PRE-PUBLICATION NOTICE

On June 4, 2024, Michael S. Regan, the EPA Administrator, signed the following document:

Action:	**Proposed Rule**
Title:	**n-Methylpyrrolidone (NMP); Regulation under the Toxic Substances Control Act (TSCA)**
FRL #:	**8330-02-OCSPP**
Docket ID #:	**EPA-HQ-OPPT-2020-0744**

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

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA-HQ-OPPT-2020-0744; FRL-8330-02-OCSPP]

RIN 2070-AK85

n-Methylpyrrolidone (NMP); Regulation under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or the "Agency") is proposing to address the unreasonable risk of injury to human health presented by n-methylpyrrolidone (NMP) under its conditions of use as documented in EPA's risk evaluation and risk determination for NMP pursuant to the Toxic Substances Control Act (TSCA). NMP is a widely used solvent in a variety of industrial, commercial, and consumer applications including the manufacture and production of electronics such as semiconductors, polymers, petrochemical products, paints and coatings, and paint and coating removers. EPA determined that NMP presents an unreasonable risk of injury to health due to the significant adverse health effects associated with exposure to NMP, including developmental post-implantation fetal loss from short-term exposure and reduced fertility and fecundity from long-term exposure. Additional adverse effects associated with exposure to NMP include liver toxicity, kidney toxicity, immunotoxicity, neurotoxicity, skin irritation, and sensitization. To address the identified unreasonable risk, EPA is proposing to: prohibit the manufacture (including import), processing, and distribution in commerce and use of NMP in several occupational conditions of use; require worker protections through an NMP workplace chemical protection program (WCPP) or prescriptive controls (including concentration limits) for most of the occupational conditions of use; require concentration limits on a consumer product; regulate certain consumer products to

prevent commercial use; and establish recordkeeping, labeling, 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-2020-0744, 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:* Clara Hull, Existing Chemicals Risk Management Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-3954; email address: *NMP.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?*

1. *General.*

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 NMP or products containing NMP. 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:

- Abrasive Product Manufacturing (NAICS Code 327910);
- Adhesive Manufacturing (NAICS Code 325520);
- Aerospace Product and Parts Manufacturing (NAICS Code 336400);
- Agriculture, Construction, and Mining Machinery Manufacturing (NAICS Code 333100);
- Aircraft Manufacturing (NAICS Code 336411);
- All Other Automotive Repair and Maintenance (NAICS Code 811198);
- All Other Basic Organic Chemical Manufacturing (NAICS Code 325199);
- All Other Miscellaneous Chemical Product and Preparation Manufacturing (NAICS Code 325998);
- All Other Miscellaneous Electrical Equipment and Component Manufacturing (NAICS Code 335999);
- All Other Miscellaneous Manufacturing (NAICS Code 339999);
- All Other Miscellaneous Store Retailers (except Tobacco Stores) (NAICS Code 453998);
- All Other Plastics Product Manufacturing (NAICS Code 326199);
- All Other Specialty Trade Contractors (NAICS Code 238990);

- Alumina and Aluminum Production and Processing (NAICS Code 331300);
- Appliance Repair and Maintenance (NAICS Code 811412);
- Architectural and Structural Metals Manufacturing (NAICS Code 332300);
- Art Dealers (NAICS Code 453920);
- Artificial and Synthetic Fibers and Filaments Manufacturing (NAICS Code 325220);
- Audio and Video Equipment Manufacturing (NAICS Code 334300);
- Automobile Dealers (NAICS Code 441110);
- Automotive Body, Paint and Interior Repair and Maintenance (NAICS Code 811121);
- Automotive Exhaust System Repair (NAICS Code 811112);
- Automotive Glass Replacement Shops (NAICS Code 811122);
- Automotive Oil Change and Lubrication Shops (NAICS Code 811191);
- Automotive Parts and Accessories Stores (NAICS Code 441310);
- Automotive Transmission Repair (NAICS Code 811113);
- Boiler, Tank, and Shipping Container Manufacturing (NAICS Code 332400);
- Books Printing (NAICS Code 323117);
- Broadwoven Fabric Mills (NAICS Code 313210);
- Car Washes (NAICS Code 811192);
- Coating, Engraving, Heat Treating, and Allied Activities (NAICS Code 332800);
- Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance (NAICS Code 811310);
- Commercial and Institutional Building Construction (NAICS Code 236220);
- Commercial and Service Industry Machinery Manufacturing (NAICS Code 333300);
- Commercial Printing (except Screen and Books) (NAICS Code 323111);
- Commercial Screen Printing (NAICS Code 323113);

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

• Communication Equipment Repair and Maintenance (NAICS Code 811213);

• Communications Equipment Manufacturing (NAICS Code 334200);

• Computer and Office Machine Repair and Maintenance (NAICS Code 811212);

• Computer and Peripheral Equipment Manufacturing (NAICS Code 334100);

• Computer Terminal and Other Computer Peripheral Equipment Manufacturing (NAICS Code 334118);

• Consumer Electronics Repair and Maintenance (NAICS Code 811211);

• Cut Stock, Resawing Lumber, and Planing (NAICS Code 321912);

• Cutlery and Handtool Manufacturing (NAICS Code 332200);

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

• Drywall and Insulation Contractors (NAICS Code 238310);

• Electric Lighting Equipment Manufacturing (NAICS Code 335100);

• Electrical Contractors and Other Wiring Installation Contractors (NAICS Code 238210);

• Electrical Equipment Manufacturing (NAICS Code 335300);

• Engine, Turbine, and Power Transmission Equipment Manufacturing (NAICS Code 333600);

• Executive Offices (NAICS Code 921110);

• Fabric Coating Mills (NAICS Code 313320);

• Facilities Support Services (NAICS Code 561200);

• Flooring Contractors (NAICS Code 238330);

• Fluid Power Cylinder and Actuator Manufacturing (NAICS Code 333995);

• Footwear Manufacturing (NAICS Code 316210);

• Forging and Stamping (NAICS Code 332100);

• Foundries (NAICS Code 331500);

• Framing Contractors (NAICS Code 238130);

• Furniture Stores (NAICS Code 442110);

• General Automotive Repair (NAICS Code 811111);

• Glass and Glazing Contractors (NAICS Code 238150);

• Hardware Manufacturing (NAICS Code 332500);

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

• Highway, Street, and Bridge Construction (NAICS Code 237310);

• Home and Garden Equipment Repair and Maintenance (NAICS Code 811411);

• Home Furnishing Merchant Wholesalers (NAICS Code 423220);

• Household Appliance Manufacturing (NAICS Code 335200);

• Independent Artists, Writers and Performers (NAICS Code 711510);

• Industrial Building Construction (NAICS Code 236210);

• Industrial Gas Manufacturing (NAICS Code 325120);

• Industrial Machinery Manufacturing (NAICS Code 333200);

• Investment Advice (NAICS Code 523930);

• Iron and Steel Mills and Ferroalloy Manufacturing (NAICS Code 331100);

• Lessors of Other Real Estate Property (NAICS Code 531190);

• Machine Shops; Turned Product; and Screw, Nut, and Bolt Manufacturing (NAICS Code 332700);

• Manufacturing and Reproducing Magnetic and Optical Media (NAICS Code 334600);

• Masonry Contractors (NAICS Code 238140);

• Materials Recovery Facilities (NAICS Code 562920);

• Medical Equipment and Supplies Manufacturing (NAICS Code 339100);

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

• Metalworking Machinery Manufacturing (NAICS Code 333500);

• Miscellaneous Intermediation (NAICS Code 523910);

• Motor Vehicle Body and Trailer Manufacturing (NAICS Code 336200);

• Motor Vehicle Manufacturing (NAICS Code 336100);

• Motor Vehicle Parts Manufacturing (NAICS Code 336300);

• Motor Vehicle Supplies and New Parts Merchant Wholesalers (NAICS Code 423120);

• Motor Vehicle Towing (NAICS Code 488410);

• Museums (NAICS Code 712110);

• Navigational, Measuring, Electromedical, and Control Instruments Manufacturing (NAICS Code 334500);

• New Car Dealers (NAICS Code 441110);

• New Housing For-Sale Builders (NAICS Code 236117);

• New Multifamily Housing Construction (except For-Sale Builders) (NAICS Code 236116);

• New Single-family Housing Construction (Except For-Sale Builders) (NAICS Code 236115);

• Nitrogenous Fertilizer Manufacturing (NAICS Code 325311);

• Nonferrous Metal (except Aluminum) Production and Processing (NAICS Code 331400);

• Non-upholstered Wood Household Furniture Manufacturing (NAICS Code 337122);

• Office Administrative Services (NAICS Code 561110);

• Oil and Gas Pipeline and Related Structures Construction (NAICS Code 237120);

• Other Aircraft Part and Auxiliary Equipment Manufacturing7 (NAICS Code 336413);

• Other Automotive Mechanical and Electrical Repair and Maintenance (NAICS Code 811118);

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

• Other Building Equipment Contractors (NAICS Code 238290);

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

• Other Concrete Product Manufacturing (NAICS Code 327390);

• Other Construction Material Merchant Wholesalers (NAICS Code 423390);

• Other Electrical Equipment and Component Manufacturing (NAICS Code 335900);

• Other Electronic and Precision Equipment Repair and Maintenance (NAICS Code 811219);

• Other Equipment and Component Manufacturing (NAICS Code 335900);

• Other Fabricated Metal Product Manufacturing (NAICS Code 332900);

• Other Foundation, Structure, and Building Exterior Contractors (NAICS Code 238190);

• Other General Purpose Machinery Manufacturing (NAICS Code 333900);

• Other Heavy and Civil Engineering Construction (NAICS Code 237990);

• Other Industrial Machinery Manufacturing (NAICS Code 333249);

• Other Measuring and Controlling Device Manufacturing (NAICS Code 334519);

• Other Nonhazardous Waste Treatment and Disposal (NAICS Code 562219);

• Other Personal and Household Goods Repair and Maintenance (NAICS Code 811490);

• Other Professional Equipment and Supplies Merchant Wholesalers (NAICS Code 423490);

• Paint and Coating Manufacturing (NAICS Code 325510);

• Painting and Wall Covering Contractors (NAICS Code 238320);

• Paper Bag and Coated and Treated Paper Manufacturing (NAICS Code 322220);

• Pesticide and Other Agricultural Chemical Manufacturing (NAICS Code 325320);

• Petrochemical Manufacturing (NAICS Code 325110);

• Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals) (NAICS Code 424720);

• Petroleum Bulk Stations and Terminals (NAICS Code 424710);

• Petroleum Lubricating Oil and Grease Manufacturing (NAICS Code 324191);

• Petroleum Refineries (NAICS Code 324110);

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

• Plumbing, Heating, and Air-Conditioning Contractors (NAICS Code 238220);

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

• Poured Concrete Foundation and Structure Contractors (NAICS Code 238110);

• Power and Communication Line and Related Structures Construction (NAICS Code 237130);

• Railroad Rolling Stock Manufacturing (NAICS Code 336500);

• Residential Remodelers (NAICS Code 236118);

• Reupholstery and Furniture Repair (NAICS Code 811420);

• Roofing Contractors (NAICS Code 238160);

• Roofing, Siding, and Insulation Material Merchant Wholesalers (NAICS Code 423330);

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

• Semiconductor and Other Electronic Component Manufacturing (NAICS Code

334400);

• Semiconductor and Related Device Manufacturing (NAICS Code 334413);

• Semiconductor Machinery Manufacturing (NAICS Code 333242);

• Service Establishment Equipment and Supplies Merchant Wholesalers (NAICS Code 423850);

• Ship Building and Repairing (NAICS Code 336611);

• Siding Contractors (NAICS Code 238170);

• Sign Manufacturing (NAICS Code 339950);

• Site Preparation Contractors (NAICS Code 238910);

• Soap and Other Detergent Manufacturing (NAICS Code 325611);

• Solid Waste Combustors and Incinerators (NAICS Code 562213);

• Solid Waste Landfill (NAICS Code 562212);

• Sporting Goods Stores (NAICS Code 451110);

• Spring and Wire Product Manufacturing (NAICS Code 332600);

• Steel Product Manufacturing from Purchased Steel (NAICS Code 331200);

• Storage Battery Manufacturing (NAICS Code 335911);

• Structural Steel and Precast Concrete Contractors (NAICS Code 238120);

• Support Activities for Printing (NAICS Code 323120);

• Testing Laboratories (NAICS Code 541380);

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

• Used Car Dealers (NAICS Code 441120);

• Used Merchandise Stores (NAICS Code 453310);

• Ventilation, Heating, Air-Conditioning, and Commercial Refrigeration Equipment

Manufacturing (NAICS Code 333400);

• Water and Sewer Line and Related Structures Construction (NAICS Code 237110); and

• Wood Kitchen Cabinet and Countertop Manufacturing (NAICS Code 337110).

2. *Applicability to importers and exporters.*

This action may also affect certain entities through pre-existing import certification and export notification requirements under TSCA (*https://www.epa.gov/tsca-import-export-requirements*). 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 NMP presents an unreasonable risk of injury to health, without consideration of costs or other non-risk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations (PESS) identified as relevant to the 2020 Risk Evaluation for NMP 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 NMP presents an unreasonable risk is in Unit III.B.1. EPA notes that all TSCA conditions of use of NMP 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, distribution in commerce, and use of NMP for five occupational conditions of use, as described in Unit IV.A.1.;

(ii) Require container size limits and labeling requirements for the manufacture (including import), processing, and distribution in commerce of NMP for seven consumer uses, as described in Unit IV.A.2.;

(iii) Require prescriptive controls, including concentration limits and personal protective equipment (PPE) for seven occupational conditions of use, as described in Unit IV.A.4.;

(iv) Require strict workplace controls, including an NMP WCPP, that would include requirements to prevent direct dermal contact with NMP, for all other occupational conditions of use, as described in Unit IV.A.3, including the commercial use of paints and coatings and paint, coating, and adhesive removers containing high concentrations of NMP in uses essential to the

missions of the Department of Defense (DOD) and National Aeronautics and Space Administration (NASA);

(v) Require a concentration limit on NMP for the import, processing, and distribution in commerce of one consumer use, as described in Unit IV.A.5.;

(vi) Establish recordkeeping and downstream notification requirements, as described in Unit IV.A.7.

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," "Direct dermal contact," "Exposure group," "Owner or operator," "Potentially exposed person," "Restricted area", and "Retailer." EPA seeks public comment on all aspects of this proposal. These definitions may be codified in another rule under 40 CFR part 751 prior to the publication of the final rulemaking for NMP. EPA seeks public comment on all aspects of this proposal.

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." NMP was the subject of a risk evaluation under TSCA section 6(b)(4)(A) that was issued in December 2020 (Ref. 1). In addition, EPA issued a revised unreasonable risk determination in December 2022 (Ref. 3), determining that NMP, 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 NMP 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 NMP presents unreasonable risk are described in Unit III.B.1.

NMP's hazards are well established. EPA's 2020 Risk Evaluation for NMP considered the hazards associated with exposure to NMP and determined that NMP presents an unreasonable risk of injury to health due to the significant adverse health effects associated with exposure to NMP. Some of the risks of adverse effects from NMP exposure may be acute and experienced for only a short duration. However, certain short duration exposures can result in irreversible impacts—such as post-implantation fetal loss. Other risks may be chronic and result in long-term impacts that are also irreversible. As described in the 2020 Risk Evaluation for NMP, post-implantation fetal loss and reduced fertility and fecundity are the most representative adverse effects of NMP exposure (Ref. 1). Other significant adverse effects include liver toxicity, kidney toxicity, immunotoxicity, neurotoxicity, irritation, and sensitization. EPA is proposing requirements so that NMP would no longer present unreasonable risk to human health, including PESS.

EPA is proposing to ban several occupational conditions of use of NMP, such as processing of NMP for incorporation into articles in lubricants and as a lubricant additive in machinery manufacturing, and industrial and commercial use of NMP in anti-freeze and de-icing products, automotive care products, and lubricants, and greases. For some of these conditions of use, EPA has not identified any current use of NMP (e.g., in antifreeze, de-icing products, and lubricants); for most others, EPA has identified possible alternatives in the alternative assessment (Ref. 4). The uses that EPA proposes to prohibit comprise an estimated 18% of the current production volume of NMP. EPA is not proposing a complete ban on NMP. EPA determined

that most consumer uses do not contribute to the unreasonable risk for NMP, largely due to the generally low concentration of NMP in consumer products and the infrequent use by consumers of those products (Ref. 1). However, the commercial use of the same types of products does contribute to the unreasonable risk because they generally contain higher concentrations of NMP and are used more frequently in commercial settings. Therefore, EPA is proposing to regulate these consumer products in a manner that will help ensure that these products are not diverted to commercial use, as is further described in Unit V.A.1.a.

This rulemaking also proposes to allow certain uses of NMP to continue, provided that sufficient worker protection measures and stringent controls are in place to prevent direct dermal contact to NMP and address the unreasonable risk driven by direct dermal contact for most of the occupational conditions of use. For many of the occupational conditions of use, EPA is proposing strict workplace controls under a WCPP. These conditions of use include the manufacturing of NMP, processing NMP as a reactant or intermediate in plastic material and resin manufacturing and other non-incorporative processing and use of NMP as a laboratory chemical. These also include the use of NMP in the manufacture of specialized electronics, such as magnet wire, semiconductors, and lithium-ion batteries used in a wide variety of applications including aerospace vehicles or electronic devices, or the use of NMP in petrochemical manufacturing as a processing aid in lubricant extraction. These conditions of use comprise an estimated 44% of the current production volume of NMP. In many of these industries, EPA expects that facilities will already have in place the types of exposure controls that EPA proposes to require. For example, EPA understands that most workplaces using NMP in semiconductor manufacturing already have stringent controls in place that reduce workplace exposures. For other conditions of use, because EPA does not believe or have specific information demonstrating that direct dermal contact can reasonably be prevented, and expects the

application method, such as spray application, to increase the contribution to the unreasonable risk from inhalation exposure, EPA is proposing limits on the weight fraction of NMP in formulated products in combination with personal protective equipment (PPE) and other workplace controls to address the unreasonable risk. These conditions of use include the commercial use of NMP in certain formulations, including various coatings, such as paint, adhesives, sealants, inks, and soldering materials in a variety of applications and their associated removers. These conditions of use comprise an estimated 37% of the current production volume of NMP. EPA is also proposing a limit on the weight fraction of NMP in one consumer use of NMP to mitigate the unreasonable risk to consumers from the use of NMP in adhesives and sealants.

As noted earlier, the conditions of use that EPA is proposing to ban comprise an estimated 18% of the current production volume of NMP. Of the conditions of use that would not be prohibited, EPA expects the production volume for certain conditions of use to decline over time. For example, EPA expects the industrial and commercial use of NMP in paints and coatings to decline over time as formulators either reformulate to a lower concentration of NMP or away from NMP, especially as the requirement to meet strict workplace controls could result in a transition in many workplaces away from NMP to other chemical alternatives, such as those identified in the alternative analysis (Ref. 4). For other conditions of use, EPA expects the production volume to increase over time. For example, EPA expects the industrial and commercial use of NMP in the manufacture of specialized electronics, including semiconductors and lithium ion batteries, to increase as the global demand for electronic devices increases.

EPA recognizes that some occupational conditions of use are important for national security applications or for other critical or essential uses for which no technically or economically feasible safer alternatives have been identified. While EPA has identified that

prescriptive controls – including limiting the weight fraction of NMP in paints, coatings, or paint and coating removers or adhesive removers - could address the unreasonable risk, EPA also understands that DOD and NASA use high concentrations of NMP in uses critical to their missions. In the context of DOD and NASA use, EPA expects that the exposure controls that could be put into place under the WCPP could address the unreasonable risk. As a result, EPA is proposing that the WCPP could be used for specific DOD and NASA uses of high concentrations of NMP from the proposed prescriptive workplace controls for industrial and commercial uses of NMP in paints and coatings and for industrial and commercial uses of NMP in paint, coating, and adhesive removers. More information about these conditions of use, and their continuance to ensure aviation, including space vehicles, and military readiness is in Unit V.A.1.c.iii. EPA emphasizes that information available to EPA does not indicate that commercial users other than DOD or NASA use such high concentrations of NMP, or that they have a need for similar paints or coatings, or paint, coating, or adhesive removal. More information and EPA's requests for comment on these conditions of use is in Unit V.A.1.c.iii.

The 2020 Risk Evaluation for NMP assessed the risk of injury to health from exposure to NMP from the combination of several routes of exposure, including dermal, inhalation, and vapor through skin intrusion. The 2020 Risk Evaluation for NMP also compared the relative exposures from these pathways with and without direct liquid contact. Table 4-54 in the 2020 Risk Evaluation shows the calculated results, which show that for most, but not all conditions of use that 99-100% of exposure to NMP is due to dermal contact with liquid. EPA identified unreasonable risk for NMP predominately due to the dermal exposure pathway, as discussed in Units III.B.2. Thus, EPA has not identified and is not proposing to set an Existing Chemical Exposure Limit (ECEL) for NMP because such a level would only account for risk resulting from the inhalation pathway. Addressing inhalation risks alone would not mitigate the

unreasonable risk from NMP. EPA's consideration of an ECEL for NMP is described further in in Unit V.A.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. 5). As described in more detail in the Economic Analysis (Ref. 5) and in Units VI.D. and X.D., EPA's analysis of the incremental monetized costs of this proposed rule is estimated to be $396 million annualized over 20 years at a 3% discount rate and $397 million annualized over 20 years at a 7% discount rate. These costs take into consideration compliance with implementation of a WCPP, which would include dermal controls to prevent direct dermal contact, applicable PPE requirements including as part of prescriptive controls requirements, and costs for reformulation and container size restrictions of numerous products. Cost estimates by use category are provided in the Economic Analysis Table 7-36 (Ref. 5). The most notable unquantified costs include possible costs from prohibition of use of NMP for certain conditions of use as changes in labor time or differences in efficacy for a specific firm's use are unknown to EPA. Unquantified costs and other uncertainties in the cost analyses are described more fully in section 7.10 of the Economic Analysis (Ref. 5).

The actions proposed in this rulemaking are expected to achieve significant health benefits for the American public, most of which, while tangible and significant, cannot at present be monetized primarily due to a lack of applicable dose-response functions, which are the relationships between exposures and any incremental adverse effects. This issue is not unique to EPA and is a government-wide issue for many noncancer endpoints. EPA is requesting public comment on methodologies for developing noncancer human dose-response curves and valuation methods for the health endpoints identified for NMP in the Risk Evaluation, specifically

willingness to pay studies. Non-monetized benefits include risk reduction of developmental and reproductive effects, liver toxicity, kidney toxicity, immunotoxicity, neurotoxicity, irritation, and sensitization. (Ref. 5) While the benefits to human health associated with risk reduction of developmental and reproductive effects, liver toxicity, kidney toxicity, immunotoxicity, neurotoxicity, irritation, and sensitization cannot be monetized at present, reductions in occurrence of these conditions clearly have monetary value to society. The importance of these reductions in occurrence should not be diminished or dismissed simply because EPA currently lacks the analytical tools to precisely monetize the positive societal impacts of this proposed regulation.

Human health risks were found at both chronic and acute exposure levels. Rather than accumulating over a lifetime, risks were found for workers exposed to NMP during the course of a workweek, or five days. The 2020 Risk Evaluation assumed one day of exposure for acute scenarios, and five days of exposure per week for chronic scenarios. Blood concentrations of NMP are expected to be eliminated over the course of a weekend with no exposure to NMP.

The 2020 Risk Evaluation for NMP identified developmental effects as the most representative adverse effects of acute NMP exposure. EPA specified post-implantation loss as the critical effect of acute exposures over the course of a day. Post-implantation loss also referred to as fetal death or fetal mortality includes miscarriage, spontaneous abortion, or stillbirth, depending on when in the pregnancy it occurs. Fetal death may result from a single maternal exposure to NMP at a developmentally critical period (Ref. 1). Exposure to NMP during a single day (over 8 hours) was found to present risks of fetal death; further information is in section 3.2.3 of the 2020 Risk Evaluation (Ref. 1). While there are some estimates of the cost of medical treatment for miscarriage and stillbirth, there are no willingness-to-pay estimates of the value of reduced risk of fetal death. It is very likely that willingness-to-pay would be much higher than

the costs of medical treatment alone; further information is in section 8.5.1 of the Economic Analysis (Ref. 5). The impacts of fetal death, including miscarriage or stillbirth, include mental health impacts, such as depression and anxiety on the woman experiencing the death of a fetus, and can also impact partners and spouses (Ref. 5). Mental health research has consistently identified both miscarriage (defined as fetal death occurring before the 20th week of gestation) and stillbirth (defined as fetal death occurring after the 20th week of gestation) as a significant emotional burden exhibited as anxiety and depression that can persist; research suggests women and men feel effects for more than a year, women can feel effects nearly three years following the event of fetal death and after the birth of a healthy child, which emphasizes effects can persist significantly longer beyond the event (Ref. 5).

The 2020 Risk Evaluation for NMP identified reproductive effects as the most representative adverse effects of chronic NMP exposure. Specifically, EPA identified reduced male fertility as the critical effect resulting from repeated exposures during the work week (Ref. 1). In addition to this critical effect, decreased female fecundity is a health effect of concern. While impacts from NMP exposure on fertility and fecundity cannot be quantified at this time with available data, for couples seeking treatment for infertility, costs of such treatment are often significant both financially and emotionally. The most comprehensive and appropriate value for benefit-cost analysis is willingness to pay. There are few studies for the reduced risk of infertility, but a recent study estimates a willingness to pay of $102,000 per statistical case of infertility avoided (Ref. 5). EPA also identified low-birth weight resulting from repeated exposures to women of child-bearing age as another health effect of concern. It is not known if there is a window of exposure that may pose greater risks to the fetus; therefore, any repeated exposure to NMP could increase risks to the fetus for reproductive effects. Even when maternal exposure ceased, the decreased fetal body weight was found to be a persistent adverse effect

(Ref. 1); consequently, a relatively brief period of maternal repeated exposure to NMP in typical workplace activities can cause fetal weight decreases. Low birth weight can have significant impacts on childhood development and the incidence of future diseases; reduced birth weight can cause serious health problems for some children, as well as long-term impacts on their lives as adults (Ref. 5).

EPA identified additional unquantified benefits from this rulemaking. While the risk evaluation does not describe kidney toxicity as resulting in specific diseases, for the purposes of characterizing potential benefits, the most relevant outcomes are acute kidney failure and chronic kidney disease. Signs and symptoms of acute kidney failure include decreased urine output, although occasionally urine output remains normal; fluid retention, causing swelling in the legs, ankles or feet; drowsiness; shortness of breath; fatigue; confusion; nausea; seizures or coma in severe cases; and chest pain or pressure. Sometimes acute kidney failure causes no signs or symptoms and is detected through lab tests done for another reason.

Chronic kidney disease is associated with many of these same symptoms over a longer period of time. Chronic kidney disease is irreversible and usually progressive, though it can be managed to some extent. In its earliest stages, chronic kidney disease may have little impact on quality of life and require minimal medical care. As chronic kidney disease progresses, however, the likelihood of symptoms increases and quality of life and ability to work and perform daily activities can be affected. When the kidney is damaged to the point that it no longer functions, dialysis or kidney transplant is necessary. This is known as kidney failure or end-stage renal disease. Kidney dialysis and kidney transplantation are expensive and incur long-term health costs with the potential for a significant decrease in a person's quality of life (Ref. 5).

There are potential increased health risks for liver toxicity for workers exposed to NMP. The most commonly known causes of this disease burden are attributable to alcoholism and viral

infections, such as hepatitis A, B, and C. These known risk factors of hepatitis infection may result in increased vulnerability of individuals exposed to organic chemicals such as NMP. Liver toxicity can lead to jaundice, weakness, fatigue, weight loss, nausea, vomiting, abdominal pain, impaired metabolism, and liver disease (notably fatty liver disease). Given the evidence in the risk evaluation it is reasonable to conclude that reductions in chronic exposures to NMP may produce benefits from reduced incidence of fatty liver disease. While the magnitude of these benefits cannot be quantified, information on the costs of fatty liver disease provides some perspective on whether those benefits might be significant (Ref. 5).

II. Background

A. *Overview of n-Methylpyrrolidone*

This proposed rule applies to NMP (CASRN 872-50-4) and is intended to address the unreasonable risk of injury to health that EPA has identified for NMP (Refs. 1, 2). NMP is a colorless liquid that is produced in and imported into the United States. NMP is manufactured, processed, distributed, used, and disposed of as part of many industrial, commercial, and consumer conditions of use. According to data submitted for the EPA's 2016 Chemical Data Reporting rule (CDR), the total aggregate annual production volume of NMP in the United States was over 160 million pounds, and, according to data submitted for the 2020 CDR, the total aggregate annual production volume of NMP ranged from 100-250 million pounds between 2016 and 2019 (Ref. 6). As outlined in further detail in Unit III.B.1., NMP is used as a processing reactant or intermediate or incorporated into a formulation, as a solvent in the production of electronics and petroleum products, polymers, and other specialty chemicals; and in a variety of commercial and consumer applications such as a paint and coating additive, in adhesives and sealants, in laboratory chemicals, and a solvent for cleaning or degreasing.

B. *Regulatory Actions Pertaining to NMP*

Because of its adverse health effects, NMP is subject to 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 NMP, as well other Federal, state, and international regulations, is in the docket (Refs. 7, 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).

Thus, the standards for chemical hazards that OSHA promulgates under the OSH Act share a broadly similar purpose with the standards that EPA promulgates under TSCA section 6(a). The control measures OSHA and EPA require to satisfy the objectives of their respective statutes may also, in many circumstances, overlap or coincide. However, as this section outlines, there are important differences between EPA's and OSHA's regulatory approaches and jurisdiction, and EPA considers these differences when deciding whether and how to account for OSHA requirements (Ref. 7) 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. 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 Code of Federal Regulations. 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 Permissible Exposure Limits (PELs), established for employers to protect their workers against the health effects of exposure to hazardous substances (29 CFR part 1910, subpart Z, part 1915, subpart Z, and part 1926, subparts D and Z). Under section 6(a) of the OSH Act, OSHA was permitted an initial 2-year window after the passage of the Act to adopt "any national consensus standard and any established Federal standard." 29 U.S.C. 655(a). OSHA used this authority in 1971 to establish PELs that were adopted from Federal health standards originally set by the Department of Labor through the Walsh-Healy Act, in which approximately 400 occupational exposure limits (OELs) were selected based on the American Conference of Governmental Industrial Hygienists (ACGIH) 1968 list of Threshold Limit Values (TLVs). In addition, about 25 exposure limits recommended by the American Standards Association (now called the American National Standards Institute or ANSI) were adopted as

PELs.

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

Further, many of OSHA's chemical-specific permissible exposure limits were adopted in the 1970s and have not been updated since they were established. Additionally, TSCA risk evaluations are subject to statutory science standards, an explicit requirement to consider risks to potentially exposed or susceptible subpopulations, and a prohibition on considering costs and other non-risk factors when determining whether a chemical presents an unreasonable risk that warrants regulatory actions—all requirements that do not apply to development of OSHA regulations. As such, EPA may find unreasonable risk for purposes of TSCA notwithstanding OSHA requirements. There is also no established OSHA standard or PEL for NMP. In addition, health standards issued under section 6(b)(5) of the OSH Act must reduce significant risk only to the extent that it is technologically and economically feasible. OSHA's legal requirement to demonstrate that its section 6(b)(5) standards are technologically and economically feasible at the time they are promulgated often precludes OSHA from imposing exposure control requirements sufficient to ensure that the chemical substance no longer presents a significant risk to workers.

While it is possible in some cases that the OSHA standards for some chemicals reviewed

under TSCA will eliminate unreasonable risk, based on EPA's experience thus far in conducting occupational risk assessments under TSCA, EPA believes that OSHA chemical standards would in general be unlikely to address unreasonable risk to workers within the meaning of TSCA, since TSCA section 6(b) unreasonable risk determinations may account for unreasonable risk to more sensitive endpoints and working populations than OSHA's risk evaluations typically contemplate and EPA is obligated to apply TSCA section 6(a) risk management requirements to the extent necessary so that the unreasonable risk is no longer presented. Because the requirements and application of TSCA and OSHA regulatory analyses differ, it is necessary for EPA to conduct risk evaluations and, where it finds unreasonable risk to workers, develop risk management requirements for chemical substances that OSHA also regulates, and it is expected that EPA's findings and requirements may sometimes diverge from OSHA's. However, it is also appropriate that EPA consider the chemical standards that OSHA has already developed to limit the compliance burden to employers by aligning management approaches required by the agencies, where alignment will adequately address unreasonable risk to workers. The following unit discusses EPA's consideration of OSHA standards in its risk evaluation and management strategies under TSCA.

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

When characterizing the risk during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in scenarios where no mitigation measures are assumed to be in place for the purpose of determining unreasonable risk (see Unit II.C.2.a.). However, there are some cases where scenarios may reflect certain mitigation measures, such as in instances where exposure estimates are based on monitoring data at facilities that have existing engineering controls in place. For example, in the 2020 Risk Evaluation for NMP, EPA used data received from the Semiconductor Industry Association to develop the occupational

exposure scenario used for several conditions of use of NMP in semiconductor manufacturing. The data included full-shift personal breathing zone sampling results at semiconductor fabrication facilities during container handling of both small containers and drums, by workers inside the fabrication rooms, maintenance workers, workers unloading trucks containing virgin NMP, and workers loading trucks with waste NMP (Ref. 1). 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 or 2022 revised risk determination for NMP regarding the occupational safety practices 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 state and local government 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 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 state and local government 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 as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency to help inform risk management decisions.

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

When undertaking risk management actions, EPA: 1) Develops occupational risk

mitigation measures to address any unreasonable risk identified by EPA, striving for consistency with applicable OSHA requirements and industry best practices, including appropriate application of the hierarchy of controls, 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.

4. *NMP and OSHA requirements.*

EPA incorporated the considerations described earlier in this unit in the 2020 Risk Evaluation for NMP, the December 2022 revised unreasonable risk determination for NMP, and this rulemaking. Specifically, in the TSCA 2020 Risk Evaluation for NMP, EPA presented risk estimates based on workers' exposures with and without respiratory protection and dermal PPE. EPA determined that even when respirators or expected dermal PPE are used by workers, most of the conditions of use evaluated presented an unreasonable risk. Additional consideration of OSHA standards in the revised unreasonable risk determination is discussed further in the *Federal Register* notice announcing that document (Ref. 3). In Units III.B.3. and Unit V., EPA

outlines the importance of considering the hierarchy of controls utilized by the industrial hygiene community (hereafter referred to as "hierarchy of controls") when developing risk management actions in general, and specifically when determining if and how regulated entities may meet a risk-based exposure limit for NMP. 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. 8). 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 IV.A. and V.A.1., EPA's risk management approach would not rely solely or primarily on the use of respirators and dermal PPE to address unreasonable risk to workers. Instead, EPA is proposing prohibitions for several conditions of use and a WCPP for most occupational conditions of use, including requirements to prevent direct dermal contact with NMP, which is the exposure route of most concern. The WCPP is discussed in full in Units IV.A.2. and V.A.1.b. and would require consideration of the hierarchy of controls before use of PPE. While EPA is proposing prescriptive controls for some occupational conditions of use, these do not solely rely on PPE for worker protection. Instead, EPA's proposed requirements would incorporate additional controls, such as concentration limits, to reduce exposures in alignment with the hierarchy of controls.

There is no chemical-specific OSHA standard or PEL for NMP. Similarly, EPA is not proposing an ECEL for NMP because the proportion of the exposure largely driving the unreasonable risk to workers is due to dermal contact with liquid NMP (Ref. 1) and an ECEL would only address risk from inhalation and vapor-through-skin (dermal exposure to vapor but not direct dermal contact with a liquid) exposures without accounting for the risk from direct

dermal exposure. This is described in more detail in Unit V.A.3. In accordance with the approach described earlier in Unit II.C.3., EPA intends for this regulation to be as consistent as possible with the existing OSHA standards, with additional requirements as necessary to address the unreasonable risk.

5. *NMP and other occupational exposure limits.*

EPA is aware of several occupational exposure limits (OELs) for NMP, including the ones described in this unit. The 2014 California Division of Occupational Safety and Health (Cal/OSHA) PEL for NMP is 1 ppm as an 8-hour TWA, along with a skin notation (California Code of Regulations, title 8, Section 5155). In the 2007 Occupational Health Hazard Risk Assessment Project for California, a range of occupational exposure limits (identified as a cREL in the document) for NMP were proposed, ranging from 0.4 to 5 ppm based on various options for duration adjustment and cumulative uncertainty factors (UFs). The cRELs were derived from decreased fetal and pup weight observed in Solomon et al, 1995 (Ref. 9). While this study was discussed in the 2020 Risk Evaluation for NMP, EPA did not select it for the point of departure (POD) derivation due to uncertainties about the actual doses achieved at the highest exposure and methodological inconsistencies with testing guidelines. Additionally, it was not the most sensitive chronic POD based on physiologically-based pharmacokinetic (PBPK) model internal dose metrics (Ref. 1).

The 8-hour TWA 2021 Occupational Alliance for Risk Science (OARS) Workplace Environmental Exposure Level (WEEL) for NMP is 15 ppm with a skin notation because of the ability of NMP to be absorbed through the skin, and the short-term TWA is 30 ppm (Ref. 10). The WEEL was based on PBPK modeling of maternal and developmental toxicity from Saillenfait et al., 2003, (Ref. 11) which was the basis of the acute point of departure in the 2020 Risk Evaluation for NMP. While OARS reviewed data from the Exxon, 1991 (Ref. 12) study for

decreased male fertility that is the basis of EPA's chronic POD, those data were not included in the WEEL calculation.

The European Chemicals Agency (ECHA) restricts the use of NMP under the 2018 EU REACH restriction 71 with three conditions (Ref. 13). The conditions are: 1) NMP shall not be placed on the market as a substance on its own or in mixtures in concentrations greater than 0.3% after May 9, 2020, unless manufacturers, importers and downstream users have included chemical safety reports and Safety Data Sheets (SDSs) with Derived No Effect Levels (DNELs) relating to workers' exposures of 14.4 mg/m3 (equivalent to 3.5 ppm) for exposure by inhalation and 4.8 mg/kg/day for dermal exposure; 2) NMP shall not be manufactured, or used, as a substance on its own or in mixtures in a concentration equal to or greater than 0.3% after May 9, 2020 unless manufacturers and downstream users take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the DNELs specified in this paragraph; and 3) the restrictions specified in this paragraph shall apply from May 9, 2024, to placing on the market for use, or use, as a solvent or reactant in the process of coating wires.

The ECHA DNELs are based on systemic developmental effects in rats. The inhalation DNEL was based on no effects observed at the highest dose in Lee at al., 1987, (Ref. 14) and adjusted to a human equivalent concentration to result in the DNEL value. The dermal DNEL is 4.8 mg/kg-day based on a dermal no observed adverse effect level of 237 mg/kg for developmental toxicity in rats. Decreased live fetuses per litter, increased resorptions, and decreased fetal weights were observed at the high dose of 750 mg/kg. This DNEL is within the range of the estimated equivalent value based on PODs derived in the EPA risk evaluation or fenceline assessment (Refs. 15, 16).

D. *Summary of EPA's Risk Evaluation Activities on NMP.*

In 2015, prior to amended TSCA, EPA published an NMP risk assessment of the occupational and consumer use of NMP in paint strippers, uses with high potential for exposure to consumers and workers (Ref. 17). In January 2017, EPA issued a proposed rule under TSCA section 6 (82 FR 7464, January 17, 2017) (FRL-9958-57), to address risks that EPA had preliminarily identified for workers and consumers from use of methylene chloride and NMP in paint and coating removal. In March 2019, EPA issued a final rule under TSCA section 6 (84 FR 11420, March 27, 2019) (FRL-9989-29), to address unreasonable risk from methylene chloride in consumer paint and coating removal. In January 2021, EPA withdrew the portion of the proposed rule under TSCA section 6 that included NMP (86 FR 3932, January 15, 2021) (FRL-10018-67).

In December 2016, EPA selected NMP as one of the first 10 chemicals for risk evaluation under TSCA section 6 (81 FR 91927, December 19, 2016) (FRL-9956-47). EPA published the scope of the NMP risk evaluation in July 2017 (81 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 December 2019, EPA published a draft risk evaluation (84 FR 60087, November 7, 2019) (FRL-10003-71), and after public comment and peer review by the Science Advisory Committee on Chemicals (SACC), published the 2020 Risk Evaluation for NMP in December 2020 in accordance with TSCA section 6(b) (85 FR 86558, December 30, 2020) (FRL-10017-18). EPA subsequently issued a draft revised TSCA unreasonable risk determination for NMP (87 FR 39511, July 1, 2022) (FRL-9943-01-OCSPP), and after public notice and receipt of comments, published a final revised Unreasonable Risk Determination for NMP (87 FR 77596, December 19, 2022) (FRL-9943-02-OCSPP). The 2020 Risk Evaluation for NMP and supplemental materials are in docket EPA-HQ-OPPT-2019-0235, with the December 2022 final revised unreasonable risk determination and additional materials supporting the risk

evaluation process in docket EPA-HQ-OPPT-2016-0743, on *https://www.regulations.gov.*

1. *2020 risk evaluation.*

In the 2020 Risk Evaluation for NMP, EPA evaluated risks associated with 37 conditions of use within the following categories: manufacture (including import), processing, distribution in commerce, industrial and commercial use, consumer use, and disposal. Descriptions of these conditions of use are in Unit III.B.1. The 2020 Risk Evaluation for NMP identified significant adverse health effects associated with exposure to NMP, including developmental effects from acute inhalation and dermal exposures, and reproductive effects from inhalation and dermal exposures to NMP. A further discussion of the hazards of NMP is in Unit III.B.2. The 2020 Risk Evaluation updated the hazard points of departure (POD) from the draft risk evaluation and 2015 risk assessment based on updated analyses performed in response to peer review comments. Updated quantitative analyses of additional studies and endpoints did not lead to a revised chronic POD, which remained at 183 hr-mg/L blood area-under-the curve (AUC), based on decreased male fertility. In contrast, updating the quantitative analyses of acute studies resulted in a revision of the acute POD from 216 mg/L to 437 mg/L peak blood concentration, which resulted in some changes to acute risk estimates, which impacted the unreasonable risk determination. Notably, with the updated POD, the consumer risk calculations resulted in identification of fewer conditions of use contributing to the unreasonable risk. EPA revised its determination regarding the contribution to unreasonable risk and did not identify the consumer use of NMP in paint and coating removers or the consumer use of NMP in cleaning and furniture care products as contributing to the unreasonable risk from NMP. This is discussed further in section 5.3 of the 2020 Risk Evaluation which presented an update to the findings from the 2015 risk assessment.

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 NMP, 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 NMP, EPA revised the original unreasonable risk determination based on the 2020 Risk Evaluation for NMP and issued a final revised unreasonable risk determination in December 2022 (Ref. 2). EPA revised the risk determination for the 2020 Risk Evaluation for NMP pursuant to TSCA section 6(b) and consistent with Executive Order 13990 (entitled "Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis") and other Administration priorities (Refs. 18, 19, and 20). The revisions consisted of making the risk determination based on the whole chemical substance instead of by individual conditions of use (which resulted in the revised risk determination superseding the prior "no unreasonable risk" determinations and withdrawing the associated TSCA section 6(i)(1) "no unreasonable risk" order) and clarifying that the risk determination does not reflect an assumption that all workers are always provided and appropriately wear PPE (Ref. 2).

In determining whether NMP 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 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 also considered the Agency's confidence in the data used in the risk estimate. This included an evaluation of the strengths, limitations, and uncertainties associated with the information used to

inform the risk estimate and the risk characterization. The peer-reviewed PBPK model used in the 2020 Risk Evaluation allowed EPA to estimate aggregate exposures from simultaneous dermal, inhalation, and vapor-through-skin exposures with relatively high confidence.

EPA determined that NMP presents an unreasonable risk of injury to health. Risks to workers and consumers contribute to the unreasonable risk from NMP. EPA did not identify risks of injury to the environment that contribute to the unreasonable risk from NMP. The NMP conditions of use that EPA evaluated and which contribute to EPA's determination that the chemical substance poses unreasonable risk to health are listed in the unreasonable risk determination (Ref. 2) and in Unit III.B.1.

3. *Fenceline screening analysis.*

The 2020 Risk Evaluation for NMP did not fully assess certain exposure pathways that were or could be regulated under another EPA-administered statute (see section 1.4.2 of the December 2020 Risk Evaluation for NMP) (Refs. 1, 2). For NMP, some exposure pathways received only a screening-level analysis. During problem formulation, EPA conducted a first-tier screening analysis for the ambient air pathway to near-field populations downwind from industrial and commercial facilities releasing NMP, which indicated low risk (83 FR 26998, June 11, 2018) (FRL-9978-40). In the 2020 Risk Evaluation for NMP, EPA conducted a first-tier analysis to estimate NMP surface water concentrations and did not identify risks from incidental ingestion or dermal contact during swimming. This resulted in the ambient air and drinking water pathways for NMP not being fully assessed in the 2020 Risk Evaluation for NMP. In June 2021, EPA made a policy announcement on the path forward for TSCA chemical risk evaluations, indicating that EPA would, among other things, examine whether the exclusion of certain exposure pathways from the risk evaluations would lead to a failure to adequately protect fenceline communities (Ref. 3, 21). EPA then conducted a more robust assessment to identify

whether there may be potential risks to people living near the fenceline of facilities releasing NMP.

To assess the potential risk to the general population in proximity to a facility releasing NMP, 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. 22). This screening level approach, which EPA believes is effective in accurately assessing where fenceline exposures are of no concern, is discussed in Unit VI.A.

III. Regulatory Approach

A. *Background*

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

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

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

• Limit the amount of the substance or mixture which may be manufactured, processed, or distributed in commerce for a particular use or above a specific concentration for a particular

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

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

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

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

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

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

As described in Unit III.B.3., EPA analyzed how the TSCA section 6(a) requirements could be applied to address the unreasonable risk, so that NMP no longer presents such unreasonable risk. EPA's proposed regulatory action and alternative regulatory actions are described in Unit IV. EPA is requesting public comment on all elements of the proposed regulatory action and the alternative regulatory actions and is providing notice that based on consideration of comments and any new information submitted to EPA during the comment period on this proposed rule, EPA may in the final rule modify elements of the proposed regulatory action. The public should understand that public comments could result in changes to elements of the proposed and alternative regulatory actions when this proposed rule is finalized. For example, elements such as timelines could be lengthened or shortened, concentration limits

could be modified, or the WCPP could have provisions within the WCPP 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.

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

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

section 6 regulatory action.

1. *Consultations.*

EPA conducted consultations and outreach in developing this proposed regulatory action. The Agency held a federalism consultation from July 22 to October 22, 2021, as part of this rulemaking process and pursuant to Executive Order 13132. This included a background presentation on September 9, 2020, and a consultation meeting on July 22, 2021. During the consultation, EPA met with state and local officials early in the process of developing the proposed action to receive meaningful and timely input into its development (Ref. 23). During the consultation, participants and EPA discussed additional reporting requirements as a risk management tool to address the unreasonable risk, EPA's consideration of safer alternatives, and potential impacts to drinking water utilities (Ref. 23).

NMP 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. 24). The Agency held a Tribal consultation from May 21 to August 27, 2021, with meetings scheduled for June 14 and July 14, 2021. Tribal officials were given the opportunity to meaningfully interact with EPA risk managers concerning the current status of risk management. During the consultation, EPA discussed risk management under TSCA section 6(a), findings from the 2020 Risk Evaluation for NMP, types of information that would be helpful to inform risk management, principles for transparency during the risk management process, and types of information EPA is seeking from Tribes (Ref. 24). 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 NMP, such as minority populations, low-income populations, and indigenous peoples. EPA's Environmental

Justice (EJ) consultation occurred from June 3 through August 27, 2021. On July 7 and July 13, 2021, EPA held public meetings as part of this consultation. These meetings were held pursuant to and in compliance with Executive Orders 12898 and 14008. EPA received one written comment following the EJ meetings, in addition to oral comments provided during the consultation (Ref. 25). In general, commenters supported strong outreach to affected communities, encouraged EPA to follow the hierarchy of controls used by the industrial hygiene community, favored prohibitions, and noted the uncertainty, and in some cases the inadequacy, of PPE. Other commenters asked about the Agency's schedule for a proposed rule while reconsidering certain aspects of the 2020 Risk Evaluation. Additionally, commenters expressed concern that the adverse health impacts of NMP, particularly to pregnant women and children, and urged EPA to ban the use of NMP in paint and coating removers (Ref. 25).

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. 26). EPA met with SERs before and during Panel proceedings, on March 28 and May 24, 2023. Panel recommendations are in Unit X.C. and in the Initial Regulatory Flexibility Analysis (IRFA) (Ref. 27). The Panel report is in the docket (Ref. 26).

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

2. *Other stakeholder engagement.*

In addition to the formal consultations described in Unit X., EPA held a webinar on February 24, 2021, providing an overview of the TSCA risk management process and the risk evaluation findings for NMP. EPA also presented on the risk evaluation and risk management under TSCA for NMP at a Small Business Administration Office of Advocacy small business roundtable on February 26, 2021. At both events, EPA staff provided an overview of the TSCA

risk management process and the findings in the 2020 Risk Evaluation for NMP (Ref. 28). 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 NMP. A list of external meetings held during the development of this proposed rule is in the docket (Ref. 29); 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 NMP; identify workplace practices, engineering controls, administrative controls, PPE, and industrial hygiene plans currently in use or feasibly adoptable to reduce exposure to NMP under the conditions of use; understand the importance of NMP in the various uses subject to this proposed rule; compile knowledge about critical uses, substitute chemicals or alternative methods; identify various standards and performance specifications; and generate potential risk reduction strategies. EPA has met with, or otherwise communicated with, a variety of companies, trade associations and non-governmental organizations to discuss the topics outlined in this paragraph; a list of external meetings held during the development of this proposed rule is in the docket (Ref. 29).

3. *Children's environmental health.*

The EPA 2021 Policy on Children's Health (Ref. 30) requires EPA to protect children from environmental exposures by consistently and explicitly considering early life exposures (from conception, infancy, early childhood and through adolescence until 21 years of age) and lifelong health in all human health decisions through identifying and integrating children's health

data and information when conducting risk assessments. TSCA section 6(b)(4)(A) also requires EPA to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." Infants, children, and pregnant women are listed as examples of subpopulations that may be considered relevant "potentially exposed or susceptible subpopulations" in the TSCA section 3(12) definition of that term. In addition, TSCA section 6(a) requires EPA to apply one or more risk management requirements under TSCA section 6(a) so that NMP no longer presents an unreasonable risk (including unreasonable risk to PESS).

The 2020 Risk Evaluation for NMP evaluated risks of NMP to workers and ONUs, consumers and bystanders, people of reproductive age, pregnant females and the developing embryo/fetus, infants, children and adolescents, people with pre-existing conditions, and people with lower metabolic capacity due to life stage, genetic variation, or impaired liver function as potentially exposed or susceptible subpopulations who may be at greater risk than the general population of adverse developmental health effects from exposure to NMP (Ref. 1). For exposures to infants and males and females of reproductive age, evidence was found of reproductive and developmental toxicity. The reproductive and developmental health effects of concern related to exposures to NMP are reduced male fertility and female fecundity and post-implantation loss (resorptions and fetal mortality). While the literature contains methodological limitations in human studies, animal studies were considered adequate to represent reproductive and development effects in the 2020 Risk Evaluation for NMP.

The 2020 Risk Evaluation for NMP considered impacts on both children and adults from occupational and consumer use from inhalation and dermal exposures, as applicable. For

occupational use, the risk evaluation considered males (>16 years of age) and females of reproductive age (>16 years of age to less than 50 years of age) for both dermal and inhalation exposures. For consumer use, EPA evaluated oral exposures based on children's exposure potential via mouthing articles for infants (<1 year), infants (1 to 2 years), and small child (3 to 5 years), and levels were well below the threshold that could result in risk. Additionally for consumer use, the risk evaluation considered dermal and inhalation exposures to females of childbearing age (16 to 49 years) as the most sensitive subpopulation for other individuals, adults, and children. (Ref. 1)

B. *Regulatory Assessment of NMP*

1. *Description of conditions of use.*

This unit describes the TSCA conditions of use that EPA proposes to regulate, including the conditions of use that EPA evaluated and considered in making its unreasonable risk determination for the chemical substance NMP. Condition of use descriptions were obtained from EPA sources such as CDR use codes, the 2020 Risk Evaluation for NMP and related documents, as well as the Organisation for Economic Co-operation and Development harmonized use codes and stakeholder engagements. For clarity and transparency, EPA has narrowly revised the titles for the NMP conditions of use in this proposed rulemaking from the 2020 Risk Evaluation for NMP by removing CDR use code terminology "not described by other codes" and "in other uses" (Refs. 31, 32). 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 NMP, the 2020 Risk Evaluation for NMP, and supplemental files (Refs. 33, 1, 34). EPA acknowledges that some of the terms in this unit may be defined under other statutes. However, the descriptions here are intended to provide clarity to the regulated entities who will implement the provisions of this rulemaking under

TSCA section 6(a).

a. *Manufacturing.*

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.

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 in plastic material and resin manufacturing and other non-incorporative processing.* This condition of use refers to when a chemical substance is used in chemical reactions for the manufacturing of another chemical substance or product. Through processing as a reactant or intermediate, NMP serves as a feedstock in the production of another chemical product via a chemical reaction in which NMP is completely consumed. For example, NMP may be used as a polymerization media to manufacture high-temperature polymers or other uses as an intermediate, as a media for synthesis, extractions, and purifications, or as some other type of processing aid.

ii. *Processing, incorporation into formulation, mixture or reaction products in multiple industrial sectors*.This condition of use refers to the process of mixing or blending several raw materials to obtain a single product or preparation. NMP may be incorporated into various formulations, mixtures, or reaction products including, but not limited to:

• Adhesives and sealant chemicals in adhesive manufacturing;

• Anti-adhesive agents in printing and related support activities;

• Paint additives and coating additives in paint and coating manufacturing and print ink

manufacturing;

• Processing aids not otherwise listed in plastic material and resin manufacturing;

• Solvents (for cleaning or degreasing) in non-metallic mineral product manufacturing, machinery manufacturing, plastic material and resin manufacturing, primary metal manufacturing, soap and cleaning compound and toilet preparation manufacturing, transportation equipment manufacturing, all other chemical product and preparation manufacturing, printing and related support activities, services, wholesale and retail trade;

• Surface active agents in soap, cleaning compound and toilet preparation manufacturing;

• Plating agents and surface treating agents in fabricated metal product manufacturing;

• Solvents (which become part of product formulation or mixture) in electrical equipment, appliance and component manufacturing; other manufacturing; paint and coating manufacturing; print ink manufacturing; soap, cleaning compound and toilet preparation manufacturing; transportation equipment manufacturing; all other chemical product and preparation manufacturing; printing and related support activities; wholesale and retail trade; and

• In oil and gas drilling, extraction and support activities; plastic material and resin manufacturing; services.

iii. *Processing, incorporation into articles in lubricants and lubricant additives in machinery manufacturing*. This condition of use refers to the process or preparation when NMP is incorporated into articles in lubricants and lubricant additives in machinery manufacturing, and metal finishing operations conducted as part of machinery manufacturing. Metal finishing is a broad term used in industry to include a wide variety of processes that alter the surface of metal substrates, such as cleaning, coating, etching, and invasive quality testing.

iv. *Processing, incorporation into articles in paint additives and coating additives in transportation equipment manufacturing*.This condition of use refers to the process or

preparation when NMP is incorporated into articles in paints and coating additives in transportation equipment manufacturing. Transportation equipment manufacturing includes motor vehicle parts motor vehicle body and trailer manufacturing, aerospace product and parts manufacturing, railroad rolling stock manufacturing, and ship and boat building.

v. *Processing, incorporation into articles as a solvent (which becomes part of a product formulation or mixture) including in textiles, apparel and leather manufacturing.*This condition of use refers to the process or preparation when NMP is incorporated into articles as a solvent in textiles, apparel and leather manufacturing.

vi. *Processing, incorporation into articles in other sectors, including in plastic product manufacturing.*This condition of use refers to the process or preparation when NMP is incorporated into articles in other sectors, including in plastic product manufacturing. For example, NMP may be used to produce polymeric resins pellets and other shapes that are then converted into final plastic articles.

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

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

c. *Industrial and commercial use.*

i. *Industrial and commercial use in paints, coatings, and other adhesive removers*. This condition of use refers to the industrial or commercial use of NMP or NMP-containing products

to remove paints, coatings, and other adhesive removers from various surfaces indoors or outdoors including, but not limited to, graffiti removal from various surfaces.

ii. *Industrial and commercial use in paints and coatings in lacquers, stains, varnishes, primers and floor finishes, and powder coatings in surface preparation*. This condition of use refers to the industrial or commercial application of NMP-containing products including but not limited to paints and coatings, lacquers, stains, varnishes, primers and floor finishes, and powder coatings in surface preparation.

iii. *Industrial and commercial use in paint additives in computer and electronic product manufacturing in electronic parts manufacturing.* This condition of use refers to the industrial or commercial use of NMP or NMP-containing paint additive and coating additive products in manufacturing and maintaining electrical or electronic parts including but not limited to magnet wire coating, capacitor, resistor, coil, transfer and other inductor manufacturing. This description includes, but is not limited to, use of NMP as an additive in polymeric coatings used to coat magnet wires, often to give them thermal and solvent resistance, and in electrical insulating films. iv. *Industrial and commercial use in paint additives and coating additives in computer and electronic product manufacturing for use in semiconductor manufacturing*. This condition of use refers to the industrial or commercial use of NMP or NMP-containing paint additive and coating additive products in manufacturing and maintaining semiconductor chip manufacturing. This description includes, but is not limited to, use of NMP as an ingredient for wafer coating and photoresist activities. v. *Industrial and commercial use in paint additives and coating additives in construction, fabricated metal product manufacturing, machinery manufacturing, other manufacturing, paint and coating manufacturing, primary metal manufacturing, transportation equipment manufacturing, wholesale and retail trade*. This condition of use refers to the industrial or commercial application of NMP-containing paint additive and coating

additive products including paints, coatings, adhesives and sealants used in construction, fabricated metal product manufacturing, machinery manufacturing, other manufacturing, paint and coating manufacturing, primary metal manufacturing, transportation equipment manufacturing, wholesale and retail trade.

vi. *Industrial and commercial use as a solvent (for cleaning or degreasing) in electronic equipment, appliance and component manufacturing*. This condition of use refers to the industrial or commercial use of NMP or NMP-containing solvent (for cleaning or degreasing) product in manufacturing and maintaining electrical or electronic parts including, but not limited to magnet wire coating, capacitor, resistor, coil, transfer and other inductor manufacturing. This description includes, but is not limited to, use of NMP as a solvent in enamels, thinners, and cleaners to remove coatings and masks and in maintenance and equipment cleaning.

vii. *Industrial and commercial use as a solvent (for cleaning or degreasing) in electronic equipment, appliance and component manufacturing for use in semiconductor manufacturing.* This condition of use refers to the industrial or commercial use of NMP or NMP-containing containing solvent (for cleaning or degreasing) product in manufacturing and maintaining semiconductor chip manufacturing. This description includes, but is not limited to, the use of NMP for cleaning and stripping wafer surfaces in preparation for other coating formulations and in maintenance and equipment cleaning activities. viii. *Industrial and commercial use in ink, toner and colorant products in printer ink and inks in writing equipment.* This condition of use refers to the industrial or commercial use of NMP in printing and writing activities with products containing NMP. This includes printing technologies that use inks containing NMP, such as lithography, flexography, screen, letterpress, and digital technologies, which includes electrophotography and inkjet printing. ix. *Industrial and commercial use in processing aids, specific to petroleum production in petrochemical manufacturing, in oil and gas drilling,*

extraction and support activities, and in functional fluids (closed systems). This condition of use refers to the industrial or commercial use of NMP to improve the processing characteristics or the operation of process equipment or to alter or buffer the pH of the substance or mixture, when added to a process or to a substance or mixture to be processed specific to petroleum production in petrochemical manufacturing. This includes, but is not limited to, use as a processing aid for the extraction, separation, and recovery of aromatic hydrocarbons and other compounds from oils, natural gas, and refinery gases. Processing agents do not become a part of the reaction product and are not intended to affect the function of a substance created. x. *Industrial and commercial use in adhesives and sealants including binding agents, single component glues and adhesives, including lubricant adhesives, and two-compound glues and adhesives including some resins.* This condition of use refers to the industrial or commercial application of NMP-containing adhesive and sealant products including binding agents, single and two-component glues and adhesives, lubricant additives, and some resins. xi. *Industrial and commercial use in soldering materials.* This condition of use refers to the industrial or commercial use of NMP in soldering materials. Soldering is a process in which two or more substrates, or parts (usually metal), are joined together by melting a filler metal material (solder or soldering flux) into the joint and allowing it to cool, thereby joining the independent parts. xii. *Industrial and commercial use in anti-freeze and de-icing products, automotive care products, and lubricants and greases.* This condition of use refers to the industrial or commercial use of automotive servicing products containing NMP in servicing and maintenance activities in automotive vehicles. Some products may be applied through aerosol activities, which typically involve the application of a solution from pressurized cans or bottles that use propellant to aerosolize the solution, allowing it to be sprayed onto substrates. xiii. *Industrial and commercial use in metal products not covered elsewhere, and lubricant and lubricant additives including hydrophilic*

coatings. This condition of use refers to the industrial or commercial use of NMP in products used in metal finishing. Metal finishing is a broad term used in industry to include a wide variety of processes that alter the surface of metal substrates, such as cleaning, coating, etching, and invasive quality testing. xiv. *Industrial and commercial use in laboratory chemicals.* This condition of use refers to the industrial or commercial use of NMP in laboratory chemicals. This condition of use refers to the industrial and commercial use of NMP, often in small quantities, in a laboratory process or in specialized laboratory equipment for instrument calibration/maintenance chemical analysis, chemical synthesis, as a carrier chemical, extracting and purifying other chemicals, dissolving other substances, executing research, development, test and evaluation methods, and similar activities. xv. *Industrial and commercial use in lithium ion battery manufacturing.* This condition of use refers to the industrial or commercial use of NMP or NMP-containing products in manufacturing and maintaining lithium-ion battery cell manufacturing. xvi. *Industrial and commercial use in cleaning and degreasing, and cleaning and furniture care products, including wood cleaners and gasket removers.* This condition of use refers to the industrial or commercial use of NMP in cleaning or degreasing applications, including, but not limited to, use in industrial facilities and commercial shops, as well as products that can be used in multiple applications including, but not limited to, furniture care products, wood cleaners, and gasket removers. EPA identified NMP-containing cleaning products used in applications including, but not limited to, aerosol degreasing, dip/immersion degreasing and cleaning, wipe cleaning, and spray application. xvii. *Industrial and commercial use in fertilizer and other agricultural chemical manufacturing, processing aids and solvents.* This condition of use refers to the industrial or commercial use of NMP in the synthesis of and as a co-solvent in the formulation of agricultural chemicals. This description includes the use as an NMP containing fertilizer additive blended into granular or liquid fertilizers. d.

Consumer uses.

EPA determined that the condition of use in Unit III.B.1.d.v contributes to the unreasonable risk for NMP. As described in this unit, while EPA determined that seven of the eight consumer uses of NMP do not contribute to the unreasonable risk, the commercial counterparts of these conditions of use do contribute to the unreasonable risk. EPA determined that the seven consumer uses of NMP do not contribute to the unreasonable risk largely due to the generally low concentration of NMP in consumer products and the infrequent use by consumers of those products. (Ref. 1). However, the commercial use of these types of products does contribute to the unreasonable risk because of their generally higher concentrations of NMP or frequency of use in a commercial setting. Therefore, EPA is proposing upstream regulation of these seven consumer uses to address the unreasonable risk from NMP by certain commercial uses so that NMP as a whole chemical no longer presents unreasonable risk, as further discussed in Unit V.A.1.a. The consumer uses that do not contribute to the unreasonable risk for NMP are identified in Unit III.B.1.d.i. through iv. and vi. through viii. Because the potential use of these consumer products by commercial users contributes to their unreasonable risk, EPA is proposing upstream regulation of these consumer conditions of use as described in Unit IV.A.2.

i. *Consumer use in paint and coating removers.* This condition of use refers to consumer use of NMP-containing products in paint and coating remover products. ii. *Consumer use in adhesive removers.* This condition of use refers to consumer use of NMP-containing products in adhesive remover products. iii. *Consumer use in paints and coatings in lacquers, stains, varnishes, primers and floor finishes.* This condition of use refers to consumer use of NMP-containing products in paints and coatings products including lacquers, stains, varnishes, primers and floor finishes. iv. *Consumer use in paint additives and coating additives in paints and arts and crafts paints.* This condition of use refers to consumer use of NMP-containing products

in paint additive and coating additive products including paints and arts and crafts paints.

v. *Consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives.* This condition of use refers to consumer use of NMP-containing products in adhesive and sealant products. vi. *Consumer use in automotive care products.* This condition of use refers to consumer use of NMP-containing products in automotive care products. This description includes automotive interior cleaning products. vii. *Consumer use in cleaning and furniture care products, including wood cleaners and gasket removers.* This condition of use refers to consumer use of NMP-containing products in cleaning and furniture care products, including wood cleaners and gasket removers. This description includes cleaners and degreasers and engine cleaners and degreasers. viii. *Consumer use in lubricant and lubricant additives, including hydrophilic coatings.* This condition of use refers to consumer use of NMP-containing products in lubricant and lubricant additive products. e. *Disposal.*

This condition of use refers to the process of disposing generated waste streams of NMP that are collected either on-site or collected and transported to a third-party site, such as waste incineration sites, for disposal.

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 NMP 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 the chemical substance NMP, EPA identified and assessed all known, intended, and reasonably foreseen processing, industrial,

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

EPA is not proposing to incorporate the descriptions in Unit III.B.1.a. through e. into the regulatory text as definitions. EPA requests comment on whether EPA should promulgate definitions for those conditions of use evaluated in the 2020 Risk Evaluation for NMP that would not be prohibited, and, if so, whether the descriptions in this unit are consistent with the conditions of use evaluated in the 2020 Risk Evaluation for NMP and whether they provide a sufficient level of detail to improve the clarity and readability of the regulation.

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 the Federal Food, Drug, and Cosmetic Act (FFDCA) section 201, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device. For example, the proposed rule does not apply to NMP used as a nail polish remover, provided it is manufactured, processed, or distributed in commerce for such use, because nail polish remover is

a cosmetic as defined in FFDCA section 201(i).

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

EPA has determined that NMP presents an unreasonable risk of injury to human health under the conditions of use based on acute and chronic non-cancer risks. As described in the TSCA section 6(b) 2020 Risk Evaluation for NMP, EPA identified non-cancer adverse effects from acute and chronic inhalation and dermal exposures to NMP. EPA identified that the best representative endpoints for non-cancer effects were from acute (developmental toxicity) and chronic (reproductive toxicity) inhalation and dermal exposures for all conditions of use. Additional risks associated with other adverse effects (e.g., liver toxicity, kidney toxicity, immunotoxicity, neurotoxicity, irritation and sensitization) were identified for acute and chronic inhalation and dermal exposures. EPA did not evaluate cancer risk from exposure to NMP because NMP is not mutagenic and is not considered carcinogenic. Unit VI.A. summarizes the health effects and the magnitude of exposures (Ref. 1).

The 2020 Risk Evaluation for NMP assessed exposure from inhalation, dermal, and vapor through skin exposure, and identified that the unreasonable risk of injury to human health is mainly driven by direct dermal contact with NMP. Therefore, EPA is proposing dermal exposure controls (or, as needed, prohibitions) to prevent direct dermal contact with NMP. While inhalation risks contribute to the unreasonable risk from NMP, addressing inhalation risks alone would not mitigate the unreasonable risk from NMP. For a small number of conditions of use where inhalation and dermal exposures both significantly contribute to the unreasonable risk, EPA is proposing inhalation and dermal exposure controls. The measures to address the unreasonable risk are discussed further in Unit IV., and the rationale for these measures are discussed further in Unit V.

To make the unreasonable risk determination for NMP, EPA evaluated exposures to

workers, ONUs, consumer users, and bystanders to consumer use using reasonably available monitoring and modeling data for inhalation and dermal exposures. EPA conducted a screening-level analysis to assess potential risks from the air and water pathways to fenceline communities. A discussion of EPA's analysis and the expected effects of this rulemaking on fenceline communities is in Unit VI.A.

For the 2020 Risk Evaluation for NMP, EPA considered PESS. EPA identified the following groups as PESS: workers, ONUs, consumers, bystanders, males and females of reproductive age, pregnant women and the developing embryo/fetus, infants, children, and adolescents, people with pre-existing conditions and people with lower metabolic capacity due to life stage, genetic variation, or impaired liver function (Ref. 1). All PESS are included in the quantitative and qualitative analyses described in the risk evaluation, and were considered in the determination of unreasonable risk for NMP. As discussed in Unit II.D. and Unit VI.A., the 2020 Risk Evaluation for NMP did not fully assess some exposure pathways, including the air and surface 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 communities a subset of the general population and categorizes them as fenceline communities; they may also be considered PESS. See Unit VI.A. for further discussion on assessing and protecting against risk to fenceline communities.

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

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

As required, EPA developed a proposed regulatory action and an alternative regulatory action, which are described in Units IV.A. and IV.B., respectively. To identify and select a regulatory action, EPA considered the two routes of exposure driving the unreasonable risk,

inhalation and dermal, and the exposed populations. For occupational conditions of use (see Unit III.B.1.f.), EPA considered how it could directly regulate manufacturing (including import), processing, distribution in commerce, industrial and commercial use, or disposal to address the unreasonable risk. EPA does not have direct authority to regulate consumer use. Therefore, EPA considered how it could exercise its authority under TSCA to regulate the manufacturing (including import), processing, and/or distribution in commerce of NMP at different points in the supply chain to eliminate exposures or restrict the availability of NMP and NMP-containing products for consumer use to address the unreasonable risk.

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

EPA also considered the regulatory authority under TSCA and other statutes such as the OSH Act, Consumer Product Safety Act (CPSA), and other EPA-administered statutes to examine: (1) Whether there are opportunities for all or part of risk management action on NMP

to be addressed under other statutes, such that a referral may be warranted under TSCA sections 9(a) or 9(b); or (2) Whether TSCA section 6(a) regulation could include alignment of requirements and definitions in and under existing statutes to minimize confusion to the regulated entities and the general public.

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

To the extent information was reasonably available, when selecting regulatory actions, EPA considered pollution prevention and the hierarchy of controls adopted by OSHA and NIOSH, with the goal of identifying risk management control methods that are permanent, feasible, and effective. EPA also considered how to address the unreasonable risk while providing flexibility to the regulated entities where appropriate. EPA considered the information presented in the 2020 Risk Evaluation for NMP, 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 alternative regulatory action described in Unit IV. Additional details related to how the requirements in this unit were incorporated into development of those actions are in Unit V.

IV. Proposed and Alternative Regulatory Actions

This unit describes the proposed regulatory action by EPA so that NMP 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 alternative regulatory action. In the case of NMP, the proposed regulatory

action is described in Unit IV.A. and the alternative regulatory action considered is described in Unit IV.B. An overview of the proposed regulatory action and alternative regulatory action for each condition of use is in Unit IV.C. The rationale for the proposed and alternative regulatory action and associated compliance timeframes are discussed in this unit and in more detail in Unit V.A. Discussion of the consideration of TSCA section 6(c)(2)(A) is further described in Unit VI.

A. *Proposed Regulatory Action*

EPA is proposing, under TSCA section 6(a) to: Prohibit the manufacture (including import), processing, distribution in commerce, and industrial and commercial use of NMP for five occupational uses; Require container size limits and labeling requirements for the manufacture (including import), processing, and distribution in commerce of NMP products for seven consumer uses; Require prescriptive controls, including concentration limits and PPE, for seven occupational conditions of use; Require strict workplace controls, including an NMP WCPP, which would include requirements to prevent direct dermal contact with NMP, for all other occupational conditions of use; Require a concentration limit on NMP for the import, processing, and distribution in commerce for one consumer use; and Establish recordkeeping and downstream notification requirements. Pursuant to TSCA section 12(a)(2), this proposed rule would apply to NMP even if being manufactured, processed, or distributed in commerce solely for export from the United States because EPA has determined that NMP presents an unreasonable risk to health or the environment within the United States.

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

than 0.1% by weight to eliminate the unreasonable risk of injury resulting from inhalation and dermal exposures from NMP-containing products during occupational and consumer conditions of use. EPA's description for how allowing for a concentration of NMP up to 0.1% would not hinder the ability of this rulemaking to address the unreasonable risk associated with NMP-containing products and rationale for this regulatory approach are in Unit V.A. EPA requests comment on allowing this de minimis level of NMP in products to account for impurities.

1. *Prohibition of certain occupational uses and manufacturing, processing, and distribution in commerce of NMP for those uses.*

EPA is proposing to prohibit the manufacturing (including import), processing, distribution in commerce, and use of NMP for the following conditions of use:

• Processing incorporation into articles in lubricants and lubricant additives in machinery manufacturing;

• Industrial and commercial use in anti-freeze and de-icing products, automotive care products, and lubricants and greases;

• Industrial and commercial use in metal products not covered elsewhere and lubricant and lubricant additives including hydrophilic coatings;

• Industrial and commercial use in cleaning and degreasing and cleaning and furniture care products, including wood cleaners and gasket removers; and

• Industrial and commercial uses in fertilizer and other agricultural chemical manufacturing-processing aids and solvents.

The industrial and commercial uses of NMP in specialized electronics, such as lithium ion battery manufacturing for use in electronic vehicles or semiconductor manufacturing, and the associated upstream manufacturing (including import) and processing uses are not prohibited. EPA supports the continuation of these specialized electronic uses while addressing the

unreasonable risk through appropriate exposure controls, detailed in Unit IV.A.3.

As discussed in Units III.B.3. and V.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 work environments and activities, and the irreversible health effects associated with NMP exposures, EPA has determined that prohibition of the conditions of use identified in this unit is the best way to address the unreasonable risk from NMP. EPA believes there are a sufficient number of alternatives for these uses, described further in Unit V.B. and the Alternatives Assessment (Ref. 4).

EPA is proposing that the prohibitions on manufacturing (including import), processing, distribution in commerce, and industrial and commercial use of NMP for these conditions of use would follow a staggered schedule, due to supply chain considerations. EPA proposes that the compliance dates for the proposed prohibitions described in this unit would come into effect in 12 months for manufacturers, 15 months for processers, 18 months for distributing to retailers, 21 months for all other distributors (including retailers), and 24 months for industrial and commercial users after the publication date of the final rule. When proposing these compliance dates as required under TSCA section 6(d), EPA considered irreversible health effects and risks associated with NMP 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. For NMP, for the conditions of use EPA is proposing to prohibit, the Agency believes either NMP may no longer be used or regulated entities would be able to meet the proposed or alternative compliance timeframes due to availability of alternatives. EPA recognizes that for other proposed regulations under TSCA section 6, including methylene chloride (88 FR 28284, May 3, 20230 (FRL-8155-02-OCSPP),

perchloroethylene (88 FR 39652, June 16, 2023) (FRL-8329-02-OCSPP), and carbon tetrachloride (88 FR 49180, July 28, 2023) (RL-8206-01-OCSPP), public comments have provided information in support of longer compliance timeframes. Similarly, for NMP, 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. EPA is also requesting comment on: (1) whether respiratory protection and dermal PPE should be required before the effective date of the prohibition; (2) to what extent inhalation and dermal PPE may already be implemented in most uses being prohibited; and (3) whether requirements that inhalation and dermal PPE be used before the effective dates of prohibitions would be overly burdensome to entities indicated in this unit that would be working to comply with the prohibition. EPA is requesting comments from the public for more information about the uses EPA is proposing to prohibit, particularly the industrial and commercial uses in fertilizer and other agricultural chemical manufacturing-processing aids and solvents, and the ability for workplaces in these conditions of use to comply with strict workplace controls like those required under the WCPP, or the ability to comply with a prohibition and reformulate to an alternative chemical or process.

Additionally, EPA recognizes that there may be instances where an ongoing use of NMP

that has implications for national security or critical infrastructure as it relates to other Federal agencies (*e.g.,* DOD, DOE, NASA) is identified after the NMP rule is finalized, but the final rule prohibits that use. For instances like that, EPA requests comments on an appropriate, predictable process that could expedite reconsideration for uses that Federal agencies or their contractors become aware of after the final rule is issued using the tools available under TSCA, aligning with the requirements of TSCA section 6(g). One example of an approach could be the establishment by rulemaking of a Federal agency category of use that would require implementation of the WCPP and periodic reporting to EPA on details of the use as well as progress in discontinuing the use or finding a suitable alternative. To utilize the category of use a Federal agency would petition EPA, supported by documentation describing the specific use (including documentation of the specific need, service life of any relevant equipment, and specific identification of any applicable regulatory requirements or certifications, as well as the location and quantity of the chemical being used); the implications of cessation of this use for national security or critical infrastructure (including how the specific use would prevent injuries/fatalities or otherwise provide life-supporting functions); exposure control plan; and, for Federal agency uses where similar adoption by the commercial sector may be likely, concrete steps taken to identify, test, and qualify substitutes for the uses (including details on the substitutes tested and the specific certifications that would require updating; and estimates of the time required to identify, test, and qualify substitutes with supporting documentation). In the event that sensitive information relating to national security or critical infrastructure would be submitted to EPA, EPA would protect the submitted information in accordance with applicable authorities. EPA requests comment on whether these are the appropriate types of information for use in evaluating this type of category of use, and whether there are other considerations that should apply. EPA would make a decision on the petition within 30 days and publish the

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

EPA continues to work with Federal agency partners to develop a regulatory approach to accommodate uses needed for national security or critical infrastructure purposes in a manner that complies with EPA requirements for implementation of a workplace chemical protection plan (WCPP) and any other EPA identified protective measures intended to mitigate an unreasonable risk of injury to health or the environment. EPA solicits comment on all aspects of its steps to accommodate these uses in this proposed rule and whether any additional measures are needed.

2. *Container size restrictions and labeling requirements.*

EPA has identified consumer products similar to the commercial products proposed to be prohibited. While EPA determined that the consumer uses of NMP listed in this unit do not contribute to the unreasonable risk, EPA found that the commercial counterparts of these conditions of use do contribute to the unreasonable risk due to the increased exposure from more frequent use. As described in Unit III.B.3., under TSCA section 6(a), EPA is required to issue a

regulation applying one or more of the TSCA section 6(a) requirements to the extent necessary so that the unreasonable risk of injury to health or the environment from a chemical substance is no longer presented. As such, EPA is proposing tailored upstream regulations for these consumer conditions of use to manage the exposures to similar commercial conditions of use. In this way, NMP would not present unreasonable risk to workers. These restrictions are intended to prevent the consumer products intended for consumer use from being unlawfully used in commercial activities. EPA is proposing to prohibit the import, processing, and distribution in commerce of NMP or NMP-containing products for these consumer uses of NMP if the containers exceed a volume more than 16 ounces. The rationale for this container size volume is described in Unit V.A.1.b.

EPA is proposing to restrict the container size and require labels for NMP-containing products for the following consumer uses:

- In paint and coating removers;
- In adhesive removers;
- In paints and coatings in lacquer, stains, varnishes, primers and floor finishes;
- In paint additives and coating additives in paints and arts and crafts paints;
- In automotive care products;
- In cleaning and furniture care products, including wood cleaners, gasket removers; and
- In lubricant and lubricant additives, including hydrophilic coatings.

EPA is requesting public comment on whether meeting this container size restriction to prevent commercial use would also have the same, though unintended, effect of reducing the consumer use.

Additionally, to prevent commercial use of these consumer products, EPA is proposing to require all importers, processors, and distributors in commerce of the NMP-containing products

for the conditions of use listed in this unit to provide a label securely attached to each product. Label information would be required to be prominently displayed in an easily readable font size, and contain the following text including the sentence "This product is only for sale in containers of 16 ounces or less and is for consumer use only" in bold print or a larger font for emphasis:

> This product contains n-methylpyrrolidone (NMP) (CASRN 872-50-4), also called n-methyl-2-pyrrolidone or 1-methyl-2-pyrrolidone, a chemical determined by the Environmental Protection Agency to present unreasonable risk of injury to health under the Toxic Substances Control Act (TSCA), based on developmental and reproductive effects. The use of NMP is restricted under 40 CFR part 751, Subpart C. **This product is only for sale in containers of 16 ounces or less and is for consumer use only**. This product shall not be used for commercial purposes.

EPA is proposing that the container size limit and labeling requirements described in this unit take effect 12 months after the publication date of the final rule in the *Federal Register* for import, processing, and distribution in commerce. EPA has no reasonably available information indicating these proposed compliance dates are not practicable for the activities that would require repackaging and labeling 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 container size restriction, and on what an appropriate container size restriction should be if not 16 ounces, and why. EPA is also seeking public comment on any alternative options to prevent diversion of consumer products to commercial uses. Comments should include documentation such as the specific container sizes of the NMP-containing products and estimates of the time and expenses required to implement the labeling requirement. EPA may finalize significantly shorter or longer compliance timeframes based on consideration of public comments.

3. *Workplace Chemical Protection Program (WCPP) for certain conditions of use.*

a. Overview.

EPA is proposing Direct Dermal Contact Control (DDCC) requirements as part of the

WCPP for the manufacturing, processing, and use of NMP for all industrial and commercial uses, except for those conditions of use which would be prohibited (as described in Unit IV.A.1) or subject to prescriptive controls (as described in Unit IV A.4). This would include requirements to comply with the WCPP for the following conditions of use:

• Manufacturing (domestic manufacturing);

• Manufacturing (import);

• All processing, excluding conditions of use for which prohibition or prescriptive controls are proposed (which are listed in Unit IV.A.1 and IV.A.4, respectively). All processing includes, but is not limited to: processing as a reactant or intermediate in plastic material and resin manufacturing and other non-incorporative processing; processing incorporation into a formulation, mixture or reaction product in multiple industrial sectors; processing incorporation into articles as a solvent (which becomes part of a product formulation or mixture) including in textiles, apparel and leather manufacturing; processing incorporation into articles in other sectors, including in plastic product manufacturing; processing by repackaging in wholesale and retail trade; processing by recycling;

• All industrial and commercial uses, excluding conditions of use for which prohibition or prescriptive controls are proposed (which are listed in Units IV.A.1 and IV.A.4, respectively). All industrial and commercial uses includes, but is not limited to: industrial and commercial use in paint additives and coating additives in computer and electronic product manufacturing in electronic parts manufacturing; industrial and commercial use in paint additives and coating additives in computer and electronic product manufacturing in semiconductor manufacturing; industrial and commercial use as a solvent (for cleaning or degreasing) in electrical equipment, appliance and component manufacturing; industrial and commercial use as a solvent (for cleaning or degreasing) in electrical equipment, appliance and component manufacturing for use

in semiconductor manufacturing; industrial and commercial use in processing aids, specific to petroleum production in petrochemical manufacturing in oil and gas drilling, extraction and support activities, and in functional fluids (close systems); industrial and commercial use in laboratory chemicals; industrial and commercial uses in lithium ion battery manufacturing; industrial and commercial use in paints and coatings and paint, coating, and adhesive removers by DOD, NASA, and their contractor for mission-critical components on government-operated aerospace vehicles, vessels, and military weapons systems, including mission- or safety-critical components; and

• Disposal.

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 (e.g., manufacturing, processing, industrial and commercial use, and disposal) conditions of use. The WCPP for NMP would encompass DDCC requirements, and the associated implementation requirements described in this unit to ensure that the chemical substance no longer presents unreasonable risk.

Under a WCPP, owners or operators would have some flexibility, within the parameters outlined in this unit, regarding how they prevent direct dermal contact. In the case of NMP, implementing the DDCC requirements for certain occupational conditions of use would address unreasonable risk to potentially exposed persons from dermal exposure.

EPA uses the term "potentially exposed person" in this unit and in the regulatory text to include workers, occupational non-users, employees, independent contractors, employers, and all other persons in the work area where NMP is present and who may be exposed to NMP under the conditions of use for which a WCPP would apply. One important reason to define a potentially exposed person for the purposes of a WCPP as any person who may be exposed in the workplace is to emphasize the broad scope of exposures which must be categorized when implementing a WCPP. EPA notes that this definition is intended to apply only in the context of risk management, and specifically in the context of a WCPP (e.g., workers directly using the chemical, workers in the vicinity of the use, students in a laboratory setting). The term is not intended as a replacement for the term Potentially Exposed or Susceptible Subpopulation as defined by TSCA section 3(12). EPA additionally recognizes that other individuals or communities may be exposed to NMP as consumers, members of fenceline communities, or members of the general population, which is separate and apart from those potentially exposed for the purposes of the regulatory requirements of the WCPP. In those instances, where regulatory requirements address exposures unrelated to a WCPP EPA would use distinct terminology to refer to those other populations. EPA's intention is to require a comprehensive WCPP that would address the unreasonable risks from NMP to potentially exposed persons directly handling the chemical or in the area where the chemical is being used.

Similarly, the 2020 risk evaluation for NMP did not distinguish between employers, contractors, or other legal entities or businesses that manufacture, process, distribute in commerce, use, or dispose of NMP.

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 NMP is present. The term includes any person who owns, leases, operates, controls, or

supervises such a workplace.

DDCC requirements are process-based approaches to prevent direct dermal contact with NMP and associated implementation requirements described in this unit to ensure that the chemical substance no longer presents unreasonable risk from dermal exposure. DDCC requirements allow regulated entities some flexibility within certain parameters outlined in this unit for preventing direct dermal contact with NMP. In the case of NMP, EPA has preliminarily determined that preventing direct dermal contact through DDCC requirements for certain conditions of use would address their contribution to the unreasonable risk from NMP. NMP is slightly volatile, and preventing direct dermal contact with NMP would also inherently reduce inhalation exposure by reducing concentration of NMP in air from volatilization, further preventing unreasonable risk to workers.

This unit includes a summary of the proposed NMP WCPP, including a description of the proposed DDCC requirements and associated implementation requirements; consideration of the NIOSH hierarchy of controls (hereafter referred to as "hierarchy of controls"); and additional requirements proposed for recordkeeping, workplace training, workplace participation, and notification. This unit also describes compliance timeframes for these proposed requirements.

b. *Direct Dermal Contact Control (DDCC) requirements.*

i. *Direct dermal contact*. DDCC requirements are a process-based set of provisions to address unreasonable risk driven by dermal exposure by preventing direct dermal contact in the workplace. To address the unreasonable risk driven by dermal exposure to NMP, DDCC requirements would include controls to separate, distance, physically remove, or isolate all person(s) from direct handling of NMP or from skin contact with surfaces that may be contaminated with NMP (i.e., equipment or materials on which NMP may be present) under routine conditions in the workplace (hereafter referred to as direct dermal contact). The 2020

Risk Evaluation for NMP assessed risks to workers from inhalation and dermal exposure, and concluded the risk was driven by the dermal exposure, mainly direct skin contact with NMP. Risk exceeding the benchmark was identified even when considering use of chemically resistant gloves in most commercial and industrial conditions of use. The 2020 Risk Evaluation deduced that direct dermal contact drives the unreasonable risk by comparing the internal exposure to workers with inhalation, vapor through skin and dermal liquid contact with internal exposure to ONUs due to inhalation and vapor through skin exposure (a subtraction technique). The percent exposure to NMP due to dermal contact with liquid is provided in table 4-54 in section 4.3.7 of the 2020 Risk Evaluation (Ref. 1). EPA's description for how the requirements related to DDCC would address the unreasonable risk resulting from dermal exposures and the rationale for this regulatory approach is outlined in Units III.B.3. and V.A.

As part of DDCC requirements, EPA is proposing to require owners and operators to implement dermal exposure controls in accordance with the hierarchy of controls. EPA also recommends and encourages the use of pollution prevention as a means of controlling exposures whenever practicable. EPA is also proposing to align DDCC requirements with the implementation of several OSHA standards, including the hazard communication (29 CFR 1910.1200) and general PPE requirements standards (29 CFR 1910.132), recognizing that OSHA has not set an exposure limit for inhalation or direct dermal exposure for NMP.

Within certain parameters outlined in this unit, DDCC requirements are non-prescriptive, in the sense that it does not require a specific control to prevent direct dermal contact. Rather, it would enable regulated entities to determine how to most effectively prevent direct dermal contact based on what works best for their workplace, in accordance with the hierarchy of controls. Each owner or operator of a workplace engaging in a condition of use for which DDCC requirements are proposed would be responsible for compliance with the DDCC requirements

and recordkeeping.

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

ii. *Incorporation of the hierarchy of controls*. EPA is proposing to require owners or operators to implement DDCC requirements in accordance with the hierarchy of controls and encourages the use of pollution prevention to control exposures whenever practicable. EPA recognizes that some owners or operators may have industrial hygiene practices already preventing direct dermal contact with NMP in the workplace. For example, the semiconductor sector has provided EPA with information about the exposure reduction measures in their facilities, which are aligned with industrial hygiene best practices to prevent direct dermal contact with NMP, similar to that EPA is proposing. For workplaces that cannot feasibly eliminate the source of NMP dermal exposure or replace NMP with a substitute, workplaces would have to use engineering and/or administrative controls to implement process changes to prevent direct dermal contact with NMP to the extent feasible. If an owner or operator chooses to replace NMP with a substitute, EPA recommends that they carefully review the available hazard and exposure information on the potential substitutes to avoid a regrettable substitution, including alternatives identified in the Alternatives Analysis, which is further described in Unit V.B. If an effort to identify and implement feasible exposure controls such as elimination, substitution, engineering controls and administrative controls is not sufficient to prevent direct dermal contact with NMP for potentially exposed persons in the workplace, EPA proposes to require each owner and operator to reduce to the extent practicable the potential for direct dermal contact with NMP in the workplace by these controls and to supplement these controls using

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

EPA requests comment on available approaches, specifically monitoring methods (e.g., charcoal patch testing) and frequency of sampling, to determine the effectiveness of engineering and administrative controls in preventing or reducing potential direct dermal contact to NMP. EPA also requests comment on whether requiring reporting on such monitoring could support enforcement and compliance assurance with this rulemaking.

EPA proposes to require that owners and operators document their implementation efforts and compliance with DDCC requirements in an exposure control plan or through any existing documentation of the facility's "Safety and Health Program" that may already be developed as part of meeting OSHA requirements or other safety and health standards (Ref. 35*), as described in* Unit IV.A.3.d.

iii. *Restricted area*. EPA is proposing to require that each owner or operator subject to a WCPP designate any area where direct dermal contact with NMP may occur (after considering elimination, substitution, engineering controls, and administrative controls) as a "restricted area." This restricted area would be demarcated using administrative controls such as highly visible signifiers, in multiple languages as appropriate (e.g., based on languages spoken by potentially

exposed persons who work in the restricted area), placed in conspicuous areas and documented through training and recordkeeping. EPA proposes to require that each owner or operator prevent access to the "restricted area" for any potentially exposed person that lacks proper training; is not wearing required PPE; or is otherwise unauthorized to enter. EPA requests comment on whether there should be general housekeeping or cleaning requirements in areas where the NMP is handled or where surfaces may be contaminated with NMP. EPA is also soliciting comment on requiring warning signs to demarcate restricted areas, similar to the requirements found in OSHA's General Industry Standard for Beryllium (29 CFR 1910.1024(m)(2)).

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

Where elimination, substitution, engineering controls, and administrative controls are not feasible or sufficient to fully prevent direct dermal contact with NMP, 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. In choosing appropriate PPE, owners and operators would be required to select gloves (which may require glove testing), clothing, and protective gear (which covers any exposed dermal area of arms, legs, torso, and face) based on specifications from the manufacturer or supplier that demonstrate an impervious barrier to NMP during expected durations of use and normal conditions of exposure within the workplace, accounting for potential chemical permeation or breakthrough times. Where respirators are prescribed, as described in Unit IV.A.4., EPA is proposing to require each owner or operator select respiratory protection in accordance with the guidelines described in this unit and 29 CFR 1910.134(a) through (l), except (d)(1)(iii) and (d)(3)(i)(B), for proper respirator use, maintenance, fit-testing, medical evaluation, and training.

Owners and operators would be required to select dermal PPE in accordance with provisions of 29 CFR 1910.132 and in alignment with the OSHA Hand Protection PPE Standard

(29 CFR 1910.138); owners and operators would also be required to select dermal PPE based on an evaluation of the performance characteristics of the PPE relative to the task(s) to be performed, conditions present, and the duration of use. Further information related to choosing appropriate PPE, including specific examples of PPE types, can be found in appendix F of the Risk Evaluation (Ref. 1).

For example, owners and operators could 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 Conditions of Continuous Contact." EPA is proposing that PPE be provided for use for a time period only to the extent and no longer than the time period for which testing has demonstrated that the PPE will be impermeable during expected durations of use and conditions of exposure. EPA is proposing to require that owners and operators also consider other factors when selecting appropriate PPE, including effectiveness of glove type when preventing exposures from NMP alone and in likely combination with other chemical substances used in the work area or when used with glove liners, permeation, degree of dexterity required to perform tasks, and temperature, as identified in the Hand Protection section of OSHA's Personal Protective Equipment Guidance and in alignment with the OSHA Hand Protection PPE Standard (29 CFR 1910.138), owners and operators would be required to select dermal PPE based on an evaluation of the performance characteristics of the PPE relative to the task(s) to be performed, conditions present, and the duration of use (Ref. 36).

EPA is proposing that owners and operators would be required to establish, either through manufacturer or supplier-provided documentation or individually prepared third-party testing, that the selected PPE would be impervious for the expected duration and conditions of exposure by reporting cumulative permeation rate as a function of time (e.g., by using the

suggested format presented in ASTM F1194, "Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing," or equivalent manufacturer- or supplier-provided testing). Owners and operators would also be required to consider likely combinations of chemical substances to which the clothing may be exposed in the work area when selecting the appropriate PPE such that the PPE will prevent direct dermal contact to NMP. EPA is proposing that PPE must be immediately provided and replaced if any person is dermally exposed to NMP longer than the breakthrough time period for which testing has demonstrated that the PPE will be impermeable or if there is a chemical permeation or breakage of the PPE.

Also consistent with 29 CFR 1910.132, owners and operators would be required to provide any person in the workplace with PPE and provide training on proper use (e.g., when and where PPE is necessary, proper application, wear, and removal of PPE, and maintenance, useful life and disposal of PPE) where the potential for direct dermal contact with NMP may exist. Owners and operators would also have to re-train any affected persons potentially exposed to direct dermal contact with NMP 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.

Additionally, EPA is proposing to require that owners and operators subject to this rulemaking comply with provisions of 29 CFR 1910.133(b) for requirements on selection and use of eye and face protection. Similarly, EPA is proposing to require that owners and operators subject to this rulemaking who would be required to administer a respiratory protection program do so with worksite-specific procedures and elements for required respirator use in accordance with 29 CFR 1910.134(a) through (l), except 29 CFR 1910.134(d)(1)(iii) and (d)(3)(i)(B), for

proper respirator use, maintenance, fit-testing, medical evaluation, and training. While EPA does not propose that the WCPP for NMP proposed for the conditions of use listed earlier in this unit include respiratory protection requirements, EPA notes that the proposed prescriptive controls for conditions of use listed in Unit IV.A.4. would include respiratory protection. For respiratory PPE, EPA is proposing that the owner or operator must ensure that all cartridges and canisters used in the workplace are labeled and color coded with the NIOSH approval label and that the label is not removed and remains legible. 29 CFR 1910.134(d)(3)(iii), which EPA is proposing to cross-reference, requires either the use of respirators with an end-of-life service indicator certified by NIOSH for the contaminant, in this case NMP, 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)). Further information related to choosing appropriate respirators, including specific examples of respirator types, can be found in appendix F of the 2020 Risk Evaluation for NMP (Ref. 1).

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).

EPA is soliciting comments on the non-prescriptive proposed DDCC requirements for

appropriate PPE selection, the effectiveness of PPE in preventing direct dermal contact with NMP in the workplace. EPA requests information on other potential dermal performance standards, and on general absorption and permeation effects to PPE as a result of direct contact. In addition, EPA understands that some workplaces rinse and reuse PPE after minimal use and is therefore soliciting comments on the impact on effectiveness of rinsing and reusing certain types of PPE, either gloves or protective clothing and gear. EPA also requests comment on the degree to which additional guidance related to use of PPE might be appropriate, including specifying PPE type or additional standard testing specifications.

EPA is also proposing that owners and operators retain records of the PPE that is used and program implementation. EPA proposes to require that owners and operators document in the exposure control plan, or other documentation of the facility's safety and health program, information relevant to any PPE program, as applicable, including: (A) the name, workplace address, work shift, job classification, and work area of each person reasonably likely to directly handle NMP or handle equipment or materials on which NMP may present and the type of PPE selected to be worn by each of these persons; (B) the basis for specific PPE selection (e.g., demonstration based on permeation testing or manufacturer specifications that each item of PPE selected provides an impervious barrier to prevent exposure during expected duration and conditions of exposure, including the likely combinations of chemical substances to which the PPE may be exposed in the work area); (C) appropriately sized PPE and training on proper application, wear, and removal of PPE, and proper care/disposal of PPE; (D) occurrence and duration of any direct dermal contact with NMP that occurs during any activity or malfunction at the workplace that causes direct dermal exposures to occur and/or glove breakthrough, and corrective actions to be taken during and immediately following that activity or malfunction to prevent direct dermal contact to NMP; and (E) training in accordance with 29 CFR 1910.132(f),

including any re-training. EPA may require more, less, or different documentation in the final rule based on consideration of public comments.

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 NMP, substitution of NMP, engineering controls, and administrative controls to prevent or reduce direct dermal contact with NMP 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 restricted area and how it is demarcated, and identification of authorized persons; and description of when the owner or operator expects potential direct dermal contact exposures;

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

(G) Occurrence and duration of any start-up, shutdown, or malfunction of the facility that

causes direct dermal contact with NMP and subsequent corrective actions taken during start-up, shutdown, or malfunctions to mitigate exposures to NMP; and

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

ii. *Workplace information and training.* EPA is also proposing to require implementation of a training program in alignment with the OSHA Hazard Communication Standard (29 CFR 1910.1200). To ensure that potentially exposed persons in the workplace are informed of the hazards associated with NMP 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), considering factors such as the skills required to perform the work activity and the existing skill level of the staff performing the work, and in multiple languages as appropriate (e.g., based on languages spoken by potentially exposed persons) to potentially exposed persons. This information and training would have to be provided prior to or at the time of initial assignment to a job involving potential exposure to NMP. 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 NMP 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 NMP and the specific operations in the workplace that could result in NMP exposure; (C) principles of safe use and handling of NMP in the workplace, including specific measures the owner or operator has implemented to prevent direct dermal contact with NMP, such as work practices and PPE used; (D) the methods and observations that may be used

to detect the presence or release of NMP in the workplace (such as visual appearance or odor of NMP when being released, etc.); and (E) the health hazards associated with exposure with NMP.

In addition to providing training at the time of initial assignment to a job involving potential exposure to NMP, and in alignment with the OSHA General Industry Standard for Beryllium (20 CFR 1910.1024), which includes an annual retraining provision, owners and operators subject to the NMP WCPP would be required to re-train each potentially exposed person annually to ensure they understand the principles of safe use and handling of NMP 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 NMP or where potentially exposed persons' direct dermal contact exposure to NMP can reasonably be expected to occur. In alignment with the OSHA General Industry Standard for Methylene Chloride (29 CFR 1910.1052) owners and operators would need to retrain any exposed person if exposure to direct dermal contact of NMP, including vapor through skin exposure, occurs. 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 potentially exposed persons on the development and implementation of exposure control plans and PPE. EPA is proposing to require owners or operators to provide potentially exposed persons, or their designated representatives, regular access to the exposure control plans 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 to NMP direct dermal contact to readily access the exposure control plans, PPE

program implementation, or any other information relevant to NMP 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.

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. All records required to be maintained by this unit could be kept in the most administratively convenient form (electronic or paper).

v. *Compliance timeframes.* With regard to the compliance timeframe for those occupational conditions of use that are subject to WCPP requirements, EPA is proposing to require that each owner or operator of a workplace subject to WCPP establish the process outlined in this unit within 12 months of publication of the final rule in the *Federal Register* for the private sector, and within 36 months of publication of the final rule in the *Federal Register* for Federal agencies and Federal contractors acting for or on behalf of the Federal government. For the private sector, EPA has no reasonably available information indicating this proposed compliance date of 12 months is not practicable for WCPP requirements, or that additional time is needed. However, EPA is concerned about the ability of certain departments and agencies of

the Federal Government, as well as Federal contractors acting for or on behalf of the Federal Government, to comply with these timeframes. The importance of NMP to mission-critical Department of Defense and National Aeronautics and Space Administration (NASA) operations and overall military readiness is discussed throughout this proposed rule, and detailed in Unit IV.A.6. While, for example, 29 CFR 1960 sets forth procedures and guidelines for ensuring that Federal workers are protected in comparable ways to their private sector counterparts, EPA believes that compliance with this proposed rulemaking would require increased and different preparations on the part of Federal agencies. For example, Federal agencies must follow procurement requirements which will likely result in increased compliance timelines. In addition, these requirements would require support in the Federal budget, which, for some agencies, is a multi-year process. Therefore, EPA is providing an additional two years for agencies of the Federal Government and their contractors, when acting for or on behalf of the Federal government, to comply with the WCPP.

EPA requests comment relative to the ability of owners or operators in the private sector to implement such processes within 12 months of publication of the final rule in the *Federal Register*, and anticipated timelines for any procedural adjustments needed to comply with the requirements outlined in this unit. EPA also requests comment on whether the additional two years provided for agencies of the Federal Government and their contractors, when acting for or on behalf of the Federal government, to comply with the WCPP, should be provided more broadly to all entities complying with the WCPP.

EPA may finalize significantly shorter or longer compliance timeframes based on consideration of public comments.

4. *Prescriptive controls.*

a. *Overview.*

In contrast to the proposed non-prescriptive requirements of DDCC where regulated entities would select controls in accordance with the hierarchy of controls to comply with the parameters outlined in this unit, EPA is proposing that it is appropriate in certain circumstances to require specific prescriptive controls for certain occupational conditions of use where preventing direct dermal contact through implementation of a WCPP or a prohibition may not be practicable. EPA's description for how these requirements would address the unreasonable risk and the rationale for this regulatory approach is outlined in Units III.B.3 and V.A.

In the 2020 Risk Evaluation for NMP, and supplemental occupational risk calculations EPA identified certain prescriptive controls, such as product reformulation to limit concentration of NMP in certain products that, in combination with PPE, would reduce exposures from NMP enough to address the unreasonable risk (Ref. 37). Therefore, EPA is proposing to require specific prescriptive controls for these occupational uses of NMP, as described in this unit. The following requirements would apply to the following conditions of use:

• A concentration of NMP no greater than 45% in formulated products, with requirements for appropriate dermal PPE, and any NIOSH Approved® air-purifying respirator equipped with organic vapor cartridges or canisters (minimum APF 10) for:

– Processing – incorporation into articles in paint additives and coating additives in transportation equipment manufacturing;

– Industrial and commercial use in paints and coatings in lacquers, stains, varnishes, primers and floor finishes, and powder coatings in surface preparation;

– Industrial and commercial use in paint additives and coating additives in construction, fabricated metal product manufacturing, machinery manufacturing, other manufacturing, paint and coating manufacturing, primary metal manufacturing, transportation equipment manufacturing, wholesale and retail trade; and

– Industrial and commercial use in adhesives and sealants including binding agents, single component glues and adhesives, including lubricant adhesives and two component glues and adhesives including some resins.

• A concentration of NMP no greater than 30% in formulated products, with requirements for appropriate dermal PPE, and any NIOSH Approved® air-purifying respirator equipped with organic vapor cartridges or canisters; any NIOSHApproved® powered air-purifying respirator equipped with NIOSH Approved® organic vapor cartridges; or any NIOSH Approved® continuous flow supplied air respirator equipped with a hood or helmet (minimum APF 25) for the industrial and commercial use in paints, coatings, and adhesive removers.

• A concentration of NMP no greater than 5% with requirements for appropriate dermal PPE for the industrial and commercial use in ink, toner, and colorant products in printer ink.

• A concentration of NMP no greater than 1% with requirements for appropriate dermal PPE for the industrial and commercial use in soldering materials.

This unit describes proposed requirements for concentration (or weight fraction) limits, appropriate dermal PPE, and respirator types with additional requirements proposed for recordkeeping. This unit also describes compliance timeframes for these proposed requirements.

b. *Concentration limits for industrial and commercial uses.*

EPA is proposing to prohibit the import, processing, distribution in commerce, or use of the NMP-containing products for the conditions of use listed in this unit with a concentration greater than those listed for each condition of use. Specifically, EPA proposes that processors, or product formulators, would not be permitted to formulate products for the conditions of use listed in in this unit with a concentration of NMP greater than specified in this unit. Similarly, importers of formulated products would be prohibited from importing products for the conditions of use listed in this unit with a concentration of NMP greater than specified in this unit. Entities

distributing in commerce products containing NMP would be prohibited from distributing any products for the conditions of use listed in this unit with a concentration of NMP greater than specified in this unit.

c. *Workplace requirements.*

To reduce exposures in the workplace and address the unreasonable risk of injury to health from NMP identified for the occupational uses listed in this unit, EPA is proposing both a concentration limit requirement and PPE requirement. Each owner or operator of a workplace who imports, processes, or industrially and commercially uses NMP under the conditions of use listed in this unit would be responsible for compliance with the requirements outlined in this unit. Specifically, concentrations of NMP in products used for the conditions of use listed in this unit would not be permitted to exceed the listed concentrations, and owners or operators would be responsible for ensuring requirements for the specified PPE and PPE program laid out in Unit IV.A.3.c. are met.

EPA is proposing to require appropriate dermal PPE, including impermeable gloves and protective clothing, in combination with comprehensive training for tasks with NMP. In selecting and providing appropriate dermal PPE and providing PPE training, owners and operators would be required to follow the PPE program and dermal protection requirements laid out in Unit IV.A.3.c. Unlike DDCC, this proposed provision would not require owners and operators to use elimination, substitution, engineering controls, and administrative controls, prior to relying on PPE, as a means of controlling exposures in accordance with the hierarchy of controls. EPA encourages owners and operators to consider the hierarchy of controls, but is only proposing to require specific respiratory PPE for several of the conditions of use listed in this unit, in combination with comprehensive training for tasks with NMP. In providing the specified respirators and training, owners and operators would be required to administer a respiratory

protection program with worksite-specific procedures and elements for required respirator use in accordance with 29 CFR 1910.134(a) through (l), except 29 CFR 1910.134(d)(1)(iii) and (d)(3)(i)(B), for proper respirator use, maintenance, fit-testing, medical evaluation, and training. EPA is proposing that the owner or operator must ensure that all cartridges, and canisters used in the workplace are labeled and color coded with the NIOSH approval label and that the label is not removed and remains legible. 29 CFR 1910.134(d)(3)(iii), which EPA is proposing to cross-reference, requires either the use of respirators with an end-of-life service indicator certified by NIOSH for the contaminant, in this case NMP, 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)). Owners and operators would also be required to follow the PPE program laid out in Unit IV.A.3.c.

d. *Recordkeeping.*

To support and demonstrate compliance, EPA is proposing that each owner or operator of a workplace that would be subject to the prescriptive controls described in this unit (including product formulators) retain compliance records for five years. EPA is proposing to require records to include:

(1) Documentation identifying implementation of and compliance with the concentration limits described in this unit;

(2) Dermal protection used by each potentially exposed person, as described in this unit;

(3) Respiratory protection used by each potentially exposed person, as described in this

unit; and

(4) PPE program implementation.

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). EPA is requesting public comment on whether additional documentation should be required to further support compliance and enforceability of the proposed regulatory requirements (e.g., requirements for labels or SDS identifying percent of NMP within a product, or downstream notification of these proposed requirements for concentration limits and PPE, or other information that would be made available to industrial and commercial users to indicate compliance with the concentration limits).

e. *Compliance timeframes.*

EPA is proposing to stagger the compliance dates for the proposed prescriptive controls described in this unit, such that the requirements would come into effect in 12 months for importers, 15 months for processors, 18 months for distributing to retailers, 21 months for all other distributors (including retailers), 24 months for industrial and commercial users after the publication date of the final rule. When proposing these compliance dates as required under TSCA section 6(d), EPA considered irreversible health effects and risks associated with NMP exposure. EPA has no reasonably available information indicating that the proposed compliance dates are not practicable for the activities that would be impacted, or that additional time is needed for product reformulation and PPE training. However, EPA requests comment on whether additional time is needed, other concentrations are required, or if there are available substitutes for this application. As discussed in Unit IV.A.1, EPA recognizes that recent

proposed rulemakings under TSCA section 6(a) have received public comments requesting longer compliance timeframes. For NMP, EPA believes that the proposed compliance timeframes for the prescriptive controls described in this unit may present fewer compliance challenges than those described by commenters on other rules. For example, for NMP, it may be more feasible to more rapidly reformulate products containing NMP or to institute workplace controls to prevent direct dermal contact (in contrast to the challenges of reducing inhalation exposures). EPA may finalize significantly shorter or longer compliance timeframes based on consideration of public comments.

5. *Concentration limits on NMP in products for consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives.*

In the 2020 Risk Evaluation, EPA determined that consumer use of NMP in adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants contributes to the unreasonable risk from NMP, due to risk of injury to health of consumers (Ref. 1). To address the unreasonable risk to consumers, EPA is proposing to require that import, processing, and distribution in commerce (including by retailers) of NMP and formulated NMP-containing products intended for consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants be limited to a concentration of NMP no greater than 45%.

As discussed in Units III.B.3. and V.A., based on consideration of the severity of the hazards of NMP in conjunction with the limited options available to address the identified unreasonable risk to consumers under TSCA section 6(a), EPA is proposing this concentration limit, supported by additional modeling using the methodology of the 2020 Risk Evaluation for NMP (Ref. 38). EPA is requesting public comment on whether additional documentation should be required to further support compliance and enforceability of the proposed regulatory requirements (e.g., requirements for labels identifying the percent of NMP within a product or

downstream notification of these proposed requirements for concentration limits).

Similar to the other compliance timeframes described in this unit, EPA is proposing to stagger the compliance dates for the proposed concentration limits described in this unit, such that the requirements would come into effect in 12 months for importers, 15 months for processors, 18 months for distributing to retailers, 21 months for all other distributors (including retailers) after the publication date of the final rule. When proposing these compliance dates as required under TSCA section 6(d), EPA considered irreversible health effects and risks associated with NMP exposure. EPA has no reasonably available information indicating that the proposed compliance dates are not practicable for the activities that would be impacted, or that additional time is needed for product reformulation. However, EPA requests comment on whether additional time is needed, other concentrations are required, or if there are available substitutes for this application. EPA may finalize significantly shorter or longer compliance timeframes based on consideration of public comments.

6. *Mission- or safety-critical uses of NMP by DOD and NASA.*

a. Overview.

For two conditions of use for which EPA is proposing prescriptive controls, EPA is aware of specific mission- or safety-critical uses for which the concentration limits EPA is proposing would negatively impact DOD and NASA, and for which technically and economically feasible safer alternatives that benefit health or the environment are not available. Based on the considerations described in this unit and Unit V.A.1.c.iii., and in accordance with TSCA section 6(c)(2), EPA is proposing that the WCPP be allowed for use of NMP at high concentrations by DOD, NASA, or their contractors within the following conditions of use:

- Industrial and commercial use in paints, coatings, and adhesive removers; and
- Industrial and commercial use in paints and coatings in lacquers, stains, varnishes,

primers and floor finishes, and powder coatings in surface preparation.

For the reasons detailed in Unit V.A.1.c.iii., EPA is restricting the applicability of the WCPP for industrial and commercial use of high concentrations of NMP in paint, coating, and adhesive removal and paints and coatings. EPA is proposing that the conditions under which the WCPP could apply for this use would be: (1) the use of NMP for paints and coatings at a concentration greater than 45% and for paint, coating, and adhesive removers at a concentration greater than 30% by DOD, NASA, or their contractor(s) performing this work only for Federal agency projects would be limited to the mission-critical components on government-operated aerospace vehicles, vessels, and military weapons systems, including mission- or safety-critical components; (2) The use of NMP for paints and coatings at a concentration greater than 45% and for paint, coating, and adhesive removal at a concentration greater than 30% would have to be conducted at Federal installations, at Federal industrial facilities, or at Federal contractor facilities performing paint or coating work, or paint, coating, or adhesive removal work only for DOD and NASA projects; (3) any of the previously listed Federal agencies or their contractors who use NMP in paints and coatings at a concentration greater than 45% or for paint, coating, or adhesive removal at a concentration greater than 30% must comply with the WCPP requirements described in Unit IV.A.3., and (4) DOD, NASA, or their contractors who use NMP in paints and coatings at a concentration greater than 45%, or for paint, coating, or adhesive removal at a concentration greater than 30% must provide a certification of their compliance with the conditions of this use.

b. *Self-certification requirements.*

To ensure that any products that exceed the concentration limits that EPA has identified as necessary for addressing the unreasonable risk for other industrial and commercial users do not become available for widespread commercial use, EPA is proposing to require DOD, NASA,

or their contractors who use NMP in paints and coatings at a concentration greater than 45%, or for paint, coating, or adhesive removal at a concentration greater than 30% must provide a certification of their compliance with the conditions of the applicability of the WCPP for this use. Specifically, each entity must provide a self-certification describing: (1) their status as either DOD or NASA, or a contractor to DOD or NASA; and (2) their implementation of and compliance with the WCPP to purchase and use NMP-containing products that exceed the concentration limits for other industrial and commercial users described in this unit.

EPA is proposing the following self-certification statement:

> I certify each of the following statements under penalty of law. This document was prepared under my direction and supervision. The facility in which this product will be used is a Federal installation, a Federal industrial facility, or a Federal contractor facility performing paint or coating work, or paint, coating, or adhesive removal work for DOD and NASA projects. This facility's implementation of the Workplace Chemical Protection Program (WCPP) for NMP was evaluated by qualified personnel and that this facility has implemented and complies with the WCPP for NMP. Based on my inquiry of the person or persons who manage the facility and/or those persons directly responsible for implementing the NMP WCPP, and to the best of my knowledge and belief, the facility is implementing the NMP WCPP, including the exposure control plan and other proper documentation of the actions taken is available at the facility upon request. I am aware that there are significant penalties, including the possibility of civil penalties for failing to comply with these requirements and criminal penalties, including fines and imprisonment, for knowingly failing to comply with these requirements. I understand that this certification shall serve as a certification that this facility will properly implement and comply with the WCPP for NMP consistent with the applicable regulatory timelines.

EPA realizes that some facilities may not engage in the NMP uses listed in this unit at the time this proposed rule is finalized. Owners or operators that may wish to purchase NMP after publication of the final rule would still be required to submit the self-certification statement to the distributor from whom NMP was initially purchased to purchase NMP, including certifying that the facility for which NMP is being purchased will implement and comply with the WCPP. EPA is also proposing that distributors review the self-certification statement to ensure it is appropriately completed to include the owner or operator's and the facility's information, as outlined in this unit. EPA is also proposing to require distributors of NMP to retain invoices,

including the name of the facility purchasing NMP, name of the owner or operator who is self-certifying, date of sale, and quantity of NMP purchased. EPA is proposing that the distributors and owners or operators maintain and retain the self-certification statement and related invoices(s) in the most administratively convenient form (electronic or paper) and retain the statement(s) and supporting documentation for five years.

c. *Recordkeeping and downstream notification.*

EPA recognizes that for DOD, NASA, or their contractors performing work for their projects to use paints and coatings and paint, coating, and adhesive removers containing NMP at concentrations greater than those proposed for other industrial and commercial use, the upstream processing (or formulation) and distribution in commerce of those products should also be allowed to continue. For these reasons, EPA proposes that processing and distributing in commerce NMP for paints and coatings at a concentration greater than 45%; and for paint, coating, and adhesive removal at a concentration greater than 30% would adhere to the following conditions: (1) Entities processing NMP for paints and coatings at a concentration greater than 45% or for paint, coating, and adhesive removal at a concentration greater than 30% must comply with the WCPP requirements described in Unit IV.A.3.; (2) Entities processing or distributing NMP for paints and coatings at a concentration greater than 45% or for paint, coating, and adhesive removal at a concentration greater than 30% must provide downstream notification of the restrictions on use of these products by adding the following language to sections 1(c) and 15 of the SDS:

> After [DATE 18 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] this chemical/product cannot be distributed in commerce to retailers for any use. After [DATE 21 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], this chemical/product is and can only be distributed in commerce or processed for the following purposes: paints and coatings or paint, coating, or adhesive removal by the Department of Defense (DOD), the National Aeronautics and Space Administration (NASA), or their contractors, at Federal installations, Federal industrial facilities, or at Federal contractor facilities performing

work only for DOD and/or NASA projects.

and (3) Entities processing or distributing these products in commerce would be required to provide a label that meets the requirements outlined in IV.A.2. that provides similar language to the SDS:

> This product contains n-methylpyrrolidone (NMP), a chemical determined by the Environmental Protection Agency to present unreasonable risk of injury to health under of the Section 6 of the Toxic Substances Control Act, based on developmental and reproductive effects. This product containing NMP is restricted for use under 40 CFR part 751, Subpart C. This product is restricted for sale and can only be used by the Department of Defense (DOD), the National Aeronautics and Space Administration (NASA), or their contractors, at Federal installations, Federal industrial facilities, or at Federal contractor facilities performing work only for DOD and NASA projects.

These entities would be subject to the proposed general recordkeeping requirements discussed in Unit IV.A.7., the WCPP recordkeeping requirements discussed in Unit IV.A.3.d.iv., and requirements to maintain records that demonstrate compliance with these requirements.

EPA requests comments on all aspects of the proposed applicability of the WCPP to these narrowly described uses of higher concentration NMP in paint, coating, and adhesive removal and paints and coatings. EPA also requests comment on whether entities other than DOD, NASA or its contractors also require high concentration NMP and, if so, the extent to which lack of availability of high concentration NMP could impact their operations or pose potential challenges to the supply chain. Finally, EPA is requesting comment on whether EPA should also require reporting to EPA during purchasing of NMP for these specific uses by DOD, NASA, or their contractors and if requiring reporting could support of enforcement and compliance assurance with this rulemaking by further assuring that distribution of these high concentration NMP products for these uses is limited to DOD, NASA, and their contractors, and if such requirements would impose significant administrative burdens in addition compliance with the WCPP.

7. *Other requirements.*

a. *Recordkeeping.*

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

b. *Downstream notification.*

For conditions of use that would not otherwise be prohibited under this proposed regulation, EPA is proposing that manufacturers (including importers), processors, and distributors, excluding retailers, of NMP and NMP-containing products provide downstream notification of the prohibitions through the SDS required by OSHA under 29 CFR 1910.1200(g) by adding the following language to sections 1(c) and 15 of the SDS:

> After [DATE 21 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], this chemical/product cannot be distributed in commerce or processed with a concentration of NMP greater than 0.1% by weight for the following purposes: Processing incorporation into articles in lubricants and lubricant additives in machinery manufacturing; Industrial and commercial use in anti-freeze and de-icing products, automotive care products, and lubricants and greases; Industrial and commercial use in metal products not covered elsewhere and lubricant and lubricant additives including hydrophilic coatings; Industrial and commercial use in cleaning and degreasing, and cleaning and furniture care products, including wood cleaners and gasket removers; and Industrial and commercial uses in fertilizer and other agricultural chemical manufacturing-processing aids and solvents.

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

To provide adequate time to update the SDS and ensure that all products in the supply chain include the revised SDS, EPA is proposing a 2-month period for manufacturers and a 6-month period for processors and distributers, excluding retailers, 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 alternative regulatory action for each condition of use is in Unit IV.C.

The primary alternative regulatory action described in this document and considered by EPA combines a WCPP and prescriptive controls to address the unreasonable risk from NMP. While in some ways it is similar to the proposed regulatory action, the primary alternative regulatory action described in this document differs from the proposed regulatory action by providing for a WCPP, including DDCC, for some conditions of use that would be prohibited or have prescriptive controls under the proposed regulatory action. Additionally, the primary alternative regulatory action considered includes the prohibition of one industrial and

commercial use and the manufacturing, processing, and distribution in commerce for one consumer use, all of which would be required to have prescriptive controls under the proposed regulatory action. The primary alternative regulatory action would not include restrictions on the container size of consumer products that may feasibly be used for commercial purposes.

The primary alternative regulatory action also includes longer compliance timeframes for implementation of WCPP and prescriptive controls, as described in this unit. EPA requests comment on this alternative regulatory action and whether any elements of this alternative regulatory action described in this unit should be considered as EPA develops the final regulatory action. EPA also requests comment on any advantages or drawbacks for the timelines outlined in this unit compared to the timelines identified for the proposed regulatory action in Unit IV.A.

1. *WCPP.*

The primary alternative regulatory action described in this document includes a WCPP, including DDCC, for the following conditions of use:

• Manufacturing (domestic manufacturing);

• Manufacturing (import);

• Processing as a reactant or intermediate in plastic material and resin manufacturing and other non-incorporative processing;

• Processing incorporation into a formulation, mixture or reaction product in multiple industrial sectors;

• Processing incorporation into articles as a solvent (which becomes part of a product formulation or mixture) including in textiles, apparel and leather manufacturing;

• Processing incorporation into articles in other sectors, including in plastic product manufacturing;

• Processing incorporation into articles in lubricants and lubricant additives in machinery manufacturing;

• Processing incorporation into articles in paint additives and coating additives in transportation equipment manufacturing;

• Processing repackaging in wholesale and retail trade;

• Processing in recycling;

• Disposal;

• Industrial and commercial use in paints, coatings, and adhesive removers;

• Industrial and commercial use in paints and coatings in lacquers, stains, varnishes, primers and floor finishes, and powder coatings in surface preparation;

• Industrial and commercial use in paint additives and coating additives in computer and electronic product manufacturing in electronic parts manufacturing;

• Industrial and commercial use in paint additives and coating additives in computer and electronic product manufacturing in semiconductor manufacturing;

• Industrial and commercial use in paint additives and coating additives in construction, fabricated metal product manufacturing, machinery manufacturing, other manufacturing, paint and coating manufacturing, primary metal manufacturing, transportation equipment manufacturing, wholesale and retail trade;

• Industrial and commercial use as a solvent (for cleaning or degreasing) in electrical equipment, appliance and component manufacturing;

• Industrial and commercial use as a solvent (for cleaning or degreasing) in electrical equipment, appliance and component manufacturing for use in semiconductor manufacturing;

• Industrial and commercial use in ink, toner, and colorant products in printer ink;

• Industrial and commercial use in processing aids, specific to petroleum production in

petrochemical manufacturing in oil and gas drilling, extraction and support activities, and in functional fluids (close systems);

• Industrial and commercial use in soldering materials;

• Industrial and commercial use in anti-freeze and de-icing products, automotive care products, and lubricants and greases;

• Industrial and commercial use in metal products not covered elsewhere and lubricant and lubricant additives including hydrophilic coatings;

• Industrial and commercial use in laboratory chemicals;

• Industrial and commercial uses in lithium ion battery manufacturing;

• Industrial and commercial use in cleaning and degreasing, and cleaning and furniture care products, including wood cleaners and gasket removers; and

• Industrial and commercial uses in fertilizer and other agricultural chemical manufacturing-processing aids and solvents.

As described in Unit V.A., EPA proposed prohibiting or requiring prescriptive controls for some uses, and WCPP requirements for the other conditions of use, because of uncertainties regarding: (i) The feasibility of implementing workplace safety control measures in open systems or when worker activities require manual application or removal of NMP or NMP-containing products; (ii) availability of alternatives; or (iii) whether the use is ongoing or phased out. In this unit, EPA describes considerations for the primary alternative regulatory action. EPA requests comment on the ways in which NMP may be used in these conditions of use, including whether activities may take place in a closed system and the degree to which users of NMP in these sectors could successfully implement a WCPP (including DDCC) and ancillary requirements described in Unit IV.A. EPA is also requesting comment on whether any of the uses listed in this unit should be prohibited instead of a WCPP, or if there are other factors like reduced

concentration limits or limited access that could address the unreasonable risk.

Under the primary alternative regulatory action, the WCPP would take effect 6 months later than under the proposed regulatory action. Regulated entities would be required to implement the WCPP requirements as described in Unit.IV.A.2. within 18 months after date of publication of the final rule in the *Federal Register*. EPA requests comment on any advantages or drawbacks for the timelines outlined in this unit compared to the timelines identified for the proposed regulatory action in Unit IV.A.

As noted in this unit, for some conditions of use, both the proposed regulatory action and primary alternative regulatory action would result in the condition of use falling under the NMP WCPP. EPA emphasizes that for those conditions of use, the primary alternative regulatory action includes a different timeline for implementation of the WCPP, in comparison to the proposed regulatory action. As discussed in more detail in Unit V.A., for those conditions of use, EPA also considered other regulatory approaches available under TSCA section 6(a). However, EPA found that none of these other regulatory approaches would address the unreasonable risk.

Where EPA has determined that a chemical substance presents unreasonable risk under TSCA section 6(b)(4), EPA must undertake rulemaking to "apply one or more of the [TSCA section 6(a)(1) through (7)] requirements to such substance . . . to the extent necessary so that the chemical substance . . . no longer presents such risk." TSCA section 6(a). "In proposing and promulgating [such] a rule," 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 . . . (II) the costs and benefits of the proposed . . . regulatory action and of the [one] or more primary alternative regulatory actions considered by [EPA]; and (III) the cost effectiveness of the proposed regulatory action and of the [one] or more primary alternative regulatory actions considered by [EPA]." EPA interprets this to mean that Congress

intended this "primary alternative regulatory action" to be another regulatory option under TSCA section 6(a)(1) through (7) that would meet the requirements of TSCA section 6(a) and address the unreasonable risk identified under TSCA section 6(b)(4) "to the extent necessary so that the chemical substance . . . no longer presents such risk." Here, the proposed regulatory action is comprised of a mix of proposed options under TSCA section 6(a), each directed at specific conditions of use and with specified timeframes for compliance. The primary alternative regulatory options considered by the Agency would adjust the overall mix of TSCA section 6(a) requirements, including compliance timeframes, resulting in a proposed regulatory action that is more restrictive in some ways and less restrictive in others. For conditions of use where both the proposed option and the primary alternative regulatory option are both variations of the NMP WCPP, the options are distinct because implementing the WCPP on differing timetables under TSCA section 6(d) would result in a different mix of regulatory options with different costs, benefits, and cost effectiveness than the proposed regulatory action.

2. *Prohibition.*

The primary alternative regulatory action considered by EPA and described in this document would prohibit the manufacturing, processing, and distribution in commerce, and use for the industrial and commercial use and prohibit the manufacture, processing, and distribution of NMP for consumer use for the following conditions of use:

• Industrial and commercial use in adhesives and sealants including binding agents, single component glues and adhesives, including lubricant adhesives and two component glues and adhesives including some resins; and

• Consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants.

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

hazards of NMP in conjunction with the limited options available to adequately address the identified unreasonable risk to consumers under TSCA section 6(a), EPA is proposing to address the contributions to the unreasonable risk from the consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants, by prohibiting the manufacturing (including import), processing, and distribution in commerce of NMP for this consumer use, and upstream industrial and commercial use to remove NMP and these products containing NMP from the market, thereby eliminating this consumer use. The alternative regulatory action differs from the proposed regulatory action in that, under the alternative regulatory action, EPA would prohibit the use of NMP in the conditions of use listed in this unit, rather than the proposed action to limit the concentration of NMP in the formulations for these uses and require PPE in the industrial and commercial use.

Regarding compliance timeframes, the alternative regulatory action for a prohibition of the uses described in this unit would follow the compliance timeframe for the proposed regulatory actions for a prohibition. Under the alternative action, compliance dates for the prohibition would be staggered such that the prohibitions would come into effect in 12 months for manufacturers, 15 months for processers, 18 months for distributing to retailers, 21 months for all other distributors (including retailers), and 24 months for industrial and commercial users after the publication date of the final rule in the *Federal Register*. With regard to the compliance timeframe for the prohibitions on manufacturing, processing, and distribution in commerce for consumer use, under the alternative regulatory action, prohibitions as described in this unit would take effect in 12 months for manufacturers, 15 months for processors, 18 months for distributing to retailers and 21 months for all other distributors (including retailers) after the publication date of the final rule.

C. *Overview of Conditions of Use and Proposed Regulatory Action and Alternative Regulatory*

Action

Table 1 presents a side-by-side summary of the proposed regulatory action and the primary alternative regulatory action for each condition of use. The purpose of this table is to succinctly convey to the public the major differences between the proposed regulatory action and the alternative regulatory action; as such the actions in each column are truncated and do not reflect all the details of the proposed and alternative regulatory actions, including differences in timeframes. The proposed and alternative regulatory actions are described more fully in Units IV.A. and B.

Table 1 – Overview of Proposed Regulatory Action and Alternative Regulatory Action by Conditions of Use

Condition of Use	**Action**	
Subcategory	**Proposed Regulatory Action**	**Primary Alternative Action**
Domestic manufacture	NMP WCPP	NMP WCPP
Import	NMP WCPP	NMP WCPP
Processing as a reactant/intermediate in plastic material and resin manufacturing and other non-incorporative processing	NMP WCPP	NMP WCPP
Processing incorporation into formulation, mixture or reaction products in multiple industrial sectors, including, but not limited to: • Adhesives and sealant chemicals in adhesive manufacturing; • Anti-adhesive agents in printing and related support activities; • Paint additives and coating additives in paint and coating manufacturing; and print ink manufacturing; • Processing aids not otherwise listed in plastic material and resin manufacturing; • Solvents (for cleaning or degreasing) in non-metallic mineral product manufacturing; machinery manufacturing; plastic material and resin manufacturing; primary metal manufacturing; soap, cleaning compound and toilet preparation manufacturing; transportation equipment manufacturing; all other chemical product and preparation manufacturing; printing and related support activities; services; wholesale and retail trade; • Surface active agents in soap, cleaning compound and toilet preparation manufacturing;	NMP WCPP	NMP WCPP

Condition of Use	Action	
Subcategory	**Proposed Regulatory Action**	**Primary Alternative Action**
• Plating agents and surface treating agents in fabricated metal product manufacturing; • Solvents (which become part of product formulation or mixture) in electrical equipment, appliance and component manufacturing; other manufacturing; paint and coating manufacturing; print ink manufacturing; soap, cleaning compound and toilet preparation manufacturing; transportation equipment manufacturing; all other chemical product and preparation manufacturing; printing and related support activities; wholesale and retail trade; • In oil and gas drilling, extraction and support activities; plastic material and resin manufacturing; services		
Processing incorporation into articles in lubricants and lubricant additives in machinery manufacturing	Prohibition	NMP WCPP
Processing incorporation into articles in paint additives and coating additives in transportation equipment manufacturing	Prescriptive controls (45% CL+PPE)	NMP WCPP
Processing incorporation into articles as a solvent (which become part of product formulation or mixture), including in textiles, apparel and leather manufacturing	NMP WCPP	NMP WCPP
Processing incorporation into articles in other sectors, including in plastic product manufacturing	NMP WCPP	NMP WCPP
Processing by repackaging in wholesale and retail trade	NMP WCPP	NMP WCPP
Processing by recycling	NMP WCPP	NMP WCPP
Industrial and commercial use in paints, coatings, and other adhesive removers	Prescriptive controls[1] (30% CL+PPE)	NMP WCPP
Industrial and commercial use in paints and coatings in lacquers, stains, varnishes, primers and floor finishes, and powder coatings in surface preparation	Prescriptive controls[2] (45% CL+PPE)	NMP WCPP
Industrial and commercial use in paint additives and coating additives in computer and electronic product manufacturing in electronic parts manufacturing	NMP WCPP	NMP WCPP
Industrial and commercial use in paint additives and coating additives in computer and electronic product manufacturing in	NMP WCPP	NMP WCPP

Condition of Use	Action	
Subcategory	**Proposed Regulatory Action**	**Primary Alternative Action**
semiconductor manufacturing		
Industrial and commercial use in paint additives and coating additives in construction, fabricated metal product manufacturing, machinery manufacturing, other manufacturing, paint and coating manufacturing, primary metal manufacturing, transportation equipment manufacturing, wholesale and retail trade	Prescriptive controls (45% CL+PPE)	NMP WCPP
Industrial and commercial use as a solvent (for cleaning or degreasing) in electrical equipment, appliance and component manufacturing	NMP WCPP	NMP WCPP
Industrial and commercial use as a solvent (for cleaning or degreasing) in electrical equipment appliance and component manufacturing in semiconductor manufacturing	NMP WCPP	NMP WCPP
Industrial and commercial use in ink, toner, and colorant products in printer ink and inks in writing equipment	Prescriptive controls (5% CL+PPE)	NMP WCPP
Industrial and commercial use in processing aids, specific to petroleum production in petrochemical manufacturing, in oil and gas drilling, extraction and support activities, and in functional fluids (closed systems)	NMP WCPP	NMP WCPP
Industrial and commercial use in adhesives and sealants including binding agents, single component glues and adhesives, including lubricant adhesives and two-component glues and adhesives including some resins	Prescriptive controls (45% CL+PPE)	Prohibition
Industrial and commercial use in soldering materials	Prescriptive controls (1% CL+PPE)	NMP WCPP
Industrial and commercial use in anti-freeze and de-icing products, automotive care products, and lubricants and greases	Prohibition	NMP WCPP
Industrial and commercial use in metal products not covered elsewhere, and lubricant and lubricant additives including hydrophilic coatings	Prohibition	NMP WCPP
Industrial and commercial use in laboratory chemicals	NMP WCPP	NMP WCPP
Industrial and commercial use in lithium ion battery manufacturing	NMP WCPP	NMP WCPP
Industrial and commercial use in cleaning and degreasing, and cleaning and furniture care products, including wood cleaners and gasket removers	Prohibition	NMP WCPP

Condition of Use	Action	
Subcategory	**Proposed Regulatory Action**	**Primary Alternative Action**
Industrial and commercial use in fertilizer and other agricultural chemical manufacturing, processing aids and solvents	Prohibition	NMP WCPP
Consumer use in paint and coating removers	16 ounce container limit[5] + labeling	Would not be regulated[4]
Consumer use in adhesive removers	16 ounce container limit[5] + labeling	Would not be regulated[4]
Consumer use in paints and coatings in lacquers, stains, varnishes, primers and floor finishes	16 ounce container limit[5] + labeling	Would not be regulated[4]
Consumer use in paint additives and coating additives in paints and arts and crafts paints	16 ounce container limit[5] + labeling	Would not be regulated[4]
Consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives	Concentration Limit (45% CL)[6]	Prohibition[3]
Consumer use in automotive care products	16 ounce container limit[5] + labeling	Would not be regulated[4]
Consumer use in cleaning and furniture care products, including wood cleaners and gasket removers	16 ounce container limit[5] + labeling	Would not be regulated[4]
Consumer use in lubricant and lubricant additives, including hydrophilic coatings	16 ounce (1 pint) container limit[5] + labeling	Would not be regulated[4]
Disposal	NMP WCPP	NMP WCPP

[1]WCPP is the proposed regulatory action for the industrial and commercial use in paint, coating, and adhesive removers for specific mission- or safety-critical uses by DOD, NASA, and their contractors.

[2]WCPP is the proposed regulatory action for the industrial and commercial use in paints and

coatings in lacquers, stains, varnishes, primers and floor finishes, and powder coatings in surface preparation for specific mission- or safety-critical uses by DOD, NASA, and their contractors.
[3]Prohibit manufacture, processing, and distribution in commerce for the consumer use.
[4]There is no primary alternative action for the consumer uses that do not contribute to the unreasonable risk because similar commercial uses would not be prohibited; rather, the primary alternative action for the commercial uses would be WCPP.
[5] Proposed container size restrictions are intended to prevent diversion of consumer products to commercial users.
[6] This is the only condition of use for consumers that contributes to the unreasonable risk from NMP.

V. Rationale for the Proposed Regulatory Action and 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 alternative regulatory actions described in Unit IV.

A. *Consideration of Risk Management Requirements Available under TSCA Section 6(a)*

1. *Proposed regulatory action.*

a. Prohibition.

EPA considered a prohibition as a regulatory option and is proposing it for certain conditions of use listed in Unit IV.A.1.a. Prohibition is the preferred option for occupational conditions of use where greater uncertainty exists relative to a sector's ability to comply with provisions of the proposed NMP WCPP, such as DDCC applications. This includes uncertainty regarding certain chemical users' ability to prevent direct dermal contact with NMP, in particular during use in open-systems or when worker activities require manual application or removal of NMP or a product containing NMP through rags, aerosols, spray applications, roll applicators, fingers, hands, or other materials. For example, the processing of NMP in lubricants and lubricant additives in machinery manufacturing includes the use of NMP in metal finishing operations. Depending on the type of substrate being prepared, this can include dip or immersion, spray, roll, or brush application. While some application methods may be automated, the extent of automated application versus use in an open sector with handheld and manual

operations is unknown. EPA has received information from DOD about mission- or safety-critical uses of NMP at high concentrations in hot dip-tank cleaning, and the ability of DOD and its contractors to successfully implement the WCPP for hot dip-tank application of NMP for cleaning and coating removal (see Unit V.A.1.c.iii for more detail on this use). As described in Unit IV.A.6., EPA is proposing to require those owners and operators comply with a WCPP rather than a prohibition. However, as described in Unit IV.A.6., EPA is restricting the applicability of the use of high concentrations of NMP for paint, coating, and adhesive removal to DOD, NASA, and their contractors due to the exposure controls that DOD, NASA, and their contractors have in place, specifically for dip application.

While EPA has received some information from stakeholders regarding what may be a similar use of NMP, EPA does not have sufficient certainty that existing exposure controls by entities outside of DOD, NASA, or their contractors could successfully apply the WCPP for high concentrations of NMP in dip application such that the unreasonable risk is addressed. Specifically, EPA considered information from a stakeholder who described their use of NMP in industrial cleaning through soaking parts directly in NMP tanks (Ref. 39). Depending on the details of the dip application of NMP, this use may be considered industrial and commercial use of NMP in paint, coating, or adhesive removers; or industrial and commercial use of NMP in cleaning and degreasing. EPA notes that the 2020 Risk Evaluation for NMP identified three distinct occupational applications for NMP-containing cleaning products, including aerosol degreasing, dip degreasing and cleaning products, and wipe and spray-applied cleaning products. This stakeholder identified engineering controls including piped fill/drain systems, closed tank and exhaust, and other measures to reduce potential exposure to NMP including minimum operator time at the tank, employee training, and PPE recommended by an industrial hygienist. While EPA believes that this type of operation could successfully implement the NMP WCPP

with formulations with a high concentration of NMP, EPA has significant uncertainty regarding the extent to which these strict workplace controls, including prevention of direct dermal contact, are applied during all other cleaning and degreasing dip-tank applications. EPA is requesting comment on the workplace protection measures or exposure reduction measures typically applied during dip application of NMP, particularly dip degreasing and cleaning in hot or cold dip-tank immersion cleaning and degreasing, and dip application of NMP for adhesive, paint, or coating removal. EPA also requests comment on the typical tasks expected during hot and cold dip cleaning or coating removal operations, including manual or automated opening and closing of the dip tank, cleaning and maintenance, the use of new or repurposed vapor degreasing machines for immersion cleaning, or any other dip-tank or immersion cleaning and degreasing activities. EPA is interested in comments on the ability of users of high concentrations of NMP in dip applications to successfully implement a WCPP, the availability of alternative chemicals, and impacts of prohibiting NMP for the hot or cold dip-tank cleaning, degreasing, or removal of adhesives, paints, or coatings. Additionally, EPA requests comment on the number of firms who utilize hot or cold dip NMP for cleaning, degreasing, or removal of adhesives, paints, and coatings, the frequency of dip applications, and size of the dip vessel. EPA also requests comment on the types of engineering controls and any PPE use by firms who use NMP in hot or cold dip applications.

Similarly, EPA's uncertainties include the challenges related to PPE protection, which are discussed in more detail in Unit V.A.1.b., and which include how PPE may present vision problems, or cause communication problems, worker fatigue, and reduced work efficiency (63 FR 1152, January 8, 1998) as well as consideration for that fact that not all workers may be able to wear PPE. Prohibition is the preferred option for occupational conditions of use where reasonably available information suggests minimal ongoing use or when feasible safer

alternatives are reasonably available. The uncertainties related to whether users under certain conditions of use could comply with the requirements of an NMP WCPP, combined with the severity of the risks of NMP, the prevalence of alternative processes and products (Unit V.B.), and in some cases reasonably available information indicating a use is no longer ongoing (Refs. 4, 5), has led EPA to propose prohibitions for several industrial and commercial uses, and the upstream manufacturing (including import), processing, and distribution in commerce for those uses.

For example, EPA expects that for the use of NMP in fertilizers, compliance with the WCPP would present challenges and notes that alternatives have been identified for NMP. Therefore, EPA is proposing to prohibit this use of NMP. EPA's proposed prohibition of this condition of use is based on the uncertainties the agency has regarding the full nature and extent of the exposures and variety of work practices related to fertilizer use, and notes that the agency's concerns that implementing the WCPP or other strict workplace controls combined with the availability of alternatives leads to the proposed prohibition. In the primary alternative regulatory action, EPA has identified WCPP for this condition of use, and, as explained in more detail in Unit V.A.2, notes that, in some cases, regulated entities may be able to undertake more extensive risk reduction measures than EPA currently anticipates. EPA requests comment and supporting information on how NMP is used in the agricultural sector, including whether there are any other application types (such as aerosol application) besides liquid product containing NMP blended with solid fertilizer pellets. EPA requests comment on the degree to which entities using NMP in fertilizer manufacture or application may comply with the proposed WCPP requirements or similar stringent workplace controls for other conditions of use of NMP. EPA also requests comment on the workplace safety protocols in place during application, including expected exposure reductions during the use of NMP in fertilizer mixing and application, current

engineering controls used, PPE usage and any standard hazard warnings or instructions in place. EPA requests comment on its conclusion that alternatives are available for NMP in all significant agricultural uses. Specifically, EPA requests comments on whether there are alternatives to NMP for solvents used in the production of fertilizers, as well as alternatives to the use of NMP to reduce the volatility of advanced fertilizer products by keeping nitrogen from volatilizing into the atmosphere before it can be absorbed into the soil. EPA also requests comment regarding the number of businesses and other entities that could potentially close as well as associated costs with a prohibition of NMP for the industrial and commercial conditions of use identified in Unit IV.A.1.a.

EPA determined prohibition would not be suitable for the remaining occupational conditions of use, such as processing as a reactant or intermediate in plastic material and resin manufacturing and other non-incorporative processing and several types of processing incorporation into a formulation, mixture, or reaction product; and industrial and commercial uses as a paint and coating additives in multiple applications or as a solvent, particularly for electronic component manufacturing applications, as a processing aid in petrochemical manufacturing, and as a laboratory chemical. EPA made this determination based on compelling reasons to not prohibit the activity and identification of a regulatory approach that would address the unreasonable risk. For example, prohibition may not be suitable for conditions of use that may have critical or essential uses for which no technologically and economically feasible safer alternative is available, or where EPA identified strict workplace controls could be implemented for these uses to address the unreasonable risk, as described in Unit IV.A.3.

Additionally, prohibition may not be suitable for conditions of use where alternative substances to NMP are at least as hazardous, in particular for other solvents undergoing risk evaluation and risk management under TSCA section 6. For example, methylene chloride is also

in risk management under TSCA section 6 and has been determined to present unreasonable risk of injury to health. For industrial and commercial use in laboratory chemicals, NMP and methylene chloride are both used as a solvent although they are not drop-in substitutes for each other. In selecting among the TSCA section 6(a) requirements for the proposed approach for the use in laboratory chemicals, EPA considered whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute.

Given the severity of the risks identified in the 2020 Risk Evaluation for NMP, EPA proposes that prohibiting manufacture (including import), processing, and distribution in commerce of NMP for the industrial and commercial uses listed in Unit IV.A.1.a. is reasonable and necessary to eliminate the unreasonable risk of NMP.

To support implementation of the proposed prohibitions and restrictions, EPA also considered, and is proposing, a de minimis level for products containing NMP to account for impurities that do not contribute to the unreasonable risk. EPA recognizes that the ability to test whether a product or entity would be regulated or not, by using a de minimis level, is beneficial and valuable to the regulated community.

EPA recognizes the importance of the OSHA Hazard Communication Standard (29 CFR 1910.1200), which sets a 0.1% de minimis level for chemicals that are carcinogens, and a limitation of 1% for chemicals that are not carcinogenic. As a matter of risk management policy, EPA believes that the widespread awareness by industrial and commercial workplaces of the de minimis levels in the OSHA Hazard Communication Standard would generally support successful implementation of the level EPA has identified. EPA notes that while NMP is not carcinogenic, EPA considered that it is identified as a substance of very high concern by the European Chemicals Agency and that Article 33(1) of the REACH Regulation details that businesses are only required to report when their products contain substances of very high

concern that exceed 0.1% (Ref. 40). While NMP is not carcinogenic, this indicates a need for a de minimis level for NMP that would be lower than 1% under the OSHA Hazard Communication Standard.

EPA conducted an analysis using the methodology in the 2020 Risk Evaluation for NMP to estimate whether there is a weight fraction of NMP in products below which the most conservative use, applied through chronic application at the high-end exposure estimate of those products, respectively, and at various air concentrations would not contribute to the unreasonable risk from NMP (Ref. 41). EPA examined the supplemental analysis and found that an NMP concentration of 0.1% would achieve exposure concentrations that do not contribute to unreasonable risk up to an air concentration of 30 mg/m3. EPA also recognizes that an NMP concentration of 0.1% or less is likely to indicate an unintentional impurity in a product rather than a functional ingredient.

Based on these analyses, and to be protective of human health while also aligning with national and international regulations, EPA is proposing a de minimis level of 0.1%. As a result, EPA is proposing to exclude from prohibition and restrictions products containing NMP at or less than 0.1% by weight, as described in Unit IV.A. EPA has identified uncertainties with a concentration limit of 0.1% addressing the unreasonable risk. For example, the expected air concentration (as a time weighted average) may less accurately estimate inhalation exposures from some applications where exposures may differ from those predicted by the model (e.g., as a result of higher NMP application rate or decreased ventilation). However, a concentration limit of 0.1% provides a margin of error to account for the uncertainties associated with the exposure model.

EPA is requesting comment on the de minimis concentration limit of NMP in products or formulations. EPA emphasizes the agency’s interest in aligning to the extent possible with the de

minimis thresholds in the OSHA Hazard Communication Standard, while also noting that additional analytical work was conducted for NMP. EPA requests comment on whether de minimis thresholds should be proposed consistent with national and international regulations, or whether there may be instances where chemical-specific analyses is appropriate. Details of the proposed prohibitions and restrictions are described in more detail in Unit IV.A.

b. *Container size restrictions.*

Some products in the Chemical Use Report were identified as intended for both commercial and consumer use. The 2020 Risk Evaluation for NMP incorporated these products into the occupational and consumer exposure scenarios, and EPA has determined that the industrial and commercial use contributes to the unreasonable risk for NMP due to worker exposure, while the consumer use of similar products does not contribute to the unreasonable risk (Ref. 1). In the 2020 Risk Evaluation for NMP, EPA considered currently available consumer products and their expected applications and evaluated exposures for consumers based on completion of a single project on a given day. EPA requests comment on if there are any NMP-containing consumer products that may require a more frequent or multiple day application, and if so, should EPA require additional restrictions for consumer products.

While EPA is not proposing to regulate the manufacture, processing, or distribution in commerce of these consumer products to address risks from the consumer use of such products, these consumer products are similar in composition and purpose to the commercial products that EPA does propose to prohibit and restrict. Therefore, EPA is also proposing regulations to prevent the consumer products that will remain available in the market from being diverted for commercial purposes. To reduce the potential of commercial users (e.g., workers) accessing NMP-containing consumer products for use in any commercial conditions of use, EPA is proposing to prohibit importing, processing (e.g., repackaging) and distribution—including to

and by retailers—of NMP and NMP-containing products in containers larger than 16 ounces for the uses listed in Unit IV.A.2. EPA believes that limiting containers to typical consumer product sizes that would be inefficient for commercial use would prevent commercial purchase and use of these products. Consumer use is expected to result in acute exposures from a one-time use (resulting only in acute exposure and effects), while commercial use is expected to include repeated exposure from frequent use (resulting in acute and chronic exposure and effects). EPA believes that commercial users would be dissuaded from using consumer products if the container sizes are limited. Instead, potential commercial users would more likely select an alternative product, since it would be impractical to purchase the large number of smaller containers necessary for commercial use. EPA requests comment on the potential impacts to consumers and the consumer use of these products from a container size requirement.

EPA is also requesting comment on whether, rather than a container size restriction requirement, a maximum concentration limit for products containing NMP be required instead. EPA is aware of a range of concentrations of NMP in consumer products on the market (Ref. 1). If products in this range of concentrations of NMP were used in an occupational setting, they would contribute to the unreasonable risk from NMP (Ref. 2). EPA requests comment on the typical or effective concentration of NMP in the following consumer products: paint and coating removers, adhesive removers, paints and coatings, paint additives and coating additives in arts and crafts paint, automotive care products, cleaning and furniture care products, and lubricant and lubricant additives, and whether a maximum concentration of NMP could be identified that would allow the product to continue to be efficacious for consumer use, but that would not exceed the concentrations EPA has identified in Unit IV.A.1.e. for addressing the contribution of these types of products to unreasonable risk for workers.

c. *WCPP.*

Regarding industrial, commercial, and consumer uses of NMP, TSCA section 6(a)(2) provides EPA with the authority to prohibit or otherwise restrict the manufacture (including import), processing, or distribution in commerce of a substance or mixture "for a particular use" to ensure that a chemical substance no longer presents unreasonable risk. For this rule, EPA proposes that "for a particular use" includes industrial, commercial, and consumer uses more broadly, which encompasses all known, intended, and reasonably foreseen uses of NMP. Given the severity and ubiquitous nature of the risks identified in the 2020 Risk Evaluation for NMP for all industrial and commercial uses evaluated, and noting that those conditions of use evaluated in the Risk Evaluation encompass all known, intended, and reasonably foreseen uses of NMP, EPA proposes establishing requirements for an NMP WCPP for all occupational conditions of use except for those conditions of use which would be prohibited or subject to prescriptive controls. An NMP WCPP would include a combination of requirements to the extent necessary to address unreasonable risk driven by direct dermal exposures in the workplace. An NMP WCPP would encompass restrictions all occupational conditions of use except those which would be prohibited or subject to prescriptive controls, and could include provisions for a DDCC, and ancillary requirements to support implementation of these restrictions. While the NMP WCPP includes stringent requirements that would be necessary to address the unreasonable risk from NMP, EPA identified a relatively large number of conditions of use where the Agency expected, based on reasonably available information, an NMP WCPP could be successfully implemented because the dermal exposures can be more effectively controlled across this broad range of facilities engaging in a relatively large number of conditions of use.

i. *DDCC requirements.* For occupational conditions of use not otherwise proposed to be prohibited or subject to prescriptive controls, including but not limited to those listed in Unit IV.A.3., EPA considered including a requirement for DDCC in the NMP WCPP. DDCC, under

the NMP WCPP, would be a process-based requirement to prevent direct dermal contact in the workplace by separating, distancing, physically removing, or isolating potentially exposed persons from direct handling of NMP or from contact with equipment or materials on which NMP may exist under routine conditions. DDCC is non-prescriptive, in the sense that it would not require a specific control to prevent direct dermal contact. Rather, DDCC would enable regulated entities to determine how to most effectively separate, distance, physically remove, or isolate potentially exposed persons from direct dermal contact with NMP based on what works best for their workplace, in accordance with the hierarchy of controls. In deciding whether DDCC would appropriately address the unreasonable risk driven by dermal exposures, EPA considered factors related to work activities that may make it difficult to eliminate direct dermal contact. Examples include work activities that may take place in open systems that require manual handling of NMP, such as application or removal of NMP or an NMP-containing product through rags, aerosols, spray guns, roll applicators, fingers, hands, or other materials or work activities that require a high range of motion or for some other reason create challenges for the implementation of dermal PPE.

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

modeled. For example, the 2020 Risk Evaluation for NMP does not consider the frequency, type, and effectiveness of gloves or other types of PPE used or specific workplaces. In addition, the 2020 Risk Evaluation for NMP does not specify the specific activity training beyond procedure for glove removal and disposal (Ref. 1).

In consideration of the 2020 Risk Evaluation for NMP, including the uncertainties, EPA has preliminarily determined that preventing direct dermal contact to NMP through DDCC requirements, including requirements to reduce exposures in a manner aligned with the hierarchy of controls, workplace specific training, and, if necessary, dermal PPE which covers any exposed skin (including hands, legs, torso, and face), and PPE training, as described in Unit IV.A.3., for certain occupational conditions of use would address the contributions to unreasonable risk from dermal exposures from these conditions of use for potentially exposed persons.

ii. *NMP WCPP.* Taking into account these considerations, EPA is proposing that occupational conditions of use other than those proposed to be prohibited or subject to prescriptive controls (as listed in Units IV.A.1 and 4), including those listed in Unit IV.A.3., would be allowed to continue if regulated entities could ensure direct dermal contact is prevented, and other requirements are met in the NMP WCPP. In contrast to considerations indicating that it is unlikely that facilities within a condition of use could successfully implement WCPP, there are certain considerations that indicate that facilities engaging in a condition of use would likely be able to achieve effective risk management via WCPP. Based on reasonably available information, including monitoring data (Ref. 42), process descriptions, and information related to considerations described previously in this unit, EPA's confidence that requirements to prevent direct dermal contact can be implemented is highest in highly standardized and industrialized settings, such as where NMP is used in a closed system. For example, one of the conditions of use for which EPA is proposing a WCPP is processing of NMP as a reactant or

intermediate in plastic and resin manufacturing and other non-incorporative processing. NMP use and exposure information submitted by industry indicates that controls may already be in place at some workplaces to prevent or reduce direct dermal contact with NMP, including enclosed transfer liquid lines, processing equipment, other engineering and administrative controls, and chemically resistant gloves (Ref. 43).

Another set of conditions of use for which EPA is proposing the WCPP is the industrial and commercial use of NMP in paint additives and coating additives and as a solvent (for cleaning or degreasing) in computer and electronic product manufacturing in semiconductor manufacturing and the industrial and commercial use of NMP in lithium ion battery manufacturing. EPA understands that most workplaces using NMP in semiconductor manufacturing and lithium ion battery manufacturing already have stringent controls in place that reduce workplace exposures. As described in public comments and through engagement with the Semiconductor Industry Association (SIA), the Lithium Ion Cell Manufacturers' Coalition (LICMC), and individual companies, these manufacturing facilities use NMP in frequent, closed processes, where it does not present opportunity for human exposure and where NMP is completely removed from the final product (Refs. 42, 44). Semiconductor manufacturing stakeholders have described how, upon delivery by tote or tank truck at refineries, NMP is directly injected from a tote into a closed processing unit or transferred from a truck into a storage tank that is directly hooked up for direct injection in a closed system. Transfer procedures of NMP are performed pursuant to comprehensive written procedures under strict PPE guidelines including, when appropriate, respirators. Information submitted by SIA indicates that worker exposure is limited to chemical unloading and transfer procedures (Ref. 42). Information submitted by LICMC indicates that their members manufacturing facilities use engineering controls like automatic mixers, closed system piping and ventilation, and where

direct contact with NMP is possible workers are provided powered air purifying respirators (APF 1000) with particulate/organic vapor cartridge, and NMP resistant gloves and boots, and other PPE as necessary including Tyvek suits, face shields, splash goggles, and latex inner gloves (Ref. 44).

While EPA understands that it is likely that the frequency and duration of exposure to NMP at semiconductor manufacturing facilities may be less than what was assumed in the risk evaluation, as described in this unit, EPA does not have any dermal monitoring data to confirm that NMP exposures are below the level modeled in the 2020 Risk Evaluation. Based on analysis in the 2020 Risk Evaluation for NMP describing expected exposures with and without use of PPE, EPA identified that even with direct dermal contact, PPE would not be sufficient to mitigate the unreasonable risk driven by dermal exposure from this condition of use. However, based on information received for this condition of use and reasonably available information, EPA believes that controls may already be in place to prevent or reduce direct dermal contact with NMP, such as using NMP in a closed system to limit exposures and implementing comprehensive written procedures with added PPE during transfer procedures.

For both of these conditions of use (processing as a reactant or intermediate in plastic and resin manufacturing and other non-incorporative processing and industrial and commercial use in semiconductor manufacturing), in the 2022 revised risk determination, EPA determined that exposures to workers drove the unreasonable risk, but exposures to ONUs did not. ONUs include supervisors, managers, and other employees that may be in the production areas but do not perform tasks that result in direct dermal contact with liquids. Additionally, the risk calculation results between worker unreasonable risk and ONU no unreasonable risk were significantly different. This suggests that, for these conditions of use, owners or operators must prevent direct dermal exposure to address the unreasonable risk, even though ONUs are not expected to be at

the exposure source like workers. This information, together with other considerations previously described indicating stringent controls may already be in place, adds to EPA's confidence that facilities engaging in these two conditions of use could meet, and may in fact already be meeting, the WCPP requirements.

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

Details of the proposed NMP WCPP, including DDCC, required implementation measures, requirements for demonstrating compliance and requirements for distributors, are described in more detail in Unit IV.A.3.

iii. *Mission- or safety-critical uses of NMP by DOD and NASA*. As described earlier in Unit IV.A.6., EPA is EPA is aware of specific mission- or safety-critical uses for which the concentration limits EPA is proposing would negatively impact DOD and NASA. EPA is proposing that the WCPP be allowed for use of NMP at high concentrations by DOD, NASA, or their contractors within two conditions of use. DOD and NASA have identified mission-critical uses for NMP in paints, coatings, and adhesive removal as well as in paints and coatings for ensuring readiness of aviation, including human-rated space vehicle hardware, and military vessels (Refs. 45). Based on reasonably available information to EPA, there are no technically and economically feasible alternatives to these products with high concentrations of NMP that benefit health or the environment. These uses are important to the military readiness of DOD's

warfighting capability and the functionality paramount to ensuring national security. These uses are also important to NASA's space projects. Based on the existence of the current exposure reduction methods and EPA's expectation that DOD, NASA, and their contractors can comply with the WCPP for NMP in a way that addresses unreasonable risk, EPA is proposing WCPP with narrow applicability for these uses.

Regarding paint, coating, and adhesive removal, DOD has identified no alternatives for the use of products containing high concentrations of NMP for the removal of coatings from mission-critical corrosion-sensitive components on military aviation and vessels, including mission- or safety-critical components made of specialty metallic, nonmetallic, and composite materials. Similarly, NASA has identified mission-critical NMP-containing products that are integral to de-processing and necessary for removing a variety of coatings from various flight hardware and avionic components, without which mission risk would be increased. For both DOD and NASA, the NMP-containing products used are higher than the 30% concentration limits EPA is proposing as part of the prescriptive controls described in Unit IV.A.4. EPA has identified products for this use containing up to 70% NMP (Ref. 1) and DOD and NASA may use pure (neat) NMP for their mission-critical processes. Additionally, NMP has been used to meet required levels of performance of certified component parts by long-standing design and function specifications that are incorporated into contracts of a complex supply chain.

While EPA is not proposing to prohibit the industrial and commercial use of NMP for removal of paints, coatings, and adhesives, EPA is proposing to limit the concentration of NMP in those products to no more than 30% as described in Unit IV.A.4. This would result in impacts to aircraft and military vessels for military missions and space exploration. A concentration of 30% NMP may not be effective enough or capable of removing paints, coatings, or adhesives on specialized equipment or parts. In many instances, only a highly concentrated amount of NMP

would be capable of successfully performing this function. As an example, NMP and products containing a high concentration of NMP are used to break down and remove materials such as cured epoxies and thermoset resins from components that would be damaged by other means. This type of operation is conducted to refurbish and reuse delicate electronic components and, more critically, to deconstruct failed hardware to allow examination for root cause analysis. Failure analysis must be conducted to collect data needed to determine potential risks to hardware that relies on the failed component and to inform vehicle architecture and hardware design efforts. Information available to EPA indicates that, for NASA, using NMP often is the only way to break down these materials without also damaging the substrate used by NASA. EPA is not aware of similar uses of such high concentration of NMP by entities outside the Federal government.

DOD and NASA have described the equipment they use for the coating removal application, and the differences between their coating removal operations and the brush-on or pour-over methods used for coating removal through other commercial or consumer products. DOD has described how the temperature, pH, and other constituents of the solution used in what is described as a hot dip-tank create hazards, separate from NMP, which are managed in DOD or contractor facilities through separation and dedicated ventilation of the tanks (and, secondarily, worker PPE). Based on the existence of the current exposure reduction methods and EPA's expectation that DOD, NASA, and their contractors can comply with the WCPP for NMP in a way that addresses unreasonable risk, EPA is proposing WCPP with narrow applicability for these uses. Information available to EPA does not indicate that commercial users other than DOD or NASA use such high concentrations of NMP, or that they have a need for similar paints or coatings. By requiring prescriptive controls that provide for a concentration of NMP that includes one currently found on the market along with implementable work practices, EPA

believes that use of NMP in paint and coating applications in commercial aviation, space travel, or uses similar to those described by DOD and NASA could continue without resulting in unreasonable risk.

Similarly, regarding paints and coatings, DOD and NASA have identified mission-critical items using products containing high concentrations of NMP in specialized coatings for military tactical equipment on military aviation and vessels and development and maintenance of component parts, including human-rated space vehicle hardware. For both DOD and NASA, the NMP-containing products used are higher than the 45% concentration limit EPA is proposing as part of the prescriptive controls described in Unit IV.A.4. One such coating is a polyimide coating used in fabrication of detectors to meet precise specifications for use by Federal Agencies in systems such as spacecraft, aircraft, balloons, rockets, and telescopes. This coating, which is 60% NMP, is critical to fabricating these detectors. Additionally, NMP has been used to meet required levels of performance of certified component parts by long-standing design and function specifications that are incorporated into contracts of a complex supply chain. While EPA is not proposing to prohibit the industrial and commercial use of NMP for paints and coatings, EPA is proposing to limit the concentration of NMP in these products to no more than 45%, as described in Unit IV.A.4. This may result in a coating ineffective for the specialized parts or processes used by DOD and NASA. In many instances only a higher concentration of NMP would be capable of successfully performing the necessary function. Additionally, information available to EPA indicates that application of these coatings typically includes very small quantities (less than 1 pound annually) under tightly controlled conditions, allowing for successful application of the WCPP and greater certainty that the unreasonable risk can be addressed in comparison to other situations in which coatings containing NMP may be applied. For these reasons, EPA is proposing WCPP with narrow applicability for these uses. As

described earlier in this unit for paints and coatings, information available to EPA does not indicate that commercial users other than DOD or NASA use such high concentrations of NMP for paint, coating, or adhesive removal in these types of uses. By requiring prescriptive control that provides for a concentration of NMP that includes one currently found on the market along with implementable work practices, EPA believes that use of NMP in paint, coating, and adhesive removal in commercial aviation, space travel, or uses similar to those described by DOD and NASA could continue without resulting in unreasonable risk.

In the narrowly described uses by DOD and NASA for mission- and safety-critical uses, in the controlled environments operated by those agencies or their contractors, EPA expects it is possible for the unreasonable risk to be addressed by the WCPP. However, EPA does not have information to support that expectation for other commercial users of these products, including by entities other than DOD or NASA engaged in commercial aviation or space travel. To prevent widespread distribution of the products containing high concentration of NMP beyond DOD, NASA, and their contractors, EPA is proposing additional requirements, including self-certification, downstream notification, and recordkeeping. These requirements are detailed in Unit IV and would not significantly burden the entities processing, distributing, or using NMP for these highly specialized uses, while providing important enforcement and compliance tools. EPA is seeking comment on whether the WCPP, with no concentration limits, should apply to all users of NMP in paints and coatings, and paint, coating and adhesive removal, rather than narrowly to DOD and NASA.

d. *Prescriptive controls.*

Another requirement EPA considered to address unreasonable risk for occupational conditions of use was requiring specific controls prescribed by EPA, including concentration limits and PPE. In the 2020 Risk Evaluation for NMP, EPA identified that certain workplace

controls could reduce exposures (Ref. 1). The prescriptive controls EPA considered (such as concentration limits and PPE) are based on information in the 2020 Risk Evaluation for NMP and supplemental analyses using methodology from the 2020 Risk Evaluation for NMP. In general, EPA does not prefer prescriptive controls as the primary method of risk management because of uncertainties about whether the prescriptive controls will be feasible for reducing exposures in all workplaces engaged in a condition of use and whether the prescriptive controls will be consistently or properly used. EPA understands that workplaces have unique processes and equipment in place and that varying levels of respiratory protection or dermal PPE may be needed for different workplaces. Additionally, as described in Unit III.A.1. and 2., EPA received input during required consultations and additional engagement that options that align with the hierarchy of controls (i.e., elimination and substitution of hazards in the workplace) should be preferred over prescriptive controls.

EPA also determined that certain prescriptive controls (i.e., PPE) may not be able to eliminate unreasonable risk contributed by some conditions of use when used in isolation. In the 2020 Risk Evaluation for NMP, analysis of occupational exposure scenarios indicated that many conditions of use still posed risk concerns even with the application of PPE (Ref. 1). Because of the uncertainty regarding the feasibility of exposure reductions through engineering controls alone, EPA determined that an NMP WCPP, which would be accompanied in tandem with the implementation of engineering controls, administrative controls, and/or PPE as elements of the program, as appropriate, would more successfully reduce exposure so that the unreasonable risk is addressed. Additionally, relying primarily on PPE to reduce exposures does not consider other more protective controls in the hierarchy, including elimination, substitution, engineering controls, and administrative controls. For occupational conditions of use where compliance with the NMP WCPP is unlikely to be successful, in most cases prohibitions (rather than prescribed

controls) would be more appropriate to ensure that NMP does not present unreasonable risk under the conditions of use.

However, based on the 2020 Risk Evaluation for NMP, EPA considered the industrial and commercial use in the uses listed in Unit IV.A.4.a. as viable candidates for prescriptive controls. These uses include the application of NMP-containing products that have been identified in a range of concentrations of NMP rather than requiring the use of pure NMP, and include application, such as brush or roll tasks where direct dermal contact may not be preventable. Therefore, EPA conducted additional analyses with the model used in the 2020 Risk Evaluation within the ranges identified for the NMP-containing products with and without PPE and determined the parameters required to address the unreasonable risk.

For the industrial and commercial use of NMP in ink, toner, and colorant products, and in soldering materials, EPA did not conduct additional modeling and used information in the 2020 Risk Evaluation for NMP. EPA modeled a range of expected concentration limits, as described in section 2.4 of the 2020 Risk Evaluation for NMP. When EPA modeled the lower bound of identified concentration of NMP in formulation at the central tendency without PPE, it did not contribute to the unreasonable risk to workers. Alternatively, when EPA modeled at the upper bound of identified concentration of NMP at the high-end without PPE it did contribute to the unreasonable risk to workers, but dermal PPE could mitigate the unreasonable risk to workers (Ref. 1). Therefore, EPA is proposing the lower bound concentration limit and dermal PPE to address the unreasonable risk and prevent product formulation with high concentration limits that were not assessed in the 2020 Risk Evaluation for NMP and could potentially contribute to the unreasonable risk.

For additional conditions of use, EPA's analysis in the 2020 Risk Evaluation for NMP indicated that for the uses identified in Unit IV.A.4.a. (not including the conditions of use ink,

toner, and colorant products, and in soldering materials) there would still be risk concerns even if chemically resistant gloves are used in combination with specific activity training for tasks where dermal exposure can be expected to occur. However, as described earlier, the 2020 Risk Evaluation for NMP identifies several uncertainties regarding the use of the dermal exposures modeled. For example, the 2020 Risk Evaluation for NMP does not consider the frequency, type, and effectiveness of gloves or other types of PPE used in these specific conditions of use (Ref. 1). In consideration of the whole of the 2020 Risk Evaluation for NMP, including these uncertainties and EPA's supplemental risk calculations, EPA identified certain exposure controls, such as limits on the concentration of NMP in certain products in combination with requirements for specified respirators and appropriate dermal PPE use, that would reduce exposures to NMP enough to address the unreasonable risk (Ref. 37). For these specific conditions of use, where expected activities like spray, brush, or roll applications of NMP-containing products results in higher air concentration levels than those conditions of use listed in Unit IV.A.3., dermal PPE alone is not expected to address the unreasonable risk. In the supplemental risk calculations EPA evaluated whether dermal PPE alone, or in combination with respirators, either APF 10 or APF 25 would address the unreasonable risk and determined that the combination of the set concentration limits and specified inhalation and dermal PPE listed in Unit IV.A.4. would address the unreasonable risk. EPA is requesting comment on whether there are additional circumstances where specific PPE (including respirators) should be prescribed, as well as the appropriateness of the proposed respiratory protection requirements for these conditions of use as listed in Unit IV.A.4 and any impacts that the prescriptive use of respiratory protection may have on workplace operations.

EPA recognizes that these different conditions of use have different expected activities or application methods, such as spray application of a paint remover that results in a higher-than-

average air concentration of NMP as compared to the roll-on application of ink that does not result in elevated air concentration of NMP. As a result, EPA is proposing four different combinations of concentration and PPE to account for the specific exposures expected while also allowing each of the conditions of use to remain efficacious.

EPA has preliminarily determined that preventing direct dermal contact with NMP through dermal PPE that covers any exposed skin and PPE training for the industrial and commercial uses listed in Unit IV.A.4. in combination with the proposed concentration limits would address the unreasonable risk from dermal exposure driven by these conditions of use for potentially exposed persons. EPA is requesting comment on whether preventing dermal contact with NMP through dermal PPE, training, and a concentration limit would adequately address the unreasonable risk from dermal exposures for these industrial and commercial use. For certain occupational conditions of use, prescribed engineering controls, administrative controls, and PPE were considered as part of the alternative regulatory action and are described in more detail later in this unit and in Unit IV.B.

e. *Concentration limit for consumer use in adhesives and sealants.*

EPA's approach for the consumer use of NMP in adhesives and sealants in glues and adhesives is similar to the prescriptive controls approach for certain occupational conditions of use, described earlier in this unit. For the consumer use listed in Unit IV.A.5., EPA proposes to allow the import, processing, and distribution in commerce of NMP for the consumer use of NMP in adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants only in a concentration of up to 45% in formulated products for consumer use. In the 2020 Risk Evaluation for NMP, EPA identified certain product concentration limits for this consumer condition of use, based on information in the 2020 Risk Evaluation for NMP and supplemental analyses using methodology from the 2020 Risk Evaluation for NMP. EPA understands that

consumers have unique processes and are not expected to have exposure reduction equipment in place or consistently use any levels of respiratory protection or dermal PPE. Therefore, EPA calculated a concentration limit that did not present unreasonable risk even without the use of PPE.

2. *Alternative regulatory actions.*

EPA acknowledges that, for some of the occupational conditions of use that it is proposing to prohibit or require strict workplace controls, there may be some activities or facilities that could conceivably implement requirements under the NMP WCPP to prevent direct dermal contact with NMP. In some cases, they may be able to undertake more extensive risk reduction measures than EPA currently anticipates. Therefore, as a primary alternative regulatory action, described in Unit IV.B., EPA is considering and requesting comment on an NMP WCPP – including requirements to prevent direct dermal contact – for some conditions of use of NMP that would be prohibited or otherwise regulated under the proposed regulatory action. For those conditions of use that would be subject to the NMP WCPP under the alternative regulatory action, but not the proposed regulatory action, EPA was not able to identify reasonably available information such as monitoring data or detailed activity descriptions to indicate with certainty that relevant regulated entities for these conditions of use could mitigate identified unreasonable risk through an NMP WCPP. Due to this uncertainty, EPA is requesting comment on the alternative regulatory action and in particular the likelihood of successful compliance with an NMP WCPP, as described in Unit IV.A., for the conditions of use listed for the alternative regulatory action of NMP WCPP in Unit IV.B. EPA notes that the primary alternative regulatory action includes WCPP for additional commercial conditions of use, rather than prohibition, which removes the need for container size restrictions on similar consumer conditions of use, because the proposed container size restrictions are intended to prevent diversion of consumer

products to commercial users.

EPA acknowledges that, for some of the occupational conditions of use that it is proposing prescriptive workplace requirements there may be some activities or facilities that could not conceivably implement the required concentration limits to reduce inhalation and dermal exposures to NMP. As part of the primary alternative regulatory action, EPA considered instead a prohibition for the industrial and commercial use in adhesives and sealants including binding agents, single component glues and adhesives, including lubricant adhesives and two component glues and adhesives including some resins and upstream activities for the consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants. However, as summarized in this unit, EPA has uncertainty regarding the necessity of a prohibition for the use of NMP in these conditions of use if the unreasonable risk could be addressed through a combination of a concentration limit and PPE (dermal and inhalation) for relevant industrial or commercial uses, and with a corresponding concentration limit for consumer products with similar purposes and attributes. EPA is soliciting comment on prohibiting for these occupational conditions of use.

Details of the alternative regulatory action are described more in Unit IV.B.

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

Since it is unlikely that all industrial or commercial facilities with occupational exposures to NMP would be able to implement a WCPP or prescriptive controls, EPA also examined the extent to which a point-of-sale self-certification requirement to purchase and subsequently use NMP would further ensure that only facilities able to implement and comply with a WCPP or prescriptive controls are able to purchase and use NMP, and self-certify to that. Under a self-certification requirement, entities would submit a self-certification to the distributor each time NMP is purchased. The self-certification would consist of a statement indicating that the facility

is implementing a WCPP or required prescriptive controls to control exposures to NMP; the self-certification would be signed and presented by a person authorized to do so by the facility owner or operator. Copies of the self-certification would be maintained as records by both the owner or operator and the distributor where NMP was purchased. While EPA is proposing to include a requirement for self-certification as part of the proposed narrow application of the WCPP for two commercial uses of NMP in paints and coatings and paint, coating, and adhesive removers, that narrowly tailored self-certification differs from a broader point-of-sale self-certification requirement that would be applicable to all commercial users of products containing NMP. The self-certification proposed for the narrow application of the WCPP relies on the adherence of a narrowly defined, highly-regulated group of users (DOD, NASA, or their contractors) performing work at clearly defined facilities for specific purposes on mission- or safety-critical components in compliance with the WCPP requirements described in Unit IV.A.3.

In contrast, a broader self-certification requirement would place requirements on large and diverse groups of users and distributors. Because of the number and types of entities where users can obtain NMP or NMP-containing products, EPA does not believe the added requirement and subsequent burden of a point-of-sale self-certification requirement for the use of NMP would be an effective tool for preventing facilities that may be unable to comply with the WCPP or prescriptive controls of this proposed rulemaking from accessing NMP or NMP-containing products. As such, EPA is not proposing a self-certification requirement as an additional component of the requirements for addressing the unreasonable risk of occupational exposures to NMP. However, EPA is requesting comment on whether to include a self-certification requirement for purchasing NMP or NMP-containing products. For example, EPA is interested in learning if, for distributors and retailers, such a self-certification requirement would provide greater certainty that any sale of NMP or NMP-containing products would be for uses that are

not prohibited and are to a facility implementing the WCPP or required prescriptive controls.

EPA considered setting an ECEL as a regulatory action to address the unreasonable risk by inhalation and dermal exposures. Previously, based on a 2015 risk assessment (Ref. 17), EPA proposed a regulatory action to restrict the use of NMP in commercial and consumer paint and coating removers that included a co-proposed option to prohibit the use of formulations with NMP more than 35% by weight and require PPE; that action was later withdrawn (Refs. 46, 47). Within the PPE requirement, in 2017, EPA proposed to require certain authorized respirators or an ECEL value. The ECEL value was dependent on inhalation and dermal exposures and weight fraction of NMP in the product. This analysis was specific to the PBPK model used for NMP which accounts for simultaneous dermal and inhalation exposure. The ECEL analysis calculated several variations in exposures and weight fractions, including 35%, 50%, and 60% NMP. At 60% NMP presented unreasonable risk to workers even with no air concentration exposure (Ref. 48). In the 2020 Risk Evaluation for NMP, EPA reanalyzed certain hazard information compared to the previous 2015 EPA Assessment, resulting in revised risk estimates in which an ECEL as an alternative to a respirator requirement would not be feasible to address the unreasonable risk for the industrial and commercial use of NMP in paints, coatings, and adhesive removers at 35% by weight NMP. The 2020 Risk Evaluation for NMP used a PBPK model that allowed EPA to evaluate aggregate exposures from simultaneous dermal, inhalation, and vapor-thorough-skin exposures associated with specific exposure scenarios (Ref. 1). The 2020 Risk Evaluation for NMP also compared the internal exposure to workers from dermal, inhalation, and vapor-through-skin pathways to the internal exposures to ONUs from inhalation and vapor-through-skin pathways. The results shows that the proportion of the exposure largely driving the unreasonable risk to workers and consumers is due to dermal contact with liquid NMP (Ref. 1) and addressing inhalation risks alone would not mitigate the unreasonable risk from NMP. Thus,

EPA has not identified and is not proposing to set an ECEL for NMP. While a level could be set that would account for risk resulting from inhalation and vapor-through-skin (dermal exposure to vapor but not direct dermal contact with a liquid) exposures and the risk from direct dermal exposure at a specified weight fraction, the Agency is concerned an ECEL value would imply that inhalation is the primary route of exposure. Further, the 2020 Risk Evaluation identified a range of NMP weight fractions in the conditions of use, and most occupational uses of NMP require weight fractions much higher than 35%, or even 60%. As described in the 2017 NMP ECEL analysis, no ECEL value would mitigate the unreasonable risk when the weigh fraction is at or above 60%. Therefore, requirements to meet an ECEL would not address the unreasonable risk from dermal exposure.

Additionally, the previous proposed ECEL in 2017 was calculated for one condition of use and exposure scenario and accounted for the specific concentration limit EPA proposed for that condition of use and associated products. The previously proposed concentration limit was intended to result in reduced dermal and inhalation exposure. As a result, the ECEL included in the 2017 proposed rule was not an ECEL for all conditions of use of NMP, or even all paint and coating removal uses of NMP (i.e., any products that would exceed the previously proposed concentration limit of 35%). This proposed rule for NMP as a whole chemical regulates 28 occupational conditions of use. For an ECEL to be useful, EPA would have to propose, for each of these conditions of use, requirements for dermal PPE, a specific concentration limit, and a corresponding ECEL. Even if it were feasible to identify such a large number of separate dermal PPE, concentration limits, and ECELs, EPA believes it would be potentially burdensome and confusing to the regulated entities if there were a multitude of requirements for specific dermal PPE, concentration limits, and inhalation ECELs for each condition of use that would continue under the WCPP. Regulated entities could potentially have to comply with several different

ECELs and concentration limits for different conditions of use within one facility which may not be technically feasible. EPA notes that those potential concentration limits would most likely be lower than pure NMP, which many processing conditions of use require, or would be lower than efficacious for some commercial formulations. Additionally, even with an ECEL, regulated entities would still have to prevent direct dermal contact by workers to NMP. For these reasons, instead of proposing a multitude of ECELs, EPA is proposing a robust WCPP that – through the requirements to develop and implement exposure control plan, identify restricted areas, and take mitigation measures to prevent direct dermal contact – will address the unreasonable risk from NMP for the specified conditions of use, without adding extra challenges of ECEL monitoring and compliance.

EPA is also not proposing an existing chemical dermal exposure limit because biomonitoring methods, such as blood concentration testing or urine analysis to measure compliance to a dermal exposure limit, may not be readily available or feasible for most workplaces to implement. OSHA requires biomonitoring for only three chemicals (benzene, cadmium, and lead), and has not required any other chemical biomonitoring since 1981 (Refs. 49, 50, 51). NIOSH has no has no RELs based on biomonitoring, and EPA is not aware of any standard biomonitoring practice in the United States for solvents. EPA does not believe that biomonitoring methods are standard procedures in most occupational uses and requests public comment if these methods are viable to implement in the workplace.

To address the unreasonable risk, EPA also considered limiting the weight fraction of NMP in products and formulations without requirements for dermal or respiratory PPE. As described in Unit V.A.1.a., EPA determined that the unreasonable risk from NMP would not be contributed to by use of products containing NMP at less than 0.1% by weight. However, for all industrial/commercial and consumer conditions of use, the concentration limit of 0.1% is so low

that it is highly unlikely that NMP would still serve its functional purpose in the product or formulation. EPA thus concluded that a weight fraction restriction without accompanying PPE requirements would essentially function as a prohibition. for the conditions of use listed in Unit IV.A.2, and EPA therefore did not propose a weight fraction for those occupational conditions of use. EPA is however proposing a de minimis level for products containing NMP at levels of less than 0.1% to account for impurities that do not contribute to the unreasonable risk., as described in Unit IV.A.1.b.

4. *Additional considerations.*

After considering the different regulatory options under TSCA section 6(a), alternatives (described in Unit V.B.), compliance dates, and other requirements under TSCA section 6(c), EPA developed the proposed regulatory action described in Unit IV.A. to address the unreasonable risk from NMP so 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 the NMP WCPP and downstream notification regarding the prohibition on manufacturing, processing, distribution in commerce, and use of NMP, including products containing NMP. These proposed requirements are described in Unit IV.A.

As required under TSCA section 6(d), any rule under TSCA section 6(a) must specify mandatory compliance dates, which shall be as soon as practicable with a reasonable transition period, but no later than 5 years after the date of promulgation of the final rule (for NMP, EPA notes an exception for the two uses exempted under TSCA section 6(g)). These compliance dates are detailed in Unit IV.A. and IV.B. EPA may finalize significantly shorter or longer compliance timeframes based on consideration of public comments.

B. *Consideration of Alternatives in Deciding Whether to Prohibit or Substantially Restrict NMP*

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. 5), EPA conducted an Alternatives Assessment, using reasonably available information (Ref. 4).

For this assessment, EPA identified and analyzed alternatives to NMP in products relevant to industrial, commercial, and consumer conditions of use proposed to be prohibited or restricted, even if such restrictions are not anticipated to substantially prevent the condition of use. Based on reasonably available information, including information submitted by industry, EPA understands viable alternatives to NMP may not be available for several conditions of use—for example, the industrial and commercial use as a solvent (for cleaning or degreasing) in electrical equipment, appliance and component manufacturing; for use in semiconductor manufacturing; or the industrial and commercial use in lithium ion battery manufacturing for certain applications (Refs. 42, 44)—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 (such as the industrial and commercial use of NMP in anti-freeze and de-icing products or in lubricants and greases), EPA was unable to identify products currently available for sale that contain NMP. EPA is soliciting comments on whether there are products in use or available for sale relevant to these conditions of use that contain NMP 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 NMP. These conditions of use are detailed in the Alternatives Assessment (Ref. 4).

For conditions of use for which products currently containing NMP were identified, EPA identified several hundred commercially available alternative products that do not contain NMP, 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 NMP 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. 4). 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 NMP for certain endpoints, while some ingredients presented higher hazard screening ratings than NMP (Ref. 4). These alternative hazard screening ratings are described in detail in the Alternatives Analysis grouped under common product use categories (Ref. 4).

Discussion of alternatives to NMP occurred 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 some available alternatives. Specifically, SERs discussed and the challenges of transitioning to alternative chemicals, which may not be as efficacious as NMP, including the lifespan of use of their current equipment, capital costs for new equipment and formulation certification, time to research alternatives and reformulate products, and compliance with any existing alternative chemical regulations (Ref. 26). SERs also identified concerns over certain chemical alternatives such as in extraction uses that are more toxic or flammable than NMP, or in coating removal uses where certain chemical alternatives also present supply chain challenges and limited or reduced availability compared to NMP. EPA

notes the concerns expressed by SERs regarding availability of feasible alternatives. These discussions with SERs informed the Panel recommendations.

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

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

A. *Health Effects of NMP and the Magnitude of Human Exposure to NMP*

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

The 2020 Risk Evaluation for NMP identified potential health effects of NMP including non-cancer adverse health effects such as reproductive toxicity, developmental toxicity, liver toxicity, kidney toxicity, immunotoxicity, neurotoxicity, and irritation and sensitization.

Among the non-cancer adverse health effects, for acute inhalation and dermal exposure scenarios, EPA identified non-cancer developmental effects (i.e., increased fetal resorptions and mortality) as the most sensitive endpoint. For chronic inhalation and dermal exposure scenarios, EPA identified non-cancer reproductive effects (decreased fertility) as the most sensitive endpoints. NMP is not mutagenic and is not considered carcinogenic, so EPA did not conduct analysis of genotoxicity and cancer hazards in the risk evaluation.

Regarding the magnitude of human exposure, one factor EPA considers for the conditions of use that contribute to unreasonable risk is the size of the exposed population, which, for NMP, EPA estimates is 226,000 workers and 193,000 ONUs (Ref. 5). The number of consumers that use adhesive products containing NMP each year is unknown. EPA did not identify any consumer adhesive and sealant products containing NMP (Ref. 5).

For the conditions of use that contribute to the unreasonable risk for NMP, PESS include workers, ONUs, consumer users, bystanders, males and females of reproductive age, pregnant women and the developing embryo/fetus, infants, children and adolescents, people with pre-existing conditions and people with lower metabolic capacity due to life stage, genetic variation, or impaired liver function.

In addition to workers, ONUs, consumers, and bystanders to consumer use directly exposed to NMP, EPA recognizes there is exposure to the general population from air and water pathways for NMP. During problem formulation, EPA conducted a first-tier screening analysis, for the ambient air pathway to near-field populations downwind from industrial and commercial facilities releasing NMP, that indicated low risk. In the 2020 Risk Evaluation, EPA conducted a first-tier analysis to estimate NMP surface water concentrations and did not identify risks from incidental ingestion or dermal contact during swimming. 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 that were unaccounted for in the NMP problem formulation and 2020 Risk Evaluation. The screening approach was developed 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. EPA’s fenceline

analysis for the air pathway did not find risks to fenceline communities from ambient air (Ref. 15). EPA's fenceline analysis for the water pathway did not find risks from drinking water (Ref. 16). EPA therefore does not intend to revisit these air and water pathways for NMP as part of a supplemental risk evaluation.

B. *Environmental Effects of NMP and the Magnitude of Exposure of the Environment to NMP*

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

The manufacturing, processing, use, and disposal of NMP can result in releases to the environment, including aquatic releases of NMP from facilities that manufacture, use, or process NMP. Fate, exposure, and environmental hazard were evaluated in the 2020 Risk Evaluation for NMP to characterize environmental risk of NMP. NMP is not likely to accumulate in sediment due to its water solubility and low partitioning to organic matter. Upon releases of NMP to the atmosphere, it is degraded via reaction with photochemically produced hydroxyl radicals in ambient air. It may migrate through soil into groundwater, where NMP readily biodegrades in environments with active microbial populations. Additionally, NMP has low potential for bioaccumulation and bioconcentration in the environment.

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

chronic exposures, NMP is a hazard to aquatic invertebrates based on reproductive effects, to fish based on an acute to chronic ratio approach extrapolating from the acute fish toxicity data, and to algae based on growth effects. EPA incorporated modeled exposure data from the Exposure and Fate Assessment Screening Tool or E-FAST as well as monitored data from the Water Quality Portal (Ref. 1), to characterize the exposure of NMP to aquatic species.

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

C. *Benefits of NMP for Various Uses*

NMP is a water-miscible, organic compound used in a variety of industrial, commercial, pharmaceutical, and consumer use applications, including as a processing aid, as a solvent in petrochemical processing, in the production of electronics, cleaning and degreasing, and producing and removing paint, coatings, adhesives, and sealants, and other uses. The physical and chemical properties of NMP, such as low-flammability, low volatility, low vapor pressure, high boiling point, low viscosity and high affinity for aromatic hydrocarbons make it a popular and effective solvent and surface treatment for many applications (Ref. 1). Besides its use as a solvent, NMP is utilized in the recovery of hydrocarbons in the processing of petrochemicals. It is also used in the absorption of hydrogen sulfide in hydrodesulfurization facilities and the commercial preparation of polyphenylene sulfide, a high-performance engineering thermoplastic. In the pharmaceutical industry, NMP is used in the formulation of oral and transdermal drugs.

The main uses of NMP, by production volume, are in paint and coating removers, paints and coatings, electronics manufacturing, and plastic and resin manufacturing (Ref. 5). NMP

effectively chemically removes various coatings from a substrate, such as furniture coatings or graffiti paint. There appears to be a trend towards alternatives to NMP in paint and coating removers as a result of the proposed rule published by EPA under TSCA section 6 in January 2017 regulating certain uses of methylene chloride and NMP (82 FR 7464). While that proposed rule was withdrawn in January of 2021, since January 2017, based on market research, the availability of consumer and commercial paint and coating removal products containing NMP has declined. However, there appears to be a market trend expanding electronic manufacturing in the United States, particularly as it related to lithium ion battery manufacturing and electronic vehicles and semiconductor chips. These production processes include uses of NMP with no known alternative and are expected to require the continued use of NMP over time.

In petrochemical manufacturing, NMP is used as a processing aid and extraction solvent. NMP is also used in a variety of cleaning products used in multiple industrial facilities and commercial shops, in soldering materials, and enhanced fertilizers.

EPA requests comments from the public about the importance of NMP in multiple existing product categories, including the potentially increased future importance of NMP to innovation and as an alternative.

D. *Reasonably Ascertainable Economic Consequences of the Proposed Rule*

1. *Likely effect of the rulemaking 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. 5). 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. 5). The economic impact of a regulation on the national economy becomes measurable only if the economic impact of the regulation reaches 0.25% to 0.5% of Gross Domestic Product (GDP). Given the current GDP, this is equivalent to a cost of $40 billion to $80 billion. Therefore, because EPA has estimated that the cost of the proposed rule would range from $396 million annualized over 20 years at a 3% discount rate and $397 million annualized over 20 years at a 7% discount rate, EPA has concluded that this rulemaking is unlikely to have any measurable effect on the national economy (Ref. 5). Cost estimates by use category are provided in the Economic Analysis Table 7-36 (Ref. 5). In addition, EPA considered the employment impacts of this proposed rule, and found that the direction of change in employment is uncertain, but EPA expects the short-term and longer-term employment effects to be small.

Of the 61,851 small businesses potentially impacted by this proposed rule, 72% or 44,388 are expected to have impacts of less than 1% to their firm revenues, 11% or 6,965 are expected to have impacts between 1 and 3% to their firm revenues, and 17% or 10,497 are expected to have impacts greater than 3% to their firm revenues. Most businesses that would be affected by this regulation are in the following sectors: paints and coatings; paint, coating, adhesive removers; adhesive and sealants; inks, toners, and colorant products; and soldering. In addition to these sectors, some users of NMP (such as in plastic and resin product manufacturing or waste and disposal) may be significantly impacted because they have specific technical requirements which make the cost of modifications in response to WCPP requirements or the efficacy of potential alternatives hard to determine and appropriately capture in the analysis.

With respect to this proposed rule's effect on technological innovation, EPA expects this rulemaking to spur more innovation than it will hinder. A prohibition or significant restriction on the manufacture, processing, and distribution in commerce of NMP 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 NMP 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 NMP. The effects of this proposed rule on public health are estimated to be positive, due to the reduced risk of non-cancer endpoints from exposure to NMP.

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

The costs and benefits that can be monetized for this proposed rule are described at length in in the Economic Analysis (Ref. 5). The monetized costs for this proposed rule are estimated to range from $396 million annualized over 20 years at a 3% discount rate and $397 million annualized over 20 years at a 7% discount rate. See the Economic Analysis Table 7-36 where total monetized costs are broken out per component of the proposed rule (Ref. 5). The health endpoints for NMP cannot be monetized at this time. However, as discussed in Unit IV.E., those endpoints can have significant, negative impacts on the lives of those exposed to NMP resulting in low birth weight, fetal loss, kidney toxicity, liver toxicity, and issues with fertility and fecundity (Ref. 5).

EPA considered the estimated costs to regulated entities as well as the cost to administer and enforce alternative regulatory actions. The alternative regulatory actions are described in detail in Unit IV.B. The estimated annualized costs of the alternative regulatory action are $165 million at a 3% discount rate and $185 million at a 7% discount rate over 20 years (Ref. 5). Again, the health endpoints for NMP cannot be monetized at this time. However, as discussed in Unit IV.E., those endpoints can have significant, negative impacts on the lives of those exposed to NMP resulting in low birth weight, fetal loss, kidney toxicity, liver toxicity, and issues with

fertility and fecundity (Ref. 5).

This proposal is expected to achieve health benefits for the American public, 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 non-monetized benefits of mitigating the non-cancer adverse effects. The multitude of adverse effects from NMP exposure can profoundly impact an individual's quality of life, as discussed in Units I.E. (estimated incremental impacts of the proposed rule), III.B.2. (description of the unreasonable risk), and VI.A. (discussion of the health effects), and also the 2020 Risk Evaluation for NMP. Chronic adverse effects of NMP exposure include the non-cancer effects listed in this unit. Acute effects of NMP exposure could be experienced for a shorter portion of life but are nevertheless significant in nature. The incremental improvements in health outcomes such as reproductive or developmental effects achieved by given reductions in exposure cannot be quantified for non-cancer health effects associated with NMP 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. Dismissing nonmonetized benefits of this rulemaking underestimates the impacts of NMP adverse outcomes and would imply there are no health benefits of this proposed rule from a reduction in NMP exposure.

3. *Cost effectiveness of the proposed regulatory action and 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. The goal of this proposed regulatory action is to prevent unreasonable risk resulting from exposure to NMP, and a major component of this regulatory action is eliminating or reducing NMP exposure to workers and ONUs. Per potentially exposed worker or ONU, the proposed regulatory action would cost $944 while the alternative regulatory action

would cost $395 (using the 3% discount rate) to achieve the same goals. At a 7% discount rate, the proposed regulatory action would cost $948 while the alternative regulatory action would cost $442 per potentially exposed worker or ONU. While the proposed option has higher monetized costs, it may allow for more flexibility in some sectors. In addition, the proposed option may result in potential lower exposures to workers and ONUs using NMP compared to the alternative option leading to reduced potential negative health outcomes for workers (Ref. 5).

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

A. *TSCA Section 9(a) Analysis*

TSCA section 9(a) provides that, if the Administrator determines, in the Administrator's discretion, that an unreasonable risk may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA, the Administrator must submit a report to the agency administering that other law that describes the risk and the activities that present such risk. TSCA section 9(a) describes additional procedures and requirements to be followed by EPA and the other Federal agency following submission of any such report. As discussed in this unit, for this proposed rule, the Administrator proposes to exercise his discretion not to determine that the unreasonable risk from NMP 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 NMP, 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 has not established a PEL for NMP. Gaps exist between OSHA's authority to set workplace standards under the OSH Act and EPA's obligations under TSCA section 6 to eliminate unreasonable risk presented by chemical substances under the conditions of use. Health standards issued under section 6(b)(5) of the OSH Act must reduce significant risk only "to the extent feasible." 29 U.S.C. 655(b)(5). To set PELs for chemical exposure, OSHA must first establish that the new standards are economically and technologically feasible (79 FR 61384, 61387, Oct. 10, 2014). But under TSCA section 6(a), EPA's substantive burden is to demonstrate that, as regulated, the chemical substance no longer presents an unreasonable risk, with unreasonable risk being determined without consideration of costs or other non-risk factors. Thus, if OSHA were to initiate a new action, the difference in standards between the OSH Act and TSCA may well result in an OSHA action insufficient 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 NMP 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 NMP in consumer products, but not in other sectors

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

EPA therefore concludes that TSCA is the only regulatory authority able to prevent or reduce unreasonable risk of NMP 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 NMP 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 listed NMP as a volatile organic compound (Ref. 7), 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)), including their associated permits.

The primary exposures and unreasonable risk to consumers and workers 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 NMP under the CAA, CWA, or RCRA cannot be estimated, nor would they address the direct human exposure to consumers and workers from the conditions of use evaluated in the 2020 Risk Evaluation for NMP. More specifically, none of EPA's other statutes (e.g., RCRA, CAA, CWA) can address exposures to workers related to the specific activities that result in occupational exposures, for example those associated with RCRA covered disposal requirements. EPA therefore concludes that TSCA is the most appropriate regulatory authority able to prevent or reduce risks of NMP 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 NMP under the conditions of use evaluated in the 2020 TSCA Risk Evaluation for NMP 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 Requirement.*

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 proposed rule would prohibit. Manufacturers or processors seeking to protect such information would be able to submit a request for nondisclosure as provided by TSCA sections 14(b)(4)(C) and 14(g)(1)(E). Any request for nondisclosure would

need to be submitted within 30 days after receipt of notice from EPA under TSCA section 14(g)(2)(A). EPA anticipates providing such notice via the Central Data Exchange or CDX.

D. *TSCA Section 26 Considerations*

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

In particular, the WCPP, prescribed concentration limits, and de minimis concentration limit are derived from the analysis in the 2020 Risk Evaluation for NMP; they likewise represent decisions based on the best available science and the weight of the scientific evidence (Ref. 37). As discussed in Unit V.A.1., EPA used supplemental modeling from the 2020 Risk Evaluation for NMP to derive the proposed de minimis concentration limit, which represents a level below which EPA would not expect product use to contribute to unreasonable risk.

The extent to which the various information, procedures, measures, methods, protocols, methodologies or models, as applicable, used in EPA's decisions have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for this rule. Additional information on the peer review and public comment process, such as the peer review plan, the peer review report, and the Agency's response to comments, can be found in EPA's risk evaluation docket (Docket ID No.: EPA-HQ-OPPT-2016-0743).

VIII. Requests for Comment

EPA is requesting public comment on all aspects of this proposal, including the proposed

and alternative regulatory actions and all individual elements of these, and all supporting analysis. Additionally, within this proposal, the Agency is soliciting feedback from the public on specific issues throughout this proposed rule. For ease of review, this unit summarizes those specific requests for comment, with numbering provided to help simplify referencing.

1. In Unit I.C., EPA seeks public comment on all aspects of this proposal.

2. In Unit I.E., EPA seeks public comment on methodologies for developing noncancer human dose-response curves and valuation methods for the health endpoints identified for NMP in the Risk Evaluation, specifically willingness to pay studies.

3. In Unit III.A., EPA is requesting public comment on all elements of the proposed regulatory action and the alternative regulatory actions and is providing notice that based on consideration of comments and any new information submitted to EPA during the comment period on this proposed rule, EPA may in the final rule modify elements of the proposed regulatory action.

4. In Unit III.B.1., EPA requests comment on whether EPA should promulgate definitions for those conditions of use evaluated in the 2020 Risk Evaluation for NMP that would not be prohibited, and, if so, whether the descriptions in this unit are consistent with the conditions of use evaluated in the 2020 Risk Evaluation for NMP and whether they provide a sufficient level of detail to improve the clarity and readability of the regulation.

5. In Unit IV.A., EPA requests comment on allowing this de minimis level of NMP in products to account for impurities.

6. In Unit IV.A.1., 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.

7. In Unit IV.A.1., EPA requests comment on whether these are the appropriate types of information for use in evaluating compliance requirements, and whether there are other considerations that should apply.

8. In Unit IV.A.1., EPA is requesting comment on: (1) Whether respiratory protection and dermal PPE should be required before the effective date of the prohibition; (2) To what extent inhalation and dermal PPE may already be implemented in most uses being prohibited; and (3) Whether requirements that inhalation and dermal PPE be used before the effective dates of prohibitions would be overly burdensome to entities indicated in this unit that would be working to comply with the prohibition.

9. In Unit. IV.A.1., EPA is requesting comments from the public for more information about the uses EPA is proposing to prohibit, particularly the industrial and commercial uses in fertilizer and other agricultural chemical manufacturing-processing aids and solvents, and the ability for workplaces in these conditions of use to comply with strict workplace controls like those required under the WCPP, or the ability to comply with a prohibition and reformulate to an alternative chemical or process.

10. In Unit IV.A.1., EPA requests comments on an appropriate, predictable process that could expedite reconsideration for uses that Federal agencies or their contractors become aware of after the final rule is issued using the tools available under TSCA, aligning with the requirements of TSCA section 6(g). EPA requests comment on whether the types of information described are the appropriate types of information for use in evaluating this type of category of use, and whether there are other considerations that should apply.

11. In Unit IV.A.1., EPA solicits comment on all aspects of its steps to accommodate in this proposed rule uses needed for national security or critical infrastructure and whether any additional measures are needed.

12. In Unit IV.A.2., EPA is requesting public comment on whether meeting this container size restriction to prevent commercial use would also have the same, though unintended, effect of reducing the consumer use.

13. In Unit IV.A.2., EPA requests comment on whether additional time is needed, for example, for products to clear the channels of trade, or for implementing the container size restriction, and on what an appropriate container size restriction should be if not 16 ounces, and why.

14. In Unit IV.A.2., EPA is also seeking public comment on any alternative options to prevent diversion of consumer products to commercial uses. Comments should include documentation such as the specific container sizes of the NMP-containing products and estimates of the time and expenses required to implement the labeling requirement. EPA may finalize significantly shorter or longer compliance timeframes based on consideration of public comments.

15. In Unit IV.A.3., EPA requests comment on available approaches, specifically monitoring methods (e.g., charcoal patch testing) and frequency of sampling, to determine the effectiveness of engineering and administrative controls in preventing or reducing potential direct dermal contact to NMP.

16. In Unit IV.A.3., EPA also requests comment on whether requiring reporting on such monitoring could support enforcement and compliance assurance with this rulemaking.

17. In Unit IV.A.3., EPA requests comment on whether there should be general housekeeping or cleaning requirements in areas where the NMP is handled or where surfaces

may be contaminated with NMP.

18. In Unit IV.A.3., EPA is also soliciting comment on requiring warning signs to demarcate restricted areas, similar to the requirements found in OSHA's General Industry Standard for Beryllium (29 CFR 1910.1024(m)(2)).

19. In Unit IV.A.3., 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)).

20. In Unit IV.A.3., EPA is soliciting comments on the non-prescriptive proposed DDCC requirements for appropriate PPE selection, the effectiveness of PPE in preventing direct dermal contact with NMP in the workplace.

21. In Unit IV.A.3., EPA requests information on other potential dermal performance standards, and on general absorption and permeation effects to PPE as a result of direct contact.

22. In Unit IV.A.3., EPA understands that some workplaces rinse and reuse PPE after minimal use and is therefore soliciting comments on the impact on effectiveness of rinsing and reusing certain types of PPE, either gloves or protective clothing and gear.

23. In Unit IV.A.3., EPA also requests comment on the degree to which additional guidance related to use of PPE might be appropriate, including specifying PPE type or additional standard testing specifications.

24. In Unit IV.A.3., 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.

25. In Unit IV.A.3., EPA requests comment relative to the ability of owners or operators in the private sector to implement such processes within 12 months of publication of the final rule in the *Federal Register*, and anticipated timelines for any procedural adjustments needed to comply with the requirements outlined in this unit. EPA also requests comment on whether the additional two years provided for agencies of the Federal Government and their contractors, when acting for or on behalf of the Federal government, to comply with the WCPP, should be provided more broadly to all entities complying with the WCPP.

26. In Unit IV.A.4., 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)).

27. In Unit IV.A.4., EPA is requesting public comment on whether additional documentation should be required to further support compliance and enforceability of the proposed regulatory requirements (e.g., requirements for labels or SDS identifying percent of NMP within a product, or downstream notification of these proposed requirements for concentration limits and PPE, or other information that would be made available to industrial and commercial users to indicate compliance with the concentration limits).

28. In Unit IV.A.4., EPA requests comment on whether additional time is needed, other concentrations are required, or if there are available substitutes for this application.

29. In Unit IV.A.5., EPA is requesting public comment on whether additional documentation should be required to further support compliance and enforceability of the proposed regulatory requirements (e.g., requirements for labels identifying the percent of NMP

within a product or downstream notification of these proposed requirements for concentration limits).

30. In Unit IV.A.5., EPA requests comment on whether additional time is needed, other concentrations are required, or if there are available substitutes for this application.

31. In Unit IV.A.6., EPA requests comments on all aspects of the proposed applicability of the WCPP to these narrowly described uses of higher concentration NMP in paint, coating, and adhesive removal and paints and coatings.

32. In Unit IV.A.6., EPA also requests comment on whether entities other than DOD, NASA or its contractors also require high concentration NMP and, if so, the extent to which lack of availability of high concentration NMP could impact their operations or pose potential challenges to the supply chain.

33. In Unit IV.A.6., EPA is requesting comment on whether EPA should also require reporting to EPA during purchasing of NMP for these specific uses by DOD, NASA, or their contractors and if requiring reporting could support of enforcement and compliance assurance with this rulemaking by further assuring that distribution of these high concentration NMP products for these uses is limited to DOD, NASA, and their contractors, and if such requirements would impose significant administrative burdens in addition compliance with the WCPP.

34. In Unit IV.A.7., EPA requests comments on the appropriateness of identified compliance timeframes for recordkeeping and downstream notification requirements described in this unit.

35. In Unit IV.B.1., EPA requests comment on this alternative regulatory action and whether any elements of this alternative regulatory action described in this unit should be considered as EPA develops the final regulatory action.

36. In Unit IV.B.1., EPA also requests comment on any advantages or drawbacks for the

timelines outlined in this unit compared to the timelines identified for the proposed regulatory action in Unit IV.A.

37. In Unit IV.B.1., EPA requests comment on the ways in which NMP may be used in these conditions of use, including whether activities may take place in a closed system and the degree to which users of NMP in these sectors could successfully implement a WCPP (including DDCC) and ancillary requirements described in Unit IV.A.

38. In Unit IV.B.1., EPA is also requesting comment on whether any of the uses listed in this unit should be prohibited instead of requiring a WCPP, or if there are other factors like reduced concentration limits or limited access that could address the unreasonable risk.

39. In Unit IV.B.1., EPA requests comment on any advantages or drawbacks for the timelines outlined in this unit compared to the timelines identified for the proposed regulatory action in Unit IV.A.

40. In Unit V.A.1., EPA requests comment on the workplace protection measures or exposure reduction measures typically applied during dip application of NMP, particularly dip degreasing and cleaning in hot or cold dip-tank immersion cleaning and degreasing, and dip application of NMP for adhesive, paint, or coating removal.

41. In Unit V.A.1., EPA also requests comment on the typical tasks expected during hot and cold dip cleaning or coating removal operations, including manual or automated opening and closing of the dip tank, cleaning and maintenance, the use of new or repurposed vapor degreasing machines for immersion cleaning, or any other dip-tank or immersion cleaning and degreasing activities.

42. In Unit V.A.1., EPA is interested in for comments on the ability of users of high concentrations of NMP in dip applications to successfully implement a WCPP, the availability of alternative chemicals, and impacts of prohibiting NMP for the hot or cold dip-tank cleaning,

degreasing, or removal of adhesives, paints, or coatings.

43. In Unit V.A.1., EPA requests comment on the number of firms who utilize hot or cold dip NMP for cleaning, degreasing, or removal of adhesives, paints, and coatings and the frequency of dip applications and size of the dip vessel per firm is also of interest to EPA.

44. In Unit V.A.1., EPA also requests comment on the types of engineering controls and any PPE use by firms who use NMP in hot or cold dip applications.

45. In Unit V.A.1., EPA requests comment on how NMP is used in the agricultural sector, including whether there are any other application types (such as aerosol application) besides liquid product containing NMP blended with solid fertilizer pellets. EPA requests comment and supporting information on the degree to which entities using NMP in fertilizer manufacture or application may comply with the proposed WCPP requirements or similar stringent workplace controls for other conditions of use of NMP. EPA also requests comment on the workplace safety protocols in place during application, including expected exposure reductions during the use of NMP in fertilizer mixing and application, current engineering controls used, PPE usage and any standard hazard warnings or instructions in place. Specifically, EPA requests comments on whether there are alternatives to NMP for solvents used in the production of fertilizers, as well as alternatives to the use of NMP to reduce the volatility of advanced fertilizer products by keeping nitrogen from volatilizing into the atmosphere before it can be absorbed into the soil."

46. In Unit V.A.1., EPA requests comment regarding the number of businesses and other entities that could potentially close as well as associated costs with a prohibition of NMP for the industrial and commercial conditions of use identified in Unit IV.A.1.a.

47. In Unit V.A.1., EPA is requesting comment on the de minimis concentration limit of NMP in products or formulations. EPA emphasizes the agency's interest in aligning to the extent

possible with the de minimis thresholds in the OSHA Hazard Communication Standard, while also noting that additional analytical work was conducted for NMP.

48. In Unit V.A.1., EPA requests comment on whether de minimis thresholds should be proposed consistent with national and international regulations, or whether there may be instances where chemical-specific analyses is appropriate.

49. In Unit V.A.1., EPA requests comment on if there are any NMP-containing consumer products that may require a more frequent or multiple day application, and if so, should EPA require additional restrictions for consumer products.

50. In Unit V.A.1., EPA requests comment on the potential impacts to consumers and the consumer use of these products from a container size requirement, as well as the appropriateness of the proposed respiratory protection requirements for these conditions of use as listed in Unit IV.A.4 and any impacts that the prescriptive use of respiratory protection may have on workplace operations.

51. In Unit V.A.1., EPA is also requesting comment on whether, rather than a container size restriction requirement, a maximum concentration limit for products containing NMP be required instead.

52. In Unit V.A.1., EPA requests comment on the typical or effective concentration of NMP in the following consumer products: paint and coating removers, adhesive removers, paints and coatings, paint additives and coating additives in arts and crafts paint, automotive care products, cleaning and furniture care products, and lubricant and lubricant additives, and whether a maximum concentration of NMP could be identified that would allow the product to continue to be efficacious for consumer use, but that would not exceed the concentrations EPA has identified in Unit IV.A.1.e. for addressing the contribution of these types of products to unreasonable risk for workers.

53. In Unit V.A.1., EPA is seeking comment on whether the WCPP, with no concentration limits, should apply to all users of NMP in paints and coatings, and paint, coating and adhesive removal, rather than narrowly to DOD and NASA.

54. In Unit V.A.1., EPA is requesting comment on whether additional circumstances where specific PPE (including respirators) should be prescribed, as well as on the impacts on operations of requirements for the prescriptive use of respiratory protection for these conditions of use as listed in Unit IV.A.4.

55. In Unit V.A.1., EPA is requesting comment on whether preventing dermal contact with NMP through dermal PPE, training, and a concentration limit would adequately address the unreasonable risk from dermal exposures for these industrial and commercial use.

56. In Unit V.A.2., EPA is considering and requesting comment on an NMP WCPP – including requirements to prevent direct dermal contact – for some conditions of use of NMP that would be prohibited or otherwise regulated under the proposed regulatory action.

57. Unit V.A.2., EPA is requesting comment on the alternative regulatory action and in particular the likelihood of successful compliance with an NMP WCPP, as described in Unit IV.A., for the conditions of use listed for the alternative regulatory action of NMP WCPP in Unit IV.B.

58. In Unit V.A.2., EPA is soliciting comment on prohibiting for these occupational conditions of use.

59. In Unit V.A.3., EPA is requesting comment on whether to include a self-certification requirement for purchasing NMP or NMP-containing products.

60. In Unit V.A.3., EPA does not believe that biomonitoring methods are standard procedures in most occupational uses and requests public comment if these methods are viable to implement in the workplace.

61. In Unit V.B., EPA is soliciting comments on whether there are products in use or available for sale relevant to these conditions of use that contain NMP 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 NMP.

62. In Unit V.B., EPA is requesting comment on the Alternatives Assessment as a whole.

63. In Unit VI.C., EPA requests comments from the public about the importance of NMP in multiple existing product categories, including the potentially increased future importance of NMP to innovation and as an alternative.

64. In Unit VII.A., EPA is requesting public comment on the sufficiency of an action taken under a Federal law not administered by EPA.

65. In consideration of Panel report recommendations (Ref. 26) 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 comment on whether to allow the use of NMP by entities that could, based on demonstrated ability through recordkeeping and utilization of a combination of controls (including engineering controls, administrative controls, and PPE requirements), eliminate direct dermal contact with NMP to address the unreasonable risk.

• EPA requests comment in the NPRM on reasonable compliance timeframes for small businesses. Specifically, EPA requests comment on whether and how to provide longer compliance timeframes for transitioning to alternatives for uses requiring reformulation. As part of this effort, EPA seeks comment on and consider compliance timelines based on the expected availability of technically and economically feasible alternatives, as well as any information that could be provided based on requirements for certification or standards relevant to pesticides, or as a solvent in products such as industrial cleaners, paint strippers, and oil refining.

• EPA request comments on differing compliance or reporting requirements or timetables that account for the resources available to small entities. Additionally, EPA seeks comment on reasonable compliance timeframes for prohibitions or phase-outs on use of NMP in chemical processing and formulation, in response to SER input and other appropriate factors, such as the lifespan of equipment, capital costs for new equipment and certification, time to research alternatives, and time to reformulate products. In addition, EPA requests comment on any additional appropriate factors for identifying reasonable compliance timeframes and how to weigh the factors for chemical processing, agricultural product manufacturing, petrochemical refining, and other industries.

• EPA requests comment in the NPRM on a *de minimis* level in the case of an impurity or trace amounts of NMP in products.

• EPA requests comment on whether any chemicals identified by the Agency as part of the TSCA risk evaluation process as presenting an unreasonable risk of injury to health or the environment as well as chemicals undergoing risk evaluation would be likely to be considered as viable alternatives and, if so, in which circumstances.

• EPA requests comment on a regulatory approach for those conditions of use where EPA has confidence that exposures to NMP can be effectively controlled, would provide flexibility for regulated entities to incorporate the hierarchy of controls and reduce exposures so that the unreasonable risk is no longer present.

• EPA seeks comment on state of the art equipment, engineering and administrative controls, and monitoring for dermal exposures.

• EPA requests public comment on a limited access program for the sale of products containing NMP that could require training and certification or restrict distribution only to users with certain equipment that could reduce or eliminate dermal exposures or type of facilities.

IX. References

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

1. EPA. Risk Evaluation n-Methylpyrrolidone. December 2020.

2. EPA. Final Revised Unreasonable Risk Determination for n-Methylpyrrolidone, Section 5. December 2022.

3. EPA. n-Methylpyrrolidone (NMP); Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability. *Federal Register*. 87 FR 242, December 19, 2022 (FRL-9943-02-OCSPP).

4. EPA. Alternatives Assessment for Use of n-Methylpyrrolidone. September 2023.

5. EPA. Economic Analysis of the Proposed Regulation of N-Methylpyrrolidone. May 2024.

6. EPA. Chemical Data Reporting. 2020. *https://www.epa.gov/chemical-data-reporting/access-cdr-data*.

7. EPA. Regulatory Actions Pertaining to N-Methylpyrrolidone. May 2024.

8. NIOSH. Hierarchy of Controls. Last Reviewed January 17, 2023. *https://www.cdc.gov/niosh/topics/hierarchy/*.

9. Solomon et al. 1-methyl-2-pyrrolidone (NMP): Reproductive and developmental toxicity study by inhalation in the rat. *http://dx.doi.org/10.3109/01480549509014324*.

10. The American Industrial Hygiene Association (AIHA). OARS WEEL Table.

https://www.tera.org/OARS/#reservations.

11. Saillenfait et al. Developmental toxicity of N-methyl-2-pyrrolidone in rats following inhalation exposure. *http://dx.doi.org/10.1016/S0278-6915(02)00300-9*.

12. Exxon Biomedical Sciences. Multigeneration Rat Reproduction Study with n-Methylpyrrolidone, Project Number 236535.

13. European Union. Regulations. April 18, 2018.

14. Lee et al. Toxicity of N-methyl-2-pyrrolidone (NMP): Teratogenic, subchronic, and two-year inhalation studies. *http://dx.doi.org/10.1016/0272-0590(87)90045-5*.

15. EPA. Memorandum of n-Methylpyrrolidone (NMP): Fenceline Technical Support – Ambient Air Pathway.

16. EPA. Memorandum of n-Methylpyrrolidone (NMP): Fenceline Technical Support – Water Pathway. July 17, 2023.

17. EPA. TSCA Work Plan Chemical Risk Assessment N-Methylpyrrolidone: Paint Stripper Use. March 2015.

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

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

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

21. EPA. EPA Announces Path Forward for TSCA Chemical Risk Evaluations. June 30, 2021. *https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations*.

22. EPA. Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2022–01. March 15–17, 2022. *https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0415-0095*.

23. EPA. Notes from Federalism Consultation on Forthcoming Proposed Rulemakings for Trichloroethylene, Perchloroethylene, and n-Methylpyrrolidone under TSCA Section 6(a). July 22, 2021.

24. EPA. Notes from Tribal Consultations on Forthcoming Proposed Rulemakings for n-Methylpyrrolidone.

25. EPA. Notes from Environmental Justice Consultations on Forthcoming Proposed Rulemakings for n-Methylpyrrolidone (NMP). July 7 and July 13, 2021.

26. Small Business Advocacy Review. Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule for n-Methylpyrrolidone (NMP).

27. EPA. Initial Regulatory Flexibility Analysis (IRFA) for Proposed Regulation of n-Methylpyrrolidone. May 2024.

28. EPA. Public Webinar on n-Methylpyrrolidone (NMP): Risk Evaluation and Risk Management under TSCA Section 6. February 24, 2021.

29. EPA. Stakeholder Meeting List for Proposed Rulemaking for N-Methylpyrrolidone under TSCA Section 6(a).

30. EPA. 2021 Policy on Children's Health. October 5, 2021.

31. EPA. Instructions for Reporting 2020 TSCA Chemical Data Reporting. May 2020.

32. EPA. Revised Titles for the NMP Conditions of Use from the Final Risk Evaluation.

33. EPA. Problem Formulation of the Risk Evaluation for N-Methylpyrrolidone. May 2018.

34. EPA. Supplemental Information on Occupational Exposure Assessment. December

2020.

35. OSHA. Recommended Practices for Safety and Health Programs. October 2016. *https://www.osha.gov/safety-management*.

36. OSHA. Personal Protective Equipment. 2004. *https://www.osha.gov/sites/default/files/publications/osha3151.pdf*.

37. EPA. NMP Supplemental File with Additional Occupational PBPK Runs. December 2023.

38. EPA. Supplemental Data File of Results of Additional Consumer PBPK Runs.

39. DuPont. Meeting with DuPont on NMP Risk Evaluation/Risk Management. September 13, 2023.

40. European Commission. Regulation (EC) No 1907/2006. December 18, 2006.

41. EPA. Supplemental Data File of Results of NMP Air Concentration and Weight Fraction Modeling.

42. Semiconductor Industry Association (SIA). Comments of the Semiconductor Industry Association (SIA) on the Draft Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone (NMP). January 21, 2020.

43. EPA. Meeting with Celanese on Risk Management under TSCA Section 6 for n-Methylpyrrolidone. March 9, 2021.

44. Lithium Ion Cell Manufacturers' Coalition (LICMC). Correspondence from the Lithium Ion Cell Manufacturers' Coalition on Risk Management for n-Methyl pyrrolidone (NMP). September 22, 2023.

45. NASA. NASA - Known Uses of n-Methylpyrrolidone. October 17, 2023.

46. EPA. Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a); Proposed Rule. *Federal Register.* 82 FR 12, January 19, 2017 (FRL-

9958-57).

47. EPA. Withdrawal of Proposed Rules; Discontinuing Three Rulemaking Efforts Listed in the Semiannual Regulatory Agenda. *Federal Register.* 86 FR 10, January 15, 2021 (FRL-10018-67).

48. EPA. Recommendation for an Existing Chemical Exposure Concentration Limit (ECEL) for Occupational Use of N-Methylpyrrolidone (NMP) and Workplace Air Monitoring Methods for NMP [RIN 2070-AK07]. January 2017.

49. OSHA. 29 CFR 1910.1028 Benzene. September 27, 2023.

50. OSHA. 29 CFR 1910.1027 Cadmium. September 27, 2023.

51. OSHA. 29 CFR 1910.1025 Lead. September 27, 2023.

52. EPA. Supporting Statement for an Information Collection Request (ICR) Under the Paperwork Reduction Act (PRA); Regulation of n-Methylpyrrolidone under TSCA Section 6(a).

53. U.S. Consumer Product Safety Commission. What You Should Know About Using Paint Strippers.

54. OMB. Guidance for Implementing Title II of [UMRA]. March 31, 1995.

X. Statutory and Executive Order Reviews

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

A. *Executive Orders 12866: Regulatory Planning and Review and 14094: Modernizing Regulatory Review*

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

12866 review is available in the docket. EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis (Ref. 5) is also available in the docket and is summarized in Unit VI.D.2.

B. *Paperwork Reduction Act (PRA)*

The information collection activities in this proposed rule have been submitted to OMB for review and comment under the PRA, 44 U.S.C. 3501 *et seq*. The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR No. 2786.01 (Ref. 52). You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

There are two primary provisions of the proposed rule that may increase burden under the PRA. The first is downstream notification, which would be carried out by updates to the relevant SDS and which would be required for manufacturers, processors, and distributors in commerce of NMP, who would provide notice to companies downstream upon shipment of NMP 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 is WCPP-related information generation, recordkeeping, and notification requirements (including development of exposure control plans and related recordkeeping; development of documentation for a PPE 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, PPE program implementation documentation including glove testing; and development of self-certification documentation demonstrating eligibility for the WCPP if relevant, and related recordkeeping).

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

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

751).

Estimated number of respondents: 63,749.

Frequency of response: On occasion.

Total estimated burden: 189,534 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $219,812,949 (per year), includes $206,079,628 annualized capital or operation and maintenance costs, specifically glove testing.

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

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs using the interface at *https://www.reginfo.gov/public/do/PRAMain*. Find this particular ICR by selecting "Currently under Review - Open for Public Comments" or by using the search function. OMB must receive comments no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. EPA will respond to ICR-related comments in the final rule.

C. *Regulatory Flexibility Act (RFA)*

As required by section 609(b) of the RFA, the EPA convened a SBAR Panel to obtain advice and recommendations from SERs that potentially would be subject to the rule's requirements. The SBAR Panel evaluated the assembled materials and small-entity comments on

issues related to elements of an IRFA. Prior to convening the Panel, EPA conducted outreach and solicited comments from the SERs. After the Panel was convened, the Panel provided additional information to the SERs and requested their input. SERs involved in the consultation included industries that manufacture fertilizer and other agricultural chemical manufacturing, chemical processors (including oil re-refiners), and formulators of paint and coating removal products. The Panel identified several significant uses of NMP and detailed workplace safety operations for consideration by the Administrator of the EPA that support the stated objectives of TSCA section 6 and minimize impacts of the proposed rule on small entities. The Panel recommended several exposure and reduction practices, including specific engineering and administrative controls and PPE, reviewed information about alternative chemicals, and discussed the regulation of NMP under FIFRA. EPA is including these considerations for the proposed rule and is soliciting comment on others. The report was finalized and transmitted to the EPA Administrator for consideration. A copy of the full SBAR Panel Report is available in the rulemaking docket, including SERs involved, materials presented to SERs, and recommendations. Pursuant to section 603 of the RFA, 5 U.S.C. 601 *et seq*., EPA prepared an initial regulatory flexibility analysis (IRFA) (Ref. 27) 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. NMP was the subject of a risk evaluation under TSCA section 6(b)(4)(A) that was issued in December 2020. In addition, in December 2022, EPA issued a revised unreasonable risk determination that NMP 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 NMP no longer presents such risk.

2. *Objectives and legal basis.*

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines through a TSCA section 6(b) risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must by rule apply one or more requirements listed in 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 NMP 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 NMP or of products containing NMP, and entities engaging in disposal. EPA estimates that the proposal would affect approximately 61,851 small entities. Most (39,215) of these entities are commercial users of NMP in two sectors: fertilizer and other agricultural chemical manufacturing and paints and coatings. EPA also estimates the uses with the next largest numbers of small entities (20,962) using NMP include: paint, coating, and adhesive removers; electronic product and semiconductor manufacturing; waste handling, disposal, treatment, and recycling; adhesives and sealants; cleaning and furniture care products; and soldering.

4. *Projected compliance requirements.*

To address the unreasonable risk EPA has identified, EPA is proposing to: prohibit the manufacture (including import), processing, distribution in commerce, and use of NMP for several occupational conditions of use. To address the unreasonable risk to workers, EPA is also proposing to require container size limits and labeling requirements for the import, processing, and distribution in commerce of NMP products for several consumer uses, to prevent diversion to commercial uses. For most other conditions of use that contribute to the unreasonable risk determination for NMP, EPA proposes to address the unreasonable risk with an NMP WCPP, which would include a combination of requirements including to prevent direct dermal contact with NMP. As described in Unit IV.A., the NMP 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 restrictions. The NMP WCPP would encompass restrictions on most occupational conditions of use and could include provisions for DDCC and ancillary requirements to support implementation of these restrictions. While the NMP WCPP includes stringent requirements that would be necessary to address the unreasonable risk from NMP, because the dermal exposures can be more effectively controlled in a broad range of facilities engaging in a relatively large number of conditions of use, EPA identified a relatively large number of conditions of use where the Agency expected, based on reasonably available information, an NMP WCPP could be successfully implemented. EPA is also proposing to require prescriptive controls, including concentration limits and PPE, for additional occupational conditions of use, instead of requirements for WCPP.

To address unreasonable risks to consumers, EPA proposes to require a concentration limit on NMP for the manufacture (including import), processing, and distribution in commerce of one consumer use.

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 NMP or NMP -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 rulemaking through WCPP would be required to develop and maintain records associated with DDCC compliance (including the exposure control plan, PPE program implementation, basis for specific PPE selection, occurrence and duration of direct dermal contact with NMP, and workplace information and training); and workplace participation. To support and demonstrate compliance, EPA is proposing that each owner or operator of a workplace subject to the WCPP retain compliance records for five years.

Third, EPA is also proposing to require specific prescriptive controls for a few occupational conditions of use of NMP, to restrict the concentration limit and require PPE as detailed in Unit IV.A.3. for imported formulations, processing, distribution in commerce, and use of NMP in those conditions of use. EPA is also proposing to restrict the import, processing, distribution in commerce of NMP for one consumer use in concentrations greater than those specified in Unit III.A.3.c. To support and demonstrate compliance, EPA is proposing that each owner or operator of a workplace subject to the prescriptive controls requirements retain compliance records for five years.

Regarding third-party notification, EPA is not proposing reporting requirements beyond downstream notification, labeling, and self-certification for entities using NMP under the narrowly-applied WCPP for certain uses.

Downstream notification: To ensure compliance with downstream notification for WCPP

EPA is proposing that manufacturers (including importers), processors, and distributors, excluding retailers, of NMP and NMP-containing products provide downstream notification of the prohibitions through the SDS required by OSHA under 29 CFR 1910.1200(g) by adding language as described in Unit IV.A.7.

Labeling: To ensure compliance with the container size restrictions for the products of the uses listed in Unit IV.A.2 EPA is proposing require products to be labeled with the prescribed text in Unit IV.A.2.

Self-certification-related information generation, recordkeeping, and notification requirements. EPA has authority under section 6 of TSCA to require recordkeeping related to the regulatory requirements imposed by EPA. This is especially important where, as here, such records are needed for effective implementation and enforcement of the TSCA section 6 rule to eliminate unreasonable risk. The self-certification would provide potentially exposed persons in a workplace with clear and necessary information and would provide EPA with a necessary evidence mechanism for effective enforcement. The regulated entities would develop, compile, and retain records that are necessary for self-certification compliance, provide workplace notification to potentially exposed persons, and serve as a reference for EPA or authorized entities. These records include a self-certification statement and all records as required by the NMP WCPP.

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 NMP, including retailers of NMP 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 NMP in commerce would be required to modify their SDS or develop another way to inform their customers of the prohibitions and requirements for WCPP. Some entities would also be required to update product labels or containers. 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 NMP in any industrial and commercial capacity that is prohibited would be required to cease under the proposed rule. While this would not require any special skills, the implementation of an alternative chemical or the cessation of use of NMP in a process or equipment may require persons with specialized skills, such as engineers or other technical experts. Instead of developing an alternative method themselves, commercial users of NMP may choose to contract with another entity to do so.

Entities that would be permitted to continue to manufacture, process, distribute, use or dispose of NMP would be required to implement a WCPP and would have to meet the provisions of the program for continued use of NMP. Entities that would be permitted to continue use of NMP in the uses listed in Unit IV.A.4 would be required to implement prescriptive controls, including concentration limits and PPE program restrictions for continued use of NMP. A transition to a WCPP or prescriptive controls may require persons with specialized skills such as an engineer or health and safety professional. Instead of implementing the WCPP or prescriptive controls for themselves, entities that use NMP may choose to contract with another entity to do so. Records would have to be maintained for compliance with a WCPP or prescriptive controls, as applicable. While this recording activity itself may not require a special skill, the information to be measured and recorded may require persons with specialized skills such as an industrial hygienist.

5. *Relevant Federal rules.*

Because of its health effects, NMP is subject to some Federal laws and regulations in the United States and is also subject to regulation by some states and other countries. The following is a summary of the regulatory actions pertaining to NMP; for a full description, see appendix A of the 2020 Risk Evaluation for NMP and the summary in the docket (Ref. 7).

NMP is listed on the Toxics Release Inventory (TRI) pursuant to section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). NMP is regulated on the Federal Food, Drug, and Cosmetic Act (FFDCA) under FFDCA section 408 NMP is currently approved for use as a solvent and co-solvent inert ingredient in pesticide formulations for both food and non-food uses and is exempt from the requirements of a tolerance limit (40 CFR Part 180.920). Under the Clean Air Act (CAA) section 183(e) and section 111(b) NMP is subject to several reporting standards and is listed on the Equipment Leaks Chemical List (40 CFR 68.130).

In addition to regulations administered by EPA, NMP is also subject to other Federal regulations. The Consumer Product Safety Commission (CPSC) issued a fact sheet in 2013, warning the public about hazards of paint and coating removal products, including those containing NMP. The fact sheet included recommendations for PPE when using products containing NMP (Ref. 53). The U.S. Food and Drug Administration (FDA) identifies NMP as an "Indirect Additive Used in Food Contact Substances" and as a Class 2 solvent, namely a solvent that "should be limited in pharmaceutical products because of their inherent toxicity." FDA established a Permissible Daily Exposure (PDE) for NMP of 5.3 mg/day with a concentration limit of 530 ppm, and its Center for Veterinary Medicine developed a method in 2011 for detection of the residues of NMP in edible tissues of cattle (21 CFR 500.1410).

When meeting certain combustibility criteria (i.e., boiling point less than 200° F), NMP may be regulated as a hazardous material by the U.S. Department of Transportation (DOT) when

transported by highway, rail, vessel, or air. As such, transporting NMP may be subject to certain requirements under Section 5103 of the Federal Hazardous Material Transportation Act (49 U.S.C. 5103) and the Hazardous Materials Regulations (HMR; 49 CFR Parts 171 through 180), such as shipping papers, marking, labeling, placarding, etc.

State actions pertaining to NMP include listing NMP in state air regulations. New Hampshire lists NMP as a regulated toxic air pollutant (Env-A 1400: Regulated Toxic Air Pollutants) and Vermont lists NMP as a hazardous air contaminant (Vermont air Pollution Control Regulations, 5261). California has a PEL for NMP of 1 part per million (ppm) as an 8-hr-time-weighted average (TWA) along with a skin notation for NMP (California Code of Regulations, title 8, section 5155). California also lists NMP on Proposition 65 due to reproductive toxicity (Cal. Code Regs. Title 27, Section 27001). California's Office of Environmental Health Hazard Assessment (OEHHA) lists a Maximum Allowable Dose Level (MADL) for inhalation exposure = 3,200 micrograms per day (µg/day) and MADL for dermal exposure = 17,000 µg/day. The California Department of Toxic Substances Control (DTSC) Safer Consumer Products Program lists NMP as a Candidate Chemical for development toxicity and reproductive toxicity. Several other states have adopted reporting laws for chemicals in children's products that include NMP. Minnesota has listed NMP as a chemical of concern to children (Minnesota Statutes 116.9401 to 116.9407).

International actions pertaining to NMP include the listing, in 2011, of NMP on the Candidate list as a Substance of Very High Concern (SVHC) under regulation (EC) No 1907/2006 to the Regulation, Evaluation, Authorisation and Restriction of Chemicals (REACH). In 2018 the European Union added NMP to REACH Annex XVII, the restricted substances list. The restriction includes three conditions: that NMP shall not be placed on the market above 0.3% unless users have chemical safety reports and SDSs with set inhalation and dermal Derived No-

Effect Levels (DNELs); NMP shall not be used above 0.3% unless appropriate risk management measures ensure that the exposure of workers is below the DNELs; and an exclusion from the regulation until May 9, 2024, for the use of NMP as a solvent or reactant in the process of coating wires. Several countries, including Australia, Belgium, Canada, Finland, Poland, and Spain have occupational exposure limits (OELs) for NMP (GESTIS International limit values for chemical agents OELs database, Accessed April 12, 2023).

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 NMP on health and the environment, the magnitude of exposure to NMP of human beings and the environment, the benefits of NMP for various uses, and the reasonably ascertainable economic consequences of the rule. As part of this analysis, EPA considered – in addition to the proposed regulatory action described in Unit IV - a wide variety of control measures to address unreasonable risk from NMP such as point-of-sale self-certification, inhalation or dermal exposure limits, and weight fraction limits. EPA's analysis of these risk management approaches (as well as additional approaches) is detailed in Unit V.A.3. In general, EPA determined that these approaches alone would not be able to address the unreasonable risk. More detail is provided in this Unit and in Unit V.A.3.

Point-of-sale self-certification: As discussed in Unit V.A.3, EPA also examined the extent to which a point-of-sale self-certification requirement in order to purchase and

subsequently use NMP would further ensure that only facilities able to implement and comply with a WCPP or prescriptive controls are able to purchase and use NMP, and self-certify to that. Under a self-certification requirement, entities would submit a self-certification to the distributor each time NMP is purchased. The self-certification would consist of a statement indicating that the facility is implementing a WCPP or required prescriptive controls to control exposures to NMP; the self-certification would be signed and presented by a person authorized to do so by the facility owner or operator. Copies of the self-certification would be maintained as records by both the owner or operator and the distributor where NMP was purchased. While EPA is proposing to include a requirement for self-certification as part of the narrow application of the WCPP for two commercial uses of NMP in paints and coatings and paint, coating, and adhesive removers for DOD, NASA, and their contractors, that narrowly tailored self-certification differs from a broader point-of-sale self-certification requirement that would be applicable to all commercial users of products containing NMP. The self-certification proposed relies on the adherence of a narrowly-defined, highly regulated group of users (DOD, NASA, or their contractors) performing work at clearly defined facilities for specific purposes on mission- or safety-critical components in compliance with the WCPP requirements described in Unit IV.A.3.

In contrast, a broader self-certification requirement would place requirements on large and diverse groups of users and distributors. Because of the number and types of entities where users can obtain NMP or NMP-containing products, EPA does not believe the added requirement and subsequent burden of a point-of-sale self-certification requirement for the use of NMP would be an effective tool for preventing facilities that may be unable to comply with the WCPP or prescriptive controls of this proposed rulemaking from accessing NMP or NMP-containing products. As such, EPA is not proposing a self-certification requirement as an additional component of the requirements for addressing the unreasonable risk of occupational exposures to

NMP.

Inhalation or dermal exposure limit: As discussed in Unit III.B.2, the 2020 Risk Evaluation for NMP assessed exposure from inhalation, dermal, and vapor through skin exposure, and identified that the unreasonable risk of injury to human health is mainly driven by direct dermal contact with NMP. EPA identified that the best representative endpoints for non-cancer effects were from acute (developmental toxicity) and chronic (reproductive toxicity) exposures for all conditions of use. Additional risks associated with other adverse effects (e.g., liver toxicity, kidney toxicity, immunotoxicity, neurotoxicity, irritation and sensitization) were identified. Therefore, EPA is proposing dermal exposure controls (or, as needed, prohibitions) to prevent direct dermal contact with NMP. While inhalation risks contribute to the unreasonable risk from NMP, addressing inhalation risks alone would not mitigate the unreasonable risk from NMP. As discussed in Unit V.A.3 of the proposed rule, EPA also examined the extent to which setting an Existing Chemical Exposure Limit (ECEL) or a dermal exposure limit as a regulatory action would address the unreasonable risk by inhalation and dermal exposures. EPA is not proposing an ECEL because the unreasonable risk to workers from NMP is driven by dermal exposures, and an ECEL would only address risk from inhalation and vapor-through-skin (dermal exposure to vapor but not direct dermal contact with a liquid) exposures. Therefore, requirements to meet an ECEL would not address the unreasonable risk from dermal exposure. EPA is also not proposing an existing chemical dermal exposure limit because biomonitoring methods, such as blood concentration testing or urine analysis to measure compliance to a dermal exposure limit, may not be readily available or feasible for most workplaces to implement. EPA does not believe that biomonitoring methods are standard procedures in most occupational uses. As such, EPA is not proposing an inhalation or dermal exposure requirement for addressing the unreasonable risk of occupational exposures to NMP.

Weight fraction limit: To address the unreasonable risk, EPA also considered limiting the weight fraction of NMP in products and formulations without requirements for dermal or respiratory PPE. As described in Unit V.A.1.a., EPA determined that the unreasonable risk from NMP would not be contributed to by use of products containing NMP at less than 0.1% by weight. However, for all industrial/commercial and consumer conditions of use, the concentration limit of 0.1% is so low that it is highly unlikely that NMP would still serve its functional purpose in the product or formulation. EPA thus concluded that a weight fraction restriction without accompanying PPE requirements would essentially function as a prohibition. for the conditions of use listed in Unit IV.A.2, and EPA therefore did not propose a weight fraction for those occupational conditions of use. EPA is however proposing a de minimis level for products containing NMP at levels of less than 0.1% to account for impurities that do not contribute to the unreasonable risk., as described in Unit IV.A.1.b.

Additionally, in the proposed rule preamble 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 proposed rule differs from the proposed regulatory action by providing for a WCPP, including DDCC, for some conditions of use that would be prohibited or have prescriptive controls under the proposed regulatory action. Additionally, the primary alternative regulatory action includes prohibitions for one industrial and commercial use and the manufacturing, processing, and distribution in commerce for one consumer use; all of which would be required to have prescriptive controls under the proposed regulatory action. The primary alternative regulatory action would not include restrictions on the container size of consumer products that may feasibly be used for commercial purposes. In its review of

alternatives, EPA determined that some methods either did not effectively address the unreasonable risk presented by NMP or there was uncertainty about whether facilities in conditions of use would be able to comply with a comprehensive WCPP to adequately protect potentially exposed persons. While EPA is soliciting comments about all aspects on each of the alternative regulatory actions, which may be incorporated into the final rulemaking, EPA has considered the primary alternative regulatory actions and found that the proposed action is more suitable for addressing the unreasonable risk to the extent necessary so that NMP no longer presents such risk, while also allowing flexibility for regulated entities to continue operations, as described in more detail in Unit IV.A. and V.A. Estimated costs of the primary alternative regulatory action can be found in chapter 7 of the Economic Analysis (Ref. 5).

D. *Unfunded Mandates Reform Act (UMRA)*

This action contains a Federal mandate under UMRA, 2 U.S.C. 1531–1538, that may result in expenditures of $100 million or more for State, local and Tribal governments, in the aggregate, or the private sector in any one year. Accordingly, the EPA has prepared a written statement required under UMRA section 202 and section 205. The statement is included in the docket for this action and is briefly summarized here.

EPA estimated the compliance costs of the proposed rule to the private sector to be approximately $396 million annualized over 20 years at a 3% discount rate and $397 million annualized over 20 years at a 7% discount rate. However, the costs of the rule to the private sector are difficult to completely quantify. It is difficult to predict firm behavior in response to regulation in the absence of firm specific revenue and cost and there are few sources that provide direct estimates for number of firms using NMP. As described in more detail in Units I.E. and VI.D.2. and Table 7-38 of the Economic Analysis (Ref. 5), EPA estimated costs assuming all firms using NMP comply with the proposed rule. Thus, the Agency concludes the cost of the rule

to the private sector may exceed the inflation-adjusted UMRA threshold of $100 million in costs in any one year.

State, local, and Tribal governments are not expected to incur large costs because of the proposed rule since they are not known to engage in the manufacture, processing, distribution, or large-scale use of NMP. Costs to State, local and Tribal governments from this proposed rule would result from requirements related to disposal of NMP or products containing NMP, which are estimated to be less than $8 million annualized over 20 years at a 3% discount rate and 7% discount rate. In addition, if State, local and Tribal governments engage in various conditions of use of NMP for commercial use, they may need to switch to different products that no longer contain NMP or change the types of PPE workers wear when using NMP. EPA has identified many alternative products currently available at comparable prices. Since there is not a significant intergovernmental mandate, there is no need for Federal financial assistance (e.g., grants or loans) or other Federal resources from either EPA or other Federal agencies to assist state, local, or Tribal governments in complying with the rule.

The rule's benefits include the prevention of the risk of numerous adverse health effects from NMP exposure. In addition to EPA's 2020 Risk Evaluation for NMP, many authorities have determined acute exposure to NMP may pose risks of developmental toxicity, notably irreversible fetal death. NMP chronic exposure is known to present risks of various non-cancer adverse health effects, including liver toxicity, kidney toxicity, reduced male fertility and reduced female fecundity impacts, and reproductive toxicity effects, notably low-birth weight.

The economic impact of a regulation on the national economy is generally considered to be measurable only if the economic impact of the regulation reaches 0.25 percent to 0.5 percent of GDP (Ref. 54). Given the current GDP of $23.17 trillion, this is equivalent to a cost of $58 billion to $116 billion. Therefore, EPA has concluded that this rulemaking is highly unlikely to

have any measurable effect on the national economy. Additional information on EPA's estimates of the benefits and costs of this action are provided in Units I.E. and VI.D.2. and in the Economic Analysis for this action (Ref. 5). Information on the authorizing legislation is provided in Unit I.B. Information on prior consultations with affected State, local, and Tribal governments is provided in Unit III.A.1.

This action is not subject to the requirements of UMRA section 203 because it contains no regulatory requirements that might significantly or uniquely affect small governments.

E. *Executive Order 13132: Federalism*

EPA has concluded that this action has federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because regulation of NMP under TSCA section 6(a) may preempt state law. As set forth in TSCA section 18(a)(1)(B), the issuance of rules under TSCA section 6(a) to address the unreasonable risk presented by a chemical substance has the potential to trigger preemption of laws, criminal penalties, or administrative actions by a state or political subdivision of a state that are: 1) Applicable to the same chemical substance as the rule under TSCA section 6(a); and 2) Designed to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of that same chemical. TSCA section 18(c)(3) applies that preemption only to the "hazards, exposures, risks, and uses or conditions of use" of such chemical included in the final TSCA section 6(a) rule.

EPA provides the following preliminary federalism summary impact statement. The Agency consulted with state and local officials early in the process of developing the proposed action to permit them to have meaningful and timely input into its development. This included background presentation on September 9, 2020, and a consultation meeting on July 22, 2021. EPA invited the following national organizations representing state and local elected officials to these meetings: American Water Works Association, Association of Clean Water

Administrators, Association of Metropolitan Water Agencies, Association of State Drinking Water Administrators, Environmental Council of the States, National Association of Counties, National Conference of State Legislatures, National Governors Association, National League of Cities, National Water Resources Association, and United States Conference of Mayors. During the consultation, stakeholders in attendance recommended additional reporting requirements as a risk management tool to address the unreasonable risk, suggested EPA look into safer alternatives, and described concerns related to current impacts on drinking water utilities from NMP (Ref. 23). A summary of the meeting with these organizations, including the views that they expressed, is available in the docket (Ref. 23). EPA provided an opportunity for these organizations to provide follow-up comments in writing but did not receive any such comments.

F. *Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. This rulemaking would not have substantial direct effects on Tribal governments because NMP is not manufactured, processed, or distributed in commerce by tribes. NMP 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.

Notwithstanding the lack of Tribal implications as specified by Executive Order 13175, EPA met with Tribal representatives on this action, consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, which EPA applies more broadly than Executive Order 13175. EPA scheduled consultations with representatives of Tribes via webinar on June 14, 2021, and July 14, 2021, concerning the prospective regulation of NMP under TSCA

section 6(a). No attendance on June 14, 2020, resulted in the first scheduled consultation to be canceled. Tribal officials were given the opportunity to meaningfully interact with EPA risk managers concerning the current status of risk management. During the consultation, EPA discussed risk management under TSCA section 6(a), findings from the 2020 Risk Evaluation for NMP, types of information to inform risk management, principles for transparency during risk management, and types of information EPA is seeking from Tribes (Ref. 24). EPA briefed Tribal officials on the Agency's risk management considerations and tribal officials raised no related issues or concerns to EPA during or in follow-up to those meetings (Ref. 24). Tribal members were encouraged to provide additional comments after the teleconferences.

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

This action is subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is a significant regulatory action under section 3(f)(1) of Executive Order 12866, and EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children due to reproductive and developmental health effects associated with NMP exposure. Accordingly, we have evaluated the environmental health effects of NMP exposure and associated health impacts on children and adults of reproductive age.

For infants and males and females of reproductive age, EPA found evidence of reproductive and developmental toxicity. The reproductive and developmental health effects of concern related to exposures to NMP are reduced male fertility and female fecundity and post-implantation loss (resorptions and fetal mortality). The results of this evaluation are in the 2020 Risk Evaluation for NMP (available in the public docket for this action) and in Unit III.A.3 and Unit VI.A.

This proposed action is preferred over other regulatory options analyzed because it will

reduce to the greatest extent the exposure to NMP for the general population and for potentially exposed or susceptible subpopulations such as children and adults of reproductive age through a combination of prohibition, and prescriptive and non-prescriptive controls, including PPE use.

Furthermore, EPA's 2021 Policy on Children's Health also applies to this action. Information on how the Policy was applied is discussed in Unit III.A.3.

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

This action is not a "significant energy action" under Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

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 establishing that selected PPE would be impervious for the expected duration and conditions of exposure to NMP. 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 report cumulative permeation rate as a function of time. Some examples of methods which meet the criteria are included in appendix F of the 2020 Risk Evaluation (Ref. 1) and

described in Unit VI.A.3. EPA recognizes that there may be voluntary consensus standards that meet the proposed criteria. EPA requests comments on whether it should incorporate such voluntary consensus standards in the rule and seeks information in support of such comments regarding the availability and applicability of voluntary consensus standards that may achieve the sampling and analytical requirements of the rule in lieu of the PBMS approach.

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

EPA believes that the human health or environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with environmental justice concerns in accordance with Executive Orders 12898 (59 FR 7629, February 16, 1994) and 14096 (88 FR 25251, April 26, 2023). As described more fully in the Economic Analysis, EPA conducted an EJ analysis to characterize the baseline conditions faced by communities and workers affected by the regulation to identify the potential for disproportionate impacts on various communities. Informed by the fenceline analysis referenced in Unit VI.A., exposure to NMP is primarily experienced by consumers using NMP-containing products and workers and occupational non-users directly on site. The baseline characterization suggests residents of nearby communities within one mile and three miles are more likely to be People of Color and low-income relative to the general population in affected locations. Workers in the industries assessed, including industrial and miscellaneous chemical and paint, coating and adhesives, are less likely to be People of Color and low-income when analyzed using national industry data; however, local variation is obscured and the use of county-industry data suggests workers in affected counties with basic chemical manufacturing NMP facilities have larger representation of non-White, including

Hispanic, workers and female workers ages 25-44. There is possible aggregate exposure concern for nearby communities given clustering of NMP facilities relative to other NMP facilities and possible cumulative exposure concern with nearby clustered TRI facilities that may also release or use other chemicals. Other indicators of cumulative concern include elevated cancer risk and PM 2.5 values for nearby communities one mile and three miles away from NMP facilities. Communities also exhibited slightly elevated perinatal mortality and very low birthweight rates, health end points of concern from NMP exposure. Note, these are indicators and not precise measures of actual risk and data limitations restrict the ability to causally link these health end points to specific facilities or workers (Ref. 1).

EPA believes that this action is likely to reduce existing disproportionate and adverse effects on communities with EJ concerns. While the regulatory options are anticipated to address the unreasonable risk from exposure to NMP to the extent necessary so that it is no longer unreasonable, EPA is not able to quantify the distribution of the change in risk across affected workers, communities, or demographic groups. EPA is also unable to quantify the changes in risks to workers, communities, and demographic groups from non-NMP-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. 5).

EPA additionally identified and addressed EJ concerns by conducting outreach to advocates in affected communities that might be subject to disproportionate exposure to NMP. On July 7, 2021, and July 13, 2021, EPA held public meetings as part of this consultation (Ref. 25). See also Unit III.A.1. These meetings were held pursuant to Executive Order 12898 and Executive Order 14008, entitled “Tackling the Climate Crisis at Home and Abroad” (86 FR 7619, February 1, 2021).

Following the EJ meetings, EPA received one written comment, in addition to oral comments provided during the consultations. In general, commenters supported strong outreach to affected communities, encouraged EPA to follow the hierarchy of controls, favored prohibitions, and noted the uncertainty, and in some cases inadequacy, of PPE. Other commenters asked about the Agency's schedule for a proposed rule while reconsidering certain aspects of the 2020 Risk Evaluation. Additionally, commenters expressed concern that the adverse health impacts of NMP, particularly to pregnant people and children and urged EPA to ban the use of NMP in paint and coating removers, for the reasons discussed in this unit EPA is not proposing this ban (Ref. 25).

The information supporting this Executive Order review is contained in Units I.E., II.D., III.A.1., VI.A., and in the Economic Analysis (Ref. 5). 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. 25).

List of Subjects in 40 CFR Part 751

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

Michael S. Regan,

Administrator.

Therefore, for the reasons stated in the preamble, EPA proposes to amend 40 CFR part 751 as follows:

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

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

Authority: 15 U.S.C. 2605, 15 U.S.C. 2625(l)(4)

2. Amend § 751.5 by adding in alphabetical order definitions for "Authorized person", "Direct dermal contact", "Exposure group", "Owner or operator", "Potentially exposed person", 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 or restricted area.

* * * * *

Direct dermal contact means direct handling of a chemical substance or mixture or skin contact with surfaces that may be contaminated with a chemical substance or mixture.

* * * * *

Exposure group means a group consisting of every person performing the same or substantially similar operations in each work shift, in each job classification, in each work area where exposure to chemical substances or mixtures is reasonably likely to occur.

Owner or operator means any person who owns, leases, operates, controls, or supervises a workplace covered by this part.

* * * * *

Potentially exposed person means any person who may be occupationally exposed to a

chemical substance or mixture in a workplace as a result of a condition of use of that chemical substance or mixture.

Restricted area means an area established by the regulated entity to demarcate areas where direct dermal contact with a specific chemical substance may occur.

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 a new subpart C to read as follows:

Subpart C—n-Methylpyrrolidone

Sec.

751.201 General.
751.203 Definitions.
751.205 Prohibitions of manufacturing, processing, distribution in commerce, and use.
751.207 Concentration limits, container size limits, and labels
751.209 Workplace Chemical Protection Program.
751.211 Prescriptive workplace requirements.
751.213 Recordkeeping requirements.
751.215 Downstream notification.
751.217 Mission- or safety-critical uses of paint, coating, or adhesive removers or paints and coatings.

Subpart C—n-Methylpyrrolidone (NMP)

§ 751.201 General.

(a) *Applicability*. This subpart establishes prohibitions and restrictions on the manufacture (including import), processing, distribution in commerce, use, and disposal of n-methylpyrrolidone (CASRN 872-50-4) (NMP), to prevent unreasonable risks of injury to health

in accordance with TSCA section 6(a).

(b) *De minimis level.*Unless otherwise specified in this subpart prohibitions and restrictions of this subpart do not apply to products containing NMP at levels less than 0.1 percent by weight.**§ 751.203 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 § 751.213.

§ 751.205 Prohibitions of manufacturing, processing, distribution in commerce, and use.

(b) *Prohibitions.* (1) After [DATE 12 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from manufacturing (including importing) NMP for the uses listed in paragraphs (a)(1) and (2) of this section.

(2) After [DATE 15 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from processing NMP, including any NMP-containing products, for the conditions of use listed in paragraphs (a)(1) and (2) of this section.

(3) After [DATE 18 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from distributing in commerce (including making available) NMP, including any NMP-containing products, to retailers for the conditions of use listed in paragraph (a)(2) of this section.

(4) After [DATE 21 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons and retailers are prohibited from distributing in commerce (including making available) NMP, including any NMP containing

products, for the conditions of use listed in paragraph (a)(2) of this section.

(5) After [DATE 24 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from industrial and commercial use of NMP, including any NMP-containing products, for the conditions of use listed in paragraphs (a)(2) of this section.

(a) *Applicability.* The provisions of this section apply to the following, as indicated in each paragraph of this section:

(1) Processing incorporation into articles in lubricants and lubricant additives in machinery manufacturing.

(2) Industrial and commercial conditions of use:

(i) Industrial and commercial use in anti-freeze and de-icing products, automotive care products, and lubricants and greases;

(ii) Industrial and commercial use in metal products not covered elsewhere and lubricant and lubricant additives including hydrophilic coatings;

(iii) Industrial and commercial use in cleaning and degreasing, and cleaning and furniture care products, including wood cleaners and gasket removers; and

(iv) Industrial and commercial uses in fertilizer and other agricultural chemical manufacturing-processing aids and solvents.

§ 751.207 Concentration limits, container size limits, and labels.

(a) *Applicability.* The provisions of this section apply to the following, as indicated in each paragraph of this section.

(1) Processing incorporation into articles in paint additives and coating additives in transportation equipment manufacturing.

(2) Industrial and commercial conditions of use:

(i) Industrial and commercial use in paints, coatings, and adhesive removers, except for paint, coating, and adhesive removers for mission- or safety-critical components of aircraft, spacecraft, and vessels that are owned or operated by the U.S. Department of Defense and the National Aeronautics and Space Administration used in accordance with the requirements listed in § 751.217;

(ii) Industrial and commercial use in paints and coatings in lacquers, stains, varnishes, primers and floor finishes, and powder coatings in surface preparation, except for paints and coatings for mission- or safety-critical components of aircraft, spacecraft, and vessels that are owned or operated by the U.S. Department of Defense and the National Aeronautics and Space Administration used in accordance with the requirements listed in § 751.217;

(iii) Industrial and commercial use in paint additives and coating additives in construction, fabricated metal product manufacturing, machinery manufacturing, other manufacturing, paint and coating manufacturing, primary metal manufacturing, transportation equipment manufacturing, wholesale and retail trade;

(iv) Industrial and commercial use in adhesives and sealants including binding agents, single component glues and adhesives, including lubricant adhesives and two component glues and adhesives including some resins, excluding industrial and commercial use in specific adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants for aviation parts;

(v) Industrial and commercial use in ink, toner, and colorant products in printer ink; and

(vi) Industrial and commercial use in soldering materials;

(3) Consumer conditions of use:

(i) Consumer use in paint and coating removers;

(ii) Consumer use in adhesive removers;

(iii) Consumer use in paints and coatings in lacquer, stains, varnishes, primers and floor finishes;

(iv) Consumer use in paint additives and coating additives in paints and arts and crafts paints;

(v) Consumer use in automotive care products;

(vi) Consumer use in cleaning and furniture care products, including wood cleaners, gasket removers;

(vii) Consumer use in lubricant and lubricant additives, including hydrophilic coatings; and

(viii) Consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives.

(b) *Concentration limits.* (1) Beginning [DATE 12 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] all persons are prohibited from importing NMP formulations and products containing:

(i) More than 45 percent by weight of NMP for the conditions of use listed in paragraphs (a)(1), (a)(2)(ii) through (iv), and (a)(3)(viii) of this section with more than 45 percent by weight of NMP.

(ii) More than 30 percent by weight of NMP for the conditions of use listed in paragraph (a)(2)(i) of this section.

(iii) More than 5 percent by weight of NMP for the condition of use listed in paragraph (a)(2)(v) of this section.

(iv) More than 1 percent by weight of NMP for the condition of use listed in paragraph (vi) of this section.

(2) Beginning [DATE 15 MONTHS AFTER THE DATE OF PUBLICATION OF THE

FINAL RULE IN THE *FEDERAL REGISTER*] all persons are prohibited from processing NMP into formulations and products containing:

(i) More than 45 percent by weight of NMP for the conditions of use listed in paragraphs (a)(1), (a)(2)(ii) though (iv) and (a)(3)(viii) of this section with more than 45 percent by weight of NMP.

(ii) More than 30 percent by weight of NMP for the conditions of use listed in paragraph (a)(2)(i) of this section.

(iii) More than 5 percent by weight of NMP for the condition of use listed in paragraph (a)(2)(v) of this section.

(iv) More than 1 percent by weight of NMP for the condition of use listed in paragraph (a)(2)(vi) of this section.

(3) After [DATE 18 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from distributing in commerce (including making available) NMP and NMP-containing products to retailers for:

(i) More than 45 percent by weight of NMP the conditions of use listed in paragraphs (a)(1), (a)(2)(ii) through (iv), and (a)(3)(viii) of this section.

(ii) More than 30 percent by weight of NMP for the conditions of use listed in paragraph (a)(2)(i) of this section.

(iii) More than 5 percent by weight of NMP for the condition of use listed in paragraph (a)(2)(v) of this section.

(iv) More than 1 percent by weight of NMP for the condition of use listed in paragraph (a)(2)(vi) of this section.

(4) After [DATE 21 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from distributing in

commerce (including making available) NMP and NMP-containing products containing:

(i) More than 45 percent by weight of NMP for the conditions of use listed in paragraphs (a)(1), (a)(2)(ii) through (iv), and (a)(3)(viii) of this section.

(ii) More than 30 percent by weight of NMP for the condition of use listed in paragraph (a)(2)(i) of this section.

(iii) More than 5 percent by weight of NMP for the condition of use listed in paragraph (a)(2)(v) of this section.

(iv) More than 1 percent by weight of NMP and for the condition of use listed in paragraph (a)(2)(vi) of this section.

(5) After [DATE 24 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons are prohibited from commercial use of NMP and NMP-containing products containing:

(i) More than 45 percent by weight of NMP for the conditions of use listed in paragraphs (a)(1) and (a)(2)(ii) through (iv) of this section.

(ii) More than 30 percent by weight of NMP for the condition of use listed in paragraph (a)(2)(i) of this section.

(iii) More than 5 percent by weight of NMP for the condition of use listed in paragraph (a)(2)(v) of this section.

(iv) More than 1 percent by weight of NMP and for the condition of use listed in paragraph (a)(2)(vi) of this section.

(c) *Container size restrictions and labels.* (1) After [DATE 12 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all persons, including retailers, are prohibited from processing and distributing in commerce (including making available) NMP or NMP-containing products in containers with a volume

more than 16 ounces for the conditions of use listed in paragraphs (a)(3)(i) through (vii) of this section.

(2) After [DATE 12 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], all processors and distributors in commerce of NMP or NMP-containing products for the conditions of use listed in paragraphs (a)(3)(i) through (vii) of this section must provide a label securely attached to each product. Label information must be prominently displayed and in an easily readable font size, with the sentence "This product is only for sale in containers of 16 ounces or less and is for consumer use only" in bold print or a larger font for emphasis. Each label must contain the following text:

> This product contains n-methylpyrrolidone (NMP) (CASRN 872-50-4), also called n-methyl-2-pyrrolidone or 1-methyl-2-pyrrolidone, a chemical determined by the Environmental Protection Agency to present unreasonable risk of injury to health under the Toxic Substances Control Act (TSCA), based on developmental and reproductive effects. The use of NMP is restricted under 40 CFR part 751, subpart C. **This product is only for sale in containers of 16 ounces or less and is for consumer use only.** This product shall not be used for commercial purposes.

§ 751.209 Workplace Chemical Protection program.

(a) *Applicability*. The provisions of this section apply to workplaces engaged in the following conditions of use of NMP, unless otherwise indicated: (1) Manufacturing (domestic manufacture).

(2) Manufacturing (import).

(3) All processing, except for the following:

(i) The processing described in § 751.205(a);

(ii) The processing described in § 751.207(a); and

(iii) The processing described in § 751.211(a).

(4) All industrial and commercial use, except for the following:

(i) Those industrial and commercial uses presented in § 751.205(a);

(ii) Those industrial and commercial uses presented in § 751.207(a); and

(iii) Those industrial and commercial uses presented in § 751.211(a).

(5) Disposal.

(b) *Direct Dermal Contact Controls (DDCC)*. The provisions of this paragraph (b) apply to any workplace engaged in the conditions of use listed in paragraph (a) of this section. (1) Beginning [DATE 36 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, [DATE 12 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] for other owners and operators, or within 30 days of introduction of NMP into the workplace, owners or operators must ensure that all persons are separated, distanced, physically removed, or isolated from direct dermal contact with NMP in accordance with the requirements of paragraph (c)(1)(i) of this section and, if necessary, paragraph (e) of this section.

(2) Owners or operators must comply with all applicable provisions of paragraphs (c) through (f) of this section.

(c) *Exposure control procedures and plan*. (1) *Methods of compliance.* (i) The owner or operator must institute one or a combination of elimination, substitution, engineering controls, or administrative controls to prevent all persons from direct dermal contact with NMP except to the extent that the owner or operator can demonstrate that such controls are not feasible.

(ii) Wherever the feasible exposure controls, including one or a combination of elimination, substitution, engineering controls or administrative controls, required under paragraph (c)(1)(i) of this section, which can be instituted are not sufficient to prevent direct dermal contact, the owner or operator must use them to reduce direct dermal contact to the extent achievable and must supplement those controls with the use of dermal PPE that complies with

the requirements of paragraph (e) of this section. Where an owner or operator cannot demonstrate direct dermal contact is prevented, including through the use of engineering controls or work practices, and has not demonstrated that it has supplemented feasible exposure controls with sufficient dermal PPE that complies with the requirements of paragraph (e) of this section, this will constitute a failure to comply with the direct dermal contact control requirements.

(iii) The owner or operator must maintain the effectiveness of engineering controls and administrative controls instituted under paragraph (c)(1)(i) of this section.

(iv) The owner or operator must document their exposure control strategy and implementation in an exposure control plan in accordance with paragraph (c)(2) of this section.

(2) *Exposure control plan requirements.* Beginning [DATE 36 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, or [DATE 12 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] for other owners and operators, owners and operators must include and document in an exposure control plan the following:(i) Identification and rationale of exposure controls used or not used in the following sequence: elimination of NMP, substitution of NMP, engineering controls and administrative controls to prevent or reduce direct dermal contact with NMP 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 restricted areas and how it is demarcated, and identification of authorized persons; and description of when the owner or operator expects exposures may be likely to result in direct dermal contact;

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

(vii) Occurrence and duration of any start-up, shutdown, or malfunction of the facility that causes any direct dermal contact with NMP and subsequent corrective actions taken during start-up, shutdown, or malfunctions to mitigate exposures to NMP; and

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

(d) *Restricted areas.* (1) Beginning [DATE 36 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] for Federal agencies and Federal contractors acting for or on behalf of the Federal Government, or [DATE 12 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] for other owners and operators, the owner or operator who has implemented all feasible engineering, work practice and administrative controls as required in paragraph (b) of this section wherever direct dermal contact with NMP may occur must establish a restricted area.

(2) The owner or operator must limit access to restricted areas to authorized persons.

(3) The owner or operator must demarcate restricted areas from the rest of the workplace in a manner that adequately establishes and alerts persons to the boundaries of the restricted area and minimizes the number of authorized persons exposed to NMP within the restricted area.

(4) Whenever any direct dermal contact with NMP may occur within the restricted area the owner or operator must supply and ensure all persons are using dermal PPE that complies

with the requirements of paragraph (e) of this section.

(5) The owner or operator must ensure that, within a restricted area, persons do not engage in non-work activities that may increase direct dermal contact exposure to NMP.

(e) *Personal Protective Equipment (PPE)*. (1) The provisions of this paragraph (e) apply to any owner or operator that is required to provide dermal protection pursuant to paragraph (c) of this section or respiratory protection pursuant to § 751.211(b)(2). (2) PPE, including respiratory and dermal protection, that is of safe design and construction for the work to be performed must be provided, used, and maintained in a sanitary, reliable, and undamaged condition. Owners and operators must select PPE that properly fits each affected person and communicate PPE selections to each affected person.

(3) Owners and operators must provide PPE training in accordance with 29 CFR 1910.132(f) to all persons required to use PPE prior to or at the time of initial assignment to a job involving potential exposure to NMP. For the purposes of this paragraph (e)(3) of this section, provisions in 29 CFR 1910.132(f) applying to an "employee" also apply equally to potentially exposed persons, and provisions applying to an "employer" also apply equally to owners or operators.

(4) Owners and operators must retrain each potentially exposed person required to use PPE annually or whenever the owner or operator has reason to believe that a previously trained person does not have the required understanding and skill to properly use PPE, or when changes in the workplace or in PPE to be used render the previous training obsolete.

(5) *Dermal protection.* (i) The owner or operator must supply and require the donning of dermal PPE that provides an impermeable barrier to prevent direct dermal contact with NMP in the specific work area where it is selected for use, selected in accordance with this paragraph, to each person who is reasonably likely to be dermally exposed in the work area through direct

dermal contact with NMP. (ii) Owners or operators must select and provide dermal PPE as specified in paragraph (e)(5) of this section, and in accordance with 29 CFR 1910.133(b), to each person who is reasonably likely to be dermally exposed in the work area through direct dermal contact with NMP. For the purposes of this paragraph (e)(5)(ii), the provisions in 29 CFR 1910.133(b) applying to an "employer" also apply equally to owners or operators.

(iii) Owners or operators must select and provide to persons appropriate dermal PPE based on an evaluation of the performance characteristics of the PPE relative to the task(s) to be performed, conditions present, and the duration of use. Such appropriate dermal PPE must at minimum include, but is not limited to, the following items:

(A) Impervious gloves selected based on specifications from the manufacturer or supplier.

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

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

(6) *Respiratory protection*. (i) The owner or operator must supply a respirator in accordance with 751.211(b) and ensure that all persons using NMP-containing products for those uses specified therein are using the provided respirators. (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 (d)(3)(i)(B)) and as specified in this paragraph. For the purposes of this paragraph (e), provisions in 29 CFR 1910.134(a) through (l) (except (d)(1)(iii) and (d)(3)(i)(B)) applying to an "employee" also apply equally to potentially exposed persons, and provisions applying to an "employer" also apply equally to owners or operators.

(iii) The respiratory protection requirements in § 751.211(b) represent the minimum respiratory protection requirements, such that any respirator affording a higher degree of protection than the required respirator may be used.

(f) *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 NMP.

(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 NMP:

(i) The requirements of this paragraph (f), as well as a means to access or obtain a copy of these requirements in the workplace;

(ii) The quantity, location, manner of use, release, and storage of NMP and the specific operations in the workplace that could result in exposure to NMP, particularly noting where there is potential for direct dermal contact or inhalation exposure with NMP;

(iii) The principles of safe use and handling of NMP and measures potentially exposed persons can take to protect themselves from NMP, including specific procedures the owner or operator has implemented to protect potentially exposed persons from exposure to NMP, such as appropriate work practices, emergency procedures, and PPE to be used;

(iv) Methods and observations that may be used to detect the presence or release of NMP

in the workplace; and

(v) The health hazards of NMP in the workplace.

(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 NMP in the workplace.

(5) Whenever there are workplace changes, such as modifications of tasks or procedures or the institution of new tasks or procedures, that increase potential for direct dermal contact or inhalation exposures, the owner or operator must update the training as necessary to ensure that each potentially exposed person has the requisite proficiency.

§ 751.211 Prescriptive workplace requirements.

(a) *Applicability*. The provisions of this section apply to the workplaces engaged in the following conditions of use of NMP, unless otherwise indicated: (1) Processing incorporation into articles in paint additives and coating additives in transportation equipment manufacturing.

(2) Industrial and commercial conditions of use:

(i) Industrial and commercial use in paints, coatings, and adhesive removers, except for those used listed in § 751.217(a);

(ii) Industrial and commercial use in paints and coatings in lacquers, stains, varnishes, primers and floor finishes, and powder coatings in surface preparation, except for those used listed in § 751.217(a);

(iii) Industrial and commercial use in paint additives and coating additives in construction, fabricated metal product manufacturing, machinery manufacturing, other manufacturing, paint and coating manufacturing, primary metal manufacturing, transportation equipment manufacturing, wholesale and retail trade;

(iv) Industrial and commercial use in adhesives and sealants including binding agents,

single component glues and adhesives, including lubricant adhesives and two component glues and adhesives including some resins, excluding industrial and commercial use in specific adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants for aviation parts;

(v) Industrial and commercial use in ink, toner, and colorant products in printer ink; and

(vi) Industrial and commercial use in soldering materials.

(b) *Prescriptive controls*. (1) The provisions of this paragraph (b) apply to any workplace engaged in the conditions of use listed in paragraph (a) of this section. (2) *Personal Protective Equipment (PPE).* (i) The provisions of this paragraph (b) apply after [DATE 12 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*] (ii) For the conditions of use listed in paragraphs (a)(1) and (a)(2)(ii) through (iv) of this section, owners or operators must ensure that all persons using NMP-containing products are provided with dermal protective equipment as required in § 751.209(e)(2) and (5), any NIOSH Approved® air-purifying respirator equipped with organic vapor cartridges or canisters (minimum APF 10) as required in § 751.209(e)(6), and training on proper use of PPE as required in § 751.209(e)(3) and (4).

(A) For the condition of use listed in paragraph (a)(2)(i) of this section, owners or operators must ensure that all persons using NMP-containing products are provided with dermal protective equipment as required in § 751.209(e)(2) and (5), any NIOSH Approved® air-purifying respirator equipped with organic vapor cartridges or canisters; any NIOSH Approved® powered air-purifying respirator equipped with organic vapor cartridges; or any NIOSH Approved® continuous flow supplied air respirator equipped with a hood or helmet (minimum APF 25) as required in § 751.209(e)(6), and training on proper use of PPE as required in § 751.209(e)(3) and (4).

(B) For the conditions of use listed in paragraphs (a)(2)(v) and (vi) of this section, owners or operators must ensure that all persons using NMP-containing products are provided with dermal protective equipment as required in § 751.209(e)(2) and (5) and training on proper use of PPE as required in § 751.209(e)(3) and (4).

§ 751.213 Recordkeeping requirements.

(a) *General records*. After [DATE 60 DAYS AFTER THE 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 NMP or NMP-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 (WCPP) compliance*. (1) *DDCC compliance*. Owners or operators subject to DDCC requirements described in § 751.209(b) must retain records of:

(i) Exposure control plan as described in § 751.209(c);

(ii) Dermal protection used by each potentially exposed person and PPE program implementation as described in § 751.209(e), including:

(A) The name, workplace address, work shift, job classification, and work area of each person reasonably likely to directly handle NMP or handle equipment or materials on which NMP may present and the type of PPE selected to be worn by each of these persons;

(B) The basis for specific PPE selection (e.g., demonstration based on permeation testing or manufacturer specifications that each item of PPE selected provides an impervious barrier to prevent exposure during expected duration and conditions of exposure, including the likely combinations of chemical substances to which the PPE may be exposed in the work area);

(C) Appropriately sized PPE and training on proper application, wear, and removal of PPE, and proper care/disposal of PPE;

(D) Occurrence and duration of any direct dermal contact with NMP that occurs during any activity or malfunction at the workplace that causes direct dermal exposures to occur and/or glove breakthrough, and corrective actions to be taken during and immediately following that activity or malfunction to prevent direct dermal contact to NMP; and

(E) Training in accordance with § 751.209(e)(3).

(iii) Information and training provided by the regulated entity to each person prior to or at the time of initial assignment to a job involving potential direct dermal contact with NMP and any re-training as required in § 751.209(f).

(2) *Workplace participation*.Owners or operators must document the notice to and ability of any potentially exposed person to NMP direct dermal contact exposure to readily access the exposure control plans, facility exposure monitoring records, PPE program implementation, or any other information relevant to NMP exposure in the workplace. (c) *Prescriptive requirements*. Owners and operators subject to the requirements described in § 751.207 and § 751.211 must retain records of: (1) Documentation identifying implementation of and compliance with the concentration limits listed in § 751.207(b);

(2) Dermal protection used by each potentially exposed person as described in § 751.211(b) and PPE program implementation, as described in § 751.209(e); and

(3) Respiratory protection used by each potentially exposed person as described in § 751.211(b) and (vi) and PPE program implementation, as described in § 751.209(e).

(d) *Additional recordkeeping for mission- or safety-critical uses of paint, coating, or adhesive removers or paints and coatings*. (1) Owners and operators subject to the requirements described in § 751.217 must retain the following: (i) Each self-certification statement for each facility that is self-certifying, including:

(A) The written statement required by § 751.217(b)(2)(i);

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

(C) Date of self-certification; and

(D) Name and address of the facility.

(ii) All records required by paragraphs (a) and (b) of this section.

(2) Sellers and distributors of NMP subject to the requirements described in § 751.217 must also retain the following:

(i) Invoices that include:

(A) Name of facility;

(B) Name of owner or operator who is self-certifying;

(C) Date of sale; and

(D) Quantity of NMP being purchased, and concentration by weight of NMP if applicable in NMP-containing products.

(ii) Self-certification statement for each purchase of NMP.

(iii) Copies of the downstream notifications required by § 751.217(b)(5).

(iv) Copies of the labels required by § 751.217(b)(6).

(e) *Retention.*Persons required to maintain records required under this section for a period of 5 years from the date that such records were generated.**§ 751.215 Downstream notification.**

(a) Beginning on [DATE 2 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], each person who manufactures (including imports) NMP for any condition of use specified in § 751.209 and § 751.211, except for those specified in § 751.217 must, prior to or concurrent with the shipment, notify companies to whom NMP is shipped, in writing, of the restrictions described in this subpart in accordance with paragraph (c) of this section.

(b) Beginning on [DATE 6 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], each person who processes or distributes in commerce NMP or any NMP-containing products for any condition of use specified in § 751.209 and § 751.211, except for those specified in § 751.217 must, prior to or concurrent with the shipment, notify companies to whom NMP 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 NMP or with any NMP-containing product:

> After [DATE 21 MONTHS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], this chemical/product cannot be distributed in commerce or processed with a concentration of NMP greater than 0.1% by weight for the following purposes: Processing incorporation into articles in lubricants and lubricant additives in machinery manufacturing; Industrial and commercial use in anti-freeze and de-icing products, automotive care products, and lubricants and greases; Industrial and commercial use in metal products not covered elsewhere and lubricant and lubricant additives including hydrophilic coatings; Industrial and commercial use in cleaning and degreasing, and cleaning and furniture care products, including wood cleaners and gasket removers; and Industrial and commercial uses in fertilizer and other agricultural chemical manufacturing-processing aids and solvents.

§ 751.217 Mission- or safety-critical uses of paint, coating, or adhesive removers or paints and coatings.

(a) *General*. To be eligible to use NMP in paint, coating, and adhesive removers and paints and coatings at concentrations higher than those prohibited under 751.207(b), regulated parties must comply with all conditions in this section. The following uses are covered by this section: (1) Import, processing, distribution in commerce, and use of paints and coatings with more than 45 percent by weight of NMP, for mission- or safety-critical components of aircraft, spacecraft, and vessels that are owned or operated by the U.S. Department of Defense and the National Aeronautics and Space Administration. (2) Import, processing, distribution

in commerce, and use of paint, coating, and adhesive removers with more than 30 percent by weight of NMP for mission- or safety-critical components of aircraft, spacecraft, and vessels that are owned or operated by the U.S. Department of Defense and the National Aeronautics and Space Administration.

(b) *Conditions*. (1) *Personnel and location*. The commercial uses listed in paragraph (a) of this section must be performed by agency employees or agency contractor employees at locations controlled by the agency or the agency's contractor. (2) *Self-certification.* The owner or operator purchasing and using NMP for the conditions of use listed in paragraph (a) of this section must self-certify each location controlled by the agency or the agency's contractor for those uses.

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

> I certify each of the following statements under penalty of law. This document was prepared under my direction and supervision. The facility in which this product will be used is a Federal installation, a Federal industrial facility, or a Federal contractor facility performing paint or coating work, or paint, coating, or adhesive removal work for DOD and NASA projects. This facility's implementation of the Workplace Chemical Protection Program (WCPP) for NMP was evaluated by qualified personnel and that this facility has implemented and complies with the WCPP for NMP. Based on my inquiry of the person or persons who manage the facility and/or those persons directly responsible for implementing the NMP WCPP, and to the best of my knowledge and belief, the facility is implementing the NMP WCPP, including the exposure control plan and other proper documentation of the actions taken is available at the facility upon request. I am aware that there are significant penalties, including the possibility of civil penalties for failing to comply with these requirements and criminal penalties, including fines and imprisonment, for knowingly failing to comply with these requirements. I understand that this certification shall serve as a certification that this facility will properly implement and comply with the WCPP for NMP consistent with the applicable regulatory timelines.

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

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

(B) Date of self-certification;

(C) Name and address of the facility; and

(D) An indication of whether this is the facility's first purchase of NMP, after publication of the final rule.

(iii) Owners or operators must provide a copy of the self-certification statement for each facility to the distributor from whom NMP is being purchased, for every purchase.

(iv) Distributors of NMP must review the self-certification statement to ensure it is appropriately completed to include the owner or operator's and the facility's information required by this section.

(3) *Workplace chemical protection program*. The owner or operator of the locations processing or engaging in the commercial uses listed in paragraph (a) of this section must comply with the Workplace Chemical Protection Program provisions in described in § 751.209.

(4) *Recordkeeping.* The owner or operator of the locations processing or engaging in the commercial uses listed in paragraph (b) of this section must comply with the recordkeeping requirements in § 751.213.

(5) *Downstream Notification.* All importers, processors and distributors in commerce of NMP for the uses listed in paragraph (a) of this section must provide downstream notification of the restrictions on use of these products by adding the following language to sections 1(c) and 15 of the SDS:After [DATE 21 MONTHS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*], this chemical/product is and can only be distributed in commerce or processed for the following purposes: paints and coatings or paint, coating, or adhesive removal by the Department of Defense (DOD), the National Aeronautics and Space Administration (NASA), or their contractors, at Federal installations, Federal industrial facilities, or at Federal contractor facilities performing work only for DOD and NASA projects.

(6) *Labeling*. All processors and distributors in commerce of NMP or NMP-containing products for the conditions of use listed in paragraph (a) of this section must provide a label securely attached to each product. Label information must be prominently displayed and in an easily readable font size. Each label must contain the following text:This product contains n-

methylpyrrolidone (NMP), a chemical determined by the Environmental Protection Agency to present unreasonable risk of injury to health under Section 6 of the Toxic Substances Control Act, based on developmental and reproductive effects. This product containing NMP is restricted under 40 CFR part 751, Subpart C. This product is only for sale and can only be used by the Department of Defense (DOD), the National Aeronautics and Space Administration (NASA), or their contractors, at Federal installations, Federal industrial facilities, or at Federal contractor facilities performing work only for DOD and NASA projects.