U.S. Environmental Protection Agency

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

EPA–HQ–OPPT–2016–0743

Response to Public Comments

December 2022

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Acronyms and Abbreviations

APF	Assigned protection factor
COU	Condition of use
EPA	U.S. Environmental Protection Agency
HBCD	Cyclic aliphatic bromide cluster
NASEM	National Academies of Science, Engineering, and Medicine
NIOSH	U.S. National Institute for Occupational Safety and Health
NMP	n-Methylpyrrolidone
ONU	Occupational non-user
OSHA	U.S. Occupational Safety and Health Administration
OSH Act	Occupational Safety and Health Act of 1970
PCE	Perchloroethylene
PEL	Permissible exposure limit
PESS	Potentially exposed or susceptible subpopulation
PF	Protection factor
PPE	Personal protective equipment
PV29	Colour Index Pigment Violet 29
SACC	Scientific Advisory Committee on Chemicals
TSCA	Toxic Substances Control Act
U.S.	United States
U.S.C.	United States Code

Introduction

On July 1, 2022, the U.S. Environmental Protection Agency (EPA) published a notice of availability and request for comment on a draft revision to the Toxic Substances Control Act (TSCA) Risk Determination for n-Methylpyrrolidone (NMP). In the notice, EPA announced that public comments would be accepted until August 1, 2022.

EPA received a total of 22 public comments and determined that one comment was a duplicate and one was a revised submission; 20 comments are unique and responsive to the request for comments. Table 1, Index of Comment Submissions Sorted by Submission Number, identifies the commenter name and the comment number for the 20 unique submissions included in this summary.

The comment summaries and responses that follow are organized into issue topic areas, as indicated in the table of contents.

Table 1: Index of Comment Submissions Sorted by Submission Number

Submission Number	Organization Name
EPA-HQ-OPPT-2016-0743-0122	Victoria Kriete
EPA-HQ-OPPT-2016-0743-0123	Stephanie Martinez
EPA-HQ-OPPT-2016-0743-0124	EaglePicher Technologies, LLC
EPA-HQ-OPPT-2016-0743-0125	Alliance for Automotive Innovation
EPA-HQ-OPPT-2016-0743-0126	American Chemistry Council
EPA-HQ-OPPT-2016-0743-0127	American Federal of Labor and Congress of Industrial Organizations
EPA-HQ-OPPT-2016-0743-0128	American Petroleum Institute and the American Fuels & Petrochemical Manufacturers
EPA-HQ-OPPT-2016-0743-0129	Chemical Users Coalition
EPA-HQ-OPPT-2016-0743-0130	Cummins Inc.
EPA-HQ-OPPT-2016-0743-0131	Environmental Defense Fund
EPA-HQ-OPPT-2016-0743-0133	Household & Commercial Products Association
EPA-HQ-OPPT-2016-0743-0134	Lithium Ion Cell Manufacturers' Coalition
EPA-HQ-OPPT-2016-0743-0135	N-Methylpyrrolidone Producers Group
EPA-HQ-OPPT-2016-0743-0136	National Association of Chemical Distributors
EPA-HQ-OPPT-2016-0743-0137	National Electric Manufacturers Association
EPA-HQ-OPPT-2016-0743-0138	Safer Chemicals Healthy Families, et al.
EPA-HQ-OPPT-2016-0743-0139	Semiconductor Industry Association
EPA-HQ-OPPT-2016-0743-0140	U.S. Chamber of Commerce
EPA-HQ-OPPT-2016-0743-0141	California Department of Toxic Substances Control, et al.
EPA-HQ-OPPT-2016-0743-0142	Environmental Protection Network (Revised submission from EPA-HQ-OPPT-2016-0743-0132)

Section 1 – General support for the draft revision to the risk determination

Comments that provided general support also provided more substantive comments that are summarized in other portions of the summary report.

Several non-governmental environmental and health advocacy organizations and an individual commenter (0122, 0131, 0138) provided general support for the NMP revised unreasonable risk determination. An individual commenter (0123) asked about previous regulations or outcomes of NMP under TSCA in support of safe measures supporting a clean environment. The organizations (0131, 0138) explained that they favored the change to a whole chemical approach because, among other things, the whole chemical approach better aligns with the goals of TSCA and the 2016 Lautenberg amendments. The organizations stated that by removing the assumptions that workers always are provided and always properly wear personal protective equipment (PPE), EPA can adopt risk management approaches that better protect not only workers but also other potentially exposed or susceptible subpopulations (PESS). Similarly, a comment submitted by several state and local government agencies and organizations (0141) expressed strong support for EPA's new path forward for TSCA risk evaluations. The commenter encouraged EPA to apply a whole-of-government approach to chemical regulation, as it has begun to do with lead and polyfluoroalkyl substances and continue to withdraw past determinations of no unreasonable risk for specific conditions of use in the first ten risk evaluations.

An advocacy organization (0142) stated that they agree with the reasoning and conclusions drawn by EPA in the July 2022 draft revision to the TSCA risk determination of NMP.

EPA RESPONSE:
EPA appreciates the support for the revised unreasonable risk determination. There are no other previous regulations for NMP promulgated under TSCA section 6.

Section 2 – General opposition to the draft revision to the unreasonable risk determination

The comment that provided general opposition also provided more substantive comments that are summarized in other portions of the summary report.

An industry trade organization (0125) stated that the revisions to the risk determination will change public interpretations of risk, have unwarranted impacts on future risk management decision-making and cause unintended regulatory impacts on articles (including replacement parts) containing certain substances.

EPA RESPONSE:
EPA would like to reiterate that this action pertains specifically to the unreasonable risk determination for NMP. While EPA intends to consider and may take additional similar actions on other of the first ten chemical substances with completed TSCA section 6 risk evaluations, EPA is taking a chemical-specific approach to revising the risk determination of this risk evaluation 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. Regarding public communication and interpretation of risk, EPA has emphasized, in both the Federal Register Notice and the final revised unreasonable

risk determination, the conditions of use that drive the unreasonable risk for NMP, as well as listing the conditions of use that do not.

With respect to impacts from this revised unreasonable risk determination on risk management of NMP, EPA will propose a regulatory action with requirements under TSCA section 6(a) to the extent necessary so that NMP no longer presents unreasonable risk. The public will have an opportunity to comment on the proposed regulatory action, and EPA will consider such public comments and any additional information before finalizing the rulemaking. As a result, EPA expects that impacts to NMP-containing articles, including consideration of replacement parts and articles under TSCA section 6(c)(2)(D) and (E), will be considered during rulemaking. EPA encourages the commenter to submit specific comments about regulatory impacts on NMP-containing articles during the future public comment period for the NMP risk management rule.

Section 3 – Legal issues

Other comments discussing legal issues with the whole chemical approach, including its consistency with TSCA, are discussed below in Section 4.1.

Section 3.1 – Statutory authority and TSCA section 26

Three industry trade organizations (0126, 0136, 0135) provided feedback on EPA's statutory authority under TSCA. The commenters stated that EPA's proposed approach does not comply with TSCA section 26 and section 6 requirements that risk evaluations be consistent with best available science and based on the weight of the scientific evidence. One of the commenters (0126) added that the legislative record for the TSCA amendments also does not support EPA's new policy direction.

An industry trade organization (0136) provided its view that EPA's final risk evaluation for NMP is predicated on a systematic review method that does not meet the scientific standards under TSCA section 26. The industry trade organization discussed how, in May 2018, EPA released a document titled "Application of Systematic Review in TSCA Risk Evaluations" (2018 SR Document) and stated that, rather than incorporating and adapting existing methodologies that represented the best available science at the time, the use of the approach in the 2018 SR Document led to pervasive problems in the first ten risk evaluations. The commenter stated that EPA's updates do not resolve the issue that the systematic review method underlying NMP's final risk evaluation may have contravened TSCA section 26. The industry trade organization stated that it does not agree that EPA may implement the proposed changes without amending the scientific analysis in the final risk evaluation for NMP, providing its view that EPA must justify these changes with additional analysis. The commenter stated the view that the final risk evaluation for NMP was of low quality. As an example of a data quality issue with the risk evaluation, the commenter discussed EPA's evaluation of the Sitarek and Stetkiewicz (2008) and Exxon (1991) studies, stating that EPA's conclusions on these studies in the work plan chemical risk assessment for NMP versus the NMP risk evaluation are inconsistent. The industry trade organization stated its view that EPA must conduct a robust systematic review and update the risk evaluation as warranted based on the review in order to satisfy the requirements of TSCA sections 26(h) and (i).

These comments were echoed by another industry trade organization (0135), though this commenter agreed with EPA that incorporating the new policy directions does not require

amending the scientific analysis in the final risk evaluation for NMP. However, the commenter warned that EPA's decision to issue the draft revised risk determination for NMP with open-ended scientific questions that are informed by reasonably available information could lead to an inference that EPA is using selective information to arrive at a pre-determined outcome. The industry trade organization stated its view that using poor quality data to support a preferred outcome does not meet the statutory standard regardless of whether the preferred outcome is more or less protective than that supported by the best available science.

Relatedly, another industry trade organization (0126) commented that the EPA 2021 Draft Systematic Review protocol significantly updated the TSCA systematic review process and developed a systematic review protocol to address the National Academies of Science, Engineering, and Medicine (NASEM) recommendations to EPA on its systematic review process for risk evaluations. The industry trade organization stated its view that the revised unreasonable risk determination should be updated to reflect the EPA 2021 Draft Systematic Review protocol in order to meet the requirements under TSCA section 26. Another industry trade organization (0135) agreed, commenting that the systematic review method underlying the former NMP risk evaluation, according to EPA, did not meet the statutory requirements under TSCA section 26. Another industry trade organization (0128) requested that their similar comments on PCE be incorporated into NMP.

***EPA RESPONSE**:*
The final revised unreasonable risk determination for NMP is based on the peer reviewed risk characterization in the December 2020 NMP Risk Evaluation, based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) and (i) to make decisions under TSCA section 6 in a manner consistent with the best available science and based on the weight of scientific evidence. While EPA has undertaken efforts to refine its 2018 approach to systematic review by developing a draft systematic review protocol that has undergone review by NASEM, the draft protocol is not a final document. EPA expects to use chemical-specific protocols in the future that are reflective of what we learned in this and the Science Advisory Committee on Chemicals (SACC) peer review process and public comment. EPA does not expect to apply adjustments retroactively; retroactive application would lead to further delays in completing the risk evaluations for the first ten substances contrary to Congressional intent. Thus, EPA maintains that the December 2020 NMP Risk Evaluation meets TSCA section 26(h) requirements. In response to comments asserting that EPA's risk evaluation does not meet the standards of TSCA section 26 (0135) or that specific analyses are flawed or inaccurate (0136), EPA emphasizes the peer reviewed hazard and exposure assessments and associated risk characterization are robust analyses that uphold the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i). EPA has also specifically responded to those comments by commenter (0128) in the Response to Comments document for the PCE revised risk determination. The policy changes described in the Federal Register Notice announcing the availability of the revised risk determination for NMP do not amend or impact the underlying data and analysis presented in the risk characterization of the December 2020 NMP Risk Evaluation. The policy changes do not impact the characterization of risk estimates by condition of use (summarized in Section 4 of the final risk evaluation), or the occupational exposures to workers and ONUs (summarized in Section 2.4 of the final risk evaluation). Further discussion of EPAs consideration of workplace

practices and implementation of OSHA-compliant standard operating procedures is in section 4.2 of this document.

In response to the commenter's assertion about the legislative record to support EPA's new policy direction, Congress was clear that TSCA provides EPA broad authority to regulate existing chemicals and delegated to EPA responsibility for implementing and overseeing a process to conduct risk evaluations to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment…under the conditions of use." See, e.g., S. REP. 114-67 (2015); 15 U.S.C. 2605(b)(4)(A). Fully consistent with that delegation, EPA expects that its interpretation of 40 CFR 702.47 will provide greater flexibility in the Agency's ability to evaluate and manage unreasonable risk from individual chemical substances. Further support for the whole chemical approach is in section 4.1.1.

Section 3.2 – Process of revising the risk determination

EPA received comments related to the process of revising the risk determination. An industry trade organization (0126) requested that EPA withdraw the draft revision to the risk determination and provide an explanation for the proposed changes and additional public comment opportunity before applying the changes. Furthermore, the commenter believes the whole chemical approach lacks clarity and will have substantial impacts on future chemical analysis.

Similarly, another industry trade organization (0136) commented that EPA did not adequately support its decision to apply the whole chemical approach and not to assume workers' use of PPE in EPA's draft revision to the risk determination for cyclic aliphatic bromide cluster (HBCD). The commenter added that EPA also did not adequately respond to some HBCD commenters' concerns raised in the HBCD docket. The commenter stated its view that the NMP draft revision lacks support in the same way as the commenter indicated that the HBCD revision did.

An advocacy group (0131) discussed at length that the *Kisor* case cannot be applied to question the viability of the whole chemical approach as the Supreme Court in this case reaffirmed the long-standing principle that courts must generally defer to agencies' reasonable interpretations of their own ambiguous regulations, and that the list of considerations provided by the Court in *Kisor* favors a reviewing court granting deference to EPA on its whole chemical approach.

***EPA RESPONSE**:*
The revised unreasonable risk determination for NMP is based on the peer reviewed risk characterization of the December 2020 risk evaluation, which was developed according to the TSCA section 26(h) requirement to make science-driven decisions, consistent with best available science, and in accordance with the TSCA section 26(i) requirement to make decisions based on the weight of scientific evidence. Changing the risk determination to a whole chemical approach does not impact the underlying data and analysis presented in the risk characterization of the risk evaluation.

The draft revised unreasonable risk determination for NMP was published in July 2022 along with the Federal Register Notice explaining the whole chemical approach to the NMP risk determination, and why EPA believes that a whole chemical approach to NMP better aligns with TSCA's objective of protecting health and the environment. The draft revised unreasonable risk

determination also explained why EPA believes that not assuming the use of PPE or other mitigating measures better aligns with TSCA. EPA understands that there could be occupational safety protections in place at 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—as noted by OSHA—"outdated and inadequate for ensuring protection of worker health,"[1] or because OSHA has not issued a chemical-specific PEL (as is the case for NMP), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements. EPA provided notice and an opportunity for public comment on the draft revised risk determination for NMP and the approach described in the Federal Register Notice. Further discussion of EPA's consideration of PPE use and OSHA standards are in section 4.2 of this document.

EPA has responded to the comments received on the draft revised unreasonable risk determination for HBCD (EPA-HQ-OPPT-2019-0237-0124)). In that document for HBCD and below, for NMP, EPA provides an expanded explanation of why the whole chemical approach to NMP better aligns with TSCA objectives (including listing of the conditions of use that do and do not drive the unreasonable risk for NMP as a whole chemical substance) and the rationale behind not assuming the use of PPE in the NMP unreasonable risk determination.

With respect to EPA's approach to changing the NMP risk determination, the revised Section 5 of the NMP Risk Evaluation describes the determination of unreasonable risk of NMP as a "whole chemical substance," details how 29 out of the 37 conditions of use EPA evaluated drive the unreasonable risk determination, and explains the change in approach regarding assuming use of PPE by workers. As mentioned, the whole chemical risk determination approach does not impact the underlying data and analysis presented in the risk characterization of the NMP Risk Evaluation. The risk evaluation already includes exposure analysis with and without PPE (see Table 4-55 in the risk evaluation). EPA has made no changes to this scientific analysis. The Agency believes that the revised risk determination is sufficiently clear that it supersedes any conflicting statements in the December 2020 risk evaluation that it is neither necessary nor an appropriate use of resources to reissue the entire risk evaluation.

EPA appreciates comments concerning the application of *Kisor v. Wilkie,* 139 S. Ct. 2400 (2019), to EPA's draft revised unreasonable risk determination for NMP. Similar to the commenter's view, EPA maintains that its interpretation of 40 CFR 702.47 as permitting the issuance of either COU-specific or whole chemical risk determinations is a reasonable interpretation of that regulation and would be entitled to *Auer* deference (*see Auer v. Robbins*, 117 S.Ct. 905 (1997)) when using the multifactor test set forth in *Kisor*.

[1] As noted on Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. https://www.osha.gov/annotated-pels.

Section 4 – Revisions to the risk determination

Section 4.1 – Whole chemical approach vs. individual condition of use (COU)

Section 4.1.1 – Support for the whole chemical approach

Several non-governmental environmental and health advocacy organizations (0131, 0138) and a union (0127) in expressing support for the whole chemical approach for NMP, stated their view that the approach is consistent with the language and purpose of TSCA. One advocacy organization (0138) stated that TSCA requires whole chemical determinations of unreasonable risk to satisfy the mandate to integrate and assess available information on hazards and exposures from the COU, especially in cases of PESS, multiple routes of exposure, and combined risk to exposed populations across the chemical's COUs and life-cycle stages. The commenter added that a whole chemical unreasonable risk determination is also more efficient and straightforward than using a COU-specific approach, reasoning that EPA both could choose not to regulate conditions of use the Agency finds to be safe and could issue clear statements with respect to the safe conditions of use for the chemical at issue. The advocacy organizations (0131, 0138) commented that TSCA unambiguously mandates EPA to conduct a whole chemical risk determination as the language of the statute referencing decision-making for a chemical substance dictates that EPA cannot segment its determination into separate findings of unreasonable risk for some conditions of use and no unreasonable risk for others. One of the advocacy organizations (0131) stated its view that EPA should take a whole chemical approach for all chemicals' future risk determination to fulfill TSCA's mandate that EPA identify the full risk posed by each chemical.

A union (0127) stated that a whole chemical approach would ensure that all workers exposed to unreasonable risks from NMP can be provided equivalent protections under TSCA.

Some commenters (0131, 0138) stated that EPA is correct to rely on the 2019 Ninth Circuit's interpretation of the governing regulation in *Safer Chemicals v. EPA* to conduct a whole chemical risk determination.

EPA RESPONSE:
EPA appreciates the comments in support of the whole chemical approach. As EPA explained in the Federal Register Notice announcing the availability of the draft revised risk determination for NMP, notwithstanding EPA's choice to issue COU-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, and the Ninth Circuit Court of Appeals also recognized the ambiguity of the regulation on this point in *Safer Chemicals et al. v. EPA* (943, F.3d 397 (9th Cir. 2019). 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. EPA expects that this case-by-case approach will provide greater flexibility to evaluate and manage unreasonable risk from individual chemical substances as required under TSCA. EPA anticipates that this flexibility will better serve TSCA's objectives by helping ensure that EPA is best positioned to present, and initiate risk management to address, chemical-specific unreasonable risk determinations. EPA believes this is a reasonable approach under TSCA and the Agency's implementing regulations.

For NMP the whole chemical approach is appropriate because there are benchmark exceedances for substantial number of conditions of use (29 of the 37 evaluated) spanning across the chemical lifecycle–from manufacturing (including import), processing, industrial and commercial use, consumer use, and disposal for workers and consumers. In addition to the breadth of identified risk, EPA also considered the severity of the health effects associated with NMP exposures, including acute and chronic non-cancer effects. Because these chemical-specific health hazards and exposures cut across the conditions of use within the scope of the risk evaluation, a substantial number of conditions of use drive the unreasonable risk, and the Agency is better positioned to achieve its TSCA objectives for NMP when issuing a whole chemical determination for NMP, it is appropriate for the Agency to make a determination that the whole chemical presents an unreasonable risk.

EPA agrees that a whole chemical approach will help ensure the public, including workers, is protected from unreasonable risks from chemicals in a way that is supported by science and the law, and appreciates the commenter's support.

In response to the comment that risk management activities could be tailored to individual conditions of use, EPA notes that, in the final revised risk determination, EPA identifies which conditions of use drive the unreasonable risk of NMP. Consistent with the statutory requirements of TSCA section 6(a), EPA would propose risk management actions to the extent necessary so that NMP no longer presents an unreasonable risk. Therefore, it is expected that EPA's risk management actions will focus 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. For example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities driving unreasonable risk (e.g., consumer use) even if the upstream activities are do not drive the unreasonable risk.

Section 4.1.2 – Opposition to the whole chemical approach

Some commenters, including industry trade associations (0125, 0126, 0128, 0129) opposed the whole chemical approach for unreasonable risk determination. Their comments included:

- EPA has not supported its claim that its whole chemical approach to risk determinations is science-based and has provided no science-based support for why a substantial amount of COUs should trigger a whole chemical unreasonable risk determination.
- EPA did not provide examples of how the whole chemical approach would provide administrative flexibility and did not adequately answer comments regarding this subject in the HBCD and PV29 draft revised risk determinations; thus, the proposed change lacks sufficient rationale. (0126).
- EPA has provided no principles or criteria by which it will determine when to take a whole chemical approach in risk determinations (0126).
- The whole chemical approach would have substantial unintended consequences, including prolonged uncertainty for the regulated community, non-science-based market

impacts, and the continued use of resources to research uses which pose no risk (0125, 0126).

- The whole chemical approach would result in a negative finding on uses that may not have an unreasonable risk, regrettable substitutions as manufacturers seek to quickly implement functional alternatives, and public confusion, as the public will not know which uses are safe and which pose risk (0125, 0126).

Another industry trade organization (0129) stated its view that EPA should continue to make COU-specific risk determinations for NMP and other chemical substances, because such an approach is grounded in the statute and regulations and supported by sound science. This commenter said that using the whole chemical approach fails to provide the clarity of EPA's decision-making regarding the risks presented and not presented by NMP that the COU-specific determinations in the December 2020 risk evaluation provided, and would result in skewed understandings of the risk of chemical substances.

This industry trade organization (0129) also said that EPA's policy changes implemented in the revised unreasonable risk determination for NMP may lead to unwarranted impacts on importers of articles containing a chemical substance for which EPA conducts a risk evaluation. The commenter explained that in the December 2020 Risk Evaluation, EPA concluded that consumer uses of NMP in paint and coating removers, adhesive removers, and in cleaning and furniture care products do not present an unreasonable risk. The commenter noted that by taking a whole chemical approach, EPA may influence a public perception that these COUs present an unreasonable risk. Also, the whole chemical approach may increase the likelihood that EPA will regulate the use of NMP in articles that were previously deemed to not present an unreasonable risk, specifically because EPA views TSCA section 6(a) as permitting EPA to regulate upstream activities in order to address downstream activities driving unreasonable risk even if those upstream activities do not drive the unreasonable risk. Likewise, an industry trade organization (0125) commented that applying a COU-specific approach allows stakeholders and EPA to focus more efficiently on uses that in fact pose unreasonable risks.

Finally, an industry trade association (0128) also incorporated by reference its comments opposed to the whole chemical approach from the PCE draft revision.

EPA RESPONSE:
As EPA explained in the Federal Register Notice announcing the availability of the draft revised risk determination for NMP, EPA acknowledges a lack of specificity in the statute and inconsistency in the regulations with respect to the presentation of risk determinations in TSCA section 6 risk evaluations. Notwithstanding EPA's choice to issue COU-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.

In response to commenters' assertions that EPA has not supported the claim that the whole chemical approach to risk determination is science-based, EPA emphasizes that the revised unreasonable risk determination for NMP is based on the peer reviewed risk characterization in the December 2020 NMP Risk Evaluation, based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) and (i) to make decisions under TSCA section 6 in a manner consistent with the best available science and based on the weight of scientific evidence.

EPA has articulated the basis for a whole chemical approach to NMP in detail in the Federal Register Notice announcing the availability of the draft revised risk determination for NMP. As explained therein, the Agency has inherent authority to replace, revise, reconsider, or repeal previously made decisions to the extent permitted by law, with a 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 29, 42 (1983). The revised unreasonable risk determination for NMP reflects EPA's objective of conducting a technically sound, manageable evaluation to determine whether the chemical substance—not just individual uses or activities—presents an unreasonable risk. 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. Regarding the commenter's concern regarding EPA's consideration of a substantial amount of conditions of use in the risk determination for NMP as a whole chemical, for NMP, the whole chemical approach is appropriate because there are benchmark exceedances for substantial number of conditions of use (spanning across most aspects of the chemical lifecycle–from manufacturing (including import), processing, industrial and commercial use, and disposal) for worker and ONU health, and the severity of the health effects associated with NMP exposures. Since these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, the Agency's risk findings and conclusions encompass a substantial amount of the conditions of use and the Agency is better positioned to achieve its TSCA objectives for NMP when using a whole chemical unreasonable risk determination for NMP, EPA concludes that the Agency's risk determination for NMP is better characterized as a whole chemical risk determination rather than COU-specific risk determination. In the case of NMP, 29 of the 37 conditions of use drive the unreasonable risk and the chemical-specific properties cut across the conditions of use within the scope of the risk evaluation; therefore, EPA has concluded that the risk determination for NMP is better characterized by the whole chemical approach. EPA believes this is a reasonable approach under TSCA and the Agency's implementing regulations.

Responding to commenters' ideas concerning conditions of use which were identified in the December 2020 NMP Risk Evaluation as not presenting unreasonable risk, and what commenters describe as the benefits of a COU-specific approach, in this final revised risk determination, EPA identifies which conditions of use drive the unreasonable risk and which conditions of use do not drive the unreasonable risk of NMP. Regarding the commenter's concern for impacts on imports or sales, as described earlier, EPA has emphasized, in both the Federal Register Notice and the final revised unreasonable risk determination, the conditions of use that drive the unreasonable risk for NMP, as well as listing the conditions of use that do not. Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management actions 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. Therefore, it is expected that EPA's risk management actions will focus on the conditions of use that drive the unreasonable risk. EPA does not expect that the issuance of a whole chemical risk determination for NMP will affect the efficiency of EPA's risk management rulemaking. 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) in order to address downstream activities (e.g., consumer uses) driving unreasonable risk even if the upstream activities do not drive the unreasonable risk.

Furthermore, there is no change in the underlying NMP risk characterization with regard to conditions of use that may relate to articles. Under TSCA section 6(c)(2)(E), any relevant consideration of replacement parts and articles will take place during the risk management rulemaking stage, based on the risk evaluation findings. The public will have an opportunity to provide comments and any additional information during the comment period of the proposed risk management rule.

Regarding the request that EPA incorporate previous comments on separate actions (0128), EPA has considered the commenter's previously submitted comments on the draft revised risk determinations for HBCD, methylene chloride, and PCE that were incorporated into its comments on the NMP draft revised risk determination and has responded in this document to the general themes raised by the commenter therein. EPA has also specifically responded to those comments in the Response to Comments documents for HBCD, methylene chloride, and PCE revised risk determinations.

Section 4.1.3 – Inconsistency with TSCA and Risk Evaluation Rule

Several industry trade organizations (0125, 0126, 0129) provided their view that a whole chemical approach is inconsistent with TSCA and its implementing regulations.

Basis for the whole chemical approach

Three commenters (0126, 0135, 0136) wrote that the whole chemical approach as described in the draft revision lacks the scientific basis or rationale required by TSCA. One of the commenters (0126) stated that by proposing a whole chemical approach, EPA contradicted TSCA and its implementing regulations, did not use sound reasoning, and lacked science-based justification to be in compliance with TSCA section 26. This commenter and an industry trade organization (0126, 0129) cited TSCA section 6(b)(4)(F)(i) and (iv) and stated that EPA must integrate and assess available information on hazards and exposures for the COUs of the chemical substance and consider the likely duration, intensity, frequency and number of exposures under the COUs.

Two industry trade organizations (0135, 0136) stated that EPA's whole chemical approach for unreasonable risk determination is based on hazard rather than risk and thus contrary to TSCA. One of the commenters (0136) provided their view that the Risk Evaluation Rule requires that risk evaluations be comprehensive and thus that risk determinations must be based on all conditions of use rather than driven by a subset of uses. The commenter further described at length their position that EPA used a hazard-based approach because the Agency did not consider aggregate exposures across conditions of use under TSCA section 6(b)(4)(F)(ii) in its final risk evaluation for NMP and did not consider risk holistically, as would be required in a risk characterization. The other industry trade organization (0135) agreed that a whole chemical approach would only be appropriate if all of the evaluated conditions of use in a final risk evaluation present an unreasonable risk or if EPA evaluated aggregate exposures across conditions of use and concluded that the aggregate exposures would present unreasonable risks.

An industry trade organization (0126) commented that language in the HBCD final risk determination and NMP draft revised risk determination departs from the draft revisions to the risk determinations for HBCD and PV29. The commenter stated that EPA's use of "substantial amount" of conditions of use to support application of a whole chemical approach is more arbitrary than the "majority" of conditions language used in the earlier draft revisions. The industry trade organization stated its view that this "substantial amount" term is inconsistent with TSCA section 26's requirements that section 6 decisions be grounded in science and thus that EPA's revision lacks a reasoned explanation. Similarly, another industry trade organization (0135) commented that EPA provided insufficient criteria for when it would apply a whole chemical approach and that this contravenes TSCA's best available science requirement.

Inconsistency with TSCA

Several commenters wrote that the draft revision is inconsistent with TSCA. An industry trade organization (0129) stated its view that a whole chemical approach would functionally disable TSCA section 6(c)(2)(E), as well as Congress' intent for including it, since the provision makes clear that the extent to which articles should be regulated is dictated by what risks a risk evaluation identifies as stemming from exposure to a chemical substance in an article, and articles should not be regulated to ameliorate risk presented by other conditions of use.

An industry trade organization (0135) commented that EPA's whole chemical approach to determinations could only be supported by rationales to allow EPA to (1) regulate any use of a given substance, regardless of whether the specific condition of use presents an unreasonable risk, on the basis that the substance, in any use, has been determined to present an unreasonable risk, or (2) manage risks presented by combinations of activities, or aggregate exposures, of uses, whether they present an unreasonable risk or not. The commenter wrote that either rationale is insufficient under TSCA. The commenter wrote that the former rationale would be inconsistent with TSCA section 6(a)'s requirement that restrictions eliminate risk presented by a substance under a condition of use, and that the latter would require EPA to evaluate and describe aggregate exposures under TSCA Section 6(b)(4)(F)(ii).

An industry trade organization (0136) stated that a whole chemical risk determination would be less useful than COU-specific ones, and thus that such an approach is contrary to TSCA section 6(b). Another industry trade organization (0135) agreed, commenting that EPA should issue orders with findings of no unreasonable risk under specific conditions of use and that such a practice would better conform with TSCA, the Final Risk Evaluation Rule, and EPA's previous risk evaluation for NMP.

An industry trade organization (0129) stated that the whole chemical approach is inconsistent with the structure created by Congress in the Lautenberg Amendments to TSCA in 2016. Specifically, the commenter said that future risk evaluations will be conducted for chemical substances that EPA has already determined "may present" an unreasonable risk through the prioritization process. The commenter stated that if the whole chemical approach is used, the distinction between the "may present" an unreasonable risk standard for prioritization and the "presents" standard for triggering risk management regulations would be lost.

The commenter, as well as another industry trade organization (0126) stated that the practical effect of the whole chemical approach is that there are unlikely to be any determinations of no unreasonable risk. The commenters stated their view that the whole chemical approach thus

impermissibly renders parts of the statute – the provisions for a finding of no unreasonable risk – superfluous. The industry trade organizations stated that the inclusion in the statute of provisions for a finding of no unreasonable risk, including, for example, TSCA section 18(a)(1)(B)(i), is evidence that Congress must have intended for specific COUs to be evaluated by the Agency and risk determinations made for each of those uses. On the other hand, an advocacy organization (0131) discounted this position, providing its view that whether industry actors believe that a whole chemical approach may result in fewer findings of "no unreasonable risk" has no bearing on the legitimacy of EPA's approach under TSCA.

Two industry trade organizations (0125, 0126) also stated their position that if the individual COU approach for unreasonable risk determination is no longer employed, then any opportunity for obtaining the federal preemption of state or local requirements provided for under TSCA Section 18(a) for COUs that pose no unreasonable risk would either be delayed by years until EPA promulgated a final risk management rule or potentially eliminated depending on the scope of the risk management rule. One commenter (0125) noted that the consequence of allowing states to issue chemical regulations while EPA assesses a chemical and until EPA issues a final risk management rule could create an unworkable and confusing set of requirements for any sector.

Similarly, another industry trade organization (0140) stated that the whole chemical approach would result in all evaluated chemicals receiving an unreasonable risk determination and thus would render TSCA's preemption provision regarding cases of no unreasonable risk superfluous.

In contrast, an advocacy group (0132) stated that in the final revised risk determination for HBCD, EPA overstated the preemptive effect on state chemical regulation of risk management rules based on whole chemical risk evaluations. The commenter asserted that, under TSCA section 18(c)(3), states are not preempted from regulating risks, hazards, or conditions of use that EPA does not restrict pursuant to TSCA section 6(a), regardless of whether they were evaluated in the final risk evaluation. The commenter provided its view that the scope of preemption is defined by the requirements of the section 6(a) risk management rules rather than the contents of the earlier risk evaluations.

Additionally, an industry trade organization (0140) commented that the whole chemical approach would contravene policies in TSCA section 3 that direct EPA to not impede unduly or create unnecessary economic barriers to technological innovation.

Inconsistency with the Risk Evaluation Rule

Two commenters (0135, 0136) wrote that the whole chemical approach is not consistent with the Risk Evaluation Rule. An industry trade organization (0135) commented that, contrary to EPA's analysis, the Proposed Risk Evaluation Rule does not support making whole chemical risk determinations on the basis of a subset of conditions of use, reasoning that doing so amounts to "cherry picking" data. The commenter added that the Proposed Risk Evaluation Rule's example of expediting a risk determination on the basis of a specific condition of use did not support making a whole chemical risk determination on that basis. The commenter also stated that EPA's reliance on preamble language from the Final Risk Evaluation Rule improperly downplays 40 C.F.R. 702.47. Furthermore, the commenter cited to statutory and regulatory language in reasoning that a complete reading of 40 C.F.R. §§ 702.31(a) and 702.41(a), and TSCA sections 6(b)(4)(B) and 6(b)(4)(A) indicates that risk determinations must be made on a COU-specific

basis. Additionally, another industry trade organization (0136) stated its view that EPA improperly dismissed a statement from the Risk Evaluation Rule regarding COU-specific determinations without providing sufficient regulatory language or rationale to support its departure from that statement. Further, the commenter stated that any ambiguity in the Final Risk Evaluation Rule as to whole chemical risk determinations should be understood as whether whole chemical determinations can supplement, rather than replace, COU-specific determinations.

Finally, an industry trade organization (0136) commented in part with a hypothetical example that it is unreasonable and contrary to 40 C.F.R. § 702.49(c) for EPA to issue a whole chemical unreasonable risk determination when eight conditions of use do not present an unreasonable risk. The commenter added that it might be appropriate to issue a whole chemical unreasonable risk determination in addition to individual COU-determinations, but this would only be appropriate if EPA concluded that the aggregate exposures across all conditions of use would present unreasonable risks.

EPA RESPONSE:
EPA followed the requirements under TSCA section 6(b)(4) in issuing this revised unreasonable risk determination for NMP, including all requirements for a risk evaluation under TSCA section 6(b)(4)(F). Specifically, Section 4 of the final risk evaluation describes how EPA integrated and assessed reasonably available information on hazards and exposures for the conditions of use for NMP (considering factors such as environmental releases, environmental monitoring and biomonitoring, as well as toxicity testing and physical and chemical properties), to workers, occupational non-users, consumers, and bystanders, using reasonably available data, including modeling.

Regarding the comment that risk evaluations should be comprehensive and thus be based on all conditions of use, in accordance with TSCA section 6(b)(4)(A), EPA evaluates chemical substances to determine whether they present unreasonable risk under the conditions of use. The risk evaluation for NMP encompasses the conditions of use within the scope of the risk evaluation. As set forth in the revised risk determination, EPA has determined that NMP, as a whole chemical substance, presents an unreasonable risk of injury to health when evaluated under its conditions of use.

As EPA explained in the Federal Register Notice announcing the availability of the draft revised risk determination for NMP, 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.

EPA emphasizes that the Agency is not amending the underlying scientific analysis. EPA also 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). (87 FR 39511 (July 1, 2022)). The policy changes do not impact the characterization of risk estimates by condition of use (and summarized in Section 4.2 of the final risk evaluation), or the occupational exposures to workers and ONUs (and summarized in Section 2.4 of the final risk evaluation), including an explanation of the different exposures between workers and ONUs, given the different tasks workers perform under each condition of use. EPA also notes that the assertion that the Agency based its determination on hazard alone is

not correct; the revised unreasonable risk determination is based on both the hazard of the chemical substance and the exposures or environmental releases, as described in Sections 3 and 2, respectively, of the December 2020 NMP Risk Evaluation, and further explained in Sections 5.2 and 5.3 of the revised unreasonable risk determination.

The revised unreasonable risk determination for NMP reflects EPA's objective of conducting a technically sound, manageable evaluation to determine whether the chemical substance—not just individual uses or activities—presents an unreasonable risk. EPA disagrees that a whole chemical approach is appropriate only for an aggregate assessment. 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 this instance a "substantial amount" of conditions of use that drive the unreasonable risk encompasses 29 out of the 37 conditions of use of NMP. A "substantial amount" of conditions of use driving the unreasonable risk is just one of the chemical specific reasons why EPA is making a whole chemical unreasonable risk determination for NMP. Moreover, for NMP, those conditions of use span the lifecycle of the chemical substance—from manufacturing (including import), processing, industrial and commercial use, consumer use, and disposal for worker and consumer health, and the severity of the health effects associated with NMP exposures. Since these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, the Agency's risk findings and conclusions encompass a substantial amount of the conditions of use and the Agency is better positioned to achieve its TSCA objectives for NMP when using a whole chemical unreasonable risk determination for NMP, EPA concludes that the Agency's risk determination for NMP is better characterized as a whole chemical risk determination rather than COU-specific risk determination. EPA disagrees with the commenter's (0135) assertion that a whole chemical approach utilizes only select data. By taking the whole chemical approach, EPA is looking at the risk characterization in the December 2020 NMP Risk Evaluation in a comprehensive manner. In the case of NMP, 29 out of 37 conditions of use drive the unreasonable risk and the chemical-specific properties cut across the conditions of use within the scope of the risk evaluation; therefore, EPA has concluded that the risk determination for NMP is better characterized by the whole chemical approach. EPA believes this is a reasonable approach under TSCA and the Agency's implementing regulations, including requirements under TSCA section 26(h) and (i) that section 6 decisions are consistent with the best available science and are supported by the weight of scientific evidence.

EPA disagrees that the rationales provided by the commenter (0135) provide the only support for a whole chemical approach. As explained in the Federal Register Notice to the draft revised unreasonable risk determination for NMP, EPA has the inherent authority to reconsider previous decisions when 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). EPA acknowledges a lack of specificity in the statute and inconsistency in the regulations with respect to the presentation of risk determinations in TSCA section 6 risk evaluations. In the December 2020 NMP Risk Evaluation, EPA applied 40 CFR 702.47 based on one particular passage in the preamble to the final Risk Evaluation Rule[2], which stated: "The final step of a risk evaluation is for EPA to determine whether the chemical substance, under the conditions of use, presents an unreasonable risk of injury to health

[2] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (82 FR 33726) (July 20, 2017).

or the environment. EPA will make individual risk determinations for all uses identified in the scope. This part of the regulation is slightly amended from the proposed rule, to clarify that the risk determination is part of the risk evaluation, as well as to account for the revised approach to [sic] that ensures each COU covered by the risk evaluation receives a risk determination." 82 FR 33726, 33744. However, 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. The text of 40 CFR 702.47 states: "[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" (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). Notwithstanding the one preambular statement about COU-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, "[a]s 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." (82 FR at 33729).

Therefore, notwithstanding EPA's choice to issue COU-specific risk determinations to date, EPA interprets its risk evaluation regulation to also allow the Agency to issue whole chemical risk determinations. At this time, and as part of this risk determination, EPA is not issuing orders with findings of no unreasonable risk for specific conditions of use (as suggested by 0135) and disagrees that this practice better conforms with TSCA or the risk evaluation rule. EPA emphasizes that either approach (COU-specific determinations or the whole chemical approach) is permissible under the regulation, and the Agency's interpretation is entitled to *Auer* deference when using the multifactor test set forth in *Kisor*. As such, notice and comment rulemaking is not necessary before revising the NMP risk determination.

The unreasonable risk determination does not consider costs or other nonrisk factors. In making the unreasonable risk determination, EPA considers relevant risk-related factors, including, but not limited to: the effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); 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 takes into consideration the Agency's confidence in the data used in the risk estimate. This includes an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimate and the risk characterization. Therefore, the NMP chemical unreasonable risk determination takes in consideration the hazard of NMP and the exposures from all conditions of use of NMP.

Furthermore, there is no change in the underlying NMP risk evaluation. EPA disagrees that a COU-specific risk determination is more useful than a whole-chemical risk determination because EPA has transparently described which conditions of use do or do not drive EPA's determination. In the final revised risk determination, EPA identifies which conditions of use drive the unreasonable risk of NMP. Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management 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) in order to address downstream activities (e.g., consumer uses) driving unreasonable risk even if the upstream activities do not drive the unreasonable risk.

There is no change in the underlying NMP risk evaluation nor in the proposed revised risk determination for NMP with regard to conditions of use that may relate to replacement parts or articles. The revised risk determination identifies conditions of use that drive unreasonable risk from NMP. Under TSCA section 6(c)(2) (D) and (E), any relevant consideration of replacement parts and articles will take place during the risk management rulemaking stage, based on the risk evaluation findings. The public will have an opportunity to provide comments and any additional information during the comment period of the proposed risk management rule.

TSCA section 18(c)(3) defines the scope of federal preemption with respect to any final rule EPA issues under TSCA section 6(a). That provision provides that federal preemption of "statutes, criminal penalties, and administrative actions" applies to "the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action the Administrator takes pursuant to [TSCA section 6(a)]." EPA reads this to mean that states are preempted from imposing requirements through statutes, criminal penalties, and administrative actions relating to any "hazards, exposures, risks, and uses or conditions of use" evaluated in the final risk evaluation and informing the risk determination that EPA addresses in the TSCA section 6(a) rulemaking. For example, federal preemption applies even if EPA does not regulate in that final rule a particular COU, as long as that COU was evaluated in the final risk evaluation.

Regarding the comment referencing TSCA section 6(c)(2)(E) and the concern regarding regulation of articles, EPA notes that the Agency has not identified conditions of use of NMP that include articles. If a condition of use included an article and it was determined to drive the unreasonable risk, EPA would apply any prohibitions or restrictions consistent with TSCA section 6(c)(2)(E) when regulating the unreasonable risk driven by an article. Specifically, EPA emphasizes that there is no change in the underlying NMP risk evaluation nor in the proposed revised risk determination for NMP with regard to conditions of use that may relate to replacement parts or articles. The revised risk determination identifies conditions of use that drive unreasonable risk from NMP. Under TSCA section 6(c)(2) (D) and (E), any relevant consideration of replacement parts and articles will take place during the risk management rulemaking stage, based on the risk evaluation findings. The public will have an opportunity to

provide comments and any additional information during the comment period of the proposed risk management rule.

Similarly, in response to the comment regarding barriers to technological innovation, EPA notes that TSCA section 2(b)(3) specifies that "authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of [TSCA] to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment." Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management action to the extent necessary so that NMP no longer presents an unreasonable risk. As required by TSCA section 6(c)(2)(A), when proposing and promulgating a TSCA section 6(a) rule for NMP, EPA will consider and publish a statement based on reasonably available information with respect to factors including the reasonably ascertainable economic consequences of the rule. The considerations related to reasonably ascertainable economic consequences include, but are not limited to, considerations of the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health.

EPA also notes that there are separate statutory standards and processes for designating chemical substances as high-priority for risk evaluation and conducting TSCA risk evaluations. Under TSCA section 6(b), EPA must designate as a high-priority substance "a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator." (TSCA section 6(b)(1)(B)(i)). EPA is required to consider statutorily-prescribed factors when conducting prioritization and to provide several opportunities for public comment, and the prioritization process must last between 9-12 months (TSCA section 6(b)(1)(A), (C)). Once EPA designates a chemical substance as a high-priority substance for risk evaluation, EPA must then initiate a longer 3- to 3.5-year risk evaluation process. Through that risk evaluation process, EPA must "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 identified as relevant to the risk evaluation by the Administrator, under the conditions of use." (TSCA section 6(b)(4)(A)). That process is subject to separate statutory requirements and considerations applicable to risk evaluations (e.g., TSCA section 6(b)(4)(D), (F)). If EPA finds unreasonable risk through a risk evaluation, EPA must proceed to address that unreasonable risk through TSCA section 6(a) risk management action. Although EPA must conduct a risk evaluation after designating a chemical substance as a high-priority substance, and the reasonably available information and findings informing prioritization will also inform EPA's risk evaluation on a high-priority substance, the standards and processes for TSCA prioritization and risk evaluation are separate and distinct.

Section 4.1.4 – Other comments on the whole chemical approach

Three industry trade organizations (0126, 0129, 0136) requested that EPA:

- Review the whole chemical approach in the context of TSCA's risk-based decision-making framework and requirements for risk management rules (0126);
- Explain how the change to a whole chemical approach may affect risk management (0126, 0129, 0136);
- Develop principles and criteria that would dictate when and how the whole chemical approach would be applied and when it would not (e.g., will it be applied if 50% of the COUs show unreasonable risk? 10%? at least one?) (0126, 0129). How will EPA treat the COUs that it determines do not present an unreasonable risk in its risk management plan when a whole chemical approach has been taken? (0126); and
- Explain how the whole chemical approach is employed in a manner consistent with the best available science or a weight of scientific evidence approach or compelled by the factors and standards dictated by Congress in the amendments to TSCA section 26 (0129).

***EPA RESPONSE**:*
EPA appreciates other comments received in connection with the NMP draft revised unreasonable risk determination. As stated previously, this action pertains only to the risk determination for NMP. While EPA may consider similar actions on other 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.

The revised unreasonable risk determination for NMP is based on the peer reviewed risk characterization of the December 2020 risk evaluation, which is based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) and (i) to make decisions under TSCA section 6 in a manner consistent with the best available science and based on the weight of scientific evidence. Changing the risk determination to a whole chemical approach does not impact the underlying data and analysis presented in the risk characterization of the risk evaluation.

For NMP, the whole chemical approach is appropriate because there are benchmark exceedances for substantial number of conditions of use (spanning across most aspects of the chemical lifecycle–from manufacturing (including import), processing, industrial and commercial use, and disposal) for worker and ONU health, and the severity of the health effects associated with NMP exposures. Since these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, the Agency's risk findings and conclusions encompass a substantial amount of the conditions of use and the Agency is better positioned to achieve its TSCA objectives for NMP when using a whole chemical unreasonable risk determination for NMP, EPA concludes that the Agency's risk determination for NMP is better characterized as a whole chemical risk determination rather than COU-specific risk determination.

With respect to the risk management, consistent with the statutory requirements of TSCA section

6(a), EPA will propose a risk management action to the extent necessary so that NMP no longer presents unreasonable risk. In the final revised risk determination for NMP, EPA has identified the conditions of use that drive the unreasonable risk for NMP and will focus its risk management efforts on addressing that unreasonable risk, as required by TSCA. Regarding how EPA may treat the COUs that it determines do not drive the unreasonable risk, EPA notes 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 options related to manufacture, processing, distribution in commerce, commercial use, and disposal in order to address the unreasonable risk. For instance, EPA may regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities driving unreasonable risk (e.g., consumer use) even if the upstream activities do not drive the unreasonable risk. The public will have another opportunity to provide comments during the comment period of the proposed risk management rule.

Section 4.2 - Baseline scenario that does not assume PPE or other mitigation measures in place

Section 4.2.1 – Support for EPA's intention not to assume PPE or other mitigation measures are in place

Several non-governmental environmental and health advocacy organizations (0131, 0138, 0127) supported EPA's decision to no longer rely on the assumption that workers always and properly use PPE when determining unreasonable risk, agreeing that EPA's baseline for determining risk to workers should not assume the use of PPE. One advocacy organization (0138) stated that the initial assumption regarding PPE lacked legal basis, departed from established federal workplace protection policy and practice, and is contrary to the realities of worker exposure to chemicals. The advocacy organization stated that EPA's revised policy approach follows the recommendation of its Science Advisory Committee on Chemicals (SACC) to base unreasonable risk determinations for workers on measured or estimated exposure levels in the absence of PPE.

A couple of advocacy organizations (0131, 0138) discussed the many limitations of PPE, including EPA's own statements that respirators are often not feasible and may be used only intermittently by workers even where legally required. The commenters stated their view that the OSHA and the National Institute for Occupational Safety and Health (NIOSH), too, have acknowledged the limitations of PPE, having prioritized hazard elimination, substitution, engineering and administrative controls over the use of PPE in the hierarchy of controls. An advocacy organization (0131) said that PPE does not address exposures to workers who are bystanders, as they are not wearing the PPE, and further stated its view that the use of a respirator cannot be used to determine if exposure is lessened sufficiently so that unreasonable risk is mitigated, because EPA does not know the baseline for a particular facility. The same commenter warned that OSHA regulations concerning PPE only apply when the employer determines that workers are subject to sufficient hazards from chemical exposure and whenever else the employer decides it is necessary. Therefore, the employer decides both whether and what hazards exist and whether use of PPE is necessary. One of the advocacy organizations (0138) also noted the SACC's assessment that EPA's characterization of unreasonable risk relying on use of PPE is not sufficiently supported by the practical realities of many workplaces.

Another commenter (0127) said that the NASEM reported that the vast majority of workplaces do not have a respiratory protection program and estimated that roughly 3.3 percent of American workers are protected by the respiratory protection program issued under OSHA standards. The commenter concluded that the revised risk determination accurately reflects the risks workers face.

An advocacy organization (0131) cited TSCA section 6(b)(4)(A), stating that this provision precludes EPA from considering risk mitigation in its workplace risk determinations. The advocacy organization claimed that consideration of the use of PPE – or any other mechanism to mitigate exposure and risk – is a non-risk factor and should thus not be considered in any form as part of the risk evaluation.

***EPA RESPONSE**:*
EPA appreciates the feedback concerning assumptions on the use of PPE in the NMP risk evaluation and the unreasonable risk determination therein, general input regarding PPE, respiratory PPE information (0127), the interaction of EPA and OSHA regulation, and worker protection.

As stated in the revised unreasonable risk determination for NMP, while not appropriate as the basis for the unreasonable risk determination, EPA believes it is appropriate to 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 because such evaluation can help inform potential risk management actions (i.e., by informing EPA's assessment of the feasibility and efficacy of different risk management options). However, as commenters note, EPA cannot reasonably assume that all facilities will have adopted these practices. Therefore, EPA is making its determination of unreasonable risk 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. This 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, 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,"[3] or because OSHA has not issued a chemical-specific PEL (as is the case for NMP), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements. EPA emphasizes that this assumption is for the purpose of unreasonable risk determination. The use of PPE as a means of addressing unreasonable risk will be considered during risk management, as appropriate.

Consistent with TSCA section 9(d), EPA is consulting and coordinating TSCA activities with OSHA, NIOSH, and other relevant federal agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements. Consultation with other relevant federal agencies is also required during the risk evaluation process under EPA's implementing regulations at 40 CFR 702.39. EPA will continue to coordinate with OSHA, NIOSH, and other relevant federal agencies during TSCA risk evaluation and risk

[3] As noted on Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. https://www.osha.gov/annotated-pels.

management activities and expects to refine its consultation process as the Agency conducts additional risk evaluations and risk management rulemakings.

In accordance with TSCA section 26(k), EPA considers reasonably available information when conducting TSCA section 6 risk evaluations and risk management rules. When undertaking risk determinations as part of TSCA risk evaluations, EPA cannot assume as a general matter that workers always or properly use PPE, although it does not question the public comments received regarding the occupational safety practices often followed by industry respondents. Under TSCA section 6(a), EPA must apply one or more risk management requirements to the extent necessary so that a chemical substance no longer presents unreasonable risk. Those requirements may include restrictions on the manufacture, processing, distribution in commerce, commercial use, or disposal of a chemical substance.

Section 4.2.2 – Opposition to EPA's intention not to assume PPE or other mitigation measures are in place

Several commenters expressed opposition to EPA's proposal to not assume the use of PPE when making its unreasonable risk determination for NMP. For example, some industry trade organizations (0129, 0126, 0134, 0136, 0135, 0140) commented that EPA's decision not to assume the use of PPE is inconsistent with the requirement to consider COUs under TSCA and contravenes explicit requirements under TSCA section 26(k) to take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the COUs, that is reasonably available to the Administrator. One industry trade organization (0129) added that when EPA rendered unreasonable risk determinations in the NMP risk evaluation and the other nine initial risk evaluations, EPA's assumption that workplaces comply with the OSHA regulations was reasonable, appropriate, and driven by data. The industry trade organization stated its view that such an approach is grounded in the statute and regulations and is supported by sound science. Similarly, an industry trade organization (0140) stated that EPA has not sufficiently supported its refusal to acknowledge the standard use of PPE practices utilized by industry and regulated by OSHA.

An industry trade organization (0126) emphasized that EPA's proposal to determine risk without considering the effects of current occupational safety standards and PPE practices is not supported by the record nor reasonably justified by any of the reasons offered by the Agency. Specifically, the commenter provided its view that EPA cited no data or records to support its belief concerning the insufficiency of PPE at OSHA regulated facilities. The commenter further stated that EPA also has not presented any evidence of widespread refusal to comply with OSHA requirements and stated its view that OSHA does require the use of appropriate PPE where needed to protect workers from chemical exposures at jobsites. Similarly, another industry trade organization (0125) stated that EPA's proposed approach would likely leave the public with the perception that facilities are out of compliance with federal and state safety standards, would artificially increase the calculated human health risk for particular uses of a chemical, and would create a false and misleading perception of worker risk. Another industry trade organization (0134) stated that EPA acknowledged in the draft revision document that there is not widespread non-compliance with OSHA, and there is no indication of non-compliance with workplace safety requirements in the industry on the administrative record. The commenter stated that they had previously provided EPA with significant data related to their specific condition of use of NMP and occupational safety practices, and EPA gave the information a data quality rating of high.

According to the commenter, the data submissions indicated that there is no dermal NMP exposure to the workers and that PPE failures are extremely rare.

An industry trade organization (0125) stated that if EPA believes that certain workplace risks are not being adequately controlled, then EPA has an obligation under TSCA section 9(a) to consult with OSHA before superseding OSHA's authority. Any such result from coordination and consultation with OSHA should also be made publicly available to further transparency, process, and due diligence. Two industry trade organizations (0135, 0136) stated that, during the first risk determination for NMP, EPA relied on information such as OSHA requirements, information supplied in public comments, and safety data sheets, but did not explain why this information was not valid in the revised risk determination. One advocacy organization (0131) also said that in the December 2020 risk evaluation, EPA evaluated conditions of use both with and without protective measures, which best informs the unreasonable risk determination and the magnitude of potential risks. The commenter said that, in order for EPA to now determine unreasonable risk and regulate chemical substances to the extent that the substance no longer presents an unreasonable risk, it must assume "intentional misuse" as though OSHA has no meaningful legal effect. According to the commenter, the assumption of misuse contradicts EPA's affirmation in the draft revised risk determination that it does not question the public comments received on the original draft risk determination, including those discussing practices of providing PPE to employees and following established worker protection standards. The commenter said that if EPA does not use reasonably available information to ground its evaluation of the substance under specific conditions of use, it is characterizing hazard, instead of risk. In addition, the commenter questioned that, to the extent that EPA discounts compliance with OSHA regulatory requirements as a reasonably foreseen condition of use in determining unreasonable risk, what would prevent an assumption of noncompliance with any future risk management rule with TSCA. The commenter also asked that, in the event that EPA re-evaluates a chemical substance, EPA should make clear the assessment does not assume any risk mitigation.

Similarly, an industry trade organization (0133) stated that manufacturers are required to follow OSHA standards and have communicated data to EPA about PPE use. The commenter stated that the non-consideration of PPE and engineering controls effectively leaves the risk determination as a hazard-based standard, which is inconsistent with the risk-based intent of TSCA.

An industry trade organization (0126) stated that EPA's proposal is not transparent about its plans for implementation of the proposed change in the risk management rule itself and would request the Agency to develop clear, accurate communication materials to explain EPA's new approach to PPE to the already OSHA-regulated community. The commenter stated that EPA's proposal could inadvertently create regulatory confusion and potentially subject companies to overlapping workplace protection requirements for workplaces that are already subject to OSHA. The industry trade organization added that such requirements would be costly and either duplicative of or inconsistent with those that OSHA has already imposed on employers and employees in OSHA-regulated businesses. Further, the commenter stated its view that EPA's rationale for no assumption of PPE in risk evaluations is inconsistent with the statutory and regulatory requirements in the Occupational Safety and Health Act of 1970 (OSH Act) and that EPA must consult with OSHA and NIOSH to understand whether current worker protection from exposure to chemicals is consistent with best available science before making any determinations about the adequacy of OSHA controls.

An industry trade organization (0125) suggested that EPA continue the approach of presenting both scenarios – NMP use with and without PPE – in its risk determinations, claiming that doing so would provide the appropriate bounding scenarios for NMP risk exposures in the workplace. The same commenter stated that waiting until EPA proceeds to the risk management phase to include the use of OSHA-required PPE and related workplace standards creates a false impression of risk that lacks transparency, will be misleading to the public, and overestimates the risk of exposure in workplaces that require workers to follow PPE practices. In addition, it would create an extra layer of work for EPA and industries to work through the risk management phase, when adequate protections may already be in place.

An industry trade organization (0135), in regard to workers that may not be covered by OSHA requirements, stated that EPA appears to speculate that it is intended, known, or reasonably foreseeable that self-employed individuals would not engage in self-protective measures. The commenter said that EPA has not provided a basis for these new assumptions. In addition, these employees are unlikely to be employed in industrial chemical facilities and potentially exposed. The commenter said that if EPA does conclude that specific measures are necessary to protect these self-employed or public sector workers, they should coordinate with OSHA to extend the protections past the boundaries of TSCA authority, instead of imposing those measures in a TSCA regulation. EPA could potentially leave workers actually employed in industrial facilities not regulated by TSCA un- or under-protected in preference of protecting self-employed workers and public sector employees who are much less likely to be exposed significantly to NMP.

***EPA RESPONSE**:*
In the final risk evaluations for the first ten chemical substances, the previous administration generally assumed that for certain conditions of use workers were always provided, and used, PPE in a manner that achieved the stated assigned protection factor (APF) for respiratory protection, or protection factor (PF) for dermal protection. EPA, however, has revisited the assumption that PPE is always used, and always used properly and effectively, in occupational settings when making risk determinations for chemical substances and this revised approach is reflected in the revised unreasonable risk determination for NMP. EPA made this change in approach due to data on violations of PPE use that indicated assumptions that PPE is always provided to workers, and worn properly, are not justified.[4] EPA understands that there could be occupational safety protections in place at 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 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,"[5] or because OSHA has not issued a chemical-specific PEL (as is the case for NMP), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements. For this reason, EPA does not identify the absence of PPE to be "intentional misuse" as the commenter asserts. Continued use of this assumption could result in a risk evaluation that underestimates the risk, and in turn, a risk management rule that may not provide the needed protections. EPA notes that under TSCA section 6(b)(4)(A), EPA is instructed to conduct risk evaluations "to determine whether a

[4] OSHA Standards and Violation Data https://www.osha.gov/top10citedstandards.
[5] As noted on Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. https://www.osha.gov/annotated-pels.

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." TSCA section 3(12) defines "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." That definition provides examples of subpopulations that may be identified as PESS but provides EPA discretion to identify relevant PESS that will be evaluated in each risk evaluation. For purposes of the NMP risk evaluation, EPA has identified workers and ONUs as PESS because these subpopulations experience greater exposure than the general population. This includes workers and ONUs that may not be covered by OSHA PPE requirements and other OSHA standards. EPA is not restricted in its identification or evaluation of workers or ONUs at commercial and industrial facilities that engage in relevant COUs.

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. 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. As described in more detail in Section 4.2.5 below, 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 noncompliance with applicable OSHA standards.

When conducting the NMP risk evaluation, EPA considered reasonably available information on NMP hazards and exposures under the conditions of use, including information on current industry practices, occupational controls and PPE use at commercial and industrial facilities handling NMP as explained in Section 2.4 of the final risk evaluation. EPA appreciates the comments providing information on specific conditions of use and occupational safety practices (0134). EPA used this information when developing exposure assessments for NMP and this information is also being considered in the development of risk management actions. However, as noted before, EPA cannot reasonably assume that all facilities will have adopted these practices. Therefore, EPA is making its determination of unreasonable risk 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.

The revised unreasonable risk determination for NMP is based on the peer reviewed risk characterization of the December 2020 NMP Risk Evaluation, which is based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) and (i) to make decisions under TSCA section 6 in a manner consistent with the best available science. The policy changes in the revised unreasonable risk determination do not impact the underlying data and analysis presented in the risk characterization of the risk evaluation, including how the risk estimates of non-cancer effects

to workers from chronic inhalation exposures at the high-end were calculated and summarized in Table 4-55 of the final risk evaluation.

As described in an earlier response, EPA also notes that the assertion that the Agency based its determination on hazard alone is not correct; the revised unreasonable risk determination is based on both the hazard of the chemical substance and the exposures or environmental releases, as described in Sections 3 and 2, respectively, of the December 2020 NMP Risk Evaluation, and further explained in Sections 5.2 and 5.3 of the revised unreasonable risk determination. The final risk evaluation already includes exposure analysis with and without PPE. Table 4-55 in the final risk evaluation presents risk estimates for each COU with and without PPE. EPA has made no changes to this analysis. Therefore, removing the assumption that workers always and appropriately wear PPE when making the unreasonable risk determination does not create a need for new analysis. The revision to the risk determination clarifies that EPA does not rely on the assumed use of PPE when making the risk determination for the whole substance. Overall, 29 conditions of use drive the NMP whole chemical unreasonable risk determination due to risks identified for human health.

As described earlier, the revised unreasonable risk determination for NMP is based on the peer reviewed risk characterization in the December 2020 NMP Risk Evaluation, based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) and (i) to make decisions under TSCA section 6 in a manner consistent with the best available science and based on the weight of scientific evidence.

EPA disagrees with those commenters who thought that eliminating the assumed use of PPE for risk determination purposes would be misleading to the public. EPA explicitly stated in the draft revised NMP risk determination and accompanying Federal Register Notice that basing the unreasonable risk determination on the baseline scenario without PPE 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, as described earlier, it reflects EPA's recognition that unreasonable risk may exist for workers (which are included in the risk evaluation as a PESS) 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,"[6] or because OSHA has not issued a chemical-specific PEL (as is the case for NMP), or EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements. 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.

Because the requirements and application of TSCA and OSHA regulatory analyses differ, it is appropriate that EPA conduct risk evaluations and, where it finds unreasonable risk to workers, develop risk management requirements for chemical substances that OSHA also regulates, and it

[6] As noted on Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. https://www.osha.gov/annotated-pels.

is understood that EPA's findings and requirements may sometimes diverge from OSHA's. However, it is also appropriate that EPA consider the standards that OSHA has already developed, so as to limit the compliance burden to employers by aligning management approaches required by the agencies, where alignment will adequately address unreasonable risk to workers.

As a general matter, when undertaking risk management actions, EPA will consider occupational risk mitigation measures that could address unreasonable risk identified by EPA, and for any such measures included in a proposed or final TSCA risk management rule, 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. When undertaking risk management actions, EPA intends to develop occupational risk mitigation measures to address any unreasonable risks identified by EPA, especially in cases where current OSHA standards may not apply or be sufficient to address the unreasonable risk.

EPA identified the conditions of use that drive the unreasonable risk in the risk determination, and options will be developed during the process of the Agency working on the risk management rulemaking to address the unreasonable risk presented by the chemical substance. The risk management rulemaking stage is not when EPA determines which conditions of use drive the unreasonable risk.

Under TSCA section 9(a), if EPA determines, in the Administrator's discretion, that an unreasonable risk may be prevented or reduced to a sufficient extent by action taken under a federal law that is not administered by EPA, EPA must submit a report to the agency administering that other authority and undertake a statutorily prescribed referral process. EPA retains the discretion to make this finding in the first instance.

In response to the commenter's request that EPA and OSHA coordinate to extend OSHA's regulations rather than EPA issue a TSCA rulemaking (0135), EPA notes that it is OSHA's purview alone whether to extend OSHA's regulations; EPA's jurisdiction would be to consider the Agency's authority under TSCA section 9 during the rulemaking process, including authority to refer action to OSHA during that process. EPA also notes that, consistent with TSCA section 9(d), EPA is regularly consulting and coordinating 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. EPA appreciates the suggestion to formalize a consultation process with OSHA, as well request for transparency regarding such consultations. EPA will continue to coordinate with OSHA and other relevant federal agencies during TSCA risk evaluation and risk management activities and expects to refine its consultation process as

the Agency conducts additional risk evaluations and risk management rulemakings. The results of any consultation with OSHA, as well as EPA's rationale for proposed risk management requirements, including consideration of the OSHA hierarchy of controls, will be reflected in the proposed rule to address the unreasonable risk presented by NMP.

The public will have an opportunity to comment on the proposed regulatory action, and EPA will consider such public comments and any additional information before finalizing the rulemaking.

Section 4.2.3 – OSHA requirements and industry best practices

An industry trade organization (0126) provided several suggestions for how EPA could address the protection of workers as a PESS including: considering other ways to address concerns about the population of workers not covered by OSHA standards, developing risk evaluations that do not assume that PPE is either always or never used in the workplace, working with OSHA during the scoping phase and discussing improved enforcement of OSHA requirements, considering the European approach to COUs for the workplace, and more.

An advocacy group (0138) discussed how OSHA and NIOSH manage chemical risks using the "hierarchy of controls." The advocacy group also stated that some commenters incorrectly stated that EPA's risk management approach under TSCA is undermining OSHA's worker protection responsibilities.

***EPA RESPONSE**:*
For purposes of making the TSCA unreasonable risk determination, it is inappropriate to assume as a general matter that industry best practices are consistently and always properly applied or that all facilities have adopted these practices. Once EPA has determined that a chemical substance presents an unreasonable risk, EPA is required to address the identified unreasonable risk through rulemaking. EPA intends to consider current best workplace practices as it develops TSCA section 6(a) risk management action to address the unreasonable risk determined in the NMP risk evaluation, for instance to help inform EPA's assessment of the feasibility and efficacy of different risk management options. Information on best workplace practices could also include information from other countries, such as the European approach mentioned by the commenters.

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 for the hierarchy of controls, to the extent that the requirements, controls, and practices eliminate the identified unreasonable risks. EPA appreciates the comment (0138) supporting EPA's intention for consistency with the hierarchy of controls and OSHA requirements where possible. Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules requiring 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. EPA will undertake a separate public notice and comment period as part of the TSCA section 6(a) risk management rulemaking for NMP and will consider public comments and any additional information before finalizing the rulemaking. Consistent with TSCA section 9(d), EPA is consulting and coordinating 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. Consultation with other relevant federal agencies is also required during the risk evaluation process under EPA's implementing regulations at 40 CFR 702.39.

As required by TSCA, when conducting risk evaluations, EPA identifies relevant PESS, and Section 2.4.1 of the December 2020 NMP Risk Evaluation includes workers and female workers of reproductive age as PESS. Notwithstanding the analysis done for NMP, EPA acknowledges the suggestions by several commenters to identify workers as a PESS for future risk evaluations and encourages the commenters to submit chemical-specific comments on PESS to assist during future risk evaluations' comment periods.

Section 4.2.4 – Other comments regarding determination of unreasonable risk not assuming PPE or other mitigations measures are in place

An advocacy organization (0131) stated that, while EPA determined that it would be inappropriate to include the assumption of PPE use for determining whether there is an unreasonable risk, the Agency stated that it would consider the use of PPE in the risk evaluation to help inform risk management decision. The organization stated that they view this as an unsupportable approach. The commenter stated that TSCA prohibits EPA from considering costs or other nonrisk factors in its risk evaluations. The commenter said that in addition to the fact that risk management is not part of the risk assessment paradigm, for EPA to include risk mitigation factors in the risk determination would improperly conflate risk management in TSCA section 6(a) with the risk determination of TSCA section 6(b). Also, for the Agency to incorporate certain risk mitigation actions into its risk evaluation and determination would conflict with the TSCA section 26 requirement that EPA use the best available science. The commenter concluded that EPA should *not* consider selected facilities' practices or regulatory requirements to determine worker risk and should recognize the limitations of using such information for risk management, as the degree of efficacy can vary depending on the facility. Similarly, an advocacy group (0138) cautioned EPA against treating PPE as a best practice in selecting risk management options.

An industry trade organization (0133) said there will likely be a delay of years between when the Agency publishes the final risk evaluation and when the Agency publishes the final risk management actions that take into account PPE. The commenter expressed concern for the workplace and the potential confusion the final risk determination could cause in this interim period. The commenter suggested that EPA incorporate a table for industrial and commercial uses that identifies whether there is an unreasonable risk without PPE and with known PPE, which would facilitate the submission of more robust and targeted comments during risk management, and effectively communicate the risk to stakeholders.

Two industry trade organizations (0135, 0136) stated that in the December 2020 risk evaluation, EPA did not identify employees not covered by OSHA requirements as a PESS in the final risk evaluation for NMP. One of these commenters (0136) said that such persons, however, are also unlikely to be exposed to the neat substances or to the substances at elevated concentrations and are therefore not reasonably foreseen. Though EPA seeks to ensure it addresses unreasonable risk in all occupational conditions of use, it must first evaluate risk presented to this category of employees under the intended, known, or reasonably foreseen conditions of use.

The commenter also stated that EPA does not explain how the proposal will be consistent with the requirement under TSCA section 9(d) that EPA must avoid the duplication of Federal action against unreasonable risk. The commenter stated that, though EPA states that it intends to consult and coordinate with OSHA, EPA also assumes that because current OSHA standards do not extend to all workplaces, regulating the substances under TSCA section 6(a) will appropriately address unreasonable risk in all occupational settings. However, as the commenter stated, EPA should also consider that not all workers employed in regulated facilities are regulated by TSCA. Further, the commenter stated that EPA should evaluate unreasonable risks to workers not covered by OSHA standards and consider necessary protections for this category of workers separately.

Similarly, an industry trade organization (0135) stated that, though EPA cites its proposal as consistent with section 9(d) such that it will not impose duplicative requirements, it is not clear, where the line will be drawn during risk management based on EPA's assumptions as to the protectiveness and applicability of OSHA standards.

An advocacy organization (0131) expressed support for EPA's proposal to discard the assumptions of existing worker protection, including use of PPE during risk determinations. However, the commenter took issue with EPA's statement in the revised risk determination that in some risk evaluations, levels of risks to workers may be evaluated with and without OSHA requirements and industry best practices scenarios that are clearly articulated to the Agency. The advocacy organization stated its view that EPA should not use worker mitigation characterizations and scenarios during risk evaluation, EPA should also recognize that there are limitations to such information during risk management.

***EPA RESPONSE**:*
EPA believes it is appropriate to 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 because such evaluation can help inform potential risk management actions (i.e., by informing EPA's assessment of the feasibility and efficacy of different risk management options). However, as commenters note, for purposes of making the TSCA unreasonable risk determination, it is inappropriate to assume as a general matter that industry best practices are consistently and always properly applied or that all facilities have adopted these practices. Once EPA has determined that a chemical substance presents an unreasonable risk, EPA is required to address the identified unreasonable risk of injury to health determined in the NMP risk evaluation and revised risk determination, including unreasonable risk driven by acute and chronic non-cancer effects. In response to the comment (0136) that EPA did not identify employees not covered by OSHA requirements as a PESS, EPA notes that in the December 2020 Risk Evaluation for NMP, EPA identified workers and ONUs (including men and women of reproductive age, and adolescents), among others, as PESS (see Section 2.4.1 and Table 4-4), regardless of whether the employees would be covered by OSHA requirements.

In response to the commenter's concern that during the time between final risk evaluation and final rule there may be potential confusion in workplaces, (0133) EPA appreciates the suggestions provided and notes that the risk evaluation already includes an exposure analysis with and without PPE. Table 4-55 in the final risk evaluation presents risk estimates for each condition of use with and without PPE. EPA has made no changes to this analysis. Therefore, removing the assumption that workers always and appropriately wear PPE when making the

unreasonable risk determination does not create a need for new analysis. The finalized revision to the risk determination clarifies that EPA does not rely on the assumed use of PPE when making the risk determination for the whole substance (section 5.1). Overall, 29 conditions of use drive the NMP whole chemical unreasonable risk determination due to risks identified for human health.

EPA understands that there could be occupational safety protections in place at 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 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,"[7] or because OSHA has not issued a chemical-specific PEL (as is the case for NMP), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements. Regarding the commenter's assertion that EPA should consider that not all industrial facilities are regulated by TSCA, EPA notes that under TSCA sections 6(a)(2) and (5), EPA has the authority to prohibit or restrict the manufacture, processing, distribution in commerce, or manner or method of commercial use of a chemical substance or mixture, with the definition of chemical substance provided in TSCA section 3.

In response to the commenter's concern regarding duplication of OSHA requirements (0135), 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 NIOSH hierarchy of controls, to the extent that the requirements, controls, and practices eliminate the identified unreasonable risks. Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules requiring 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. Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management action to the extent necessary so that NMP no longer presents an unreasonable risk. Also, consistent with TSCA section 9(d), EPA is consulting and coordinating TSCA activities with OSHA, NIOSH, and other relevant federal agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements. In the proposed rules under TSCA section 6(a), EPA will explain the consultation and coordination with other appropriate Federal executive departments and agencies, including OSHA, as required by TSCA section 9(d). EPA will undertake a separate public notice and comment period as part of the TSCA section 6(a) risk management rulemaking for NMP, and will consider public comments and any additional information before finalizing the rulemaking.

In response to the commenter's concern (0131) that EPA is incorporating risk management actions into the risk evaluation, the Agency clarifies that 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. As described earlier, the revised

[7] As noted on Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. https://www.osha.gov/annotated-pels.

unreasonable risk determination for NMP is based on the peer reviewed risk characterization in the December 2020 NMP Risk Evaluation, based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) and (i) to make decisions under TSCA section 6 in a manner consistent with the best available science and based on the weight of scientific evidence.

Regarding the comment on PPE as a risk management option, EPA notes that 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.

Section 4.2.5 – Permissible exposure limits (PELs)

In response to EPA's statement in the draft revision to the NMP risk determination that the Agency intends to make its unreasonable risk determination from a baseline scenario that does not assume compliance with OSHA standards, one commenter (0131) discussed OSHA's PELs. In expressing support for EPA's proposed assumption, the advocacy organization stated that OSHA itself has noted that many of its PELs are outdated and inadequate for ensuring protection of worker health. The commenter concluded that, therefore, even when a company may be in compliance with an OSHA requirement, its worker protection program may nevertheless result in unreasonable risks to workers.

The advocacy organization (0131) also commented that in the NMP risk determination, EPA incorrectly suggests that compliance with OSHA PELs may protect against unreasonable risks. The commenter stated its view that this is misleading since, in determining risk under TSCA, EPA is directed to not consider cost or other nonrisk factors; in contrast, in setting a PEL, OSHA must consider technological and economic feasibility. In addition, a greater degree of risk is acceptable under the OSH Act (significant risk) than under TSCA (unreasonable risk). The commenter concluded that an unreasonable risk under TSCA would not likely be considered a significant risk under the OSH Act and, therefore, it is not clear how EPA could envision that compliance with the OSHA standards would consistently protect against unreasonable risks.

EPA RESPONSE:
EPA notes that for NMP there is no established chemical-specific OSHA PEL and therefore the consideration of a NMP PEL was not a factor in the revised unreasonable risk determination. EPA recognizes that some level of respiratory protection could be used at some workplaces due to the OSHA PEL for respirable dust particulates (OSHA PNOR PEL); however, EPA has revisited the assumption that PPE is always used properly and effectively in occupational settings when making risk determinations for a chemical substance and this revised approach is reflected in the revised unreasonable risk determination for NMP.

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. The General Duty Clause of the OSH Act requires employers to keep their workplace 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. Because the requirements and application of TSCA and OSHA regulatory analyses differ, it is appropriate that EPA 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 understood that EPA's findings and requirements may sometimes diverge from OSHA's. It is appropriate, however, that EPA consider the chemical standards that OSHA has already developed, so as to limit the compliance burden to employers by aligning management approaches required by the agencies, where alignment will adequately address unreasonable risk to workers.

EPA conducts baseline assessments of risk and makes its determination of unreasonable risk from a baseline scenario that is not based on an assumption of 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 noncompliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by 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,"[8] or because OSHA has not issued a chemical-specific PEL (as is the case for NMP), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements

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 NIOSH hierarchy of controls, to the extent that the requirements, controls, and practices address the identified unreasonable risks according to TSCA section 6(a).

Section 5 – Conditions of use that drive the unreasonable risk determination

Section 5.1 – Processing

An industry trade organization (0128) stated that EPA's final risk evaluation for NMP did not accurately reflect risk to workers in the petroleum and petrochemical industry because it did not take proper account of the safety protocols in place at refineries, such as the use of chemically resistant gloves or respirators. The commenter said that EPA's approach to assessing occupational exposure was based on a generalized scenario, not the real condition of use of NMP in lubricant extraction. The commenter said that if there are other processing uses that occur outside of refineries and are subject to different conditions, EPA should consider them separately and not apply generalized least-common-denominator assumptions.

The industry trade organization explained that lubricant extraction is a refining step that uses a solvent to physically separate undesirable aromatic and polar components from the lubricant base

[8] As noted on Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. https://www.osha.gov/annotated-pels.

stocks. The commenter described in detail the lubricant extraction process and stated that lubricant extraction removes the polycyclic aromatic hydrocarbons, most of which have carcinogenic ratings, and improves the finished lube base stocks oxidative and thermal stability, which results in less oil breakdown and deposit formation during end-use conditions. The industry trade organization asserted that the industry has developed safe operating protocols for lubricant extraction operations including the use of NMP and stated that these specific operating protocols exist within the broader framework of the robust hazard communication and safety programs at refineries. In addition, the commenter stated that NMP is a safer alternative to solvents previously commercialized for lube extraction, due to its low volatility, thermal stability, and other physio-chemical attributes that make it highly suitable and safe for use.

EPA RESPONSE:
EPA has evaluated exposures to workers, occupational non-users, consumer users, and bystanders using reasonably available monitoring and modeling data for exposures to NMP as required under TSCA section 6(b). The policy changes described in the Federal Register Notice announcing the availability of the revised risk determination for NMP do not amend or impact the underlying data and analysis presented in the risk characterization of the December 2020 NMP Risk Evaluation. The policy changes do not impact the characterization of risk estimates by condition of use (summarized in Section 4 of the final risk evaluation), or the occupational exposures to workers and ONUs (summarized in Section 2.4 of the final risk evaluation).

EPA appreciates the comment describing the safety protocols in refineries and the petrochemical industry about lubricant extraction (0128) and notes that further information on the data and information EPA considered related to petrochemical manufacturing in the December 2020 NMP Risk Evaluation can be found in the Supplemental Information on Occupational Exposure Assessment[9] file. EPA intends to consider current best workplace practices as it develops TSCA section 6(a) risk management action to address the unreasonable risk determined in the NMP risk evaluation; for instance, to help inform EPA's assessment of the feasibility and efficacy of different risk management options.

EPA will consider this context during the development the upcoming proposed risk management rule, which will be available for public comment. EPA will undertake a separate public notice and comment period as part of the TSCA section 6(a) risk management rulemaking for NMP, and will consider public comments with any additional information, particularly related to proper safety protocols in place at refineries, before finalizing the rulemaking.

Section 5.2 – Industrial and commercial use

A product manufacturer (0124) stated that its use of NMP in its battery production activities is unique, narrow, and highly specialized. The product manufacturer described in detail the specific condition of NMP use, including the role NMP plays in making the anodes and cathodes for national security batteries. The commenter stated that NMP-containing binder and powders are enclosed in a mixer, blended and the resulting fully-mixed electrode slurry is transferred to a sealed, pressurized tank. The slurry is then pumped directly to a coater, where it is automatically spread onto a foil substrate via a sealed slot die or reverse comma coating head. This material

[9] NMP Supplemental Information on Occupational Exposure Assessment is located in the docket EPA-HQ-OPPT-2019-0236-0093. https://www.regulations.gov/docket/EPA-HQ-OPPT-2019-0236/document?filter=occupational&pageNumber=2

then runs through a heated, negative pressure drying oven, where it undergoes a thermal drying process that causes the NMP binder to evaporate, leaving behind a dry plate. The commenter urged that this production process relies on NMP's unique chemical properties, which cannot be replicated by other substances; further, there are no technically and economically feasible safer alternative to NMP. The product manufacturer also stated that the risk of hazard and exposure is low for this condition of NMP use, since only small quantities of NMP are used and the limited manufacturing steps that involve NMP are highly controlled in a manner that minimizes exposure risks. The commenter discussed the criteria for a TSCA section 6(g) exemption and asserted that its use of NMP for battery production fits squarely within the exemption criteria. Specifically, the commenter urged that its use of NMP to produce mission-critical lithium ion and silver oxide zinc batteries warrants an exemption under TSCA section 6(g), because preventing this use would significantly disrupt national security. In addition, the product manufacturer stated that its batteries are also used in critically important medical applications.

Relatedly, an industry trade organization (0134) stated that, compared to other industries in the electronic parts category, the handling of NMP in small containers in lithium ion cell manufacturing is limited to infrequent use in the laboratory with personnel equipped with extensive PPE for no more than 30 minute shifts. As a result of the engineering controls and PPE used in lithium ion cell manufacturing, direct contact with NMP is strictly prohibited and avoided, and thus the commenter asserts that their workplace practices present no unreasonable risk to employees. The commenter added that this conclusion was supported by EPA's Supplemental File on Occupational Risk Calculations from December 2020 with respect to six tasks modeled for lithium ion cell manufacturing. In summary, the commenter said they believe EPA's draft finding of unreasonable risk for workers during lithium ion cell manufacturing remains grounded upon erroneous assumptions concerning how the industry handles NMP, implements engineering controls, and protects workers. In addition, the commenter stated that it is essential for EPA to understand and provide a balanced description of NMP that captures the crucial role of the solvent in strategically important, domestic manufacturing operations. The commenter said that the regulation of NMP in the U.S. is a question of major economic significance and national security. The commenter said that lithium ion batteries are used in a variety of products that are of critical importance to numerous domestic goals, including those outlined in Executive Order 13990. The commenter requested that EPA revise the NMP description to capture the critical role of the substance in several industries, and acknowledge that there are currently no commercially available or technically proven substitutes for NMP in the manufacturing process. The commenter said that lithium ion cells cannot be manufactured without NMP.

An industry trade organization (0125) also stated that NMP is used in the manufacture of lithium-ion cells. The commenter expressed support for the comments submitted by the Lithium-Ion Cell Manufacturers' Coalition. In addition, the commenter said that NMP is also used in the automotive sector, for which feasible substitutes are not readily available, and where substitutes do exist, the uncertainty created by EPA's focus on a number of solvents hindered the testing and selection of a substitute as industry is concerned about the possibility of a regrettable substitution. The commenter requested that EPA provide some clarity regarding substitutes, which would make identifying NMP substitutes a more viable option.

An industry trade organization (0139) expressed disagreement with EPA's conclusion in the final risk evaluation for NMP that certain conditions of use in the semiconductor industry present an

unreasonable risk to workers. The commenter said that they provided voluminous information to EPA which EPA deemed to be of high quality, and which supports the conclusion that the conditions of use of NMP in semiconductor fabrication in the U.S. safely mitigates worker exposure and present no unreasonable risk to workers. The commenter submitted this information in an attachment to its comment and requested that the information be included in the docket for the NMP risk determination. The commenter said that they submitted a request for correction to the Risk Evaluation, to which EPA still has not responded, and the issues have not been addressed in the revised risk determination. The commenter requested that EPA review and reconsider the extensive information they submitted and conclude that existing management practices within the semiconductor industry are sufficient to mitigate worker exposure.

An industry trade organization (0137) expressed disagreement with EPA's finding that NMP poses an unreasonable risk to human health or the environment in the conditions of use applicable to the electroindustry. In response to the previous risk determination, the commenter said that they provided EPA with information about the polymer applicator and curing oven, and informed EPA that human exposure to NMP is controlled through the use of PPE and engineering controls. The commenter stated that the strength and reliability of this information was deemed "high" by EPA. The commenter stated that EPA must grant a critical use exemption for the electroindustry and that imposing a ban on manufacturers would render them less competitive in the global marketplace and threaten US-based jobs. In addition to an exemption, the commenter requested that EPA provide de minimis exemptions for articles containing less than 1.0% (by weight) of NMP, replacement parts exemptions, large-scale manufacturing equipment exemptions, and an inventory "sell through."

EPA RESPONSE:
EPA appreciates the information regarding the industrial and commercial uses of NMP in the electroindustry, battery production and semiconductor manufacturing, submitted by commenters (0124, 0125, 0134, 0137, 0139). EPA notes that consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management actions to the extent necessary so that NMP no longer presents an unreasonable risk. As stated in the revised unreasonable risk determination for NMP, EPA believes it is appropriate to 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 because such evaluation can help inform potential risk management actions (i.e., by informing EPA's assessment of the feasibility and efficacy of different risk management options). EPA encourages the commenters to submit specific comments about worker protection measures, including engineering controls and administrative controls, during the future public comment period for the forthcoming NMP risk management rule. As part of that rulemaking, EPA will consider reasonably available information on worker protection measures, including information provided by regulated industries.

In response to the request (0125) that EPA provide some clarity regarding substitutes, EPA strives to keep stakeholders informed of future prioritization and risk evaluations and encourages them to access publications put forth by EPA such as those in the Federal Register and the EPA's webpages on assessing and managing risks of chemical substances under TSCA. EPA expects to publish an Alternatives Assessment with the proposed risk management rule.

In response to the request (0139) that EPA revise its assessment in the December 2020 Risk Evaluation for the condition of use of NMP in the semiconductor industry, EPA appreciates the information provided and will consider it as part of risk management. However, as noted previously, EPA has revisited the assumption that PPE is always used properly and effectively in occupational settings when making risk determinations for a chemical substance and this revised approach is reflected in the revised unreasonable risk determination for NMP. The policy changes described in the Federal Register Notice announcing the availability of the final risk determination for NMP do not amend the underlying data and analysis presented in the risk characterization of the December 2020 NMP Risk Evaluation. EPA's response to the open request for correction case submitted by the stakeholder is still in review. Please visit https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration for information regarding the status of the request.

EPA appreciates the comment (0137) requesting the following exemptions from the upcoming proposed rulemaking under TSCA section 6(a): de minimis value for articles, replacement parts, large scale manufacturing equipment, and an inventory sell through. EPA also appreciates the information provided by comment (0124) requesting a TSCA section 6(g) exemption. EPA emphasizes that consistent with the statutory requirements of TSCA section 6(a), EPA must propose risk management actions to the extent necessary so that the chemical substance no longer presents an unreasonable risk. Additionally, 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 will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect. Under TSCA section 6(c)(2)(D) and (E), any relevant consideration of replacement parts and articles will take place during the risk management rulemaking stage, based on the risk evaluation findings. The public will have an opportunity to comment on the proposed regulatory action, and EPA will consider such public comments and any additional information and the proposed regulatory action before finalizing the rulemaking.

Section 6 – Comments regarding conditions of use that do not drive the unreasonable risk determination

An industry trade organization (0133) commented that there is no indication in the current proposal how COUs that do not pose an unreasonable risk will be addressed. The commenter stated its view that this creates uncertainty in the marketplace and may lead to unnecessary supply disruptions that could have been avoided. In addition, the industry trade organization stated that it is not clear how this would impact the preemptive effects of TSCA. The commenter recommended that the Agency clearly indicate how EPA intends to approach COUs that do not pose an unreasonable risk throughout the rest of the risk evaluation process.

An advocacy organization (0131) expressed support for EPA's approach, in that the Agency is not limited to regulating the precise activities that drive unreasonable risk and for example, may choose to regulate upstream COUs, such as processing and distribution in commerce, to avoid downstream unreasonable risk drivers, such as consumer use, even if the upstream activities are not unreasonable risk drivers.

The advocacy organization (0131) recommended that EPA re-evaluate its risk determination for distribution in commerce considering exposures from spills and leaks, as well as its assumption that compliance with existing regulations for the transportation of hazardous materials will not result in an unreasonable risk. The advocacy organization stated its view that spills and leaks can result in significant exposures and are not infrequent, unpredictable events; thus, EPA should not have excluded spills and leaks from the risk evaluation. In addition, the commenter stated that EPA's assumption that compliance with existing regulations for the transportation of hazardous materials will not result in an unreasonable risk is without rationale. The advocacy organization recommended that EPA re-evaluate its risk determination for distribution in commerce considering exposures from spills and leaks and explain its assumption that compliance with existing regulations for the transportation of hazardous materials will not result in an unreasonable risk.

EPA RESPONSE:
EPA understands there is strong public interest in learning how unreasonable risk from NMP will be addressed, including potential impacts on specific conditions of use, including those that do not drive the unreasonable risk for NMP. Consistent with the statutory requirements of TSCA section 6(a), EPA will by rule apply one or more of the risk management options in TSCA section 6(a) 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, as one commenter suggests (0131), 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. EPA agrees with the commenter that, as a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities (e.g., consumer uses) driving unreasonable risk even if the upstream activities do not drive the unreasonable risk.

Regarding preemption, as described earlier in this document, TSCA section 18(c)(3) defines the scope of federal preemption with respect to any final rule EPA issues under TSCA section 6(a). That provision provides that federal preemption of "statutes, criminal penalties, and administrative actions" applies to "the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action the Administrator takes pursuant to [TSCA section 6(a)]." EPA reads this to mean that states are preempted from imposing requirements through statutes, criminal penalties, and administrative actions relating to any "hazards, exposures, risks, and uses or conditions of use" evaluated in the final risk evaluation and informing the risk determination that EPA addresses in the TSCA section 6(a) rulemaking. For example, federal preemption applies even if EPA does not regulate in that final rule a particular COU, as long as that COU was evaluated in the final risk evaluation.

With respect to the comment related to distribution in commerce, spills, and leaks (0131), as in the December 2020 risk evaluation, EPA's final revised risk determination maintains that distribution in commerce of NMP is the transportation associated with the moving of NMP in commerce. EPA has determined that unreasonable risk to workers and ONUs is not driven by the activities associated with this COU, which consists of the actual moving of the chemical in commerce. The loading and unloading activities are associated with other conditions of use (e.g.,

processing). EPA assumed limited emissions from the actual transportation of chemicals (i.e., neither persons nor the environment would be exposed to the chemical in the transportation container), given the fact that these chemicals are transported according to existing hazardous materials transportation rules. In the NMP revised unreasonable risk determination, EPA recognizes that, due to the practical realities of how chemicals are transported and the fact that the condition of use is limited to the movement of the chemical in commerce, exposures to workers are expected to be minimal. Spills and leaks generally were not included within the scope of the first 10 TSCA risk evaluation, including for NMP. Further information on the assessment of spills and leaks in the risk evaluation are included in the Summary of External Peer Review and Public Comments and Disposition for n-methylpyrrolidone (NMP) (EPA-HQ-OPPT-2019-0236-0082).

Based on the limited emissions from the transportation of chemicals, EPA has determined that distribution in commerce of NMP does not drive the unreasonable risk determination for NMP.

Section 7 – Comments regarding EPA's withdrawal of the associated orders

An industry trade organization (0135) requested that EPA not withdraw the order for the NMP COUs that were found not to present an unreasonable risk under the December 2020 risk evaluation. This commenter requested that EPA not withdraw the existing associated orders to avoid regulatory issues in states which promulgate risk management rules before EPA finalizes their federal rule and create preemption concerns over state and federal requirements. The industry trade organization requested that EPA keep the associated orders in place until a second round of risk evaluations for the ten Work Plan chemicals have been completed to provide additional certainty throughout the process and until new risk management rules are in place.

This industry trade organization (0135) also urged that a finding of no unreasonable risk under TSCA for one or more conditions of use is considered a final EPA action and must be issued by order, and EPA's proposed action to withdraw its final determination of no unreasonable risk in the draft revised risk determination for NMP thus violates this requirement.

***EPA RESPONSE**:*
EPA does not plan to conduct a second risk evaluation on NMP prior to finalizing the revised unreasonable risk determination. 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 after consideration of the public comments received on the draft is now finalizing a revised risk determination for NMP. EPA disagrees with the commenter (0135) that the Agency has violated a requirement to issue a no unreasonable risk determination for specific conditions of use. 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. Consistent with the statutory requirements of TSCA

section 6(a), the Agency will propose risk management actions to the extent necessary to address the unreasonable risk presented by NMP.

TSCA section 18(c)(3) defines the scope of federal preemption with respect to any final rule EPA issues under TSCA section 6(a). That provision provides that federal preemption of statutes, criminal penalties, and administrative actions applies to the hazards, exposures, risks, and uses or conditions of use of the chemical substance included in any final action the Administrator takes pursuant to TSCA section 6(a). EPA reads this to mean that states are preempted from imposing requirements through statutes, criminal penalties, and administrative actions relating to any hazards, exposures, risks, and uses or conditions of use evaluated in the final risk evaluation and informing the risk determination that EPA addresses in the TSCA section 6(a) rulemaking. For example, federal preemption applies even if EPA does not regulate in that final rule a particular COU, but that COU was evaluated in the final risk evaluation.

Section 8 – Comments on EPA's screening approach to assess risks from air and water pathways

An industry trade organization (0126) commented that any supplemental analyses for the risk evaluations that have the potential to influence the risk management rules (including a screening approach to assess potential risks from the air and water pathways) must be made available for public comment.

A comment submitted by several state and local government agencies and organizations (0141) encouraged EPA to consider all exposure pathways for current and future TSCA risk evaluations, including areas that are, or could be, regulated under other statutes, such as the Clean Air Act, Clean Water Act, Safe Drinking Water Act, and Resource Conservation and Recovery Act. The commenter stated its view that EPA's past exclusion of those exposure pathways for the first ten chemicals was concerning and expressed support for the reevaluation of those findings. The state government agency encouraged close coordination of TSCA regulatory processes with other related processes, such as regulation of hazardous air pollutants. The commenter also suggested that EPA establish an improved screening approach to assess exposures and risks for fenceline communities and other PESS.

***EPA RESPONSE**:*
As described in the Federal Register Notice, the NMP risk determination has been revised to reflect announced policy changes to help ensure the public is protected from unreasonable risks from chemicals in a way that is supported by science and the law. Separately, EPA is conducting a screening approach to assess risks from the air and water pathways for several of the first 10 chemicals, including NMP. In January 2022, EPA released the TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities for public comment and peer review; in March 2022, EPA held a public virtual meeting of the Science Advisory Committee on Chemicals (SACC) to peer review the approach. EPA presented Version 1.0 of a screening level methodology for assessing potential air and water pathway chemical exposures to fenceline communities. Along with presenting this methodology, EPA also presented results of applying the screening methodology (case studies) to 1-brompropane (air pathway), n-methylpyrrolidone (water pathway), and methylene chloride (air and water pathways). The proposed screening level methodology went through a public comment period and peer review (by the SACC) for comments on the proposed methodology as well as recommended revisions or

improvements to the methodology. The SACC delivered its report in May 2022. Following public comment and peer review, EPA is reviewing comments, recommendations, and improvements; and modifying the fenceline methodology, as appropriate. EPA expects to describe its findings regarding the chemical-specific application of this screening-level approach in the forthcoming proposed TSCA section 6(a) risk management rule for NMP.

EPA notes that the Agency engages in intra-agency review on TSCA risk evaluations, as well as coordination within EPA to promote the type of coordination the commenter describes. EPA also notes the opportunities for public engagement throughout the risk evaluation process and appreciates the comments from state government agencies and others received to date.

Section 9 – Other comments related to the draft revision of the risk determination

Risk Management

An industry trade organization (0125) requested that EPA identify a *de minimis* level for NMP below which EPA has no reasonable basis to conclude that there is an unreasonable risk and recommended that EPA establish a *de minimis* level for chemicals in articles and mixtures based on a reasonable potential for exposure. The commenter stated that EPA has recently recognized the practicality of *de minimis* thresholds in its "Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule; Supplemental Proposal" and stated its view that a standard default *de minimis* of 0.1% would allow EPA to focus on major sources and would allow for more effective use of the automotive industry's long-term investment in its internal IMDS system. The commenter said that EPA could also use a data driven approach to establish higher threshold levels if appropriate.

EPA RESPONSE:
EPA will consider relevant information in the development of the risk management rule, including the suggestion (0125) for identifying a *de minimus* level (though EPA notes that the commenter incorrectly implies that EPA proposed a *de minimus* threshold in the cited supplemental proposed Significant New Use Rule). EPA will undertake a separate public notice and comment period as part of the proposed TSCA section 6(a) risk management rulemaking for NMP and will consider public comments and any additional information before finalizing the rulemaking.

Other

An industry trade organization (0140) expressed support for the goal of implementing TSCA to eliminate unreasonable human health risks, while at the same time preserving the use of essential chemistries and products that are important to the U.S. economy. The commenter encouraged EPA to work with stakeholders to ensure consistent, proper, and successful implementation of TSCA, specifically in these precedent-setting risk determination revisions.

A comment submitted by several state and local government agencies and organizations (0141) provided the following recommendations for the TSCA risk evaluation and risk management processes:

- Establish a process that expands EPA's required federalism consultations to create a more meaningful and substantive dialogue with state, local and Tribal governments on its

TSCA risk evaluations. EPA should directly consult with state and local governments early in the risk evaluation process to ensure its scoping for risk evaluation casts a broad net and is comprehensive in considering all specific and local uses, hazards, exposures, and PESS.

- All sources of exposure must be considered, including sources from products (including articles), the workplace, manufacturing and processing facilities, recycling and disposal, and legacy sources. EPA should evaluate cumulative and aggregate exposures to individuals and communities across multiple pathways, such as air, water, food, and dermal contact, in work and living settings rather than considering each pathway in isolation.
- Risk assessment and risk management rules must fully consider, address, and eliminate impacts on key at-risk or PESS.
- EPA cannot fully evaluate safety and should not make determinations of no unreasonable risk when there is a lack of chemical use, exposure, human health, or eco-toxicological data. When gaps exist, EPA must fully utilize its TSCA authorities to fill data gaps.
- Risk management regulations that could preempt existing state or local statutes and regulations should be executed with extreme caution if they are not equally protective in effect and scope.
- Create systems to support shifts to safer alternatives, prevent use of regrettable substitutes that are also hazardous, and support small businesses in those transitions through existing TCSA authority or through seeking additional authority or resources.
- Disposal and other end-of-life considerations should be fully addressed in each risk management rule, including occupational safety and impacts from pollution at legacy disposal sites, manufacturing sites, household hazardous wastes, and wastewater and stormwater discharges.

A product manufacturer (0130) requested that EPA grant an exemption for under hood applications of on-highway vehicles and non-road mobile machinery because the condition of use is a critical or essential use for which no safer alternative exists. The commenter stated that should EPA decide not to grant an exemption, then a 7-year transition period, contingent on the compliance status of upstream parts and components suppliers, be granted. In addition, the commenter requested that EPA grant specific exemption for replacement parts, service parts, and components with no known technical or economically feasible alternatives for non-road mobile machines.

An industry trade organization (0135) commented that it had previously submitted comments on the same policy changes proposed in the revised NMP risk determination, as proposed in the draft revision to the HBCD risk determination. The commenter stated that EPA's responses to those previous comments were not adequate under the Administrative Procedure Act and did not address the merits of those comments; instead, EPA merely restated its previous arguments without addressing the specific points raised. The industry trade organization asserted that the current draft revised risk determination for NMP appears to be nothing more than a block copy and paste version of the draft revised risk determination for HBCD.

Another industry trade organization (0137) recommended that a formal government-industry council be established to provide an ongoing opportunity for regulators and regulated parties to confer as issues develop. The commenter suggested that EPA and manufacturers could work together to find reasonable, workable solutions to the challenge of balancing jobs and the economy while ensuring chemicals are managed appropriately for human health and the environment.

***EPA RESPONSE**:*
EPA thanks the commenters for their support of ongoing risk evaluation and risk management of chemical substances under TSCA. EPA appreciates the commenter's recommendations for future risk evaluations and the forthcoming risk management rules and encourages the commenter to submit chemical-specific comments during future risk evaluation and rulemaking comment periods, including on the issues the commenters have raised, such as data gaps consideration of PESS, and sources of exposure. The revised unreasonable risk determination for NMP is based on the peer reviewed risk characterization in the December 2020 Risk Evaluation, based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) and (i) to make decisions under TSCA section 6 in a manner consistent with the best available science and based on the weight of scientific evidence. The December 2020 Risk Evaluation included conditions of use in which NMP was intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of, including disposal-related hazards and exposures to workers and ONUs at disposal facilities The policy changes described in the Federal Register Notice announcing the availability of the draft revised risk determination for NMP do not amend or impact the underlying data and analysis presented in the risk characterization of the December 2020 NMP Risk Evaluation.

With respect to impacts from this revised unreasonable risk determination on risk management of NMP, EPA will propose a regulatory action with requirements under TSCA section 6(a) to the extent necessary so that NMP no longer presents unreasonable risk of injury to health, including unreasonable risk to identified PESS.

EPA appreciates the information regarding the industrial and commercial uses of NMP in under hood applications of on-highway vehicles and non-road mobile machinery submitted by the commenter (0130). EPA notes that consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management actions to the extent necessary so that NMP no longer presents an unreasonable risk. Such comments can help inform potential risk management actions (i.e., by informing EPA's assessment of the feasibility and efficacy of different risk management options). EPA encourages the commenters to continue to engage with EPA, particularly within information related to worker protection measures, including engineering controls and administrative controls, during the future public comment period for the forthcoming NMP risk management rule. As part of that rulemaking, EPA will consider reasonably available information on worker protection measures, including information provided by regulated industries.

Regarding comments submitted on the HBCD draft risk determination, EPA has responded to the comments received on the draft revised unreasonable risk determination for HBCD (EPA-HQ-OPPT-2019-0237-0124)). In that document for HBCD and below, for NMP, EPA provides an expanded explanation of why the whole chemical approach to NMP better aligns with TSCA

objectives (including listing of the conditions of use that do and do not drive the unreasonable risk for NMP as a whole chemical substance) and the rationale behind not assuming the use of PPE in the NMP unreasonable risk determination.

In response to the recommendation that EPA establish a government-industry council (0137), EPA acknowledges the best practices established by states and industry experts and appreciates the public's contributions to the risk evaluation and ongoing risk management. During development of the TSCA section 6(a) risk management rulemaking for NMP EPA has engaged in required consultations such as the federalism consultation as specified in Executive Order 13132 (64 FR 43255, August 10, 1999) and the tribal consultation as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), to solicit feedback from the perspective of state and local governments. In addition to the formal consultations, EPA has met directly with state and local regulators to hear concerns and gain insight on existing regulations, research, and best practices. Additionally, EPA has engaged in discussions with representatives from different industries, non-governmental organizations, technical experts, and users of NMP, and welcomes continued engagement throughout the development of a risk management rulemaking.

Section 10 – Comments on potential revisions to other risk determinations for the first ten chemicals

An advocacy organization stated (0138) that the Agency must make holistic risk determinations for all of the initial 10 risk evaluations and apply the whole chemical approach to all risk evaluations moving forward. In other words, as they describe, EPA should only consider a whole chemical approach because it accurately profiles the unreasonable risk a chemical may pose to human health and the environment. An industry trade organization (0140) commented that as EPA enacts rulemakings for other chemicals in the future, it should revert to evaluating these substances on an individual COU basis to ensure innovation and production in the chemical industry and broader economy are not restricted at the state level. The commenter stated its view EPA should avoid an approach that could result in the undesired and unintended outcome of imposing high costs and strain on industry without the intended decrease in risk.

EPA RESPONSE:
EPA appreciates the comment. As EPA explained in the Federal Register Notice announcing the availability of the draft revised risk determination for NMP, 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. EPA emphasizes that throughout the risk evaluation process, EPA must "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors" (TSCA section 6(b)(4)(A)), which would include considerations for innovation and the national economy. However, during the TSCA section 6(a) risk management rulemaking for any chemical found to present unreasonable risk, EPA does, as part of the requirements under TSCA section 6(c), consider the reasonably ascertainable economic consequences of the rule, including consideration of the effect of the rule on the national economy, small business, technological innovation, the environment, and public health.