risk Evaluation for TCE, and supplemental files (Refs. 37, 1, 38). EPA acknowledges that some of the terms used in this unit may also be defined under other statutes; however, the descriptions here are intended to provide clarity to the regulated entities who would be subject to the provisions of this proposed rule under TSCA section 6(a).

a. Manufacturing.

i. Domestic manufacture.

This condition of use refers to the making or producing of a chemical substance within the United States (including manufacturing for export), or the extraction of a component chemical substance from a previously existing chemical substance or a complex combination of substances. This description does not apply to TCE 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. 39).

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.

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This condition of use refers to processing TCE in chemical reactions for the manufacturing of another chemical substance or product, notably including but not limited to 1,1,1,2-tetrafluoroethane, an HFC also known as HFC-134a, which is used as a refrigerant and in fluorocarbon blends for refrigerants. This condition of use includes reuse of byproduct or residual TCE as a reactant.

ii. Processing: incorporation into a formulation, mixture, or reaction product.

This condition of use refers to when TCE is added to a product (or product mixture) prior to further distribution of the product; such products include but are not limited to solvents (for cleaning or degreasing), adhesives and sealant chemicals, and solvents that become part of a product formulation or mixture (e.g., lubricants and greases, paints and coatings, other uses).

iii. Processing: incorporation into articles.

This condition of use refers to when a chemical substance becomes an integral component of an article distributed for industrial, commercial, or consumer use.

iv. Processing: repackaging.

This condition of use refers to the preparation of a chemical substance for distribution in commerce in a different form, state, or quantity. This includes but is not limited to transferring the chemical from a bulk container into smaller containers.

v. Processing: recycling.

This condition of use refers to the process of managing used solvents that are collected, either on-site or transported to a third-party site, for commercial purpose other than disposal. Spent solvents can be restored via solvent reclamation/recycling. The recovery process may involve an initial vapor recovery or mechanical separation step followed by distillation, purification, and final packaging.

c. Industrial and commercial use.

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i. Industrial and commercial use as solvent for open-top batch vapor degreasing.

This condition of use refers to the process of heating TCE to its volatilization point and using its vapor to remove dirt, oils, greases, and other surface contaminants (such as drawing compounds, cutting fluids, coolants, solder flux, and lubricants) from metal parts, electronics, or other articles in batch open-top vapor degreasers (OTVDs).

ii. Industrial and commercial use as solvent for closed-loop batch vapor degreasing.

This condition of use refers to the process of heating TCE to its volatilization point and using its vapor to remove dirt, oils, greases, and other surface contaminants (such as drawing compounds, cutting fluids, coolants, solder flux, and lubricants) from metal parts, electronics, or other articles in batch closed-loop vapor degreasers.

iii. Industrial and commercial use as solvent for in-line conveyorized vapor degreasing.

This condition of use refers to the process of heating TCE to its volatilization point and using its vapors to remove dirt, oils, greases, and other surface contaminants from textiles, glassware, metal surfaces, and other articles using in-line conveyorized degreasing machines.

iv. Industrial and commercial use as solvent for in-line web cleaner vapor degreasing.

This condition of use refers to the process of heating TCE to its volatilization point and using its vapors to remove dirt, oils, greases, and other surface contaminants from textiles, glassware, metal surfaces, and other articles using in-line web cleaning degreasing machines.

v. Industrial and commercial use as solvent for cold cleaning.

This condition of use refers to the industrial and commercial use of TCE as a non-boiling solvent in cold cleaning to dissolve oils, greases and other surface contaminants from textiles, glassware, metal surfaces, and other articles.

vi. Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner and mold release.

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This condition of use refers to industrial and commercial use of TCE in aerosol degreasing as an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from fabricated parts or machinery (including circuit boards and electronics). This description also applies to the use of TCE in products to remove dirt, grease, stains, spots, and foreign matter, including but not limited to release agent residues, from molds and casting surfaces.

vii. Industrial and commercial use as a lubricant and grease in tap and die fluid.

This condition of use refers to industrial and commercial use of TCE in products such as, but not limited to, metalworking, cutting, and tapping fluid to reduce friction, heat generation and wear, to assist in metal shaping, and to protect the part being shaped from oxidation. This description does not apply to use of TCE in products intended as penetrating lubricant, which are described in a different condition of use.

viii. Industrial and commercial use as a lubricant and grease in penetrating lubricant.

This condition of use refers to the industrial and commercial use of TCE in products as a lubricant and grease in penetrating lubricant, to reduce friction, heat generation and wear between surfaces. This description does not apply to use of TCE in products intended as metalworking, cutting and tapping fluids, which are described in a different condition of use.

ix. Industrial and commercial use as an adhesive and sealant in solvent-based adhesives and sealants; tire repair cement/sealer; mirror edge sealant.

This condition of use refers to industrial and commercial use of TCE in adhesive and sealant products to promote bonding between other substances, promote adhesion of surfaces, or prevent seepage of moisture or air.

x. Industrial and commercial use as a functional fluid in heat exchange fluid.

This condition of use refers to the industrial and commercial use of TCE as a functional

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fluid in heat exchange fluid used to transmit or to remove heat from another material in a closed system.

xi. Industrial and commercial use in paints and coatings as a diluent in solvent-based paints and coating.

This condition of use refers to industrial and commercial use of TCE in paints and coatings that are applied to surfaces to enhance properties such as, but not limited to, water repellency, gloss, fade resistance, ease of application, or foam prevention.

xii. Industrial and commercial use in cleaning and furniture care products in carpet cleaner and wipe cleaning.

This condition of use refers to the industrial and commercial use of TCE in products to remove dirt, grease, stains, spots, and foreign matter from furniture and furnishings, including but not limited to carpets and rugs. This description also applies to use of TCE in degreasing and cleaning products to remove dirt, grease, stains, spots, and foreign matter from furniture and furnishings or to cleanse, sanitize, bleach, scour, polish, protect, or improve the appearance of surfaces through wipe cleaning. This description does not apply to the use of TCE as a spot remover for laundry and dishwashing, which is described in a different condition of use.

xiii. Industrial and commercial use in laundry and dishwashing products in spot remover.

This condition of use refers to industrial and commercial use of TCE as a solvent in products for cleaning in laundry and dishwashing applications to remove dirt, grease, stains, spots, and foreign matter from garments and dishware.

xiv. Industrial and commercial use in arts, crafts, and hobby materials in fixatives and finishing spray coatings.

This condition of use refers to the industrial and commercial use of TCE in aerosol products, such as, but not limited to, fixatives, shellacs, or other spray applied coatings intended

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to cover or hold other arts and crafts materials to a surface.

xv. Industrial and commercial use in corrosion inhibitors and anti-scaling agents.

This condition of use refers to the industrial and commercial use of TCE in corrosion inhibitors and anti-scaling agents as a chemical substance used to prevent or retard corrosion or the formation of scale. As a corrosion inhibitor, TCE is used to prevent or retard corrosion on metallic materials. As an anti-scaling agent, TCE is added to products to prevent the build-up of inorganic oxide deposits.

xvi. Industrial and commercial use in processing aids in process solvent used in battery manufacture; process solvent used in polymer fabric spinning, fluoroelastomer manufacture and Alcantara manufacture; extraction solvent used in caprolactam manufacture; precipitant used in beta-cyclodextrin manufacture.

This condition of use refers to industrial and commercial use of TCE as a processing aid. A process solvent is a chemical substance used to improve the processing characteristics or the operation of process equipment when added to a process or to a substance or mixture to be processed. The chemical substance is not intended to become a part of the reaction product nor has function in the reaction product.

xvii. Industrial and commercial use as ink, toner, and colorant products in toner aid.

This condition of use refers to the industrial and commercial use of TCE in ink, toner, and colorant products in toner aid as chemical substance used for writing, printing, creating an image on paper and other substrates, or applied to substrates to change their color or hide images. This includes but is not limited to pigmented liquids, toners or powders contained in cartridges, bottles, or other dispensers used in printers and copy machines. This category includes printing inks for commercial applications.

xviii. Industrial and commercial use in automotive care products in brake and parts

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cleaner.

This condition of use refers to the industrial and commercial use of TCE in products to remove dirt, grease, stains, and foreign matter from interior and exterior vehicle surfaces. This description includes but is not limited to use of products for motorized vehicle maintenance and their parts.

xix. Industrial and commercial use in apparel and footwear care products in shoe polish.

This condition of use refers to the industrial or commercial use of TCE in apparel and footwear care products as post-market waxes, polishes, or other mediums and applied to footwear, textiles, or fabrics to impart color or other desirable properties.

xx. Industrial and commercial use in hoof polish, gun scrubber, pepper spray, other miscellaneous industrial and commercial uses.

This condition of use refers to the industrial and commercial use of TCE in which it is expected to act similar to a cleaning solvent used to remove dirt or other contaminants from substrates. This description also refers to other miscellaneous products which contain TCE as an additive to impart or enhance desirable properties of another material (e.g., adhesive, sealant, propellant). Additionally, this condition of use refers to the industrial and commercial use of TCE, often in small quantities, in a laboratory for chemical analysis (e.g., to test hot mix asphalt binder content, as a reference standard, etc.), chemical synthesis, extracting and purifying other chemicals, dissolving other substances, and similar activities.

d. Consumer use.

i. Consumer use as a solvent in brake and parts cleaner.

This condition of use refers to the consumer use of TCE in products to remove dirt, grease, stains, and foreign matter from interior and exterior vehicle surfaces, particularly in brake cleaner and parts cleaner.

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ii. Consumer use as a solvent in aerosol electronic degreaser/cleaner.

This condition of use refers to the consumer use of TCE as a solvent in degreasing and cleaning products used to remove dirt, grease, stains, spots, and foreign matter through a process that uses an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from electronics.

iii. Consumer use as a solvent in liquid electronic degreaser/cleaner.

This condition of use refers to the consumer use of TCE as a solvent in degreasing and cleaning products used to remove dirt, grease, stains, spots, and foreign matter through a process that uses a liquid solvent to remove residual contaminants from electronics.

iv. Consumer use as a solvent in aerosol spray degreaser/cleaner.

This condition of use refers to the consumer use of TCE as a solvent in degreasing and cleaning products used to remove dirt, grease, stains, spots, and foreign matter through a process that uses an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from metals and other fabricated materials not described elsewhere in this unit.

v. Consumer use as a solvent in liquid degreaser/cleaner.

This condition of use refers to the consumer use of TCE as a solvent in liquid degreasing and cleaning products used to remove dirt, grease, stains, spots, and foreign matter from metals and other fabricated materials not described elsewhere.

vi. Consumer use as a solvent in aerosol gun scrubber.

This condition of use refers to the consumer use of TCE as a solvent in aerosol products in which it is expected to act similar to a cleaning solvent used to remove residue, dirt, grease, or other contaminants, in particular but not limited to gun scrubber.

vii. Consumer use as a solvent in liquid gun scrubber.

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This condition of use refers to the consumer use of TCE as a solvent in liquid products in which it is expected to act similar to a cleaning solvent used to remove residue, dirt, grease, or other contaminant, in particular but not limited to gun scrubber.

viii. Consumer use as a solvent in mold release.

This condition of use refers to the consumer use of TCE in mold release products to create barriers to prevent certain materials from adhering to each other, and assist in the removal of dirt, grease, oils, and other contaminants from metal molds.

ix. Consumer use as a solvent in aerosol tire cleaner.

This condition of use refers to the consumer use of TCE as an additive in aerosol products to impart or enhance desirable properties of another material, particularly in use as tire cleaner.

x. Consumer use as a solvent in liquid tire cleaner.

This condition of use refers to the consumer use of TCE as an additive in liquid products to impart or enhance desirable properties of another material, particularly in use as tire cleaner.

xi. Consumer use as a lubricant and grease in tap and die fluid.

This condition of use refers to the consumer use of TCE in products to reduce friction, heat generation and wear between solid surfaces, particularly in tap and die fluid.

xii. Consumer use as a lubricant and grease in penetrating lubricant.

This condition of use refers to the consumer use of TCE in products to reduce friction, heat generation and wear between solid surfaces, particularly in penetrating lubricant.

xiii. Consumer use as an adhesive and sealant in solvent-based adhesive and sealants.

This condition of use refers to the consumer use of TCE as a solvent in single or two component products used to fasten other materials together or prevent the passage of liquid or gas. This description does not apply to products for mirror edge sealant or tire repair, which are

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described in different conditions of use.

xiv. Consumer use as an adhesive and sealant in mirror edge sealant.

This condition of use refers to the consumer use of TCE in single or two component products used to fasten other materials together or prevent the passage of liquid or gas, particularly in mirror edge sealant.

xv. Consumer use as an adhesive and sealant in tire repair cement/sealer.

This condition of use refers to the consumer use of TCE in single or two component products used to fasten other materials together or prevent the passage of liquid or gas, particularly in cement or sealant for tire repair.

xvi. Consumer use as a cleaning and furniture care product in carpet cleaner.

This condition of use refers to the consumer use of TCE as a solvent in cleaning and furniture care products used to remove dirt, grease, stains, spots, foreign matter, and residual contaminants, particularly in carpet cleaner.

xvii. Consumer use as a cleaning and furniture care product in aerosol spot remover.

This condition of use refers to the consumer use of TCE as a solvent in cleaning and furniture care products used to remove dirt, grease, stains, spots, and foreign matter through a process that uses an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants, particularly in aerosol spot remover.

xviii. Consumer use as a cleaning and furniture care product in liquid spot remover.

This condition of use refers to the consumer use of TCE as a solvent in cleaning and furniture care products in the form of a solid or liquid cleaner, used to remove dirt, grease, stains, spots, foreign matter, and residual contaminants, particularly in liquid spot remover.

xix. Consumer use in arts, crafts, and hobby materials in fixative and finishing spray coatings.

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This condition of use refers to the consumer use of TCE in arts, crafts, and hobby products that uses an aerosolized solvent spray, typically applied from a pressurized can, intended to cover or hold other arts and crafts materials to a surface, particularly in fixative and finishing spray coatings.

xx. Consumer use in apparel and footwear products in shoe polish.

This condition of use refers to the consumer use of TCE in apparel and footwear care products as post-market waxes, polishes, or other mediums and applied to footwear, textiles, or fabrics to impart color or other desirable properties.

xxi. Consumer use in fabric spray.

This condition of use refers to the consumer use of TCE in aerosol products, typically applied from a pressurized can, as an additive to enhance desirable properties of another material, particularly in fabric spray and as an anti-fray spray.

xxii. Consumer use in film cleaner.

This condition of use refers to the consumer use of TCE in products as an additive to impart or enhance the desirable properties of another material, particularly in film cleaner.

xxiii. Consumer use in hoof polish.

This condition of use refers to the consumer use of TCE as an additive to impart or enhance desirable properties of another material, particularly in hoof polish.

xxiv. Consumer use in toner aid.

This condition of use refers to the consumer use of TCE in products as an additive to impart or enhance the desirable properties of another material, particularly in toner aid.

e. Disposal.

This condition of use refers to the process of disposing of generated waste streams of TCE that are collected either on-site or transported to a third-party site. This includes the mixing

of TCE with wastewater and the discharge of TCE-contaminated wastewater pursuant to a NPDES permit, and specifically includes discharge to industrial pre-treatment, industrial treatment, or publicly owned treatment works. While EPA views the disposal condition of use under TSCA broadly (see, e.g., EPA's proposed regulation on certain conditions of use of chrysotile asbestos (Ref. 40), for the purpose of this rulemaking under TSCA section 6(a), based on the underlying analysis in the 2020 TCE risk evaluation, EPA's proposed regulations specifically address the risk to PESS from disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works. EPA recognizes that this includes activities that may not be considered disposal under other statutes, such as RCRA and the CWA.

f. Terminology in this proposed rule.

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

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

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"industrial and commercial use" refers to all industrial and commercial uses, including known, intended, or reasonably foreseen TCE industrial and commercial use.

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

EPA further notes that this proposed rule does not apply to any substance excluded from the definition of "chemical substance" under TSCA section 3(2)(B)(ii) through (vi). Those exclusions include, but are not limited to, any pesticide (as defined by the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; and any food, food additive, drug, cosmetic, or device, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA), when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device.

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

EPA has determined that TCE presents an unreasonable risk of injury to human health under the conditions of use based on acute and chronic non-cancer risks and chronic cancer risks (Ref. 2). As described in the TSCA section 6(b) 2020 Risk Evaluation for TCE, EPA identified

non-cancer adverse effects from acute and chronic inhalation and dermal exposures to TCE, and for cancer from chronic inhalation and dermal exposures to TCE (Ref. 1). In the TCE risk characterization, the endpoints identified by EPA as the basis for the unreasonable risk determination in the Risk Conclusions were immunosuppression effects for acute inhalation and dermal exposures, and autoimmunity effects for chronic inhalation and dermal exposures (Ref. 1). Additional risks associated with other non-cancer adverse effects (e.g., developmental toxicity, immunosuppression, liver toxicity, kidney toxicity, neurotoxicity, autoimmunity, and reproductive toxicity) were identified for acute and chronic inhalation and dermal exposures, as well as cancer (liver, kidney, and non-Hodgkin lymphoma) for chronic inhalation and dermal exposures. EPA also concluded, based on EPA's Guidelines for Carcinogen Risk Assessment (Ref. 41), that TCE is considered to be carcinogenic by all routes of exposure and calculated cancer risks from chronic inhalation and dermal exposures (Ref. 1). Unit IV. summarizes the health effects and the magnitude of the exposures.

To make the unreasonable risk determination for TCE, EPA evaluated exposures to potentially exposed or susceptible subpopulations including workers, ONUs, consumer users, and bystanders to consumer use by using reasonably available monitoring and modeling data for inhalation and dermal exposures. (Ref. 1). EPA conducted a screening-level analysis to assess potential risks from the air and water pathways to fenceline communities. A discussion of EPA's analysis and the expected effects of this rulemaking on fenceline communities is in Unit VII.A.

For the 2020 Risk Evaluation for TCE, and as discussed in Unit II.D.1. and Unit III.A.3., EPA considered PESS. EPA identified the following groups as PESS: workers and ONUs, including men and women of reproductive age, adolescents, and biologically susceptible subpopulations; and consumer users (age 11 and older) and bystanders (of any age group, including infants, toddlers, children, and elderly), including biologically susceptible

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subpopulations. Additionally, older pregnant women are identified as especially susceptible to cardiac defects in their developing fetus based on epidemiological data (Ref. 1). All PESS are included in the quantitative and qualitative analyses described in the 2020 Risk Evaluation for TCE and were considered in the determination of unreasonable risk for TCE (Ref. 1, 2). As discussed in Unit II.D. and Unit IV.B., the 2020 Risk Evaluation for TCE excluded the air and water exposure pathways to the general population from the published risk evaluations and may have caused some risks to be unaccounted for in the risk evaluation. EPA considers these groups a subset of the general population and categorizes them as fenceline communities; they may also be considered PESS. See Unit VII.A. for further discussion on assessing and protecting against risk to fenceline communities.

3. Description of TSCA section 6 requirements for risk management.

EPA examined the TSCA section 6(a) requirements (listed in Unit III.A.) to identify which ones have the potential to address the unreasonable risk for TCE.

As required, EPA developed a proposed regulatory action and one or more primary alternative regulatory actions, which are described in Units V.A. and V.B., respectively. To identify and select a regulatory action, EPA considered the two routes of exposure driving the unreasonable risk, inhalation and dermal, and the exposed populations. For occupational conditions of use (see Unit III.B.1.f.), EPA considered how it could directly regulate manufacturing (including import), processing, distribution in commerce, industrial and commercial use, or disposal to address the unreasonable risk. EPA does not have direct authority to regulate consumer use. Therefore, EPA considered how it could exercise its authority under TSCA to regulate the manufacturing (including import), processing, and/or distribution in commerce of TCE at different points in the supply chain to eliminate exposures or restrict the availability of TCE and TCE-containing products for consumer use in order to address the

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unreasonable risk.

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

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

In addition, EPA followed other TSCA requirements such as considering the availability of alternatives when contemplating prohibition or a substantial restriction (TSCA section

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6(c)(2)(C), as outlined in Unit VI.B.), and setting proposed compliance dates in accordance with the requirements in TSCA section 6(d)(1) (described in the proposed and alternative regulatory action in Unit V.).

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

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

IV. Considerations of Health Effects of TCE

TSCA section 6(a) rules must be promulgated "in accordance with subsection (c)(2)." TSCA section 6(c)(2)(A) requires EPA, in proposing and promulgating TSCA section 6(a) rules, to "consider and publish a statement based on reasonably available information" with respect to listed criteria, including the effects and magnitude of exposure to human health and the environment, the benefits of the chemical substance for various uses, and the reasonably ascertainable economic consequences of the rule. Under TSCA section 6(c)(2)(B), EPA must "factor in, to the extent practicable," the considerations under TSCA section 6(c)(2)(A) when selecting among prohibitions and other restrictions in TSCA section 6(a) rules. This section discusses the health effects of TCE. Other TSCA section 6(c)(2) considerations are discussed further in Unit VII.

EPA's analysis of the health effects of TCE is in the 2020 Risk Evaluation (Ref. 1). This unit presents a summary of that information and an explanation of how EPA considered that information in developing the proposed and alternative regulatory options.

TCE has a large database of human health toxicity data. The 2020 Risk Evaluation for TCE identified several endpoints, such as kidney toxicity, immunotoxicity, or developmental toxicity, and often a single endpoint was examined by multiple studies. For acute exposures, EPA identified non-cancer effects (developmental toxicity and immunosuppression). For chronic exposures, EPA identified non-cancer effects (liver toxicity, kidney toxicity, neurotoxicity, autoimmunity, reproductive toxicity, and developmental toxicity) as well as cancer (liver, kidney, and non-Hodgkin lymphoma), with kidney cancer identified as acting through a mutagenic mode of action (Ref. 1). As discussed in this unit, the 2020 Risk Evaluation for TCE contains quantitative risk estimates using several points of departure (PODs), including both the immunotoxicity endpoints as well as the more sensitive developmental toxicity endpoints, specifically fetal cardiac defects, and both demonstrate that TCE presents risk.

Additionally, in developing the 2020 Risk Evaluation for TCE, EPA analyzed the reasonably available information to ascertain whether some human subpopulations may have greater exposure or greater susceptibility than the general population to the hazard posed by the chemical substance. Factors affecting susceptibility examined in the reasonably available studies on TCE include lifestage, sex, genetic polymorphisms, race/ethnicity, preexisting health status, lifestyle factors, and nutrition status. Groups of individuals for which one or several of these factors apply may be considered PESS (Ref. 1).

A. ECEL value of 0.0011 ppm based on developmental toxicity (proposed).

Because TSCA section 6(c)(2)(B) directs EPA to factor in, to the extent practicable, the health effects of TCE under TSCA section 6(c)(2)(A), TSCA section 6(c) thereby provides EPA

with the flexibility to tailor the regulatory restrictions to account for particular health effects identified in the underlying risk evaluation. With this consideration, EPA found that, in some cases, a regulatory option that could reduce exposures such that they would achieve the benchmark margin of exposure for the most sensitive non-cancer endpoint (developmental toxicity) would address any risk for other non-cancer endpoints. Older pregnant workers and ONUs, who may be especially susceptible to TCE- induced cardiac defects in their developing fetus, are classified as a PESS, and the associated POD and risk estimates were included in the 2020 Risk Evaluation in consideration of PESS groups. EPA has carefully considered the health effects of TCE on pregnant workers and ONUs as part of the Agency's development of proposed requirements that would be applicable to certain occupational conditions of use of TCE. In order for this rulemaking to appropriately address risk to all workers and ONUs exposed to TCE through the occupational conditions of use for which EPA is proposing an ECEL associated with a WCPP, EPA has factored in consideration of additional health effects applicable to PESS, including older pregnant workers and ONUs (the group identified as most susceptible to fetal cardiac defects) pursuant to TSCA section 6(c)(2), and is proposing an ECEL value of 0.0011 ppm based on developmental toxicity (Ref. 13).

In the risk characterization section of the 2020 Risk Evaluation for TCE, EPA acknowledged that fetal cardiac defects are an acute, non-cancer endpoint of concern for older pregnant women, while also acknowledging uncertainty surrounding the use of this endpoint to inform the determination of whether TCE presents unreasonable risk of injury to health for all affected human populations. In the 2020 Risk Evaluation for TCE, EPA presented the Agency's findings with respect to different endpoints and characterized the immunotoxicity endpoints as the "best overall" non-cancer endpoints for use in the risk conclusions and risk determination. The endpoints were characterized in this way precisely because of the quantitative uncertainties

surrounding the use of the fetal cardiac defects endpoint and other considerations. Further, as noted in Unit II.D.1., EPA has received numerous comments on EPA's 2020 TSCA Risk Evaluation policy choice regarding endpoint selection that have raised concerns pertaining to political interference and scientific integrity, among other issues. Among the non-cancer adverse health effects, the drivers for EPA's whole chemical unreasonable risk determination for TCE under TSCA were identified as immunotoxicity, acute immunosuppression, and chronic autoimmunity from inhalation and dermal exposures (Ref. 2). EPA received significant feedback on this aspect of the 2020 Risk Evaluation for TCE, including focused attention on this issue from the SACC and public commenters reacting to the draft Risk Evaluation for TCE (Ref. 42). Moreover, based on the discussion included in the peer review report of the 2020 Risk Evaluation, EPA also concluded that reasonable scientists would not disallow the use of the fetal cardiac defects studies, and that therefore other EPA program reliance on the fetal cardiac defects endpoint is scientifically valid (e.g., IRIS).

The 2020 Risk Evaluation for TCE identified the developmental toxicity endpoint of fetal cardiac defects, which presents a lower POD than the immunotoxicity endpoints. The magnitude of the unreasonable risk from exposures to TCE would have been greater had the Agency relied upon the developmental toxicity endpoint (Ref. 1). Specifically, EPA identified the risk of fetal cardiac defects most strongly associated with offspring of older mothers, and therefore included risk estimates for fetal cardiac defects that account for susceptible mothers and their offspring in addition to PESS groups with other susceptibilities (*e.g.,* diabetes, infection status, drug exposure, stress, and metabolic sensitivity due to increased enzymatic activity of cytochrome P450 2E1 (CYP2E1) (Ref. 1).

EPA developed the ECEL for the most sensitive health endpoint (developmental toxicity) in support of risk management efforts on TCE under TSCA, to identify that ambient exposures

that are kept at or below the 8-hour ECEL of 0.0011 ppm would protect against risk of injury to health due to fetal cardiac defects, if those levels can be achieved. In addition, EPA expects that at the acute non-cancer ECEL of 0.0011 ppm, any potentially exposed person in the workplace would be protected against other non-cancer effects resulting from occupational exposures, as well as excess risk of cancer (Ref. 13). EPA expects that if a facility were able to meet the ECEL (0.0011 ppm) requirement associated with the WCPP under the proposed regulatory action outlined in Unit V.A.2., it would protect PESS during the phaseout period before the full prohibition.

B. ECEL value of 0.0040 ppm based on immunotoxicity (primary alternative).

In other risk management actions under TSCA section 6, EPA has proposed basing its worker protection requirements, such as an ECEL, on a single acute or chronic exposure endpoint that provided the basis for the unreasonable risk determination (Ref. 40). While EPA is proposing a different basis for the ECEL for the WCPP for TCE (0.0011 ppm) (to protect a sensitive PESS), EPA recognizes that among the non-cancer adverse health effects of TCE, the drivers for EPA's whole chemical unreasonable risk determination for TCE under TSCA were identified as immunotoxicity, namely acute immunosuppression and chronic autoimmunity from inhalation and dermal exposures (Ref. 2). For this reason, the primary alternative regulatory action provided by EPA includes a WCPP with a different ECEL (0.0040 ppm), based on the endpoint that drives the unreasonable risk. As described in more detail in Unit V.B.2., reducing exposures to or below the ECEL of 0.0040 ppm would address that component of the unreasonable risk of injury to health from TCE that is driven by inhalation exposures in an occupational setting (Refs. 1, 14). If ambient exposures are kept at or below the 8-hour ECEL of 0.0040 ppm, EPA expects that workers and ONUs would be protected against not only the chronic non-cancer effects for autoimmunity described in this unit, but also effects resulting from

acute non-cancer exposure (immunosuppression) and cancer.

As described in Unit V.A.2., for the ECEL value of 0.0011 ppm, proposed as part of the WCPP, EPA requests comment on the use of TSCA section 6(c)(2) to tailor the risk management actions where necessary to protect PESS. Also, as described in Unit V.B.2., EPA is requesting comment on the use of the ECEL value of 0.0040 ppm in the WCPP in the alternative regulatory action. Specifically, EPA is requesting comment on the selection of the fetal cardiac defects endpoint for the ECEL of 0.0011 ppm in the proposed regulatory action, rather than the immunotoxicity endpoint on which the unreasonable risk determination is based, which would result in an ECEL of 0.0040 ppm. EPA is also requesting comment on additional ways to protect workers and ONUs who are or may become pregnant.

V. Proposed and Primary Alternative Regulatory Actions

This unit describes the proposed regulatory action by EPA so that TCE will no longer present an unreasonable risk of injury to health. In addition, as indicated by TSCA section 6(c)(2)(A), EPA must consider the costs and benefits and the cost effectiveness of the proposed regulatory action and one or more primary alternative regulatory actions. In the case of TCE, the proposed regulatory action is described in Unit V.A. and the primary alternative regulatory action considered is described in Unit V.B. An overview of the proposed regulatory action and primary alternative regulatory action for each condition of use is in Unit V.C. The rationale for the proposed and primary alternative regulatory actions and associated compliance timeframes are discussed in this unit and in more detail in Unit VI.A.

A. Proposed regulatory action.

EPA is proposing under TSCA section 6(a) to: Prohibit all manufacture (including import), processing, distribution in commerce, and industrial and commercial use of TCE for all uses (including all consumer uses), with longer timeframes and workplace controls for certain

processing and industrial and commercial uses (including proposed phaseouts and TSCA section 6(g) exemptions); prohibit the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works with a 50-year TSCA section 6(g) exemption for cleanup projects; and establish recordkeeping and downstream notifications requirements. Prohibitions on manufacturing (including import) and processing, including staggered implementation timeframes to account for the supply chain, are outlined in Unit V.A.1.a.; prohibitions on industrial and commercial uses and distribution in commerce are outlined in Unit V.A.1.b.; and prohibitions related to consumer uses are outlined in Unit V.A.1.c.

EPA is proposing longer compliance timeframes (with workplace controls) for prohibitions on certain conditions of use. The timeframe for a prohibition or phaseout under TSCA section 6(d) must begin as soon as practicable, but not later than 5 years, with the full implementation of the prohibition or phase-out requirements occurring as soon as practicable and providing for a reasonable transition period. For a TSCA section 6(g) exemption for a specific condition of use, EPA must establish a time limit as reasonable on a case-by-case basis as long as the exemption meets the criteria under TSCA section 6(g)(1). First, EPA is proposing to prohibit the manufacturing (including import) and processing of TCE as an intermediate for the manufacture of HFC-134a through an 8.5-year phaseout, as outlined in Unit V.A.1.d. Second, EPA is proposing a 10-year phaseout for the industrial and commercial use of TCE as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production for Federal agencies and their contractors, conditioned on a final pre-launch test within 5 years of rocket booster nozzles that have been produced without using TCE, as outlined in Unit V.A.1.e. Third, EPA is proposing a time-limited exemption for 10 years under a TSCA section 6(g) exemption related to prohibitions on the industrial and commercial use of TCE as a processing aid for battery separator manufacturing, as outlined in Unit V.A.3.b.i.

Fourth, EPA is proposing a time-limited exemption for 10 years under a TSCA section 6(g) exemption related to prohibitions on industrial uses of TCE for DoD vessel requirements for potting, bonding and sealing compounds, and bonding and cleaning requirements for naval combat systems, radars, sensors, equipment, and fabrication and prototyping processes, as outlined in Unit V.A.3.b.ii. Fifth, EPA is proposing a time-limited exemption for 50 years under a TSCA section 6(g) exemption related to prohibitions on the industrial and commercial use of TCE in laboratory use for essential laboratory activities and some research and development activities, as outlined in Unit V.A.3.b.iii. Sixth, EPA is proposing a time-limited exemption for 7 years under a TSCA section 6(g) exemption related to prohibitions on the industrial and commercial use of TCE as a solvent in closed loop vapor degreasing necessary for human-rated rocket engine cleaning by NASA and its contractors. Seventh, EPA is proposing a time-limited exemption for 10 years under a TSCA section 6(g) exemption for emergency industrial and commercial use of TCE for specific conditions of use which are critical or essential in furtherance of NASA's mission and for which no technically and economically safer alternative is available. Where conditions of use would be prohibited under timeframes longer than one year, EPA's proposal aims to align with elements of existing OSHA regulations and industrial hygiene best practices to the extent possible by implementing a Workplace Chemical Protection Program (WCPP). The WCPP includes requirements for an inhalation exposure limit and glove requirements to limit exposure to TCE until the prohibitions take effect, as outlined in Unit V.A.2. Lastly, EPA is proposing to prohibit certain disposal of TCE (specifically, the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works), as outlined in Unit V.A.1.f., with a time limited 50-year exemption for cleanup projects as outlined in Unit V.A.3.b.iv; and establish recordkeeping and downstream notification requirements, as outlined in Unit V.A.4. EPA requests comment on the applicability to the private sector of

proposed regulatory actions pertaining specifically to Federal agencies, namely industrial uses for DoD vessel requirements and closed-loop batch vapor degreasing for rayon fabric scouring for rocket booster nozzle production. EPA requests comment on the extent to which the private sector would be affected by a prohibition on these uses.

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

a. Prohibitions on manufacturing (including import) and processing of TCE.

EPA is proposing to prohibit the manufacturing (including import) and processing of TCE based on the unreasonable risk to workers and ONUs driven by these conditions of use (Ref. 2). As the manufacture and processing of TCE presents and unreasonable risk to health in the United States, the manufacture and processing of TCE for export would also be prohibited in accordance with TSCA section 12(a)(2).

As discussed in Units III.B.3. and VI.A., based on the Agency's consideration of alternatives under TSCA section 6(c)(2)(C), uncertainty relative to the feasibility of exposure reduction to sufficiently address the unreasonable risk across the broad range of occupational environments and activities that occur in manufacturing (including import) and processing conditions of use, and the irreversible health effects associated with TCE exposures, EPA has determined that prohibition is the best way to address the unreasonable risk.

EPA is proposing that the prohibitions on manufacturing (including import) and processing of TCE would follow a staggered schedule, due to supply chain considerations. EPA proposes that the compliance dates for the proposed prohibitions described in this unit, such that the requirements would come into effect in 90 days (3 months) for manufacturers and in 180 days (6 months) for processors, with different timeframes related to specific conditions of use. Specifically, for processing TCE as a reactant/intermediate, EPA is proposing that the

compliance dates for the proposed prohibitions described in this unit would come into effect in 1.5 years for manufacturers and 2 years for processors. There are additional exceptions from the prohibition for the manufacturing and processing associated with certain processing and industrial and commercial uses, including those described later in this unit (for which EPA is proposing longer compliance timeframes, including phaseouts (see Units V.A.1.b., d., and e.) or time-limited exemptions under TSCA section 6(g) (see Unit V.A.3.b.)). The rationale for longer timeframes for certain conditions of use is described in Unit VI.A.1.

b. Prohibitions on industrial and commercial use and distribution in commerce of TCE.

EPA is proposing to prohibit the industrial and commercial use of TCE, based on the unreasonable risk to workers and ONUs driven by these conditions of use (Ref. 2). As discussed in Units III.B.3. and VI.A., based on consideration of alternatives under TSCA section 6(c)(2)(C), uncertainty relative to the feasibility of exposure reduction to sufficiently address the unreasonable risk across the broad range of work environments and activities represented by industrial and commercial uses of TCE, and the irreversible health effects associated with TCE exposures, EPA has determined that prohibition is the best way to address the unreasonable risk. However, in consideration of the challenges several sectors may encounter in adopting alternatives to TCE, EPA is proposing longer compliance timeframes for certain uses under this prohibition.

EPA is proposing compliance dates for the proposed prohibitions that would come into effect for most industrial and commercial users 270 days after the publication date of the final rule. However, EPA is proposing longer compliance timeframes under this prohibition for some industrial and commercial uses and for the associated manufacturing (including import), processing, and distribution in commerce. Specifically, for two batch vapor degreasing conditions of use (open-top and closed-loop), EPA is proposing that the compliance dates for the

proposed prohibitions described in this unit would come into effect in 180 days for manufacturers, in 270 days (9 months) for processors, specifically for processing into a formulation and for recycling, and in 1 year for the industrial and commercial uses of TCE in open-top and closed-loop batch vapor degreasers (see Unit III.B.1.c.i. and ii. for descriptions of these conditions of use and Unit VI.A.1. for a rationale for the slightly longer timeframe). For a sub-set of the closed-loop batch vapor degreasing condition of use (industrial and commercial use of TCE as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production for Federal agencies and their contractors) EPA is proposing that the compliance dates for the proposed prohibitions described in this unit would come into effect in five or 10 years for manufacturers, processors, distributors, and industrial and commercial users, depending on whether the conditions of the phaseout are met (see Unit V.A.1.e. for a description of the conditions of this proposed exemption, and Unit VI.A.1. for the rationale for this timeframe). Also, EPA is proposing that the compliance dates for the proposed prohibitions described in this unit would come into effect for commercial use of TCE as a processing aid in 1.5 years for manufacturers, in 2 years for processors, and in 2 years for industrial and commercial use of TCE in: processing aid in process solvent used in battery manufacture; process solvent used in polymer fiber spinning, fluoroelastomer manufacture and Alcantara manufacture; extraction solvent used in caprolactam manufacture; and precipitant used in beta-cyclodextrin manufacture (see Unit III.B.1.c.xvi. for a description of this condition of use and Unit V.A.1. for a rationale for the different timeframe).

To aid with implementation of the compliance dates for the proposed prohibitions on manufacturing, processing, and industrial and commercial use of TCE, and ensure that those prohibitions effectively address the unreasonable risk identified, EPA is also proposing prohibitions on distribution in commerce of TCE. Generally, for most conditions of use EPA is

proposing that the compliance date for the proposed prohibition on distributors in commerce of TCE would come into effect 180 days (6 months) following publication of the final rule. In instances where EPA is proposing a prohibition on manufacturing and processing TCE for a particular industrial and commercial use that is later than 180 days after publication of the final rule, the compliance date for the proposed prohibition on distribution in commerce would be the same as the compliance date of the proposed prohibition on manufacturing and processing TCE.

As noted in Unit III.B.1.f., this proposal does not apply to any substance excluded from the definition of "chemical substance" under TSCA section 3(2)(B)(ii) through (vi). EPA requests comment on the impacts, if any, that a prohibition on the processing of TCE into a formulation, mixture or reaction product in other chemical products and preparations, or other aspects of this proposal, may have on the production and availability of any pesticide or other substance excluded from the TSCA definition of "chemical substance." EPA also requests comment on whether it should consider a *de minimis* level of TCE in formulations to account for impurities (e.g., 0.1% or 0.5%) when finalizing the prohibitions described in this unit, and, if so, information on and rationale for any level that should be considered *de minimis*.

When proposing the compliance dates described in this unit as required under TSCA section 6(d), EPA considered irreversible health effects associated with TCE exposure. EPA has no reasonably available information indicating that the proposed compliance dates are not practicable for the activities that would be prohibited, or that additional time is needed for products to clear the channels of trade. However, EPA requests comment on whether additional time is needed, for example, for products to clear the channels of trade, or for implementing the use of substitutes; comments should include documentation such as the specific use of the chemical throughout the supply chain; concrete steps taken to identify, test, and qualify substitutes for those uses (including details on the substitutes tested and the specific certifications

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

c. Prohibitions of manufacturing, processing, and distribution in commerce of TCE for consumer use.

The consumer uses evaluated in the 2020 Risk Evaluation for TCE constitute all known, intended, and reasonably foreseen consumer uses of TCE. As described in this unit, EPA is proposing to prohibit all manufacturing (including import) and processing of TCE to address the unreasonable risk to workers and ONUs driven by those conditions of use (Ref. 2). EPA does not believe any delays are necessary for prohibitions on manufacture (including import), processing, or distribution in commerce of TCE for consumer use. EPA notes that not only did all but one of the 24 consumer uses of TCE evaluated in the 2020 Risk Evaluation for TCE support the unreasonable risk determination for TCE (Refs. 1, 2), but also the manufacture (including import) and processing of TCE for consumer uses generally supports EPA's unreasonable risk determination for workers and ONUs, as further discussed in Unit V.A. For these reasons, and based on considerations of the severity of the hazards of TCE, EPA is proposing to prohibit the manufacturing (including import), processing, and distribution in commerce of TCE for all uses, which includes all consumer uses.

EPA is proposing that the compliance dates for the proposed prohibitions described in this unit relevant to consumer uses would come into effect for manufacturers 90 days (3 months) and for processors 180 days (6 months) after the publication date of the final rule in the *Federal Register*. EPA is also proposing prohibitions on distribution in commerce of TCE for consumer

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uses to aid with effective implementation of the prohibitions on manufacturing and processing, and to address the unreasonable risk to consumers and bystanders. EPA proposes that the compliance dates for the proposed prohibition on distribution in commerce of TCE for consumer use would come into effect 180 days (6 months) after the publication date of the rule in the *Federal Register.* EPA considered the risk of irreversible health effects associated with TCE exposure when proposing these compliance dates. EPA has no reasonably available information indicating these proposed compliance dates are not practicable for the activities that would be prohibited or that additional time is needed for products to clear the channels of trade. However, EPA requests comment on whether additional time is needed, for example, for products to clear the channels of trade, or for implementing the use of substitutes; comments should include the considerations described in Unit V.A.1.b. EPA may finalize significantly shorter or longer compliance timeframes based on consideration of public comments.

EPA also requests comment on whether it should consider a *de minimis* level of TCE in formulations to account for impurities (e.g., 0.1% or 0.5%) when finalizing the prohibitions described in this unit, and, if so, information on and rationale for any level that should be considered *de minimis*.

d. Phaseout of TCE for processing as an intermediate for the manufacture of HFC-134a.

As described in this unit, EPA is proposing a longer phaseout timeframe for the manufacturing (including import) and processing of TCE as an intermediate for the manufacture of HFC-134a (1,1,1,2-Tetrafluroethane; CAS Number 811-97-2). EPA is proposing an 8.5-year phaseout subject to the requirements discussed in this unit. All other processing of TCE as a reactant/intermediate would be subject to the proposed prohibitions described in Unit V.A.1.b. EPA is proposing to require a phaseout for processing of TCE as an intermediate for the manufacture of HFC-134a, which EPA expects would begin at the final rule's effective date and

end 8.5 years after the publication of the final rule. Associated with this phaseout, EPA would require the establishment of the TCE WCPP, outlined in Unit V.A.2., within 6 months after publication of the final rule, as workplace protections during the period of the phaseout. To set the phaseout volumes, EPA would require any facility processing TCE as an intermediate to manufacture HFC-134a in the United States to establish a baseline of the annual quantity of TCE processed by the facility as a feedstock to manufacture HFC-134a. EPA is proposing to require that within 6 months after the publication of the final rule the manufacturer could use the average of any 12 consecutive months in the 36 months preceding the publication of the final rule to calculate their baseline, based on records that demonstrate how the baseline annual volume was calculated. Following the establishment of a baseline volume, the regulated entity would then be required to implement a 4-step phaseout process; specifically, the phaseout would be a 25 percent reduction from the baseline volume every 2 years as follows: 1) 2.5 years after the publication of the final rule each manufacturer of HFC-134a who processes TCE as an intermediate would not be permitted to process TCE as an intermediate at an annual volume greater than 75 percent of the baseline; 2) 4.5 years after the publication of the final rule each manufacturer of HFC-134a who processes TCE as an intermediate would not be permitted to process TCE as an intermediate at an annual volume greater than 50 percent of the baseline; 3) 6.5 years after the publication of the final rule each manufacturer of HFC-134a who processes TCE as an intermediate would not be permitted to process TCE as an intermediate at an annual volume greater than 25 percent of the baseline; and 4) 8.5 years after the publication of the final rule each manufacturer of HFC-134a would be prohibited from processing TCE as an intermediate.

EPA notes that the prohibition for manufacture (including importing), processing, and distribution in commerce of TCE for this condition of use would occur after 8.5 years to account

for availability of TCE through the supply chain during the period of the phaseout of processing of TCE as an intermediate for the manufacture of HFC-134a. This timeframe would be longer than the prohibitions on manufacturing and processing TCE described in Unit V.A.1.a.

EPA is also proposing to require regulated entities to keep records of the annual quantity of TCE purchased and processed from the year 2023 until the termination of all processing of TCE as an intermediate. EPA requests comment on whether additional recordkeeping requirements are warranted or additional time would be needed, for example, to begin the phaseout of processing TCE as an intermediate for the manufacture of HFC-134a.

EPA notes, per TSCA section 6(c)(2)(C), that although the use of TCE to produce HFC-134a would be prohibited eventually due to unreasonable risk, the use of PCE to produce HFC-134a is proposed to continue in perpetuity under a WCPP (88 FR 39652, July 16, 2023). As such, the refrigerant would remain available while protecting workers.

e. Phaseout of TCE in industrial and commercial use as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for rocket booster nozzle production.

EPA is proposing a longer phaseout timeframe for industrial and commercial use as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production by Federal agencies and their contractors. This is the industrial and commercial use of TCE in a closed-loop batch vapor degreaser to clean, or 'scour,' rayon fabric to remove sizing (i.e., protective filler or glaze on textiles), oils, and other contaminants from the rayon fabric that is used to line the inside of rocket booster nozzles; the degreasing is essential in preparing the rayon fabric before a carbonization process ahead of being used in the rocket booster nozzles. If contaminants are not removed properly from the rayon, the result could include nozzle failure (Ref. 43). More information on this use and the rationale for the phaseout are in Unit VI.A.1. For this sub-set of the vapor degreasing condition of use, when conducted by

Federal agencies and their contractors, EPA is proposing a 10-year phaseout subject to the requirements discussed in this unit. (All other industrial and commercial use of TCE as a solvent for vapor degreasing, including use of TCE in closed-loop batch vapor degreasing of other parts or materials, would be subject to the proposed prohibitions described in Unit V.A.1.b.). For the phaseout, EPA is proposing that within 5 years of the publication date of the final rule the Federal agency that is the end user of the rayon fabric for rocket booster nozzle production (e.g., the U.S. Department of Defense (DOD) or the NASA) would need to conduct a final pre-launch test of rocket boosters without using TCE; this test is further discussed in Unit VI.A.1.a. By 10 years from the publication date of the final rule, the phaseout would be complete and industrial and commercial use of TCE as a solvent for closed-loop batch vapor degreasing, including for rayon fabric scouring for end use in rocket booster nozzle production by Federal agencies and their contractors, would be prohibited. As part of this phaseout, EPA would require a TCE WCPP, described in Unit V.A.2., within 6 months after publication of the final rule, as workplace protections during the period of the phaseout until the full prohibition takes effect. Additionally, this phaseout would include recordkeeping requirements beginning 6 months after publication of the final rule related to the rayon fabric scouring for end use in rocket booster nozzle production. The entity must have records indicating that their closed-loop batch vapor degreasing with TCE is for rayon fabric scouring for end use in rocket booster nozzle production for a Federal agency or a contractor. Beginning 5 years after the publication of the final rule, to continue to use TCE for closed-loop batch vapor degreasing for this specific use, the user must have records from a Federal agency indicating that a final pre-launch test for the rayon fabric scouring has been conducted with an alternative chemical or process.

f. Prohibition of disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works.

Due to the unreasonable risk to workers exposed to TCE while performing industrial wastewater pre-treatment and treatment, EPA is proposing to prohibit this mode of disposal of TCE (i.e., generated wastewater that contains TCE that is collected on site or transported to a third party site, and includes the mixing of TCE with wastewater and the discharge of TCE-contaminated wastewater) (description of disposal for the purposes of this rulemaking is in Unit III.B.2.d.). TSCA section 6(a) provides EPA the authority to prohibit or otherwise regulate any manner or method of disposal of a chemical substance by its manufacturer, processor, or any other person who uses or disposes of it for commercial purposes. EPA is proposing to prohibit the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works. Facilities generating solid waste with TCE concentrations above the RCRA regulatory level of 0.5 mg/L using the Toxicity Characteristic Leaching Procedure (see 40 CFR 261.24) would need to manage TCE separately from wastewater and dispose of TCE through a different disposal mechanism, due to the prohibition in RCRA against using dilution as a substitute for appropriate treatment (see 40 CFR 268.3), while following the appropriate RCRA requirements when handling waste containing TCE. Dilution of hazardous waste (including by mixing it with wastewater) as a substitution for adequate treatment is prohibited under RCRA (see 40 CFR 268.3).

EPA is proposing that the compliance date for the proposed prohibition described in this unit would be 270 days (9 months) after the publication date of the final rule for manufacturers, processors, distributors, and industrial and commercial users disposing of TCE to wastewater. EPA has no information indicating that the proposed compliance dates would not be practicable for purposes of finding an alternative disposal method, or that additional time would be needed, for example, for facilities to transition to an alternative disposal method. EPA's understanding is that only 1 percent of TCE is disposed of as wastewater. However, EPA requests comment on

whether the 270-day proposed compliance date is practicable, whether additional time is needed, for example, for a regulated entity to implement a change to their disposal processes or to transition to alternative disposal methods, including what those alternative disposal methods would be, and their cost and feasibility. EPA is also proposing, as described in Unit V.A.3., a time-limited exemption for 50 years under TSCA section 6(g) for disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works for the purpose of cleanup projects of TCE-contaminated groundwater and other wastewater.

2. WCPP for certain conditions of use.

a. Overview.

As described in Unit III.B.3., EPA is required to issue a regulation applying one or more of the TSCA section 6(a) requirements to the extent necessary so that the unreasonable risk of injury to health or the environment from a chemical substance is no longer presented. The TSCA section 6(a) requirements provide EPA the authority to limit or restrict a number of activities, alone or in combination, including the manufacture, processing, distribution in commerce, commercial use, and disposal of the chemical substance. Given this authority, EPA may find it appropriate in certain circumstances to propose requirements under a WCPP for certain occupational conditions of use (e.g., manufacturing, processing, industrial and commercial use). However, for the reasons described in Unit VI., including the challenges of reliably reducing exposure below the ECEL and being able to monitor at the appropriate action level, EPA's proposed requirement for the TCE WCPP is that owners or operators ensure that no person is exposed to TCE in excess of the ECEL as an 8-hr TWA to the extent possible (supported by documentation further described in Unit V.A.2.d.i.) rather than (as has been proposed in other rules under TSCA section 6) a requirement that exposures do not exceed the ECEL. Due to these challenges, as well as the severity of the hazard from TCE, EPA notes that long-term

implementation of the WCPP would not be a feasible means of addressing TCE unreasonable risk and thus EPA believes that prohibition of the COUs would ultimately be necessary to address the unreasonable risk. Furthermore, when selecting among proposed prohibitions and other restrictions that would apply to those occupational conditions of use, EPA has also factored in considerations relating to health effects on PESS, including on older pregnant workers and ONUs (the group identified as most susceptible to fetal cardiac defects), further discussed in Units V.A.1. and VI.A. For the time period before which a prohibition would become effective, for several conditions of use, EPA is proposing a TCE WCPP to address to the extent possible the unreasonable risk. The WCPP would include a TCE ECEL of 0.0011 ppm, the associated implementation requirements, and may include other components, such as dermal protection, as described in this unit.

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

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

An ECEL is a risk-based inhalation exposure threshold. The ECEL would be accompanied by monitoring, training, recordkeeping, and other requirements so that exposures to TCE are reduced to the extent possible (as supported by documentation further described in Unit V.A.2.d.i.). With an ECEL, the WCPP provides the least uncertainty regarding the protection afforded to workers, requires regulated entities to consider more protective controls in the hierarchy, and lessens the burden on workers. Under this proposal, regulated entities would have some flexibility in the manner in which they implement modifications, within certain parameters outlined in this unit, or otherwise aim to prevent exceedances of the ECEL at their facilities. Therefore, EPA generally refers to the ECEL and ancillary requirements as a non-prescriptive approach. This unit includes a summary of the proposed TCE WCPP, including a description of the proposed ECEL of 0.0011 ppm; proposed implementation requirements and an EPA ECEL action level; proposed monitoring requirements; a description of potential exposure controls, which consider the hierarchy of controls; information that may be used to inform respirator selection; proposed glove requirements; and additional requirements proposed for recordkeeping, and worker training, participation, and notification. This unit also describes proposed compliance timeframes for these proposed requirements.

EPA does not believe that long-term implementation of the WCPP would be a feasible means of addressing unreasonable risk indefinitely; thus prohibition of the use of TCE for affected COUs is ultimately necessary to address the risk so that it is no longer unreasonable, due to the severity of the hazard, the magnitude of the exposures, and the challenges of consistently reducing exposures below the low TCE ECEL in a way that is consistent with the hierarchy of controls, further described in Unit VI.A.1. However, for the conditions of use which would continue for longer than a year, as well as during the proposed TSCA section 6(g) time-limited exemption, EPA is proposing the WCPP to reduce to the extent possible the unreasonable risk

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from TCE during the time period before compliance dates for the proposed prohibition would come into effect. EPA is not proposing the WCPP for uses that would be prohibited within 1 year from the effective date of the final rule. Based on reasonably available information, EPA expects that the ECEL is likely to be exceeded and that compliance with the WCPP would require large investments into PPE and engineering controls at facilities. For this reason, EPA's proposal aims to encourage facilities engaged in uses that would be prohibited within a year from finalization to focus their resources on the transition to alternatives to TCE. EPA is requesting comment on how entities could demonstrate that they are reducing exposures to the extent possible (including considerations for technological feasibility) and is also requesting comment on whether EPA's requirement should be that entities ensure that exposures are reduced below the ECEL, rather than to the extent possible or lowest achievable level described further in Unit V.A.2.d.i. Should regulated entities be able to consistently demonstrate compliance with an ECEL through effective controls, EPA requests comments regarding replacing the proposed prohibitions with compliance with the WCPP.

b. Existing Chemical Exposure Limit (ECEL).

i. ECEL and ECEL action level.

To reduce exposures in the workplace and eliminate the unreasonable risk of injury to health resulting from inhalation exposures to *TCE* identified under the occupational conditions of use in the TSCA 2020 Risk Evaluation for TCE, EPA is proposing an ECEL of 0.0011 parts per million (ppm) (0.0059 mg/m^3) for inhalation exposures to *TCE* as an 8-hour TWA. As described in Unit IV.A., this ECEL is based on developmental toxicity, the most sensitive acute and chronic non-cancer health endpoint, specifically calculated based on the occupational acute, non-cancer human equivalent concentration (HEC) for fetal cardiac defects (Ref. 13). EPA is proposing to establish requirements for an ECEL as part of the WCPP until the prohibition

compliance date for certain conditions of use that would be permitted to continue for longer than a year after the effective date of the final rule, including the conditions of use described in Unit V.A.1.a., as well as the conditions of use that would be subject to the phaseout described in Unit V.A.1.d. and the TSCA section 6(g) exemptions described in Unit V.A.3.

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

In order for this rulemaking to appropriately reduce risk to all potentially exposed persons that may be exposed to TCE through the occupational conditions of use for which EPA is proposing compliance with the WCPP as a protection measure, EPA has factored in consideration of additional health effects applicable to PESS pursuant to TSCA section 6(c)(2), outlined in Unit VI.A. EPA developed the ECEL for the most sensitive health endpoint (fetal cardiac defects) in support of risk management efforts on TCE under TSCA, to identify at what level ambient exposures would protect against unreasonable risk of injury to health due to fetal cardiac defects. The level identified is an 8-hour ECEL of 0.0011 ppm, which, when possible to achieve, is the concentration at which an adult human would be unlikely to experience the specified adverse effects if exposed during a working lifetime, including susceptible subpopulations. In addition, at the acute non-cancer ECEL of 0.0011 ppm, any potentially exposed person in the workplace would be protected against other non-cancer effects resulting from occupational exposures, as well as excess risk of cancer (Ref. 13). However, as noted in Unit IV., EPA does not believe that long-term implementation of the WCPP with this low ECEL would be a feasible means of addressing unreasonable risk indefinitely, and EPA is uncertain if

the ECEL and associated action level can be met reliably as discussed further in Unit VI.A.1.

EPA invites comment on the existing practices (e.g., engineering controls, administrative controls, PPE) involving TCE for the conditions of use listed in Unit V.A.1.a., Unit V.A.1.d., and Unit V.A.3., whether activities may take place in closed systems, and the degree to which users of TCE in these sectors could successfully implement the WCPP, including an ECEL of 0.0011 ppm for TCE, dermal protection, and ancillary requirements described in Unit IV.A. EPA acknowledges that reducing and accurately detecting exposures from the current OSHA PEL of 100 ppm to the proposed TSCA ECEL of 0.0011 ppm would be very difficult. EPA also invites comment on the potential to develop future technologies (e.g., engineering controls, administrative controls, PPE) involving TCE for the conditions of use listed in Unit V.A.1.a., Unit V.A.1.d., and Unit V.A.3., that would facilitate successful implementation of the WCPP, including an ECEL of 0.0011 ppm for TCE, dermal protection, and ancillary requirements described in Unit IV.A. EPA is also requesting comment on the feasibility of controlling worker exposures to TCE at or below the proposed ECEL, and the accuracy of measurements at this level. This is important for determining whether there are realistic and effective exposure controls that can be used by industry for effectively controlling exposures to levels at or below the ECEL. To the extent time is needed to ensure methods are available to accurately measure TCE at or below the ECEL, EPA is requesting comment on whether a phased approach to an ECEL is desirable; that is, an approach that would establish a timeframe for meeting the ECEL as well as a shorter timeframe for meeting a concentration level higher than the ECEL (but lower than the PEL) that is currently considered achievable. EPA welcomes data or information to demonstrate that meeting the proposed ECEL over a sustained period of time would be feasible and measurable.

EPA is also proposing to establish an ECEL action level of 0.00055 ppm as an 8-hour

TWA for *TCE*. Air concentrations at or above the action level would trigger more frequent periodic monitoring of exposures to *TCE*, as described in this unit. EPA is proposing to adopt the action level approach in implementing the TSCA ECEL, similar to the action level approach used by OSHA in the implementation of OSHA standards, although the values differ due to differing statutory authorities. As explained by OSHA, due to the variable nature of employee exposures, compliance with an action level provides employers with greater assurance that their employees will not be exposed to concentrations above the PELs (Ref. 44). EPA agrees with this reasoning and, like OSHA, expects the inclusion of an ECEL action level will stimulate innovation within industry to reduce exposures to levels below the action level. Therefore, EPA has identified a need for an action level for *TCE and is proposing a level that would be half the 8-hour ECEL, which* is in alignment with the precedented approach established under most OSHA standards. EPA is soliciting comment regarding an ECEL action level that is half the ECEL and any associated provisions related to the ECEL action level when the ECEL is significantly lower than the OSHA PEL. EPA is also soliciting comment on whether the ECEL action level should be aligned with OSHA PEL action levels (typically set at half the limit) due to the fact that PEL accounts for technological feasibility and the action level is not necessarily designed to be health protective. Since exposure below the ECEL would be health protective, EPA seeks comment on whether the action level should be set at a different value closer to the ECEL that would trigger increased monitoring to ensure that the ECEL is not exceeded, and whether technological feasibility should be considered in setting the action level.

In summary, EPA is proposing that each owner or operator of a workplace subject to compliance with the TCE WCPP must ensure that no person is exposed to an airborne concentration of *TCE* in excess of 0.0011 ppm (0.0059 mg/m3) as an 8-hour TWA (ECEL), with an action level identified as 0.00055 ppm (0.0029 mg/m3) (ECEL action level) to the extent

possible, as supported by documentation further described in Unit V.A.2.d.i.). For conditions of use for which the requirements to comply with the WCPP are being proposed, EPA expects that measurement of extremely low-ppm levels of TCE may present challenges to the regulated community. During the development of the TCE ECEL, EPA conducted a search to identify relevant NIOSH, OSHA, and EPA analytical methods that may be used to monitor for the presence of TCE in indoor air. While EPA identified analytical methods that may be used, based on information from stakeholders, EPA also recognizes that it may be difficult to operationalize routine use of these methods for detection at the low levels needed for the TCE ECEL and ECEL action level. Specifically, these methods may be challenging to use for personal breathing zone monitoring to detect lower air concentration levels at the ECEL and ECEL action level based on the developmental toxicity endpoint for fetal cardiac defects (Ref. 13). However, EPA acknowledges that in recent years commercial passive air sampling devices have improved and may be available for use for personal air sampling at extremely low-ppm levels of TCE (Ref. 45). EPA is requesting comment on personal air sampling devices that are capable of detecting indoor air TCE concentrations at or below the ECEL action level of 0.00055 ppm (0.0029mg/m3) with the requisite precision and accuracy.

EPA acknowledges that the challenge of suitable personal breathing zone monitoring methods to detect TCE air concentration levels at the ECEL of 0.0011 ppm and ECEL action level of 0.00055 ppm could cause difficulty in determining whether a workplace is in compliance with the ECEL. EPA is therefore requesting comment on whether to require compliance with an interim exposure level based on the limit of detection of established analytical methods. This interim level, unlike the ECEL, would not necessarily eliminate unreasonable risk, but rather reduce risk to an extent that corresponds to the air concentration that current analytical methods can reliably measure to and would be the exposure limit during the period in which TCE is still

in use until its eventual prohibition. EPA requests comment on setting such an interim level for TCE based on a limit of detection that is the lowest limit of detection using analytical methods developed by OSHA/NIOSH for personal breathing zone monitoring. More specifically, EPA requests comment on using OSHA Method 1001, which has a personal breathing zone limit of detection for TCE of 18 ppb, or 0.018 ppm, to set an interim exposure limit of 0.036 ppm, with an action level of 0.018 ppm (Ref. 46).

Under this approach, EPA would initially establish an exposure value that would be technically feasible to detect in the near-term, with a step down to the ECEL at a later date, until the applicable prohibition would take effect. This approach would significantly reduce exposures to TCE from the current OSHA PEL of 100 ppm by establishing an interim exposure value of 0.036 ppm and action level of 0.018 ppm, until advancements in technologies reliably support measurement at the ECEL or below. EPA requests comments that provide supported recommendations for one or more incremental exposure values and associated timelines for achieving the incremental exposure levels and the currently proposed ECEL of 0.0011 ppm, and comments that consider and provide information on the needed advancements in exposure monitoring methods, analytical methods, and exposure controls, including expected timelines for developing these capabilities.

The proposed requirements would be applicable to owners and operators of workplaces where manufacturing (including import), processing, and industrial and commercial use of TCE would be permitted to continue more than 1 year after the publication of the final rule. The proposed requirements would be applicable from the date of publication of the final rule until the prohibition compliance date for those conditions of use. However, the proposed requirements of the WCPP would not be applicable to owners and operators of workplaces where EPA is proposing to prohibit manufacturing and processing for certain industrial and commercial use

and consumer uses within 1 year of the effective date of the final rule. The WCPP would also not be applicable to owners and operators of workplaces where EPA is proposing to prohibit distribution in commerce or disposal to industrial pre-treatment, industrial treatment, or publicly owned treatment works.

As described further in Unit VI.A.1., EPA believes that long-term implementation of the WCPP for continued use of TCE is not a feasible means of addressing unreasonable risk such that prohibition ultimately would be necessary to address the unreasonable risk.

ii. Monitoring requirements.

Overview. Monitoring requirements are a key component of implementing EPA's proposed WCPP. Initial monitoring for TCE would be critical for establishing a baseline of exposure for potentially exposed persons and for identifying the lowest achievable exposure level in a facility; similarly, periodic exposure monitoring would assure that exposures continue to be reduced to the lowest level achievable so that unreasonable risk of injury is reduced for potentially exposed persons in the workplace. Periodic exposure monitoring frequency could change if certain conditions are met, which are described in this unit. Additionally, in some cases, a change in workplace conditions with the potential to impact exposure levels would warrant additional monitoring, which is also described. To ensure compliance with monitoring activities, EPA proposes exposure monitoring recordkeeping requirements outlined in this unit.

Initial exposure monitoring. Under the proposed regulation, each owner or operator of a workplace where any condition of use subject to a WCPP is occurring would be required to perform initial exposure monitoring to determine the extent of exposure of potentially exposed persons to TCE. Initial monitoring would notify owner or operators of the magnitude of possible exposures, to their potentially exposed persons with respect to their unique work conditions and environments. The results of the initial exposure monitoring would be used to help determine the

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lowest achievable level in a facility, the frequency of future periodic monitoring, whether additional exposure controls are necessary (such as engineering controls, administrative controls, and/or respiratory protection), and whether the owner or operator would need to demarcate a regulated area as described in this unit.

EPA is proposing to require each owner or operator to establish an initial baseline monitoring sample to determine the magnitude of exposure for all persons who may be exposed to TCE within 180 days (6 months) after the date of publication of the final rule in the *Federal Register*. Where TCE is present in the workplace, each owner or operator would be required to determine each potentially exposed person's exposure by either taking a personal breathing zone air sample of each potentially exposed person or taking personal breathing zone air samples that are representative of each potentially exposed person's exposure performing the same or substantially similar operations in each work shift, in each job classification, and in each work area (hereinafter identified as an "exposure group"). Representative 8-hour TWA exposures must be determined based on one or more samples representing full-shift exposures for each shift for each person in each job classification in each work area. Monitoring samples must be taken when and where the operating conditions are best representative of each potentially exposed person's full-shift exposures, and also must represent the highest TCE exposures likely to occur under reasonably foreseeable conditions of use. EPA expects that owners and operators would attempt to monitor a baseline for all of the tasks during the same timeframe; however, EPA understands that certain tasks occur less frequently, and EPA is soliciting comments regarding the timing of the initial exposure monitoring so that it would be representative of all tasks involving TCE where exposures may approach the ECEL. If the owner or operator chooses a representative sample, such sampling must include persons that are the closest to the source of TCE, so that the monitoring results are representative of the most highly exposed persons in the workplace. EPA

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is also soliciting comments regarding use of area source monitoring instead of personal breathing zone as a representative sample of exposures.

EPA also recognizes that some entities may already have exposure monitoring data. If the owner or operator has monitoring data conducted within five years prior to the effective date of the final rule and the monitoring would satisfy the monitoring requirements described in this unit, including the requirement that the data represent the highest TCE 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.

EPA proposes to require each owner or operator to perform exposure monitoring to identify the lowest achievable exposure level in relation to the ECEL value, and ensure to the extent possible (supported by documentation further described in Unit V.A.2.d.i) that no person is exposed to an airborne concentration of TCE in exceedance of the ECEL. EPA requests comment on how owners and operators should identify the lowest achievable exposure level, what documentation would be needed to support that further reductions are not possible, and whether EPA should provide a definition of meeting the ECEL to the extent possible. Additionally, EPA requests comment on whether current monitoring methods (Ref. 13) are able to detect airborne concentrations at the ECEL and action level values. EPA expects that detection and adherence to extremely low-ppm levels of TCE may present challenges to some in the regulated community; therefore, EPA is also requesting comment on whether EPA should propose specific requirements following results indicating non-detectable concentrations of TCE (non-detects), or a requirement that a specific monitoring method be used.

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

• If all samples taken during the initial exposure monitoring reveal a concentration below the ECEL action level (0.00055 ppm 8-hour TWA), the owner or operator must repeat the periodic exposure monitoring at least once every five years.

• If the initial or most recent exposure monitoring indicates that airborne exposure is above the ECEL (0.0011 ppm 8-hour TWA), the owner or operator must repeat the periodic exposure monitoring within 3 months of the most recent exposure monitoring.

• If the most recent exposure monitoring indicates that airborne exposure is at or above the ECEL action level (0.00055 ppm 8-hour TWA) but at or below the ECEL (0.0011 ppm 8-hour TWA), the owner or operator must repeat the periodic exposure monitoring within 6 months of the most recent exposure monitoring.

• If the most recent (non-initial) exposure monitoring indicates that airborne exposure is below the ECEL action level, the owners or operators must repeat such monitoring within 6 months of the most recent monitoring until two consecutive monitoring measurements taken at least seven days apart, are below the ECEL action level (0.00055 ppm 8-hour TWA), at which time the owner or operator must repeat the periodic exposure monitoring at least once every 5 years.

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

The proposed periodic monitoring requirements are also outlined in Table 1. EPA

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requests comment on the timeframes for periodic monitoring outlined in this unit. EPA may finalize significantly shorter or longer compliance timeframes based on consideration of public comments. EPA requests comment on the ability for a facility to perform the proposed periodic monitoring requirements, specifically whether monitoring methods can detect the ECEL action level and ECEL value.

Table 1 – Periodic Monitoring Requirements

Air Concentration Condition	Periodic Monitoring Requirement
If all initial exposure monitoring is below the ECEL action level (< 0.00055 ppm 8-hour TWA)	Periodic exposure monitoring is required at least once every 5 years.
If the initial or most recent exposure monitoring indicates that airborne exposure is above the ECEL (> 0.0011 ppm 8- hour TWA)	Periodic exposure monitoring is required within 3 months of the most recent exposure monitoring.
If the initial or most recent exposure monitoring indicates that airborne exposure is at or above the ECEL action level but at or below the ECEL (≥ 0.55 ppb 8- hour TWA, ≤ 0.0011 ppm 8- hour TWA)	Periodic exposure monitoring is required within 6 months of the most recent exposure monitoring.
If the two most recent (non-initial) exposure monitoring measurements, taken at least seven days apart within a 6-month period, indicate that airborne exposure is below the ECEL action level (< 0.00055 ppm 8- hour TWA)	Periodic exposure monitoring is required within 5 years of the most recent exposure monitoring.
If the owner or operator engages in a condition of use for which compliance with the WCPP would be required but does not manufacture, process, use, or dispose of TCE in that condition of use over the entirety of time since the last required monitoring event	The owner or operator may forgo its current periodic monitoring event. However, documentation of cessation of use of TCE as well as periodic monitoring would be required when the owner or operator resumes or starts any of the conditions of use for which compliance with the WCPP is proposed.

Additional exposure monitoring. In addition to the initial and periodic exposure monitoring, EPA is proposing that each owner or operator conduct additional exposure monitoring whenever a change in the production, process, control equipment, personnel, or work

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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. In the event of start-up, shutdown, spills, leaks, ruptures or other breakdowns that may lead to employee exposure, EPA is proposing that each owner or operator must conduct additional initial exposure monitoring to potentially exposed persons (using personal breathing zone sampling) after the cleanup of the spill or repair of the leak, rupture or other breakdown. An additional exposure monitoring event may result in an increased frequency of periodic monitoring. For example, if the initial monitoring results from a workplace are above the ECEL action level, but below the ECEL, periodic monitoring is required every 6 months. If additional monitoring is performed because increased exposures are suspected, and the results are above the ECEL, subsequent periodic monitoring would have to be performed every 3 months. The required additional exposure monitoring should not delay implementation of any necessary cleanup or other remedial action to reduce the exposures to persons in the workplace.

Other monitoring requirements. For each monitoring event, EPA is proposing to require owners or operators ensure that their methods be accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of *TCE*. Also, EPA is proposing to require use of appropriate sampling and analytical methods used to determine *TCE* exposure, including as relevant: (A) Use of an analytical method already approved by EPA, OSHA or NIOSH, or another analytical method that has been demonstrated to meet the proposed accuracy requirement at an appropriate limit of detection for the ECEL and ECEL action level; (B) Compliance with the Good Laboratory Practice Standards at 40 CFR part 792. Additionally, EPA is proposing to require owners and operators to re-monitor within 15 working days after receipt of the results of any exposure monitoring when results indicate non-detect or air

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monitoring equipment malfunction, unless an Environmental Professional as defined at 40 CFR 312.10 or a Certified Industrial Hygienist reviews the monitoring results and determines re-monitoring is not necessary.

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

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

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

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

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

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

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

iii. Incorporation of the hierarchy of controls.

EPA is proposing to require owners or operators to implement the WCPP in accordance with the hierarchy of controls and encourages the use of pollution prevention to control exposures whenever practicable. Pollution prevention, also known as source reduction, is any practice that reduces, eliminates, or prevents pollution at its source (e.g., elimination and

substitution). Similarly, the hierarchy of controls includes, in order of preference, elimination, substitution, engineering controls, and administrative controls, prior to relying on PPE as a means of controlling exposures (Ref. 12). EPA is proposing to require owners or operators to reduce inhalation exposures below the ECEL in accordance with the hierarchy of controls to the extent possible as supported by documentation further described in Unit V.A.2.d.i.). EPA expects that, for conditions of use for which EPA is proposing a WCPP as a protection measure, compliance at most workplaces would be part of an existing industrial hygiene program. Workplaces would have to institute one or a combination of elimination, substitution, engineering controls, or administrative controls to reduce exposures to the extent feasible (Ref. 12). If an owner or operator chooses to replace TCE with a substitute, EPA recommends that they carefully review the available hazard and exposure information on the potential substitutes to avoid a regrettable substitution.

If an effort to identify and implement feasible exposure controls, in accordance with the hierarchy of controls, such as elimination, substitution, engineering controls, and administrative controls is found not to be sufficient to reduce exposures to or below the ECEL for all persons in the workplace, EPA proposes to require each owner or operator to use such controls to reduce TCE concentrations in the workplace to the lowest levels achievable and, only after levels cannot be further reduced, supplement these controls using respiratory protection before persons are permitted to enter a regulated area, as described in this unit. In such cases, EPA would require that the owner or operator provide those persons exposed or who may be exposed to TCE by inhalation above the ECEL with respirators so that exposures can be reduced to the extent possible (supported by documentation further described in Unit V.A.2.d.i.). EPA also proposes to require that each owner or operator document their evaluation of elimination, substitution, engineering and administrative exposure control strategies and, if applicable, the reasons why

they found these strategies infeasible to control exposures below the ECEL, in an exposure control plan as described in this unit. In addition, a regulated entity would be prohibited from rotating work schedules of potentially exposed persons to comply with the ECEL 8-hour TWA. EPA may require more, less, or different documentation regarding exposure control strategies in the final rule based on consideration of public comments. The Agency understands that certain engineering controls can reduce exposures to people inside the workplace but may lead to increased ventilation of TCE outside of the workplace, thereby potentially increasing risks of adverse health effects from exposures to TCE in ambient air to people in fenceline communities. EPA expects that processing and commercial use of TCE for the conditions of use for which the WCPP would apply will decrease ahead of the prohibition compliance dates (Ref. 3) and therefore expects that any risks to fenceline communities would also decrease. More information on EPA's analysis of ambient air and water pathways is in Unit VII.A. To understand more fully the potential impacts to fenceline communities of requirements to reduce workplace exposure to TCE, EPA is requesting comment on whether industry anticipates increased releases of TCE to outdoor air associated with the implementation of the WCPP. In order to avoid unintended increases in exposures to people from TCE emissions to ambient air, EPA requests comment on whether owners and operators should be required to attest in their exposure control plan that engineering controls selected do not increase emissions of TCE to ambient air outside of the workplace and document in their exposure control plan whether additional equipment was installed to capture emissions of TCE to ambient air. EPA requests comment on how such a requirement could impact the availability, feasibility, or cost of engineering controls as a means to reduce workplace exposures to or below the proposed ECEL.

iv. Regulated area.

Based on the exposure monitoring, EPA is proposing to require that owners or operators

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of workplaces subject to a WCPP as a protection measure demarcate any area where airborne concentrations of TCE exceed or are reasonably expected to exceed the ECEL. Regulated areas would be demarcated using administrative controls, such as warning signs or highly visible signifiers, in multiple languages as appropriate (e.g., based on languages spoken by potentially exposed persons), placed in conspicuous areas, and documented through training and recordkeeping. The owner or operator would be required to restrict access to the regulated area from anyone who is not an authorized user, which includes any potentially exposed person that lacks proper training, is not wearing required PPE as described in this unit or is otherwise unauthorized to enter. EPA is proposing to require owners and operators demarcate a regulated area, beginning 9 months after the date of publication of the final rule, or within 3 months after receipt of any exposure monitoring that indicates exposures exceeding the ECEL. EPA is soliciting comment on requiring warning signs to demarcate regulated areas, such as the requirements found in OSHA's General Industry Standard for Beryllium (29 CFR 1910.1024(m)(2)). EPA is also requesting comment on whether the owner or operator should be required to permit designated representatives of employees and other workers to enter regulated areas to observe exposure monitoring similar to typical OSHA Standard requirements, e.g., 29 CFR 1910.1024(d)(7).

v. Notification of monitoring results.

EPA proposes that the owner or operator must, within 15 working days after receipt of the results of any exposure monitoring, notify each person whose exposure is represented by that monitoring in writing, either individually to each potentially exposed person or by posting the information in an appropriate and accessible location, such as public spaces or common areas, outside the regulated area. This notice must include the exposure monitoring results, identification and explanation of the ECEL and ECEL action level in plain language,

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identification of the lowest achievable exposure level, if applicable, any corresponding required respiratory protection, if applicable, the quantity, location, manner of TCE use and identified releases of TCE that could result in exposure to TCE, and whether the airborne concentration of TCE exceeds the ECEL. The notice must also include a description of actions taken by the owner or operator to reduce inhalation exposures to or below the ECEL, if applicable, or refer to a document available to the potentially exposed persons which states the actions to be taken to reduce exposures. The notice would be required to be posted in multiple languages if necessary (e.g., notice must be in a language that the potentially exposed person understands, including a non-English language version representing the language of the largest group of workers who cannot readily comprehend or read English).

c. Personal Protective Equipment (PPE) program.

Where elimination, substitution, engineering controls, and administrative controls are not feasible to reduce the air concentration to or below the ECEL for all potentially exposed persons, EPA is proposing to require implementation of a PPE program in alignment with OSHA's General Requirements for Personal Protective Equipment at 29 CFR 1910.132. Consistent with 29 CFR 1910.132, owners and operators would be required to provide PPE, including respiratory protection and dermal protection selected in accordance with the guidelines described in this unit, that is of safe design and construction for the work to be performed. EPA is proposing to require owners and operators ensure each potentially exposed person who is required by this unit to wear PPE to use and maintain PPE in a sanitary, reliable, and undamaged condition. Owners and operators would be required to select and provide PPE that properly fits each potentially exposed person who is required by this unit to use PPE and communicate PPE selections to each affected person.

As part of the PPE program, EPA is also proposing that owners and operators must

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

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

i. Respiratory protection.

Where elimination, substitution, engineering and administrative controls are not feasible to reduce the air concentration to or below the ECEL, EPA proposes to set minimum respiratory PPE requirements based on an entity's most recent measured air concentration and the level of PPE that EPA determined would be needed to reduce exposure to the ECEL. In those circumstances, EPA is proposing to require a respiratory protection PPE program with worksite-specific procedures and elements for required respirator use. The respiratory protection PPE program proposed by EPA would be based on the most recent exposure monitoring concentration measured as an 8-hour TWA and would be administered by a suitably trained program administrator. EPA is also proposing to require each owner or operator select

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respiratory protection in accordance with the guidelines described in this unit and 29 CFR 1910.134(a) through (l), except (d)(1)(iii), for proper respirator use, maintenance, fit-testing, medical evaluation, and training. EPA is not proposing to cross reference 29 CFR 1910.134(d)(1)(iii) because the WCPP contains requirements for identifying TCE respiratory hazards in the workplace.

Required Respiratory Protection. EPA is proposing to require each owner or operator supply a respirator, selected in accordance with this unit, to each person who enters a regulated area within 3 months after the receipt of any exposure monitoring that indicates exposures exceeding the ECEL and thereafter must ensure that all persons within the regulated area are using the provided respirators whenever TCE exposures exceed or can reasonably be expected to exceed the ECEL. Given the risks associated with TCE exposure above the ECEL, prompt compliance with the respiratory protection requirements is important, but EPA expects that most owners or operators will need some time after the exposure monitoring results are received to acquire the correct respirators and establish a respiratory protection program, including training, fit-testing, and medical evaluations. While EPA believes that 3 months should be sufficient for this purpose, EPA is seeking comment on whether this timeframe should be shorter (e.g., within two weeks after the receipt of any exposure monitoring that indicates exposure exceeding the ECEL), given the severity of the effect. EPA is also proposing that owners or operators who would be required to administer a respiratory protection program must supply a respirator selected in accordance with 29 CFR 1910.134(d)(1) (except (d)(1)(iii)). Additionally, EPA is proposing that the owner or operator must ensure that all filters, cartridges, and canisters used in the workplace are labeled and color coded with the NIOSH approval label and that the label is not removed and remains legible. 29 CFR 1910.134(d)(3)(iii), which EPA is proposing to cross-reference, requires either the use of respirators with an end-of-life service indicator certified by

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NIOSH for the contaminant, in this case TCE, or implementation of a change schedule for canisters and cartridges that ensures that they are changed before the end of their service life. EPA is requesting comment on whether there should be a requirement to replace cartridges or canisters after a certain number of hours, such as the requirements found in OSHA's General Industry Standard for 1,3-Butadiene (29 CFR 1910.1051(h)), or a requirement for a minimum service life of non-powered air-purifying respirators such as the requirements found in OSHA's General Industry Standard for Benzene (29 CFR 1910.1028(g)(3)(D)).

EPA is proposing the following requirements for respiratory protection, based on the exposure monitoring concentrations measured as an 8-hour TWA that exceed the ECEL (0.0011 ppm). EPA is proposing to establish minimum respiratory protection requirements, such that any respirator affording a higher degree of protection than the following proposed requirements may be used. This unit includes respirator selection requirements for respirators of assigned protection factors (APFs) of 1,000 or greater.

• If the measured exposure concentration is at or below 0.0011 ppm (1.1 ppb): no respiratory protection is required.

• If the measured exposure concentration is above 0.0011 ppm (1.1 ppb) and less than or equal to 0.0055 ppm (5.5 ppb) (5 times ECEL): Any NIOSH-certified air-purifying quarter mask respirator (APF 5).

• If the measured exposure concentration is above 0. 0055 ppm (5.5 ppb) and less than or equal to 0.011 ppm (11.0 ppb) (10 times ECEL): Any NIOSH-certified air-purifying half mask or full facepiece respirator equipped with NIOSH-approved organic vapor cartridges or canisters; or any negative pressure (demand mode) supplied air respirator equipped with a half mask (APF 10).

• If the measured exposure concentration is above 0.0011 ppm (1.1 ppb) and less than or

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equal to 0.0275 ppm (27.5 ppb) (25 times ECEL): Any NIOSH-certified air-purifying full facepiece respirator equipped with NIOSH-approved organic vapor cartridges or canisters; any NIOSH-certified powered air-purifying respirator equipped with NIOSH-approved organic vapor cartridges; or any NIOSH-certified continuous flow supplied air respirator equipped with a hood or helmet (APF 25).

• If the measured exposure concentration is above 0.0275 ppm (27.5 ppb and less than or equal to 0.055 ppm (55.0 ppb) (50 times ECEL): Any NIOSH-certified air-purifying full facepiece respirator equipped with NIOSH-approved organic vapor cartridges or canisters; any NIOSH-certified powered air-purifying respirator equipped with a tight-fitting half facepiece and NIOSH-approved organic vapor cartridges or canisters; any NIOSH-certified negative pressure (demand mode) supplied-air respirator equipped with a full facepiece; any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting half facepiece; any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a tight-fitting half facepiece; or any NIOSH-certified negative pressure (demand mode) self-contained breathing apparatus respirator equipped with a full facepiece (APF 50).

• If the measured exposure concentration is above 0.055 ppm (55.0 ppb) and less than or equal to 1.1 ppm (1,100 ppb) (1,000 times ECEL): Any NIOSH-certified powered air-purifying respirator equipped with a full facepiece and NIOSH-approved organic vapor cartridges or canisters; or any NIOSH-certified supplied air respirator equipped with a full facepiece and operated in a continuous flow mode or pressure demand or other positive pressure mode (APF 1,000).

• If the measured exposure concentration is greater than 1.1 ppm (1,100 ppb) (1,000 times ECEL) or the concentration is unknown: Any NIOSH-certified self-contained breathing apparatus (SCBA) equipped with a full facepiece and operated in a pressure demand or other

positive pressure mode; or any NIOSH-certified supplied air respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode in combination with an auxiliary SCBA operated in a pressure demand or other positive pressure mode (APF 10,000).

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

ii. Dermal protection.

EPA is proposing to require use and provision of chemically resistant gloves by potentially exposed persons in combination with specific activity training (e.g., glove selection (type, material), expected duration of glove effectiveness, actions to take when glove integrity is compromised, storage requirements, procedure for glove removal and disposal, chemical hazards) for tasks where dermal exposure can be expected to occur. EPA is proposing that owners and operators must also consider other glove factors, such as compatibility of multiple chemicals used simultaneously while wearing TCE-resistant gloves or with glove liners, permeation, degree of dexterity required to perform a task, and temperature, as identified in the Hand Protection section of OSHA's Personal Protection Equipment Guidance (Ref. 47), when selecting appropriate PPE. Furthermore, owners and operators can select gloves that have been tested in accordance with the American Society for Testing Material (ASTM) F739 "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under

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Conditions of Continuous Contact." EPA requests comment on the degree to which additional guidance related to use of gloves might be necessary. Additionally, EPA requests comment on whether EPA should incorporate additional dermal protection requirements into the exposure control plan or require consideration of the hierarchy of controls for dermal exposures.

d. General WCPP requirements.

i. Exposure control plan.

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

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

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

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

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

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

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(F) Identification of the lowest achievable exposure level and why further reductions are not possible;

(G) Regular inspections, evaluations, and updating of the exposure controls to ensure effectiveness and confirmation that all persons are implementing them as required;

(H) Occurrence and duration of any start-up, shutdown, or malfunction of the facility that causes air concentrations to be above the ECEL or lowest achievable exposure level and subsequent corrective actions taken during start-up, shutdown, or malfunctions to mitigate exposures to TCE; and

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

ii. Workplace information and training.

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

As part of the training and information program, the owner or operator would be required to provide information and comprehensive training in an understandable manner (i.e., plain language) and in multiple language as appropriate (e.g., based on languages spoken by potentially exposed persons) to potentially exposed persons prior to or at the time of initial assignment to a job involving potential exposure to TCE. In alignment with the OSHA Hazard Communication Standard, owners and operators would be required to provide information and

training to all potentially exposed persons that includes (A) the requirements of the TCE WCPP and how to access or obtain a copy of the requirements of the WCPP; (B) the quantity, location, manner of use, release, and storage of TCE and the specific operations in the workplace that could result in TCE exposure; (C) principles of safe use and handling of TCE in the workplace, including specific measures the owner or operator has implemented to reduce inhalation exposures or prevent dermal contact with TCE, such as work practices and PPE used; (D) the methods and observations that may be used to detect the presence or release of TCE in the workplace (such as monitoring conducted by the owner or operator, continuous monitoring devices, visual appearance or odor of TCE when being released, etc.); and (E) the health hazards associated with exposure to TCE.

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

iii. Workplace participation.

EPA encourages owners or operators to consult with persons that have potential for exposure on the development and implementation of exposure control plans and PPE/respirator

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programs. EPA is proposing to require owners or operators to provide potentially exposed persons or their designated representatives regular access to the exposure control plans, exposure monitoring records, and PPE program implementation and documentation. To ensure compliance in workplace participation, EPA is proposing that the owner or operator document the notice to and ability of any potentially exposed person that may reasonably be affected by *TCE* inhalation exposure or dermal contact with TCE to readily access the exposure control plans, facility exposure monitoring records, PPE program implementation, or any other information relevant to *TCE* inhalation or dermal exposure in the workplace. EPA is requesting comment on how owners and operators can engage with potentially exposed persons on the development and implementation of an exposure control plan and PPE program.

iv. Recordkeeping.

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

(A) the exposure control plan;

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

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

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

(D) The exposure monitoring records;

(E) Notification of exposure monitoring results; and

(F) To the extent that the owner or operator relies on prior exposure monitoring data,

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records that demonstrates that it meets all of the proposed WCPP requirements.

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

v. Compliance timeframes.

EPA is proposing to require each owner or operator of a workplace subject to an ECEL conduct initial baseline monitoring according to the process outlined in this unit by 6 months after date of publication of the final rule in the *Federal Register*. EPA is proposing to require each owner or operator ensure that the airborne concentration of TCE does not exceed the ECEL or lowest achievable exposure level for all potentially exposed persons within 9 months after the date of publication of the final rule in the *Federal Register*, and 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 3 months after receipt of the results of any exposure monitoring that indicates exposures exceeding the ECEL or, if using monitoring data conducted within five years prior to the effective date of the final rule that satisfies all other requirements of the proposed WCPP, within 9 months after the date of publication of the final rule in the *Federal Register*. EPA is also proposing to require owners and operators demarcate a regulated area within 3 months after receipt of any exposure monitoring that indicates exposures exceeding the ECEL. Regulated entities should then proceed accordingly to implement an exposure control plan within 12 months after date of publication of the final rule in the *Federal Register*. EPA requests comment relative to the ability of owners or operators to conduct initial monitoring within 6 months after date of publication of the final rule in the *Federal Register*, and anticipated timeframes for any procedural adjustments (i.e., use of

new technologies for personal breathing zone monitoring at extremely low-ppm levels of TCE) needed to comply with the requirements outlined in this unit, including establishment of a respiratory protection program and development of an exposure control plan.

EPA understands that the regulated community may have difficulty measuring at or below the ECEL consistently over an entire work shift. Therefore, EPA is requesting comment regarding the amount of time, if any, it would take the regulated community to develop a method to measure at or below the ECEL over an entire work shift. EPA is interested in what levels of detection are possible based on existing monitoring methods, justification for the timeframe of the specific steps needed to develop a more sensitive monitoring method, and any additional detailed information related to establishing a monitoring program to reliably measure TCE at or below the ECEL.

With regard to the compliance timeframe for those occupational conditions of use which are subject to dermal protection requirements, EPA is proposing to require each owner or operator of a workplace subject to dermal protection requirements to establish dermal protection outlined in this unit by 6 months after publication of the final rule in the *Federal Register*. EPA requests comment relative to the ability of owners or operators to implement dermal protection within 6 months of publication of the final rule in the *Federal Register*, and anticipated timeframes for any procedural adjustments needed to comply with the requirements outlined in this unit. EPA may finalize shorter or longer compliance timeframes based on consideration of public comments.

3. TSCA section 6(g) exemptions.

Under TSCA section 6(g)(1), EPA may grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture if the Agency makes one of three findings. TSCA section 6(g)(1)(A) permits such an exemption if the

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specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available. Under TSCA section 6(g)(1)(B), EPA must find that compliance with the requirement would significantly disrupt the national economy, national security, or critical infrastructure to provide an exemption. Finally, TSCA section 6(g)(1)(C) allows for an exemption based on an EPA finding that the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety. Based on discussions and information provided by industry stakeholders and consultation with DOD and NASA, EPA has analyzed the need for several different exemptions and is proposing to grant six. This unit presents the results of that analysis.

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

a. Analysis of the need for TSCA section 6(g)(1) exemptions for uses of TCE that are critical or essential.

i. Analysis of the need for a TSCA section 6(g)(1)(B) exemption for industrial and commercial use of TCE as a processing aid for battery separator manufacturing (lead-acid and lithium battery separators).

As part of industry stakeholder engagement and interagency consultation with other

Federal agencies following publication of the 2020 Risk Evaluation for TCE (Ref. 35 stakeholder meeting list), EPA was made aware that some U.S. battery separator manufacturers continue to rely on TCE to manufacture specialty separator materials of lead-acid and lithium batteries (Refs. 48, 49). In the 2020 Risk Evaluation for TCE, EPA evaluated the industrial and commercial use of TCE as a processing aid for battery separator manufacturing. EPA understands that the manufacture of battery separators takes place separately from overall battery manufacture, that both lead-acid and lithium batteries require separators for operation, and that the lead-acid and lithium battery separator manufacturing processes are highly engineered specialty products manufactured with precision to stringent technical specifications essential to power vehicles and systems in the U.S. supply chain for multiple critical infrastructure sectors within the national economy.

EPA understands that separators are fundamental components in batteries that provide the necessary separation between the internal anode and cathode components that make batteries work, and that a restriction on TCE use for the production of battery separators would critically impact the U.S. battery manufacturing supply chain and impede the expansion of domestic battery production capacity (Refs. 50, 51). Industry stakeholders as well as other Federal agencies have discussed with EPA the potential adverse implications of banning or severely restricting use of TCE for battery separator production, as it would disrupt the supply chain and leave the U.S. reliant on foreign suppliers to the extent that they are available to support the national economy, national security, and critical infrastructure (Refs. 48, 49). EPA agrees these assertions have merit. Lead-acid and lithium batteries are essential to serve critical infrastructure such as transportation systems, security systems, as well as to energize the national defense base (e.g., nuclear submarine batteries). Two companies requested that EPA provide exemptions under TSCA section 6(g) to allow for the continued use of TCE in the manufacture of battery

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separators, noting their significant concern about potential prohibitions under TSCA on the use of TCE. Both companies emphasized the need for the continued use of TCE in the manufacture of battery separators to strengthen critical supply chains by revitalizing domestic manufacturing and research and development in accordance with Executive Order 14017 (86 FR 11849, March 1, 2021). Additionally, the companies noted that a potential ban on TCE would be contrary to the Administration's national security priorities, which are to reduce supply chain risks by building a robust domestic renewable power sector, transitioning to a clean energy-based economy, growing a mature and competitive high-capacity battery industry, and leading global innovation and production in advanced technology products through a strong domestic manufacturing base.

One company requested a TSCA section 6(g) exemption for the use of TCE and described the specific use of TCE as an "extraction solvent" during the separator manufacturing process for both lead-acid and lithium battery separators (Ref. 48). The company makes lead-acid and lithium battery separators from naphthenic process oil during the extrusion process in order to form a thin sheet or film for each separator. During the extrusion process, a precise amount of process oil must be removed from the separator, which requires the use of a solvent (i.e., TCE) to rapidly extract the process oil and leave behind the desired porosity to allow ion flow in each finished battery. The finished separators must contain a specific percentage of residual process oil that ranges between 15% to 20% for lead-acid battery separators (for oxidation resistance in the finished battery) and less than 1% for lithium separators. Once the solvent has removed the precise amount of oil from each separator, the solvent must be evaporated/removed from the separator, and post-evaporation, the separator must have the specific porosity and wettability to provide low electrical (ionic) resistance (i.e., enabling ion transport) within a battery. For these established separator manufacturing processes, TCE is a high-performance process solvent that provides a unique combination of chemical properties

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(e.g., non-flammability, rapid extrusion of process oil, compatibility with process equipment, etc.), which facilitate the controlled removal of process oil in both lead-acid and lithium separator production processes. The company also detailed that there is no other chemical alternative that is suitable or available to replace TCE in its lead-acid or lithium separator processes.

A second company requested a TSCA section 6(g) exemption for the use of TCE as a necessary solvent for the manufacture of lead-acid battery separators and indicated that prohibiting the use of TCE would harm the U.S. manufacturing, energy, transportation, and defense sectors (Ref. 49). The company describes its use of TCE as specific to the manufacture of polyethylene plate separators used by others in commercial wet cell batteries. Their lead-acid battery separators are made of silica, process oil, and PE resin, a unique polymer that is extruded into a sheet form using the process oil. After the sheet is formed, an oil-extraction process employs TCE to extract the process oil, which reduces the oil content within the sheet to 20-25%, and, once the solvent has removed the precise amount of oil from the lead-acid separator, the solvent is evaporated/removed from the separator to yield the required porosity to allow ion flow in the finished battery. Finally, the extracted oil and 99.7% of TCE are captured and reused in the extraction process. The company notes that its lead-acid battery separators are essential in gasoline and electric-powered commercial vehicles, emergency response and military vehicles, marine engines, nuclear power providers, as well as other business sectors. The company further reiterates the unique chemical properties that are essential to facilitate the controlled removal of process oil while allowing the company to recover and recycle previously-used TCE efficiently for reuse in the battery separator production process in a manner that they describe as minimizing worker exposure, while resulting in a product with the characteristics required by battery producers. The company has provided details to EPA on its sophisticated engineering

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process that follows the hierarchy of controls to minimize worker exposure. This includes a separate enclosed structure under negative pressure as a work area for TCE processing; limiting the time personnel are allowed to enter spaces where they could be potentially exposed to 15 minutes at a time; work area ventilation and filtration using carbon beds; and PPE including either a half-face or full-face air purifying respirator for any entry into the work area, as well as chemical-resistant gloves, chemical-resistant aprons, goggles, and face shields (Ref. 49, 53).

Both companies that requested a time-limited exemption for use of TCE for battery separator production in the U.S. have demonstrated to EPA the facility-specific research, development, and implementation of sophisticated control measures to minimize TCE exposures, while also searching for reasonably available alternative solvents and processes (Refs. 48, 49).

According to the requesters, there are several properties that make TCE uniquely suitable for use in the manufacture of battery separators. First, TCE is non-flammable. According to one requester, the only other solvent that is currently in use in this application is hexane, which is explosive and highly flammable, presenting a safety risk. Other key properties described by the requesters include TCE's rapid extraction of process oil, its compatibility with the metallurgy of the process equipment, the ease by which TCE is distilled from the process oil for recovery and reuse, and its vapor pressure that both allows for evaporation and permits condensation from the atmosphere using cooling coils. One requester evaluated more than a dozen potential alternatives, including hexane, other chlorinated solvents such as methylene chloride and perchloroethylene, 1-bromopropane, acetone, alcohols, siloxanes, and water. Some were eliminated as not being compatible with the process, such as water, which is not miscible with the process oil, so it cannot be used to extract the oil. Others were found to be much less effective than TCE at extracting process oils, while some were not as easy to recover and reuse. Even the more promising solvents, such as perchloroethylene, were not drop-in replacements and

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would, according to the requester, require expensive equipment modifications and a multi-year customer approval process. Based on requester submissions and EPA's general understanding of the battery separator manufacturing process, EPA believes that there are no feasible alternatives to TCE available at present (Refs. 48, 49, 52).

One company requested a fixed exemption period of 25 years due to the critical nature of TCE use, current lack of any safer technologically or economically feasible alternative, and to avoid grave disruption to the U.S. economy, critical infrastructure, and defense base (Ref. 54). The company further explained that a restriction on TCE without sufficient time to identify, develop, and test a technically and economically feasible alternative (should such an alternative be identified and become available) would pose significant cost and safety concerns for the automobile and other critical infrastructure industries. The requester further explained that battery manufacturer customers and end users require compliance with strict performance testing, and, in addition, if a technically feasible alternative does become available, it will take multiple years to retrofit and obtain approvals required for the technical, economic and commercial feasibility of the separators. The company offered to provide EPA periodic reports every five years on its efforts to identify and assess feasible alternatives; in this way, EPA would receive ongoing alternatives analyses to ensure forward progress, while the company would obtain the regulatory certainty needed to maintain sustainable production for its customers (Ref. 48).

Similarly, the second company requested a 25-year exemption from restrictions on this use of TCE, with an additional request that EPA consider future extensions for additional time, in order to allow its use of TCE until a safer, feasible alternative is available (Ref. 49). The company justified the lengthy exemption request by explaining its ongoing search for alternatives since 2014, and its estimates that, while it will be another five years before a suitable

alternative is identified, the period for trial use, customer vetting and approval and construction of a new manufacturing plant is expected to last at least 20 years. In addition, the second requester also offered to submit to EPA periodic reports every five years to detail their efforts to identify and assess feasible alternatives.

Based on the information provided to EPA, EPA proposes that compliance at this time with a prohibition for this specific condition of use would significantly disrupt national security and critical infrastructure. EPA agrees that the use of lead-acid batteries and lithium battery separators is crucial to each of these sectors at this time. These batteries are essential for critical infrastructure such as transportation and security systems, as well as for energizing the national defense base (e.g., nuclear submarine batteries). Furthermore, EPA agrees that compliance with the prohibition would disrupt national security priorities of reducing supply chain risks by building a robust domestic renewable power sector and transitioning to a clean energy-based economy.

Despite the request for a 25-year exemption from two separate companies, EPA is proposing a 10-year time-limited TSCA section 6(g) exemption. EPA believes that a 10-year exemption from the prohibition on TCE as a processing aid, specific to lead-acid and lithium battery separator manufacturing, is reasonable because it would be sufficient to provide EPA with an updated analysis of any technically feasible alternative, the supply chain of the U.S. battery industry, as well as global innovation and production in high-technology products. Under TSCA section 6(g), EPA can consider revisiting or extending time-limited exemptions by rulemaking until a safer, feasible alternative becomes available, provided EPA receives an updated analysis of the specific use. EPA considered the emphasis in TSCA section 6(d) that compliance dates be as soon as practicable, and that TSCA section 6(g) requires that any exemptions be well-justified. EPA also took into consideration the regulatory scheme under the

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European Chemicals Agency for this use of TCE for battery separator manufacturing, and the periodic reporting cycle established in the European Union and United Kingdom. In the EU and UK, authorizations are chemical- and facility-specific and for a duration of either 7 or 12 years. Under the current EU and UK authorizations, in which a panel reviewed the scientific and economic implications of the specific TCE use, each battery separator manufacturing company was approved for a 7-year authorization period (with a 2023 expiration date); both companies have applied for a renewal for an additional 12 years after 2023 (Ref. 55). Noting that this industry has been able to provide updated applications for authorization to the EU and UK in a renewal cycle that has been shorter than 10 years, the two companies' interest in providing periodic updates to EPA, and the fast pace of battery technology development, EPA proposes that 10 years is sufficient for this time-limited exemption, and that this timeframe would also align with the EU and UK approaches. EPA requests comment on whether 10 years is an appropriate timeframe for the proposed TSCA section 6(g) exemption for industrial and commercial use of TCE as a processing aid for battery separator manufacturing (lead-acid and lithium battery separators).

ii. Analysis of the need for a TSCA section 6(g)(1)(B) exemption for TCE use for DoD naval vessels.

During the analysis for this rulemaking of the use of TCE, EPA has identified that it is necessary to allow for the continued use of TCE for industrial uses for DoD naval vessel requirements for potting, bonding and sealing compounds, bonding and cleaning requirements for naval combat systems, radars, sensors, equipment, and fabrication and prototyping processes. These naval vessel-related COUs cover the platform itself and/or specific systems, equipment, or processes. The use of TCE for industrial uses on DoD naval vessels is critical and essential, and a prohibition for this specific condition of use would significantly disrupt national security and

critical infrastructure. An exemption for DoD uses for naval vessels would enable the continued use of TCE for the COUs described which relate to vessels and their systems, and which enable maintenance, fabrication and sustainment and thus the operation of naval vessels and equipment. DOD has been unable to identify suitable alternatives for TCE for these uses. Based on information received from DoD, a 10-year timeframe for this exemption would prevent disruption of national security and allow critical infrastructure priorities to be met.

iii. Analysis of the need for TSCA section 6(g)(1)(A) exemption of TCE for laboratory use that for essential laboratory activities.

During the analysis for this rulemaking of the uses of TCE, EPA agrees that it is necessary to allow the continued use of TCE for laboratory use for essential laboratory activities (this use is within the condition of use "Industrial and commercial use of TCE in hoof polish; gun scrubber; pepper spray; and other miscellaneous industrial and commercial uses," described in Unit III.B.1.c.xx.). Under essential laboratory activities, EPA includes chemical analysis, chemical synthesis, extracting and purifying other chemicals, or dissolving other substances. Additionally, EPA includes as an essential laboratory activity research and development for new technologies related to monitoring and remediation for cleanup activities related to TCE contamination and for new analytical methods for exposure monitoring (e.g., for the ECEL).

Under TSCA section 6(g)(1)(A), EPA determined that TCE use as a laboratory chemical for essential laboratory activities is a critical and essential use with no technically and economically available substitutes. The use of TCE in laboratory use for essential laboratory activities is critical for ongoing Federal, state, and local government cleanup projects, in which it is necessary to use TCE as a laboratory chemical for the analysis of TCE-contaminated soil, air, and water samples. In these projects which are specific to TCE, the continued use of TCE in laboratory settings for chemical analysis when applied to cleanup and exposure monitoring is

critical to efforts to improve health, the environment, and public safety and is without a technically available substitute. Additionally, industrial laboratory analysis is essential in monitoring for the presence of TCE for the adequate reduction of overall exposure to TCE in alignment with the hierarchy of controls. In order to accurately conduct exposure monitoring of TCE to implement the WCPP for the uses with longer timeframes, industrial and commercial use of TCE as a laboratory chemical to provide for the chemical analysis of samples is critical and essential and without a technical alternative. A 50-year timeframe for the continued use of TCE for uses in a laboratory for chemical analysis would allow a sufficient time for TCE remediation to occur at most identified clean-up sites, as well as sites not yet identified. EPA also proposes to include in this exemption the use by NASA of TCE in essential laboratory activities as a laboratory reagent, calibration standard, and for dissolving other substances (Ref. 56). Following interagency consultation with NASA, EPA understands NASA's critical use of TCE in laboratories to include sample preparation and equipment calibration related to the search for chlorinated hydrocarbons on Mars, calibration of gas mixture used in identification of contaminants in breathing air in human-rated space and aerospace systems, and preparation of quality assurance samples for groundwater analysis. EPA is also aware of an additional critical use of TCE in laboratories by NASA to dissolve substances, such as for wax removal from infrared sensors. The wax is applied to protect the sensors during the development of infrared detectors incorporated into specialty instruments. TCE is used to remove the wax, and, unlike other solvents, has not been found to damage other delicate components of the infrared sensors.

As an example of this use, EPA notes that the devices that require this kind of wax removal are built in the Detector Development Lab, which is an International Standards Organization 5 cleanroom dedicated to fabrication of detectors (including infra-red). The lab utilizes semiconductor like processes to create these devices in silicon wafers or similar

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substrates, through build up or removal of layers toward meeting NASA missions. Detectors and devices are built in the lab that are not typically found in industry yet are needed to meet NASA requirements. The devices built tend to be unique, one-of-a-kind devices created using equally unique and highly specialized processes. One of these processes uses TCE. Part of device fabrication requires building up or removing material from both sides of the wafer. To do so, while protecting one side, a sacrificial substrate is commonly adhered to the silicon substrate using a wax material as glue. In many cases, when the process is complete, the wax is dissolved away to remove the sacrificial substrate. Common waxes that achieve this process are readily dissolved in a polar solvent such as acetone. The build-up or removal of material is done in a manner to create very specific patterns with each layer. These patterns are transferred to the substrate using a polymer material called photoresist. Once the pattern transfer is complete the photoresist is removed using acetone or other means.

In the case of creating certain types of infra-red detectors, there is a need to embed a photoresist pattern within the wax layer when gluing a sacrificial substrate to the silicon wafer. The requirement is that the patterned resist remain intact after dissolving the wax. Using solvents such as acetone would simultaneously dissolve the resist pattern or in the case of some solvents deform or weaken the photoresist beyond rendering it unusable. TCE is the only product identified that can perform this process. Specifically, TCE is able to dissolve the wax layer and leave the patterned resist layer uncompromised. The use of TCE is solely for dissolving material and is always used in an exhausted hood in the laboratory. Each hood is inspected yearly by an on-site Industrial Hygiene Office to ensure proper airflow and operation. The hood has a local alarm for airflow that is tested daily for operation. The clean room has vertical laminar air flow, pushing air into the exhausted hoods as air is pulled by the exhaust fans. The room is maintained at a positive pressure of 0.08 inches on water column. For added exposure reduction, the

laboratory is equipped with a separate emergency exhaust fan which, if activated, creates a negative pressure in the laboratory. All potentially exposed persons are provided a full set of PPE that includes apron with arm guards, face shield, safety glasses, standard issue nitrile gloves and chemical gloves rated for chlorinated solvents.

The process consists of the following steps: First, the wafer is soaked in 200-2000 mL of TCE (volume dependent on wafer size). When the wax is fully dissolved, the wafer is transferred to a second (fresh) TCE container of 200-2000mL and soaked for several minutes. Then, the effluent is rinsed with de-ionized water and the waste TCE is captured in waste containers for disposal by an on-site Environmental Group. This process is conducted over the span of approximately one week and is required an average of 3 times per year. When the process is complete all chemicals are disposed of or stored in screw capped bottles within an exhausted enclosure. Based on the information available to EPA, EPA is including the use of TCE in laboratories by NASA to dissolve substances as part of the proposed exemption for use of TCE in laboratories for essential laboratory activities. In addition, based on the information provided by NASA and other Federal agencies, EPA has considered and is including in this proposal an exemption for additional research and development activities and test and evaluation method activities, and similar laboratory activities, conducted by Federal agencies and their contractors, provided the use is essential to the agency's mission. As described more fully in Unit V.A.3.a.vi., for example, NASA's mission requires that it operate at the cutting edge of science, in environments that are hostile to life, especially human life. While NASA is skilled at addressing problems presented by these environments, EPA is concerned that the proposed limits on this laboratory use exemption in general would negatively affect NASA's ability to respond to issues that arise in spaceflight, particularly human spaceflight. Similarly, EPA believes that the DoD's unique mission requires additional flexibilities for research and development in order to maintain

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military readiness at all times.

It should be noted that the use of TCE in laboratory settings for testing asphalt would not be included in this TSCA section 6(g) exemption because it is not critical nor essential, and because alternative testing methods exist, including the Nuclear Asphalt Content Gauge and the Ignition Method (Ref. 57). EPA requests comment on whether 50 years is a reasonable timeframe for the TSCA section 6(g) exemption for the industrial and commercial use of TCE in laboratory use essential for chemical analysis. Specifically, EPA requests comment on the anticipated duration of TCE cleanup projects, and whether there will be projects that continue and require the use of TCE as a laboratory chemical for the analysis of contaminated soil, air, and water samples past 50 years. Additionally, EPA requests comment on if the exemption for laboratory use of TCE should include research and development purposes for objectives broader than cleanup activities or exposure monitoring, such research into TCE alternatives, whether these broader objectives should be limited to Federal agencies and their contractors or expanded to include others, and whether a shorter time period, such as 10 years, should be imposed on these broader research and development activities.

iv. Analysis of the need for a TSCA section 6(g)(1)(A) exemption for disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works for the purposes of cleanup projects of TCE-contaminated groundwater and other wastewater.

EPA has conducted an analysis of the application of this rulemaking and found that the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works for the purposes of cleanup projects of TCE-contaminated groundwater and other wastewater should be permitted to continue for some period of time to avoid adverse impacts on these important remediation projects.

TCE is a contaminant of concern in a significant number of cleanup sites that are

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managed under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), also known as Superfund sites, as well as under the Resource Conservation and Recovery Act (RCRA) and state programs authorized under RCRA. The remediation of these sites, including the removal and treatment of TCE-contaminated groundwater, is critical to EPA's mission to protect human health and the environment. The disposal of wastewater that contains TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works is an important method used in these cleanup efforts. In EPA's analysis of this rulemaking, EPA determined that at many contaminated sites, TCE-contaminated wastewater is pumped out of the ground and either sent to offsite industrial treatment or publicly owned treatment works. EPA acknowledges that the cleanup of these sites is vital work in which the disposal of TCE is a critical or essential use for which no technically and economically feasible safer alternative is available that must continue under CERCLA, RCRA, authorized state programs, and/or orders or permits issued under those authorities. Taking into consideration hazards and exposure, a prohibition on disposal without this exemption could result in prolonged exposure to TCE-contaminated groundwater for affected communities. EPA is concerned that eliminating a common disposal method for TCE-contaminated groundwater would be a significant burden on these cleanups and would likely slow the pace of remediation at the numerous sites where TCE-contaminated groundwater is a problem. EPA also understands that there are other sites where TCE-contaminated groundwater is being addressed under the authority of other federal environmental laws or state and local government authorities, including at sites that are currently implementing remedies selected through relevant statutory and regulatory processes, and the impact of a prohibition on an important disposal method is expected to be similar. EPA therefore is proposing a 50-year exemption from the prohibition on disposal of TCE by industrial pre-treatment, industrial treatment, or publicly owned treatment works for cleanup projects

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undertaken under the authority of CERCLA, RCRA, or other federal, state, or local government environmental laws, regulations, or requirements.

A 50-year timeframe for the continued disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works for the purposes of federal, state, and local government cleanup projects would allow a sufficient time for TCE remediation to occur at most sites. Additionally, the 50-year timeframe aligns with the proposed 50-year time-limited TSCA section 6(g)(1)(A) exemption for industrial and commercial use of TCE as a laboratory chemical in essential laboratory activities, which is also intended to support cleanup operations through allowing for the analysis of samples. EPA requests comment on whether 50 years is a reasonable timeframe for a TSCA section 6(g)(1)(A) exemption for the cleanup of TCE-contaminated water and groundwater sites. Specifically, EPA requests comment on the anticipated duration of TCE cleanup projects, and whether there will be projects that may continue and require the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works beyond 50 years.

v. Analysis of the need for a TSCA section 6(g)(1)(B) exemption for industrial and commercial use of TCE as a solvent in closed loop vapor degreasing necessary for human-rated rocket engine cleaning by NASA and its contractors.

EPA has conducted an analysis of the application of this rulemaking to the industrial and commercial use of TCE as a solvent in closed-loop vapor degreasing necessary for human-rated rocket engine cleaning by NASA and its contractors and proposes to find that a TSCA section 6(g) exemption is warranted. Under TSCA section 6(g)(1)(B), EPA proposes to determine that a prohibition at this time on the manufacture, processing, and distribution in commerce of TCE as a solvent for closed-loop vapor degreasing for human-rated rocket engine cleaning by NASA and its contractors would significantly disrupt national security and critical infrastructure.

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The United States Space Priorities Framework notes that space systems (e.g., flight components of satellites and space craft) are part of the nation's critical infrastructure and that the United States has significant national security interests in space (Ref. 58). NASA operates on the leading edge of science seeking innovative solutions to future problems in environments that offer little to no margin for error. Identification and qualification of compatible materials in the context of the less forgiving environments in which NASA operates is an iterative, collaborative process between original equipment manufacturers and NASA, especially in the case of human space flight operations (Ref. 59). NASA's mission architecture requirements often are developed many years in advance of an actual launch occurring. As part of mission planning, space systems are designed, full scale mock-ups are built, and mission critical hardware is constructed using materials qualified for spaceflight. According to NASA, for Artemis Program applications, in particular, losing access to a qualified high-performance substance like TCE in a short period of time has the potential to introduce an unacceptable level of risk to crew, vehicle, and mission viability (Ref. 43).

As described by NASA, their use of TCE in closed-loop vapor degreasing involves cleaning small diameter parts, such as rocket engine nozzle coolant tubes, and removing the fluids used for manufacturing. Substitutes for TCE and alternative processes do not meet the technical specifications required to clean certain complex aerospace parts, namely small diameter parts. Specifically, these small diameter parts cannot be cleaned with other solvents due to the likelihood of entrapment issues (i.e., a solvent carried out of a degreaser that adheres to or is entrapped in the part being removed) (Ref. 60). As discussed in Unit V.B.3.a.i., similar concerns have been expressed by a manufacturer of commercial jetliners and defense, space, and security systems, although the manufacturer states that potential alternatives have been identified for nearly all applications. Given that the small diameter parts identified by NASA are for human-

rated space flight, there is a rigorous safety standard that must be met, and according to NASA, TCE is the only solvent currently qualified for degreasing these specific parts. The engines and devices in which these parts are used include Space Shuttle engines or hardware being reused; others are designed to leverage proven Space Shuttle technology and require use of certain fluids, such as TCE, that have been qualified for human space flight.

EPA notes that this proposed exemption of use of TCE as a solvent in closed loop vapor degreasing necessary for human-rated rocket engine cleaning by NASA and its contractors differs from the exemption for TCE in vapor degreasing for essential aerospace parts and components, described in the primary alternative regulatory action. As a principal matter, this proposed exemption is limited only to NASA and its contractors due to the critical infrastructure and national security needs of human-rated spaceflight rocket engines. In contrast, the alternative is much broader and covers all aerospace entities, including commercial aviation. This proposed exemption also differs from the alternative regulatory action in that the exemption is limited to use of TCE only in closed-loop vapor degreasing, while the alternative regulatory action would provide an exemption under TSCA section 6(g) for 7 years before prohibition for all vapor degreasing with TCE (e.g., open top, in-line conveyorized, in-line web cleaner, and other types of vapor degreasing in addition to closed loop). Vapor degreasing as an industry has some of the higher exposures of TCE to workers and ONUs and this industry would have to make significant changes in order to comply to the extent possible with a WCPP until prohibition. However, of the types of vapor degreasing processes, closed-loop vapor degreasing has the lowest exposures to TCE for workers and ONUs, and as such, facilities with a closed-loop process are best situated to comply with an interim WCPP and to the extent possible, meet the ECEL until prohibition. Further, EPA believes that the facilities involved in this particular application of vapor degreasing for human-rated rocket engine cleaning by NASA or their contractors already have

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sophisticated industrial hygiene plans in place. EPA notes that a prohibition on vapor degreasing with TCE for all uses was proposed in 2017 (Ref. 67). While that proposal was withdrawn pending the completion of a risk evaluation for TCE under amended TSCA, which evaluated all conditions of use including vapor degreasing, EPA expects that since the 2017 proposal, certain stakeholders have made significant progress in identifying and adopting substitutes for vapor degreasing with TCE in anticipation of potential restrictions on TCE under amended TSCA. For instance, EPA is aware that many users have transitioned to a substitute for TCE in vapor degreasing where possible or are planning for technologically feasible adjustments (Refs. 32, 43. 60). EPA requests comment on whether 7 years is an appropriate timeframe for the proposed TSCA section 6(g) exemption for industrial and commercial use of TCE in closed loop vapor degreasing necessary for human-rated rocket engine cleaning by NASA and its contractors.

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

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

NASA operates on the leading edge of science seeking innovative solutions to future problems where even small volumes of an otherwise prohibited chemical substance could be vital to crew safety and mission success. During interagency review, NASA expressed concerns that there will likely be circumstances where a specific, EPA-prohibited condition of use may be identified by NASA during an emergency as being needed in order to avoid or reduce situations

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of harm or immediate danger to human health, or the environment, or avoid imperiling NASA space missions. In such cases, it is possible that no technically and economically feasible safer alternative would be available that meets the stringent technical performance requirements necessary to remedy harm or avert danger to human health, the environment, or avoid imperiling NASA space missions.

An emergency is a serious and sudden situation requiring immediate action to remedy harm or avert danger to human health, the environment, or to avoid imperiling NASA space missions. In NASA's case, there may be instances where the emergency use of TCE for specific conditions of use is critical or essential to remedying harm or averting danger to human health, the environment, or avoiding imperiling NASA space missions. Because of the immediate and unpredictable nature of emergencies described in this unit and of the less forgiving environments NASA operates in that offer little to no margin for error, it is likely that, at the time of finalization of this proposal, alternatives to emergency TCE use may not be available in a timely manner to avoid or reduce harm or immediate danger (Ref. 59). In this way, these emergencies for particular conditions of use meet the criteria for an exemption under TSCA section 6(g)(1)(A), because the emergency use of TCE for listed conditions of use is critical or essential and no technically and economically feasible safer alternative will be available in a timely manner, taking into consideration hazard and exposure.

In support of the TSCA section 6(g)(1)(A) emergency use exemption, NASA submitted detailed criteria which they must use to screen, qualify, and implement materials to be used in spacecraft equipment, as well as historical case studies that outline the loss of life and loss of assets in the discharge of previous missions. In one of several examples detailed, the Apollo I command module fire that claimed the lives of three American astronauts demonstrated the need for careful testing and continuity of materials (Ref. 59). Moreover, due to NASA's rigorous

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safety testing requirements under various environmental conditions, technically and economically feasible safer alternatives may not be readily available during emergencies and may require certain conditions of use of TCE to alleviate the emergency.

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

The identification and qualification of compatible materials in the context of aviation is iterative and involves expansive collaboration between original equipment manufacturers, federal agencies, and qualifying institutions. This is equally, if not more so, the case in the context of human space flight operations undertaken by NASA (Ref. 59). NASA's mission architecture requirements often are developed many years in advance of an actual launch occurring. As part of mission planning, space systems are designed, full scale mock-ups are built, and mission critical hardware is constructed using materials qualified for spaceflight. Once NASA's mission architecture requirements are developed, NASA may need to retain emergency

access to TCE because its alternatives may not have yet gone through NASA's rigorous certification process before their use. Allowing NASA to retain emergency use of TCE would reduce the chances that this rule will hinder future space missions for which mission architecture infrastructure is being developed or is already built. While NASA considers alternatives to the chemical substances it currently uses in its space system designs, NASA has not yet identified technically and economically feasible alternatives to proven chemistries in many current applications. While EPA acknowledges that the use of TCE in emergency situations may be necessary in the near term, it is also EPA's understanding that NASA will continue its work to identify and qualify alternatives to TCE. Thus, EPA is proposing an exemption duration of 10 years.

b. Proposed TSCA section 6(g) exemptions.

i. Proposed 10-year exemption for industrial and commercial use of TCE as a processing aid for battery separator manufacturing (lead-acid and lithium battery separators).

For the reasons discussed in this unit, EPA is proposing a 10-year exemption from the prohibition on the industrial and commercial use of TCE as a processing aid, specific to battery separator manufacturing. The proposed conditions for the exemption are: 1) The use of TCE would be limited to use as a processing aid for battery separator manufacturing to supply the essential battery components to continue to support the national economy, national security, and critical infrastructure; 2) This specific industrial and commercial use of TCE as a processing aid would be required to be conducted at industrial facilities already using TCE to manufacture the lithium ion or lead acid separators; and 3) Owners or operators of facilities where TCE is used as a processing aid for battery separator manufacturing and entities that manufacture (including import) TCE as a processing aid would be required to comply with the WCPP requirements described in Unit V.A.2. until the expiration of the exemption and the prohibition compliance

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date.

ii. Proposed 10-year exemption for TCE for industrial uses for DoD naval vessel requirements.

For reasons discussed in this unit, EPA is proposing a 10-year exemption from the prohibition on industrial and commercial use of TCE for the industrial and commercial use of TCE as potting compounds for naval electronic systems and equipment; sealing compounds for high and ultra high vacuum systems; bonding compounds for materials testing and maintenance of underwater systems and bonding of nonmetallic materials; and cleaning requirements (which includes degreasing using wipes, sprays, solvents, and vapor degreasing) for: materials and components required for military ordinance testing; temporary resin repairs in vessel spaces where welding is not authorized; ensuring polyurethane adhesion for electronic systems and equipment repair and installation of elastomeric materials; various naval combat systems, radars, sensors, equipment; fabrication and prototyping processes to remove coolant and other residue from machine parts; machined part fabrications for naval systems; installation of topside rubber tile material aboard vessels; and vapor degreasing required for substrate surface preparation prior to electroplating processes. The proposed conditions for the exemption are: 1) The use of TCE would be limited to use only for DoD naval vessels and their systems, and in the maintenance, fabrication, and sustainment for and of such vessels and systems; and 2) Owners or operators of facilities where TCE is used for DoD naval vessels and entities that manufacture (including import) or process TCE for use in DoD naval vessels would be required to comply with the WCPP requirements described in Unit V.A.2. until the expiration of the exemption and the prohibition compliance date.

iii. Proposed 50-year exemption for TCE laboratory use for essential laboratory activities.

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For the reasons discussed in this unit, EPA is proposing a 50-year exemption from the prohibition on industrial and commercial use of TCE, for other miscellaneous industrial and commercial use of TCE in laboratory use for essential laboratory activities, excluding the testing of asphalt, as previously discussed. The proposed conditions for the exemption are: 1) The use of TCE would be limited to use in an industrial or commercial laboratory for essential laboratory activities, including chemical analysis, chemical synthesis, extracting and purifying other chemicals, dissolving other substances, and research and development for the advancement of cleanup activities and analytical methods for monitoring related to TCE contamination or exposure monitoring, with the exclusion of laboratory testing for asphalt; 2) Federal agencies and their contractors would be permitted to conduct research and development activities and test and evaluation method activities, and similar laboratory activities, provided the use is essential to the agency's mission; and 3) Owners or operators of facilities where TCE is used in laboratory settings and entities that manufacture (including import) or process TCE for use as a laboratory chemical would be required to comply with the WCPP requirements described in Unit V.A.2. until the expiration of the exemption and the prohibition compliance date.

iv. Proposed 50-year exemption for disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works for the purposes of cleanup projects of TCE-contaminated groundwater and other wastewater.

For the reasons discussed in this Unit, EPA is proposing a 50-year exemption from the prohibition on disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works for the purposes of cleanup projects of TCE-contaminated groundwater and other wastewater. The proposed conditions for the exemption are: 1) The disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works would only be permitted for the purposes of cleanup projects of TCE-contaminated water and groundwater at

sites undergoing remediation under CERCLA, RCRA, or other Federal, state, and local government laws, regulations or requirements; and 2) Owners and operators of the locations where workers are handling TCE wastewater, and owners and operators of facilities where TCE is disposed to industrial pre-treatment, industrial treatment, or publicly owned treatment works, would be required to comply with the WCPP requirements described in Unit V.A.2. and the recordkeeping requirements described in Unit V.A.4. until the expiration of the exemption and the prohibition compliance date.

v. Proposed 7-year exemption for industrial and commercial use of TCE as a solvent in closed-loop vapor degreasing necessary for human-rated rocket engine cleaning by NASA and its contractors.

For the reasons discussed in this unit, EPA is proposing a 7-year exemption from the prohibition on the industrial and commercial use of TCE as a solvent in closed-loop vapor degreasing necessary for human-rated rocket engine cleaning by NASA and its contractors, and the manufacture (including import), processing, and distribution in commerce of TCE for this use. The proposed conditions for the exemption are: 1) The use of TCE would be limited to closed-loop vapor degreasing necessary for human-rated rocket engine cleaning by NASA and its contractors; and 2) Owners or operators of facilities where TCE is used in closed-loop vapor degreasing necessary for human-rated rocket engine cleaning by NASA and its contractors, and entities that manufacture (including import) or process TCE for such use, would be required to comply with the WCPP requirements described in Unit V.A.2. until the expiration of the exemption and the prohibition compliance date.

vi. Proposed exemption for uses of TCE for emergency uses in the context of human space flight for certain uses.

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

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emergency use of TCE in furtherance of NASA's mission for the following specific conditions of use:

(1) Industrial and commercial use as solvent for open-top or closed-loop batch vapor degreasing;

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

(3) Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner and mold release;

(4) Industrial and commercial use as a lubricant and grease in tap and die fluid;

(5) Industrial and commercial use as a lubricant and grease in penetrating lubricant;

(6) Industrial and commercial use as an adhesive and sealant in solvent-based adhesives and sealants;

(7) Industrial and commercial as a functional fluid in heat exchange fluid;

(8) Industrial and commercial use in corrosion inhibitors and anti-scaling agents; and

(9) Industrial and commercial use of TCE as a processing aid.

EPA is also proposing to include additional requirements as part of the exemption, pursuant to TSCA section 6(g)(4), including required notification and controls for exposure, to the extent feasible: 1) NASA and its contractors must provide notice to the EPA Administrator of each instance of emergency use within 15 days; and 2) NASA and its contractors would have to comply with the ECEL.

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

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EPA expects NASA and its contractors have the ability to implement a WCPP as described in Unit V.A.2. for the identified uses in the context of an emergency, to some extent even if not to the full extent of WCPP implementation. Therefore, EPA is proposing to require that during emergency use, NASA must comply with the ECEL to the extent technically feasible in light of the particular emergency.

Under the proposed exemption, NASA and its contractors would still be subject to the proposed general recordkeeping requirements discussed in Unit V.A.

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

4. Other requirements.

a. Recordkeeping.

In addition to the recordkeeping requirements for the WCPP outlined in this unit, for conditions of use that would not otherwise be prohibited one year after the effective date of this proposed regulation, EPA is also proposing that manufacturers, processors, distributors, and commercial users maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with the prohibitions, restrictions, and other provisions of this proposed regulation; and to maintain such records for a period of 5 years from the date the record is generated. EPA is proposing that this compliance date would begin at the effective date of the rule (60 days following publication of the final rule in the *Federal Register*). Recordkeeping requirements would ensure that owners or operators can demonstrate compliance with the

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regulations if necessary. EPA may require more, less, or different documentation in the final rule based on consideration of public comments.

b. Downstream notification.

For conditions of use that are not otherwise prohibited under this proposed regulation, EPA is proposing that manufacturers (including importers), processors, and distributors, excluding retailers, of TCE and TCE-containing products provide downstream notification of the prohibitions through the Safety Data Sheets (SDS) required by OSHA under 29 CFR 191.1200(g) by adding to sections 1(c) and 15 of the SDS the following language:

> After [DATE 6 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], this chemical/product is and can only be domestically manufactured, imported, processed, or distributed in commerce for the following purposes until the following prohibitions take effect: (1) Processing as an intermediate a) for the manufacture of HFC-134a until [DATE 8.5 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] and b) for all other processing as a reactant/intermediate until [DATE 2 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*]; (2) Industrial and commercial use as a solvent for open-top batch vapor degreasing until [DATE 1 YEAR AFTER DATE OF PUBLICATION OF FINAL RULE IN THE *FEDERAL REGISTER*]; (3) Industrial and commercial use as a solvent for closed-loop batch vapor degreasing until [DATE 1 YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], except for industrial and commercial use as a solvent for closed-loop batch vapor degreasing necessary for human-rated rocket engine cleaning by NASA and its contractors until [DATE 7 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], and except for industrial and commercial use as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production by Federal agencies and their contractors until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*]; (4) Industrial and commercial use in processing aid a) for battery separator manufacturing until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] and b) in process solvent used in polymer fiber spinning, fluoroelastomer manufacture and Alcantara manufacture; in extraction solvent used in caprolactam manufacture; and in precipitant used in beta-cyclodextrin manufacture until [DATE 2 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*]; (5) Industrial and commercial uses for DoD naval vessels and their systems, and in the maintenance, fabrication, and sustainment for and of such vessels and systems until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*]*;*and (6) Industrial and commercial use for laboratory use for essential laboratory activities until [DATE 50 YEARS AFTER DATE OF

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PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*].

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

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

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

B. Primary alternative regulatory action.

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

The primary alternative regulatory action described in this notice of proposed rulemaking (NPRM) and considered by EPA combines prohibitions and requirements for a WCPP. While in some ways it is similar to the proposed regulatory action, the primary alternative regulatory action described in this NPRM differs from the proposed regulatory action by providing longer timeframes for prohibitions, and by describing an ECEL based on a different health endpoint

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(i.e., immunotoxicity), as part of the WCPP that would be required for the conditions of use of TCE that would be permitted to continue for longer than one year after publication of the final rule until the prohibition compliance dates. As described in Unit IV.B., this ECEL is based on the endpoint used for EPA's unreasonable risk determination for TCE under TSCA, (i.e., immunotoxicity (Ref. 2), rather than the most sensitive health endpoint (developmental toxicity), which is the basis for the ECEL for the WCPP under the proposed regulatory action (the rationale for these differences is described in Unit VI.A.1.a.). EPA requests comment on this primary alternative regulatory action and whether any elements of this primary alternative regulatory action described in this unit should be considered as EPA develops the final regulatory action. For example, EPA could finalize a rule that includes the longer timeframes for prohibitions that are included in this primary alternative regulatory action and the ECEL based on the fetal cardiac defects endpoint (0.0011 ppm) that is included in the proposed regulatory action. EPA also requests comment on the practicability of the timeframes outlined in this unit compared to the timeframes identified for the proposed regulatory action in Unit V.A.

1. Prohibitions.

The primary alternative regulatory action considered by EPA would prohibit the manufacture (including import) and processing of TCE for all uses; prohibit the distribution in commerce and industrial and commercial use of TCE, as well as prohibitions on the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works. The primary alternative regulatory action includes longer compliance timeframes for all prohibitions.

Under the primary alternative action, the prohibitions would follow a staggered schedule and would generally take effect three months later than in the proposed regulatory action. Under a compliance timeframe that would be three months longer than the proposed regulatory action, the prohibitions for the manufacturing (including import) and processing would come into effect

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in 180 days (6 months) for manufacturers and 270 days (9 months) for processors, except for the manufacturing and processing associated with certain processing and industrial and commercial uses described later in this unit, due to supply chain considerations. Associated with this prohibition, EPA would prohibit the manufacturing (including import) and processing for all uses, including for all consumer uses, under the primary alternative regulatory action.

The prohibition compliance dates for most industrial and commercial users would be one year after the publication of the final rule under the primary alternative regulatory action. However, under the primary alternative regulatory action, there would be longer timeframes for the prohibition of some industrial and commercial uses and for the associated manufacturing (including import) and processing. For all manufacturing (including import), processing, and industrial and commercial use of TCE that would continue more than one year after the publication of the final rule, the WCPP would be in effect until the respective prohibition compliance dates or, if applicable, expiration of the TSCA section 6(g) exemption. The WCPP under the primary alternative would include an ECEL of 0.004 ppm, as described in Units IV.B. and V.B.2. Furthermore, to aid with the implementation of the prohibitions under the primary alternative regulatory action, the prohibitions on distribution in commerce of TCE would take effect concurrent with the compliance date for the prohibition on the manufacture and processing TCE for a particular condition of use.

For the two conditions of use that encompass industrial and commercial batch vapor degreasing (i.e., open-top and closed-loop), prohibitions under the primary alternative regulatory action described in this unit would take effect in 24 months for manufacturers, in 27 months for processors, and in 30 months for the industrial and commercial users of TCE used as a solvent for open-top and closed-loop batch vapor degreasing after the publication date of the final rule (with the exception of industrial and commercial use of TCE as a solvent for closed-loop batch

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vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production by Federal agencies and their contractors, which is described in Unit V.B.3.).

For certain processing and industrial and commercial conditions of use, the prohibitions under the primary alternative regulatory action described in this unit would take effect in two and a half years after the publication date of the final rule for manufacturers and in three years after the publication date of the final rule for processors for two conditions of use: 1) Processing as a reactant/intermediate, and 2) Industrial and commercial use as a processing aid in: process solvent used in battery manufacture; process solvent used in polymer fiber spinning, fluoroelastomer manufacture and Alcantara manufacture; extraction solvent used in caprolactam manufacture; and precipitant used in beta-cyclodextrin manufacture. Additionally, a TSCA section 6(g) exemption would be part of the primary alternative regulatory action for the industrial and commercial use of TCE as a processing aid (specifically for battery separator manufacture) and industrial and commercial use of TCE as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production by Federal agencies and their contractors (see Unit V.B.3.).

Furthermore, compliance dates for prohibition would vary for processing TCE as an intermediate (specifically for HFC-134a manufacture), which would be subject to a longer phaseout, and for the prohibition of processing TCE as a reactant/intermediate. Under the primary alternative regulatory action, the manufacturing (including import) and processing of TCE as an intermediate for the manufacture of HFC-134a would be prohibited. Under the primary alternative regulatory action, there would be a nine-and-a-half-year phaseout (with an extra year to start compliance compared to the eight-and-a-half-year phaseout for the proposed regulatory action) following the requirements discussed in this unit. Under the primary alternative regulatory action, the prohibition would start one year later than under the proposed

regulatory action, and thus the compliance timeframe would be one year longer than under the proposed regulatory action described in Unit V.A.1.b. Under the primary alternative regulatory action, a phaseout on processing of TCE as an intermediate for the manufacture of HFC-134a would begin at the final rule's effective date and end nine years and six months after the publication of the final rule. Within 18 months after the publication of the final rule, any facility using TCE as a feedstock to manufacture HFC-134a in the United States would establish a baseline within 12 months after the publication of the final rule of the annual quantity of TCE processed by the facility as a feedstock to manufacture HFC-134a. While this is similar to the proposed regulatory action, the timeframes allowed for establishment of the baseline would be longer under the primary alternative regulatory action. The manufacturer would use the average of any 12 consecutive months in the preceding 36 months to calculate the baseline and would have records that demonstrate how the baseline annual volume was calculated. Following the establishment of a baseline volume, under the alternative regulatory action, following a similar four-step phaseout process described in Unit V.A., the following compliance dates would take effect after the publication of the final rule: 1) In three years and six months each manufacturer of HFC-134a who uses TCE as an intermediate would not be permitted to process TCE as an intermediate at an annual volume greater than 75 percent of the baseline so established; 2) In five years and six months each manufacturer of HFC-134a who uses TCE as an intermediate would not be permitted to process TCE as an intermediate at an annual volume greater than 50 percent of the baseline so established; 3) In seven years and six months each manufacturer of HFC-134a who uses TCE as an intermediate would not be permitted to process TCE as an intermediate at an annual volume greater than 25 percent of the baseline so established; and 4) In nine years and six months each manufacturer of HFC-134a would be prohibited from using TCE as an intermediate. Additionally, manufacturing (including import) for this condition of use and

distribution in commerce for this condition of use would follow a corresponding longer phaseout timeframe to account for the availability of TCE through the supply chain during the period of the phaseout of processing TCE as an intermediate for the manufacture of HFC-134a. Under the primary alternative regulatory action, regulated entities would keep records of the annual quantity of TCE purchased and processed from the year 2024 until the termination of all processing of TCE as an intermediate.

EPA requests comment on the practicability of the timeframes outlined in this unit compared to the timeframes identified for the proposed regulatory action in Unit V.A.1.c., including consideration of the need for manufacturing (including import), and distribution in commerce to continue during the period of the phaseout.

Furthermore, with regard to the prohibition of the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works, under the primary alternative regulatory action, the prohibition would start three months later than under the proposed regulatory action, and thus the compliance timeframe would be two years and three months longer than under the proposed regulatory action described in Unit V.A.4. (description of disposal for the purposes of this rulemaking is provided in Unit III.B.2.d.). Under the primary alternative regulatory action, the prohibition described in this unit would take effect in three years for domestic manufacturers, processors, and industrial and commercial users disposing of TCE to wastewater, including disposing of TCE-containing wastewater to industrial pre-treatment, industrial treatment, or publicly owned treatment works. EPA recognizes there may be challenges in identifying and implementing an alternative disposal process separate from disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works. EPA requests comment on whether the three-year alternative timeline would be practicable or whether additional time is needed, for example, for a regulated entity to implement

a change to their wastewater collection, treatment, or disposal processes or infrastructure, and what those alternative disposal methods may be.

2. Workplace Chemical Protection Program for certain conditions of use.

As in the proposed regulatory action described in Unit V.A.1., EPA's primary alternative regulatory action would include a WCPP as a requirement, which would encompass an ECEL as well as dermal requirements to reduce inhalation and dermal exposures to TCE. However, the WCPP under the primary alternative regulatory action would include an ECEL based on a different health endpoint, immunotoxicity, as further discussed in this unit. The WCPP would be in place until the prohibition compliance date for those conditions of use of TCE that would continue for longer than one year after publication of the final rule, which would be: manufacturing (including import); processing: as a reactant/intermediate; incorporation into formulation, mixture or reaction product; repackaging; recycling; industrial and commercial use: as a solvent for open-top batch vapor degreasing; industrial and commercial use as a solvent for closed-loop batch vapor degreasing; and industrial and commercial use as a processing aid in process solvent used in battery manufacture; process solvent used in polymer fiber spinning, fluoroelastomer manufacture and Alcantara manufacture; extraction solvent used in caprolactam manufacture; and precipitant used in beta-cyclodextrin manufacture.

As discussed in Unit V.A.2., and for the reasons described in Unit V., EPA does not believe that long-term implementation of the WCPP would be a feasible means of addressing unreasonable risk indefinitely and that prohibition of the affected COUs would ultimately be necessary to eliminate the unreasonable risk. Under the primary alternative regulatory action, the WCPP for several conditions of use of TCE would reduce to the extent possible the unreasonable risk during the time period before a prohibition would become effective.

For the primary alternative regulatory action, the WCPP would encompass an ECEL

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based on immunotoxicity, following the associated implementation requirements discussed in Unit V.A.2., in addition to longer timeframes described in this unit. EPA's primary alternative regulatory action includes an ECEL of 0.0040 ppm (0.021 mg/m3) as an eight-hour TWA, which is based on the chronic non-cancer occupational HEC for autoimmunity (Ref. 14). As discussed in Unit VI.A., among the adverse health effects, the drivers for EPA's revised unreasonable risk determination for TCE under TSCA were identified as cancer, immunotoxicity, acute immunosuppression and chronic autoimmunity from inhalation and dermal exposures (Ref. 2). Therefore, reducing the remaining exposures to or below the ECEL of 0.0040 ppm would address the unreasonable risk of injury to health from TCE that is driven by inhalation exposures in an occupational setting (Refs. 1, 14). If ambient exposures are kept at or below the eight-hour ECEL of 0.0040 ppm, EPA expects that workers and ONUs would be protected against not only the chronic non-cancer effects for autoimmunity described in Unit III.B.2., but also effects resulting from acute non-cancer exposure (immunosuppression) and cancer. Associated with the ECEL of 0.0040 ppm, under the alternative regulatory action, EPA would establish an ECEL action level at half of the eight-hour ECEL, or 0.002 ppm as an eight-hour time-weighted average.

EPA believes that longer timeframes may facilitate compliance; therefore, the primary alternative regulatory action would provide longer timeframes for implementation of a WCPP than the proposed regulatory action. With a compliance timeframe that would be six months later than in the proposed regulatory action, the compliance timeframe for the WCPP under the primary alternative regulatory action would be extended as follows: regulated entities would establish initial exposure monitoring according to the process outlined in Unit V.A.2.ii. within 12 months (in contrast to six months in the proposed regulatory action described in Unit V.A.2.ii.) and proceed accordingly, based on the outcome of the initial monitoring. EPA requests comment

on the ability of regulated entities to conduct initial monitoring within 12 months, anticipated timeframes for any procedural adjustments needed to comply with the requirements, and the extent to which this option could result in additional exposure, compared to the proposed regulatory option as described in Unit V.A. Overall, EPA requests comment on the practicability of the timeframes outlined in this unit, when compared to the timeframes identified for the proposed regulatory action in Unit V.A. EPA requests comment on whether any elements of the primary alternative regulatory action described in this unit should be considered as EPA develops the final regulatory action, e.g., whether EPA should consider the timeframes for implementation of a WCPP presented in this primary alternative regulatory action and the ECEL value presented in the proposed regulatory action.

EPA does not have sufficient information as to whether the conditions of use that would continue for longer than one year under the primary alternative regulatory action listed in this unit could meet *requirements of a WCPP for TCE, including* an ECEL of 0.0040 ppm for TCE. Therefore, EPA requests comment on the existing practices (e.g., engineering controls, administrative controls, PPE) involving TCE use in these conditions of use*,* as to whether activities may take place in closed systems and the degree to which users of TCE in these sectors could successfully implement an ECEL of 0.0040 ppm, dermal protection, and ancillary requirements, described in Unit V.A.2., until the prohibitions would become effective, including for the manufacturing, processing, and distribution in commerce that account for the supply chain.

3. TSCA section 6(g) exemptions.

Under TSCA section 6(g)(1), EPA may grant an exemption from a requirement of a TSCA section 6(a) rule for uses that are critical or essential. Based on discussions with and information provided by industry stakeholders and consultation with other Federal agencies,

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EPA has analyzed the need for two different exemptions, described in the proposed regulatory action discussed in Units I.A.3.a. and b., and would grant both with a longer time limit if the primary alternative regulatory action described in this NPRM is adopted in the final rule. Furthermore, under the primary alternative regulatory action, EPA has analyzed the need for additional exemptions for essential uses of open-top and closed-loop batch vapor degreasing for aerospace use (including for rayon fabric scouring for rocket booster nozzle production) as well as narrow tubing used in medical devices, and EPA would provide the additional exemptions if the primary alternative regulatory action described in this NPRM is adopted in the final rule. (EPA notes that the use of TCE for vapor degreasing narrow tubing used in medical devices is not excluded by TSCA section (3)(2)(B)(vi) because TCE is not intended to become part of the medical device that incorporates the narrow tubing). This unit presents the results of the analysis for the requested exemption for industrial and commercial use of TCE in vapor degreasing, as well as the time limits indicated under the primary alternative regulatory action.

a. Primary alternative analysis of the need for TSCA section 6(g)(1) exemptions for uses of TCE that are critical or essential.

i. Analysis of the need for a TSCA section 6(g)(1)(B) exemption for industrial and commercial use of TCE in vapor degreasing for essential aerospace parts and components.

EPA has conducted an analysis of the application of this rulemaking to the industrial and commercial use of TCE in vapor degreasing and found that a TSCA section 6(g) exemption may be warranted for certain aerospace parts and components if the primary alternative regulatory action considered by EPA is adopted, in its entirety or in relevant part, in the final rule.

EPA received a request for a TSCA section 6(g) exemption from prohibition for the use of TCE in vapor degreasing of aerospace parts from a manufacturer of commercial jetliners and defense, space, and security systems (Refs. 60 and 61). As the requester describes, they

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manufacture and procure these parts and have identified that TCE vapor degreasing is necessary due to technical challenges with other substitute chemicals or alternative methods.

The requester has spent many years developing, qualifying, and implementing alternative materials and processes to replace TCE vapor degreasing with aqueous cleaning where technically viable. According to the requester, while the transition to aqueous cleaning has been successful for many detail parts (e.g., stringers, spars, seat tracks, brackets, etc.), substitutes and alternative processes do not meet the technical specifications required to clean certain complex aerospace parts, specifically, gaseous oxygen tubing systems, non-oxygen tubing, as well as honeycomb core and rotorcraft mechanical systems. The requester notes the ongoing research and development activities over the years for the TCE vapor degreasing uses without viable alternatives, and highlights that a potential replacement technology has been identified for vapor degreasing oxygen and non-oxygen tubing systems. However, for the honeycomb core and rotorcraft mechanical systems parts, the requestor explains the continued challenge to identify a replacement solvent due to entrapment issues (i.e., a solvent carried out of a degreaser that adheres to or is entrapped in the part being removed) and processing concerns.

The requester notes that an adequate transition period for this technically challenging aerospace use requires substantial investment and time to develop viable alternatives. The requester is currently in the process of identifying a replacement solvent that can adequately clean, cause no harm to parts, and is not an equally toxic material to TCE. Based on the submitted request, conversion from vapor degreasing to aqueous cleaning is a capital-intensive investment that the requester expects would require several years to plan, permit, construct, and install. Additionally, the requester notes that the aerospace industry needs to ensure that aerospace parts meet DOD and other Federal Aviation Administration (FAA) specifications to ensure safety of flight. For example, in order to replace the chemical with an alternative, the

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requester notes that they must identify, test, and select an alternative that meets technical requirements derived from FAA mandated standards for a typical part used in a commercial aircraft, such as specifications for specific gravity (ASTM D 792), Water Absorption (ASTM D 750), and other test requirements, which may be a lengthy process (Ref. 62). According to the information submitted, certification with FAA could take at least nine months for individual parts of components or up to several years for major subsystems or complete aircraft (Ref. 62). The requester also notes that while they do not know the extent that their supply chain has transitioned away from use of TCE in vapor degreasing, TCE has been used in vapor degreasing to meet required levels of cleanliness of certain supplied parts by long-standing design specifications that are incorporated into contracts of a complex supply chain. The requester also told EPA the suppliers are not required to inform the requester of the process they use to clean parts that the supplier provides to the requester, and the requester therefore may not know which solvent a supplier has selected for vapor degreasing or what factors were considered when selecting cleaning systems. According to the requester, material declarations and auditing processes to validate usage may be burdensome, considering that a large portion of the requester's supply chain includes small suppliers. Due to the concerns raised with transitioning to aqueous cleaning or another new cleaning method, the requester has requested that EPA exempt use of TCE in vapor degreasing of aerospace parts for 10 years.

As discussed in this unit, substitute chemicals for vapor degreasing of aerospace parts may not be available at this time for meeting the cleanliness standards of certain parts as required by DOD and FAA specifications or other specifications included in existing contracts within the supply chain such that significant disruption to national security and critical infrastructure would occur without a longer timeframe for transition to an alternative. More time is needed for companies to make the capital-intensive transition from TCE vapor degreasing to aqueous

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cleaning for those parts that can be cleaned using the aqueous method. In addition, the requester states that they are continuing to work towards identifying a replacement solvent that is able to adequately clean complex machining parts and actuation systems parts without harming them and that is not a regrettable substitution. Therefore, EPA has preliminarily determined that if the use of TCE for vapor degreasing were not available in the near term for aerospace parts, or if industry could not meet the requirements of the prohibition considered as the proposed regulatory action, compliance with such requirement could significantly disrupt national security and critical infrastructure. In addition, due to availability concerns, EPA has preliminarily determined that a ban on the manufacture, processing, and distribution in commerce of TCE for vapor degreasing of aerospace parts could also significantly disrupt national security and critical infrastructure. A prohibition on the use of TCE for vapor degreasing of aerospace parts could negatively affect DOD's capability and readiness, which includes the ability to adequately maintain aircraft. Such a prohibition could also negatively affect the maintenance of civilian aircraft and potentially have impacts on the safety of civilian flight.

Similarly, EPA is aware of a highly specific use of vapor degreasing for aerospace components as part of production of booster rocket nozzles for national security or critical infrastructure uses (Ref. 43). In the production of booster rocket nozzles, TCE is used in vapor degreasing as a solvent in rayon fabric scouring, an intensive cleaning process to remove contaminants. Cleaning is a critical step of this process; if contaminants are not sufficiently removed in the scouring stage, the fabric will be degraded during the chemical reaction that occurs during carbonization which could result in failure of the nozzle during a launch and catastrophic effects for the rockets.

A Federal agency involved in this use, specifically NASA, has attempted at length to identify an alternative to TCE in vapor degreasing; while NASA had preliminarily identified an

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alternative solvent, the manufacturer of the substitute chemical announced they would be voluntarily ceasing production (Ref. 63), making this alternative solvent no longer viable. NASA has restarted the identification and qualification of a non-TCE cleaning method. While aqueous cleaning has been explored as an alternative method of rayon fabric scouring, it is not a viable alternative as the rayon fiber is hydrophilic and water can cause damage to the fiber itself, impacting its ablation performance (Ref. 43). Currently, substitutes and alternative processes do not meet the technical specifications required to clean the rayon fabric in order to safely produce and launch rockets that are important for national security or critical infrastructure. NASA has provided to EPA an estimated timeline for the identification and replacement of TCE in the vapor degreasing of this component. The replacement of TCE involves intense testing as it is part of spaceflight, notably a new process would have to undergo various rounds of testing culminating in a full-scale static motor test using a booster nozzle manufactured with an alternative cleaning solvent. For NASA specifically, the first opportunity to conduct a full-scale static motor test with a booster nozzle produced using a non-TCE alternative would be 2027; before that is planned to occur, NASA has launches planned with eight booster rockets, which cannot proceed unless all components are safely produced. Therefore, EPA has preliminarily determined that if TCE was not available for this sub-use of closed-loop batch vapor degreasing for this aerospace component, there would be a significant, disruptive impact on national security and critical infrastructure. In addition, due to availability concerns, EPA has preliminarily determined that a ban on the manufacture, processing, and distribution in commerce of TCE for vapor degreasing of aerospace parts could also significantly disrupt national security and critical infrastructure.

ii. Analysis of the need for a TSCA section 6(g)(1)(A) exemption for industrial and commercial use of TCE in closed-loop and open-top batch vapor degreasing for narrow tubing

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used in medical devices.

EPA also finds that a TSCA section 6(g)(1)(A) exemption may be warranted for vapor degreasing of narrow metal tubing used in medical devices if the primary alternative regulatory action considered by EPA is adopted in the final rule. According to a manufacturer of metal tubing for medical devices (Ref. 64), TCE is the only solvent that they have found that effectively removes all lubricants from their tubing products, allowing them to meet the stringent cleanliness standards for medical devices.

Information provided to EPA from the tubing manufacturer indicates that their tubing products consist of over 20 different alloys processed with more than 25 different lubricants, for use primarily in the medical industry. The tubing is incorporated into devices used in the body for diagnostic and surgical procedures as well as permanent implants for orthopedic and cardiovascular applications. The tubing produced by the manufacturer ranges in diameter from 0.005” to 0.625”, and both the inner and outer diameters of the tubing must be degreased at various points in the manufacturing process (Ref. 64).

According to this manufacturer, the use of specialty lubricants in the drawing and annealing processes create unique degreasing demands for narrow tube manufacturers and TCE has historically been the industry standard for effective removal of these lubricants. Cleanliness is paramount, as even the slightest degreasing failure may cause corrosion, which could result in a critical failure of an implantable medical device. Alternative solvents such as methylene chloride or 1-bromopropane are not feasible alternatives for a variety of reasons, including that they do not always achieve the required cleanliness standards, could result in a facility exceeding emission caps under the Clean Air Act, and are also in the process of being regulated by EPA under TSCA. Other alternative chemicals have been explored by the manufacturer, such as parachlorobenzotrifluoride, which is not a hazardous air pollutant under the Clean Air Act.

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While promising, this solvent could not remove some of the manufacturer's lubricants and specialty coatings, thus not meeting the customer's cleanliness standard. This alternative is also flammable, which would require additional equipment design and infrastructure to use safely.

The information provided by this manufacturer of tubing for use in medical devices regarding TCE vapor degreasing is consistent with the information provided by the aerospace industry regarding challenges with finding a replacement for TCE in vapor degreasing of tubing. It is also consistent with information provided to EPA during the public comment period for EPA's 2017 proposal on TCE in vapor degreasing (82 FR 7432, January 19, 2017). A commenter on that proposal indicated that aqueous cleaners did not effectively remove most of the materials in their lubrication system, so effective lubricants and coating systems would need to be developed that are compatible with aqueous cleaners (Ref. 65). Experiments with other lubricants were not successful, the commenter found that lubricants that could be effectively aqueous degreased were less effective at lubricating, requiring more drawing steps as well as more cleaning steps. Further, according to this commenter, aqueous cleaning requires large, heated water tanks and hot air drying chambers, increasing energy use and industrial effluent volumes.

In addition, EPA did not impose additional Clean Air Act emission reductions on aerospace manufacturing and maintenance facilities or on facilities manufacturing narrow tubing in 2007, recognizing the unique nature of the vapor degreasing done by these industries. In the 2007 final rule, EPA found that the level of control called for by the 1994 National Emission Standard for Halogenated Solvent Cleaning for aerospace manufacturing and maintenance and narrow tube manufacturing facilities reduced hazardous air pollutant emissions to levels that presented an acceptable level of risk, protected public health with an ample margin of safety, and prevented any adverse environmental effects (Ref. 66). As noted in the 2007 final rule, the

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finding regarding an "ample margin of safety" was based on a consideration of the additional costs of further control as represented by compliance with emissions limits adapted for these industry sectors, considering availability of technology, costs and time to comply with further controls. EPA further notes that the term "narrow tube" as used in the 2007 final rule was tubing with a portion of the outside diameter being a quarter of an inch or less, which is different from the diameters provided by the narrow tube manufacturer (Ref. 64).

EPA acknowledges the importance of properly cleaned narrow tubing used in medical devices. The failure of a medical device used in a medical or surgical procedure, or implanted in the body, can have immediate and significant negative impacts on human health. Further, a complete prohibition on the use of TCE for vapor degreasing in the near term could result in shortages of narrow tubing for use in such medical devices, which would also have significant negative impacts on human health. Therefore, EPA requests comment on the extent to which the use of TCE for vapor degreasing of narrow tubing is a critical use for which no technically and economically feasible safer alternative is available. In addition, due to availability concerns, a ban on the manufacture, processing, and distribution in commerce of TCE for vapor degreasing of narrow tubing used in medical devices could significantly disrupt a critical use for which no technically and economically feasible safer alternative is available.

iii. Analysis of the need for a TSCA section 6(g)(1)(A) exemption for industrial and commercial use of TCE as a processing aid for specialty polymeric microporous sheet materials.

EPA has conducted an analysis of the application of this rulemaking to the industrial and commercial use of TCE as a processing aid and preliminarily found that a TSCA section 6(g)(1)(A) exemption may be warranted for certain industrial and commercial purposes if the primary alternative regulatory action considered by EPA is adopted, in its entirety or in relevant part, in the final rule. As part of industry stakeholder engagement, EPA was made aware that at

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least one U.S. materials manufacturer relies on TCE to manufacture a specialty microporous sheet material. This company has requested an exemption under TSCA section 6(g) for the continued use of TCE for this purpose (Ref. 67).

As the requestor describes, specialty polymeric microporous sheet materials are fundamental components in the production of critical or essential products. EPA preliminarily agrees that certain applications of these specialty polymeric microporous sheet materials are critical and essential uses for which no technically and economically feasible safer alternative is available. This exemption on processing TCE would be limited to processing for applications of the specialty polymeric microporous sheet materials that are critical and essential, specifically; driver's licenses and identification cards of U.S. states and territories; passports (including U.S. passports and e-passports); labels for chemical drums, complex filtration elements and cartridges (such as for oil/water and bilge water separations); and for use in membranes in energy recovery ventilators. Any application of the specialty polymeric microporous sheet materials for uses not listed above would not be covered under this exemption.

EPA believes that these uses would preliminarily also qualify for an exemption under TSCA section 6(g)(1)(B). These critical and essential products are also important for the national economy, national security, and critical infrastructure and EPA preliminarily agrees that compliance with the prohibition within the timeframes proposed would be disruptive. The proper identification of individuals is important for maintaining national security and critical infrastructure. Systems such as travel, healthcare, and law are all reliant on identification. Further, the proper labeling of chemicals is important for protecting critical infrastructure. Similarly, complex filtration elements and cartridges (such as for oil/water and bilge water separations) and membranes in energy recovery ventilation are essential for the operations of critical infrastructure.

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Each of these products includes the use of TCE in their development. The requester described the specific use of TCE as a "process solvent" during the manufacturing of a "unique polymeric microporous sheet material" (Ref. 67). The company makes the microporous sheet material using process oil (white mineral oil) during the extrusion process in order to form a thin plastic sheet containing 55-60% process oil by weight. The process oil is then removed from the plastic sheet, which requires the use of a solvent (i.e., TCE) to rapidly extract the process oil and leave behind the desired microporosity for the material. The requestor describes how specific microporosity is important for performance of the material. Once the solvent has removed the oil from the sheet, the solvent must be evaporated to remove it from the sheet; post-evaporation, the separator must leave behind the desired microporosity crucial to the performance of the material. Finally, the extracted oil and much of the TCE is captured and reused in the extraction process. TCE that is not captured and reused is released from a discharge stack; the requestor describes that the air released contains no more than 10 ppm of TCE.

The requestor describes this manufacturing process as well-established and reliant on TCE as a high-performance process solvent that provides a unique combination of chemical properties (e.g., non-flammability, rapid extrusion of process oil, compatibility with process equipment, etc.). The requestor describes how this unique combination of properties facilitate the controlled removal of process oil in the production of the specialty polymeric microporous sheet material, resulting in the specific microporosity important for the performance of the material.

The requester has provided some details to EPA on its efforts to reduce worker exposure to TCE. The exposure mitigation program includes a separate area under negative pressure for TCE processing and use of PPE as necessary to comply with the OSHA PEL for TCE (Refs. 67, 10). While EPA's proposed ECEL is much lower than the OSHA PEL, EPA expects the requester to make appropriate changes to its worker exposure mitigation program to comply with

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the WCPP and attempt to meet the ECEL to the extent possible for the duration of this exemption.

According to the requester, there are several properties that make TCE uniquely suitable for use in the manufacture of the specialty microporous sheet material. The key properties described by the requester include TCE's rapid extraction of process oil, the ease by which TCE is distilled from the process oil for recovery and reuse, and its vapor pressure, which both allows for evaporation and permits condensation from the atmosphere. TCE is also non-flammable. The requester evaluated more than a dozen potential alternatives that could be compatible with their process for manufacturing specialty polymeric microporous sheet materials, including hexane, trans-1,2-dichloroethylene, perchloroethylene, and 1-bromopropane. Many of these substitutes were found to be less effective than TCE at extracting process oils, while some were not as easily recovered and reused. Even the more promising solvents, such as perchloroethylene, were not drop-in replacements and would, according to the requester, require expensive equipment modifications and a multi-year approval process. Many of the potential substitute chemicals would need to be blended with an HFC that is being phased out, or the chemical itself is being phased out due to concern over PFAS or due to high Global Warming Potential. In addition to these challenges, the requestor describes how any blend would be a challenging substitute because the different chemicals in the blend evaporate at different rates and could become flammable during this process. The requester emphasized that it is using modeling to seek out potential alternatives, but that further study is required and that there is no other chemical alternative that is suitable or available to replace TCE in this process. Based on the requester's submission and EPA's general understanding of the manufacturing process for the specialty microporous sheet material, EPA believes that there are no feasible alternatives to TCE available at present.

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While the requester did not describe a time limit for the exemption, EPA has identified a 15-year time-limited TSCA section 6(g) exemption under the alternative regulatory action. EPA believes that a 15-year exemption from the prohibition on the industrial and commercial use of TCE as a processing aid, specific to the manufacturing of specialty microporous sheet materials, would be reasonable because it would be sufficient to provide EPA with an updated analysis of any technically feasible alternative, the supply chain of the U.S. materials industry, as well as global innovation and production in high-technology products. Under TSCA section 6(g), EPA can consider revisiting or extending time-limited exemptions by rulemaking until a safer, feasible alternative becomes available. EPA requests comment on whether 15 years is an appropriate timeframe for the proposed TSCA section 6(g) exemption for industrial and commercial use of TCE as a processing aid for specialty polymeric microporous sheet materials.

b. Primary alternative exemptions for uses of TCE that are critical or essential.

i. Primary alternative 15-year exemption for industrial and commercial use as a processing aid for battery separator manufacturing (lead-acid and lithium battery separators).

As part of the primary alternative regulatory action, based on the analysis in Unit V.A.3.a.i., EPA would grant a 15-year exemption from the prohibition on TCE for the industrial and commercial use as a processing aid for battery separator manufacturing. The primary alternative regulatory action differs from the proposed regulatory action in that it extends the compliance date for the exemption by five years, allowing a longer timeframe for stakeholders to continue the use until its prohibition, in recognition of the challenge to transition to an alternative chemical or process, further discussed in Unit V.B. The conditions for the exemption under the primary alternative regulatory action would be: 1) The use of TCE would be limited to use as a processing aid for battery separator manufacturing to supply the essential battery components to continue to support the national economy, national security, and critical infrastructure; 2) this

specific industrial and commercial use of TCE as a processing aid must be conducted at industrial facilities already using TCE to supply the lithium ion or lead acid battery components; and 3) Industry stakeholders who use TCE as a processing aid for battery separator manufacturing and entities that manufacture (including import), process, and distribute in commerce TCE to be available as a processing aid must comply with the WCPP requirements described in Unit V.B.2., including meeting the ECEL to the extent possible until the prohibition compliance date.

ii. Primary alternative 30-year exemption for industrial and commercial use of TCE in laboratory use for essential laboratory activities.

As part of the primary alternative regulatory action, based on the analysis discussed in Unit V.A.3.a.iii., there would be a 30-year exemption from the prohibition on TCE in other miscellaneous industrial and commercial use of TCE in laboratory use for essential laboratory activities. The primary alternative regulatory action differs from the proposed regulatory action in that it shortens the compliance date by 20 years. The conditions for the primary alternative proposed exemption are: 1) The use of TCE is limited to uses in an industrial or commercial laboratory for essential laboratory activities, including chemical analysis, chemical synthesis, extracting and purifying other chemicals, dissolving other substances, with the exclusion of laboratory testing for asphalt; and 2) Stakeholders who use TCE in laboratory settings and stakeholders who manufacture (including import), process, and distribute in commerce TCE to be available as a laboratory chemical must comply with the WCPP requirements described in Unit V.B.2., including meeting the ECEL to the extent possible until the prohibition compliance date.

iii. Primary alternative seven-year exemption for industrial and commercial use of TCE in batch vapor degreasing for essential aerospace parts and components and narrow tubing used

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in medical devices.

For the reasons discussed in this unit, EPA would grant a seven-year exemption from the prohibition as part of the primary alternative regulatory action for the industrial and commercial use of TCE in batch vapor degreasing for essential aerospace parts and components and narrow tubing used in medical devices. While one requester suggested that an appropriate length of time for an exemption would be 10 years, and another did not specify, EPA notes that a prohibition on vapor degreasing with TCE for all uses was proposed in 2017 (Ref. 68). While that proposal was withdrawn pending the completion of a risk evaluation for TCE under amended TSCA, which included the evaluation of the vapor degreasing conditions of use, EPA expects that certain stakeholders have made significant progress on substitutes since then in anticipation of similar restrictions on TCE under amended TSCA. For instance, EPA is aware that many users have transitioned to a substitute for TCE where possible or are planning for technologically feasible adjustments (Refs. 32, 43).

The conditions for the exemption would be: 1) TCE could only be used for batch vapor degreasing of aerospace parts or components (including rayon fabric) where other alternatives present technical feasibility or cleaning performance challenges to meet specifications from other Federal agencies or other long-standing design specifications that are included in existing contracts, or for batch vapor degreasing of narrow tubing used in medical devices; and 2) Industry stakeholders who use TCE for batch vapor degreasing of aerospace parts or components or narrow tubing used in medical devices and entities that manufacture (including import), process, and distribute in commerce TCE to be available for TCE vapor degreasing would comply with the WCPP requirements described in Unit V.B.2. to the extent possible until the prohibition compliance date. EPA requests comments on all aspects of the exemption request and the exemption in the primary alternative regulatory action from the prohibition on use of TCE in

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batch vapor degreasing, including whether compliance with the WCPP should also be required during the period of the exemption. Additionally, EPA is soliciting comment on whether it should specify the type of batch vapor degreasing operation, such as open-top or closed loop batch vapor degreasing, that would be exempt from prohibition as part of the primary alternative regulatory action for the industrial and commercial use of TCE in batch vapor degreasing for essential aerospace parts and components and narrow tubing for medical devices. EPA also requests comment whether it should consider different exemption timeframes for different types of vapor degreasing operations.

iv. Primary alternative 15-year TSCA section 6(g)(1)(A) exemption for industrial and commercial use of TCE as a processing aid for specialty polymeric microporous sheet materials.

As part of the primary alternative regulatory action, based on the analysis in Unit V.A.3.c., EPA would grant a 15-year exemption from the prohibition on TCE for the industrial and commercial use as a processing aid for specialty polymeric microporous sheet material manufacturing. Under the primary alternative regulatory action, in accordance with TSCA section 6(g)(4), the conditions for the exemption that EPA believes are necessary to protect health and the environment would be: 1) The use of TCE would be limited to use as a processing aid for the manufacturing of specialty polymeric microporous sheet materials ; and 2) Stakeholders who use TCE as a processing aid for the manufacturing of specialty polymeric microporous sheet materials and entities that manufacture (including import), process, and distribute in commerce TCE to be available as a processing aid must comply with the WCPP requirements described in Unit V.B.2., including meeting the ECEL to the extent possible until the prohibition compliance date. EPA requests comments on all aspects of the exemption in the primary alternative regulatory action from the prohibition on industrial and commercial use of TCE as a processing aid, specific to the manufacturing of specialty microporous sheet materials,

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including whether compliance with the WCPP should also be required during the period of the exemption. EPA also requests comment on whether 15 years would be an appropriate timeframe for a TSCA section 6(g)(1)(A) exemption for this use.

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

Table 2 is a side-by-side depiction of the proposed regulatory action with the primary alternative action for each condition of use identified as driving the unreasonable risk (Ref. 2). The purpose of this table is to succinctly convey to the public the major differences between the proposed regulatory action and the primary alternative regulatory action; as such the actions in each column are truncated and do not necessarily reflect all the details of the proposed and alternative regulatory action, including differences in timeframes. EPA notes that "prohibit + WCPP" listed in the table indicates that a condition of use would be prohibited, but in the time before the prohibition goes into effect, there would be a WCPP. For the proposed action, the WCPP would include an ECEL of 0.0011 ppm based on the fetal cardiac defects endpoint so that the developing fetus is best protected (see Unit V.A.), especially for the sensitive PESS group of older pregnant workers and ONUs (the group identified as most susceptible to fetal cardiac defects), while under the primary alternative regulatory action, the WCPP would include an ECEL of 0.0040 ppm based on the immunotoxicity endpoint (see Unit V.B.). The rationale for these differences is detailed in Unit VI.A.1.

The proposed and alternative regulatory actions are described more fully in Units V.A. and B.

Table 2 – Overview of Proposed Regulatory Action and Alternative Regulatory Action by Conditions of Use

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	Action	
Condition of Use	**Proposed Regulatory Action[1]**	**Primary Alternative Action**
Manufacturing: domestic manufacture	Prohibit + WCPP includes an ECEL of 0.0011 ppm for inhalation exposures to TCE as an eight-hour TWA based on developmental toxicity	Prohibit + WCPP includes an ECEL of 0.0040 ppm for inhalation exposures to TCE as an eight-hour TWA based on immunotoxicity
Manufacturing: import	Prohibit + WCPP includes an ECEL of 0.0011 ppm for inhalation exposures to TCE as an eight-hour TWA based on developmental toxicity	Prohibit + WCPP includes an ECEL of 0.0040 ppm for inhalation exposures to TCE as an eight-hour TWA based on immunotoxicity
Processing: processing as a reactant/intermediate	Prohibit; includes a phaseout of TCE for processing as an intermediate for the manufacture of HFC-134a + WCPP includes an ECEL of 0.0011 ppm for inhalation exposures to TCE as an eight-hour TWA based on developmental toxicity	Prohibit; includes a phaseout of TCE for processing as an intermediate for the manufacture of HFC-134a + WCPP includes an ECEL of 0.0040 ppm for inhalation exposures to TCE as an eight-hour TWA based on immunotoxicity
Processing: incorporation into a formulation, mixture, or reaction product	Prohibit + WCPP includes an ECEL of 0.0011 ppm for inhalation exposures to TCE as an eight-hour TWA based on developmental toxicity	Prohibit + WCPP includes an ECEL of 0.0040 ppm for inhalation exposures to TCE as an eight-hour TWA based on immunotoxicity
Processing: incorporation into articles	Prohibit	Prohibit
Processing: repackaging	Prohibit + WCPP includes an ECEL of 0.0011 ppm for inhalation exposures to TCE as an eight-hour TWA based on developmental toxicity	Prohibit + WCPP includes an ECEL of 0.0040 ppm for inhalation exposures to TCE as an eight-hour TWA based on immunotoxicity
Processing: recycling	Prohibit + WCPP includes an ECEL of 0.0011 ppm for inhalation exposures to TCE as an eight-hour TWA based on developmental toxicity	Prohibit + WCPP includes an ECEL of 0.0040 ppm for inhalation exposures to TCE as an eight-hour TWA based on immunotoxicity
Industrial and commercial use as a solvent for open-top batch vapor degreasing	Prohibit	Prohibit; includes a TSCA section 6(g) exemption for the industrial and commercial use as solvent for open-top batch vapor degreasing for essential

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	Action	
Condition of Use	**Proposed Regulatory Action[1]**	**Primary Alternative Action**
		aerospace use + WCPP includes an ECEL of 0.0040 ppm for inhalation exposures to TCE as an eight-hour TWA based on immunotoxicity
Industrial and commercial use as a solvent for closed-loop batch vapor degreasing	Prohibit; includes a phaseout of TCE for industrial and commercial use as a solvent for closed loop batch vapor degreasing for rayon fabric scouring for end use rocket booster nozzle production by Federal Agencies and their contractors and a TSCA section 6(g) exemption for industrial and commercial use as a solvent for closed loop batch vapor degreasing necessary for human-rated rocket engine cleaning by NASA and its contractors+ WCPP for one sub-use includes an ECEL of 0.0011 ppm for inhalation exposures to TCE as an eight-hour TWA based on developmental toxicity	Prohibit; includes a TSCA section 6(g) exemption for the industrial and commercial use as solvent for closed-loop batch vapor degreasing for essential aerospace use and medical tubing + WCPP includes an ECEL of 0.0040 ppm for inhalation exposures to TCE as an eight-hour TWA based on immunotoxicity
Industrial and commercial use as a solvent for in-line conveyorized vapor degreasing	Prohibit	Prohibit
Industrial and commercial use as a solvent for in-line web cleaner vapor degreasing	Prohibit	Prohibit
Industrial and commercial use as a solvent for cold cleaning	Prohibit	Prohibit
Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner and mold release	Prohibit	Prohibit
Industrial and commercial use as a lubricant and grease in tap and die fluid	Prohibit	Prohibit

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	Action	
Condition of Use	**Proposed Regulatory Action[1]**	**Primary Alternative Action**
Industrial and commercial use as a lubricant and grease in penetrating lubricant	Prohibit	Prohibit
Industrial and commercial use as an adhesive and sealant in solvent-based adhesives and sealants; tire repair cement/sealer; mirror edge sealant	Prohibit	Prohibit
Industrial and commercial use as a functional fluid in heat exchange fluid	Prohibit	Prohibit
Industrial and commercial use in paints and coatings as a diluent in solvent-based paints and coatings	Prohibit	Prohibit
Industrial and commercial use in cleaning and furniture care products in carpet cleaner and wipe cleaning	Prohibit	Prohibit
Industrial and commercial use in laundry and dishwashing products in spot remover	Prohibit	Prohibit
Industrial and commercial use in arts, crafts, and hobby materials in fixatives and finishing spray coatings	Prohibit	Prohibit
Industrial and commercial use in corrosion inhibitors and anti-scaling agents	Prohibit	Prohibit
Industrial and commercial use as a processing aid for battery separator manufacturing and for the manufacturing of specialty polymeric microporous sheet materials; process solvent used in polymer fabric spinning, fluoroelastomer manufacture and Alcantara manufacture; extraction solvent used in caprolactam manufacture; precipitant used in beta-cyclodextrin manufacture	Prohibit; includes a TSCA section 6(g) exemption for the industrial and commercial use as a processing aid for battery separator manufacturing + WCPP includes an ECEL of 0.0011 ppm for inhalation exposures to TCE as an eight-hour TWA based on developmental toxicity	Prohibit; includes TSCA section 6(g) exemptions for the industrial and commercial use as a processing aid for battery separator manufacturing and for the manufacturing of specialty polymeric microporous sheet materials + WCPP includes an ECEL of 0.0040 ppm for inhalation exposures to TCE

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	Action	
Condition of Use	**Proposed Regulatory Action[1]**	**Primary Alternative Action**
		as an eight-hour TWA based on immunotoxicity
Industrial and commercial use as ink, toner and colorant products in toner aid	Prohibit	Prohibit
Industrial and commercial use in automotive care products in brake parts cleaner	Prohibit	Prohibit
Industrial and commercial use in apparel and footwear care products in shoe polish	Prohibit	Prohibit
Industrial and commercial use in hoof polish; gun scrubber; pepper spray; other miscellaneous industrial and commercial uses	Prohibit; includes a TSCA section 6(g) exemption for the industrial and commercial use as a laboratory chemical for essential laboratory activities and some research and development activities + WCPP includes an ECEL of 0.0011 ppm for inhalation exposures to TCE as an eight-hour TWA based on developmental toxicity	Prohibit; includes a TSCA section 6(g) exemption for the industrial and commercial use as a laboratory chemical for essential laboratory activities + WCPP includes an ECEL of 0.0040 ppm for inhalation exposures to TCE as an eight-hour TWA based on immunotoxicity
Consumer use as a solvent in brake and parts cleaners	Prohibit[2]	Prohibit[2]
Consumer use as a solvent in aerosol electronic degreaser/cleaner	Prohibit[2]	Prohibit[2]
Consumer use as a solvent in liquid electronic degreaser/cleaner	Prohibit[2]	Prohibit[2]
Consumer use as a solvent in aerosol spray degreaser/cleaner	Prohibit[2]	Prohibit[2]
Consumer use as a solvent in liquid degreaser/cleaner	Prohibit[2]	Prohibit[2]
Consumer use as a solvent in aerosol gun scrubber	Prohibit[2]	Prohibit[2]
Consumer use as a solvent in liquid gun scrubber	Prohibit[2]	Prohibit[2]
Consumer use as a solvent in mold release	Prohibit[2]	Prohibit[2]

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	Action	
Condition of Use	**Proposed Regulatory Action[1]**	**Primary Alternative Action**
Consumer use as a solvent in aerosol tire cleaner	Prohibit[2]	Prohibit[2]
Consumer use as a solvent in liquid tire cleaner	Prohibit[2]	Prohibit[2]
Consumer use as a lubricant and grease in tap and die fluid	Prohibit[2]	Prohibit[2]
Consumer use as a lubricant and grease in penetrating lubricant	Prohibit[2]	Prohibit[2]
Consumer use as an adhesive and sealant in solvent-based adhesives and sealants	Prohibit[2]	Prohibit[2]
Consumer use as an adhesive and sealant in mirror edge sealant	Prohibit[2]	Prohibit[2]
Consumer use as an adhesive and sealant in tire repair cement/sealer	Prohibit[2]	Prohibit[2]
Consumer use as a cleaning and furniture care product in carpet cleaner	Prohibit[2]	Prohibit[2]
Consumer use as a cleaning and furniture care product in aerosol spot remover	Prohibit[2]	Prohibit[2]
Consumer use as a cleaning and furniture care product in liquid spot remover	Prohibit[2]	Prohibit[2]
Consumer use in arts, crafts, and hobby materials in fixative and finishing spray coatings	Prohibit[2]	Prohibit[2]
Consumer use in apparel and footwear products in shoe polish	Prohibit[2]	Prohibit[2]
Consumer use in fabric spray	Prohibit[2]	Prohibit[2]
Consumer use in film cleaner	Prohibit[2]	Prohibit[2]
Consumer use in hoof polish	Prohibit[2]	Prohibit[2]
Consumer use in toner aid	Prohibit[2]	Prohibit[2]
Disposal to industrial pre-treatment, industrial treatment, or publicly owned treatment works	Prohibit the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works; with a TSCA section 6(g) exemption for the disposal of TCE from cleanup projects.	Prohibit

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[1] Does not include exemptions under TSCA section 6(g); for certain industrial and commercial uses of TCE for DoD naval vessels and their systems, and in the maintenance, fabrication, and sustainment for and of such vessels and systems + WCPP, which includes an ECEL of 0.0011 ppm for inhalation exposures to TCE as an eight-hour TWA based on developmental toxicity; or for the emergency industrial and commercial use of TCE in furtherance of the NASA mission for specific conditions that are critical or essential and for which no technically and economically feasible safer alternative is available + WCPP, which includes an ECEL of 0.0011 ppm for inhalation exposures to TCE as an eight-hour TWA based on developmental toxicity.
[2] Prohibit manufacture, processing, and distribution in commerce for the consumer use.

VI. Rationale for the Proposed Regulatory Action and Primary Alternative Regulatory Action

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

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

1. Proposed regulatory action.

a. Prohibition.

EPA considered a prohibition as a regulatory option and is proposing it for all manufacturing (including import), processing, distribution in commerce, use, and certain types of disposal of TCE (Unit V.A.). EPA proposes that prohibition is necessary to address the unreasonable risk for all occupational conditions of use after taking into consideration other combinations of controls such as a non-prescriptive WCPP or prescriptive controls (i.e., engineering controls, administrative controls, and PPE). As described in Unit V.A., EPA's bases for the need for this regulatory approach are similar to those for the Agency's determination of unreasonable risk, and include severity of the hazard, exposed populations, magnitude of risk, and uncertainties (Ref. 2). Throughout this proposed rule, EPA has described the severity of the hazard of TCE (including immunotoxicity, developmental, and cancer risks), based on the 2020 Risk Evaluation for TCE, as well as the populations exposed to the 52 conditions of use that drive the unreasonable risk, which include numerous workers, ONUs, consumers, and

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bystanders, including PESS such as workers of reproductive age (in particular, older pregnant women).

The significance of the magnitude of exposures for TCE is highlighted when considering the margins of exposure (MOEs, or the health point of departure for an endpoint divided by the exposure concentration) in the risk evaluation that estimate non-cancer risk for acute and chronic exposure. Estimated MOEs are compared to a benchmark, described in more detail in the risk evaluation, as part of the unreasonable risk determination (Refs. 1, 2). An MOE lower than the benchmark supports a determination of unreasonable risk of injury to health, based on noncancer effects. As an example, for commercial use of TCE in open top vapor degreasing, the chronic MOE for fetal cardiac defects is 0.0006, which is several orders of magnitude lower than then benchmark of 10. Even with engineering controls, the only way to reduce exposures more than 1,000-fold would be PPE with an APF of 10,000 (Ref. 1). This level of APF would require workers to constantly wear a full-face self-contained breathing apparatus (SCBA) in pressure demand mode or other positive pressure mode, which is considered unsustainable for the long-term and the least preferred approach to worker protection in the hierarchy of controls. There are many documented limitations to successful implementation of respirators with an APF of 10,000, including difficulties in fit and use rendering them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator (Refs. 69, 70) (63 FR 1152, January 8, 1998). EPA requests comments on subsections of conditions of use, which by nature of their infrequent occurrence, could meet the ECEL without having their employees wear high APF levels of PPE on a daily basis. Given that the magnitude of risk from TCE is so high, and that the extremely high level of PPE would be an ineffective long-term way of addressing that risk along with information provided by stakeholders, including during consultations (Refs. 70, 31), EPA has significant uncertainty that

any measures short of prohibition would be sufficient to address the unreasonable risk. Therefore, EPA proposes that prohibition is the preferred option to ultimately address unreasonable risk. EPA believes that the extremely low ppm level of the ECEL, while fully addressing unreasonable risk, will be infeasible for industry to reliably meet due to the need for a combination of engineering, administrative controls, and full-face, self-contained, air-supplied respirators. As such, the only way to protect human health consistently, reliably, and continually from unreasonable risk would be to prohibit TCE.

Ultimately, a prohibition would result in elimination of unreasonable risk from TCE, rather than allowing TCE use to continue in perpetuity, which would necessitate burdensome requirements to achieve exposure reductions to implement a technically challenging long-term program to meet a very low exposure limit. Recognizing that longer compliance timeframes and TSCA section 6(g) time-limited exemptions would nevertheless be necessary for certain critical uses to continue for a period of time as, described previously in Units V.A.1.d., V.A.1.e., and V.A.1.f., it is necessary to protect workers, including PESS, such as older pregnant workers and ONUs (the group identified as most susceptible to fetal cardiac defects). Therefore, as described in Unit IV., EPA is proposing the WCPP ECEL of 0.0011 ppm, based on the fetal cardiac defects endpoint, so that the developing fetus is best protected. EPA's primary alternative regulatory option bases the WCPP ECEL for TCE on the immunotoxicity endpoint. Because it would not be as protective for the subset of PESS that include older pregnant workers and ONUs as specific under TSCA section 6(b), the ECEL based on immunotoxicity was not put forth as the proposed ECEL. In other words, under the immunotoxicity ECEL of 0.0040 ppm, workers and ONUs would be protected from immunosuppression resulting from an acute (eight-hour) exposure, and from an excess risk of cancer resulting from lifetime exposure, as well as other adverse health effects such as reproductive toxicity, liver toxicity, kidney toxicity, and neurotoxicity. When the

ECEL of 0.0011 ppm based on fetal cardiac defects is used, EPA expects that a fetus would be protected from the effects of maternal exposure by workers and ONUs, in addition to the protections noted previously. Given this gap in protectiveness, the immunotoxicity ECEL of 0.0040 ppm is being considered as the alternative regulatory option rather than the proposed approach. As noted in Unit V.A.2., EPA has significant uncertainty about the extent to which some members of the regulated community could measure or reliably meet either the ECEL of 0.0011 ppm (in the proposed WCPP) or the ECEL of 0.0040 ppm (in the primary alternative regulatory action), which contributes to EPA's proposal that prohibition is the best long-term risk management option for TCE.

EPA understands that additional time may be necessary for certain processing and industrial and commercial conditions of use to achieve a full prohibition, including the need for upstream manufacturing, processing, and distribution in commerce for those uses to continue to ensure availability for the supply chain. In particular, EPA recognizes that processing TCE as a reactant/intermediate often takes place in unique closed-systems, and facilities processing TCE may need additional time to transition to adjust the physical plant design to accommodate an alternative manufacturing process or chemical substance and avoid significantly disrupting the supply chain. For example, EPA understands that the manufacturing (including import) and processing of TCE as an intermediate for the manufacture of HFC-134a is expected to phase down (absent a TSCA prohibition) over time as users move to more climate-friendly alternatives under the requirements of the AIM Act. In this instance, EPA is proposing requirements as part of a WCPP to reduce the worker exposures to TCE until the prohibition compliance date. In addition, EPA recognizes that industrial and commercial use of TCE as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production by Federal agencies and their contractors is a highly specific use with a uniquely long

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qualification process for alternatives. In the production of booster rocket nozzles, TCE is used in vapor degreasing as a solvent in rayon fabric sourcing, an intensive cleaning process to remove contaminants. This rayon fabric is then carbonized as part of an ablative process in the nozzle production and used to line the inside of the nozzles on booster rockets (Ref. 43). Cleaning is a critical step of this process; if contaminants are not sufficiently removed in the scouring stage, the fabric will be degraded during the chemical reaction that occurs during carbonization, which could result in failure of the nozzle during a launch and catastrophic effects for the rockets.

For this use, NASA has presented information to EPA on the necessity of additional time to transition to an alternative, given that 8 rocket launches are planned using booster sets with a component produced with TCE (Ref. 43). These launches could not occur if prohibition occurred on a shorter timeframe. In particular, given the end use of the components in human-rated spaceflight, EPA recognizes that NASA must conduct an array of tests to qualify an alternative solvent to TCE, including a variety of booster rocket function tests culminating in a full-scale static motor test. Even if an alternative were identified and qualified through a successful testing cycle, additional time would be needed for updates to workflows and production of new booster nozzles (Ref. 43). As such, EPA has provided additional time for the industrial and commercial use as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production by Federal agencies and their contractors. EPA recognizes that other Federal agencies may also rely on rayon fabric scouring for their rocket booster nozzle production and so proposes that the phaseout for this sub-set of the industrial and commercial use of TCE as a solvent in closed-loop batch vapor degreasing apply to Federal agencies generally and their contractors. As a condition for the phaseout, EPA has specified that a final pre-launch test of rocket booster nozzles without using TCE must be conducted within 5 years, with a full prohibition in 10 years on the use of TCE in scouring rayon fabric for end use in

nozzles in rocket boosters. For this phaseout period, EPA is proposing requirements as part of a WCPP to reduce the worker exposures to TCE until the prohibition compliance date, and Unit V.A.2. explains that the establishment of a WCPP is intended to allow more flexibility to regulated entities than requiring specific prescriptive controls. Similarly, EPA is proposing the WCPP to reduce to the extent possible the unreasonable risk until the prohibition compliance date for certain conditions of use that would be permitted to continue for longer than a year after publication of the final rule, as discussed in Unit V.A.

Additionally, prohibition is the preferred option for occupational conditions of use where reasonably available information suggests minimal ongoing use or when feasible safer alternatives are reasonably available. As described in this unit, EPA is highly uncertain as to whether users could comply with the requirements of a TCE WCPP, and EPA is also concerned with the severity of the risks of TCE. EPA notes the prevalence of alternative processes and products (Unit VI.B.). In some cases, reasonably available information indicating a use is no longer ongoing (Refs. 71, 3), has led EPA to propose more immediate prohibitions for most industrial and commercial uses of TCE, including the upstream manufacturing, processing, and distribution in commerce for those uses. EPA requests public comment on the rationale for proposing prohibitions as the preferred risk management approach. In addition, EPA requests comment regarding the number of businesses and other entities that could potentially close as well as associated costs with a prohibition of TCE for the industrial and commercial conditions of use identified in Unit V.A.1.

TSCA section 6(a)(2) provides EPA with the authority to prohibit or otherwise restrict the manufacture (including import), processing, or distribution in commerce of a substance or mixture “for a particular use” to ensure that a chemical substance no longer presents unreasonable risk. For this rulemaking, EPA proposes that “for a particular use” include

consumer use, which encompasses all known, intended, and reasonably foreseen consumer uses for TCE (Ref. 1). Given the severity and ubiquitous nature of the risks identified in the 2020 Risk Evaluation for TCE for processing of TCE into formulation as well as for all but one consumer use (pepper spray) and, noting that those conditions of use encompass all known, intended, and reasonably foreseen consumer use, EPA proposes that prohibiting manufacture (including importing), processing, and distribution in commerce of TCE for consumer use is reasonable and necessary to address the unreasonable risk from TCE driven by manufacturing (including importing) and processing TCE into formulation (the upstream conditions of use for products intended for consumer use), and that this proposed approach will also address the unreasonable risk to consumers and bystanders. Furthermore, amongst the broad prohibition of TCE, EPA considered and acknowledges the likely future unavailability of TCE for the consumer use of pepper spray, and EPA expects the prohibition on industrial and commercial use of TCE in pepper spray, as well as the upstream prohibition on manufacturing, processing, and distribution of TCE for commercial or consumer uses, would result in no TCE-containing pepper spray being produced for consumer use (Ref. 71).

Details of the proposed prohibitions are described in more detail in Unit V.A.

b. Workplace Chemical Protection Program (WCPP).

i. Overall. Prohibition is the preferred option for all occupational COUs, because significant uncertainty exists relative to any sector's ability to comply with a notably low exposure limit for TCE, particularly given the magnitude of exposure for many conditions of use (see Unit V.A.1.). A more immediate prohibition is the preferred option for occupational conditions of use where greater uncertainty exists relative to a sector's ability to comply with provisions of a WCPP, in particular a very low ECEL, as well as additional requirements that would support implementation of these restrictions (described in Unit V.A.2.). The 8-hour TWA

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ECEL of 0.0011 ppm for TCE that EPA is proposing, based on the developmental toxicity endpoint, is significantly lower than the OSHA PEL of 100 ppm, and there is a high degree of uncertainty as to whether users under the conditions of use in any sector would be able to comply with such a level and, thus, whether the unreasonable risk would be addressed. However, to address, to the extent possible, the unreasonable risk during the time period before a prohibition would become effective, EPA is proposing a WCPP until the prohibition compliance date. The WCPP would include a combination of restrictions to reduce the unreasonable risk from TCE driven by inhalation and dermal exposures in the workplace until the prohibition compliance date and is proposed only for certain conditions of use. EPA requests public comment related to the ability of regulated entities to meet the ECEL of 0.0011 ppm, and whether EPA should prescribe mandatory restrictions and PPE levels.

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

A central component of the TCE WCPP is the exposure limit. Exposures remaining at or below the ECEL would address any unreasonable risk of injury to health driven by inhalation exposures for occupational conditions of use. In the case of TCE, EPA has calculated the ECEL to be 0.0011 parts per million (ppm) (0.0059 mg/m^3) for inhalation exposures as an 8-hour TWA

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in workplace settings, based on the most sensitive acute non-cancer occupational HEC for fetal cardiac defects (Ref. 13). The differences between the ECEL and the OSHA PEL are discussed in more detail in Unit II.C.1.b. EPA chose the acute non-cancer developmental toxicity endpoint for TCE as the basis for the exposure limit for the proposed regulatory action as it is the most sensitive endpoint and, therefore, would be protective of both acute and chronic non-cancer as well as cancer inhalation endpoints over the course of a working day and lifetime, including for potentially exposed or susceptible subpopulations (additional explanation is in Unit VI.A.). However, as discussed in Unit V.A.2., EPA expects that detection of and adherence to extremely low-ppm levels of TCE may present challenges to the regulated community (Ref. 45), and so EPA is proposing the WCPP until the prohibition compliance date. EPA emphasizes the time limited nature of this WCPP, due to the likely need for reliance on air-supplied respirators of APF 1,000 or 10,000 that would be needed to address the unreasonable risk, even when engineering and administrative controls are put into place. More details are provided later in this unit.

iii. Dermal protection. As part of the WCPP, EPA is proposing to require use and provision of chemically resistant gloves by potentially exposed persons in combination with specific activity training (e.g., appropriate procedures for glove removal, replacement, and disposal) for tasks where dermal exposure can be expected to occur. However, EPA understands these tasks are expected to occur for conditions of use, such as processing TCE as a reactant, where closed system processes are already in place to minimize exposure to TCE. EPA is not proposing to require owners or operators to document consideration of the hierarchy of controls for dermal exposures to TCE because EPA intends to prohibit all uses of TCE, EPA is proposing relatively rapid compliance dates for the prohibitions for most uses of TCE, and dermal PPE programs are somewhat more straightforward to implement than respiratory PPE programs. In

proposing dermal requirements, EPA took into consideration the volatile nature of TCE because the dermal absorption of TCE depends on the type and duration of exposure. For the conditions of use that would be subject to the WCPP, EPA also considered the unique, closed system processes of each use which aid to reduce dermal exposure.

iv. WCPP considerations. EPA is proposing a WCPP for several conditions of use of TCE to reduce the unreasonable risk to the extent possible during the time period before a prohibition becomes effective, described in Unit V.A.2.

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

EPA also considered the feasibility of exposure reduction sufficient to reduce the

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unreasonable risk, including in facilities currently complying with the OSHA PEL for TCE or implementing other recommended OELs such as the ACGIH TLV. While EPA acknowledges the regulated community's expected familiarity with OSHA PELs generally, as well as facilities' past and ongoing actions to implement the TCE PEL, the value of EPA's exposure limit is almost five orders of magnitude lower than the OSHA PEL. (The differences between the ECEL and the OSHA PEL are discussed in more detail in Unit II.C.4.) This creates a significant degree of uncertainty as to whether facilities engaging in most conditions of use could implement engineering or administrative controls to reduce exposures in a manner aligned with the hierarchy of controls to meet the ECEL (and associated action level) and whether they could do so without relying primarily on the use of PPE (which is the least preferred option in the hierarchy of controls) to supplement exposure reduction efforts.

EPA understands that this uncertainty extends to the feasibility of respirators as a long-term risk management practice as well, since the complexity and burden of wearing respirators increases with increasing APF. Although respirators, specifically SCBAs (APF 10,000), could reduce exposures to levels that protect against non-cancer and cancer risks, not all workers may be able to wear respirators. Individuals with impaired lung function due to asthma, emphysema, or chronic obstructive pulmonary disease, for example, may be physically unable to wear a respirator. OSHA requires that a determination regarding the ability to use a respirator be made by a physician or other licensed health-care professional, and annual fit testing is required for tight-fitting, full-face piece respirators to provide the required protection. Individuals with facial hair, such as beards or sideburns that interfere with a proper face-to-respirator seal, cannot wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue, and reduced work efficiency (63 FR 1152, January 8, 1998). According to OSHA, "improperly selected respirators may afford no protection at all (for

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example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health." (63 FR 1189 through 1190). Furthermore, depending on the air concentrations and proximity to the regulated area, other employees in the area may also need to wear respiratory PPE. EPA understands, based on reasonably available information, that occupational exposures tend to fluctuate depending on the task being performed and the frequency of the task, which could create challenges for reliably effective implementation of respiratory PPE (Refs. 70, 72, 35).

EPA reviewed reasonably available information, including monitoring data, and information related to considerations described previously in this unit. EPA expects attempts to implement the WCPP to include increased monitoring and that industry would likely need to exclusively rely on PPE when aiming to reach the ECEL, including the use of high APF respirators, such as fit-tested, air-supplied respirators of APF 1,000 or APF 10,000. Given the high APF of respirators that are likely needed to reach the ECEL, EPA recognizes that this equipment and its programmatic maintenance could be highly burdensome. EPA believes this could create implementation challenges and is not a long-term, sustainable use of the WCPP. The WCPP would be in place for a relatively short period of time (less than 10 years for the vast majority of production value) until the eventual prohibition, because of the likely need for such extensive PPE. The ultimate goal for TCE is prohibition given the difficulty of maintaining a WCPP long term.

One of the conditions of use for which EPA is proposing a WCPP until the prohibition goes into effect is processing TCE as a reactant/intermediate. The majority of the annual production volume of TCE processed as an intermediate under this condition of use goes almost entirely toward the manufacture of one HFC, HFC-134a (Refs. 3, 70, 73). Monitoring

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information submitted by facilities processing TCE as an intermediate to manufacture HFC-134a suggests that TCE is largely confined to the process reactors, which require infrequent loading and unloading activities taking place approximately 20 times per year and resulting in low-ppm TCE exposure levels (Ref. 70). The information submitted also highlights that TCE is consumed and transformed during the reaction process (Ref. 70). Additionally, HFC-134a is one of the regulated substances that are subject to a phasedown under the AIM Act, and as discussed in Unit I.D., EPA understands that HFC-134a has a lower GWP compared to other refrigerants, which will likely continue to be used to facilitate the transition from certain other HFCs pursuant to the phasedown under the AIM Act. Providing a longer phaseout under TSCA for processing TCE as an intermediate for the manufacture of HFC-134a, while subject to a WCPP, is consistent with the agency's efforts to address climate-damaging HFCs, such as HFC-134a, under the AIM Act. EPA is seeking comment on the actions that manufacturers who process TCE for the production of HFC-134a would take as a result of this proposed phaseout and whether this would motivate a decision to cease manufacture earlier than they would otherwise under the AIM Act phase-down. For the remaining volume of TCE processed as a reactant/intermediate for chemical synthesis other than manufacturing HFC-134a, additional time may be necessary to reconfigure or otherwise adjust the physical plant to accommodate an alternative manufacturing process, so a WCPP is also associated with the prohibition of other processing as a reactant/intermediate uses; however, the phaseout does not apply to the other uses for which EPA is proposing a more immediate prohibition discussed in Unit V.A.

Additionally, EPA considered other industrial and commercial uses as candidates for a WCPP. Similar to the processing of TCE as a reactant/intermediate, unique, closed-system processes exist for the industrial and commercial use as: processing aid in process solvent used in battery manufacture; a process solvent used in polymer fiber spinning, fluoroelastomer

manufacture and Alcantara manufacture; an extraction solvent used in caprolactam manufacture; and a precipitant used in beta-cyclodextrin manufacture. Where TCE is used as a processing aid, TCE is consumed or captured and reused in the process. Monitoring data suggests low-ppm TCE exposure levels but may involve daily worker tasks. EPA understands that some of the industrial and commercial uses of TCE as a processing aid occur outside of the U.S., or may no longer be ongoing in the U.S. However, EPA received and reviewed substantive information from the battery separator manufacturing industry, specifically for lead-acid and lithium-ion battery separator manufacturing processes, along with a request for a TSCA section 6(g) exemption under this TSCA rulemaking. EPA agrees that battery separator manufacturing is critical to the national economy and national security; therefore, EPA is proposing to grant a 10-year exemption from the prohibition for the industrial and commercial use of TCE as a processing aid for battery separator manufacturing. For this exemption EPA is proposing to impose the WCPP requirements as a condition for the TSCA section 6(g) exemption. All other industrial and commercial processing aid uses (e.g., process solvent used in polymer fabric spinning, fluoroelastomer manufacture, etc.) must comply with the more stringent prohibition detailed in Unit V.A.

Furthermore, EPA considered industrial and commercial uses of TCE as an essential laboratory chemical as necessary to continue following the WCPP requirements, during the period of the TSCA section 6(g) time-limited exemption described in Unit V.A. Industrial and commercial use as a laboratory chemical is necessary to provide for the analysis of monitoring samples required to implement the ECEL requirements under the WCPP as part of this proposed regulation, as well as for essential chemical analysis, including for ongoing cleanup projects that fall under the Superfund program or other EPA jurisdictions, described in Unit V.A.3. Furthermore, EPA expects laboratory settings to be more conducive to the implementation of

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engineering controls such as fume hoods to ventilate vapors and reduce overall exposure to TCE in alignment with the hierarchy of controls.

Lastly, for TCE to be available for the downstream uses described in this unit, it must be manufactured (including imported), processed, and distributed in commerce. Therefore, as discussed in Unit V.A., EPA is proposing the WCPP for manufacturing (including importing) and processing for certain industrial and commercial uses, to allow a continuous supply chain for the specified conditions of use expected to continue 1 year after the final rule is published until the prohibition compliance dates.

2. Primary alternative regulatory action.

EPA acknowledges that, for some conditions of use that it is proposing to prohibit, there may be some activities or facilities that need longer compliance timeframes in order to appropriately transition. Therefore, the primary alternative regulatory action accounts for additional time under a prohibition to provide the flexibility for facilities to comply, for example, to account for issues in the supply chain, such as the availability of alternatives to reformulate products. In selecting among the TSCA section 6(a) requirements for the primary alternative regulatory action for use of TCE-containing products, EPA considered risk-related factors, including but not limited to, the population exposed and the severity of the hazard of TCE and, separately, of other alternative solvents, which are undergoing risk evaluation and risk management under TSCA section 6, such as PCE (as part of a separate rulemaking under RIN 2070-AK84). For example, there may be instances where PCE and TCE may be desired because they are non-flammable solvents used as cleaning agents for energized electrical equipment (e.g., circuit boards). In these instances, additional time may be needed to identify an alternative chemical or process to avoid flammability concerns.

EPA also considered a TSCA section 6(g) time-limited exemption for additional

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conditions of use that are critical or essential, or where a prohibition could have significant impacts on the national economy, national security, and infrastructure As described in Unit V.B.3.a.ii., EPA requests comments on a TSCA section 6(g) exemption, and based on the information received may find that an exemption may be warranted under the primary alternative regulatory action for the industrial and commercial use of TCE in batch vapor degreasing for critical aerospace or medical device applications, if the workplaces engaged in that condition of use cannot meet the requirements of the proposed regulatory action.

Similar to the proposed regulatory action, the primary alternative regulatory action would include a WCPP for several conditions of use of TCE to reduce to the extent possible the unreasonable risk during the time period before a prohibition becomes effective, including as a condition to the TSCA section 6(g) exemption, per TSCA section 6(g)(4). For the implementation of the TCE WCPP, EPA considered providing additional time under the primary alternative regulatory action for the WCPP requirements given the difference in order of magnitude for the exposure limit under TSCA compared to levels required by OSHA or other recommended guidelines. These provisions would include, for instance, identifying appropriate monitoring methods to comply with an TSCA exposure limit that is five orders of magnitude lower than the OSHA PEL (i.e., 0.0040 ppm *vs.* 100 ppm, respectively), as well as providing for respiratory protection corresponding to a higher assigned protection factor than required by OSHA, further described in Unit II.C.

Further, the WCPP under the primary alternative regulatory action would include an ECEL of 0.0040 ppm to address inhalation exposures to TCE in occupational settings that is based on the immunotoxicity endpoint. EPA believes that this ECEL would be less protective than the ECEL of 0.0011 ppm based on the developmental toxicity endpoint, that EPA would require under the proposed regulatory action. (A summary of EPA's risk evaluation activities

under TSCA is provided in Unit II.D., and the health effects of TCE, including the difference in the two human health endpoints as the basis for the two different ECELs, are discussed in Unit VI.A.) EPA considered the extremely low-ppm values of both ECELs and acknowledges the uncertainties regarding the ability of traditional industrial hygiene methods to meet the limit of detection associated with either ECEL action level, and the feasibility of combining existing engineering and administrative controls to reduce the exposure of TCE to extremely low-ppm levels before relying on PPE. Therefore, EPA does not consider long-term implementation of the WCPP a feasible means of addressing unreasonable risk indefinitely; as such, prohibition of the affected conditions of use is ultimately necessary to address the unreasonable risk under both the proposed and primary alternative regulatory actions.

The primary alternative regulatory action is described in more detail in Unit V.B.

3. Risk management requirements considered but not proposed.

EPA considered but is not proposing to regulate the weight fraction of TCE in products for industrial and commercial or consumer use because TCE is the main constituent (e.g., cleaning component) of the majority of TCE-containing product formulations and EPA understands that decreasing the concentration of TCE decreases the efficacy of the product (Refs. 74, 75).

EPA also examined the extent to which a self-certification and limited-access program restricting TCE use to trained and licensed users could ensure that only certain workers employed by a facility would be able to purchase and subsequently use TCE. Under a limited access program such as a point-of-sale self-certification, entities would submit a self-certification to the distributor at the point of purchasing the products. The self-certification could consist of a statement indicating that the facility is implementing the required workplace safety measures to control exposures to TCE. However, a point-of-sale self-certification is not a viable option for

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this proposed rulemaking. Given the eventual full prohibition of TCE and the significant investments users may have to make toward establishing a WCPP, EPA does not believe it would be practicable to add an additional burden of implementing a limited access program. Therefore, EPA is not proposing a self-certification and limited access program as part of this rulemaking. EPA requests comment on the effectiveness of a limited access program, such as a point-of-sale self-certification or other administrative controls, to address the unreasonable risk of TCE, in particular for facilities with occupational exposures to TCE that may not be able to meet the WCPP requirements of this proposed rulemaking.

Another option that EPA considered was requiring prescribed engineering controls, administrative controls, or personal protective equipment to reduce exposures to TCE in occupational settings. Prescriptive requirements would be supported by information in the 2020 Risk Evaluation for TCE. However, as described in Unit III.A.1. and 2., EPA received input during required consultations and additional stakeholder engagement that regulatory options that align with the hierarchy of controls (i.e., elimination and substitution of hazards in the workplace) should be preferred over prescriptive controls (which alternatively could be accomplished through the implementation of a WCPP with a risk-based exposure limit) (Refs. 12, 31). Inadequacy of engineering, administrative, and personal protective equipment control measures to lower exposure below the exposure limit would mean that elimination or substitution would be the only viable methods of addressing unreasonable risk. Additionally, the WCPP approach EPA is considering under the proposed action is a more flexible approach as prescriptive controls present significant uncertainties related to their feasibility, given the site-specific operations and variable configurations, and need for consistency of proper use.

EPA determined that such controls (i.e., engineering or administrative controls, or PPE) may not be able to eliminate unreasonable risk for some conditions of use when used in isolation.

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In the 2020 Risk Evaluation for TCE, many conditions of use still drive unreasonable risk even with the application of air-supplied APF 50 respirators (Ref. 1). Reasonably available data indicated additional uncertainty regarding the feasibility of exposure reductions through engineering controls alone, considering the unique closed-system processes already in place (Refs. 70, 48). For occupational conditions of use, prohibitions (rather than prescribed controls) would be more appropriate to ensure the elimination of unreasonable risk of TCE. Nevertheless, EPA determined that a WCPP, including requirements for an ECEL (which would be accompanied by monitoring requirements) in tandem with the implementation of engineering controls, administrative controls, and/or PPE, as appropriate, would be necessary for reducing exposures to TCE prior to the proposed prohibition compliance dates.

4. Additional considerations.

After considering the different regulatory options under TSCA section 6(a), alternatives (described in Unit V.B.), compliance dates, and other requirements under TSCA section 6(c), EPA developed the proposed regulatory action described in Unit V.A. to address the unreasonable risk from TCE so that it is no longer unreasonable. To ensure successful implementation of this proposed regulatory action, EPA considered other requirements to support compliance with the proposed regulations, such as requiring monitoring and recordkeeping to demonstrate compliance with a WCPP and downstream notification regarding the prohibition on manufacturing (including import), processing, and distribution in commerce of TCE, and products containing TCE, for industrial and commercial use as well as consumer uses. These proposed requirements are described in Unit V.A.

As required under TSCA section 6(d), any rule under TSCA section 6(a) must specify mandatory compliance dates, which shall be as soon as practicable with a reasonable transition period, but no later than 5 years after the date of promulgation of the rule (except in the case of a

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use exempted under TSCA section 6(g) or for full implementation of ban or phaseout requirements). These compliance dates are detailed in Units V.A. and V.B. EPA may finalize significantly shorter or longer compliance timeframes based on consideration of public comments.

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

Under TSCA section 6(c)(2)(C), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, EPA must consider, to the extent practicable, whether technically and economically feasible alternatives that benefit human health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect. To that end, in addition to an Economic Analysis (Ref. 3), EPA conducted an Alternatives Assessment, using reasonably available information (Ref. 71).

For this assessment, EPA identified and analyzed alternatives to TCE in products relevant to industrial, commercial, and consumer conditions of use proposed to be prohibited or restricted. Based on reasonably available information, including information submitted by industry, EPA understands viable alternatives to TCE may not be available for several conditions of use, for example, processing TCE as an intermediate for the manufacture of HFC-134a, and considered that information to the extent practicable in the development of the regulatory options as described in Unit III.B.3. For some conditions of use, EPA was unable to identify products currently available for sale that contain TCE. EPA is soliciting comments on whether there are products in use or available for sale relevant to these conditions of use that contain TCE at this time, so that EPA can ascertain whether there are alternatives that benefit human health or the environment as compared to such use of TCE. These conditions of use are detailed in the

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Alternatives Assessment (Ref. 71).

For conditions of use for which products currently containing TCE were identified, EPA identified several hundred commercially available alternative products that do not contain TCE, and listed in the Alternatives Assessment, to the extent practicable, their unique chemical components, or ingredients. For each of these chemical components or ingredients, EPA identified whether it functionally replaced TCE for the product use and screened product ingredients for human health and environmental hazard, as well as identified flammability and global warming potential where information was reasonably available (Ref. 71). EPA then assigned a rating to the human health and environmental hazards, using a methodology described in the Alternatives Assessment document. In general, EPA identified products containing ingredients with a lower hazard screening rating than TCE for certain endpoints, while some ingredients presented higher hazard screening ratings than TCE (Ref. 71). These alternative hazard screening ratings are described in detail in the Alternatives Assessment grouped under common product use categories (Ref. 71).

Discussion of alternatives to TCE was discussed during the SBAR Panel process outreach meetings. EPA's consideration of alternatives was informed by the information provided by SERs, which included known problems and risks with several available alternatives, such as flammability, toxicity, and water limitations due to drought. Specifically, SERs discussed how some chlorinated solvents are currently undergoing TSCA risk evaluations, while other alternatives may be labeled as severe fire hazards by the National Fire Protection Association. SERs also mentioned that in the automotive and aerospace industries, alternative solvent degreasers may have their own hazard profile, which can include flammability, lower boiling temperatures, and toxicity (Ref. 32). SERs expressed concern for future regulation of chemicals undergoing risk evaluation, and also described the challenges of alternative processes, such as

aqueous methods. Specifically, SERs described how in certain regions it is difficult to justify installation of these systems due to limited space or water availability. One SER provided an account about one of their customers, who had an aqueous cleaning system installed and was unable to source the required amount of water to run it. EPA notes the concerns expressed by SERs regarding availability of feasible alternatives that could be subject to market forces that may impact availability of alternatives (e.g., certain fluorinated chemicals) or potentially be subject to future EPA regulations. EPA notes that SERs described how available alternatives for lubricants in spray applications are mostly fluorinated organic compounds; although non-fluorinated options may exist, the SERs expressed concern for future potential regulatory activity. A trade organization SER highlighted that some fluorinated alternatives to TCE are under increased regulatory scrutiny, especially at state levels, because they may be subject to state PFAS laws based on their chemical structure and properties (Ref. 32). These discussions with SERs informed the Panel recommendations.

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

VII. TSCA Section 6(c)(2) Considerations: Magnitude of Human Exposure, Environmental Effects of TCE, Benefits of TCE for Various Uses, and Reasonably Ascertainable Economic

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Consequences

As described in Unit IV., TSCA section 6(a) rules must be promulgated "in accordance with subsection (c)(2)." TSCA section 6(c)(2)(A) requires EPA, in proposing and promulgating TSCA section 6(a) rules, to "consider and publish a statement based on reasonably available information" with respect to listed criteria, including the effects and magnitude of exposure to human health and the environment, the benefits of the chemical substance for various uses, and the reasonably ascertainable economic consequences of the rule. Under TSCA section 6(c)(2)(B), EPA must "factor in, to the extent practicable," the considerations under TSCA section 6(c)(2)(A) when selecting among prohibitions and other restrictions in TSCA section 6(a) rules. EPA's consideration of the health effects of TCE is in Unit IV.; EPA's consideration of the remaining considerations under TSCA section 6(c)(2) are in this unit.

A. Magnitude of human exposure to TCE.

TSCA section 6(c)(2)(B) directs EPA to factor in, to the extent practicable, the magnitude of human exposure to TCE under TSCA section 6(c)(2)(A). EPA's analysis of the magnitude of human exposure to TCE are in the 2020 Risk Evaluation for TCE (Ref. 1). A summary is presented here.

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 TCE, EPA estimates is 43,675 workers, 8,920 ONUs, and 20,600 consumers (Ref. 3).

For the conditions of use that drive the unreasonable risk for TCE, PESS include workers and occupational non-users (ONUs), including men and women of reproductive age, adolescents, and biologically susceptible subpopulations; and consumer users (age 11 and older) and bystanders (of any age group, including infants, toddlers, children, and elderly), including biologically susceptible subpopulations.

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In addition to workers, ONUs, consumers, and bystanders to consumer use directly exposed to TCE, EPA recognizes there is exposure to the general population from air and water pathways for TCE. As mentioned in Unit II.D., EPA has separately conducted a screening approach to assess whether there may be potential risks to the general population from these exposure pathways. The screening approach was developed in order to allow EPA to determine—with confidence—situations which present no unreasonable risk to fenceline communities or where further investigation would be needed to develop a more-refined estimate of risk. The fenceline technical support memos for the ambient air pathway and the water pathway provide the Agency with a quantitative assessment of exposure. For TCE, the results from applying this screening approach did not allow EPA to rule out unreasonable risk to fenceline communities. This unit summarizes the results of that fenceline analysis. Although EPA is not making a determination of unreasonable risk based on the fenceline screening analysis, the proposed regulatory action described in Unit V. – which would ultimately prohibit all conditions of use of TCE is expected to eliminate the risks identified in the screening approach.

As described in Unit II.D., EPA's analysis methodology was presented to the SACC peer review panel in March 2022, and EPA considered SACC feedback (including the SACC recommendation to EPA to consider multiple years of release data to estimate exposures and associated risks) when applying the fenceline analysis to TCE. EPA also plans to consider SACC feedback and make decisions regarding how to build upon the screening approach so that EPA can more accurately assess and quantify general population exposures in upcoming risk evaluations, such as for the 1,4-dioxane supplement, the forthcoming 20 High Priority Substances, and manufacturer-requested risk evaluations. For TCE, EPA is including a multi-year assessment of the ambient air pathway in light of peer review comments on the initial

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methodology.

EPA interpreted risk estimates in relation to the benchmark values corresponding to each hazard value. In the case of acute and chronic exposures to drinking water, as well as incidental oral and incidental dermal exposures in ambient waters, potential for noncancer risk was identified by those risk estimates below the benchmark MOE for acute and chronic non-cancer immunotoxicity and developmental endpoints. While cancer risks were not assessed for incidental oral or dermal exposure pathways, cancer risks were assessed for inhalation exposures. For cancer, potential for risk was identified by those risk estimates above the benchmark. For the air pathway, EPA's analysis identified risk estimates that did not exceed the benchmarks for at least two non-cancer endpoints (developmental and immunotoxicity), and risk estimates above the benchmark for cancer. Estimates of cancer risk to fenceline communities were calculated and compared to 1×10^{-6} as a benchmark value for cancer risk in fenceline communities. Cancer benchmarks used by EPA and other regulatory agencies in interpreting the significance of cancer risks range from 1 in 1,000,000 to 1 in 10,000 (i.e., $1x10^{-6}$ to $1x10^{-4}$) depending on the subpopulation exposed (see, e.g., EPA's interpretation set forth in the *Federal Register* of September 14, 1989 (54 FR 38044) which discusses the use of benchmarks for purposes of assessing exposures to individuals living in the vicinity of air emissions sources under section 112 of the Clean Air Act (CAA); see also EPA's interpretation of the upper bound of acceptable risk and the preferred benchmark described in the Letter of Concern regarding EPA Complaint Nos. 01R-22-R6, 02R-22-R6, and 04R-22-R6 (Ref. 76, see page 3 footnotes 5 and 6, and page 6)). While EPA is unable to formally determine, based on the screening level fenceline analysis, whether risks to the general population drive the unreasonable risk, as a matter of risk management policy EPA considers the range of 1 in 1,000,000 to 1 in 10,000 (i.e., $1x10^{-6}$ to $1x10^{-4}$) as the appropriate values for interpreting the significance of increased cancer risk for the

general population, including fenceline communities. It is preferable to have the air or water concentrations of TCE result in an increased cancer risk closer to the 1 in 1,000,000 ($1x10^{-6}$) value, with the 1 in 10,000 ($1x10^{-4}$) value generally representing the upper bound of acceptability for estimated excess cancer risk. Benchmark values help inform decisions regarding the significance of risk, and the Agency considers a number of other factors when determining whether risks are significant, such as the endpoint under consideration, the reversibility of effect, and exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed).

In this unit, EPA presents the results of its ambient air and water pathways fenceline analysis and the uncertainties associated with the analysis. Overall, EPA's fenceline analysis for the air and water pathways for TCE did not allow EPA to rule out unreasonable risk to fenceline communities with confidence. Additionally, based on the fenceline analysis for the ambient air and water pathways for TCE, including the strengths, limitations, and uncertainties associated with the information used to inform the analysis, EPA is unable to determine with this analysis whether those risks drive the unreasonable risk of injury to health presented by TCE. EPA also describes how the proposal to prohibit the manufacturing (include importing), processing, and distribution in commerce of TCE for all uses of TCE (including all consumer use) is expected to eliminate the potential risks identified in the screening analysis to any general population or fenceline communities close to facilities engaging in TCE use. This unit also describes how EPA believes the proposed WCPP requirements may reduce exposures to the general population for facilities identified in the fenceline analysis with expected exposures to fenceline communities that are associated with conditions of use for which EPA is proposing longer compliance timeframes (including under a TSCA section 6(g) time-limited exemption). EPA therefore does not intend to revisit the air or water pathways for TCE as part of a supplemental risk evaluation.

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1. Ambient air pathway analysis.

The ambient air fenceline analysis was divided into three components: (1) A single-year ambient air analysis, (2) A multi-year ambient air analysis, and (3) A land use analysis. EPA conducted an ambient air analysis for a single year and multiple years to assess where estimates exceeded the one in a million risk estimates for non-cancer and cancer risk for real and generic, or modeled, facilities at multiple distances. After doing an initial screen (the single year ambient air screening analysis) that did not rule out unreasonable risk, EPA conducted additional analyses (the multi-year ambient air analysis) from which it derived risk estimates that, with a small number of exceptions, are within the cancer benchmarks used by EPA and other regulatory agencies of 1 in 10,000 to 1 in 1,000,000. The single year ambient air screening analysis and the multi-year ambient air analysis allow EPA to mathematically calculate a cancer risk in fenceline communities. The Agency then conducted a land use analysis as part of both the single-year and multi-year analyses to determine if EPA could reasonably expect an exposure to fenceline communities to occur within the modeled distances for facilities where there was an indication of risk. This review consisted of a visual analysis using aerial imagery and interpreting land/use zoning practices around each facility to identify where residential, industrial/commercial businesses, or other public spaces are present within those radial distances indicating risk (as opposed to uninhabited areas), as well as whether the radial distances lie outside the boundaries of the facility.

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

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latitude/longitude coordinates may represent the mailing address location of the office building associated with a very large facility or some other area of the facility rather than the actual release location (e.g., a specific process stack). This discrepancy between the coordinates reported in TRI and the actual release point could result in an exposure concentration that does not represent the actual distance where fenceline communities may be exposed. The fenceline analysis also evaluated the most "conservative exposure scenario" that consists of a facility that operates year-round (365 days per year, 24 hours per day, 7 days per week) in a South Coastal meteorologic region and a rural topography setting (Ref. 77). Therefore, the modeled exposures to people who live in fenceline communities may be overestimated if there are fewer exposure days per year or hours per day.

Additionally, the ambient air fenceline analysis (as well as the water pathway analysis, described in Unit VII.A.2.) organizes facilities and associated risks by OES and generally crosswalks each OES with the associated condition of use of TCE (Ref. 77). For some OES, EPA identified the associated conditions of use to the category level in the November 2020 Risk Evaluation for TCE, but, for the air pathway, was unable to identify the conditions of use to the subcategory level due to limited information on activities and use of TCE reported under TRI. Therefore, some OES indicating increased risk from ambient air exposures to TCE in the air fenceline analysis may be associated with one or more conditions of use of TCE.

EPA's analysis included inhalation hazard values for cancer and non-cancer risk (acute and chronic immunological and developmental endpoints). Because risk estimates did not exceed the benchmarks for any risks of non-cancer effects, the results presented focus on cancer risks. EPA's single year fenceline analysis for the ambient air pathway, based on methods presented to the SACC, evaluated TCE releases reported to TRI over the 2019 reporting year. This single-year fenceline analysis identified risk estimates exceeding one in a million for cancer risk for 99

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of the 133 facilities (including generic, or modeled, facilities) at multiple distances, representing 13 OES. While the analysis identified facilities with some indication of releases and potential exposure with associated increased cancer risk that exceeds one in a million at a distance of 100 meters or more from the releasing facility, the analysis did not identify any facilities exceeding 1 in 10,000; the highest risk estimate is in the 1 in 100,000 range. Separately, following SACC feedback, EPA applied a slightly modified pre-screening methodology to evaluate 6 years of TCE release data (2015 through 2020 TRI data as well as the 6-year average of that data) rather than a single year of data for facilities with reported releases in TRI. Although the multi-year analysis identified several additional facilities with risk estimates above one in a million for cancer farther out when compared to the single year analysis or that were not captured in the single-year analysis, the results of the overall risk profiles (i.e., OES and corresponding conditions of use with risk estimates above one in a million for cancer at the distances evaluated) indicated a higher risk profile than the single year analysis: the multi-year analysis identified 217 facilities and found risk estimates above one in a million for cancer in 133 of those facilities at a distance of 100 meters from the releasing facility. Based on the multi-year analysis, 58 of these 133 facilities either had risks above one in a million for cancer at distances farther out than 100 meters when compared to the single year analysis or are facilities that were not captured in the single-year analysis (e.g., did not report in 2019 TRI). The analysis did not identify any facilities exceeding 1 in 10,000 at a distance greater than 100 meters; the highest risk estimate is in the 1 in 100,000 range (Ref. 77).

EPA conducted a land use analysis to determine if EPA can reasonably expect an exposure to fenceline communities to occur within the modeled distances for facilities where there was an indication of risk in the single year or multi-year fenceline analysis. This review consisted of a visual analysis using aerial imagery and interpreting land/use zoning practices

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around the facility to identify where residential, industrial/commercial businesses, or other public spaces are present within those radial distances indicating risk (as opposed to uninhabited areas), as well as whether the radial distances lie outside the boundaries of the facility. The land use analysis of the 85 facilities with risk indicating risk in the single-year fenceline analysis identified 69 facilities with expected exposure to fenceline communities. The land use analysis of the 58 facilities indicating risk in the multi-year fenceline analysis (i.e., facilities where risk estimates were above one in a million for cancer at distances farther out when compared to the single-year analysis or facilities that were not captured in the single year analysis) identified a total of 55 facilities with expected exposure to fenceline communities. Those facilities represent 10 OES and include: degreasing (batch open-top degreasing; batch closed-loop degreasing; conveyorized vapor degreasing; web vapor degreasing; cold cleaning); formulation of aerosol and non-aerosol products; industrial processing aid; manufacturing; metalworking fluids; other industrial uses; process solvent recycling and worker handling of wastes; processing as a reactant; recycling and disposal; and repackaging (Ref. 77).

Under the proposed regulatory action described in Unit V.A., each of the conditions of use that indicate risk relative to the one in a million cancer risk estimate would ultimately be prohibited, many of them within one year. As a result, exposures to any fenceline communities from these facilities would be eliminated under the prohibitions in this proposed rulemaking. The risks to fenceline communities from exposure further strengthens the impetus for EPA's prohibition of TCE.

EPA recognizes that there are some facilities for which risks are indicated that may exceed the one in a million risk estimate and with expected exposure to fenceline communities that may be associated with the following conditions of use that EPA is proposing to prohibit under longer compliance timeframes: degreasing (batch open-top degreasing; batch closed-loop

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degreasing; conveyorized vapor degreasing; web vapor degreasing; cold cleaning); industrial processing aid; manufacturing; and processing as a reactant. For processing as a reactant, EPA notes that while the analysis identified facilities with some indication of releases and potential exposure with associated increased cancer risk that exceeds one in a million at a distance of 100 meters from the releasing facility, the analysis did not identify any facilities exceeding 1 in 10,000; the highest risk estimate is in the 1 in 100,000 range. For this and other conditions of use that may be associated with facilities that indicate risks with expected exposure to fenceline communities, the proposed rule would require strict workplace exposure controls via implementation of a WCPP as described in Unit V.A.2., until the prohibition compliance date. Under the proposed WCPP requirements, facilities would need to monitor indoor TCE air concentrations, which would allow facilities to better understand and manage the total releases of TCE. Furthermore, under the WCPP requirements, facilities would need to evaluate controls to determine how to reduce releases and exposures to potentially exposed persons in the workplace. EPA anticipates that this analysis would help facilities to determine the most effective ways to reduce exposures (including possible engineering controls or elimination/substitution of TCE) and whether those methods for exposure reduction impact releases, and therefore may reduce the overall risk to fenceline communities from facilities permitted to use TCE under a longer compliance timeframe until the prohibition compliance date. As further detailed in Unit V.A.2.b.iii., EPA is also requesting comment on whether industry anticipates increased releases of TCE to outdoor air associated with the implementation of the WCPP. In order to avoid unintended increases in exposures to people from TCE emissions to ambient air, EPA requests comment on whether owners and operators should be required to attest in their exposure control plan that engineering controls selected do not increase emissions of TCE to ambient air outside of the workplace and document in their exposure control plan whether additional equipment was

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installed to capture emissions of TCE to ambient air. EPA requests comment on how such a requirement could impact the availability, feasibility, or cost of engineering controls as a means to reduce workplace exposures to or below the proposed ECEL. EPA is also soliciting comment on the frequency and nature of air monitoring EPA should consider including as requirements in the final rule.

In the instances where efforts to reduce exposures in the workplace to levels below the ECEL could lead to adoption of engineering controls that ventilate more TCE outside, EPA believes this potential exposure would be limited as a result of the existing NESHAP for TCE for these conditions of use under the CAA. Applicable NESHAP include: 40 CFR part 63, Subpart F, Synthetic Organic Chemical Manufacturing Industry; 40 CFR part 63, Subpart DD, Off-Site Waste and Recovery Operations; 40 CFR part 63, Subpart VVV, Publicly Owned Treatment Works; 40 CFR part 63, Subpart VVVVVV, Chemical Manufacturing Area Sources; 40 CFR part 63, Subpart GG, Aerospace Manufacturing and Rework Facilities; 40 CFR part 63, Subpart T, Halogenated Solvent Cleaning, which impose emission standards and work practice requirements reflecting maximum achievable control technology and generally available control technology. The CAA required residual risk reviews for standards reflecting maximum achievable control technology, and technology reviews are required every 8 years for all NESHAP.

2. Water pathway analysis.

The methods used to assess the water pathways (i.e., drinking water or incidental dermal or oral exposure in ambient waters) for TCE are consistent with the methods described in the 2022 Fenceline report that underwent peer review (Ref. 78). Briefly, EPA assessed exposure via drinking water, incidental oral ingestion, and incidental dermal contact based on modeled stream and water body concentrations, using information described and documented in the November

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2020 TCE Risk Evaluation (Ref. 1). This included the amount of chemical released to wastewater, the release days per year (with a high end of 250 to 365 days per year, and a low end of 20 days per year), the percent removal from wastewater treatment, and site-specific stream flow or dilution factors.

There are some uncertainties associated with the fenceline analysis for the water pathway for TCE. For the ambient water pathway, exposures were evaluated based on modeled stream and water body concentrations using E-FAST 2014, which is subject to a number of uncertainties. For example, stream flow data available in the E-FAST 2014 at the time of this analysis were 15 to 30 years old and therefore may not represent current conditions at a particular location. Additionally, E-FAST 2014 estimates waterbody surface water concentrations at the point of release without considering certain post-release environmental fate of degradation processes, which may lead to higher predicted surface water concentrations. Similarly, estimated drinking water exposures are based on assumptions that an individual is exposed to potential waterbody concentrations at the point of release without any potential for transport, dilution, or treatment and therefore represent higher-end estimates of possible drinking water exposures (Ref. 79). An additional uncertainty relates to the crosswalk of a given facility to a particular OES and then condition of use; as described in Unit VII.A.2., due to limited information on activities and use of TCE in the data sources available, there is uncertainty if the facilities associated with a specific OES were correctly cross-walked to the appropriate condition of use, or whether some OESs indicating increased risk from water exposures to TCE should be associated with more than one condition of use.

EPA's screening level analysis for the water pathway for TCE, based on methods presented to the SACC, found potential risks from several OES from exposure to drinking water, incidental dermal or incidental oral exposure in ambient waters. The estimated exposure values

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for the screening level assessed water pathway resulted in estimated acute noncancer, chronic noncancer, or cancer risk for relative to their respective benchmark values for various evaluated OESs (Ref. 79).

The drinking water analysis modeled a total of 101 releases across all OES for the 20-day release scenario, and modeled a total of 103 releases for the maximum days of release scenario. For the drinking water exposure, risks relative to the benchmark for the acute non-cancer developmental endpoint for both the 20-day and maximum days of release scenarios for at least one facility in each of the following OES: Manufacturing; Processing as a Reactant; Degreasing; Repackaging; Process Solvent Recycling; Adhesives, Sealants, Paints and Coatings; Industrial Processing Aid, and Other Industrial Uses. For drinking water exposures, at least one facility indicated an increased cancer risk at or above 1 in 1,000,0000 (but less than 1 in 100,000) for both the 20-day and maximum days of release scenarios for the Degreasing and Repackaging OES. EPA did not identify source water drinking water intakes for public drinking water systems within 10 miles downstream of facilities with known locations discharging to identifiable waterbodies. No risks relative to acute or chronic exposures for the immune endpoint or for chronic exposures for the developmental endpoint benchmarks were identified for any OES for drinking water exposures; for the immune endpoint, estimated margins of exposure were at least 4-fold higher than benchmarks.

For the incidental oral exposure in ambient water, a total of 113 releases were modeled across all OES for the 20-day release scenario, and a total of 115 releases were modeled across all OES for the maximum days of release scenario. Risks relative to the benchmark were identified for at least one facility for the acute non-cancer developmental endpoint under the 20-day scenarios for Processing as a Reactant; Degreasing; Repackaging; Process Solvent Recycling; Adhesives, Sealants, Paints, and Coatings; and Other Industrial Uses OESs were

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identified for the 20-days of release scenario. For the maximum days of release scenario, risks relative to the benchmark for the acute developmental endpoint were identified for: Processing as a Reactant and Degreasing. For the immune endpoint, no risks were identified relative to the acute exposures benchmark. For chronic scenarios, risk was identified relative to the benchmarks for both the immune and developmental endpoints for the 20-day and maximum days of release scenarios. Specifically, at least one facility in the Degreasing OES was identified as showing risk relative to both endpoints for the maximum risk scenarios for both types of releases (20-day and maximum), and at least one facility in the Processing as a Reactant OES was identified as showing risk relative to the developmental endpoint for both the 20-day and maximum release scenarios.

Similarly, for the incidental dermal exposure in ambient waters pathway, a total of 113 releases were modeled across all OES for the 20-day release scenario, and a total of 115 releases were modeled across all OES for the maximum days of release scenario. For both incidental oral and incidental dermal exposures, EPA did not assess cancer risk because repeated exposures are not expected to continue across a lifetime. For acute scenarios, risk was identified for at least one facility relative to both the immune and developmental endpoints for the 20-day and maximum release scenarios. For 20-day release scenarios, the immune endpoint had identified risk relative to the benchmark for at least one facility in the Degreasing OES, while the developmental endpoint had identified risk relative to the benchmark for the at least one facility in the following OES: Processing as a Reactant; Degreasing; Repackaging; Process Solvent Recycling; Adhesives, Sealants, Paints, and Coatings; Industrial Processing Aid; and Other Industrial Uses. For the maximum days of release scenarios, risk relative to the developmental endpoint was identified for at least one facility in the Processing as a Reactant and the Degreasing OES. For chronic scenarios, risk was identified relative to both the immune and developmental endpoint

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benchmarks for at least one facility for both the 20-day and maximum days of release scenarios. For 20-day release scenarios, the Processing as a Reactant and Degreasing OES had risks identified relative to the immune and developmental endpoint benchmarks; for the maximum days release scenarios, the Processing as a Reactant and Degreasing OES had risks identified relative to the immune and developmental endpoint benchmarks.

Overall, for the analysis of the water pathway, EPA identified potential risks that exceed the benchmark for non-cancer endpoints from several facilities, representing benchmark exceedances between 1 and 10 OES, depending on whether the drinking water, incidental oral, or incidental dermal exposures are considered. In each case for the screening level analysis, risks were identified only for the maximum risk scenarios (or facilities with the highest reported results), and for a relatively small number of facilities. In instances where a facility may be engaging in a condition of use with a longer phase-out, EPA notes that in no instances did EPA identify drinking water intakes within 10 miles of a discharging facility, and emphasizes that the scenarios analyzed include significant uncertainties and assumptions within the high-end risk estimates due to reliance on the highest-reported results from several facilities (Ref. 79). Regarding cancer risks, while the analysis identified facilities with some indication of releases and potential drinking water exposure with associated increased cancer risk that exceeds more than 1 in 1,000,000, the analysis did not identify any facilities exceeding more than 1 in 10,000; the highest potential risk estimate is in the 1 in 100,000 range (Ref. 79).

Under the proposed regulatory action described in Unit V.A., all conditions of use would ultimately be prohibited and so any potential risk indicated by this screening analysis would be eliminated. In particular, under the proposed regulatory action the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works would be prohibited. The risks to fenceline communities from exposure through water further strengthen the impetus for

EPA's prohibition of TCE. EPA therefore does not intend to revisit the water pathway for TCE as part of a supplemental risk evaluation.

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

EPA's analysis of the environmental effects of TCE and the magnitude of exposure of the environment to TCE are in the 2020 Risk Evaluation for TCE (Ref. 1). The unreasonable risk determination for TCE is based solely on risks to human health (Ref. 2); based on the TSCA 2020 Risk Evaluation for TCE, EPA determined that exposures to the environment did not drive the unreasonable risk. A summary is presented here.

For all conditions of use, amphibian, fish, and aquatic invertebrate acute and chronic exposures to TCE do not drive the unreasonable risk. To characterize the exposure to TCE by aquatic organisms, EPA assessed environmental exposures derived from predicted and measured concentrations of TCE in surface water in the U.S. Specifically, the aquatic exposures associated with the industrial and commercial conditions of use were predicted through modeling, and the aquatic exposure assessment also includes an analysis of collected measured surface water concentrations from monitoring data. EPA considered the biological relevance of the species to determine the concentrations of concern for the location of surface water concentration data to produce risk quotients, as well as frequency and duration of the exposure. EPA determined that the evaluation does not support an unreasonable risk determination to aquatic organisms.

The toxicity of TCE to sediment-dwelling invertebrates is similar to the toxicity to aquatic invertebrates. TCE is expected to remain in aqueous phases and not adsorb to sediment due to its water solubility and low partitioning to organic matter. TCE has relatively low partitioning to organic matter and biodegrades slowly, so TCE concentrations in sediment pore water are expected to be similar to the concentrations in the overlying water or lower in the deeper part of sediment where anaerobic condition prevails. Thus, the TCE detected in sediments

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is likely from the pore water. Therefore, for sediment-dwelling organisms, the risk estimates, based on the highest ambient surface water concentration, do not support an unreasonable risk determination to sediment-dwelling organisms from acute or chronic exposures.

For terrestrial organisms, TCE exposure is expected to be low since physical-chemical properties do not support an exposure pathway through water and soil pathways to these organisms. Therefore, for terrestrial organisms, the risk estimates, based on the EPA 2003 Guidance for Ecological Soil Screening Levels, do not support an unreasonable risk determination from acute or chronic exposures.

C. Benefits of TCE for various uses.

TCE has a wide range of uses, including as an intermediate during the manufacture of refrigerants, specifically HFC-134a, and is also used as a solvent, frequently in cleaning and degreasing (including spot cleaning, vapor degreasing, cold cleaning, and aerosol degreasing). A variety of consumer and commercial products use TCE as adhesives and sealants, in paints and coatings, and in other miscellaneous products. TCE is subject to Federal and State regulations and reporting requirements.

The largest uses of TCE, by production volume, are for processing as a reactant/intermediate as well as aerosol and vapor degreasing uses. Based on the 2020 Risk Evaluation for TCE, over 84% of the production volume of TCE is processed as a reactant/intermediate, the majority of the volume is for TCE processed as an intermediate in the production of HFC-134a, a refrigerant widely used in a broad range of applications. The second largest use of TCE is in industrial and commercial uses for aerosol and vapor degreasing. TCE is a relatively inexpensive solvent useful for cleaning contaminated metal parts and other fabricated materials (Ref. 3).

TCE has many other uses, which, based on the 2020 Risk Evaluation for TCE,

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collectively constitute about 1% of the production volume (Ref. 1). In battery separator manufacturing, TCE is used as an extraction solvent to produce the desired porosity in lead-acid and lithium battery separators, which are essential to power vehicles and systems in the U.S. supply chain.

D. Reasonably ascertainable economic consequences of the proposed rule.

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

The reasonably ascertainable economic consequences of this proposed rule include several components, all of which are described in the Economic Analysis for this proposed rule (Ref. 3). With respect to the anticipated effects of this proposed rule on the national economy, EPA considered the number of businesses and workers that would be affected and the costs and benefits to those businesses and workers and did not find that there would be an impact on the national economy (Ref. 3). The economic impact of a regulation on the national economy becomes measurable only if the economic impact of the regulation reaches 0.25% to 0.5% of Gross Domestic Product (GDP) (Ref. 80). Given the current (real) GDP [of $60.4 trillion (2022)], this is equivalent to a cost of $151 billion to $302 billion. Therefore, because EPA has estimated that the monetized cost of the proposed rule would range from $33.1 million annualized over 20 years at a 3% discount rate and $40.6 million annualized over 20 years at a 7% discount rate, EPA has concluded that this action is highly unlikely to have any measurable effect on the national economy (Ref. 3). EPA does not have data to quantify employment impacts of the proposed rule, and large employment impacts are not expected. Instead, workers currently using TCE are expected to continue employment while shifting away from TCE use and towards alternatives. However, EPA acknowledges that transitional employment impacts may be experienced by some workers at facilities that opt to close or shift operations abroad

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instead of complying with requirements at the facilities currently using TCE. EPA considered the employment impacts of this proposed rule, and found that the direction of change in employment is uncertain, but EPA expects the short-term and longer-term employment effects to be small.

Of the small businesses potentially impacted by this proposed rule, 99.1% are expected to have impacts of less than 1% to their firm revenues, 0.5% are expected to have impacts between 1 and 3% to their firm revenues, and 0.4% are expected to have impacts greater than 3% to their firm revenues. The largest segment of businesses that would be affected by this regulation are commercial users of liquid and aerosol degreasers. Costs of alternatives were found to be both higher and lower than products containing TCE. For most product types, alternatives with similar efficacy are available with costs that both lower and higher than TCE products. However, there may be some applications where TCE is more effective, reducing labor time and wait time, and or where extensive safety testing might be required. EPA was unable to quantify these costs.

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

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

The costs and benefits that can be monetized for this proposed rule are described at

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length in in the Economic Analysis (Ref. 3). The monetized costs for this proposed rule are estimated to range from $33.1 million annualized over 20 years at a 3% discount rate and $40.6 million annualized over 20 years at a 7% discount rate. The monetized benefits are estimated to range from $18.1 to $21.5 million annualized over 20 years at a 3% discount rate and $8.2 to $10.3 million annualized over 20 years at a 7% discount rate.

EPA considered the estimated costs to regulated entities as well as the cost to administer and enforce alternative regulatory actions. The primary alternative regulatory action is described in detail in Unit V.B. The estimated annualized costs of the alternative regulatory action are $34.4 million at a 3% discount rate and $41.2 million at a 7% discount rate over 20 years (Ref. 3). The monetized benefits of this alternative regulatory action are estimated to range from $18.1 to $21.5 million annualized over 20 years at a 3% discount rate and $8.2 to $10.3 million annualized over 20 years at a 7% discount rate over 20 years (Ref. 3).

This proposal is expected to achieve health benefits for the American public, some of which can be monetized and others that, while tangible and significant, cannot be monetized. EPA believes that the balance of costs and benefits of this proposal cannot be fairly described without considering the additional, non-monetized benefits of mitigating the non-cancer adverse effects. These effects may include neurotoxicity, kidney toxicity, liver toxicity, immunological and hematological effects, reproductive effects, and developmental effects. The multitude of adverse effects from TCE exposure can profoundly impact an individual's quality of life, as discussed in Unit II.A. (overview), Unit III.B.2. (description of the unreasonable risk), Unit V.A. (discussion of the health effects), and the 2020 Risk Evaluation for TCE. Chronic adverse effects of TCE exposure include both cancer and the non-cancer effects listed in this paragraph. Acute effects of TCE 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

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reductions in exposure cannot be quantified for non-cancer health effects associated with TCE 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 TCE adverse outcomes and therefore underestimates the benefits of this proposed rule.

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

Cost effectiveness is a method of comparing certain actions in terms of the expense per item of interest or goal. A goal of this proposed regulatory action is to achieve the risk reduction standard in a [more] cost-effective manner, with estimated [lower] costs and [higher] net benefits, than other considered alternative regulatory actions (Ref. 3). The proposed regulatory action would cost $6.8-7.7 million per potential prevented cancer case while the primary alternative regulatory action would cost $7.1-8.0 million (using the 3% discount rate) to achieve the same goals. While the primary alternative regulatory action is lower in cost compared to the proposed regulatory action, the difference is small (Ref. 3).

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

A. TSCA section 9(a) analysis.

TSCA section 9(a) provides that, if the Administrator determines, in the Administrator's discretion, that an unreasonable risk may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA, the Administrator must submit a report to the agency administering that other law that describes the risk and the activities that present such risk. TSCA section 9(a) describes additional procedures and requirements to be

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followed by EPA and the other Federal agency following submission of any such report. As discussed in this unit, for this proposed rule, the Administrator proposes to exercise his discretion not to determine that the unreasonable risk from TCE under the conditions of use may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA.

In addition, TSCA section 9(d) instructs the Administrator to consult and coordinate TSCA activities with other Federal agencies for the purpose of achieving the maximum enforcement of TSCA while imposing the least burdens of duplicative requirements. For this proposed rule, EPA has and continues to coordinate with appropriate Federal executive departments and agencies including OSHA and the Consumer Product Safety Commission (CPSC), to, among other things, identify their respective authorities, jurisdictions, and existing laws with regard to TCE, which are summarized in this unit.

OSHA requires that employers provide safe and healthful working conditions by setting and enforcing standards and by providing training, outreach, education and assistance. As described in Unit II.C., OSHA, in 1971, established a PEL for TCE 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 2 hours. However, the exposure limits established by OSHA are higher than the exposure limit that EPA determined would be sufficient to address the unreasonable risk identified under TSCA from occupational inhalation exposures associated with certain conditions of use. Gaps exist between OSHA's authority to set workplace standards under the OSH Act and EPA's obligations under TSCA section 6 to eliminate unreasonable risk presented by chemical substances under the conditions of use. Health standards issued under section 6(b)(5) of the OSH Act must reduce significant risk only "to the extent feasible." 29

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U.S.C. 655(b)(5). To set PELs for chemical exposure, OSHA must first establish that the new standards are economically and technologically feasible (79 FR 61384 and 61387, Oct. 10, 2014). But under TSCA section 6(a), EPA's substantive burden is to demonstrate that, as regulated, the chemical substance no longer presents an unreasonable risk, with unreasonable risk being determined without consideration of costs or other nonrisk factors. Thus, if OSHA were to initiate a new action to lower its PEL, the difference in standards between the OSH Act and TSCA may well result in the OSHA PEL being set at a higher level than the exposure limit that EPA determined would be sufficient to address the unreasonable risk under TSCA.

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

CPSC, under authority provided to it by Congress in the CPSA, protects the public from unreasonable risk of injury or death associated with the use of consumer products. Under the CSPA, CPSC has the authority to regulate TCE in consumer products, but not in other sectors such as automobiles, industrial and commercial products, or aircraft for example (Ref. 81). Further, a consumer product safety rule under the CPSA must include a finding that "the benefits expected from the rule bear a reasonable relationship to its costs," 15 U.S.C. 2058(f)(3)(E), whereas EPA must apply TSCA risk management requirements to the extent necessary so that the chemical no longer presents unreasonable risk and only consider costs and benefits of the regulatory action to the extent practicable, 15 U.S.C. 2605(a), (c)(2). Additionally, the 2016 amendments to TSCA reflect Congressional intent to "delete the paralyzing 'least burdensome'

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requirement," 162 Cong. Rec. S3517 (June 7, 2016), a reference to TSCA section 6(a) as originally enacted, which required EPA to use "the least burdensome requirements" that protect "adequately" against unreasonable risk, 15 U.S.C. 2605(a) (1976). However, a consumer product safety rule under the CPSA must impose "the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated." 15 U.S.C. 2058(f)(3)(F). Analogous requirements, also at variance with recent revisions to TSCA, affect the availability of action CPSC may take under the Federal Hazardous Substances Act (FHSA) relative to action EPA may take under TSCA. 15 U.S.C. 1262.

EPA therefore concludes that TSCA is the only regulatory authority able to prevent or reduce unreasonable risk of TCE to a sufficient extent across the range of conditions of use, exposures, and populations of concern. This unreasonable risk can be addressed in a more coordinated, efficient, and effective manner under TSCA than under different laws implemented by different agencies. Moreover, the timeframe and any exposure reduction as a result of updating OSHA or CPSC regulations cannot be estimated, while TSCA requires a much more accelerated 2-year statutory timeframe for proposing and finalizing regulatory requirements to address unreasonable risk. Further, there are key differences between the finding requirements of TSCA and those of the OSH Act, CPSA, and FHSA. For these reasons, in the Administrator's discretion, the Administrator has analyzed this issue and does not determine that unreasonable risk from TCE may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA. However, EPA is requesting public comment on this issue (i.e., the sufficiency of an action taken under a Federal law not administered by EPA).

B. TSCA section 9(b) analysis.

If EPA determines that actions under other Federal laws administered in whole or in part by EPA could eliminate or sufficiently reduce a risk to health or the environment, TSCA section

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

Although several EPA statutes have been used to limit TCE exposure (Ref. 9), regulations under those EPA statutes have limitations because they largely regulate releases to the environment, rather than occupational or consumer exposures. While these limits on releases to the environment are protective in the context of their respective statutory authorities, regulation under TSCA is also appropriate for occupational and consumer exposures and in some cases can provide upstream protections that would prevent the need for release restrictions required by other EPA statutes (e.g., Resource Conservation and Recovery Act (RCRA), CAA, Clean Water Act (CWA)).

The primary exposures and unreasonable risk to consumers, bystanders, workers, and ONUs would be addressed by EPA's proposed prohibitions and restrictions under TSCA section 6(a). In contrast, the timeframe and any exposure reduction as a result of updating regulations for TCE under the CAA, CWA, or RCRA cannot be estimated, nor would they address the direct human exposure to consumers, bystanders, workers, and ONUs from the conditions of use evaluated in the 2020 Risk Evaluation for TCE. More specifically, none of EPA's other statutes (e.g., RCRA, CAA, CWA) can address exposures to workers and ONUs related to the specific activities that result in occupational exposures, for example those associated with RCRA covered disposal requirements, such as in 40 CFR 261.24 and 40 CFR 268.3. EPA therefore concludes

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that TSCA is the most appropriate regulatory authority able to prevent or reduce risks of TCE to a sufficient extent across the range of conditions of use, exposures, and populations of concern.

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

C. TSCA section 14 requirements.

EPA is also providing notice to manufacturers, processors, and other interested parties about potential impacts to CBI that may occur if this rulemaking is finalized as proposed. Under TSCA section 14(b)(4), if EPA promulgates a rule pursuant to TSCA section 6(a) that establishes a ban or phase-out of a chemical substance, the protection from disclosure of any CBI regarding that chemical substance and submitted pursuant to TSCA will be "presumed to no longer apply," subject to the limitations identified in TSCA section 14(b)(4)(B)(i) through (iii). If this rulemaking is finalized as proposed, then pursuant to TSCA section 14(b)(4)(B)(iii), the presumption against protection from disclosure would apply only to information about the specific conditions of use that this rulemaking would prohibit or phase out. Manufacturers or processors seeking to protect such information would be able to submit a request for nondisclosure as provided by TSCA sections 14(b)(4)(C) and 14(g)(1)(E). Any request for nondisclosure would need to be submitted within 30 days after receipt of notice from EPA under TSCA section 14(g)(2)(A). EPA anticipates providing such notice via the Central Data Exchange or CDX.

D. TSCA section 26 considerations.

In accordance with TSCA section 26(h), EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best

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

In particular, the ECEL values considered for the WCPP are derived from the analysis in the 2020 Risk Evaluation for TCE. The proposed ECEL value of 0.0011 ppm as an 8-hour TWA is based on developmental toxicity, the most sensitive acute and chronic non-cancer health endpoint, specifically calculated based on the occupational acute, non-cancer human equivalent concentration (HEC) for fetal cardiac defects (Ref. 13). This is the concentration at which an adult human would be unlikely to experience the specified adverse effects if exposed for a working lifetime, including susceptible subpopulations. Similarly, the ECEL identified under the primary alternative regulatory option, based on a different health endpoint, immunotoxicity, is derived from the analysis in the 2020 Risk Evaluation for TCE. This ECEL is 0.0040 ppm as an 8-hour TWA which is based on the chronic non-cancer occupational HEC for autoimmunity (Ref. 14). As discussed in Unit VI.A., among the non-cancer adverse health effects, the drivers for EPA's whole chemical unreasonable risk determination for TCE under TSCA were identified as immunotoxicity, acute immunosuppression, and chronic autoimmunity, from inhalation and dermal exposures (Ref. 2). Therefore, reducing exposures remaining above the ECEL of 0.0040 ppm would reduce the contribution to the unreasonable risk of injury to health driven by inhalation exposures in an occupational setting for those conditions of use identified as presenting unreasonable risk in the 2020 Risk Evaluation for TCE under TSCA (Ref. 1, 14).

The extent to which the various information, procedures, measures, methods, protocols, methodologies or models, as applicable, used in EPA's decisions have been subject to

independent verification or peer review is adequate to justify their use, collectively, in the record for this rulemaking. Additional information on the peer review and public comment process, such as the peer review plan, the peer review report, and the Agency's response to comments, can be found in EPA's risk evaluation docket (Docket ID No.: EPA-HQ-OPPT-2016-0737).

IX. Requests for Comment

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

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

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

3. EPA requests comment on information that would allow EPA to quantify the magnitude of avoided risk of fetal cardiac defects due to reductions in TCE exposure under the proposed rulemaking.

4. EPA requests comment on whether EPA should promulgate definitions for each condition of use evaluated in the 2020 Risk Evaluation for TCE, and, if so, whether the descriptions in Unit III.B.1. are consistent with the conditions of use evaluated in the 2020 Risk Evaluation for TCE and whether they provide a sufficient level of detail to improve the clarity and readability of the regulation.

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

6. As noted in Unit III.B.1.f., this proposal does not apply to any substance excluded from the definition of "chemical substance" under TSCA section 3(2)(B)(ii) through (vi). EPA requests comment on the impacts, if any, that a prohibition on the processing of TCE into a formulation, mixture or reaction product in other chemical products and preparations, or other aspects of this proposal, may have on the production and availability of any pesticide or other substance excluded from the TSCA definition of "chemical substance."

7. EPA requests comment on whether it should consider a *de minimis* level of TCE in formulations to account for impurities (e.g., 0.1% or 0.5%) when finalizing the prohibitions described in Units V.A.1.b. and c., and, if so, information on and rationale for any level that should be considered *de minimis*.

8. EPA requests comment on whether additional recordkeeping requirements are warranted or additional time would be needed, for example, to begin the phaseout of processing TCE as an intermediate for the manufacture of HFC-134a.

9. EPA is seeking comment on the actions that manufacturers who process TCE for the

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production of HFC-134a would take as a result of the proposed phaseout in Unit V.A.1.d, and whether this would motivate a decision to cease manufacture earlier than they would otherwise under the AIM Act phase-down.

10. EPA requests comment on whether the 270-day proposed compliance date is practicable, whether additional time is needed, for example, for a regulated entity to implement a change to their disposal processes or to transition to alternative disposal methods and what those alternative disposal methods would be, and their cost and feasibility.

11. EPA is requesting comment on how entities could demonstrate that they are reducing exposures to the extent possible (including considerations for technological feasibility) and is also requesting comment on whether EPA's requirement should be that entities ensure that exposures are reduced below the ECEL, rather than to the extent possible or lowest achievable level.

12. For the ECEL value of 0.0011 ppm, proposed as part of the WCPP, EPA requests comment on the use of TSCA section 6(c)(2) to tailor the risk management actions where necessary to protect PESS.

13. EPA is requesting comment on the use of the ECEL value of 0.0040 ppm in the WCPP in the alternative regulatory action.

14. EPA is requesting comment on the selection of the fetal cardiac defects endpoint for the ECEL of 0.0011 ppm in the proposed regulatory action, rather than the immunotoxicity endpoint on which the unreasonable risk determination is based, which would result in an ECEL of 0.0040 ppm, as further detailed in Unit IV.A.

15. EPA is requesting comment on personal air sampling devices that are capable of detecting indoor air TCE concentrations at or below the proposed ECEL action level of 0.00055 ppm (0.0029 mg/m3) with the requisite precision and accuracy.

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16. EPA is requesting comment on using OSHA Method 1001, which has a personal breathing zone limit of detection for TCE of 18 ppb, or 0.018 ppm, to set an interim exposure limit of 0.036 ppm, with an action level of 0.018 ppm, as described further in Unit V.A.2.b.i.

17. EPA requests comments regarding replacing the proposed prohibitions with compliance with the WCPP, in the instance that regulated entities are able to consistently demonstrate compliance with an ECEL through effective controls.

18. EPA requests comment on the potential to develop future technologies (e.g., engineering controls, administrative controls, PPE) involving TCE for the conditions of use listed in Unit V.A.1.a., Unit V.A.1.d., and Unit V.A.3 that would facilitate successful implementation of the WCPP, including an ECEL of 0.0011 ppm for TCE, dermal protection, and ancillary requirements described in Unit IV.A.

19. EPA requests comment on the feasibility of controlling worker exposures to TCE at or below the proposed ECEL, and the accuracy of detections measurements at this level.

20. EPA requests comment on whether a phased approach to an ECEL is desirable; that is, an approach that would establish a timeframe for meeting the ECEL as well as a shorter timeframe for meeting a concentration level higher than the ECEL (but lower than the PEL) that is currently considered achievable. EPA welcomes data or information to demonstrate that meeting the proposed ECEL over a sustained period of time would be feasible and measurable.

21. EPA requests comments that provide supported recommendations for one or more incremental exposure values and associated timelines for achieving the incremental exposure levels and the currently proposed ECEL of 0.0011 ppm, and comments that consider and provide information on the needed advancements in exposure monitoring methods, analytical methods, and exposure controls, including expected timelines for developing these capabilities. 22. EPA requests comment on how owners and operators should identify the lowest achievable

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exposure level, what documentation would be needed to support that further reductions are not possible, and whether EPA should provide a definition of meeting the ECEL to the extent possible. Additionally, EPA requests comment on whether current monitoring methods are able to detect airborne concentrations at the ECEL and action level values. EPA expects that detection and adherence to extremely low-ppm levels of TCE may present challenges to some in the regulated community; therefore, EPA is also requesting comment on whether EPA should propose specific requirements following results indicating non-detectable concentrations of TCE (non-detects), or a requirement that a specific monitoring method be used.

23. EPA is soliciting comment regarding an ECEL action level that is half the ECEL and any associated provisions related to the ECEL action level when the ECEL is significantly lower than the OSHA PEL. EPA is also soliciting comment on whether the ECEL action level should be aligned with the OSHA PEL action level (typically set at half the limit), due to the fact that PEL accounts for technological feasibility and the action level is not necessarily designed to be health protective. Since exposure below the ECEL would be health protective, EPA seeks comment on whether the action level should be set at a different value closer to the ECEL that would trigger increased monitoring to ensure that the ECEL is not exceeded, and whether technological feasibility should be considered in setting the action level..

24. EPA requests comment on whether the action level should be set at a different value closer to the ECEL that would trigger increased monitoring to ensure that the ECEL is not exceeded, and whether technological feasibility should be considered in setting the action level.

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

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26. EPA requests comment on the timeframes for periodic monitoring outlined in Table 1 of Unit V.A.2.

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

28. EPA is requesting comment on whether the owner or operator should be required to permit designated representatives of employees and other workers to enter regulated areas to observe exposure monitoring similar to typical OSHA Standard requirements, e.g., 29 CFR 1910.1024(d)(7).

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

30. EPA is requesting comment on whether the timeframe to provide PPE to exposed workers should be shorter (e.g., within two weeks after the receipt of any exposure monitoring that indicates exposure exceeding the ECEL), given the severity of the effect, as discussed in Unit V.A.2.

31. EPA requests comment on the degree to which additional guidance related to use of gloves might be necessary. Additionally, EPA requests comment on whether EPA should incorporate additional dermal protection requirements into the exposure control plan or require consideration of the hierarchy of controls for dermal exposures.

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

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33. EPA requests comment relative to the ability of owners or operators to conduct initial monitoring within 6 months after date of publication of the final rule in the *Federal Register*, and anticipated timeframes for any procedural adjustments (i.e., use of new technologies for personal breathing zone monitoring at extremely low-ppm levels of TCE) needed to comply with the requirements outlined in Unit V.A.2., including establishment of a respiratory protection program and development of an exposure plan.

34. EPA is requesting comment regarding the amount of time, if any, it would take the regulated community to develop a method to measure at or below the ECEL over an entire work shift. EPA is interested in what levels of detection are possible based on existing monitoring methods, justification for the timeframe of the specific steps needed to develop a more sensitive monitoring method, and any additional detailed information related to establishing a monitoring program to reliably measure TCE at or below the ECEL.

35. EPA also requests comment relative to the ability of owners or operators to implement dermal protection within 6 months of publication of the final rule in the *Federal Register*, and anticipated timeframes for any procedural adjustments needed to comply with the requirements outlined in Unit V.A.2.

36. EPA requests comment on whether 10 years is an appropriate timeframe for the TSCA section 6(g) exemption for industrial and commercial use of TCE as a processing aid for battery separator manufacturing (lead-acid and lithium battery separators).

37. EPA requests comment on whether 50 years is an appropriate timeframe for the TSCA section 6(g) exemption for the industrial and commercial use of TCE as a laboratory chemical (specifically in lab use essential for essential laboratory activities), Specifically, EPA requests comment on the anticipated duration of TCE cleanup projects, and whether there will be projects that continue and require the use of TCE as a laboratory chemical for the analysis of

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contaminated soil, air, and water samples past 50 years.

38. EPA requests comment on the TSCA section 6(g) exemption for continued emergency use of TCE in the furtherance of NASA's mission as described in Unit V.A.3.iii.a.vi, and whether any additional conditions of use should be included, in particular for any uses qualified for space flight for which no technically or economically feasible safer alternative is available. Additionally, EPA requests comment on what would constitute sufficient justification of an emergency.

39. EPA requests comments on the appropriateness of identified compliance timeframes for recordkeeping and downstream notification requirements described in Unit V.A.2.

40. EPA requests comment on the primary alternative regulatory action and whether any elements of this primary alternative regulatory action described in Unit IV.B. should be considered as EPA develops the final regulatory action. EPA also requests comment on the practicability of the timeframes under the primary alternative regulatory action outlined in Unit V.B. compared to the timeframes identified for the proposed regulatory action in Unit V.A.

41. EPA requests comment on the practicability of the timeframes outlined for the phaseout of processing TCE as an intermediate for HFC-134a manufacture in Unit V.B. compared to the timeframes identified for the proposed regulatory action in Unit V.A., including consideration of the need for manufacturing (including import), and distribution in commerce to continue during the period of the phaseout.

42. EPA requests comment on the applicability to the private sector of proposed regulatory actions pertaining specifically to Federal agencies, namely industrial uses for DoD vessel requirements and for closed-loop batch vapor degreasing for rayon fabric scouring for rocket booster nozzle production. EPA requests comment on the extent to which the private sector would be affected by a prohibition on these uses.

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43. EPA requests comment on whether the three-year alternative timeline would be practicable or whether additional time is needed, for example, for a regulated entity to implement a change to their wastewater collection, treatment, or disposal processes or infrastructure, and what those alternative disposal methods may be.

44. EPA requests comment on the ability of regulated entities to conduct initial monitoring within 12 months, anticipated timeframes for any procedural adjustments needed to comply with the requirements, and the extent to which this option could result in additional exposure, compared to the proposed regulatory option as described in Unit V.A.

45. EPA requests comment on the practicability of the timeframes outlined in this unit, when compared to the timeframes identified for the proposed regulatory action in Unit V.A. EPA requests comment on whether any elements of the primary alternative regulatory action described in this unit should be considered as EPA develops the final regulatory action, e.g., whether EPA should consider the timeframes for implementation of a WCPP presented in this primary alternative regulatory action and the ECEL value presented in the proposed regulatory action.

46. EPA requests comment on the existing practices (e.g., engineering controls, administrative controls, PPE) involving TCE use in these conditions of use, as to whether activities may take place in closed systems and the degree to which users of TCE in these sectors could successfully implement an ECEL of 0.0011 ppm or an ECEL of 0.0040 ppm as an 8-hour TWA, dermal protection, and ancillary requirements described in Units V.A.2. and V.B.2.

47. EPA requests comment on the extent to which the use of TCE for vapor degreasing of narrow tubing is a critical use for which no technically and economically feasible safer alternative is available.

48. EPA therefore requests comment on the Agency’s consideration of an exemption

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from the prohibition on disposal of TCE by industrial pre-treatment, industrial treatment, or publicly owned treatment works for cleanup projects undertaken under the authority of CERCLA, RCRA, or other federal, state, or local government environmental laws, regulations, or requirements.

49. EPA requests comment on whether 50 years is a reasonable timeframe for a TSCA section 6(g)(1)(A) exemption for the cleanup of TCE-contaminated water and groundwater sites. Specifically, EPA requests comment on the anticipated duration of TCE cleanup projects, and whether there will be projects that may continue and require the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works beyond 25 years.

50. EPA requests comment on whether industry anticipates increased releases of TCE to outdoor air associated with the implementation of the WCPP. EPA requests comment on whether owners and operators should be required to attest in their exposure control plan that engineering controls selected do not increase emissions of TCE to ambient air outside of the workplace and document in their exposure control plan whether additional equipment was installed to capture emissions of TCE to ambient air. EPA requests comment on how such a requirement could impact the availability, feasibility, or cost of engineering controls as a means to reduce workplace exposures to or below the proposed ECEL. EPA is also soliciting comment on the frequency and nature of air monitoring EPA should consider including as requirements in the final rule.

51. EPA requests comments on all aspects of the TSCA section 6(g) exemptions described in Units V.A.3. and V.B.3., including whether compliance with the WCPP should also be required during the period of the exemption.

52. EPA is soliciting comment on if the exemption for laboratory use of TCE as described in Unit V.A.3.a.iii should include lab use of TCE for research and development

purposes for objectives broader than cleanup activities or exposure monitoring, such as research into TCE alternatives, whether these broader objectives should be limited to federal agencies and their contractors or expanded to include others, and whether a shorter time period, such as 10 years, should be imposed on these broader research and development activities.

53. EPA is soliciting comment on whether it should specify the type of batch vapor degreasing operation, such as open-top or closed loop batch vapor degreasing, that would be exempt from prohibition as part of the primary alternative regulatory action for the industrial and commercial use of TCE in batch vapor degreasing for essential aerospace parts and narrow tubing used in medical devices and whether EPA should consider different exemption timeframes for different types of vapor degreasing operations.

54. EPA requests comments on subsections of conditions of use, which by nature of their infrequent occurrence, could meet the ECEL without having their employees wear high APF levels of PPE on a daily basis.

55. EPA requests public comment on the rationale for proposing prohibitions as the preferred risk management approach. In addition, EPA requests comment regarding the number of businesses and other entities that could potentially close as well as associated costs with a prohibition of TCE for the industrial and commercial conditions of use identified in Unit V.A.1.

56. EPA requests comment on the effectiveness of a limited access program, such as a point-of-sale self-certification or other administrative controls, to address the unreasonable risk of TCE, in particular for facilities with occupational exposures to TCE that may not be able to meet the WCPP requirements of this proposed rulemaking.

57. EPA is soliciting comments on whether there are products in use or available for sale relevant to these conditions of use that contain TCE at this time, so that EPA can ascertain whether there are alternatives that benefit human health or the environment as compared to such

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use of TCE.

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

59. EPA is requesting public comment on an issue raised in its TSCA section 9(a) Analysis described in Unit VIII.A., (*i.e.,* the sufficiency of an action taken under a Federal law not administered by EPA).

60. Following Panel report recommendations (Ref. 32) and in response to input provided by SERs, EPA is requesting comment on the following topics as outlined in the SBAR Panel Report:

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

• EPA requests public comment on reasonable compliance timeframes for small businesses, specifically on whether and how to provide longer compliance timeframes for transitioning to alternatives for uses requiring reformulation and cleaning processes for cleaning parts for national defense or cleaning medical devices.

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

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

• EPA requests public comment the feasibility of entities complying with and monitoring for a potential ECEL of either 0.0011 ppm or 0.0040 ppm, specifically regarding potential costs that could be incurred using strategies to meet the requirements of such a standard, such as

engineering, administrative, or prescriptive controls and how feasible it would be for entities to implement these strategies in their operations.

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

• EPA requests public comment on a training and certification program for a commercial user to obtain a TCE-containing product from a retailer, such as industrial supply stores or online retailers.

• EPA requests public comment on a *de minimis* level in the case of an impurity or trace amounts of TCE in products.

• EPA requests public comment on whether to allow the use of TCE by entities that could, based on demonstrated ability through monitoring data, meet the ECEL under a workplace chemical protection program.

• EPA requests public comment on how the rulemaking should consider TCE alternatives in light of ongoing regulatory scrutiny.

• EPA requests public comment on whether chemicals undergoing risk evaluation would be likely to be considered as viable alternatives and, if so, in which circumstances.

• EPA requests public comment on potential challenges associated with monitoring TCE below 0.0011 ppm and 0.0040 ppm.

• EPA requests public comment on whether the use of TCE in a closed-loop vapor degreasing system, when combined with requirements of a potential workplace chemical protection program, could meet the ECELs for TCE.

X. 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,

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including documents that are referenced within the documents that are included in the docket, even if the referenced document is not itself physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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3. EPA. Economic Analysis of the Proposed Regulation of Trichloroethylene. 2023.

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XI. Statutory and Executive Order Reviews

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

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

This action is a "significant regulatory action" as defined in Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023). Accordingly, EPA submitted this action to OMB for Executive Order 12866 review. Documentation of any changes made in response to the Executive Order 12866 review is available in the docket. EPA prepared an economic analysis (Ref. 3) of the potential costs and benefits associated with this action, which is available in the docket and is summarized in Unit VI.D.

B. Paperwork Reduction Act (PRA).

The information collection activities in this proposed rule have been submitted to OMB 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. 2775.01 (Ref. 82). You can find a copy of the ICR in the docket for this rulemaking, and it is briefly summarized here.

There are two primary provisions of the proposed rule that may increase burden under the PRA. The first is downstream notification, which would be carried out by updates to the relevant SDS and which would be required for manufacturers, processors, and distributors in commerce of TCE, who would provide notice to companies downstream upon shipment of TCE about the prohibitions. The information submitted to downstream companies through the SDS would provide knowledge and awareness of the restrictions to these companies. The second primary provision of the proposed rule that may increase burden under the PRA is WCPP-related information generation, recordkeeping, and notification requirements (including development of

exposure control plans; exposure level monitoring and related recordkeeping; development of documentation for a PPE program and related recordkeeping; development of documentation for a respiratory protection program and related recordkeeping; development and notification to potentially exposed persons (employees and others in the workplace) about how they can access the exposure control plans, exposure monitoring records, PPE program implementation documentation, and respirator program documentation; and development of documentation demonstrating eligibility for an exemption from the proposed prohibitions, and related recordkeeping).

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

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

Estimated number of respondents: 22,113.

Frequency of response: On occasion.

Total estimated burden: 12,197 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $1,702,625 (per year), includes $722,586 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 certain EPA regulations in 40 CFR are listed in 40 CFR part 9 and displayed on the form and instructions or collection portal, as applicable.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this proposed rule. EPA will respond to ICR-related comments in the final rule. You may also send your ICR-related comments to OMB's

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Office of Information and Regulatory Affairs using the interface at *https://www.reginfo.gov/public/do/PRAMain*. Find this particular ICR by selecting "Currently under Review - Open for Public Comments" or by using the search function. OMB must receive comments no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

C. Regulatory Flexibility Act (RFA).

Pursuant to section 603 of the RFA, 5 U.S.C. 601 *et seq*., EPA prepared an initial regulatory flexibility analysis (IRFA) (Ref. 33) that examines the impact of the proposed rule on small entities along with regulatory alternatives that could minimize that impact. The complete IRFA is available for review in the docket and is summarized here.

1. Need for the rule.

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines after a TSCA section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a PESS identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements listed in TSCA section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents such risk. TCE was the subject of a risk evaluation under TSCA section 6(b)(4)(A) that was issued in November 2020. In addition, in January 2023, EPA issued a revised unreasonable risk determination that TCE as a whole chemical substance presents an unreasonable risk of injury to health under the conditions of use. As a result, EPA is proposing to take action to the extent necessary so that TCE no longer presents such risk.

2. Objectives and legal basis.

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

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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. EPA has determined through a TSCA section 6(b) risk evaluation that TCE presents an unreasonable risk under the conditions of use.

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

The proposed rule potentially affects small manufacturers (including importers), processors, distributors, retailers, users of TCE or of products containing TCE, and entities engaging in disposal. EPA estimates that the proposal would affect approximately 22,113 overall firms, of which 21,571 small entities have estimated impacts. End users with economic and technologically feasible alternatives are estimated to only incur costs associated with rule familiarization.

4. Projected compliance requirements.

To address the unreasonable risk EPA has identified, EPA is proposing to: Prohibit the manufacture (including import), processing, and distribution in commerce of TCE for all uses (including all consumer uses), with longer timeframes for manufacture and processing related to certain uses; prohibit the industrial and commercial use and distribution in commerce of TCE, with longer timeframes for certain uses; prohibit the manufacture (including import) and processing of TCE as an intermediate for the manufacture of HFC 134-a, following an 8.5-year phaseout; prohibit the industrial and commercial use of TCE as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production by Federal agencies and their contractors, following a 10-year phaseout; prohibit the manufacturing (including import), processing, distribution in commerce, and use of TCE as a processing aid for battery separator manufacturing following a 10-year TSCA section 6(g) exemption; prohibit the

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manufacturing (including import), processing, distribution in commerce, and use of TCE as a laboratory chemical (specifically in lab use essential for essential laboratory activities) following a 50-year TSCA section 6(g) exemption; Require strict workplace controls, including a TCE workplace chemical protection program (WCPP), which would include requirements for an inhalation exposure limit and glove requirements to limit dermal exposure to TCE, for conditions of use with long term phaseouts or time-limited exemptions under TSCA section 6(g); prohibit disposal to industrial pre-treatment, industrial treatment, or publicly owned treatment works following a 50-year TSCA section 6(g) exemption for cleanup projects; and establish recordkeeping and downstream notification requirements.

EPA is proposing to prohibit all conditions of use. EPA is proposing longer timeframes (with workplace controls) for prohibitions on certain conditions of use. For the reasons described in Unit V., EPA notes that long-term implementation of the WCPP is not a feasible means of addressing unreasonable risk and that prohibition of the COUs is ultimately necessary to address the unreasonable risk. Furthermore, when selecting among proposed prohibitions and other restrictions that would apply to those occupational conditions of use, EPA has also factored in considerations relating to health effects on PESS, including older pregnant women (the group identified as most susceptible to fetal cardiac defects), further discussed in Unit VI.A. EPA is proposing a WCPP for several conditions of use of TCE in order to address to the extent possible the unreasonable risk during the time period before a prohibition becomes effective. The WCPP would include the ECEL, the associated implementation requirements, and may include other components, such as dermal protection.

As described in Unit V.A., the TCE WCPP would be non-prescriptive, in the sense that regulated entities would not be required to use specific controls prescribed by EPA to achieve the exposure concentration limit. Rather, it would be a performance-based exposure limit that would

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enable owners or operators to determine how to most effectively meet the exposure limit based on conditions at their workplace.

A central component of the TCE WCPP is the exposure limit. Exposures remaining at or below the ECEL would address any unreasonable risk of injury to health driven by inhalation exposures for occupational conditions of use in the TSCA 2020 Risk Evaluation. For TCE, EPA is proposing an ECEL of 0.0011 parts per million (ppm) (0.0059 mg/m^3) for inhalation exposures to TCE as an 8-hour TWA. As discussed in Unit V.A.2.b.i., EPA acknowledges the challenges of complying with the WCPP due to suitable personal breathing zone monitoring methods to detect TCE air concentration levels at the ECEL, and requests comment on using OSHA Method 1001 to set an interim exposure limit.

Where elimination, substitution, engineering controls, and administrative controls are not feasible to reduce the air concentration to or below the ECEL for all potentially exposed persons, EPA is proposing to require implementation of a PPE program in alignment with OSHA's General Requirements for Personal Protective Equipment at 29 CFR 1910.132. Consistent with 29 CFR 1910.132, owners and operators would be required to provide PPE, including respiratory protection and dermal protection selected in accordance with the guidelines described in this unit, that is of safe design and construction for the work to be performed. EPA is proposing to require owners and operators ensure each potentially exposed person who is required by this unit to wear PPE to use and maintain PPE in a sanitary, reliable, and undamaged condition. Owners and operators would be required to select and provide PPE that properly fits each potentially exposed person who is required by this unit to use PPE and communicate PPE selections to each affected person.

As described further in Unit VI., EPA believes that long-term implementation of the WCPP for continued use of TCE is not a feasible means of addressing unreasonable risk such

that prohibition may ultimately be necessary to address the unreasonable risk.

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

The second is recordkeeping related to WCPP compliance: under the proposed regulatory action, facilities complying with the rule through the WCPP would be required to develop and maintain records associated with ECEL exposure monitoring (including measurements, compliance with Good Laboratory Practice Standards, and information regarding monitoring equipment); compliance with the ECEL or lowest achievable exposure level (including the exposure control plan, PPE program implementation, and workplace information and training); PPE compliance (including the exposure control plan, PPE program implementation, basis for specific PPE selection, and workplace information and training); and workplace participation. This would also include recordkeeping related to the exemptions proposed under TSCA section 6(g), which would provide longer compliance dates for entities engaged in specific activities with TCE for which prohibition in the short term would be disruptive to national security or critical infrastructure. To maintain eligibility for the time-limited exemptions, EPA is proposing that owners and operators maintain records demonstrating compliance with the specific conditions of the exemption, including compliance with the WCPP by meeting the ECEL to the extent possible. To support and demonstrate compliance, EPA is proposing that each owner or operator of a workplace subject to the WCPP retain compliance records for five years.

The third is recordkeeping related to the phaseouts for processing TCE in manufacture of HFC-134a (for which each manufacturer of HFC-134a who uses TCE as an intermediate would be required to maintain production volume records demonstrating compliance with setting the baseline and the phaseout) or use as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring (for which each person using TCE would be required to maintain records demonstrating that the end use is for rocket booster nozzle production for Federal agencies and their contractors and would, within five years, be required to maintain records that demonstrate that a final pre-launch test of rocket booster nozzles was completed without using TCE in the production of rocket booster nozzles for Federal agencies and their contractors).

a. 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 TCE, including retailers of TCE for end-consumer uses.

b. Professional skills needed to comply.

Entities that would be subject to this proposal that manufacture (including import), process, or distribute TCE in commerce would be required to cease under the proposed rule. The entity would be required to modify their SDS or develop another way to inform their customers of the prohibition on manufacture, processing, and distribution of TCE. They would also be required to maintain ordinary business records, such as invoices and bills-of-lading, that demonstrate compliance with the prohibitions, restrictions, and other provisions of this proposed regulation. These are all routine business tasks that do not require specialized skills or training.

Entities that use TCE in any industrial and commercial capacity would be required to cease under the proposed rule, with some timeframes for prohibitions longer than others. Restriction or prohibition of these uses would likely require the implementation of an alternative

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chemical or the cessation of use of TCE 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 TCE may choose to contract with another entity to do so.

Entities that would be permitted to continue on a time-limited basis until prohibition to manufacture, process, distribute, or use TCE would be required to implement a WCPP and would have to attempt to meet the provisions of the program to the extent possible for continued use of TCE. A transition to a WCPP may require persons with specialized skills such as an engineer or health and safety professional. Instead of implementing the WCPP to the extent possible, entities that use TCE may choose to contract with another entity to do so. Records would have to be maintained for compliance with a WCPP by meeting the ECEL to the extent possible. While this recording activity itself may not require a special skill, the information to be measured and recorded may require persons with specialized skills such as an industrial hygienist.

5. Relevant Federal rules.

Because of its health effects, TCE is subject to numerous State, Federal, and international regulations restricting and regulating its use. The following is a summary of the regulatory actions pertaining to TCE; for a full description see appendix A of the 2020 Risk Evaluation for TCE and the summary in the docket (Ref. 9).

EPA has published numerous rules and *Federal Register* documents pertaining to TCE under its various authorities.

Under a Significant New Use Rule (SNUR), (81 FR 20535, April 8, 2016), issued under the authority of TSCA section 5(a), TCE is subject to notifications for manufacture (including import) or processing of TCE for use in a consumer product except for use in cleaners and

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solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants and pepper spray. This SNUR ensures that EPA will have the opportunity to review any new consumer uses of TCE and, if appropriate, take action to prohibit or limit those uses.

The TSCA section 8(a) Chemical Data Reporting (CDR) Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States. TCE manufacturing (including importing), processing, and use information is reported under the CDR rule (76 FR 50816, August 16, 2011).

TCE is a hazardous air pollutant under the CAA (42 U.S.C. 7412(b)(1)). Under section 112(d), EPA has established national emission standards for hazardous air pollutants (NESHAPs) for a number of source-specific categories that emit TCE, including synthetic organic chemical manufacturing (40 CFR part 63, subparts F, G, and H), miscellaneous organic chemical manufacturing (40 CFR part 63, subpart FFFF), and aerospace manufacturing and rework facilities (40 CFR part 63, subpart GG). Under sections 112(d) and 112(f), EPA has promulgated a number of risk and technology review (RTR) NESHAPs, including the RTR NESHAP for Halogenated Solvent Cleaning (40 CFR part 63, subpart T). With this proposed rule under TSCA section 6, uses and emissions already regulated under these NESHAPs would be prohibited, with some of these uses identified for a longer phaseout timeframe under TSCA section 6.

Under the CAA section 612, EPA's Significant New Alternatives Policy (SNAP) program listed TCE as an acceptable substitute for methyl chloroform and chlorofluorocarbon (CFC)-113 in metals, electronics, and precision cleaning; as an alternative to CFC-11, CFC-113, methyl chloroform, and hydrochlorofluorocarbon (HCFC)-141b for aerosol solvent use; and as an alternative for methyl chloroform for use as a carrier solvent in adhesives, coatings, and inks

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(59 FR 13044, March 18, 1994). TCE was also noted to have essentially no ozone depletion potential and cited as a volatile organic compound (VOC)-exempt solvent and acceptable substitute for ozone-depleting substances (72 FR 30142, May 30, 2007). TCE is also listed under the National Volatile Organic Compound Emission Standards for Aerosol Coatings (40 CFR part 59, subpart E). Under the American Innovation and Manufacturing Act (AIM Act) that directs EPA to phase down the production and consumption of HFCs, EPA set HFC production and consumption baseline levels from which reductions will be made (86 FR 55116, October 5, 2021). The rule also establishes an initial methodology for allocating and trading HFC allowances for 2022 and 2023. TCE is identified as a feedstock chemical for HFC production, specifically HFC-134a.

TCE is designated as a toxic pollutant under section 307(a)(1) of the Clean Water Act and as such is subject to effluent limitations. Also under section 304, TCE is included in the list of total toxic organics (TTO) (40 CFR 413.02(i)). In 2015, EPA published updated ambient water quality criteria for TCE, including recommendations for "water + organism" and "organism only" human health criteria for States and authorized tribes to consider when adopting criteria into their water quality standards (80 FR 36986, June 29, 2015). TCE is also subject to National Primary Drinking Water Regulations (NPDWR) under the Safe Drinking Water Act (SDWA) with a maximum contaminant level goal (MCGL) of zero and an enforceable maximum contaminant level (MCL) of 0.005 mg/L (40 CFR 141.50; 40 CFR 141.61).

Programs within EPA implementing other environmental statutes, including, but not limited to, the RCRA, the Comprehensive Environmental Response, Compensation and Liability Act, the Safe Drinking Water Act, and the CWA, classify TCE as a characteristic and listed hazardous waste (40 CFR 261.24, 40 CFR 261.31, 40 CFR 261.33(f)). In 2013, EPA modified its hazardous waste management regulations to conditionally exclude solvent-contaminated wipes

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that have been cleaned and reused from the definition of solid waste under RCRA and to conditionally exclude solvent-contaminated wipes that are disposed from the definition of hazardous waste (78 FR 46448, July 31, 2013). However, TCE-contaminated wipes were not eligible for this exclusion due to health and safety concerns.

EPA notes that TCE was first registered as an antimicrobial and conventional chemical in 1985 pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). TCE is not currently used in pesticides, either as an active or inert ingredient. While TCE was previously used as an inert, EPA removed TCE from its list of inert ingredients used in pesticide products in 1998 (63 FR 34384, June 24, 1998).

While TSCA shares equity in the regulation of TCE, EPA does not anticipate this rulemaking to duplicate nor conflict with the aforementioned programs' classifications and associated rules.

In addition to EPA actions, TCE is also subject to other Federal regulations. Under the OSH Act, OSHA established the PEL for TCE at 100 ppm as an 8-hour TWA with an acceptable ceiling concentration of 200 ppm and an acceptable maximum peak above the acceptable ceiling concentration for an 8-hour shift of 300 ppm, maximum duration of 5 minutes in any 2 hours (29 CFR 1910.1000). However, EPA recognizes that the existing PEL does not eliminate the unreasonable risk identified by EPA under TSCA, and EPA is therefore proposing prohibitions based on the unreasonable risk identified following the TSCA 2020 Risk Evaluation for TCE, with time-limited requirements to meet to the extent possible a new, lower exposure limit. The implementation of those requirements would align with existing OSHA requirements where possible. For TCE, this approach would eliminate the unreasonable risk driven by certain conditions of use, reduce burden for complying with the regulations, and provide the familiarity of a pre-existing framework for the regulated community.

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Under the FFDCA, the Food and Drug Administration established tolerances for residues of TCE resulting from its use as a solvent in the manufacture of decaffeinated coffee and spice oleoresins (21 CFR 173.290). Under the Atomic Energy Act, the Department of Energy Worker Safety and Health Program requires its contractor employees to use the 2005 ACGIH TLV for TCE, which is 10 ppm (8-hour TWA) and 25 ppm Short Term Exposure Limit. Under the Federal Hazardous Material Transportation Act, the Department of Transportation has designated TCE as a hazardous material, and there are special requirements for marking, labeling, and transporting it (49 CFR part 171, 49 CFR part 172, 40 CFR 173.202, and 40 CFR 173.242).

6. Significant alternatives to the proposed rule.

EPA analyzed alternative regulatory approaches to identify which would be feasible, reduce burden to small businesses, and achieve the objective of the statute (i.e., applying one or more requirements listed in TSCA section 6(a) to the extent necessary so that the chemical substance or mixture no longer presents an unreasonable risk). As described in more detail in Unit V., EPA considered several factors, in addition to identified unreasonable risk, when selecting among possible TSCA section 6(a) requirements. To the extent practicable, EPA factored into its decisions: the effects of TCE on health and the environment, the magnitude of exposure to TCE of human beings and the environment, the benefits of TCE for various uses, and the reasonably ascertainable economic consequences of the rule. As part of this analysis, EPA considered – in addition to the prohibitions described in Unit V. – a wide variety of control measures to address the unreasonable risk from TCE such as a WCPP, weight fractions, a certification and limited access program, and prescriptive controls. EPA's analysis of these risk management approaches is detailed in Unit V.A.3. In general, EPA determined that these approaches alone would either not be able to address the unreasonable risk, or, in the case of a

weight fraction limit, would result in a product containing so little TCE that it would have the effect of a prohibition.

Additionally, in this proposed rule and the Economic Analysis, EPA has examined a primary alternative regulatory action. The primary alternative regulatory action described in this proposed rule and considered by EPA combines prohibitions and requirements for a WCPP. While in some ways it is similar to the proposed regulatory action, the primary alternative regulatory action described in this NPRM differs from the proposed regulatory action by providing longer timeframes for prohibitions and by describing an ECEL based on a different health endpoint (i.e., immunotoxicity), as part of the WCPP, for the conditions of use of TCE that would be permitted to continue for longer than 1 year after publication of the final rule until the prohibition compliance dates. The primary alternative regulatory action was considered and found to provide greater uncertainty in addressing the unreasonable risk from TCE under the conditions of use, resulting in EPA's proposed action. Estimated costs of the primary alternative regulatory action can be found in Chapter 7 of the Economic Analysis (Ref. 3).

As indicated by this overview, and detailed in Unit VI.A., in the review of alternatives, EPA determined that some methods either did not effectively eliminate the unreasonable risk presented by TCE or, for many conditions of use, there was a high degree of uncertainty regarding whether compliance with a comprehensive WCPP would be possible to adequately protect potentially exposed persons. While EPA is soliciting comments about all aspects on the alternative regulatory actions, which may be incorporated into the final rulemaking, EPA has considered the primary alternative regulatory action and found that the proposed action is more suitable for addressing the unreasonable risk to the extent necessary so that TCE no longer presents such risk, while also allowing flexibility for regulated entities to continue operations under time-limited exemptions, as described in more detail in Units V.A. and VI.A.

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Regarding timeframes for compliance, as described in Units V.A.1., 2., and 3., the proposed compliance dates incorporate EPA's consideration of sustained awareness of risks resulting from TCE exposure as well as precedent established by the OSHA standards (62 FR 1494, January 10, 1997). TSCA requires that EPA propose timeframes that are "as soon as practicable" under TSCA section 6(d)(1)(B) and 6(d)(1)(D). EPA has no information indicating that the proposed compliance dates are not practicable for the activities that would be prohibited, or that additional time is needed for products affected by the proposed restrictions to clear the channels of trade. As noted in Unit IX., EPA is seeking public comment on whether additional time is needed for compliance with prohibitions, for products to clear the channels of trade, or for implementing a WCPP. EPA may finalize shorter or longer compliance timeframes based on public comment. Regarding potential regulatory flexibilities for compliance dates and timeframes, EPA notes that the alternative regulatory action would include longer compliance timeframes for prohibitions. Given the potential severity of impacts from exposure to TCE, EPA's proposed regulatory action would include relatively rapid compliance timeframes. However, it is possible that longer timeframes would be needed for entities to come into compliance; therefore, the primary alternative regulatory action described in the proposed rule would include longer timeframes for implementation than the proposed regulatory action. These timeframes are detailed in Unit V.B.

As required by section 609(b) of the RFA, the EPA also convened a SBAR Panel to obtain advice and recommendations from SERs that potentially would be subject to the rule's requirements. The SBAR Panel evaluated the assembled materials and small-entity comments on issues related to elements of an IRFA. A copy of the full SBAR Panel Report (Ref. 32) is available in the rulemaking docket.

D. Unfunded Mandates Reform Act (UMRA).

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This action does not contain a Federal mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action would affect entities that use TCE. It is not expected to affect State, local, or Tribal governments because the use of TCE by government entities is minimal. This action is not expected to result in expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (when adjusted annually for inflation) in any 1 year. Accordingly, this action is not subject to the requirements of sections 202, 203, or 205 of UMRA.

E. Executive Order 13132: Federalism.

EPA has concluded that this action has federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because regulations under TSCA section 6(a) may preempt State law. As set forth in TSCA section 18(a)(1)(B), the issuance of rules under TSCA section 6(a) to address the unreasonable risk presented by a chemical substance has the potential to trigger preemption of laws, criminal penalties, or administrative actions by a State or political subdivision of a State that are: 1) Applicable to the same chemical substance as the rule under TSCA section 6(a); and 2) Designed to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of that same chemical. TSCA section 18(c)(3) applies that preemption only to the "hazards, exposures, risks, and uses or conditions of use" of such chemical included in the final TSCA section 6(a) rule.

EPA provides the following preliminary federalism summary impact statement. The Agency consulted with State and local officials early in the process of developing the proposed action to permit them to have meaningful and timely input into its development. This included background presentation on September 9, 2020, and a consultation meeting on July 22, 2021. EPA invited the following national organizations representing State and local elected officials to

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these meetings: Association of State Drinking Water Administrators, National Association of Clean Water Agencies, Western States Water Council, National Water Resources Association, American Water Works Association, Association of Metropolitan Water Agencies, Association of Clean Water Administrators, Environmental Council of the States, National Association of Counties, National League of Cities, County Executives of America, U.S. Conference of Mayors, and National Association of Attorneys General. As described in Unit III.A.1., during the meeting participants and EPA discussed preemption; the authority given under TSCA section 6 to regulate identified unreasonable risk; which activities would be potentially regulated in the proposed rule; TSCA reporting requirements; key local constituencies; and the relationship between TSCA and existing statutes, particularly the CWA and SDWA. A summary of the meeting with these organizations, including the views that they expressed, is available in the docket (Ref. 26). EPA provided an opportunity for these organizations to provide follow-up comments in writing but did not receive any such comments.

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

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. This rulemaking would not have substantial direct effects on Tribal government because TCE is not manufactured, processed, or distributed in commerce by Tribes. TCE is not regulated by Tribes, and this rulemaking would not impose substantial direct compliance costs on Tribal governments. Thus, Executive Order 13175 does not apply to this action.

Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, EPA consulted with Tribal officials during the development of this action. The Agency held a

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Tribal consultation from May 17, 2021, to August 20, 2021, with meetings on June 15, 2021, and July 8, 2021. Tribal officials were given the opportunity to meaningfully interact with EPA risk managers concerning the current status of risk management. During the consultation, EPA discussed risk management under TSCA section 6(a). EPA risk managers briefed Tribal officials on the Agency's risk management considerations and Tribal officials raised issues and concerns. Issues raised by Tribal officials included concerns from Tribal members about the TCE OSHA exposure limits being outdated, Tribal interest in seeing TCE phased out and an interest in reducing greenhouse gas emissions, and concerns that third party disposal may be occurring near Tribal lands, with a particular interest in protecting workers at publicly owned treatment works.

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. While the environmental health or safety risks addressed by this action present a disproportionate risk to children due to TCE's developmental toxicity, this action is not subject to Executive Order 13045 because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866.

However, EPA's 2021 Policy on Children's Health applies to this action. Information on how the Policy was applied is presented in Unit III.A.3. In addition, this action's health and risk assessments are contained in Units III.B.2., VI.A. and B., and the 2020 Risk Evaluation for TCE (section 4 in Ref. 1) and the Economic Analysis for this proposed rulemaking (Ref. 3).

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

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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.

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 TCE. Consistent with the Agency's Performance Based Measurement System (PBMS), the Agency proposes not to require the use of specific, prescribed analytic methods. Rather, the Agency plans to allow the use of any method that meets the prescribed performance criteria. The PBMS approach is intended to be more flexible and cost-effective for the regulated community; it is also intended to encourage innovation in analytical technology and improved data quality. EPA is not precluding the use of any method, whether it constitutes a voluntary consensus standard or not, as long as it meets the performance criteria specified.

For this rulemaking, the key consideration for the PBMS approach is the ability to accurately detect and measure airborne concentrations of TCE 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. 46). EPA recognizes that there may be voluntary consensus standards that meet the proposed criteria (Ref. 12). EPA request comments on whether it should incorporate such voluntary consensus standards in the rule and seeks information in support of such comments regarding the availability and applicability of voluntary consensus standards that may achieve the sampling and analytical requirements of the rule in lieu of the PBMS approach.

EPA requests comment on the degree to which additional guidance related to use of methods might be necessary.

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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. As described more fully in the Economic Analysis, EPA conducted an analysis to characterize the baseline conditions faced by communities and workers affected by the regulation to identify the potential for disproportionate impacts on communities with EJ concerns in accordance with Executive Order 12898 (59 FR 7629, February 16, 1994) and Executive Order 14096 (88 FR 25251, April 26, 2023). 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. Based on reasonably available information, EPA believes that there are potential EJ concerns in communities surrounding facilities subject to this regulation (Ref. 3).

EPA believes that this action is likely to reduce existing disproportionate and adverse effects on communities with environmental justice concerns. While the regulatory options are anticipated to address the unreasonable risk from exposure to TCE to the extent necessary so that it is no longer unreasonable, EPA is not able to quantify the distribution of the change in risk for affected populations. EPA is also unable to quantify the changes in risks for affected populations from non-TCE-using technologies or practices that firms may adopt in response to the regulation to determine whether any such changes could pose EJ concerns. Data limitations that prevent EPA from conducting a more comprehensive analysis are summarized in the Economic Analysis (Ref. 3).

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EPA additionally identified and addressed EJ concerns by conducting outreach to advocates of communities that might be subject to disproportionate exposure to TCE. On June 16, 2021, and July 6, 2021, EPA held public meetings as part of this consultation (Ref. 32). See also Unit III.A.1. Following the EJ meetings, EPA received five written comments, in addition to oral comments provided during the consultations. In general, commenters supported strong regulation of TCE to protect lower-income communities and workers. 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.

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 and fact sheets for the EJ consultations related to this rulemaking, are available at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/materials-june-and-july-2021-environmental-justice.* These materials and a summary of the consultation are also available in the public docket for this rulemaking (Ref. 32).

List of Subjects in 40 CFR Part 751

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

Michael S. Regan,

Administrator.

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Therefore, for the reasons stated in the preamble, EPA proposes to amend 40 CFR part 751 as follows:

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

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

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

2. Amend § 751.5 by adding in alphabetical order definitions for "Authorized person", "ECEL", "Exposure group", "Owner or operator", "Potentially exposed person", "Regulated area", and "Retailer" to read as follows:

§ 751.5 Definitions.

* * * * *

Authorized person means any person specifically authorized by the owner or operator to enter, and whose duties require the person to enter a regulated area.

* * * * *

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 consisting of every person performing the same or substantially similar operations in each work shift, in each job classification, and in each work area where exposure to chemical substances or mixtures is reasonably likely to occur.

Owner or operator means any person who owns, leases, operates, controls, or supervises a workplace covered by this part.

* * * * *

Potentially exposed person means any person who may be occupationally exposed to a

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chemical substance or mixture in a workplace as a result of a condition of use of that chemical substance or mixture.

Regulated area means an area established by the regulated entity to demarcate areas where airborne concentrations of a specific chemical substance exceed, or there is a reasonable possibility they may exceed, the ECEL or the EPA STEL.

Retailer means a person who distributes in commerce or makes available a chemical substance or mixture to consumer end users, including e-commerce internet sales or distribution. Any distributor with at least one consumer end user customer is considered a retailer. A person who distributes in commerce or makes available a chemical substance or mixture solely to commercial or industrial end users or solely to commercial or industrial businesses is not considered a retailer.

2. Add new subpart D to read as follows:

Subpart D—Trichloroethylene

Sec.

§ 751.301 General.

This subpart establishes prohibitions and restrictions on the manufacture (including import), processing, distribution in commerce, use, and disposal of trichloroethylene (TCE) (CASRN 79-01-6) to prevent unreasonable risk of injury to health in accordance with TSCA section 6(a).

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§ 751.303 Definitions.

The definitions in subpart A of this part apply to this subpart unless otherwise specified in this section. In addition, the following definitions apply:

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 §§ 751.313 and 751.315.

ECEL action level means a concentration of airborne TCE of 0.00055 parts per million (ppm) calculated as an eight (8)-hour time-weighted average (TWA).

§ 751.305 Prohibitions of manufacturing, processing, distribution in commerce, use and disposal.

(a) *Applicability.*

The provisions of this section apply to the following:

(1) Manufacturing (including importing);

(2) Processing;

(3) All industrial and commercial uses;

(4) All consumer uses;

(5) Distribution in commerce; and

(6) Disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works.

(b) *Prohibitions.*

(1) After [DATE 3 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from manufacturing (including importing) TCE, except as specified in paragraphs (b)(4) through (13) of this section.

(2) After [DATE 6 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from processing and

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distributing in commerce (including making available) TCE, including any TCE-containing products, except as specified in paragraphs (b)(4) through (13) of this section.

(3) After [DATE 9 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from industrial and commercial use of TCE, including any TCE-containing products, except as specified in paragraphs (b)(4) through (13) of this section.

(4) After [DATE 6 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from manufacturing (including importing) TCE for industrial and commercial use for batch vapor degreasing in open-top and closed-loop degreasing equipment, except for the use specified in paragraphs (b)(9) and (11) of this section.

(5) After [DATE 9 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from processing TCE for industrial and commercial use for batch vapor degreasing in open-top and closed-loop degreasing equipment, except for the use specified in paragraphs (b)(9) and (11) of this section.

(6) After [DATE 1 YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from the industrial and commercial use of TCE for batch vapor degreasing in open-top and closed-loop degreasing equipment, except for the use specified in paragraphs (b)(9) and (11) of this section.

(7) After [DATE 18 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from manufacturing (including importing) TCE for processing of TCE as a reactant/intermediate and processing TCE for the industrial and commercial use of TCE as a processing aid for: battery separator manufacturing; process solvent used in polymer fiber spinning, fluoroelastomer manufacture and

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Alcantara manufacture; extraction solvent used in caprolactam manufacture; precipitant used in beta-cyclodextrin manufacture, except for those uses specified in paragraphs (b)(10) and (12) of this section.

(8) After [DATE 2 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from processing TCE as a reactant/intermediate and from processing TCE for the industrial and commercial use of TCE as a processing aid in: process solvent used in battery manufacture; process solvent used in polymer fiber spinning, fluoroelastomer manufacture and Alcantara manufacture; extraction solvent used in caprolactam manufacture; precipitant used in beta-cyclodextrin manufacture, except for those uses specified in paragraphs (b)(10) and (12) of this section.

(9) After [DATE 5 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] all persons are prohibited from the industrial and commercial use of TCE as a solvent in closed-loop batch vapor degreasing for rayon fabric scouring for end use in producing rocket booster nozzles for Federal agencies and their contractors, and manufacturing (including importing), processing, and distribution in commerce of TCE for such use, unless such persons obtain and maintain the records required by § 751.309 demonstrating that a final pre-launch test was completed using an alternative to TCE in the production of the rocket booster nozzles.

(10) After [DATE 8.5 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from manufacturing (including import), distribution in commerce, and processing of TCE as an intermediate for manufacturing hydrofluorocarbon 134-a, also known as 1,1,1,2-Tetrafluroethane (HFC-134a: CAS Number 811-97-2).

(11) After [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL

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RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from the industrial and commercial use of TCE as a solvent in closed-loop batch vapor degreasing for rayon fabric scouring for end use in producing rocket booster nozzles for Federal agencies and their contractors, and manufacturing (including importing), processing, and distribution in commerce of TCE for such use.

(12) After [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from the industrial and commercial use of TCE as a processing aid for battery separatory manufacturing, and the manufacturing (including importing), processing, and distribution in commerce of TCE for such use.

(13) After [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], for DoD naval vessels and their systems, and in the maintenance, fabrication, and sustainment for and of such vessels and systems, prohibit the industrial and commercial use of TCE as potting compounds for naval electronic systems and equipment; sealing compounds for high and ultra high vacuum systems; bonding compounds for materials testing and maintenance of underwater systems and bonding of nonmetallic materials; and cleaning requirements (which includes degreasing using wipes, sprays, solvents and vapor degreasing) for: materials and components required for military ordnance testing; temporary resin repairs in vessel spaces where welding is not authorized; ensuring polyurethane adhesion for electronic systems and equipment repair and installation of elastomeric materials; various naval combat systems, radars, sensors, equipment; fabrication and prototyping processes to remove coolant and other residue from machine parts; machined part fabrications for naval systems; installation of topside rubber tile material aboard vessels; and vapor degreasing required for substrate surface preparation prior to electroplating processes.

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(14) After [DATE 50 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from industrial and commercial uses of TCE for the laboratory uses for essential laboratory uses described in § 751.317(b)(1), and from the manufacturing (including importing), processing, and distribution in commerce of TCE for such uses.

(15) After [DATE 9 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons manufacturing (including importing), processing, and using TCE are prohibited from disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works except as specified in paragraph (b)(16) of this section.

(16) After [DATE 50 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works for the purposes of cleanup projects of TCE-contaminated water and groundwater as described in § 751.317(b)(2).

(17) After [DATE 7 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from the industrial and commercial use of TCE as a solvent in closed-loop vapor degreasing necessary for human-rated rocket engine cleaning by NASA and its contractors as described in § 751.317(c)(3) and the manufacturing (including importing), processing, and distribution in commerce of TCE for such use.

§ 751.307 Phaseout of trichloroethylene use in manufacture of HFC-134a.

(a) *Baseline.*

Before [DATE 6 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE

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IN THE *FEDERAL REGISTER*], each manufacturer of HFC-134a who processes TCE as an intermediate must establish a baseline annual volume of TCE processed as an intermediate.

(1) The manufacturer must use the average of any 12 consecutive months in the 36 months preceding [DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] to calculate the baseline.

(2) The manufacturer must retain records that demonstrate how the baseline annual volume was calculated, in accordance with § 751.315(d)(1).

(b) *Phaseout.*

(1) Beginning [DATE 2.5 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], each manufacturer of HFC-134a who processes TCE as an intermediate is not permitted to process TCE as an intermediate at an annual volume greater than 75 percent of the baseline.

(2) Beginning [DATE 4.5 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], each manufacturer of HFC-134a who processes TCE as an intermediate is not permitted to processes TCE as an intermediate at an annual volume greater than 50 percent of the baseline.

(3) Beginning [DATE 6.5 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], each manufacturer of HFC-134a who processes TCE as an intermediate is not permitted to processes TCE as an intermediate at an annual volume greater than 25 percent of the baseline so established.

(4) Beginning [DATE 8.5 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], each manufacturer of HFC-134a who processes TCE as an intermediate is prohibited from processing TCE as an intermediate.

(c) Workplace chemical protection program.

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All persons using TCE in accordance with this section must comply with § 751.311.

§ 751.309 Phaseout of trichloroethylene use in vapor degreasing for booster rocket nozzles.

(a) In accordance with § 751.305(b)(9), until [DATE 5 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], TCE may be manufactured (including imported), processed, distributed in commerce, and used as a solvent in closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production by Federal agencies and their contractors.

(b) From [DATE 5 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], TCE may only be manufactured (including imported), processed, distributed in commerce, and used as a solvent in closed-loop batch vapor degreasing for rayon fabric scouring, for end use in rocket booster nozzle production by Federal agencies and their contractors by persons who maintain records demonstrating that a final pre-launch test of rocket booster nozzles without using TCE was completed.

(c) All persons using TCE in accordance with this section must comply with § 751.311.

§ 751.311 Workplace chemical protection program.

(a) *Applicability.*

The provisions of this section apply to workplaces engaged in the following conditions of use of TCE that are allowed to temporarily continue past one year, in accordance with § 751.305(b)(4) through (13), § 751.307, and § 751.309:

(1) Manufacturing (domestic manufacture);

(2) Manufacturing (import);

(3) Processing as a reactant/intermediate;

(4) Processing into formulation, mixture or reaction product;

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(5) Processing (repackaging);

(6) Processing (recycling);

(7) Industrial and commercial use as a processing aid in process solvent used in battery manufacture; process solvent used in polymer fiber spinning, fluoroelastomer manufacture and Alcantara manufacture; extraction solvent used in caprolactam manufacture; precipitant used in beta-cyclodextrin manufacture;

(8) Industrial and commercial use in other miscellaneous industrial and commercial uses (laboratory use for essential laboratory activities);

(9) Industrial and commercial use of TCE as a solvent in closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production by Federal agencies and their contractors;

(10) Disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works for the purposes of cleanup projects of TCE-contaminated water and groundwater;

(11) Industrial and commercial use of TCE for DoD naval vessels and their systems, and in the maintenance, fabrication, and sustainment for and of such vessels and systems; as potting compounds for naval electronic systems and equipment; sealing compounds for high and ultra high vacuum systems; bonding compounds for materials testing and maintenance of underwater systems and bonding of nonmetallic materials; and cleaning requirements (which includes degreasing using wipes, sprays, solvents and vapor degreasing) for: materials and components required for military ordnance testing; temporary resin repairs in vessel spaces where welding is not authorized; ensuring polyurethane adhesion for electronic systems and equipment repair and installation of elastomeric materials; various naval combat systems, radars, sensors, equipment; fabrication and prototyping processes to remove coolant and other residue from machine parts;

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machined part fabrications for naval systems; installation of topside rubber tile material aboard vessels; and vapor degreasing required for substrate surface preparation prior to electroplating processes; and

(12) Industrial and commercial use of TCE as a solvent in closed-loop vapor degreasing necessary for human-rated rocket engine cleaning by NASA and its contractors.

(b) *Existing chemical exposure limit (ECEL).*

(1) *Applicability.* The provisions of this paragraph (b) apply to any workplace engaged in the conditions of use listed in paragraphs (a)(1) through (9) of this section.

(2) *ECEL.* Beginning [DATE 9 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], or beginning 4 months after introduction of TCE into the workplace if TCE use commences after [DATE 6 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER], the owner or operator must ensure to the extent possible that no person is exposed to an airborne concentration of TCE in excess of 1.1 parts of TCE per billion parts of air (0.0011 ppm) as an eight (8)-hour TWA, in accordance with the requirements of paragraph (c) of this section and, if necessary, paragraph (e) of this section:

(3) *Exposure monitoring.*

(i) *General.*

(A) Owners or operators must determine each potentially exposed person's exposure by either:

(*1*) Taking a personal breathing zone air sample of each potentially exposed person's exposure; or

(*2*) Taking personal breathing zone air samples that are representative of the 8-hour TWA of each person whose exposure must be monitored.

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(B) Representative 8-hour TWA exposures must be determined on the basis of one or more full-shift exposure of at least one person that represents, and does not underestimate, the potential exposure of every person in each exposure group and that represents the highest TCE exposures likely to occur under reasonably foreseeable conditions of use.

(C) Exposure samples must be analyzed using an appropriate analytical method by a laboratory that complies with the Good Laboratory Practice Standards in 40 CFR part 792.

(D) Owners or operators must ensure that methods used to perform exposure monitoring produce results that are accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of TCE.

(ii) *Initial monitoring*.

(A) Each owner or operator who has a workplace or work operation covered by this section, except as provided for in paragraph (b)(3)(ii)(B) of this section, must perform initial monitoring of potentially exposed persons regularly working in areas where TCE is present.

(B) The initial monitoring required in paragraph (b)(3)(ii)(A) of this section must be completed by [DATE 6 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] or within 30 days of introduction of TCE into the workplace, whichever is later. Where the owner or operator has monitoring within five years prior to [DATE 2 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE 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 paragraph (b)(3)(ii)(A) of this section.

(iii) *Periodic monitoring.* The owner or operator must establish an exposure monitoring program for periodic monitoring of exposure to TCE in accordance with Table 1 to this paragraph (b)(3)(iii).

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Table 1 to § 751.311(b)(3)(iii) – Periodic Monitoring Requirements

Air Concentration Condition	Periodic Monitoring Requirement
If all initial exposure monitoring is below the ECEL action level (< 0.00055 ppm 8- hour TWA)	Periodic exposure monitoring is required at least once every 5 years.
If the initial or most recent exposure monitoring indicates that airborne exposure is above the ECEL (> 0.0011 ppm 8- hour TWA)	Periodic exposure monitoring is required within 3 months of the most recent exposure monitoring.
If the initial or most recent exposure monitoring indicates that airborne exposure is at or above the ECEL action level but at or below the ECEL (≥ 0.00055 ppm 8- hour TWA, ≤ 0.0011 ppm 8- hour TWA)	Periodic exposure monitoring is required within 6 months of the most recent exposure monitoring.
If the two most recent (non-initial) exposure monitoring measurements, taken at least seven days apart, indicate that airborne exposure is below the ECEL action level (< 0.00055 ppm 8- hour TWA)	Periodic exposure monitoring is required within 5 years of the most recent exposure monitoring.
If the owner or operator engages in a condition of use for which compliance with the WCPP would be required but does not manufacture, process, use, or dispose of *TCE* in that condition of use over the entirety of time since the last required monitoring event	The owner or operator may forgo its current periodic monitoring event. However, documentation of cessation of use of *TCE* as well as periodic monitoring would be required when the owner or operator resumes any of the conditions of use for which compliance with the WCPP is proposed.

(iv) *Additional monitoring*.

(A) The owner or operator must conduct additional initial exposure monitoring whenever there has been a change in the production, process, control equipment, personnel or work practices that may reasonably be expected to result in new or additional exposures above the ECEL action level or when the owner or operator has any reason to believe that new or additional exposures above the ECEL action level have occurred.

(B) Whenever start-ups, shutdown, spills, leaks, ruptures, or other breakdowns occur that may lead to exposure to potentially exposed persons, the owner or operator must conduct additional initial exposure monitoring (using personal breathing zone sampling) after the cleanup

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of the spill or repair of the leak, rupture, or other breakdown.

(v) *Notification of monitoring results*.

(A) The owner or operator must inform persons whose exposures are represented by the monitoring of the monitoring results within 15 working days.

(B) This notification must include the following:

(*1*) Exposure monitoring method(s) and results;

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

(*3*) Any corresponding required respiratory protection as described in paragraph (e) of this section;

(*4*) Descriptions of actions taken by the regulated entity to reduce exposure to or below the ECEL;

(*5*) Quantity of TCE in use;

(*6*) Location of TCE use;

(*7*) Manner of TCE use;

(*8*) Identified releases of TCE; and

(*9*) Whether the airborne concentration of TCE exceeds the ECEL

(C) Notice must be provided in plain language writing, in a language that the person understands, to each potentially exposed person or posted in an appropriate and accessible location outside the regulated area with an English-language version and a non-English language version representing the language of the largest group of workers who do not read English.

(4) *Regulated areas.*

(i) Beginning [DATE 9 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], beginning 4 months after introduction of trichloroethylene into the workplace if trichloroethylene use commences after [DATE 6

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MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], owners or operators must establish a regulated area wherever any person's exposure to airborne concentrations of TCE exceeds or can reasonably be expected to exceed the ECEL

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

(iii) The owner or operator must demarcate regulated areas from the rest of the workplace in a manner that adequately establishes and alerts persons to the boundaries of the area and minimizes the number of authorized persons exposed to TCE within the regulated area.

(iv) The owner or operator must supply a respirator that complies with the requirements of paragraph (e) of this section and must ensure that all persons within the regulated area are using the provided respirators whenever TCE exposures may exceed the ECEL.

(v) An owner or operator who has implemented all feasible engineering, work practice and administrative controls as required in paragraph (c)(1)(i) of this section, and who has established a regulated area as required by paragraph (b)(4)(i) of this section where TCE exposure exceeds or can reasonably be expected to exceed the ECEL only on certain days (for example, because of work or process schedule) must have persons use respirators in that regulated area on those days.

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

(vii) The owner or operator must ensure that while persons are wearing respirators in the regulated area, they do not engage in activities which interfere with respirator seal or performance.

(c) *ECEL control procedures and plan.*

(1) *Methods of compliance.* The owner or operator must institute one or a combination of

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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 as an interim measure. Wherever the feasible exposure controls, including one or a combination of elimination, substitution, engineering controls or administrative controls, which can be instituted are not sufficient to reduce exposure at or below the ECEL, the owner or operator must use them to reduce exposure to the lowest levels achievable by these controls and must supplement them by the use of respiratory protection that complies with the requirements of paragraph (e) of this section. Where an owner or operator cannot demonstrate exposure below the ECEL or exposure at the lowest achievable level for the facility, including through the use of engineering controls or work practices, and has not demonstrated that it has supplemented feasible exposure controls with respiratory protection, this will constitute a failure to comply with the ECEL. The owner or operator must maintain the effectiveness of engineering controls or administrative controls instituted under paragraph (d)(1)(i)(A) of this section. The owner or operator must not implement a schedule of personnel rotation as a means of compliance with the ECEL. The owner or operator must document their exposure control strategy and implementation in an exposure control plan in accordance with paragraph (d)(2) of this section.

(2) *Exposure control plan requirements*. If any monitoring conducted in accordance with paragraph (b)(3) of this section shows worker exposures at or above the ECEL action level in the workplace, the owner or operator, within [DATE 12 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], must include and document in an exposure control plan the following:

(i) Identification and rationale of exposure controls used or not used as a time-limited measure in the following sequence: elimination of TCE, substitution of TCE, engineering

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controls and administrative controls to reduce exposures in the workplace to either at or below the ECEL or to the lowest achievable level of TCE in the workplace;

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

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

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

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

(vi) Identification of the lowest achievable exposure level and why further reductions are not possible;

(vii) Regular inspections, evaluations, and updating of the exposure controls to ensure effectiveness and confirmation that all persons are implementing them as required until the prohibition compliance date;

(viii) Occurrence and duration of any start-up, shutdown, or malfunction of the facility that causes air concentrations to be above the ECEL or lowest achievable exposure level and subsequent corrective actions taken during start-up, shutdown, or malfunctions to mitigate exposures to TCE; and

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

(d) *Workplace information and training.*

(1) The owner or operator must provide information and training for each person prior to

or at the time of initial assignment to a job involving potential exposure to TCE.

(2) The owner or operator must ensure that information and training is presented in a manner that is understandable to each person required to be trained.

(3) The following information and training must be provided to all persons assigned to a job involving potential exposure to TCE:

(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 TCE and the specific operations in the workplace that could result in exposure to TCE, particularly noting where exposures may be above the ECEL;

(iii) Methods and observations that may be used to detect the presence or release of TCE in the workplace (such as monitoring conducted by the owner or operator, continuous monitoring devices, visual appearance or odor of TCE when being released, etc.);

(iv) The health hazards of TCE in the workplace; and

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

(4) The owner or operator must re-train each potentially exposed person annually to ensure that each such person maintains the requisite understanding of the principles of safe use and handling of TCE in the workplace.

(5) Whenever there are workplace changes, such as modifications of tasks or procedures or the institution of new tasks or procedures, which increase exposure, and where those

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exposures exceed or can reasonably be expected to exceed the ECEL action level, the owner or operator must update the training as necessary to ensure that each potentially exposed person has the requisite proficiency.

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

(1) *Applicability.* The provisions of this paragraph (e) apply to any owner or operator that is required to provide respiratory protection or dermal protection pursuant to paragraphs (c)(1) and (d) of this section.

(2) *Selection.* PPE, including respiratory and dermal protection, that is of safe design and construction for the work to be performed must be provided, used, and maintained in a sanitary, reliable, and undamaged condition. Owners and operators must select PPE that properly fits each affected person and communicate PPE selections to each affected person.

(3) *Respiratory protection.*

(i) After 3 months of receipt of any exposure monitoring or within [DATE 9 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], the owner or operators must supply a respirator, selected in accordance with this paragraph, to each person who enters a regulated area and must ensure that all persons within the regulated area are using the provided respirators whenever TCE exposures may exceed the ECEL.

(ii) Owners or operators must provide respiratory protection in accordance with the provisions outlined in 29 CFR 1910.134(a) through (l) (except (d)(1)(iii)) and as specified in this paragraph for persons exposed or who may be expose to TCE in concentrations above the ECEL. For the purpose of this paragraph (e), the maximum use concentration (MUC) as used in 29 CFR 1910.134 must be calculated by multiplying the assigned protection factor (APF) specified for a respirator by the ECEL. For the purposes of this paragraph (e), provisions in 29 CFR 1910.134(a) through (l) (except (d)(1)(iii)) applying to an “employee” also apply equally to

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potentially exposed persons, and provisions applying to an "employer" also apply equally to owners or operators.

(iii) Owners or operators must select and provide to persons appropriate respirators as indicated by the most recent monitoring results, as follows:

(A) If the measured exposure concentration is at or below 0.0011 ppm (1.1 ppb): no respiratory protection is required.

(B) If the measured exposure concentration is above 0.0011 ppm (1.1 ppb) and less than or equal to 0.0055 ppm (5.5 ppb) (5 times ECEL): Any National Institute for Occupational Safety and Health (NIOSH)-certified air-purifying quarter mask respirator (APF 5).

(C) If the measured exposure concentration is above 0.0055 ppm (5.5 ppb) and less than or equal to 0.011 ppm (110 ppb) (10 times ECEL): Any NIOSH-certified air-purifying half mask or full facepiece respirator equipped with NIOSH-approved organic vapor cartridges or canisters (APF 10).

(D) If the measured exposure concentration is above 0.011 ppm (11.0 ppb) and less than or equal to 0.0275 ppm (27.5 ppb) (25 times ECEL): Any NIOSH-certified air-purifying full facepiece respirator equipped with NIOSH-approved organic vapor cartridges or canisters; any NIOSH-certified powered air-purifying respirator equipped with NIOSH-approved organic vapor cartridges; or any NIOSH-certified continuous flow supplied air respirator equipped with a hood or helmet (APF 25).

(E) If the measured exposure concentration is above 0.0275 ppm (27.5 ppb) and less than or equal to 0.055 ppm (55.0 ppb) (50 times ECEL): Any NIOSH-certified air-purifying full facepiece respirator equipped with NIOSH-approved organic vapor cartridges or canisters; or any NIOSH-certified powered air-purifying respirator equipped with a tight-fitting half facepiece and a NIOSH-approved organic vapor cartridges or canisters; any NIOSH-certified negative

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pressure (demand mode) supplied-air respirator equipped with a full facepiece; any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting half facepiece; any NIOSH-certified supplied air respirator equipped with a half facepiece and operated in a pressure demand or other positive pressure mode; or any NIOSH-certified negative pressure (demand mode) self-contained breathing apparatus respirator equipped with a full facepiece (APF 50).

(F) If the measured exposure concentration is above 0.055 ppm (55.0 ppb) and less than or equal to 1.1 ppm (1,100 ppb) (1,000 times ECEL): Any NIOSH-certified powered air-purifying respirator equipped with a full facepiece and NIOSH-approved organic vapor cartridges or canisters; any NIOSH-certified supplied air respirator equipped with a full facepiece and operated in a continuous flow mode or pressure demand or other positive pressure mode (APF 1,000).

(G) If the measured exposure concentration is greater than 1.1 ppm (1,100 ppb) (1,000 times ECEL) or the concentration is unknown: Any NIOSH-certified self-contained breathing apparatus equipped with a full facepiece and operated in a pressure demand or other positive pressure mode; or any NIOSH-certified supplied air respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode (APF 10,000).

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

(v) When a person whose job requires the use of a respirator cannot use a negative-pressure respirator, the owner or operator must provide that person with a respirator that has less breathing resistance than the negative-pressure respirator, such as a powered air-purifying

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respirator or supplied-air respirator, when the person is able to use it and if it provides the person with adequate protection.

(vi) Owners or operators must document the notice to and ability of any potentially exposed person to access the exposure control plan and other associated records.

(4) *Dermal protection.* The owner or operator must supply and require the donning of gloves that are chemically resistant to TCE with activity-specific training where dermal contact with TCE is possible, after application of the requirements in paragraph (e) of this section, in accordance with the hierarchy of controls.

(5) *PPE training.* (i) Owners and operators must provide PPE training in accordance with 29 CFR 1910.132(f) to all persons required to use PPE prior to or at the time of initial assignment to a job involving potential exposure to TCE. For the purposes of this paragraph (e)(5)(i), 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.

(ii) Owners and operators must retrain each potentially exposed person required to use PPE annually or whenever the owner or operator has reason to believe that a previously trained person does not have the required understanding and skill to properly use PPE, or when changes in the workplace or in PPE to be used render the previous training obsolete.

§ 751.313 Downstream notification.

(a) Beginning on [DATE 2 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], each person who manufactures (including imports) TCE for any use must, prior to or concurrent with the shipment, notify companies to whom TCE is shipped, in writing, of the restrictions described in this subpart in accordance with paragraph (c) of this section.

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(b) Beginning on [DATE 6 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], each person who processes or distributes in commerce TCE or any TCE-containing products for any use must, prior to or concurrent with the shipment, notify companies to whom TCE 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 TCE or with any TCE-containing product:

> After [DATE 6 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], this chemical/product is and can only be distributed in commerce or processed for the following purposes until the following prohibitions take effect: (1) Processing as an intermediate; a) for the manufacture of HFC-134a until [DATE 8.5 YEARS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE *FEDERAL REGISTER*] and b) for all other processing as a reactant/intermediate until [DATE 2 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*]; (2) Industrial and commercial use as a solvent for open-top batch vapor degreasing until [DATE 1 YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*]; (3) Industrial and commercial use as a solvent for closed-loop batch vapor degreasing until [DATE 1 YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], except for industrial and commercial use as a solvent for closed-loop batch vapor degreasing necessary for human-rated rocket engine cleaning by NASA and its contractors until [DATE 7 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL* REGISTER], and except for industrial and commercial use as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production by Federal agencies and their contractors until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*]; (4) Industrial and commercial use as a processing aid in: a) battery separator manufacturing until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] and b) process solvent used in polymer fiber spinning, fluoroelastomer manufacture and Alcantara manufacture; extraction solvent used in caprolactam manufacture; precipitant used in beta-cyclodextrin manufacture until [DATE 2 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*]; (5) Industrial and commercial uses for DoD naval vessels and their systems, and in the maintenance, fabrication, and sustainment for and of such vessels and systems until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*]*;* and (6) Industrial and commercial use for laboratory use for essential laboratory activities until [DATE 50 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE

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FEDERAL REGISTER].

§ 751.315 Recordkeeping requirements.

(a) *General records.*

After [DATE 60 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons who manufacture, process, distribute in commerce, or engage in industrial or commercial use of TCE or TCE-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 this subpart.

(b) *Workplace chemical protection program compliance.*

(1) *ECEL exposure monitoring.* For each monitoring event of TCE, owners or operators subject to the ECEL described in § 751.311(b) must document the following:

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

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

(iii) Identification of all persons represented by the representative sampling monitoring, indicating which persons were actually monitored;

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

(v) Use of appropriate sampling and analytical methods, such as analytical methods already approved by EPA, Occupational Safety and Health Administration (OSHA) or NIOSH, or compliance with an analytical method verification procedure;

(vi) Compliance with the Good Laboratory Practice Standards in accordance with 40

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CFR part 792; and

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

(2) *ECEL compliance.* Owners or operators subject to the ECEL described in § 751.311(b) must retain records of:

(i) Exposure control plan as described in § 751.311(d)(2);

(ii) Facility exposure monitoring records;

(iii) Notifications of exposure monitoring results;

(iv) The name, workplace address, work shift, job classification, work area and respiratory protection used by each potentially exposed person and PPE program implementation, as described in §751.311(e), including fit-testing and training; and

(v) Information and training provided by the regulated entity to each person prior described in paragraph § 751.311(d) and(e).

(c) *Records related to § 751.317 exemptions.*

To maintain eligibility for an exemption described in § 751.317, owners or operators must maintain records demonstrating compliance with the specific conditions of the exemption.

(d) *Records related to §§ 751.307 and 751.309 phaseouts.*

(1) Each manufacturer of HFC-134a who uses TCE as an intermediate must maintain records of the annual quantity of TCE purchased and processed from the year 2023 until the termination of all processing of TCE as an intermediate.

(2) Each person using TCE under § 751.309 for industrial and commercial use as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production by Federal agencies and their contractors, must maintain records demonstrating that the end use is in rocket booster nozzle production for Federal agencies and

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their contractors.

(3) After [DATE 5 YEARS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE *FEDERAL REGISTER*], each person using TCE under § 751.309 for industrial and commercial use as a solvent for closed-loop batch vapor degreasing, specifically for rayon fabric scouring, must maintain records that demonstrate that a final pre-launch test of rocket booster nozzles without using TCE was completed.

(e) *Minimum record retention periods.*

(1) The records required under paragraphs (a) through (c) of this section must be retained for at least 5 years from the date that such records were generated.

(2) The records required under paragraph (d) of this section must be retained for at least 5 years after the use of TCE has ceased.

§ 751.317 Exemptions.

(a) *In general.*

(1) The time-limited exemptions established in § 751.305(b)(12) and (13) are established in accordance with 15 U.S.C. 2605(g).

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

(b) *Exemptions under 15 U.S.C. 2605(g)(1)(A).*

(1) *Laboratory use for essential laboratory activities until [DATE 50 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].* The following are specific conditions of the exemption for laboratory use at § 751.305(b)(13):

(i) The industrial and commercial use of TCE as a laboratory chemical must only be for the following:

(A) Essential laboratory activities, including chemical analysis, chemical synthesis,

extracting or purifying other chemicals, dissolving other substances, and research and development for the advancement of cleanup activities and analytical methods for monitoring related to TCE contamination or exposure monitoring.

(B) Federal agencies and their contractors conducting research and development activities and test and evaluation method activities, other than those described in paragraph (b)(1)(i)(A) of this section, and similar laboratory activities, provided the use is essential to the agency's mission.

(ii) TCE must not be used as a laboratory chemical for testing asphalt.

(iii) The use of TCE as a laboratory chemical must be performed on the premises of industrial or commercial laboratories.

(iv) The owner or operator of the location where such use of TCE occurs, and manufacturers (including importers) and processors of TCE for such use, must comply with the Workplace Chemical Protection Program provisions in § 751.311.

(v) The owner or operator of the location where such use of TCE occurs must comply with the recordkeeping requirements in § 751.315.

(2) *Disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works for the purposes of cleanup projects of TCE-contaminated water and groundwater until [DATE 50 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].* The following are specific conditions of the exemption for disposal at § 751.305(b)(15):

(i) The disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works must only be for the purposes of cleanup projects of TCE-contaminated water and groundwater. The disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works is limited to only sites undergoing remediation under CERCLA,

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RCRA, or other Federal, state, and local government laws, regulations, or requirements.

(ii) The owner or operator of the location where workers are handling TCE wastewater, and owners or operators of facilities where TCE is disposed to industrial pre-treatment, industrial treatment, or publicly owned treatment works, must comply with the Workplace Chemical Protection Program provisions in § 751.311.

(iii) The owner or operator of the location where such use of TCE occurs must comply with the recordkeeping requirements in § 751.315.

(3) *Use of TCE or TCE-containing products for the specific conditions of use identified in paragraph (b)(3)(i) 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 until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].*

(i) *Applicability*. The emergency use exemption described in this paragraph (b)(3) applies to the following specific conditions of use as described in paragraph (b)(3)(i)(A) of this section.

(A) *Conditions of use subject to this exemption*.

(*1*) Industrial and commercial use as solvent for open-top or closed-loop batch vapor degreasing.

(*2*) Industrial and commercial use as solvent for cold cleaning.

(*3*) Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner and mold release.

(*4*) Industrial and commercial use as a lubricant and grease in tap and die fluid.

(*5*) Industrial and commercial use as a lubricant and grease in penetrating lubricant.

(*6*) Industrial and commercial use as an adhesive and sealant in solvent-based adhesives. and sealants.

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(*7*) Industrial and commercial as a functional fluid in heat exchange fluid.

(*8*) Industrial and commercial use in corrosion inhibitors and anti-scaling agents.

(*9*) Industrial and commercial use of TCE as a processing aid.

(B) *Emergency use*.

(*1*) *In general*. An emergency is a serious and sudden situation requiring immediate action, within 15 days or less, necessary to protect:

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

(*ii*) NASA's missions;

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

(*iv*) The environment.

(*2*) *Duration*. Each emergency is a separate situation; if use of TCE exceeds 15 days, then justification must be documented.

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

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

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

(ii) *Requirements*. To be eligible for the emergency use exemption described in this paragraph (b)(3), the NASA and its contractors must comply with the following conditions:

(A) Notification. Within 15 working days of the emergency use by NASA and its contractors, NASA must provide notice to EPA that includes the following:

(*1*) Identification of the conditions of use detailed in paragraph (b)(3)(i)(A) of this section that the emergency use fell under;

(*2*) An explanation for why the emergency use met the definition of emergency in

paragraph (b)(3)(i)(B) of this section; and

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

(B) Exposure control. The owner or operator must comply with the Workplace Chemical Protection Program provisions in § 751.311, to the extent technically feasible in light of the particular emergency.

(C) Recordkeeping. The owner or operator of the location where the use takes place must comply with the recordkeeping requirements in § 751.315.

(c) *Exemptions under 15 U.S.C. 2605(g)(1)(B).*

(1) *Lead-acid and lithium battery separator manufacturing until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].* The following are specific conditions of the exemption for use as a processing aid in the manufacturing of lead-acid and lithium battery separators at § 751.305(b)(12):

(i) The use of TCE as a processing aid for battery separator manufacturing must be limited to lead acid or lithium battery separator manufacturing.

(ii) The owner or operator of the location where such use occurs, and manufacturers (including importers) and processors of TCE for such use, must comply with the Workplace Chemical Protection Program provisions in § 751.311.

(iii) The owner or operator of the location where such use of TCE occurs must comply with the recordkeeping requirements in § 751.315.

(2) *Certain industrial and commercial uses of TCE for DoD naval vessels and their systems, and in the maintenance, fabrication, and sustainment for and of such vessels and systems until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].* The following are specific conditions of the exemption for

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industrial and commercial uses of TCE for DoD naval vessel and their systems, and in the maintenance, fabrication, and sustainment for and of such vessels and systems:

(i) The industrial and commercial use of TCE must be limited for DoD naval vessels and their systems, and in the maintenance, fabrication, and sustainment for and of such vessels and systems; as potting compounds for naval electronic systems and equipment; sealing compounds for high and ultra high vacuum systems; bonding compounds for materials testing and maintenance of underwater systems and bonding of nonmetallic materials; and cleaning requirements (which includes degreasing using wipes, sprays, solvents and vapor degreasing) for: materials and components required for military ordnance testing; temporary resin repairs in vessel spaces where welding is not authorized; ensuring polyurethane adhesion for electronic systems and equipment repair and installation of elastomeric materials; various naval combat systems, radars, sensors, equipment; fabrication and prototyping processes to remove coolant and other residue from machine parts; machined part fabrications for naval systems; installation of topside rubber tile material aboard vessels; and vapor degreasing required for substrate surface preparation prior to electroplating processes

(ii) The owner or operator of the location where such use occurs, and manufacturers (including importers) and processors of TCE for such use, must comply with the Workplace Chemical Protection Program provisions in § 751.311.

(iii) The owner or operator of the location where such use of TCE occurs must comply with the recordkeeping requirements in § 751.315.

(3) *Closed-loop vapor degreasing necessary for human-rated rocket engine cleaning by NASA and its contractors until [DATE 7 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER]*. The following are specific conditions of the exemption for industrial and commercial use of TCE as a solvent for closed-loop vapor

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degreasing necessary for human-rated rocket engine cleaning by NASA and its contractors § 751.305(b)(12):

(i) The use of TCE in industrial and commercial as a solvent for closed-loop vapor degreasing is limited to the closed-loop vapor degreasing necessary for human-rated rocket engine cleaning by NASA and its contractors.

(ii) The owner or operator of the location where such use occurs, and manufacturers (including importers) and processors of TCE for such use, must comply with the Workplace Chemical Protection Program provisions in § 751.311.

(iii) The owner or operator of the location where such use of TCE occurs, and manufacturers (including importers) and processors of TCE for such use, must comply with the recordkeeping requirements in § 751.315.