U.S. Environmental Protection Agency

1-Bromopropane (1-BP); Revision to Toxic Substances Control Act (TSCA) Risk Determination

EPA–HQ–OPPT–2016–0741

Response to Public Comments

December 2022

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Acronyms and Abbreviations

1-BP	1-bromopropane
ACGIH	American Conference of Governmental Industrial Hygienists
APF	Assigned protection factor
COU	Condition of use
EPA	U.S. Environmental Protection Agency
HBCD	Cyclic aliphatic bromide cluster
NIOSH	U.S. National Institute for Occupational Safety and Health
ONU	Occupational non-user
OSHA	U.S. Occupational Safety and Health Administration
OSH Act	Occupational Safety and Health Act of 1970
PEL	Permissible exposure limit
PESS	Potentially exposed or susceptible subpopulation
PF	Protection factor
PPE	Personal protective equipment
PV29	Colour Index Pigment Violet 29
TSCA	Toxic Substances Control Act
U.S.	United States
U.S.C.	United States Code

Introduction

On July 20, 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 1-Bromopropane (1-BP). In the notice, EPA announced that public comments would be accepted until August 9, 2022.

EPA received a total of seven public comments and determined that all 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 seven 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	Commenter Name
EPA-HQ-OPPT-2016-0741-0105	Household & Commercial Products Association
EPA-HQ-OPPT-2016-0741-0106	Environmental Defense Fund
EPA-HQ-OPPT-2016-0741-0107	Chemical Users Coalition
EPA-HQ-OPPT-2016-0741-0108	American Chemistry Council
EPA-HQ-OPPT-2016-0741-0109	Anonymous
EPA-HQ-OPPT-2016-0741-0110	Alliance for Automotive Innovation
EPA-HQ-OPPT-2016-0741-0111	American Federal of Labor and Congress of Industrial Organizations

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.

A non-governmental environmental advocacy organization (0106) provided general support for the revised 1-BP unreasonable risk determination. The organization 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 organization 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).

EPA RESPONSE:
EPA appreciates the support for the revised unreasonable risk determination.

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 (0110) 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 1-BP. 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 1-BP, 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 1-BP, EPA will propose a regulatory action with requirements under TSCA section 6(a) to the extent necessary so that 1-BP 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 1-BP-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 1-BP-containing articles during the future public comment period for the 1-BP risk management rule.

Section 3 – Legal issues

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

Section 3.1 – Statutory authority and TSCA section 26

An industry trade organization (0108) 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. The commenter added that the legislative record for the TSCA amendments also does not support EPA's new policy direction.

***EPA RESPONSE**:*
The final revised unreasonable risk determination for 1-BP is based on the peer reviewed risk characterization in the August 2020 1-BP 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. Thus, EPA maintains that the August 2020 1-BP 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, 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 section 26(h) and (i). The policy changes described in the Federal Register Notice announcing the availability of the draft revised risk determination for 1-BP do not amend or impact the underlying data and analysis presented in the risk characterization of the August 2020 1-BP 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 2.2 of the final risk evaluation). Further discussion of EPA's 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 (0108) 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.

An advocacy group (0106) 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 1-BP is based on the peer reviewed risk characterization of the August 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 1-BP was published in July 2022 along with the Federal Register Notice explaining the whole chemical approach to the 1-BP unreasonable risk determination, and why EPA believes that a whole chemical approach to 1-BP 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 as part of the risk evaluation 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 OSHA has not issued a chemical-specific permissible exposure limit (PEL) (as is the case for 1-BP), 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 1-BP 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.

With respect to EPA's approach to changing the 1-BP risk determination, the revised Section 5 of the 1-BP Risk Evaluation describes the determination of unreasonable risk of 1-BP as a "whole chemical substance," details how all but two of the 25 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 2020 1-BP Risk Evaluation. The risk evaluation already includes exposure analysis with and without PPE (see Table 4-58 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 August 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 1-BP. 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*.

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

A non-governmental environmental advocacy organization (0106) and a union (0111), in expressing support for the whole chemical approach for 1-BP, stated their view that the approach is consistent with the language and purpose of TSCA. The advocacy organization (0106) 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. The commenter 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 (0111) stated that a whole chemical approach would ensure that all workers exposed to unreasonable risks from 1-BP can be provided equivalent protections under TSCA.

The advocacy organization (0106) 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 1-BP, 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 Circ. 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 1-BP, the whole chemical approach is appropriate because there are benchmark exceedances for a substantial number of conditions of use (23 of the 25 evaluated) spanning across the chemical lifecycle–from manufacturing (including import), processing, industrial and commercial use, consumer use, and disposal for workers, occupational non-users (ONUs), consumers, and bystanders. In addition to the breadth of identified risk, EPA also considered the severity of the health effects associated with 1-BP exposures, including cancer, chronic non-cancer, and acute 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 1-BP when issuing a whole chemical determination for 1-BP, 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.

Section 4.1.2 – Opposition to the whole chemical approach

Some commenters, including industry trade associations and an individual commenter (0110, 0108, 0107, 0109), 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 (0108).
- 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 (0108, 0110).
- 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 (0108, 0110).

Another industry trade organization (0107) stated its view that EPA should continue to make COU-specific risk determinations for 1-BP 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 1-BP that the COU-specific determinations in the August 2020 risk evaluation provided, and would result in skewed understandings of the risk of chemical substances.

This industry trade organization (0107) also said that EPA’s policy changes implemented in the revised unreasonable risk determination for 1-BP may lead to unwarranted impacts on importers

of articles containing a chemical substance for which EPA conducts a risk evaluation. 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 1-BP 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. Finally, an industry trade organization (0110) commented that applying a COU-specific approach allows stakeholders and EPA to focus more efficiently on uses that in fact pose unreasonable risks.

EPA RESPONSE:

As EPA explained in the Federal Register Notice announcing the availability of the draft revised risk determination for 1-BP, 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 1-BP is based on the peer reviewed risk characterization in the August 2020 1-BP 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 1-BP in detail in the Federal Register Notice announcing the availability of the draft revised risk determination for 1-BP. 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 1-BP 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. In the case of 1-BP, 23 of the 25 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 1-BP 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 August 2020 1-BP 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 1-BP. Consistent with the statutory requirements of TSCA section

6(a), EPA will propose risk management actions to the extent necessary so that 1-BP 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 1-BP 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 1-BP risk characterization with regard to conditions of use that may relate to articles. Under TSCA section 6(c)(2)(E), any relevant consideration of 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.

Section 4.1.3 – Inconsistency with TSCA and Risk Evaluation Rule

Several industry trade organizations (0110, 0108, 0107) provided their view that a whole chemical approach is inconsistent with TSCA and its implementing regulations.

Basis for the whole chemical approach

Three commenters (0110, 0108, 0107) 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 (0108) 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 (0108, 0107) 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.

An industry trade organization (0108) commented that language in the HBCD final risk determination and 1-BP 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.

Inconsistency with TSCA

Several commenters wrote that the draft revision is inconsistent with TSCA. An industry trade organization (0107) 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 (0107) 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 (0108) 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 group (0106) 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.

Similarly, two industry trade organizations (0108, 0110) 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 (0110) 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.

EPA RESPONSE:

EPA followed the requirements under TSCA section 6(b)(4) in issuing this revised unreasonable risk determination for 1-BP, 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 1-BP (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.

As EPA explained in the Federal Register Notice announcing the availability of the draft revised risk determination for 1-BP, 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.

Regarding the comment that TSCA requires that changes in approach have scientific support, EPA notes that the revised unreasonable risk determination for 1-BP is based on the peer reviewed risk characterization in the August 2020 1-BP 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 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 43265 (July 20, 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 August 2020 1-BP Risk Evaluation, and further explained in Sections 5.2 and 5.3 of the revised unreasonable risk determination.

The revised unreasonable risk determination for 1-BP 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. In this instance a “substantial amount” of conditions of use that drive the unreasonable risk encompasses 23 out of the 25 conditions of use of 1-BP. 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 1-BP. Moreover, for 1-BP, 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, ONU, consumer, and bystander health, and the severity of the health effects associated with 1-BP 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 1-BP when using a whole chemical unreasonable risk determination for 1-BP, EPA concludes that the Agency’s risk determination for 1-BP is better characterized as a whole chemical risk determination rather than COU-specific risk determination. In the case of 1-BP, 23 out of 25 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 1-BP 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.

As explained in the Federal Register Notice to the draft revised unreasonable risk determination for 1-BP, 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 August 2020 1-BP Risk Evaluation, EPA applied 40 CFR 702.47 based on one particular passage in the preamble to the final Risk Evaluation Rule[1], 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 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. Either 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 1-BP risk determination.

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

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 1-BP chemical unreasonable risk determination takes in consideration the hazard of 1-BP and the exposures from all conditions of use of 1-BP.

Furthermore, there is no change in the underlying 1-BP 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 1-BP. Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management action to the extent necessary so that 1-BP 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.

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 identified only one condition of use of 1-BP that includes articles: the consumer and commercial use of 1-BP in rigid board insulation. This condition of use does not drive EPA's unreasonable risk determination for 1-BP. 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 1-BP risk evaluation nor in the proposed revised risk determination for 1-BP 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 1-BP. 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.

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

Two industry trade organizations (0108, 0107) 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 (0108);
- Explain how the change to a whole chemical approach may affect risk management (0108, 0107);
- 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?) (0108, 0107). 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? (0108); 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 (0107).

***EPA RESPONSE**:*
EPA appreciates other comments received in connection with the 1-BP draft revised unreasonable risk determination. As stated previously, this action pertains only to the risk determination for 1-BP. 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 1-BP is based on the peer reviewed risk characterization of the August 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 1-BP, 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, consumer use, and disposal) for the health of workers, ONUs, consumers, and bystanders to consumer use, and the severity of the health effects associated with 1-BP 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 1-BP when using a whole chemical unreasonable risk determination for 1-BP, EPA concludes that the Agency’s risk determination for 1-BP 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 risk management action to the extent necessary so that 1-BP no longer presents unreasonable risk. In the final revised risk determination for 1-BP, EPA has identified the conditions of use that drive the unreasonable risk for 1-BP 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 assumes 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

A non-governmental environmental advocacy group (0106) and a union (0111) 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.

The advocacy organization (0106) 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 commenter stated its view that the U.S. Occupational Safety and Health Administration (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. The advocacy organization 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.

A union (0111) said that the National Academies of Science 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 (0106) 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 1-BP risk evaluation and the unreasonable risk determination therein, general input regarding PPE, the interaction of EPA and OSHA regulation, and worker protection.

As stated in the revised unreasonable risk determination for 1-BP, 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. Additionally, as commenters note, workers not directly engaged in handling the chemical (such as occupational non-users (ONUs)) are not expected to be provided or wear PPE. 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,"[2] or because OSHA has not issued a permissible exposure limit (PEL) (as is the case for 1-BP), 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 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

Two commenters expressed opposition to EPA's proposal to not assume the use of PPE when making its unreasonable risk determination for 1-BP. For example, two industry trade organizations (0107, 0108) 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

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

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 (0107) added that when EPA rendered unreasonable risk determinations in the 1-BP 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.

An industry trade organization (0108) 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 (0110) 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.

An industry trade organization (0110) 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.

An industry trade organization (0105) 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 (0108) 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 (0110) suggested that EPA continue the approach of presenting both scenarios – 1-BP use with and without PPE – in its risk determinations, claiming that doing so would provide the appropriate bounding scenarios for 1-BP 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.

***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 1-BP. Regarding the commenter's assertion that OSHA general requirements include PPE, and that EPA has an insufficient rationale for basing the determination without assuming use of PPE, EPA notes that the Agency 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.[3] 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,"[4], or because OSHA has not issued a chemical-specific PEL (as is the case for 1-BP), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements. 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 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

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

of the 1-BP 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.

When conducting the 1-BP risk evaluation, EPA considered reasonably available information on 1-BP 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 1-BP as explained in Section 2.3.1 of the final risk evaluation. EPA used this information when developing exposure assessments for 1-BP. This information is also helpful to inform potential 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 1-BP is based on the peer reviewed risk characterization of the August 2020 1-BP 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 to workers were calculated and summarized in 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 August 2020 1-BP 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 4-58 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, 23 conditions of use would drive the 1-BP whole chemical unreasonable risk determination due to risks identified for human health.

As described earlier, the revised unreasonable risk determination for 1-BP is based on the peer reviewed risk characterization in the August 2020 1-BP 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 1-BP 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,"[5], or because OSHA has not issued a chemical-specific PEL (as is the case for 1-BP), 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 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 PESS. 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.

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

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.

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 1-BP.

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 (0108) 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.

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 1-BP risk evaluation, for instance to help inform EPA's assessment of the feasibility and efficacy of different risk management options. Information on the 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. 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 1-BP 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 Sections 4.4.1 and 2.4 of the August 2020 1-BP Risk Evaluation describes workers and occupational non-users, including male and female workers of reproductive age, as PESS. Notwithstanding the analysis done for 1-BP, 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 (0106) 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.

An industry trade organization (0105) 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.

An advocacy organization (0106) 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 1-BP risk evaluation and revised risk determination, including unreasonable risk driven by acute and chronic non-cancer and cancer effects. 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 risk. 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 1-BP 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 1-BP, and will consider public comments and any additional information before finalizing the rulemaking.

In response to the commenter's (0105) concern that during the time between final risk evaluation and final rule there may be potential confusion in workplaces, EPA appreciates the suggestions provided and notes that the risk evaluation already includes an exposure analysis with and without PPE.

In response to the commenter's concern (0106) 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 unreasonable risk determination for 1-BP is based on the peer reviewed risk characterization in the August 2020 1-BP 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 1-BP 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 (0106) 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.[6] 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 (0106) also commented that in the 1-BP risk determination, EPA incorrectly suggests that compliance with OSHA requirements 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

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

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.

An individual commenter (0109) stated that even though OSHA does not have a PEL for 1-BP, it does enforce overexposure under the General Duty Clause by using the American Conference of Governmental Industrial Hygienists (ACGIH) 0.1 ppm limit. In addition, the commenter said that 1-BP is not a confirmed human carcinogen, but it is an A3 carcinogen under ACGIH, meaning it is a confirmed animal carcinogen with unknown relevance to humans.

EPA RESPONSE:
In response to the comment regarding OSHA regulations (0109), EPA notes that 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 where applicable, 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,"[7] or because OSHA has not issued a chemical-specific PEL (as is the case for 1-BP), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

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

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).

Regarding the statements from the commenter on the carcinogenicity of 1-BP (0109), EPA notes that the policy changes described in the Federal Register Notice announcing the availability of the final revised risk determination for 1-BP do not amend the underlying data and analysis presented in the risk characterization of the August 2020 1-BP Risk Evaluation. In that risk evaluation, EPA describes how, under the criteria presented in EPA's Guidelines for Carcinogen Risk Assessment, 1-BP may be considered "Likely to be Carcinogenic in Humans" based on the positive findings for carcinogenicity in more than one test species, together with positive findings for the direct reactivity of 1-BP with DNA and suggestive but inconclusive evidence for genetic toxicity. More information regarding the hazards of 1-BP that EPA identified are in Section 3 of the 1-BP risk evaluation.

Section 5 – Unreasonable risk determination

An advocacy organization (0106) stated its view that EPA should not treat workers differently than the general population when making an unreasonable risk determination for 1-BP under TSCA section 6(b)(4), because such differential treatment is based on nonrisk factors and is thus prohibited under TSCA section 6(b)(4). Specifically, the advocacy organization stated that in the risk evaluation for 1-BP, EPA identified unreasonable risks for cancer from chronic inhalation and dermal exposure to 1-BP to workers and ONUs, and the Agency's determinations of unreasonable risk were based on different cancer benchmarks depending on the subpopulation. The commenter stated that EPA's bifurcated approach to workers vs. everyone else for cancer risks is illogical, inconsistent, and unsupported by TSCA. The advocacy organization further stated that workers often face higher risks than the general population, making a less protective standard particularly unjustified.

***EPA RESPONSE**:*
EPA evaluates exposures to workers, occupational non-users, consumer users, and bystanders using reasonably available monitoring and modeling data for exposures to 1-BP as required under TSCA section 6(b). Certain assumptions about exposure are taken into account when considering what constitutes an unreasonable risk presented to the general population and subpopulations (e.g., workers). A consideration of the exposure circumstances for workers compared to those of the general population illustrates that it is appropriate to consider a range of benchmarks to inform risk management approaches. For example, in 2017 when EPA's Office of Water updated the Human Health Benchmarks for Pesticides, the benchmark for a "theoretical upper-bound excess lifetime cancer risk" from pesticides in drinking water was identified as 1 in 1,000,000 to 1 in 10,000 over a lifetime of exposure.[8] Similarly, EPA's approach under the Clean Air Act to evaluate residual risk and to develop standards is a two-step approach that "includes a presumptive limit on maximum individual lifetime [cancer] risk (MIR) of approximately 1 in 10 thousand" and consideration of whether emissions standards provide an

[8] EPA. Human Health Benchmarks for Pesticides: Updated 2017 Technical Document (pp.5). (EPA 822-R -17 - 001). Washington, DC: U.S. Environmental Protection Agency, Office of Water. January 2017. https://www.epa.gov/sites/production/files/2015-10/documents/hh-benchmarkstechdoc.pdf).

ample margin of safety to protect public health "in consideration of all health information, including the number of persons at risk levels higher than approximately 1 in 1 million, as well as other relevant factors" (54 FR 38044, 38045, September 14, 1989).

The cancer risk estimates in the 1-BP risk evaluation represent the incremental increase in probability of an individual in an exposed population developing cancer over a lifetime following exposure to 1-BP. As such, EPA calculated cancer risk estimates from 1-BP exposure for workers and occupational non-users under an 8-hour time weighted average (TWA) and a lifetime average daily concentration (LADC). The calculation of the cancer risk (i.e., the analysis of the cancer dose response data) is a scientific analysis. It is typical practice at EPA to calculate a range of cancer risks from $1x10^{-4}$ to $1x10^{-6}$. However, the benchmark used in risk management is a policy choice that considers the scientific analysis. As such, the benchmark value for risk management of cancer findings is not a bright line and appropriately EPA has discretion. Though EPA has the discretion to make an unreasonable risk determination for any chemical substance based on other benchmarks as appropriate (such as $1x10^{-6}$ depending on the subpopulation exposed), $1x10^{-4}$ was applied as the benchmark for the cancer risk to individuals in industrial and commercial workplaces for 1-BP. The $1x10^{-4}$ for cancer risk to workers is consistent with the NIOSH cancer guidance for occupational exposures from 2017. Further information related to this is in section 5.2.3 of the final revised risk determination and sections 2.3.1.2 and 4.2.4 of the August 2020 1-BP Risk Evaluation.

In each risk evaluation under TSCA, EPA determines whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use. EPA makes the unreasonable risk determination without the consideration of costs or other non-risk 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 potentially exposed or susceptible subpopulation or PESS); the severity of hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties. EPA also 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. This approach is in keeping with EPA's obligation under TSCA section 26(h) to base its decisions on the best available science, and the Agency's final rule, Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (82 FR 33726, July 20, 2017).

Section 6 – Conditions of use that drive the unreasonable risk determination

Section 6.1 – Industrial and commercial use

An industry trade organization (0108) commented that EPA is ignoring how 1-BP is handled in industrial settings in the revised risk determination to justify an expansion of the conditions of use that pose an unreasonable risk. The industry trade organization stated that this could have long-term implications for the development and innovation of new chemistries that utilize 1-BP as a building block chemical.

An individual commenter (0109) stated that 1-BP is used extensively in semiconductor manufacturing, and there is no immediate substitute available.

Another industry trade organization (0110) discussed the use of 1-BP in the automotive sector, stating that 1-BP may be used as an aerosol cleaner, cleaning solvent, and cleaner/degreaser in the manufacturing process. The commenter asserted that thousands of articles and replacement parts may have been manufactured in the presence of 1-BP and, as a result, may have residues and impurities associated with 1-BP. The industry trade organization stated that where substitutes may exist, the uncertainty created by EPA's focus on a number of solvents and degreasers has hindered the testing and selection of a substitute, as industry is concerned about the possibility of a regrettable substitution, and requested that EPA provide some certainty regarding substitutes so that identifying 1-BP substitutes would be a more viable option for any ongoing uses.

EPA RESPONSE:

EPA appreciates the information provided by each of the commenters (0108 and 0109) regarding their particular use(s) of 1-BP. EPA notes that the unreasonable risk determination does not consider costs or other nonrisk factors; EPA intends to consider information regarding potentially negative consequences on manufacture of products during risk management, consistent with TSCA section 6. As suggested by several commenters, EPA will be considering the information in the development of the risk management rule. EPA will consider this context during the development of 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 1-BP and will consider public comments and any additional information before finalizing the rulemaking.

In response to the concerns regarding the potential for trace amounts of 1-BP to be present in articles within the automotive industry in a manner as described by the industry trade organization (0110), 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. EPA appreciates the separate issue that the commenter raised regarding the possibility for regrettable substitution as multiple solvents are evaluated and may be found to present unreasonable risk, in which case each would be subject to regulation, 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 7 – Comments regarding conditions of use that do not drive the unreasonable risk determination

An advocacy organization (0106) 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 (0106) 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.

An industry trade organization (0105) 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.

EPA RESPONSE:
EPA understands there is strong public interest in learning how unreasonable risk from 1-BP will be addressed, including potential impacts on specific conditions of use, including those that do not drive the unreasonable risk for 1-BP. 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 1-BP 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 (0106), 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 (0106), as in the August 2020 risk evaluation, EPA's final revised risk determination maintains that distribution in commerce of 1-BP is the transportation associated with the moving of 1-BP 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 1-BP 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 1-BP. 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 1-BP (EPA-HQ-OPPT-2019-0235-0066).

Based on the limited emissions from the transportation of chemicals, EPA has determined that distribution in commerce of 1-BP does not drive the unreasonable risk determination for 1-BP.

Section 8 – Comments regarding EPA's withdrawal of the associated orders

An industry trade organization (0110) requested that EPA not withdraw the order for the 1-BP COUs that were found not to present an unreasonable risk under the August 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.

***EPA RESPONSE**:*
EPA does not plan to conduct a second risk evaluation on 1-BP. EPA is issuing a final revised unreasonable risk determination for the 1-BP risk evaluation after consideration of the public comments received on the draft. For purposes of TSCA section 6(i), EPA is making a risk determination on 1-BP as a whole chemical. Under the revised approach, the "whole chemical" risk determination for 1-BP supersedes the no unreasonable risk determinations for 1-BP 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 August 2020 1-BP 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 1-BP. EPA does not plan to conduct a second risk evaluation on 1-BP.

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

An industry trade organization (0108) 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.

***EPA RESPONSE**:*
As described in the Federal Register Notice, the 1-BP 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 1-BP. 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-bromopropane (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 1-BP.

Section 10 – Other comments related to the draft revision of the risk determination

Previously submitted comments

A union (0111) requested that EPA incorporate by reference their comments on the HBCD and methylene chloride revised risk determinations into this docket.

***EPA RESPONSE**:*
EPA has considered the commenter's previously submitted comments on the draft revised risk determinations for HBCD and methylene chloride that were incorporated into its comments on the 1-BP draft revised risk determination, and has responded in this document to the general themes raised by the commenter therein.

Risk Management

An industry trade association (0110) requested that EPA identify a *de minimis* level for 1-BP 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 urged 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 International Material Data 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 (0110) 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 1-BP and will consider public comments and any additional information before finalizing the rulemaking.