TABLE II—NOCS APPROVED * FROM 11/1/2022 TO 11/30/2022—Continued

Case No.	Received date	Commencement date	If amendment, type of amendment	Chemical substance
P–18–0362	11/03/2022	10/20/2022	N	(S) 1,3-propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with 2, 4-diisocyanato-1-methylbenzene, alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)] and alpha, alpha prime, alpha double prime-1,2, 3-propanetriyltris[omega-hydroxypoly[oxy(methyl-1,3-ethandiyl)]], me et ketone oxime blocked.
P–19–0019A	11/16/2022	08/21/2021	Amended generic chemical name.	(G) Chlorofluoroalkane.
P–19–0108	11/11/2022	11/11/2022	N	(S) Benzoic acid, 2-chloro-4-methyl-, ethyl ester.
P–19–0187	11/11/2022	11/11/2022	N	(S) Benzoic acid, 2-chloro-4-methyl-, sodium salt (1:1).

* The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission.

In Table III of this unit, EPA provides the following information (to the extent such information is not subject to a CBI claim) on the test information that has been received during this time period: The EPA case number assigned to the test information; the date the test information was received by EPA, the type of test information submitted, and chemical substance identity.

TABLE III—TEST INFORMATION RECEIVED FROM 11/1/2022 TO 11/30/2022

Case No.	Received date	Type of test information	Chemical substance
P–13–0021	11/15/2022	Test Data Validation Study	(G) Perfluoroacrylate polymer.
P–16–0543	11/28/2022	Exposure Monitoring Report	(G) Halogenophosphoric acid metal salt.
P–16–0543	11/14/2022	Exposure Monitoring Report	(G) Halogenophosphoric acid metal salt.

If you are interested in information that is not included in these tables, you may contact EPA's technical information contact or general information contact as described under **FOR FURTHER INFORMATION CONTACT** to access additional non-CBI information that may be available.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: December 13, 2022.

Pamela Myrick,

Director, Project Management and Operations Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2022–27448 Filed 12–16–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2016–0743; FRL–9943–02–OCSPP]

n-Methylpyrrolidone (NMP); Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of the final revision to the risk determination for the n-methylpyrrolidone (NMP) risk evaluation issued under the Toxic Substances Control Act (TSCA). The revision to the NMP risk determination reflects the announced policy changes to ensure the public is protected from unreasonable risks from chemicals in a way that is supported by science and the law. EPA determined that NMP, as a whole chemical substance, presents an unreasonable risk of injury to health when evaluated under its conditions of use. In addition, this revised risk determination does not reflect an assumption that workers always appropriately wear personal protective equipment (PPE). EPA understands that there could be adequate occupational safety protections in place at certain workplace locations; however, not assuming use of PPE reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by Occupational Safety and Health Administration (OSHA) standards, or their employers are out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being ''outdated and inadequate for ensuring protection of worker health,'' or because OSHA has not issued a chemical-specific permissible exposure limit (PEL) (as is the case for NMP), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements. This revision supersedes the condition of use-specific no unreasonable risk determinations in the December 2020 NMP Risk Evaluation and withdraws the associated TSCA order included in the December 2020 NMP Risk Evaluation.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0743, is available online at *https://www.regulations.gov* or in-person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Additional instructions on 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, Office of Pollution Prevention and Toxics (7404M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202)

564–3954; email address: *hull.clara@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. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to those involved in the manufacture, processing, distribution, use, disposal, and/or the assessment of risks involving chemical substances and mixtures. You may be potentially affected by this action if you manufacture (defined under TSCA to include import), process (including recycling), distribute in commerce, use or dispose of NMP, including NMP in products. Since other entities may also be interested in this revision to the risk determination, EPA has not attempted to describe all the specific entities that may be affected by this action.

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

TSCA section 6, 15 U.S.C. 2605, requires EPA to conduct risk evaluations to determine whether 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 potentially exposed or susceptible subpopulation (PESS) identified as relevant to the risk evaluation by the Administrator, under the conditions of use. 15 U.S.C. 2605(b)(4)(A). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that provide instruction on chemical substances that must undergo evaluation, the minimum components of a TSCA risk evaluation, and the timelines for public comment and completion of the risk evaluation. TSCA also requires that EPA operate in a manner that is consistent with the best available science, make decisions based on the weight of the scientific evidence, and consider reasonably available information. 15 U.S.C. 2625(h), (i), and (k).

The statute identifies the minimum components for all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C. 2605(b)(4)(D). The statute further provides that each risk evaluation must also: (1) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on relevant potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposures. 15 U.S.C. 2605(b)(4)(F)(i) through (ii) and (iv) through (v). Each risk evaluation must not consider costs or other nonrisk factors. 15 U.S.C. 2605(b)(4)(F)(iii).

EPA has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision to the extent permitted by law and supported by reasoned explanation. *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009); *see also Motor Vehicle Mfrs. Ass'n* v. *State Farm Mutual Auto. Ins. Co.,* 463 U.S. 29, 42 (1983). Pursuant to such authority, EPA has reconsidered and is now finalizing a revised risk determination for NMP.

C. What action is EPA taking?

EPA is announcing the availability of the final revision to the risk determination for the NMP risk evaluation issued under TSCA that published in December 2020 (Ref. 1). In July 2022, EPA sought public comment on the draft revisions (87 FR 39511, July 1, 2022). EPA appreciates the public comments received on the draft revision to the NMP risk determination. After review of these comments and consideration of the specific circumstances of NMP, EPA concludes that the Agency's risk determination for NMP is better characterized as a whole chemical risk determination rather than condition-of-use-specific risk determinations. Accordingly, EPA is revising and replacing section 5 of the December 2020 NMP Risk Evaluation (Ref. 2) where the findings of unreasonable risk to health were previously made for the individual conditions of use evaluated. EPA is also withdrawing the previously issued TSCA section 6(i)(l) order for 11 conditions of use previously determined not to present unreasonable risk which was included in section 5.4.1 of the December 2020 NMP Risk Evaluation (Ref. 2).

This final revision to the NMP risk determination is consistent with EPA's plans to revise specific aspects of the first ten TSCA chemical risk evaluations to ensure that the risk evaluations better align with TSCA's objective of protecting health and the environment. As a result of this revision, removing the assumption that workers always and appropriately wear PPE (see unit II.C.) means that: three additional conditions of use in addition to the original 26 drive the unreasonable risk for NMP, and for five conditions of use, acute effects in addition to chronic effects also drive the unreasonable risk to workers. However, EPA is not making condition-of-use-specific risk determinations for those conditions of use, and for purposes of TSCA section 6(i), EPA is not issuing a final order under TSCA section 6(i)(1) for the conditions of use that do not drive the unreasonable risk, and does not consider the revised risk determination to constitute a final agency action at this point in time. Overall, 29 conditions of use out of 37 EPA evaluated drive the NMP whole chemical unreasonable risk determination due to risks identified for human health. The full list of the conditions of use evaluated for the NMP TSCA risk evaluation is in Table 1–6 of the December 2020 NMP Risk Evaluation (Ref. 2).

II. Background

A. Why is EPA re-issuing the risk determination for the NMP risk evaluation conducted under TSCA?

In accordance with Executive Order 13990 (''Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis'') and other Administration priorities (Refs. 3, 4, 5, and 6), EPA reviewed the risk evaluations for the first ten chemical substances, including NMP, to ensure that they meet the requirements of TSCA, including conducting decision-making in a manner that is consistent with the best available science.

As a result of this review, EPA announced plans to revise specific aspects of the first ten risk evaluations in order to ensure that the risk evaluations appropriately identify unreasonable risks and thereby help ensure the protection of human health and the environment (Ref. 7). Following a review of specific aspects of the December 2020 NMP Risk Evaluation (Ref. 2) and after considering comments received on a draft revised risk determination for NMP, EPA has determined that making an

unreasonable risk determination for NMP as a whole chemical substance, rather than making unreasonable risk determinations separately on each individual condition of use evaluated in the risk evaluation, is the most appropriate approach for NMP under the statute and implementing regulations. In addition, EPA's final risk determination is explicit insofar as it does not rely on assumptions regarding the use of PPE in making the unreasonable risk determination under TSCA section 6, even though some facilities might be using PPE as one means to reduce worker exposures; rather, the use of PPE as a means of addressing unreasonable risk will be considered during risk management, as appropriate.

Separately, EPA is conducting a screening approach to assess risks from the air and water pathways for several of the first 10 chemicals, including this chemical. For NMP the exposure pathways that were or could be regulated under another EPA administered statute were not fully assessed as part of the final risk evaluation (see section 1.4.2 of the December 2020 NMP Risk Evaluation). 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. In the December 2020 NMP 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. This resulted in the ambient air and drinking water pathways for NMP not being fully assessed in the risk evaluation published in December 2020. The goal of the recently-developed screening approach is to provide a more robust assessment of these pathways for NMP and to determine if there may be risks that were unaccounted for in the NMP risk evaluation. The screening-level approach has gone through public comment and independent external peer review through the Science Advisory Committee on Chemicals (SACC). The Agency received the final peer review report on May 18, 2022, and has reviewed public comments and SACC comments. EPA expects to describe its findings regarding the chemical-specific application of this screening-level approach in the forthcoming proposed rule under TSCA section 6(a) for NMP.

This action pertains only to the risk determination for NMP. While EPA intends to consider and may take additional similar actions on other of the first ten chemicals, EPA is taking a chemical-specific approach to reviewing these risk evaluations and is incorporating new policy direction in a surgical manner, while being mindful of Congressional direction on the need to complete risk evaluations and move toward any associated risk management activities in accordance with statutory deadlines.

B. What is a whole chemical view of the unreasonable risk determination for the NMP risk evaluation?

TSCA section 6 repeatedly refers to determining whether a chemical *substance* presents unreasonable risk under its conditions of use. Stakeholders have disagreed over whether a chemical substance should receive: A single determination that is comprehensive for the chemical substance after considering the conditions of use, referred to as a whole-chemical determination; or multiple determinations, each of which is specific to a condition of use, referred to as condition-of-use-specific determinations.

As explained in the **Federal Register** document announcing the availability of the draft revised risk determination for NMP (87 FR 39511, July 1, 2022 (FRL–9943–01–OCSPP)), the proposed Risk Evaluation Procedural Rule (Ref. 8) was premised on the whole chemical approach to making unreasonable risk determinations. In that proposed rule, EPA acknowledged a lack of specificity in statutory text that might lead to different views about whether the statute compelled EPA's risk evaluations to address all conditions of use of a chemical substance or whether EPA had discretion to evaluate some subset of conditions of use (*i.e.,* to scope out some manufacturing, processing, distribution in commerce, use, or disposal activities), but also stated that ''EPA believes the word 'the' [in TSCA section 6(b)(4)(A)] is best interpreted as calling for evaluation that considers all conditions of use.'' The proposed rule, however, was unambiguous on the point that unreasonable risk determinations would be for the chemical substance as a whole, even if based on a subset of uses. See Ref. 8 at pages 7565–66 (''TSCA section 6(b)(4)(A) specifies that a risk evaluation must determine whether 'a chemical substance' presents an unreasonable risk of injury to health or the environment 'under the conditions of use.' The evaluation is on the chemical substance—not individual conditions of use—and it must be based on 'the conditions of use.' In this context, EPA believes the word 'the' is best interpreted as calling for evaluation that considers all conditions of use.''). In the proposed regulatory text, EPA proposed to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use. (Ref. 8 at 7480.)

The final Risk Evaluation Procedural Rule stated (82 FR 33726, July 20, 2017 (FRL–9964–38)) (Ref. 9): ''As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents'' (40 CFR 702.47). For the unreasonable risk determinations in the first ten risk evaluations, EPA applied this provision by making individual risk determinations for each condition of use evaluated as part of each risk evaluation document (*i.e.,* the condition-of-use-specific approach to risk determinations). That approach was based on one particular passage in the preamble to the final Risk Evaluation Rule which stated that EPA will make individual risk determinations for all conditions of use identified in the scope. (Ref. 9 at 33744).

In contrast to this portion of the preamble of the final Risk Evaluation Rule, the regulatory text itself and other statements in the preamble reference a risk determination *for the chemical substance* under its conditions of use, rather than separate risk determinations for each of the conditions of use of a chemical substance. In the key regulatory provision excerpted previously from 40 CFR 702.47, the text explains that ''[a]s part of the risk evaluation, EPA will determine whether *the chemical substance* presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents'' (Ref. 9, emphasis added). Other language reiterates this perspective. For example, 40 CFR 702.31(a) states that the purpose of the rule is to establish the EPA process for conducting a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B). Likewise, there are recurring references to whether the chemical substance presents an unreasonable risk in 40 CFR 702.41(a). See, for example, 40 CFR 702.41(a)(6), which explains

that the extent to which EPA will refine its evaluations for one or more condition of use in any risk evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk. Notwithstanding the one preambular statement about condition-of-use-specific risk determinations, the preamble to the final rule also contains support for a risk determination on the chemical substance as a whole. In discussing the identification of the conditions of use of a chemical substance, the preamble notes that this task inevitably involves the exercise of discretion on EPA's part, and ''as EPA interprets the statute, the Agency is to exercise that discretion consistent with the objective of conducting a technically sound, manageable evaluation to determine whether a chemical substance—not just individual uses or activities—presents an unreasonable risk'' (Ref. 9 at 33729).

Therefore, notwithstanding EPA's choice to issue condition-of-use-specific risk determinations to date, EPA interprets its risk evaluation regulation to also allow the Agency to issue whole-chemical risk determinations. Either approach is permissible under the regulation. A panel of the Ninth Circuit Court of Appeals also recognized the ambiguity of the regulation on this point. *Safer Chemicals* v. *EPA,* 943 F.3d. 397, 413 (9th Cir. 2019) (holding a challenge about ''use-by-use risk evaluations [was] not justiciable because it is not clear, due to the ambiguous text of the Risk Evaluation Rule, whether the Agency will actually conduct risk evaluations in the manner Petitioners fear'').

EPA plans to consider the appropriate approach for each chemical substance risk evaluation on a case-by-case basis, taking into account considerations relevant to the specific chemical substance in light of the Agency's obligations under TSCA. The Agency expects that this case-by-case approach will provide greater flexibility in the Agency's ability to evaluate and manage unreasonable risk from individual chemical substances. EPA believes this is a reasonable approach under TSCA and the Agency's implementing regulations.

With regard to the specific circumstances of NMP, EPA has determined that a whole chemical approach is appropriate for NMP in order to protect health and the environment. The whole chemical approach is appropriate for NMP because there are benchmark exceedances for a substantial number of conditions of use (spanning across most aspects of the chemical lifecycle—from manufacturing (including import), processing, industrial and commercial use, consumer use, and disposal) for workers and consumers and risk of irreversible health effects (specifically developmental post implantation fetal loss and reduced fertility and fecundity) associated with NMP exposures. Because these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, a substantial amount of the conditions of use drive the unreasonable risk; therefore, it is appropriate for the Agency to make a determination for NMP that the whole chemical presents an unreasonable risk.

As explained later in this document, the revisions to the unreasonable risk determination (section 5 of the December 2020 NMP Risk Evaluation (Ref. 2)) follow the issuance of a draft revision to the TSCA NMP unreasonable risk determination (87 FR 39511, July 1, 2022) and the receipt of public comment. A response to comments document is also being issued with the final revised unreasonable risk determination for NMP (Ref. 10). The revisions to the unreasonable risk determination are based on the existing risk characterization section of the December 2020 NMP Risk Evaluation (Ref. 2) (section 4) and do not involve additional technical or scientific analysis. The discussion of the issues in this **Federal Register** document and in the accompanying final revised risk determination for NMP supersede any conflicting statements in the December 2020 NMP Risk Evaluation (Ref. 2) and the earlier response to comments document (Ref. 11). EPA views the peer reviewed hazard and exposure assessments and associated risk characterization as robust and upholding the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i).

For purposes of TSCA section 6(i), EPA is making a risk determination on NMP as a whole chemical. Under the revised approach, the ''whole chemical'' risk determination for NMP supersedes the no unreasonable risk determinations for NMP that were premised on a condition-of-use-specific approach to determining unreasonable risk and also contains an order withdrawing the TSCA section 6(i)(1) order in section 5.4.1 of the December 2020 NMP Risk Evaluation (Ref. 2).

C. What revision is EPA now making final about the use of PPE for the NMP risk evaluation?

In the risk evaluations for the first ten chemical substances, as part of the unreasonable risk determination, EPA assumed for several conditions of use that workers were provided and always used PPE in a manner that achieves the stated assigned protection factor (APF) for respiratory protection, or used chemically-resistant gloves for dermal protection. In support of this assumption, EPA used reasonably available information such as public comments indicating that some employers, particularly in the industrial setting, provide PPE to their employees and follow established worker protection standards (*e.g.,* OSHA requirements for protection of workers).

For the December 2020 NMP Risk Evaluation (Ref. 2), EPA assumed, based on reasonably available information, including public comment and safety data sheets for NMP, that workers use PPE—specifically, respirators with an APF 10 and gloves with a protection factor (PF) ranging from 5 to 10—for all occupational conditions of use. In the December 2020 NMP Risk Evaluation, EPA determined that there is unreasonable risk to these workers for 25 of the 28 occupational COUs even with this assumed PPE use.

EPA is revising the assumption for NMP that workers always and properly use PPE. However, this does not mean that EPA questions the veracity of public comments which describe occupational safety practices often followed by industry. EPA believes it is appropriate when conducting risk evaluations under TSCA to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. This approach of not assuming PPE use by workers considers the risk to potentially exposed or susceptible subpopulations of workers who may not be covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan. It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place.

In addition, EPA believes it is appropriate to evaluate the levels of risk present in scenarios considering applicable OSHA requirements (*e.g.,* chemical-specific permissible exposure limits (PELs) and/or chemical-specific PELs with additional substance-specific standards), as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. Consistent with this approach, the December 2020 NMP Risk Evaluation

(Ref. 2) characterized risk to workers both with and without the use of PPE. By characterizing risks using scenarios that reflect different levels of mitigation, EPA risk evaluations 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, or to ensure that applicable OSHA requirements or industry or sector best practices that address the unreasonable risk are required for all potentially exposed and susceptible subpopulations (including self-employed individuals and public sector workers who are not covered by an OSHA State Plan).

When undertaking unreasonable risk determinations as part of TSCA risk evaluations, however, EPA does not believe it is appropriate to assume as a general matter that an applicable OSHA requirement or industry practice related to PPE use is consistently and always properly applied. Mitigation scenarios included in the EPA risk evaluation (*e.g.,* scenarios considering use of various PPE) likely represent what is happening already in some facilities. However, the Agency cannot assume that all facilities have adopted these practices for the purposes of making the TSCA risk determination (Ref. 12).

Therefore, EPA is making a determination of unreasonable risk for NMP from a baseline scenario that does 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 the baseline scenario 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 non-compliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being ''outdated and inadequate for ensuring protection of worker health,'' (Ref. 13), or because OSHA has not issued a permissible exposure limit (PEL) (as is the case for NMP), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements.

In accordance with this approach, EPA is finalizing the revision to the NMP risk determination without relying on assumptions regarding the occupational use of PPE in making the unreasonable risk determination under TSCA section 6; rather, information on the use of PPE as a means of mitigating risk (including public comments received from industry respondents about occupational safety practices in use) will be considered during the risk management phase, as appropriate. This represents a change from the approach taken in the December 2020 NMP Risk Evaluation (Ref. 2). As a general matter, when undertaking risk management actions, EPA intends to strive for consistency with applicable OSHA requirements and industry best practices, including appropriate application of the hierarchy of controls, to the extent that applying those measures would address the identified unreasonable risk, including unreasonable risk to potentially exposed or susceptible subpopulations. Consistent with TSCA section 9(d), EPA will consult and coordinate 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, comprehensive 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 or be sufficient to address the unreasonable risk.

Removing the assumption that workers always and appropriately wear PPE in making the whole chemical risk determination for NMP means that: three conditions of use in addition to the original 26 drive the unreasonable risk for NMP (industrial and commercial use in ink, toner, and colorant products; industrial and commercial use in other uses soldering materials; and industrial and commercial use in other uses in fertilizer and other agricultural chemical manufacturing—processing aids and solvents). Additionally, for five conditions of use, acute effects in addition to chronic effects also drive the unreasonable risk to workers (the five conditions of use are: processing for incorporation into articles in paint additives and coating additives not described by other codes in transportation equipment manufacturing; 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, powder coatings (surface preparation); industrial and commercial use paint additives and coating additives in multiple manufacturing sectors; and industrial and commercial use in adhesives and sealants including binding agents, single component glues and adhesives, including lubricant additives, two-component glues, and adhesives including some resins). The finalized revision to the NMP risk determination clarifies that EPA does not rely on the assumed use of PPE when making the risk determination for the whole substance; rather, the use of PPE as a means of addressing unreasonable risk will be considered during risk management, as appropriate.

D. What is NMP?

NMP is a water-miscible, organic solvent that is often used as a substitute for halogenated solvents. NMP exhibits a unique set of physical and chemical properties that have proven useful in a range of industrial, commercial, and consumer applications. NMP has a wide range of uses, including in the production of paints and coatings, as a solvent for cleaning and degreasing, and in the manufacture of electronics. There are also a variety of consumer and commercial products that contain NMP, such as adhesives and sealants, as well as adhesive removers, automotive care products, and paints and coatings. NMP is both manufactured domestically and imported into the United States.

E. What conclusions is EPA finalizing today in the revised TSCA risk evaluation based on the whole chemical approach and not assuming the use of PPE?

EPA determined that NMP presents an unreasonable risk to health under the conditions of use. EPA's unreasonable risk determination for NMP as a chemical substance is driven by risks associated with the following conditions of use, considered singularly or in combination with other exposures:

- Manufacturing—Domestic manufacture;
- Manufacturing—Import;
- Processing as a reactant or intermediate in plastic material and resin manufacturing and other non-incorporative processing;

- Processing for incorporation into a formulation, mixture, or reaction product in multiple sectors;
- Processing for incorporation into articles—in lubricants and lubricant additives in machinery manufacturing;
- Processing for incorporation into articles in paint additives and coating additives not described by other codes in transportation equipment manufacturing;
- Processing for incorporation into articles as a solvent (which become part of product formulation or mixture), including in textiles, apparel, and leather manufacturing;
- Processing for incorporation into articles in other sectors, including in plastic product manufacturing;
- Processing in recycling;
- Processing for repackaging (wholesale and retail trade);
- 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, powder coatings (surface preparation);
- Industrial and commercial use in paint additives and coating additives not described by other codes in computer and electronic product manufacturing in electronic parts manufacturing;
- Industrial and commercial use paint additives and coating additives not described by other codes in computer and electronic product manufacturing in semiconductor manufacturing;
- Industrial and commercial use paint additives and coating additives in multiple manufacturing sectors;
- 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 in semiconductor manufacturing;
- Industrial and commercial use in processing aids specific to petroleum production in petrochemical manufacturing, in other uses in oil and gas drilling, extraction, and support activities, and in functional fluids (closed systems);
- Industrial and commercial use in adhesives and sealants including binding agents, single component glues and adhesives, including lubricant additives, two-component glues, and adhesives including some resins;
- Industrial and commercial use in other uses 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 uses in other uses in laboratory chemicals;
- Industrial and commercial uses in other uses in lithium ion battery manufacturing;
- Industrial and commercial uses in other uses in cleaning and furniture care products including wood cleaners and gasket removers;
- Industrial and commercial use in ink, toner, and colorant products (printer ink; inks in writing equipment);
- Industrial and commercial use in other uses in soldering materials;
- Industrial and commercial use in other uses in fertilizer and other agricultural chemical manufacturing in processing aids and solvents;
- Consumer use in adhesives and sealants (glues and adhesives including lubricant adhesives); and
- Disposal.

The following conditions of use do not drive EPA's unreasonable risk determination for NMP:

- Distribution in commerce;
- Consumer use in paint and coating removers;
- Consumer use in adhesive removers;
- Consumer use in paints and coatings in lacquers, stains, varnishes, primers and floor finishes;
- Consumer use in paint additives and coating additives not described by other codes in paints and arts and crafts paints;
- Consumer use in other uses in automotive car products;
- Consumer use in other uses in cleaning and furniture care products, including wood cleaners and gasket removers; and
- Consumer use in other uses in lubricant and lubricant additives, including hydrophilic coatings.

EPA is not making condition of use-specific risk determinations for these conditions of use, is not issuing a final order under TSCA section 6(i)(1) for the conditions of use that do not drive unreasonable risk, and does not consider the revised risk determination for NMP to constitute a final agency action at this point in time.

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose a risk management regulatory action to the extent necessary so that NMP no longer presents an unreasonable risk. EPA expects to focus its risk management action on the conditions of use that drive the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (*e.g.,* processing, distribution in commerce) to address downstream activities (*e.g.,* consumer uses) driving unreasonable risk, even if the upstream activities do not drive the unreasonable risk.

III. Summary of Public Comments

EPA received a total of 22 public comments on the July 1, 2022, draft revised risk determination for NMP during the comment period that ended August 1, 2022, of which 20 were unique and responsive to the request for comments. Commenters included trade organizations, industry stakeholders, environmental groups, and non-governmental health advocacy organizations. A separate document that summarizes all comments submitted and EPA's responses to those comments has been prepared and is available in the docket for this notice (Ref. 10).

IV. Revision of the December 2020 NMP Risk Evaluation

A. Why is EPA revising the risk determination for the NMP risk evaluation?

EPA is finalizing the revised risk determination for the NMP risk evaluation pursuant to TSCA section 6(b) and consistent with Executive Order 13990, (''Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis'') and other Administration priorities (Refs. 3, 4, 5, and 6). EPA is revising specific aspects of the first ten TSCA existing chemical risk evaluations in order to ensure that the risk evaluations better align with TSCA's objective of protecting health and the environment. For the NMP risk evaluation, this includes: (1) Making the risk determination in this instance based on the whole chemical substance instead of by individual conditions of use and (2) Emphasizing that EPA does not rely on the assumed use of PPE when making the risk determination.

B. What are the revisions?

EPA is now finalizing the revised risk determination for the December 2020 NMP Risk Evaluation (Ref. 2) pursuant to TSCA section 6(b). Under the revised determination (Ref. 1), EPA concludes that NMP, as evaluated in the risk

evaluation as a whole, presents an unreasonable risk of injury to health when evaluated under its conditions of use. This revision replaces the previous unreasonable risk determinations made for NMP by individual conditions of use, supersedes the determinations (and withdraws the associated order) of no unreasonable risk for the conditions of use identified in the TSCA section 6(i)(1) no unreasonable risk order, and clarifies the lack of reliance on assumed use of PPE as part of the risk determination.

These revisions do not alter any of the underlying technical or scientific information that informs the risk characterization, and as such the hazard, exposure, and risk characterization sections are not changed, except to statements about PPE assumptions in section 2.4.1.1 (Occupational Exposures Approach and Methodology) and 4.2.2 (Risk Estimation for Worker Exposures for Occupational Use of NMP). The discussion of the issues in this *notice* and in the accompanying final revision to the risk determination supersede any conflicting statements in the prior executive summary, and section 2.4.1.1 and section 4.2.2 from the December 2020 NMP Risk Evaluation (Ref. 2) and the response to comments document (Ref. 11).

The revised unreasonable risk determination for NMP includes additional explanation of how the risk evaluation characterizes the applicable OSHA requirements, or industry or sector best practices, and also clarifies that no additional analysis was done, and the risk determination is based on the risk characterization (section 4) of the December 2020 NMP Risk Evaluation (Ref. 2).

C. Will the revised risk determination be peer reviewed?

The risk determination (section 5 of the December 2020 NMP Risk Evaluation (Ref. 2)) was not part of the scope of the Science Advisory Committee on Chemicals (SACC) peer review of the NMP risk evaluation. Thus, consistent with that approach, EPA did not conduct peer review of the final revised unreasonable risk determination for the NMP risk evaluation because no technical or scientific changes were made to the hazard or exposure assessments or the risk characterization.

V. Order Withdrawing Previous Order Regarding Unreasonable Risk Determinations for Certain Conditions of Use

EPA is also issuing a new order to withdraw the TSCA section 6(i)(1) no unreasonable risk order issued in section 5.4.1 of the December 2020 NMP Risk Evaluation (Ref. 2). This final revised risk determination supersedes the condition of use-specific no unreasonable risk determinations in the December 2020 NMP Risk Evaluation (Ref. 2). The order contained in section 5.5 of the revised risk determination (Ref. 1) withdraws the TSCA section 6(i)(1) order contained in section 5.4.1 of the December 2020 NMP Risk Evaluation (Ref. 2). Consistent with the statutory requirements of section 6(a), the Agency will propose risk management action to address the unreasonable risk determined in the NMP risk evaluation.

VI. 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 physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Unreasonable Risk Determination for n-Methylpyrrolidone (NMP). December 2022.
2. EPA. Risk Evaluation for n-Methylpyrrolidone (NMP). December 2020. EPA Document #740–R–18–009. *https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0236-0081.*
3. 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.
4. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. **Federal Register**. 86 FR 7009, January 25, 2021.
5. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. **Federal Register**. 86 FR 7619, February 1, 2021.
6. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. **Federal Register**. 86 FR 8845, February 10, 2021.
7. EPA. Press Release; EPA Announces Path Forward for TSCA Chemical Risk Evaluations. June 2021. *https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations.*
8. EPA. Proposed Rule; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. **Federal Register**. 82 FR 7562, January 19, 2017 (FRL–9957–75).
9. EPA. Final Rule; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. **Federal Register**. 82 FR 33726, July 20, 2017 (FRL–9964–38).
10. EPA. Response to Public Comments to the Revised Unreasonable Risk Determination; n-Methylpyrrolidone (NMP). December 2022.
11. EPA. Summary of External Peer Review and Public Comments and Disposition for n-Methylpyrrolidone (NMP). December 2020. Available at: *https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0236-0082.*
12. Occupational Safety and Health Administration (OSHA). Top 10 Most Frequently Cited Standards for Fiscal Year 2021 (Oct. 1, 2020, to Sept. 30, 2021). Accessed October 13, 2022. *https://www.osha.gov/top10citedstandards.*
13. OSHA. Permissible Exposure Limits—Annotated Tables. Accessed June 13, 2022. *https://www.osha.gov/annotated-pels.*

Authority: 15 U.S.C. 2601 *et seq.*

Dated: December 13, 2022.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2018–0774; FRL–10472–02–ORD]

Proposed Information Collection Request; Evaluating End User Satisfaction of EPA's Research Products (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), ''Evaluating End User Satisfaction of EPA's Research Products'' (EPA ICR No. 2593.02, OMB Control No. 2080–0085) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through August 31, 2023. An